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DRUG PRICING IN AMERICA: A PRESCRIPTION FOR CHANGE, PART III

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UNITED STATES SENATE

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DRUG PRICING IN AMERICA: A PRESCRIPTION FOR CHANGE, PART III

TUESDAY, APRIL 9, 2019

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC.

The hearing was convened, pursuant to notice, at 10:13 a.m., in room SD–215, Dirksen Senate Office Building, Hon. Chuck Grassley (chairman of the committee) presiding.

Present: Senators Cornyn, Thune, Portman, Scott, Cassidy, Lankford, Daines, Young, Wyden, Stabenow, Cantwell, Menendez, Carper, Cardin, Brown, Bennet, Casey, Whitehouse, Hassan, and Cortez Masto.

Also present: Republican staff: Brett Baker, Senior Health Advisor; Stuart Portman, Health Policy Advisor; and Karen Summar, Chief Health Policy Advisor. Democratic staff: Joshua Sheinkman, Staff Director; Anne Dwyer, Senior Health-care Counsel; Elizabeth Jurinka, Chief Health Advisor; Matt Kazan, Senior Health Advisor; and Kristen Lunde, Winston Fellow.

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. Good morning, everybody.

The committee will come to order. Today the committee continues to look at why prescription drug costs are so high and what can be done to reduce them.

I would like to welcome all of our witnesses. Thank you for coming. These are top executives for major pharmacy benefit managers. Around this town we refer to them as PBMs.

Medicare prescription drug plans hire PBMs to manage Part D benefits. Medicaid State-managed care organizations also employ PBMs. We know that drug companies set the list price. Our February hearing with CEOs of major manufacturers focused on those high prices.

We now today turn our attention to PBMs. These organizations negotiate with the drug companies as well as pharmacies to arrive at a price for a drug and its ultimate cost.

This system of private entities negotiating is what I envisioned as an author of the Part D program of Medicare. I still believe that this is absolutely the right approach. I oppose any effort to undo the non-interference clause currently in the statute. However, as this hearing indicates, it is our duty to understand how the system is working today and what we can do to improve it.

In addition to negotiating prices, PBMs also determine what drugs are covered and what patients pay out of pocket. Despite this vast influence over what often amounts to life or death, many consumers have very little insight into the workings of PBMs. PBMs report rebates and other price concessions to the Centers for Medicare and Medicaid Services. But the statute severely restricts what can be done with that information. More transparency is needed. The current system is so opaque that it is easy to see why there are many questions about PBMs' motives and practices.

One question we must ask is whether or not PBMs prefer a high-cost drug with big rebates over a cheaper drug. Some even argue that PBMs force drug companies to raise their list price.

Senator Wyden and I are investigating pricing and rebating practices related to insulin. This will help us more broadly determine whether PBMs and manufacturers today are focused on patients or their own bottom line.

Mergers and vertical integration is another area that has increasingly prompted concern. All of the PBMs here today are owned by or affiliated with an insurance plan. In many cases the combined company also owns pharmacies and other players in the health industry. It is important to look to see whether such integration actually helps patients and consumers, or whether it just opens the door for anti-competitive activity.

Last year, I sent a letter to the Federal Trade Commission, a letter on this very issue, and asked them to keep me apprised of their work. I am putting my letter and the response in the record. Without objection, that will be included.

[The letters appear in the appendix beginning on p. 103.]

The CHAIRMAN. I realize that I have raised many issues. I look forward to hearing what the witnesses have to say, providing insight and helping us find solutions.

Ranking Member Wyden and I are committed to working on a bipartisan basis to bring down the cost of drugs. Our next step is to work with committee members to develop policies to help Medicare and Medicaid patients and to protect the taxpayers.

Senator Wyden?

[The prepared statement of Chairman Grassley appears in the appendix.]

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON

Senator WYDEN. Thank you very much, Mr. Chairman. I want to pick up right where you left off because, as you have noted, this is a bipartisan effort to end this pharmaceutical price-gouging that does so much harm to American consumers and to our taxpayers. And I think we all understand that there is a lot of heavy lifting to do in the days ahead.

And at the same time I want to note that the committee has already begun to put some points on the board. Just last week the Congress passed our bipartisan legislation, legislation the chairman and I worked on for months to stop a blatant rip-off where big pharmaceutical companies were fleecing Medicaid and taxpayers.

Now this morning the committee is going to be looking at one of the most confounding, gnarled riddles in American health care

today. Pharmacy benefit managers are among the most profitable companies in America. What these pharmacy benefit managers actually do to rake in all of these profits is a mystery. The deals they strike with drug makers and insurers are a mystery. How much they are pocketing out of the rebates they negotiate is a mystery. With Americans learning about schemes like "spread pricing" in Medicaid, whether pharmacy benefit managers bring any real value to taxpayers is a mystery.

The pharmacy benefit managers are supposed to be negotiators who get a better deal, a fairer shake for the consumer on prescription drugs. What they actually are are middlemen who are raking in these profits while the drug prices soar into the stratosphere.

As most people will tell you—as I hear at town hall meetings continually, most Americans think that there are already too many middlemen taking a big juicy cut out of the American health-care system.

Just a little bit of history and some basic facts: pharmacy benefit managers first showed up decades ago, back when prescription drugs were being utilized more extensively. The PBMs told the insurance companies, "We are the ones who know drug pricing. We will handle the negotiations for you."

But there is little evidence that these pharmacy benefit managers have actually held down the prices in a meaningful way. In fact, most of the evidence shows just the opposite. Pharmacy benefit managers actually make more money when they pick a higher-price drug over a lower-price drug.

Colleagues, let us remember that all the way through this discussion. Benefit managers make more money when they pick a higher-price drug over a lower-price drug. The logic on this is not exactly complicated graduate-level economics.

PBM profits are based on taking their slice of the prescription drug pie. More expensive drugs mean there is a bigger pie. When there is a bigger pie, there are bigger slices for the pharmacy benefit managers.

I have been looking at this issue extensively, as has the chairman. And I am of the view that pharmacy benefit managers guard their operations with greater secrecy than HBO is guarding the ending of "Game of Thrones."

Now we know there has never been more outrage in the country over the rising cost of medicine, and I say that looking all the way back to my days when I was director of the Gray Panthers. If PBMs had clear, hard evidence proving that they are getting patients a better deal on prescription drugs, they would be leafleting the countryside and shouting it from the rooftops. Instead they work overtime to keep patients and taxpayers in the dark.

Today the committee is going to get a thousand different versions of the same talking point: "We are all about getting the best possible price for patients." But based on what I have seen so far, we are not getting actual proof.

The bottom line is, pharmacy benefit managers are middlemen who strike deals with drugmakers in secret. In my experience, that kind of negotiation rarely results in an act of charity for consumers and taxpayers.

Now, because of our jurisdiction, I just want to close with a few specifics with respect to the Federal health programs.

First on Medicaid: a PBM scheme known as spread pricing to rip off taxpayers through Medicaid has set off alarm bells in the States from one end of the country to another. It has nothing to do with cream cheese, all this spread pricing. But here is how it works. The PBMs pay one set price to pharmacies for a particular drug. But then they turn around and charge Medicaid and other health-care payers far more for the same prescription.

The chairman and I are digging into this. So this will continue our bipartisan efforts. We have asked the Health Department Inspector General to take a look. If there are changes that can be made to clamp down on this exploitation of Medicare, I think it is important we consider it. The chairman and I are looking into it. It is as clear a middleman rip-off as you are going to find.

Now with respect to Medicare, some key issues. First, Part D is one of the few health benefits in America that does not have an out-of-pocket cap. That means seniors with catastrophic illnesses can face costs of thousands and thousands of dollars. These are folks on fixed incomes. This is a flaw that needs to be fixed, and I have introduced the Rx Cap to protect seniors in our country from having to pay more and more out of pocket for their medicine.

Next, Medicare Part D encourages drugmakers and PBMs to push seniors on to more expensive drugs. That is because, after a certain amount of spending on drugs, seniors on Medicare are on the hook for 85 percent of the cost. After that point, PBMs pay only 15 percent, and drugmakers are just home free. So it is good business for the drug industry when seniors cross that threshold as fast as possible.

Second, rebates are working against the seniors who need the benefit most. Drug rebates in Part D get sent straight to the insurance companies. In theory, they use the rebates to lower premiums, which sounds good if you are healthy. It is not such a good deal for seniors who battle illnesses. The amounts they pay for their prescriptions are based on list prices, not on the prices factoring in rebates.

Again, I have introduced legislation, the C–THRU Act, so that patients can finally see whether these rebates are worth the trade-off. And my understanding is that there is progress on this in the House of Representatives as well.

The administration has proposed new rules having to do with this topic as well. I continue to be concerned that the Trump approach could produce a windfall for the drug companies at the end, if the administration is unprepared to take the next steps to reign in the pharmaceutical companies and bring down list.

Mr. Chairman, I appreciate very much that we are pursuing this in a bipartisan way. You mentioned insulin, mentioned our new effort with respect to Medicaid and so-called "spread pricing."

Colleagues, we have got to move with urgency. Twenty-nineteen is the year to get this done. We all know that 2020—there are going to be a couple of things going on in America in 2020. So let us continue with a sense of urgency and get this done in 2019 and stop the price-gouging.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator Wyden.

[The prepared statement of Senator Wyden appears in the appendix.]

The CHAIRMAN. And thank you for your cooperation on this and several other issues as we try to do things in a bipartisan way.

So first of all, in the introduction of these witnesses, I should not only say "thank you" for being here today to discuss an important topic, but I want to thank you—as far as I know, I have not heard anything negative from staff. You came here without a lot of hassle. And we have had some witnesses on this subject—it was quite a hassle to get them here. So thank you for your cooperation. We are grateful for that.

First is Dr. Steve Miller, Cigna chief clinical officer, who leads all of the company's clinical policies, quality, and performance efforts.

Derica Rice is executive vice president for CVS Health and also president of CVS Caremark, the company's pharmacy benefit management business.

Dr. William Fleming is segment president, healthcare services, where he is responsible for Humana's clinical and pharmacy business.

John Prince currently serves as chief executive officer of OptumRx.

Finally, Mike Kolar currently serves as interim president and CEO of Prime Therapeutics.

So we will start with Dr. Miller and go from my left to my right. I know that all of you have more to say than 5 minutes will allow, so for all of you a longer statement will be very much appreciated and will be put in the record.

So go ahead, Dr. Miller.

STATEMENT OF STEVE MILLER, M.D., EXECUTIVE VICE PRESIDENT AND CHIEF CLINICAL OFFICER, CIGNA CORPORATION, BLOOMFIELD, CT

Dr. MILLER. Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for inviting me to testify and for your interest and leadership on these important topics.

I am Dr. Steve Miller, executive vice president and chief clinical officer at Cigna. From 2005 to 2018, I served as senior vice president and chief medical officer at Express Scripts.

I am a kidney doctor by training. I work in this industry by choice. As a nephrologist, I could help one patient at a time. In my current role, I can help over 100 million Americans achieve better health with greater choice, affordability, and predictability.

When I started practicing medicine, patients diagnosed with cancer were most likely to undergo surgery to treat their condition. Since then, pharmaceutical companies have discovered and developed innovative medicines that have transformed care, leading to cures for previously untreatable conditions.

Now the preferred treatment for cancer patients and patients with many other diagnoses is increasingly prescription drug therapy before surgery. Accordingly, prescription drug spending has become the fastest-growing portion of total medical expenditures.

Innovations can yield exciting life-changing new therapies and treatments that improve or extend life. But innovation in the pharmaceutical sector often comes with a high price tag.

At Cigna, we are focused on accelerating solutions that support both innovation and price stability. Express Scripts has a range of world-class capabilities that enhance clinical quality, reduce costs, and improve or accelerate access to therapies. These include specialty pharmacy care and distribution, formulary management, medical and drug data analytics, and patient care services.

We employ hundreds of nurses and thousands of pharmacists who deliver life-saving drugs to patients, make sure patients know how to use them, and ensure that the treatment is working. The coordination of care is a huge part of what we do and what makes my job so rewarding. Thousands of health plans, unions, government plans, and employers, including many pharmaceutical companies, trust us to manage the pharmacy and medical benefits of millions of Americans. Our clients are sophisticated purchasers who demand value and innovation from us every day.

We deliver safer, more affordable medicine, and provide specialized care with tailored solutions, including specialized pharmacists with deep understanding of specific disease states. We negotiate discounts for prescription drugs so that the innovations created by the biopharmaceutical industry can be accessed by all.

For example, 4 years ago our society faced a challenge treating patients with hepatitis C. A cure was developed that had an extraordinary price tag of $1,000 per tablet for 84 pills. That meant for the first time a curative treatment was going to be reserved for only the sickest patients.

The situation was unacceptable, and Express Scripts worked to solve it. We did this by driving competition between clinically similar products and innovating to guarantee adherence.

In the first year, we treated 50,000 patients to cure, achieved higher adherence than the drug's clinical trial, and saved patients and health systems over $1 billion. But we have more work to do. Approximately 90 percent of all prescriptions we fill are generics. And there are some cases where generics are not an option. The remaining 10 percent are branded drugs which represent 70 percent of the spend on prescription drugs.

We believe there are targeted solutions to address this 70 percent. We work to do this through sophisticated evidence-based negotiations for clinically equivalent therapies. For example, over 7 million Americans diagnosed with diabetes use insulin. For some patients, the increasing price of insulin limits access and adherence. When Cigna and Express Scripts announced the merger, we clearly stated that we would improve choice, affordability, and predictability. Within the first 100 days of our combination with Cigna, we announced a Patient Assurance Program, which will cap the cost at $25 a month for patients who take insulin. This is just one example of private-sector innovations and solutions aligning incentives in the financing and delivery of care.

Cigna is excited to do our part. We look forward to working with the committee on solutions ensuring that drugs are affordable for all Americans. We have highlighted proposals in our submitted testimony, but I will mention a few.

We recommend improving price transparency tools for patients and physicians at the point of prescribing and prioritizing public policy that speeds biosimilars and generics to market. We recommend the administration move forward with proposals to introduce more private-market tools into Medicare Part B and Part D programs.

I welcome the opportunity to discuss these recommendations and issues and look forward to your questions.

The CHAIRMAN. Thank you very much.

[The prepared statement of Dr. Miller appears in the appendix.]

The CHAIRMAN. Now, Mr. Rice.

STATEMENT OF DERICA RICE, EXECUTIVE VICE PRESIDENT, CVS HEALTH; AND PRESIDENT, CVS CAREMARK, WOONSOCKET, RI

Mr. RICE. Chairman Grassley, Ranking Member Wyden, and members of the committee, I want to thank you for the opportunity to join you today.

My name is Derica Rice, and I am an executive vice president at CVS Health, and also president of CVS Caremark. I joined CVS Health because I believe in the company's vision of helping patients on their path to better health. We want to make health care more accessible, more affordable, and improve health outcomes for the communities that we serve.

Never has our work been more important than today. The rising costs of health care and prescription drugs affect every household in this Nation and are a critical issue for consumers and policymakers. Our job is to work with the employers, unions, and government programs we serve to ensure that when their members get to the pharmacy counter, they get the medicines that they need at the lowest possible cost.

As drug prices increase and consumers shoulder more of the burden, we believe we can and must do more to deliver affordable care. In the spirit of our common goal of reducing health-care costs for consumers and the overall system, I am here to share what we as CVS Caremark are doing to directly reduce consumers out-of-pocket costs at the pharmacy counter and to discuss policies that would help further advance that agenda.

Our goal as a PBM is simple: to reduce costs and improve health outcomes. We do this by negotiating discounts with manufacturers, designing formularies that encourage the use of generics and biosimilars, and creating new tools to help bring escalating drug prices under control. Some of the new tools we have put to work for our employees and our clients include point-of-sale rebates at the pharmacy counter that directly lower out-of-pocket costs, in particular during the deductible phase. Currently, almost 10 million of our clients' members are in plans offering these savings.

We also offer the first and only Medicare Part D plan offering point-of-sale rebates through our SilverScript Allure plan, which leaves the choice to the individual beneficiaries as to what plan best serves their needs. We provide zero-dollar copays on preventive medications for chronic conditions to our employees. And we have redoubled our efforts to encourage our clients to do the same.

Our hard work has had a real impact. Over the last 3 years, we have saved our clients and their members $141 billion in drug costs. At the same time in 2018 alone, 44 percent of our clients saw their net prescription drug prices decline. And 85 percent of our members utilizing their prescription benefit spent less than $300 on their prescriptions.

We recently announced our guaranteed net cost pricing model, a new pricing option that provides our clients with a guaranteed price for retail, mail, and specialty drug products regardless of product or price inflation. This heightens our focus on the lowest actual cost of the drug, and 100 percent of the rebates are passed through.

As we have interacted with consumers, they have told us that they want to know whether their drug is covered and what their out-of-pocket costs are going to be. So we now provide member-specific information in the doctor's office, at the pharmacy counter, and directly to consumers on their phones and online.

We call this "real-time benefits." That means prescribers can see the actual cost of the drug to the member or patient based on their current coverage and up to five potentially lower-cost options, enabling them to make informed decisions and help patients save money while improving their care.

But as much as we have been able to accomplish, we also understand that more must be done. We support the FDA's focus on bringing more lower-cost alternatives to market faster.

As I have detailed at length in my written testimony, we also support many of the policies authored by members of this committee, including Chairman Grassley's and Ranking Member Wyden's policies that would bring more competition to the market and limit out-of-pocket expenses for seniors.

Thank you again for the opportunity to testify. I am happy to answer any questions.

The CHAIRMAN. Thank you, Mr. Rice.

[The prepared statement of Mr. Rice appears in the appendix.]

The CHAIRMAN. Now it is Dr. Fleming's turn.

STATEMENT OF WILLIAM K. FLEMING, Pharm.D., SEGMENT PRESIDENT, HEALTHCARE SERVICES, HUMANA, INC., LOUISVILLE, KY

Dr. FLEMING. Good morning, Chairman Grassley, Ranking Member Wyden, and members of the committee. Thank you for the opportunity to be here and for your leadership in creating and advancing Part D. I have spent my career in a variety of pharmacists' roles. And today I lead Humana's clinical organization including pharmacy, home health, and behavioral health.

We provide Medicare Part D coverage to approximately 8.4 million seniors. I am passionate about improving health outcomes. And I appreciate the committee examining the root causes of high drug costs, advancing policy solutions, and gaining a deeper understanding of what integrated health plans do.

Today, more than 43 million seniors are covered by Part D. The program was designed to leverage market competition to provide affordable access to prescription drug coverage. The private market has responded to that construct by creating competition that has

resulted in generic dispensing rates greater than 90 percent; stable premiums through 13 years of the program, averaging around $30 per month; and beneficiary satisfaction rates of nearly 90 percent.

And our efforts have not just been on the negotiation side. The majority of our employees develop and manage patient engagement programs as well as advance the interoperability between Humana and doctors as well as with pharmacies.

For example, we have a tool called Intelligent Rx which provides actionable information to doctors at the time of prescribing. By linking information on formulary coverage and cost in the electronic medical record right into the physician's workflow, the doctor and her patient can have a holistic discussion about the patient's needs.

Part D is working incredibly well for the majority of seniors, but we have a rising tide of high-cost specialty drugs driving unsustainable costs for seniors and taxpayers. Fifty thousand to $100,000 treatments did not exist in 2003 when Part D was signed into law. Today it is common for new innovations.

In 2018, 2 percent of our members used specialty drugs that comprised 36 percent of our total Part D spending. In 2 years, we project it could rise to nearly 50 percent. Nearly one of every two specialty drugs results in members entering catastrophic coverage on their very first fill.

As we approach the 2020 coverage year, we anticipate the Part D rebate model will be changed to one where the rebates that manufacturers are willing to offer will be applied at point of sale. This regulatory action will have mixed results. All beneficiaries will pay higher premiums. While 12 percent will see savings of greater than $70 per year, 5 percent will see savings of less than $70 per year. Eighty-three percent will pay higher total cost, given the premium increases.

There are numerous moving pieces associated with such a tremendous policy change. While we are still reviewing, we are encouraged by CMS's announcement last Friday addressing one of our key implementation concerns. And we will continue working with HHS and CMS to identify additional opportunities to minimize beneficiary disruption and to create sustainability and competition. The rebate rule does not solve the drug affordability problem. To truly protect beneficiaries from high drug costs and to ensure sustainability in Part D, we would encourage the committee to explore policy ideas modernizing the benefit.

At a high level, this could mean placing limits on out-of-pocket costs, creating a special funding mechanism for today's high-cost specialty drugs, and including new flexibilities for Part D plan design such as options for beneficiaries on high-cost specialty drugs or dually eligible Medicaid/Medicare beneficiaries. We also strongly encourage Congress to continue evolving FDA and patent policy to create competition.

Chairman Grassley, Ranking Member Wyden, and members of the committee, I look forward to your questions. Thank you.

[The prepared statement of Dr. Fleming appears in the appendix.]

The CHAIRMAN. Now, Mr. Prince.

STATEMENT OF JOHN M. PRINCE, CHIEF EXECUTIVE OFFICER, OPTUMRX, MINNETONKA, MN

Mr. PRINCE. Chairman Grassley, Ranking Member Wyden, and members of the committee, I am honored to be here today on behalf of OptumRx, a pharmacy care services company whose dedicated employees work to ensure that the people we serve have affordable access to the drugs they need.

Our team includes 5,000 licensed pharmacists and pharmacy technicians who help patients learn how to take their medications, avoid harmful drug interactions, and manage their chronic conditions. Our nurses infuse life-saving drugs in patients' homes. Our pharmacists serve behavioral health patients in 450 community mental health centers and Federally Qualified Health Centers. Our opioid program is helping lower over-prescribing of opioids, promoting compliance with CDC prescribing guidelines, and advancing the use of medication-assisted therapies to reduce opioid dependency.

OptumRx services increase medication adherence, which in turn reduces unnecessary ER visits and hospitalizations and improves consumer health. We also manage pharmacy benefits on behalf of employer, union, commercial, and government customers. We achieve savings by designing drug benefits that promote clinically effective drugs at the lowest possible cost, as a result reducing annual drug costs on average by $1,600 per person per client.

This starts with a clinical assessment by our Pharmacy and Therapeutics Committee comprised of independent pharmacists and physicians. They evaluate formula placement based on scientific evidence about drugs' efficacy and comparative effectiveness, not cost. The meetings are open and transparent to our customers.

Cost only becomes a factor after this independent committee has identified clinically effective drugs in a therapeutic class. If a lower net cost generic or biosimilar exists, we prefer it on our formularies, which is why about 90 percent of the prescription claims we administer are for generics.

If there is no generic or biosimilar option or more than one brand or biologic drug in a class, we negotiate meaningful discounts for manufacturers and prefer the drug with the lowest overall cost on our formularies. Approximately 98 percent of the discounts we negotiate go to our customers.

We know consumers have felt the manufacturers' list price increases in the form of higher out-of-pocket cost. We have heard the call for action, and we have taken action to make sure consumers directly benefit from the savings we are negotiating.

Last year, we dramatically increased the availability of the discounts at the pharmacy counter for millions of eligible consumers who are now saving on average $130 per eligible prescription. In 2020, all new employer-sponsored plans we serve will provide discounts to their members at the pharmacy counter.

But more needs to be done. Manufacturers continue to increase the list and net prices at unsustainable rates because the lack of meaningful competition allows them to. List prices have increased on the 20 most prescribed brand drugs for seniors by an average of 12 percent for each of the past 5 years.

Prices for specialty drugs, in particular, are spiraling out of control. Less than 2 percent of Americans take a specialty drug, yet those drugs will make up half of the total drug spending by 2022.

Manufacturers also engage in anti-competitive practices such as pay-for-delay deals and evergreening their patents. A recent study found that 78 percent of drugs associated with new patents were not new drugs, but just extensions of existing ones. So called "authorized generics" are not a solution. They are not generics. They are a tactic used by manufacturers to give the appearance of competition, but they do not lower overall costs.

Real solutions reform the patent system, promote competition, and lower costs. These include passing the CREATES Act, prohibiting pay-for-delay deals, restricting evergreening of patents, accelerating biosimilar treatment options, and reducing the exclusivity period for drugs.

We also need to drive meaningful value-based payment models for drugs, just as is happening throughout the health-care system. With reforms that promote competition and value-based payments, we will all get far more value for our considerable investment in prescription drugs.

We appreciate the opportunity to be here today. The 28,000 women and men of OptumRx are committed to doing our part to make sure prescription drugs are more affordable.

I look forward to answering your questions. Thank you.

The CHAIRMAN. Thank you.

[The prepared statement of Mr. Prince appears in the appendix.]

The CHAIRMAN. Now, Mr. Kolar.

STATEMENT OF MIKE KOLAR, INTERIM PRESIDENT AND CEO, PRIME THERAPEUTICS, LLC, EAGAN, MN

Mr. KOLAR. Chairman Grassley, Ranking Member Wyden, members of the committee, thank you for the opportunity to be here today to discuss how pharmacy benefit managers and Prime Therapeutics provide value to the health-care system.

I am Mike Kolar, and I serve as the interim president and CEO of Prime. At Prime, we make health care work better by helping people get the medicine they need to feel better and live well. We do this by ensuring that plan members get the medication most appropriate for their condition at a cost that is the most affordable in the context of their overall insurance benefit.

Prime is a unique PBM. We are owned and controlled by 18 not-for-profit Blue plan clients. We are focused on driving savings for these plans instead of margins. Our business model is based upon delivering the lowest net cost on prescription medicines and the lowest overall cost of care for the benefit of our plans and ultimately their members. Getting the right drug for the right patient at the right time at a cost as affordable as possible in the context of their insurance benefit helps to ensure sustainability and optimal health outcomes.

We appreciate the committee's efforts to examine the problem of high drug prices. We see firsthand the challenges that these high costs cause for plans, members, and taxpayers every day.

Prime and PBMs are often misperceived as transactional middlemen. This entirely ignores the immense value we bring by using

deep pharmacy expertise to ensure clinically appropriate drug use and to drive improved safety, quality, outcomes, and savings.

While high prices are and should remain a central issue in this discussion, it is important to acknowledge the impact of our clinical expertise in ensuring appropriate utilization, resulting in lower costs for plans and individual members.

As a client-owned PBM, our business is built upon transparency, and we understand the importance of transparency in the health-care system. Our model encompasses full client transparency and meaningful actionable pharmacy, provider, and patient transparency. We believe that transparency to the right parties for the right reasons can improve our health-care system and lower costs.

Rebates and the role they play have been key areas of focus in the drug cost debate. In our view, rebates are a powerful tool to offset high prices which are set by pharmaceutical companies and pharmaceutical companies alone. The fact that rebates are not offered on many of the highest-cost drugs and that studies show no correlation between prices and rebates, underscores that rebates are a key to mitigating, rather than causing high drug prices.

We pass rebates through fully to our plans. And we believe our plans should be able to choose how to apply these rebates in ways that best serve their members and market needs by balancing premiums and cost-sharing.

This is particularly true since the majority of commercial members we serve do not face high coinsurance or high deductibles. Nevertheless, we are proud to offer our plans a commercial point-of-sale rebate solution to provide pricing relief where appropriate.

We are also strong proponents of value-based contracting. We use these programs to align the interests of manufacturers, payers, and patients by tying reimbursement to quality outcomes and value.

We agree that high drug prices must be addressed, and we support necessary inquiry and change. We believe that opportunities for meaningful improvement lie in increasing competition and in greater use of proven clinical tools to drive down costs. Pharmaceutical competition allows us to use our clinical expertise to add value and produce savings.

However, patent abuses and restrictions on formularies and utilization management result in less competition and higher costs. We support efforts to correct these market imbalances.

We appreciate the committee's interest in our perspective on drug prices, the role that we play in lowering drug costs for plans and members, and policy initiatives that can provide solutions to the drug cost problem. We believe that all parts of the drug supply chain should be carefully studied and considered in evaluating possible solutions, and we are committed to working with you to help bring lower costs to the most important stakeholder in this conversation, the patient.

We look forward to answering the questions you have regarding these issues. Thank you.

[The prepared statement of Mr. Kolar appears in the appendix.]

The CHAIRMAN. I compliment all of you for staying within the 5 minutes, and I am sure all of you have put in a longer statement. We will take all of that into consideration as well.

I am picking my first questions for Rice, Prince, and Miller for the reason that you are the largest with us.

We all agree that seniors are sensitive to premium prices. When you negotiate drug prices with plans, is a premium impact for beneficiaries considered? Start with Mr. Rice.

Mr. RICE. Yes, Senator.

The CHAIRMAN. Okay, and then Mr. Prince?

Mr. PRINCE. When we negotiate, we focus on the lowest net cost for that drug.

The CHAIRMAN. Does that say that the consumer is taken into consideration or is that one and the same?

Mr. PRINCE. Yes, absolutely. The consumer is taken into consideration, so they pay the lowest price.

The CHAIRMAN. And Dr. Miller?

Dr. MILLER. Most definitely.

The CHAIRMAN. Yes.

Now to the same three people. Without rebates—so forget rebates—what tools do you have to keep drug prices and premiums low? I will start with Mr. Rice.

Mr. RICE. Senator, we use a number of different tools. As you heard me articulate in my opening remarks, we negotiate with manufacturers. Putting rebates to the side, we provide point-of-sale rebates in order to provide benefits to the consumer at the counter to keep their out-of-pocket costs low.

We provide formulary and clinical program management which improves adherence for members, and we know that this downstream—through that improved adherence—it saves medical costs downstream. And you also heard me reference in my remarks that we also provide what we call "real-time benefits" to bring visibility both to the clinicians and physicians, as well as the patient, as to what the lowest possible cost options are for them, given their specific plan design, in order to make sure health care is affordable and accessible for them.

The CHAIRMAN. Yes.

So, Mr. Prince, to the extent to which you do some of the same things, just say that and then whatever else you do that he did not cover.

Mr. PRINCE. Sure.

In terms of the value we deliver, we save our clients about $1,600 per person in value each year, and that is driven. Other things that we do are the negotiations with retail pharmacies. We have 67,000. We negotiate a better price for our consumers.

We do other types of drug utilization review. But if you lost the tool for some type of mechanism for controlling for rebates, that would actually take a lot of value out of the system and increase cost.

The CHAIRMAN. Okay.

Dr. Miller?

Dr. MILLER. Much of the same. Remember that we prefer generics. So most of the time—in fact 90 percent of the dispenses we have are for generic products. And that is one of the greatest tools to help lower costs.

But really important is the coordination of care. If the patient is not taking the drug, we are not getting the medical benefit. And

so helping those patients identify gaps in care, fill those gaps and be able to make sure their drugs are working appropriately, is crucial to the success of treating the patient.

The CHAIRMAN. Okay.

And on the next question, I am going to concentrate on the same three people.

I would like to talk about consolidation, including the recent integration of PBMs with insurance companies. Last year I wrote the Justice Department on the issues. It reported that the three largest PBMs—who are before us today—now cover 71 percent of Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.

Such market power raises questions. So the first question—I want to hear briefly from each of you whether the PBM industry is competitive. For example, are there high barriers to entry for new competitors? And I think that is an important point, but you do not have to just concentrate on high barriers.

Let us go with Dr. Miller.

Dr. MILLER. Thank you. So the consolidation in the industry is actually in an effort to really take better care of patients. By looking at total cost of care across medical and pharmacy, we believe we can do an even better job of controlling costs and improving care.

As far as barrier to entry, this is actually a wildly competitive marketplace with over 60 players. People buy based on their needs. Some people want to use a regional player or a local player. Some people want to use a national player. And there is plenty of selection of all.

The CHAIRMAN. Mr. Rice?

Mr. RICE. Senator, this is a highly competitive space. In addition to the three that you have pointed out here, there is—I think CMS has noted there are over 60 PBMs across the U.S. So therefore, the competition there is more than—there are many options for the employers that are out there, government entities as well as unions, to choose from, given their specific needs.

And we have seen that play out in terms of each of us trying to get to—for our clients and their members, their patients—the lowest possible cost we can to keep premiums low and out-of-pocket cost burdens low as well.

The CHAIRMAN. And then, Mr. Prince?

Mr. PRINCE. Senator, I would say the market is very competitive. Every time we go out to a bid, there are at least three to five other competitors in the market.

Our clients are very sophisticated. They use complicated spreadsheets to evaluate the clinical value and the cost-effectiveness of proposals. They have outside advisors that help them in that process.

When you get to the broader market, there are dozens of other competitors, especially as you get into the mid-size employers. So it is a very competitive market with a lot of pricing pressure.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. Thank you.

Gentlemen, when I am home, what Oregonians tell me is that the whole system is just rigged against them. And they look at the drug companies, the middlemen, the insurance companies, and

they say they are just a bunch of health-care corporations scratching each other's backs and keeping our prices up and taking advantage of us.

And all of you as pharmacy benefit managers consistently say—this is your message: you bring value and fight for the lowest price.

So I am going to use a couple of examples to try to see how that works in the real world. Amgen manufactures a brand-name cholesterol drug that is very expensive. I have covered my concerns with high list prices with them.

They recently launched an identical version of the drug that cost 60 percent less than the original. Now here is a copy of a prior authorization form that CVS requires doctors to fill out if the doctor wants to prescribe a cheaper version of this cholesterol drug. I am going to ask unanimous consent to enter this document into the record.

[The form appears in the appendix on p. 234.]

Senator WYDEN. The CVS forms says, and I quote: "The two products are the exact same, and they are made in the same manufacturing facility." But they ask the doctor to answer detailed questions about the patient's medical history.

Mr. Rice, why is CVS—based on this form—putting arbitrary barriers between patients and cheaper medicine? Is it because you get a bigger rebate on a more expensive drug?

Mr. RICE. Senator, I understand your question, and the short answer is, absolutely not. What you may find is that, in many cases, the highest list price drug, or the lowest list price drug in the particular example you cite, may not be the absolute lowest-cost drug.

So what we tend to do is, we look at the drug's cost after all discounts have been taken into account, because that then is what allows members to keep out-of-pocket costs low as well as the plans to keep their premiums low for their members. And in that particular scenario, the branded drug was still the lowest cost for——

Senator WYDEN. You are making the argument the consumer somehow, by your analysis, wins on net price. Is that the argument you are making?

Mr. RICE. Yes, Senator.

Senator WYDEN. Okay.

To me that answer is a prime example of our broken drug system favoring the big corporations rather than patients. At the pharmacy counter anywhere in America, patients pay cost-sharing based off the list price.

And my view is—we will talk to you some more about it—when I use that form and I hear your answer, it sure looks to me like you all are taking deliberate actions to pad your bottom line at the expense of patients.

Now, Mr. Prince, a question for you, because time is short. A February 11, 2019 article describes letters United sent to several drug manufacturers late last year and early this year—Mr. Chairman, I would ask unanimous consent to enter that article into the record.

The CHAIRMAN. Without objection, so ordered.

[The article appears in the appendix on p. 235.]

Senator WYDEN. Mr. Prince, the letters demanded that drug manufacturers give United almost 2 years' notice if they intend to

lower prices, giving manufacturers, again, an easy excuse to keep list prices high. Even more galling, United demanded that these lower prices would not diminish the rebates United receives. The letters say United should receive equivalent rebates off the lower prices.

So, Mr. Prince, you all argue, PBMs, that drug prices set by manufacturers need to come down. But in private, United seems only to care about the size of their rebate and when their bottom line might take a hit.

Mr. Prince, do you have any agreements with drug manufacturers, similar to this letter, that penalize the drug manufacturers if they choose to lower their price?

Mr. PRINCE. So, Senator, regarding that letter that was sent out in December of last year, it was intended to make sure that our clients we work with—Part D plans—we wanted to make sure that when they put in their bids, they understood what would be the rebate amounts so that they could enter a bid accurately.

And you know how the part D program works: you have to submit your bid in June of one year for the next 7 months.

Senator WYDEN. My time is short.

The question was, do you have any agreements with the drug manufacturers, similar to this letter, that penalize the drug manufacturers if they choose to lower their prices? "Yes" or "no"?

Mr. RICE. We strongly encourage people to lower list price. We support——

Senator WYDEN. I would like to see any agreements.

My time is up. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cornyn?

Before Senator Cornyn's time starts, there is going to be a vote. I thought it started right now. So we are going to keep this meeting going. And while I am gone, Senator Cassidy is going to control the time.

Senator Cornyn?

Senator CORNYN. Gentlemen, in our meetings in my office and elsewhere, I told you we are trying to understand the basic features of the contracts between the manufacturers and the PBMs and how those relate to the consumer.

So I would like to ask five questions to establish some basic facts about how your companies operate. And if possible, I would like for you to answer "yes" or "no" just so we can establish some basic facts. We can come back for further explanation in some format or another. I am not trying to cut you off, but I am trying to work within the guidelines and the time we have today.

So, does your company structure an agreement where rebates and fees are a percentage of list price? Dr. Miller?

Dr. MILLER. Yes.

Senator CORNYN. Mr. Rice?

Mr. RICE. Yes.

Senator CORNYN. Dr. Fleming?

Dr. FLEMING. Yes. It is wholesale acquisition cost.

Senator CORNYN. Mr. Prince?

Mr. PRINCE. No, for Medicare. No, for Medicaid. No, for generics. And we pass on 98 percent in the commercial.

Senator CORNYN. Mr. Kolar?

Mr. KOLAR. Yes.

Senator CORNYN. The second question is, has your company proposed in a contract or otherwise prohibited or penalized a manufacturer from decreasing the price of a drug?

Dr. Miller?

Dr. MILLER. No.

Senator CORNYN. Mr. Rice?

Mr. RICE. Absolutely not.

Senator CORNYN. Dr. Fleming?

Dr. FLEMING. Absolutely not.

Senator CORNYN. Mr. Prince?

Mr. PRINCE. No.

Senator CORNYN. Mr. Kolar?

Mr. KOLAR. No. We welcome lower prices.

Senator CORNYN. Third question: has your company proposed in a contract or otherwise demanded that manufacturers give advance notice of a price decrease? I think this may relate to some of what the ranking member was asking.

Let me ask that again. Has your company proposed in a contract or otherwise demanded that manufacturers give advance notice of a price decrease? Dr. Miller?

Dr. MILLER. No.

Senator CORNYN. Mr. Rice?

Mr. RICE. No.

Senator CORNYN. Dr. Fleming?

Dr. FLEMING. No.

Senator CORNYN. Mr. Prince?

Mr. PRINCE. Yes.

Senator CORNYN. Mr. Kolar?

Mr. KOLAR. No.

Senator CORNYN. Fourth question: has your company proposed in a contract or otherwise demanded that manufacturers pay a higher fee or rebate if list prices do not increase above a certain percentage in that contract year?

Dr. Miller?

Dr. MILLER. No.

Senator CORNYN. Mr. Rice?

Mr. RICE. No.

Senator CORNYN. Dr. Fleming?

Dr. FLEMING. No.

Senator CORNYN. Mr. Prince?

Mr. PRINCE. No.

Senator CORNYN. Mr. Kolar?

Mr. KOLAR. No.

Senator CORNYN. Finally, has your company proposed in a contract or otherwise demanded that manufacturers pay a certain rebate amount even if they decrease—decrease—their list price?

Dr. Miller?

Dr. MILLER. The manufacturer is required to continue to pay the rebate until renegotiation.

Senator CORNYN. So that would be a "yes"?

Dr. MILLER. Yes.

Senator CORNYN. Mr. Rice?

Mr. RICE. We focus on, with the manufacturers, getting to the lowest possible cost, whether it is rebate or if they can reduce the list even further below the fully discounted value.

Senator CORNYN. Is that a "yes" or "no"? Has your company proposed in a contract or otherwise demanded that manufacturers pay a certain rebate amount even if they decrease their list price?

Mr. RICE. Not that I am aware of.

Senator CORNYN. Dr. Fleming?

Dr. FLEMING. Not that I am aware of. Most of our discounts are a percentage of wholesale acquisition cost.

Senator CORNYN. Mr. Prince?

Mr. PRINCE. For the specific case that was referenced, yes. But in general, 100 percent—it was only for the Part D program, and 100 percent of those rebates were passed on to CMS and to our consumers.

Senator CORNYN. Mr. Kolar?

Mr. KOLAR. No, Senator. Not that I am aware of.

Senator CORNYN. Mr. Chairman, I would like to submit a question for the record. I will do it in writing to each of these gentlemen. But I want to give you warning ahead of time of what is coming so you can prepare.

I would like to know from each of you the total dollar amount that you obtain from pharmaceutical manufacturers in any form, such as rebates, fees, and the like, and secondly, what the total dollar amount that you remit to health plans is.

We will give you a chance to respond in writing, but I wanted to give you a fair notice at this hearing.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Thank you, Mr. Chairman.

And welcome to each of you. Obviously, this is an incredibly important topic. You have each indicated this is the fastest driver of health-care costs, and certainly for families, for seniors, for individuals there is deep, deep concern.

There was an issue that Michigan pharmacists brought to me a little over a year ago that we were able to successfully address on a bipartisan basis. My Know the Lowest Price Act was signed into law after it was clear that pharmacists were extremely concerned that people were walking into a pharmacy, handing over their insurance card, paying the copay, assuming it was the lowest price, and sometimes—in fact, the report showed 23 percent of the time the person could have gotten a lower price paying cash out of pocket. And yet, the pharmacists could not tell people.

So when we raised that, we heard basically from everybody that nobody did it. It was just a few bad guys. Nobody did it, and in fact, it was just a couple of bad actors, not a common practice. And so we were able to fix that.

So my first question is, can you tell me if there are any other egregious anti-consumer PBM practices taking place anywhere in your industry like this that you would want to highlight today?

[No response.]

Senator STABENOW. Okay, so let me go on to the next question. So I am assuming that is a "no" because no one responded.

So let me go on then and talk about negotiation, talk about the various tools that you have to be able to bring down costs for people. And one of the main tools is negotiating. I am assuming when you look at the number of customers, it is about bulk purchase, being able to secure the best price; right?

So when we look at it, Express Scripts has 100 million Americans covered, CVS 90 million, OptumRx 65 million, Prime Therapeutics 27 million, Humana 21 million. And yet we still, Americans still pay the highest prices in the world even though you are negotiating for millions of people.

And so my question is, the VA has its own pharmacy benefit manager service. They negotiate for 9 million people, 9 million veterans. And they pay on average 40 percent less for the same drugs that the rest of the health-care system pays.

Despite greater volume, you are unable to secure these kinds of low prices. With all due respect, you guys are pretty bad negotiators, given the fact that the VA can get 40 percent less.

And so, I would like to know from each of you why that is the case. Dr. Miller?

Dr. MILLER. Yes, so part of the equation is giving patients choice. And so at the VA, they actually limit their formulary more than any of us at this table do.

And so oftentimes they will have one beta blocker, one ACE inhibitor. And so if it is going to get to that level of choice, then we could get better prices also.

Senator STABENOW. But let me also just jump in in the interest of time. I know you create nationwide drug formularies, you have pre-authorization, you give preferred status to certain medications.

So you do not use any of those tools that the VA is using? Because you do.

Dr. MILLER. We definitely use those tools. But we also give people choice. It is crucial for both physicians and patients to have the choice of the products they want to be able to access. So many of our plans want us to have broad formularies. And so when you have more products, it means you move less market share. You cannot get——

Senator STABENOW. And so they get 40 percent more—so basically 40-percent premium, you are saying? It gives them more choice.

I mean, I would like to ask people how much they would think that is a good trade-off given the cost of medicine today. And I would welcome the opportunity to look at the tools in detail that each of you have, versus the VA. Because when I look at it, it does not look to be that much different.

But in the interest of time—Mr. Rice?

Mr. RICE. Yes, Senator.

Senator STABENOW. Any comments?

Mr. RICE. Yes, Senator. What we have seen is that when we are able to manage a more tight formulary versus an unmanaged formulary, we can actually drive lower costs for the patients as well as for the cost of the plans.

And we have seen through our own data that an unmanaged plan—which means it has an open formulary, as was being ref-

erenced—may have an average cost of $108 versus a managed plan that may have a cost on average closer to $80.

Senator STABENOW. So would you support doing something like what the VA does in terms of how they manage their plans, then? Is that what you are suggesting, that they have a more narrow focus and that that would be better for consumers?

Mr. RICE. What I would support, Senator, is choice and optionality. And with our members and their respective clients, that is what we have provided such that in our own case, if you take the example of our Med D plan for seniors, we provide a plan that can be as cheap as a premium of $30 all the way to a premium of $80 depending upon which choices those members think best meet their specific needs.

And that $80 premium begins to contemplate things like point-of-sale rebates.

Senator STABENOW. Yes. No, I understand that.

Mr. Chairman, I know that—I would like to hear from everyone else, but I do recognize that I am out of time. So I will follow up in writing with each of you.

I do want to say, though, that Medicare does have 59 million beneficiaries, much less than many of you have as well. And I do not understand why they are not allowed to negotiate best price in terms of what is best for consumers.

Thank you, Mr. Chairman.

Senator CASSIDY [presiding]. Ms. Cantwell?

Senator CANTWELL. Thank you, Mr. Chairman.

And I want to thank the chairman and ranking member for holding this briefing. I want to emphasize that, obviously, one of the themes of today is the lack of transparency, and in the 2009 legislation, I authored a PBM transparency provision that is current law. This provision requires the PBMs to confidentially report information to the Secretary of Health and Human Services, including the total amount and types of rebates, discounts, and price concessions that PBMs negotiate on behalf of insurance plans.

So, that information is somewhere in this government. And I would suggest that we work with Secretary Azar on that information, not that it can be made public, but that it will give us what we need to see today, that we have a lack of direct negotiating ability, in my opinion, by States and other jurisdictions. I personally would give States better negotiating authority.

I get that this is a business model for PBMs. But there is no reason why that business model has to exclude having other market competition.

When I look at the fact that three PBMs have 85 percent of the market or that the CVS-Aetna merger was opposed by the American Medical Association because it raised concerns about reduced competition, then my question is, why can we not induce more competition into this marketplace by allowing States to negotiate on behalf of various plans within their State?

So I am not asking for an answer that I already asked the drug companies. They think that is unfair. I am pretty sure you are going to say the same thing. So I do not need to hear that answer.

What we need to do is get the answers from Secretary Azar about what is currently happening in the marketplace and move

forward with giving States the ability, or the Federal Government, to negotiate on price.

Thank you, Mr. Chairman.

Senator CASSIDY. Thank you.

The chair calls on himself. There is no one else to call on.

Now, I have thought a lot about your business model. And multiple times it was said that if you do a point-of-sale rebate, premiums will rise. Now if you think about that, what that is saying is that those patients who actually need medications are the ones who are lowering the premiums for those who do not.

Now, it is kind of a reverse Robin Hood. We are going to take from the sick and give to the well. Now on the one hand, you could say that is just a business decision. But you could imagine that this could be manipulated, that the way to keep somebody requiring expensive drugs off of your plan, maybe to get on their spouses' plan, would be to make them pay more.

Now I say that—I am not accusing. I just cannot help but reflect upon that. And so I want to then—can we show that second poster, please? This one.

Now, one thing I have noted is, we have heard several times that the amount of PBM retained revenue on retail prescription drugs by source is—and this would be the maroon that would be related to rebates. And this would be related to fees. [Indicating.]

And so the amount related to fees is increasing dramatically. And the amount related to rebates is decreasing.

So what it tells me is that you seem to be passing more of these rebates on, or else getting fewer, less rebates. I suspect that more are being passed on.

But this is what concerns me, that $16.6 billion. I think it was you, Mr. Rice, who said that the amount paid for drugs is flat or decreasing.

Does that also include these other fees that might be related to the filling of the prescription? Is the fee—put differently, you probably understand what I am asking, but just for the record—put differently, when you say "the drug cost is remaining flat," is that everything included, including that which is charged at the pharmacy as a dispensing fee or any other fee which may be included? Or is it merely the price of the medication itself?

Mr. RICE. It is all-inclusive, Senator. We pass through 100 percent of all rebates——

Senator CASSIDY. Now, not related to the rebates——

Mr. RICE [continuing]. And fees to our clients on behalf of their members.

Senator CASSIDY. So if there is a DIR fee collected from the pharmacist, then that is rebated to the payer even if not to the patient? So when you say—and the flat cost to the patient includes this increased amount of fees that are going into your business model?

Mr. RICE. Yes, Senator. In many of our cases with our clients today, they have progressed to what we call a "transparent arrangement," which is, there is no spread between the two.

Senator CASSIDY. Now is this the same for each of you, that when you say the cost of the drug has remained flat, that you are including the cost of the ancillary fees?

I will just go down, Mr. Kolar, and go this way.

Mr. KOLAR. So, Senator, when we negotiate with pharmaceutical companies, we are fully transparent with our clients about the amounts we receive. We pass those back to the plans.

Senator CASSIDY. So is that 100-percent pass-through?

Mr. KOLAR. It is. We do—there are——

Senator CASSIDY. On the fees?

Mr. KOLAR. There are elements of fees that we retain, but we retain them in lieu of charging our clients administrative fees.

Senator CASSIDY. I am almost out of time, so I will not ask the others.

So I have also thought about the retained fees—because I have had several good meetings with you guys.

But one of the things that was raised with me was that sometimes clients would rather have a fee retained, as opposed to paying a fee. And I have read that that is a way to circumvent the Obamacare MLR rule. And I say that not to ask your comment, because it is not your decision, it is the payer or the insurance company. But for the record, it has been at least labeled as that way.

Next, I once went to a site of a pharmacy benefit manager, and I was very impressed with much of what you do. But one thing I saw was bottles being emptied, and then the same pill that had formerly been in one bottle was then placed in another bottle. And the second bottle is that which was sent.

And I did not understand that for the life of me. But at one point I was told that that allows it to be billed at a higher NDC code, that, sure we acquire, but because we empty one bottle and fill another, we can now even as much as triple the cost of the basis of the drug being shipped out to the patients.

So let me just ask you, "yes" or "no," if your company does that. Dr. Miller?

Dr. MILLER. No.

Senator CASSIDY. Okay.

Mr. RICE. No.

Dr. FLEMING. No.

Mr. PRINCE. No.

Mr. KOLAR. No.

Senator CASSIDY. Now it was, I think, Express Scripts that I toured and saw that. And I kind of lose track of who is who. Who now would be the recipient of Express Scripts?

Dr. MILLER. I am Express Scripts.

Senator CASSIDY. So I did remember seeing that. Is this, therefor, a practice that has been discontinued?

Dr. MILLER. What you probably remember is, in our high-volume filler, we take—to make sure we have accuracy, we put the pills into these containers. When they are moved from the pill bottle—we can only buy the largest volume that the manufacturer makes. We use the high-volume fillers for mail order pharmacy. We move them from the small containers into a larger container. The NDC does not change, and that does not change the price.

Senator CASSIDY. The NDC does not change. That is my key point.

Okay, I yield back. Thank you. And I will have some QFRs, but thank you very much.

Senator Brown?

Senator BROWN. You always call on me when nobody else is sitting here. [Laughter.] Thank you.

Thanks to all five of you for joining us. It is not exactly breaking news that Ohioans do not trust pharmacy benefit managers. Between repeated reports on the egregious use of spread pricing, alleged breaches of contract, accusations of anti-competitive behavior, a misuse of taxpayer dollars, a general lack of transparency, I cannot say that I blame them.

Several of you, I understand, are making a conscious effort to rebuild trust with Ohio pharmacies, and consumers and taxpayers. I appreciate that, but I need you to do that better, and we need you to do that faster.

Part of that means changing the way you think about your business, and it means considering models that benefit the Ohioan at the pharmacy counter, as much as it benefits your direct client or the other half of your business. It is past time to put patients ahead of profits and Ohio taxpayers before shareholders. So I ask you to do that.

I want to ask a few "yes" or "no" questions, starting with you, Mr. Kolar, and if you really would answer "yes" or "no" just right to left. Does your company play a role in setting list prices of any drugs?

Mr. KOLAR. No, we do not.

Mr. PRINCE. No.

Dr. FLEMING. No.

Mr. RICE. No.

Dr. MILLER. No.

Senator BROWN. Okay. Thank you.

If the administration's rebate rule were finalized as proposed, would you in some way be required to change the way you do business?

Mr. KOLAR. Yes, Senator, we would.

Mr. PRINCE. Yes.

Dr. FLEMING. Yes.

Mr. RICE. Yes.

Dr. MILLER. Yes.

Senator BROWN. Okay. Thank you.

If the administration's rebate rule were finalized as proposed, do you believe any pharma company would be required to change the way it does business?

Mr. KOLAR. No, Senator.

Mr. PRINCE. No.

Dr. FLEMING. No.

Mr. RICE. No.

Dr. MILLER. No.

Senator BROWN. Okay. Last—this question is a short answer if you can. And thank you for your cooperation.

What percentage of prescriptions that you fill across Part D actually receive a rebate? Roughly what percentage?

Mr. KOLAR. So, Senator, approximately 8 percent of the prescriptions that we cover in Part D are associated with a rebate.

Senator BROWN. Okay.

Mr. Prince?

Mr. PRINCE. Senator, I do not know the exact number. I know overall business, about 7 percent.

Senator BROWN. Okay. Thank you.

Dr. FLEMING. About 7 to 8 percent.

Senator BROWN. Okay.

Mr. RICE. Senator, I do not know the exact number, but we pass through 100 percent of all rebates and discounts.

Senator BROWN. Okay.

Dr. MILLER. Ninety percent of the prescriptions will be generic. Of the 10 percent that are branded, about two-thirds have rebates. So it is about 7——

Senator BROWN. Seven or 8 percent like the others. Okay.

To recap, PBMs do not set drug prices, forcing you to change the way you do business as the administration's rule would not change that fact. And while the rule might impact a small percentage of drugs in Part D that receive a rebate, it does nothing to lower costs, as your answer suggests, for the other 90 percent of prescriptions you fill.

Most importantly, absolutely nothing in the proposed rule would require Secretary Azar's former employer, or any other pharma company, to lower the price of insulin or any other drug. It is important to establish that. So, thank you for that.

In fact, no pharma company is willing to commit to lowering the price of their drugs if this rule goes into effect. Instead of relying on the administration's claims that the proposed rebate rule will solve the drug pricing problem, we should be focusing on solutions that are sure to result in lower drug prices, like my legislation to allow Medicare to negotiate on behalf of all Part D drugs and to prohibit manufacturers from price-gouging.

In the last couple of minutes—many of you acknowledge in your testimony the fact that biosimilars have enormous potential to help lower drug prices for all Americans. As you know, biosimilars are approved by the FDA based on safety and efficacy. And in every circumstance that I am aware of, they have a lower list price than their innovator product, not surprisingly.

I understand that many of your plans sometimes require the use of higher list price innovator brand-name products over the use of a cheaper therapeutically equivalent FDA-approved biosimilar or generic. This is short-sighted. It is already having a chilling effect on the potential for a robust biosimilar market in the U.S.

My time is about to expire, but I would like to ask each of you to answer for the record what more your company can and will do and what more Congress should do to ensure the U.S. develops a robust biosimilar product.

Why don't we start with you, Dr. Miller, if you would?

Dr. MILLER. So one of the biggest problems facing the industry is the lack of biosimilars. They have come to the marketplace. The FDA has approved many biosimilars that still are not in the marketplace. They are caught up in law in the legal actions. And so, shortening the period of exclusivity could make a huge difference in bringing these biosimilars to the marketplace.

And so we are strongly supportive, and have been for over a decade, to get biosimilars out there. And when they are there, we often take great advantage of them to lower the cost for our plans.

Senator BROWN. Thank you.

And, Mr. Rice, as you answer the same question, include in it any pushback ideas on manufacturers' tactics like bundling rebates and rebate blocking.

So go ahead. Thank you, Mr. Rice.

Mr. RICE. Yes, Senator. As you have heard previously from my counterpart here, we absolutely are supportive of bringing more competition into the marketplace. We have seen, even in the space of insulin, when we have been able to have that competition, a biosimilar introduction, we were actually able to reduce the out-of-pocket burden for the members by 9 percent.

And so having more competition like that on the market would be extremely beneficial. And we know today that the U.S. still lags Europe in the availability of biosimilars.

Senator BROWN. Thank you.

Dr. Fleming?

The CHAIRMAN. Senator Hassan?

Senator BROWN. Could they answer the question?

The CHAIRMAN. Yes. I thought you just had one question.

Senator BROWN. It is one for all of them.

The CHAIRMAN. Everybody answer his question, and then we go to Senator Hassan.

Dr. FLEMING. Yes, Senator. We need more competition. We love biosimilars. When they do come out, we try to put them in parity position with the originator drug to allow the biosimilar to compete, but the big problem we have today is, we need more. More competition allows prices to come down for the same therapeutic area.

Senator BROWN. In a shorter window, as Dr. Miller suggested would work. Okay.

Mr. Prince?

Mr. PRINCE. Senator, there is a lot that needs to be done to increase competition in the biosimilars market. We are very strong supporters of it.

There are over 50 biosimilars that are actually used in Europe. Less than six—around six or seven are in the market in the United States.

So the main reform areas could be in the FDA. So there is a series of things. If you follow up, we would love to provide solutions that you can work on.

Thank you.

Senator BROWN. Mr. Kolar?

Mr. KOLAR. So, Senator, we are very supportive of biosimilars. We generally treat them on parity or preferred over brand. We assess them on a lowest net cost basis.

We do not engage—you asked about bundling. Bundling is not a practice for us that creates a meaningful barrier to biosimilar uptake.

We think one of the biggest barriers to uptake of biosimilars is lack of final FDA guidance on interchangeability.

The CHAIRMAN. Senator Hassan?

Senator BROWN. Mr. Chairman, one more thing. I am sorry. I apologize.

I think their answers really do show the importance of a shorter window on biosimilars, on exclusivity.

So thank you, Mr. Chairman.

The CHAIRMAN. Senator Hassan?

Senator HASSAN. Well, thank you, Mr. Chairman. And I thank you and Ranking Member Wyden for having this hearing. Thank you to our witnesses for being here today.

Mr. Prince, as you mentioned in your testimony, we cannot lose sight of some of the truly obscene price increases from drug manufacturers that we have seen in recent years. And I agree that we cannot solve the problem of skyrocketing prescription drug costs without addressing that.

But we do have a responsibility to look at all points in the supply chain. We spend a lot of time attempting to educate patients, for instance, about the value of choosing lower-cost generic alternatives. And many formularies penalize consumers financially when they do not.

You point out in your testimony that there are times when—because of rebates and discounts that you negotiate—the brand name drug may be the better value to the plan than the authorized generic. I certainly understand that and recognize that you have to balance the needs of a variety of payers in developing your plan.

But just this week, my office heard from a constituent, not for the first time, who was baffled about why he is being told to pay more for the brand name drug instead of using the generic. In the cases where the brand-name drug is the better financial option for your company and for the plan purchaser, why are you not charging the end-use consumer the lower copay?

Mr. PRINCE. So, Senator, just to frame the overall discussion around how things go on a formulary, then I will talk about how we then——

Senator HASSAN. Yes.

Mr. PRINCE. So our formulary process starts with an independent pharmaceutical and therapeutics committee that is independent from our company.

Senator HASSAN. I do want to hear about that. I would ask you to keep it short, because I have another question. And I am really trying to get at why doesn't the consumer get the benefit that you also say in your testimony here your company does?

Mr. PRINCE. We absolutely agree with you that the consumer should get all the value that we are negotiating. And that is why last year and this year, we have made such a huge effort around making sure that every discount we get is passed on to the consumer point-of-sale.

Senator HASSAN. So——

Mr. PRINCE. We now have 9 million people as a part of that program. We are not going to take any additional customers in 2020 without that, but not all of our customers have that yet.

But we are sharing the evidence with them around the value for that program.

Senator HASSAN. Okay.

So, in the case of a consumer being told they have to buy a brand-name drug and pay more for it because, ultimately, you are directing them that way because it increases the profits for your

company, you are saying here that you want to get to a place where the consumer recognizes the savings and could be charged the lower copay.

The PBM is choosing the brand name, in some cases, and the consumer should not be stuck with that decision by your company, is my point.

Mr. PRINCE. So, Senator, it is a rare circumstance where a brand would be less expensive. But in rare circumstances—because we negotiate on behalf of our customers—the price of the generic would actually be higher than the brand after you look at all the discounts.

So the actual price—not for us, but for our client, is less expensive, and we want to make sure that that value is then passed on to the consumer, which is why we are advocating for point-of-sale discounts in the commercial market.

Senator HASSAN. All right.

I am going to follow up with you a little bit after this hearing about that, because I just think what my constituents are seeing is, they are being told they have to purchase a brand name, and they are being charged the higher copay for it.

Mr. PRINCE. Okay.

Senator HASSAN. Okay.

To all of the witnesses, I know there has been a discussion here about Chairman Grassley's inquiry to the FTC. In theory, we know that PBMs help patients by helping negotiate lower prices. But I am concerned that the lack of competition in this area may mean that the industry is falling short of that goal today. And I know there has been discussion already about what level of competition you all think there is.

The Federal Trade Commission oversees PBMs and has already begun looking into concentration and competition in this market. And Chairman Grassley mentioned this in his opening statement and sent a letter to the FTC about the issue this fall.

The FTC has the authority to do more, to request rebate and fee information and analyze the impact of your companies' drug prices. I think that is a good idea, and I plan to join Chairman Grassley in talking with the FTC and ultimately encouraging them to look into it further.

So I would just like your commitment today that if the FTC requests information from you, your companies will cooperate fully and provide the information that the agency needs to conduct a rigorous analysis.

And we will just start at the end of the table, and I just would—Dr. Miller?

Dr. MILLER. Yes. We look forward to participating.

Senator HASSAN. Thank you.

Mr. RICE. Absolutely, Senator.

Senator HASSAN. Thank you.

Dr. FLEMING. Yes, Senator.

Senator HASSAN. Thank you.

Mr. PRINCE. Yes, Senator. We will cooperate.

Senator HASSAN. Thank you.

Mr. KOLAR. Yes, Senator, absolutely.

Senator HASSAN. Thank you very much.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Daines?

Senator DAINES. Thank you, Mr. Chairman.

I am hearing from folks all over Montana—in fact in every corner of our State—on the need to lower prescription drug costs, particularly out-of-pocket costs. I believe one way to help lower costs of prescription drugs is to shine light on the role of the middlemen, which is why you are here today. That is what you are. You are between the pharmaceutical company and the consumer.

It is your role, as I understand, to negotiate better drug prices for patients. But what we are seeing today is that there are higher profits on your end and we are not seeing lower costs ultimately for the end-user, for Montanans. In fact in Montana, there is a bill before legislature as we speak that aims to hold you all accountable, and then pass along the savings to consumers, versus profits back to the PBMs.

We need more transparency on drug pricing to lower costs for patients. And I am exploring legislative options to do just that.

My question to the panel is—we are getting a lot of resistance back in Montana. And why are you all fighting so hard against that legislation in Montana and efforts here to increase transparency and to pass on that savings that you negotiate to patients?

Whoever wants to take the question first.

Mr. RICE. Senator, I am not familiar with that specific piece of legislation, but as it pertains to transparency overall, we at CVS Caremark are very supportive. We provide full visibility to our clients of all our contracts and the discounts that we negotiate on their behalf.

As I stated earlier, we pass through in the Medicaid/Medicare book of business 100 percent of all rebates and discounts. We pass through overall more than 98 percent.

In the spirit of transparency, we have been supportive of policies like legislation being proposed by MedPAC. What we have done to try to further enhance transparency is, we provide a real-time benefit such that the members themselves, the patients actually, have that same visibility. And we too are concerned about the out-of-pocket burden on patients.

And so, therefore, we brought forward tools that can specifically help them, like point-of-sale rebates, like preventative drug lists for maintenance drugs that would have a zero-dollar copay, so then they would not have to worry about the deductible phase with high-deductible plans.

These are things that can impact the patient immediately.

Senator DAINES. I want to shift gears.

Mr. Prince, we saw the report that Optum sent a letter to drug makers in December asking for 7 quarters' advance notice—that is nearly 2 years—if a manufacturer is going to lower their price for patients. When Montana patients are choosing not to fill their prescriptions, and we get these stories, because of high out-of-pocket costs, requesting a nearly 2-year advanced notice frankly shocked me.

In fact, this type of demand would have prevented Montanans from getting about a 60-percent price reduction in their cholesterol-lowering medications after a drug maker announced they were

dropping their list price just last year. Working that out, that is nearly $8,000 per year, per patient for those Montanans who take that drug.

Montanans cannot afford to pay higher prices for 2 years for the sake of keeping industry happy, and perhaps Wall Street.

My question is, why does the company need to take more money out of the pockets of Montanans for nearly 2 years, versus you doing your job and negotiating lower costs for patients?

Mr. PRINCE. Well, Senator, specifically on rebates and discounts in the Medicare market, we pass 100 percent on to the plan, and it is just fully disclosed to CMS. So the discounts are fully passed on.

And then in terms of the commercial market for employers, we are an advocate for point-of-sale discounts. We rolled that out dramatically. So the discounts that we are delivering actually get passed on. So we actually are not going to be taking additional customers in 2020 unless we pass on the discounts.

So overall, the people from Montana are getting the value from what we deliver.

Senator DAINES. Why the 7 quarters?

Mr. PRINCE. Senator, that was a technical, legal contract that was making sure that we could get information so that our clients, when they submitted their bids, the preview in June, would have all the information they needed to actually submit their bids correctly.

And as you know, in the Medicare Part D program, you submit a bid in June for the following year, so that covers the 7 quarters.

Senator DAINES. On another note, I think we can all agree on the importance of cracking down on drug companies discouraging low-cost generic drugs from coming to market. Since last Congress, I have worked with Chairman Grassley on the CREATES Act to combat anti-competitive practices and improve Montana's access to lower-cost generic drugs.

I am going to continue to push for this common-sense legislation to be signed into law and pursuing other legislative priorities that will lower drug costs for folks in every corner of Montana and across this Nation.

Thank you.

The CHAIRMAN. The Senator from Nevada.

Senator CORTEZ MASTO. Thank you, Mr. Chairman.

Thank you, gentlemen, for being here. I appreciate the opportunity. I have met with some of you as well and had the opportunity to talk to you.

And one of the things we talked about was rebates. Many of you discussed products that you offer clients that allow for point-of-sale rebates. And I am curious, in those contracts, do you keep any portion of the rebate for yourself?

And if we would just kind of go down the table——

Mr. KOLAR. No, we do not.

Mr. PRINCE. No, we do not.

Dr. FLEMING. Senator, no.

Mr. RICE. No, we do not.

Dr. MILLER. No.

Senator CORTEZ MASTO. Thank you. I appreciate that.

Let me ask you, Dr. Fleming: in your testimony you say Humana's analysis of the rebate rule—and we are talking about the administration's rebate rule now. But you say that Humana's analysis of the rule found that approximately 17 percent of beneficiaries will see savings at the pharmacy counter as a result of this rule.

Can you tell me a little bit more about who these people are, and what kind of conditions they have?

Dr. FLEMING. Senator, that would be a number of members who are taking brand drugs for which we get rebates. And so it could vary all the way from the common chronic conditions, things like diabetes or hypertension or high cholesterol, all the way over to occasionally, not usually, but occasionally on the specialty drug side, when you think of some medications like treatments for rheumatoid arthritis, multiple sclerosis, places where there is competition.

Senator CORTEZ MASTO. Okay.

So let me ask you this, and then I will open it up to everyone.

There is a lot of hesitancy from all sides of the industry to talk about models that would enable HHS to negotiate directly with manufacturers. But there are a handful of therapies—those are the sole source drugs for which there is no therapeutic alternative—where you have no leverage to negotiate better prices.

One of my concerns with the rebate rule is that it would not address this issue. Is there any situation where you would support or perhaps remain neutral on giving the Secretary the ability to negotiate prices for that subsection of drugs? And I am curious to hear from the witnesses, and we will open it up.

Mr. KOLAR. So, Senator, we would have to study the issue more closely. But from our perspective, while the Secretary would certainly be able to aggregate volume, what we bring is clinical expertise and the pharmacy expertise to better negotiate with manufacturers. That would have to be replicated within the Department or an agency in order to do that effectively.

Senator CORTEZ MASTO. Okay.

So you would want to study it before you signed off on, or supported, or remained neutral whether or not the Secretary could negotiate for those drugs?

Mr. KOLAR. With respect to the question of government negotiation overall, our perspective is that it would require a significant development of formulary expertise within the government to replicate the work that we do with respect to the narrow drugs that you mentioned. We would want to study the issue. Our inclination is that that would not be as effective as what we do as PBMs.

Senator CORTEZ MASTO. For sole source drugs?

Mr. KOLAR. Correct.

Senator CORTEZ MASTO. Correct.

Do you feel the same way?

Mr. PRINCE. Senator, we think the solution is around creating more competition, addressing patent issues, addressing biosimilars in the market. And that would be the solution that we think would solve it.

Senator CORTEZ MASTO. Okay.

Dr. FLEMING. Senator, similarly, we need more competition. We need more biosimilars. My concern with government negotiation for

those sole-source drugs would be higher list prices, initially, when those drugs come out to offset what the manufacturer may have to give up.

And I invite a conversation at the right time around other tools we can employ around value-based contracts. We are asking physicians to engage in value-based contracts. We are asking hospitals to engage in them. We have programs with pharmacies.

But we need more tools. We need the flexibility to bring more tools to market so that when these sole-source drugs are out, we have the ability to hold them accountable for the clinical outcomes that they are intended for.

Senator CORTEZ MASTO. Okay.

Mr. RICE. We too, Senator, believe that, before we move down that path, we should look to exhaust all the other options that are available to us today, such as bringing more competition into this space.

We know—via the hep C example that was cited earlier this morning—that when we have competition, we can bring down drug prices, and we do have leverage in that equation.

Senator CORTEZ MASTO. Thank you.

Dr. MILLER. Like my colleagues, we believe that competition is the key to bringing down the drug prices. And using the tools that we have in value-based contracting, which is not allowed in Part D, would be crucial to help—it would be one more of those tools that would help.

Senator CORTEZ MASTO. Okay.

And the final question I have—and let me direct it to Mr. Prince. When I was in Las Vegas recently, I spoke with a constituent who was prescribed Xolair, a specialty medication for uncontrolled moderate to severe asthma. His copay for that medication is $489 per month.

In September of 2018, the Institute for Clinical and Economic Review found that all five of the major biological asthma treatments that are on the market, including Xolair, were overpriced. The Institute also said that the cost of Xolair, specifically, should be cut in half if the price of the drug were to properly reflect its efficacy.

Do you use evidence like this in negotiations with drug companies, and if so, how effective is it?

Mr. PRINCE. So, Senator, we use evidence-based clinical information initially to see if it goes on the formulary. So our process actually starts with independent pharmacists and physicians to evaluate the clinical effectiveness of a drug, the comparative effectiveness, to determine whether it goes on the formulary or not.

Then we go use that same data as part of the cost negotiations. So it is part of the process.

Senator CORTEZ MASTO. Okay.

Thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Yes. Senator Young?

Senator YOUNG. Thank you, Mr. Chairman.

Various stakeholders have called for more transparency in your transactions, specifically into the rebates and administrative fees paid by manufacturers. If Congress did what these stakeholders are calling for and made all PBM negotiations with the manufacturer, insurer, wholesaler, and pharmacy transparent and publicly

available, how would that affect your drug pricing? Would there be a race to the top, or perhaps a race to the bottom?

We will start with Dr. Miller and down the line, please.

Dr. MILLER. Yes, so we are really a strong proponent for transparency for those who pay for health care. So the patient should know exactly what they are going to pay. Our plan sponsors need to know exactly what is in their contract.

The FTC and the SEC have both demonstrated that if you provide transparency for competitors, what that does is, it puts a floor on negotiations. It does not put a ceiling.

And so what happens is, you would have shallower rebates. So the ability to negotiate is enhanced by the competitors not knowing each other's data.

Senator YOUNG. Mr. Rice?

Mr. RICE. Yes, Senator. We are very supportive of transparency. And transparency—today we report and fully disclose not only to our clients, but to CMS. And we have been very supportive of legislative proposals like MedPAC's. And many of you heard me comment earlier today about even bringing transparency to the patient through our real-time benefits.

What we are not supportive of is public transparency that would inhibit our ability to effectively negotiate with drug manufacturers to get to the lowest possible cost for patients and to lower their out-of-pocket premiums and the cost to plans.

Senator YOUNG. Right down the line.

Yes, sir.

Dr. FLEMING. Senator, we are an integrated health plan. So we spend a lot of time with transparency, both at the patient level and at the physician level. I mentioned our Intelligent Rx tool. I submitted in our testimony about how we give physicians information right on the glass in the exam room so that they can have really important conversations with the patient.

In this example that you are talking about, the thing I worry about is behaviors—in this case, the manufacturer behavior of wanting to negotiate to the lowest possible price if everything is fully transparent.

Will they regress to the mean? Will they want to demonstrate that one company has gotten a better deal than another company because it is fully transparent?

I do not know what that looks like. I do not know how that will show up. But I am not convinced that full transparency will allow the manufacturers to negotiate as feverishly as they could otherwise.

Mr. PRINCE. Senator, if our discounts were publicly available, it would hurt our ability to negotiate effectively. Our discounts are transparent to our clients. Our clients have audit rights to actually look at our rebate contracts, look at the——

Senator YOUNG. They have what rights? I am sorry, sir.

Mr. PRINCE. Audit rights.

So actually, our clients have audit rights to look at our rebate contracts, to look at line-item detail on how much we get and tie it back to their contract. So we have transparency to who hires us. We also are transparent to the government in terms of disclosing it to CMS in terms of our rebates.

But if you disclose that to the external market, it would hurt our ability to a get a good value for the people we negotiate for.

Mr. KOLAR. So, Senator, our business model is founded on the basis of transparency. And we are strong believers in transparency where it is meaningful and actionable in ways that can help improve the system and lower costs.

So we believe in client transparency. We believe in actionable provider and patient transparency. We do share the concern around the transparency of our negotiations with pharmacies, with pharma, and the impact that that would have on our ability to drive savings for our plans and ultimately to their members.

Senator YOUNG. Is there an issue that any of you could speak to, perhaps a challenge where, if we require transparency in a more robust way, there will be adverse selection, especially in the Medicare Part D program, which is a voluntary program?

[No response.]

Senator YOUNG. Does that resonate with anyone?

[No response.]

Senator YOUNG. No? Okay.

Is there a way to inject transparency into the entire pricing system without giving proprietary information away?

Dr. MILLER. I will tell you that transparency tools are crucial in giving doctors transparency at the time of prescribing. It is crucial to the patient and the doctor, choosing the right drug.

We have actually run an analysis where we have a real-time benefit check in the hands of about 120,000 doctors already. And we can see that when they have that information, the patient and the physician can choose the lower-cost drug, and even the lower-cost channels to get the drug, either the right pharmacy or a mail order pharmacy.

So you are correct that transparency tools done well will make a huge difference in the market.

Senator LANKFORD [presiding]. Senator Thune?

Senator THUNE. Thank you, Mr. Chairman. Thanks for holding this hearing. And thanks to our witnesses for being here today.

I hear often from South Dakotans frustration—from health-care providers—regarding transparency and the power that a few PBMs in the market wield, particularly when it comes to the retroactive application of DIR fees for pharmacies, from any of these pharmacies, especially those serving rural areas. It is difficult for them to run their businesses not knowing how much PBMs will pull back later.

We have heard support from the panel for a few of the bills that Chairman Grassley and others have introduced. I think many of us would like to see some ideas on the table for what role that your industry can play in advancing transparency in the drug supply chain.

I think the thing that most people find frustrating is just how opaque the health care pricing system is generally, whether it is hospitals or pharmaceuticals, all these things, they are—in most free market economies, you know, competition helps drive prices down. But people know what prices are. If you go into a store, there is usually a list price and the discount might be on there: "we are marking it down 40 percent."

People understand that. And in a free market, they can make very informed decisions because they have an opportunity to comparison-shop. And it just seems to me that in this area of health care, like in other areas of health care, there is not that transparency.

I understand what you are saying about the ability to negotiate contracts and propriety and not being able to give away trade secrets and that sort of thing, but it does really detract, you have to understand, from people's understanding of this market.

And there is a list price. And there is a rebate. And there are discounts. And there is a net price, ultimately, that is offered out there. But it all happens in this kind of opaque world that I think people just find really, really uncomfortable and question. It raises a lot of doubts.

For the panel: in testimony from Mr. Kolar and Mr. Prince, there was some discussion about the decisions for PBMs to consider clinical value and efficacy first when setting formularies, as opposed to price and rebates, the importance of, obviously, premiums in negotiations.

We have heard a lot about that today between manufacturers and PBMs, where rebates are used to incentivize placement of a more costly brand-name drug over a generic, or where rebates are conditioned based on the exclusion of another cheaper, clinically effective drug from the formulary.

Do all of the panelists take the same approach to negotiation? And how do you assess and determine clinical value in making the decisions? And how do you respond if price and rebates become the driving factor in the negotiation instead?

This question has been kind of asked in different ways today, but somebody take a shot at that. Anybody?

Mr. KOLAR. Senator, if I understand the question, our approach—again as a transparent client-owned PBM—our approach in setting formularies and making formulary recommendations, as you said—you referenced the testimony—starts first with an assessment of clinical safety and efficacy.

Then we assess if there are competing drugs available. And we have talked much today about the need for competition.

We do assess on a lowest net cost basis—so what is going to be the lowest net cost alternative for our plans to adopt for the benefit of their members. We do also consider the impact of patient transition in making formulary recommendations to our plans.

Senator THUNE. Does everybody follow that same negotiating tactic? Do you take into consideration efficacy?

Mr. RICE. Absolutely, Senator. We start with first making sure that we provide the highest level of quality of clinical care. And then, only when we have met that threshold do we begin to bring into consideration costs and providing the lowest-cost alternative to the members, because we have seen that when the drugs are more affordable for those members, they tend to have better adherence and then downstream have better medical outcomes.

And that, in essence, brings down total health-care costs.

Dr. FLEMING. Senator, the thing I might add is, we think about safety, efficacy, outcomes, and unit cost in that order.

If I had a dream, I would have more outcomes for when these medications come to market. Typically, all we know is that they are safe and effective. It is over time that we build a body of evidence to understand does this drug really avoid a hospitalization? Does it avoid an ER visit? Does it help with some sort of activity of daily living that has nothing to do with other health-care costs?

But those conversations are really important as we think about coverage and providing the best health outcomes for our patients.

Senator THUNE. Mr. Rice and Dr. Miller, you both reference legislation that I have worked on with Senator Carper to apply value-based insurance design to high-deductible health plans for chronic disease management. And I will have you—and maybe submit this for the record—but I would like to know if enacted, how you expect plans to utilize this tool, and what will be the impact on drug prices and health-care spending more broadly.

And like I said, my time has expired, Mr. Chairman. But if you would take that one for the record, I would like to get your reaction.

Thank you.

Senator LANKFORD. Thank you.

Senator Portman?

Senator PORTMAN. Thank you, Mr. Chairman.

And thank you all for being here today to shed light on a complicated area. I hear a lot of frustration back home over the cost of prescription drugs, and for some people, they actually are not taking the prescription drugs they should be taking because of those high costs. So it is affecting their health care.

And everybody has a role to play in this along the chain, going from the manufacturer to the pharmacy and to the consumer. And one is the PBMs. You have a role to play in trying to lower costs and bring more transparency—the word has been used a lot here today—to the system. People have a right to know.

And in Ohio, as Mr. Rice and Mr. Prince probably know, there is currently a lot of discussion about that. I am sure you have seen the investigative reports from *The Columbus Dispatch* and other stories regarding disputes between the State and your respective companies.

With regard to CVS, there have been concerns that you are withholding savings from the State Medicaid program and not providing equitable reimbursement to pharmacies. In regards to OptumRx, the State has raised concerns, again, regarding the company withholding savings from Medicaid, and the Attorney General has also accused your company of failing to disclose certain rebates to the Ohio Bureau of Workers Comp that are contractually supposed to be passed along to the State and to beneficiaries.

I am sure you are aware of those allegations and the stories. First, I would like to know what your answers are as to why the State and other stakeholders in the system would accuse you of hiding this kind of information. And again, getting back to my comment on transparency, wouldn't transparency solve a lot this, particularly with regard to the rebates?

Mr. RICE. Senator, I will go first. Let me start by first saying that I absolutely share your interests in making sure that we bring the utmost level of transparency to not only the plans, but also the

members and the constituencies and consumers in your State as well as other States.

The things that we have done—and I think it has been validated through the independent audit report that was conducted as well—I think we saved the State about $145 million. In the course of that, we have now made a decision as of January 1st of this year, that we no longer have spread pricing.

And as it relates to your commentary around pharmacy reimbursement, we reimburse the independent pharmacies far higher than the other major chains, including CVS pharmacy retailers as well.

So we try to bring a level of transparency such that people can make the right decisions, and even to Senator Thune's earlier comments about health-care consumers needing to be able to act like consumers, we have also tried to be transparent at the patient level. And the way we have tried to do that is equipping them with the data and the visibility to it such that they can comparison-shop.

So today we have real-time benefits which enable a physician to—in their office through electronic health records—share with that patient——

Senator PORTMAN. I totally support that. I think that is critical to getting costs down, ultimately.

Mr. RICE. Yes.

Senator PORTMAN. Consumers are pretty smart.

But I want to give Mr. Prince a chance to respond on the rebates.

And let me just say this. If the Ohio government, which can bring the full weight of the government down on this issue to find out what the rebates ought to be, is having trouble getting information, how about the small business out there? I mean, why shouldn't these rebates be more transparent to the beneficiary, which ultimately is the people I represent in terms of the Medicaid system and its workers' comp system?

Mr. RICE. The fact that we share, Senator—we pass through 100 percent of the rebates and discounts.

Senator PORTMAN. But——

Mr. RICE. One hundred percent.

Senator PORTMAN. Transparency has been the issue that we have not been able to resolve even in this case with the State of Ohio bringing pressure on the PBM system.

Mr. Prince?

Mr. PRINCE. Senator, we believe we have delivered against our contract for the State and also for the Bureau. We are not going to go into—I am not going to go into the details in the litigation here. But I guess I would say overall we are working closely with them to resolve the matter and make sure we address the concerns for them.

But overall our organization, we are very focused on—from a rebate standpoint—point-of-sale discounts. We actually made—as an organization we pass on 100 percent in the Medicare market, 100 percent in the Medicaid market, and we are committed in the commercial market to moving to everybody having point-of-sale discounts.

We are not taking on any additional customers in 2020 and beyond unless they do point-of-sale discounts.

Senator PORTMAN. Again, that is a matter of transparency also, so people can see what it is and understand what they are getting.

Let me give you one quick story here where PBMs, I think, play a constructive role. And this is with regard to investigations we did in the permanent subcommittee, investigations on the Evzio product, which is a naloxone product. It is a life-saving thing in the opioid epidemic. This is a miracle drug that reverses the effects of an overdose.

Kaléo, a company which provides this Evzio product, had dramatically increased their price, and they did it through kind of a loophole under the Part D Medicare program, saying that doctors should say it is medically necessary. And in that case, the PBM actually was encouraging the lower-priced alternative.

And I think that is what your role ought to be. In other words, you all stepped in as a PBM and said this life-saving care can be provided at a lower cost.

Now when they found the loophole, frankly, the PBMs did not have any additional role to play, and because the loophole is in our law, we are trying to fix that. And ultimately, I will tell you that the cost went down dramatically once we shone some light on this.

But I give that as an example where I think PBMs can play a positive role in the case of trying to keep drug costs down for beneficiaries.

Thank you, Mr. Chairman.

The CHAIRMAN. Senator Cardin?

Senator CARDIN. Thank you, Mr. Chairman. And I thank all of our witnesses for being here.

I want to drill down a little bit on your responsibility in regards to the public itself. You are the benefit managers. You are at the best interest of the people who need your services.

Today there are—according to the FDA, 270 drugs currently are in shortage. I know of specific drugs that are absolutely essential for infants' health, including eye drops, that are not readily available, for cancer treatment that are not readily available.

These are inexpensive drugs that are not difficult to produce, that are not being produced because the pharmaceutical manufacturer—usually one source—does not think it is worthwhile from a profit point of view.

Now, you have contracts with pharmaceutical manufacturers. Why have you not done something to act on making sure that in this country we do not have shortages of drugs that are essential for the health of the people in our community? You enter into contracts every day with pharmaceutical companies. Why is this not one of your goals, to make sure that in the wealthiest nation in the world, common drugs that are absolutely essential for serious health-care needs are not in shortage?

Who can answer that for me?

[No response.]

Senator CARDIN. Mr. Chairman, the silence is deafening.

Dr. MILLER. I will help you, mostly from a physician standpoint, and not as a PBM.

Senator CARDIN. Please.

Dr. MILLER. Let me help you out here.

Having drugs in supply is crucial. And so we do everything we can to make sure our patients have the drugs they need.

There are drugs that are used in-hospital which are different than the ones that we administer as outpatient, as a pharmacy benefit manager. The vast majority of the shortages in the last several years have been in-hospital drugs——

Senator CARDIN. So do any of your people who are in your plans ever use hospitals?

Dr. MILLER. Most definitely, they use hospitals.

Senator CARDIN. Do you care about their health?

Dr. MILLER. And so we care passionately about their health, and I as a physician care tremendously.

Senator CARDIN. So why have you not taken up this issue with the pharmaceutical manufacturers?

Dr. MILLER. We do. So we actually have predictive models where we can try to see which drugs are in short supply.

The biggest problem that we have had in the United States is when there is a single-source manufacturer.

Senator CARDIN. Yes.

Dr. MILLER. And usually the problem is specific to that product. So it is either——

Senator CARDIN. And do you not have contracts with that single-source manufacturer on other drugs?

Dr. MILLER. So they either flunk—sometimes, sometimes not. But when they flunk an FDA evaluation at their factory, they are forced to shut down. So we have worked with—and I think Dr. Gottlieb has done a great job at the FDA.

If you look at the number of shortages, they have actually dropped dramatically over the last several years because he is actually prioritizing review of those products to make sure that other companies can either compete or that product can get back into the marketplace.

Senator CARDIN. You know, we all hear about using market forces. I was very impressed with our conversations of how market forces bring down the cost, and how you use that in your bargaining power with pharmaceutical companies to get the very best possible price for your customers, for your consumers.

Why do you not use that market force to make sure we do not have drug shortages? That is my point.

You can make a difference today on this issue. You can use market forces to say, "Look, we will not tolerate our subscribers not having access to absolutely essential medicines because there is a single-source manufacturer who has made an economic decision that it is not worth it to manufacturer that drug."

Do any of you have an explanation why we are not doing something? You do not want government to set price, but you want government to deal with shortages when you could deal with shortages.

Any ideas here?

Mr. RICE. The best idea, Senator—and we talked about this a bit—is competition, is working with the FDA to make more generics. And quite frankly, the shortages that we are talking

about are usually for those single-source or generics, and making more generics available to the marketplace would help.

And we talked about ways that we can try to incentivize manufacturers to pursue and to manufacture more generics than we do today.

Senator CARDIN. I cannot accept that. I will tell you why.

You are a major factor in the pharmaceutical delivery system. Market forces are allowing you to make profits, which is fine.

You have leverage over pharmaceutical manufacturers. You can affect whether they will be on a formulary or not. You really determine their financial success, and that is why you negotiate your price.

But it is more than the unit price of a particular drug that my constituents and your subscribers are interested in. They are interested in their general health.

And if they cannot get a medicine today to deal with their cancer, and that is a real example, why are you not taking the initiative to change that?

I really do not understand that. If you have a useful role in this process, then deal with this issue.

Senator LANKFORD [presiding]. Senator Menendez?

Senator MENENDEZ. Thank you, Mr. Chairman. Thank you all for being here.

I would like to start off with the same free advice I gave the pharma CEOs who appeared before the committee in February, which is—and as someone who appreciates the industry as a whole from the State of New Jersey, either you come to the table with real solutions to help patients in terms of the costs, or you will find a legislative response that you will not care for.

So I really urge you to be part of the solution at the end of the day, or you will find a legislative response you do not care for.

Having said that, there are widespread reports that PBMs engage in spread pricing, especially for generic drugs, where they pay the pharmacy one price but turn around and charge their clients several times the price the pharmacy received.

So let me tell you how this little game seems to me. It is like asking your mom for $10 to buy a T-shirt that costs $8, and giving the seller only $7 and keeping the rest for yourself.

So have any of you here today ever engaged in that practice? Just go down the line and give me an answer, "yes" or "no."

Dr. MILLER. We provide our clients with a lot of options on how to pay for their pharmacy benefit, and spread pricing is one of those options.

Senator MENENDEZ. So the answer to that is "yes."

Next, Mr. Rice?

Mr. RICE. Yes, we too provide our clients with options which include spread pricing.

Senator MENENDEZ. Dr. Fleming?

Dr. FLEMING. Senator, thank you. For 8.4 million Part D members, absolutely no, never. For our commercial, fully insured members, no. And for our limited self-funded block of business, we do offer that option. That is about 200,000 members.

Senator MENENDEZ. Mr. Prince?

Mr. PRINCE. Senator, we do not do it in the Medicare program. In the commercial and Medicaid market, it is a client choice about how they want to pay for our services. Ninety-eight percent of the time, we actually offer the solution either way. And the client chooses how they want to pay for our services.

Mr. KOLAR. So, Senator, in our model we are focused on creating savings for our plans and not margins. We do not engage in spread pricing as a part of our business model.

Senator MENENDEZ. So what is the difference between the rebates you negotiate—let me ask this of Mr. Prince and Dr. Miller. Are the rebates you negotiate from pharmaceutical companies in the separate administrative fees that you charge the same companies?

Mr. Prince?

Mr. PRINCE. So in the Medicare program, we only collect a fixed rebate from pharmaceutical manufacturers and pass 100 percent of that on. We do not have an administrative fee in the Medicare market or the Medicaid market.

Those markets are—we have just fixed discounts that we pass on. In the commercial market, we do have an administrative fee that is disclosed to our client. And that is for clinical services.

Senator MENENDEZ. Dr. Miller?

Dr. MILLER. So in Medicare, as you know, all the fees pass back to the government. In the commercial marketplace, we give our plans options as to how they want to pay us.

Many of them take all the rebates and the administrative fees. Some choose to let us keep a portion.

Senator MENENDEZ. Are these administrative fees based on list price like the rebates? Just give me a simple "yes" or "no."

Dr. MILLER. The administrative fee is usually a fixed fee, not based on the rebate. And it is for services——

Senator MENENDEZ. Are they based on the list price?

Dr. MILLER. Are they based on the list price? I would have to—I believe that there are options to base it on the list price or to have a flat fee.

Senator MENENDEZ. Mr. Prince?

Mr. PRINCE. Senator, as I said before, the administrative fees are only in the commercial market. They are linked to the services that we offer. Today they are linked to a percent, but we are open to changing that to a fair market value that is fixed.

Senator MENENDEZ. Because as the list prices increase, the administrative fees you collect, as well, increase. Is that not true?

Dr. MILLER. That is why we give our plans the option.

Mr. PRINCE. That is why I also give our plans the options of how to pay for our services.

Senator MENENDEZ. Finally, when a drug company does lower their list price, how long does it take for the patient at the pharmacy counter to see that savings, if ever? Let me give you an example. Last fall, you may have read in the news that the list price for one PCSK9 inhibitor, a cholesterol-lowering drug, went down by 60 percent.

Despite the price decrease, putting the drug's price below the threshold for specialty tier status, I recently read that PBMs have

kept the drug on a specialty tier, which means it is more expensive for Medicare beneficiaries.

Going down the line, can you tell me in one or two sentences why a list price cut would not lead to lower prices for consumers? And if you are going to tell me it is the different national codes, then if you get guidance on how to handle this NDC issue, can we expect lower list prices leading to immediate tier changes?

Dr. MILLER. Thanks for the question, Senator. As you know, we were the ones that actually negotiated with that PCSK9 inhibitor company to bring that lower price to the marketplace. And so we definitely believe those prices should be reflected in what the patients pay.

Mr. RICE. Senator, when those lower list prices result in the lowest net cost for the patient as well as for the plan, then absolutely, that is the preferred drug on formulary.

Dr. FLEMING. Senator, we like lower list prices. And candidly, had we known that the manufacturer was going to lower its list price, or bring an authorized generic to market, or bring one of these other things that allow their prices to come down during the formulary-setting time for Medicare, which is around this time of the year, in 2018 for this 2019 period, we absolutely would have had that drug on formulary.

We absolutely anticipate including those drugs on formulary for the 2020 benefit year.

Mr. PRINCE. Senator, we strongly encourage pharmaceutical companies to lower the list price and do that in our discussions with them. We are a strong advocate for making sure we pass on the value of all the discounts we negotiate to that consumer.

That is why last year we expanded that program dramatically. It will serve 9 million people in 2019. We can only have new customers—in 2020—that pass on the consumer discount, all that value to the consumer at the point of sale.

Mr. KOLAR. So, Senator, as a PBM focused on driving savings for our plans, we welcome lower list prices as well. When a lower list price drug becomes available, we will assess the net cost effect to our plan as well as the impact of transition across members.

And if the drug is the lower net cost, we will prefer that drug, and those savings will pass through to the members.

Senator MENENDEZ. Thank you.

Senator LANKFORD. Senator Carper?

Senator CARPER. Thanks; our thanks to each of you. I think my staff and I have had the privilege to meet with most of you in the run-up to today's hearing. We appreciate your time.

As I mentioned to those with whom I have met, when we took up the Affordable Care Act, in this room, there were witnesses saying that folks in Japan were spending 8 percent of GDP for health-care costs—8 percent. We are spending 18 percent.

They got better results and covered everybody. And we did not get better results. You had about 40 million people at the time going to bed at night without health-care coverage, and we said, "We can do better than that." And in some respects, we have done better than that.

I think if we had more cooperation from some of our friends on the other side of the aisle and the current President, we could do

even better in terms of getting better results for less money, providing care the people need.

We have a strong interest in pharmaceuticals in my State. It is consumers, patients, people who pay for health care, and also employment. We have some very fine companies that are involved in pharmaceuticals, as you may know.

One of the things I would like to try to do is develop consensus, and to find consensus on a panel like this is what I would like to do in the next couple of minutes.

But in the last Finance hearing on drug prices, we heard from drug manufacturers that passing rebates directly to consumers, improving transparency, and adopting value-based arrangements would help reduce prescription costs.

I am not going to ask you to comment on those points, but there is a fourth one that came up, and that was putting a cap on patients' out-of-pocket drug cost. And they suggested that putting a cap on patients' out-of-pocket drug cost may well help reduce prescription drug prices. And I would just like to hear from each of you.

We will start with you, Mr. Kolar. I do not think I had a chance to meet with you before the hearing. So let us start off with you.

Do you agree with that? Why or why not?

Mr. KOLAR. So, Senator, capping patient cost—I assume you are speaking about Part D and a proposal to cap costs there. We believe that that is an issue worth studying.

When the Part D benefit design was rolled out, it was not the drug pricing environment that we have today. Patients are exposed to very high drug costs at the pharmacy counter, a percentage of them.

We do believe, however, that that is going to require all stakeholders to be a part of the conversation. We cannot squeeze the balloon and then have increased costs in the form of higher premiums for beneficiaries, or higher cost to taxpayers. It is going to have to require manufacturer participation and list price relief.

Senator CARPER. Thank you.

Mr. Prince?

Mr. PRINCE. Senator, we would support a capping of the Part D out-of-pocket costs if it is part of a broader reform of the part D program. The program has been around and delivered a lot of value for seniors over the last decade-plus, for almost 50 million seniors.

And so, as part of a broader reform that looks at all the implications for other changes too——

Senator CARPER. All right. Thank you.

Dr. Fleming?

Dr. FLEMING. Senator, thank you. We absolutely support modernizing Part D. I think the notion of putting caps on out-of-pocket costs is one of the tools that could be used, and dealing with the specialty drug issue where nearly half the drug spend in the next couple of years will be consumed by specialty drugs—consumed by 2 percent—is another example.

I am not convinced that just putting caps on member out-of-pocket costs will cause the manufacturers to lower the list price. I think you are going to need to think through what are the tools

and levers to maybe have the manufacturers participate in those out-of-pocket limits, or other levers to pull there.

But I do think out-of-pocket cost is something that is important for consumers.

Senator CARPER. Thank you.

Mr. Rice?

Mr. RICE. Senator, we absolutely share the concern in terms of the burden of out-of-pocket costs on today's patients and American citizens. We absolutely would support putting a spending limit or cap for seniors in terms of their out-of-pocket exposure.

At the same time, we also support tools such as preventative drug lists with zero copays as another means of also trying to deal with the out-of-pocket burdens of Americans in this country.

Senator CARPER. All right. Thanks.

Dr. Miller?

Dr. MILLER. Yes. Thanks for the question.

I think targeted copay caps are really crucial. As you know, just a couple weeks ago we rolled out the Patient Assurance Program where we capped insulin at $25 a month. We believe that it is really important for our diabetic patients to be able to take their medications. That is the best way to lower costs for the country and improve health outcomes. But it should be in a very targeted manner.

Senator CARPER. Mr. Chairman, my time has expired. I want to just mention a question for the record, but I just want to get it out here, and it relates to the first question.

For the 40 percent of drugs in Medicare Part D that do not offer rebates, what are your recommendations for lowering their prices? And I will give you that question to respond to for the record.

All right. Thank you very much.

Senator LANKFORD. Thank you.

Senator Casey?

Senator CASEY. Thanks, Mr. Chairman. I want to thank the witnesses for being here.

I think I may have said this to each of you at various times when we have discussed these issues, that when it comes to this issue, the cost of prescription drugs, if this issue were playing out in isolation, that would be one thing. Unfortunately, the folks who are bearing the burden of this, bearing the cost, are the same folks who have lived in a country where wages went up by 12 percent over 40 years by one estimate. So, in 4 decades, wages went up only 12 percent.

And the costs of everything you can imagine for the middle class and folks trying to get into the middle class are skyrocketing. If you are younger and you have a family, it is the cost of child care and maybe saving for college.

It seems like everyone is impacted by the cost of prescription drugs going through the roof. I just had a witness from Pennsylvania at our Aging Committee hearing, Barbara Cisek, who is from southwestern Pennsylvania and is 63 years old. She has multiple chronic conditions, including ulcers, COPD, severe migraines, and the list gets longer and longer. Five hundred bucks a month she is paying just on prescription drugs. That does not include premiums, and it does not include doctor visits.

So Barbara is emblematic of that senior citizen carrying yet another cost. It is like American families have bags of rocks put on their back. And prescription drugs are just another bag of rocks that gets thrown on them.

A lot of people are just face-down on the pavement from these costs. And I heard your testimony, and I read through some of the ideas you have. And we appreciate those ideas.

But I think there has to be, from you and from manufacturers, a sense of urgency about this. Not just ideas thrown around, but a sense of urgency and what more you can do.

And that leads me to Medicaid, which is—you all are familiar with the program, but maybe not until 2017 were enough Americans familiar with the program, and certainly politicians were not. But politicians found out in 2017 that Medicaid is an "us" program, not a "them" program.

They found out that in a State like mine, Pennsylvania, 40 percent of the kids benefit from Medicaid, roughly. Approximately half the people with disabilities benefit, and more than 60 percent of the people in my State who are over the age of 65 benefit from Medicaid—seniors, kids, and people with disabilities.

And that program is being decimated before our eyes. Or at least attempts were made to do it.

And another thing we need your help on is to speak up when proposals are made here. There is a House Republican budget proposal, voted on by the House Budget Committee, that would cut Medicaid by more than a trillion and a half dollars.

The administration, just days ago, proposed another trillion and a half cut to Medicaid over 10 years. The silence on that side is deafening. I hope the silence in your board rooms, from your companies, is not deafening.

We need your help on this. We need your help to fight against these kinds of cuts. It will hurt Americans who are very vulnerable. It will also hurt each of you in your own way.

This question we will do very quickly, because you have already answered it, but I want to hear it again. One of the things that Senator Menendez raised was so-called "spread pricing contract behavior" in which pharmacy benefit managers mark up the difference between how much they reimburse pharmacies and the amount they charge the plan sponsor.

I want to ask each of you, have you engaged in that practice, number one? And number two, if you have not, does your company plan to do anything to make sure that you never engage in that process?

I will start with Dr. Miller and go down. And you can amplify it in written form, because we are running out of time.

Dr. MILLER. Yes. So in limited cases, we do engage in spread pricing. We give our clients the options of how they want to reimburse us. And that is one of the options available to them.

Senator CASEY. Mr. Rice?

Mr. RICE. Senator, it is an option that we do provide to our clients in terms of how they want to engage in remuneration.

Dr. FLEMING. Senator, we are an integrated health plan—for Medicare members, no. For Medicaid, no. For our fully insured commercial, no. It is available on a limited basis for our self-funded

population, which is about 200,000 members. And it is client choice.

Mr. PRINCE. Senator, we do not engage in that in the Medicare program. In the Medicaid program, it is client choice about how they want to contract and pay for our services. In the commercial market, it is also client choice on how they want to pay.

Usually, each client in the commercial market asks for a bid with it and without it. And it is a client choice about how they want to pay for our services.

Mr. KOLAR. So, Senator, our business model is transparent and passed through. With our clients, our model is not to engage in spread pricing.

Senator CASEY. Thank you, Mr. Chairman.

Senator LANKFORD. Senator Whitehouse?

Senator WHITEHOUSE. Thank you, Mr. Chairman.

Are the pharmacy benefit managers the most formidable force that the pharmaceutical industry faces in terms of bringing its pricing down?

[No response.]

Senator WHITEHOUSE. Somebody is going to answer that, right?

Mr. KOLAR. Senator, I would say competition would be the other force that heavily influences.

Senator WHITEHOUSE. But, as an institution, you guys are organized. You have a lot of expertise on your side. And you tangle with the pharmaceutical industry to bring rebates that then go through to your clients, who are mostly insurers, and that ends up supporting clients.

That is kind of the theory of the case, is not it? Yes?

Mr. RICE. Yes, Senator.

Senator WHITEHOUSE. Yes. So let me—two quick numbers here. The pharmaceutical industry, last year, declared $27.5 million in lobbying. And the individual drug companies add another $194 million, for a total of $221.5 million in lobbying by the pharmaceutical industry, which as a general proposition, if you want to understand what is wrong with Congress, just ask about one industry that does $220 million in lobbying in 1 year. So that is one figure—that $220-plus-million on lobbying.

The other is that, out of $480 billion that the U.S. spends on drugs, my figures are that $323 billion of that goes to the pharmaceutical industry, and $23 billion of it goes to you.

So that makes you 7 percent of what the pharmaceutical industry gets, and 5 percent of the total spending. So if we whacked you in half, that would affect prices by 3½ percent.

Fair math?

[No response.]

Senator WHITEHOUSE. So it has to be interesting to you all to witness how the pharmaceutical industry has been able to take pressure on their pricing and turn it into, with political Jiu-Jitsu of an almost magical variety, pressure on their greatest adversary, the most powerful force for pushing prices down.

So I hope that you at least respect what they have been able to pull off here. That is quite a trick on their part.

You do not decide where the rebate goes when you send it through your client, do you?

Mr. RICE. No.
Senator WHITEHOUSE. No.
Do some of you have State Medicaid programs as your clients?
Mr. RICE. Yes.
Senator WHITEHOUSE. Yes.
Dr. FLEMING. Yes.
Senator WHITEHOUSE. Yes.
Mr. PRINCE. Yes.
Senator WHITEHOUSE. Yes.
Mr. KOLAR. Yes.
Senator WHITEHOUSE. Yes.
Dr. MILLER. Through some of our health plans; correct?
Senator WHITEHOUSE. Okay, indirectly, then. Four "yeses" and one "indirectly."
And presumably those State Medicaid plans have the same rights as your other clients to audit and look into your methodology and your cost in your rebate structure?
Mr. KOLAR. So, Senator, just to clarify, my answer was also an indirect "yes."
Senator WHITEHOUSE. Got it.
Mr. KOLAR. Yes, our direct——
Senator WHITEHOUSE. With respect to my question, can any State Medicaid program look at your books as a client?
Mr. KOLAR. Our clients have extensive audit rights in our business, and their clients have audit rights into our business. Correct.
Senator WHITEHOUSE. Great.
So the State Medicaid programs do have audit rights in your business?
Mr. KOLAR. Correct.
Senator WHITEHOUSE. True for all five of you?
Mr. RICE. Indirectly, yes.
Senator WHITEHOUSE. Directly or indirectly.
Dr. FLEMING. Senator, I might add that in the primary State where we have Medicaid business, the State does its own rebates and formulary.
Senator WHITEHOUSE. Yes.
And there is legislation pending to provide transparency into your business model, both to MedPAC and to MACPAC who would then be in a position to provide expert advice to Congress on whether there were problems with the industry and things that we should address without having to divulge every part of your business. By the way, I would support full transparency, but this is not my hearing. This is your hearing.
So one-by-one, do each of you support or oppose the legislation that would give MedPAC and MACPAC the ability to examine your business model and report to Congress?
Dr. MILLER. Support.
Senator WHITEHOUSE. Support.
Mr. RICE. Support.
Senator WHITEHOUSE. Support.
Dr. FLEMING. Senator, we are neutral on that.
Senator WHITEHOUSE. Okay. No opposition.
Dr. FLEMING. No opposition.
Senator WHITEHOUSE. Even through your lobby groups?

Dr. FLEMING. Right.

Senator WHITEHOUSE. Because sometimes people say they have no opposition, and then they send their lobbyists out the opposite.

Mr. PRINCE. We support if kept confidential—if the data is kept confidential.

Senator WHITEHOUSE. Yes, but the advice to us can be, you need to look at this, this, and this. And you understand that? There is an advice to Congress function in that.

Mr. PRINCE. Right, as long as the data is kept confidential.

Senator WHITEHOUSE. Got it.

Mr. KOLAR. We support.

Senator WHITEHOUSE. Support. Okay.

Well, let us hope we can at least get that piece of legislation moving, which I think would be very helpful, and I think a considerable number of members of this committee support it. And then we will keep looking, but I guess my point is, I appreciate the scrutiny of the PBMs, but let us not go away without remembering that they are $23 billion out of a $480-billion problem.

And just as somebody who sees a lot of this around here, I stand in awe of the pharmaceutical industry's Jiu-Jitsu magic to have gotten their prime antagonists to become the focus of the problem with, by my count, $457 billion remaining to be looked at.

Thank you, Mr. Chairman.

Senator LANKFORD. Thank you.

The chair recognizes himself for some time for questions.

Gentlemen, thank you for being here. Thanks for a very long morning to be able to go through this kind of dialogue. There are a lot of questions that you have been peppered with during the course of the day.

Let me bring up some specifics that maybe we have not dealt with already. The administration has put out a point-of-sale effort for DIR fees. Does anyone here have a problem with what the administration has put out so far as a recommendation for how to do a point-of-sale effort for DIRs?

Dr. MILLER. Are you talking about the point-of-sale rebate?

Senator LANKFORD. Yes.

Dr. MILLER. So we really support the sentiment. We believe that lowering cost at the counter is really crucial to patients.

However, I am not convinced that this mechanism is going to be very successful. A couple of things: one is, it shifts cost to the taxpayer. CMS auditors have estimated that to be about $196 billion over the next 10 years.

Second is, many patients will pay down their copay so they will get stuck on a branded product instead of switching to a generic that is equally effective and, therefore, continue to cause high cost.

Third is that, when you make the rebates publicly known, it will make our ability to negotiate deeper discounts that much less effective. And so you will not get as effective discounts, and you will decrease our negotiations. You will take the pressure off of pharmaceutical companies; you will raise the premium for 100 percent of the beneficiaries while only helping a minority of the beneficiaries.

And so we believe, while the intent is really good, there are targeted ways to achieve the same thing without these problems.

Senator LANKFORD. What would those be?

Dr. MILLER. So one of the things we did is, if you look at the categories of drugs that are creating the pain for the patients at the pharmacy counter, they fall into several buckets. It is diabetic agents. It is hepatitis C. It is asthma. Those are the ones that actually—if you had a targeted solution for those, you would actually relieve most of the patients who have the problem.

If you think about patients with cancer who have an enormous burden at the counter—because there are no rebates in those products—they do not benefit at all from moving the rebate to the point of sale.

Senator LANKFORD. Right.

Does anyone have any other feedback on that, on both the administration's recommendation or responses to it?

Mr. RICE. Yes, Senator. We are absolutely supportive of the administration's goal of reducing out-of-pocket costs for seniors and lowering overall health-care costs. We too—when we look at the proposed rule—have a few concerns where there may be elements of it that would drive costs higher actually, not lower. The types of solutions that we would put forward are, again, point-of-sale rebates as an option. And we were the first Med D plan to provide that option in 2019 for seniors who want to sign up.

In addition to that, we would also be very supportive of preventive drug lists with $0 copays, again, as another means of reducing the out-of-pocket burden for seniors that we are all worried about.

Senator LANKFORD. So, let me switch subjects on this a little bit.

When I talk to independent pharmacies, they will talk about the DIR fees 100 percent of the time, and clawbacks. They are a standalone rural pharmacy, and there are two issues that come up. Let me deal with them in order.

One of them is, obviously, they get a bill at some point for $50,000 that they are clawing back from something 6 or 7 months before, and they did not know that was coming back. Obviously, cash flow becomes exceptionally difficult on that.

They will reference that there are performance metrics put on them, but I can never hear what those performance metrics are. Can anyone give me an example of what performance metrics might be for an independent pharmacy to avoid the clawbacks?

Dr. FLEMING. Senator, I am a pharmacist. Forever, pharmacists have wanted to be paid for cognitive services, to be at the top of the list.

Senator LANKFORD. I am limited on time. I understand for the cognitive part of it.

Dr. FLEMING. Yes, sir. So the example of performance fees that we put in place to get the pharmacists engaged are things that will help the patient with drug adherence, identify those patients who are not as adherent, engage with them.

And through these programs, we have seen a 2 percentage-point increase in drug adherence in several disease states year over year over year because of getting the pharmacist engaged in a value-based conversation just like we asked doctors and hospitals——

Senator LANKFORD. All right.

Any other examples of metrics? Are those proprietary, the metrics that go out to independent pharmacies?

Dr. FLEMING. Senator, no.

Senator LANKFORD. Okay.

We will kind of walk through that somewhat. I have had several independent pharmacists who have said to me, they will have a particularly large requirement for a DIR fee, a clawback. And within 2 weeks after that big check comes in, they will get a phone call from a PBM that also owns pharmacies that will say, "How are things going? Would you consider selling to us?"

They find those things strangely coincidental, that they have a big check for a clawback and then a phone call to say, "Are you interested in being able to sell back to us?"

Now, I would certainly hope those two are not aligned. But that is a concern that they have, that is expressed. I cannot be the first person who has expressed that to anyone here.

Let me express one thing, because I do not expect us to be able to answer that without knowing the specifics on the location. Do you ever negotiate a higher list price for a drug to give you more flexibility on the rebate side? Is there a time when you work with a manufacturer to negotiate a higher list price to give you more flexibility? And let's have each of you answer that.

Dr. MILLER. No.

Mr. RICE. No.

Dr. FLEMING. No.

Mr. PRINCE. No.

Mr. KOLAR. No.

Senator LANKFORD. Do any of you ever, when a generic becomes available—do you put the generic on a formulary with the branded group? So there are branded tiers, generic tiers, and such where the generic would enter the formulary in a branded tier. Does that happen with you at all on the pricing?

Dr. MILLER. I would have to—on the basis of the large number of drugs, I would have to get back to you if there is any specific example. But that would not be our practice.

Senator LANKFORD. Okay.

Mr. Rice?

Mr. RICE. Senator, our focus is providing the lowest cost option.

Senator LANKFORD. So that generics would not be on a branded tier?

Mr. RICE. If it is the lowest cost option.

Dr. FLEMING. Senator, I can think of limited circumstances, very rare, where that is the case, usually because of the 6-month exclusivity rule when a generic hits the market.

Mr. PRINCE. Senator, our objective is around lowest net cost for drugs in what tier it goes on. But in terms of what might be—I am not sure if there would be examples where that might occur. But it would be rare.

Senator LANKFORD. Okay.

Mr. KOLAR. Senator, I cannot think of a specific example, but our model would be to prefer the lowest net cost drug.

Senator LANKFORD. To the consumer?

Mr. KOLAR. To the plan.

Senator LANKFORD. Okay.

Mr. KOLAR. For the benefit of the member.

Senator LANKFORD. Okay.

Senator Wyden?

Senator WYDEN. Thank you, Senator Lankford.

And I also note that the chairman of the committee, Senator Grassley, is here, and he was kind enough——

The CHAIRMAN. Let me thank Senator Lankford for taking over for me while I met with the Iowa hospital people.

Senator WYDEN. And I want to thank Chairman Grassley as well for being able to ask this extra question.

So, gentlemen, a couple of hours ago I said the whole system—drug companies, middlemen, insurance companies—the citizens think this is all one big scam. It is a ripoff. They are all scratching each other's back and trying to keep the prices up, and everybody is blaming each other.

My own view is—and I have talked to the chairman about this—every sector of American health care has got to bring more value and lower prices. In other words, you have to get beyond the blame game.

Now, for 2 hours you heard from both sides of the dais, the Democratic side and the Republican side, that there are not a lot of people up here on this side of the dais holding rallies for spread pricing.

Okay. And the reason why you heard this from Democrats and Republicans is that spread pricing is a ripoff, plain and simple. When a PBM pays a set price to a pharmacy and then the PBM turns around and charges Medicare and Medicaid many times more for that prescription, that is plain old price-gouging.

So I just want to ask a question and want to hear you answer it in a "yes" or "no" fashion. If the Congress proposes to ban spread pricing in Medicare and Medicaid, will you oppose it?

Let us go right down the row. This is just a "yes" or "no."

Dr. MILLER. We look forward to working with you on it.

Senator WYDEN. "Yes" or "no"? Are you going to support it if Congress proposes a ban on spread pricing in Medicare and Medicaid; "yes" or "no"? Will you oppose it?

Dr. MILLER. If it becomes market standard, we are supportive.

Mr. RICE. Yes.

Dr. FLEMING. One hundred percent support. We always have, always will.

Senator WYDEN. Good. We're making some headway. We are going to save taxpayers some money.

Sir?

Mr. PRINCE. We do not do spread pricing in Medicare, and it is the choice of the client on the——

Senator WYDEN. Will you oppose it if we propose, in Medicare and Medicaid, outlawing it? That is a "yes" or "no"?

Mr. PRINCE. Probably neutral.

Senator WYDEN. Okay.

Mr. KOLAR. We would not oppose.

Senator WYDEN. Great. So, out of the five of you, we got three who will be with us if we propose getting rid of spread pricing in Medicare and Medicaid. And we got one "neutral," and one I am just going to scratch my head about a little bit and try to figure out.

Gentlemen, you heard from Democrats and Republicans——

Mr. RICE. Senator, I want to make sure we are clear. I was saying "yes," we would support——

Senator WYDEN. The ban.

Mr. RICE. Yes.

Senator WYDEN. Yes. There are five of you. We got three of you to be with us, one of you to be neutral, and one to take a position that I am going to have to decipher.

But the point really is, gentlemen, this is a gut question. I do not think it is really complicated.

As Chairman Grassley and I have talked about, this taxpayer money, Medicare and Medicaid—some of the States have already been blowing the whistle. We have not even talked about Kentucky yet.

So I am leaving here saying I got 60 percent of you to say we are going to protect taxpayers, but we have a lot more to do. And I want you to know that everybody in this—the drug companies, the middlemen, yourselves, the other players—has got to be part of it, the insurers. So I hope that we will keep the record open. I hope all of you are going to join me in saying we ought to ban spread pricing in Medicare and Medicaid.

Mr. Chairman, thank you for the chance to get into an additional area.

The CHAIRMAN. Thank you very much.

First of all, I thank you for your attendance. Thank you for the preparation. I assume you had to put a lot of preparation into it, even though you know your business well.

We thank you for that. And you know the inside, and you know that I have said it is kind of an opaque business, and we need more transparency, and all that. So you have helped us considerably on that. And I assume that we will be back to you, or we will be hearing from you as we progress. I hope you will cooperate with us. I know you will, so I do not have any questions about that.

I am going to ask all the members, if you have questions in writing for these five witnesses, Tuesday, April the 23rd, is the deadline for that. And then, in turn, the extent to which you have to respond to those, I hope you can do it as soon as possible.

With that, this hearing is adjourned. And thanks, everybody, for attending.

[Whereupon, at 12:47 p.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF WILLIAM K. FLEMING, PHARM.D., SEGMENT PRESIDENT, HEALTHCARE SERVICES, HUMANA, INC.

Chairman Grassley, Ranking Member Wyden, and the members of the committee, thank you for the opportunity to be here today. My name is Dr. William Fleming, and I am a pharmacist. I have spent nearly 30 years working in a variety of pharmacist roles, including 25 years with Humana. I currently serve as Segment President of Humana's clinical organization, which includes pharmacy, home health, and behavioral health.

I am honored to join you today, and I look forward to working with the committee to achieve our shared goals of reducing prescription drug prices for Americans and improving the Medicare Part D prescription drug program for current and future beneficiaries.

Humana is an integrated health and wellness company focused on providing value to seniors by operating a holistic, health outcomes-driven model that is beneficiary-centric, and which focuses on chronic care and contains locally integrated health capabilities. Humana currently provides Medicare prescription drug coverage for more than 8.4 million seniors across all 50 States, with approximately 4 million Medicare Advantage (MA) members and 4.4 million Medicare Prescription Drug Plan (PDP) members. We also provide medical coverage for approximately 1.5 million commercial customers, more than 340,000 Medicaid beneficiaries, and 5.9 million TRICARE enrollees in the eastern United States. Humana is unique in that our pharmacy and medical teams are tightly integrated and focused solely on serving our own members—not those of other payers. As a result, the savings we achieve through our pharmacy programs, such as manufacturer rebates and discounts, accrue directly to our members through lower premiums and improved benefits.

Humana's integrated approach to serving seniors delivers a personalized and simplified experience through a value-based health ecosystem that improves clinical outcomes. This ecosystem includes 233 owned, jointly-owned, or allied primary care facilities; an ownership interest in the Nation's largest home health and hospice providers;[1] as well as initiatives to address social determinants of health.

HUMANA'S TRANSPARENCY AND CLINICAL INNOVATION TOOLS

Humana is focused on providing seniors with the best care possible. As part of that goal, Humana has developed innovative solutions for ensuring that our members are informed when making decisions about their prescription drugs to reduce costs and improve health outcomes including:

- *IntelligentRx:* Humana was the first Part D plan to provide real-time access to drug cost and formulary information to physicians and their patients through our IntelligentRx tool. IntelligentRx enables physicians and their patients to make joint treatment decisions based upon efficacy and cost for 3.1 million prescriptions annually. The tool is currently available to all 10 million Humana members, including individuals with Medicare, Medicaid, and employer coverage.

[1] Forty percent stake in Kindred At Home and CURO Health Services.

- *Maximize Your Benefits (MYB) Program:* Humana continuously analyzes our members' prescription drug claims to identify opportunities for them to save money by switching to a lower-cost drug or by pointing them to other savings programs such as foundation-based cost-sharing assistance. Based upon that analysis, we proactively reach out to our members and provide instructions on how to maximize their savings opportunities. We estimate that the program saved our members almost $200 million in 2018.
- *Clinical Pharmacy Programs:* Humana also ensures that seniors are taking the right combination of drugs necessary to improve their health through our clinical programs—medication therapy management (MTM) and medication reconciliation during transitions of care from facility to home. Through these programs, we help seniors by eliminating duplicative drugs, identifying lower-cost options, supporting medication adherence, and identifying possible adverse drug interactions. As a result of these initiatives, beneficiaries have increased medication adherence by as much as 13 percent and have experienced reduced emergency room visits, urgent care visits, and hospital admissions.

I appreciate the committee's keen interest in working to understand better the root causes of high drug costs and advancing policy solutions.

EVOLUTION OF THE MEDICARE PART D PROGRAM

Less than 15 years ago, Americans did not have access to an outpatient prescription drug benefit under Medicare. Today, more than 43 million seniors have access to life-improving medicines through Part D.[2]

At the inception of the Medicare Part D program, Congress designed a competitive marketplace where prescription drug plan sponsors competed based upon premium. As a result, seniors enrolled in prescription drug coverage have gained significant value from the program's focus on market competition including:

- Stable premiums through the 13 years of the program averaging approximately $30 per month by negotiating rebates to lower costs for all seniors;[3]
- Generic dispensing rates near 90 percent;[4]
- Medicare beneficiaries average more than 26 Part D plan sponsor options;[5]
- A 50 percent reduction in medication non-adherence due to affordability;[6] and
- Beneficiary satisfaction rates near 90 percent.[7]

Despite the benefits realized by Part D beneficiaries, there are still seniors who struggle with the increasing cost of prescription drugs. This is especially true for the 1 million beneficiaries who are not eligible for the low-income subsidy who reach the catastrophic phase of the benefit each year and generally spend more than $3,041 in out-of-pocket costs for their prescription drug needs.[8]

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[2] "March 2019 Report to the Congress: Medicare Payment Policy:" *http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0.*

[3] *Ibid.*

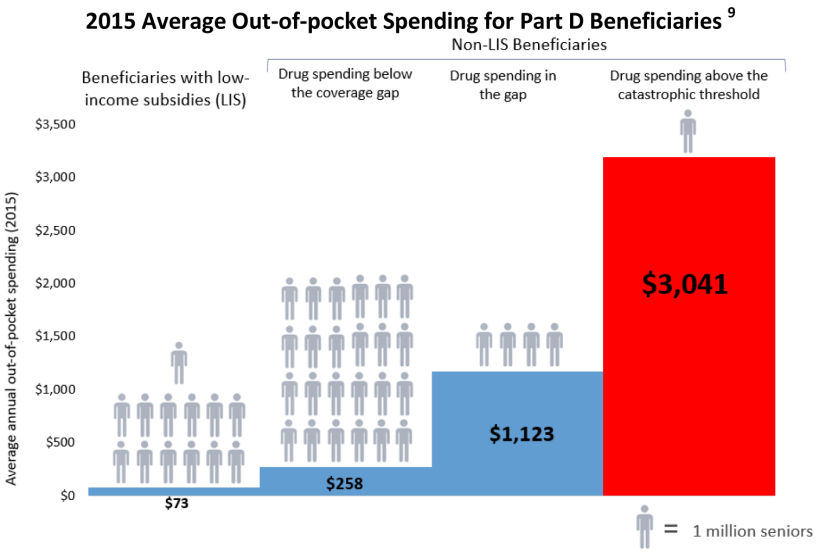
[4] *Ibid.*

[5] *Ibid.*

[6] Diebold, Jeffrey. "The Effects of Medicare Part D on Health Outcomes of Newly Covered Medicare Beneficiaries." *The Journals of Gerontology:* Series B, Volume 73, Issue 5, July 2018, pages 890–900: *https://academic.oup.com/psychsocgerontology/article/73/5/890/2631953.*

[7] 2018 Medicare Today Senior Satisfaction Survey: *http://medicaretoday.org/resources/senior-satisfaction-survey/.*

[8] *See* Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter, available here: *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf.*



The most recent Medicare Payment Advisory Commission (MedPAC) Report to the Congress from March 2019 echoed the challenges for the populations of seniors with high drug costs:[10]

- *Beneficiaries in the catastrophic phase continue to see increasing costs:* Spending for high-cost beneficiaries (those who reached the catastrophic phase) increased from 40 percent of Part D spending in 2011 to 58 percent in 2016.
- *The average list price increased 10 percent annually:* MedPAC cites the growth in the average price of drugs filled by high-cost beneficiaries as the most significant factor for spending growth among high-cost beneficiaries. The price per standardized, 30-day prescription for high-cost beneficiaries grew annually at 10 percent from 2010–2016.
- *Ten times the number of seniors reached the catastrophic phase on first fill in 2016:* The number of seniors who reached the catastrophic phase through a single claim increased from 33,000 in 2010 to 360,000 in 2016. Non-LIS beneficiaries were more likely to have this claim than LIS beneficiaries.
- *Spending on specialty drugs accounted for four times the share since 2007:* Specialty-tier drugs accounted for 25 percent of Part D overall gross spending in 2017, an increase from 6 percent in 2007.

Humana's experience reflects the challenges faced throughout the Part D program. In 2018, two percent of our beneficiaries who utilized specialty drugs comprised 36 percent of total Part D spending. In 2 years, Humana projects that seniors utilizing specialty drugs could account for as much as 50 percent of total Part D spending.

Ultimately, policymakers are faced with the challenge of preserving the benefits of the Part D program—which has been successful for many—while modernizing the

[9] Kaiser Family Foundation. "No Limit Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending:" *https://www.kff.org/report-section/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/;* Kaiser Family Foundation. "10 Essential Facts About Medicare and Prescription Drug Spending." January 29, 2019: *https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/;* Kaiser Family Foundation. "Medicare Part D in 2016 and Trends Over Time." September 16, 2016: *https://www.kff.org/report-section/medicare-part-d-in-2016-and-trends-over-time-section-4-the-low-income-subsidy-program/*. Part D enrollment figures reflect 2016 enrollment.

[10] "March 2019 Report to the Congress: Medicare Payment Policy:" *http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0.*

program to address the new challenges in the prescription drug market since the program's inception in 2003.

ANTI-COMPETITIVE BEHAVIOR BY DRUG MANUFACTURERS

As members of the committee have highlighted in previous drug pricing hearings, a major factor contributing to the increase in drug spending is the list price of prescription drugs. *Drug manufacturers alone set the list price of prescription drugs.* Drug manufacturers have also historically engaged in a host of tactics meant to delay generic competition, including preventing generic manufacturers from obtaining drug samples, utilizing the Risk Evaluation and Mitigation Strategy (REMS) process to block timely entry of generics, utilizing loopholes in the patent system to delay and thwart the market entry of lower cost competitors, and paying generic manufacturers to delay market entry. According to the Federal Trade Commission (FTC), these anti-competitive "pay-for-delay" actions alone increase costs for seniors and American taxpayers by $3.5 billion annually.[11]

Blocking Entry of Generic Competitors

One tactic for blocking competition is the practice commonly known as patent "evergreening" or "product hopping" where drug manufacturers extend a brand drug's patent exclusivity through the development of new formulations or products that offer clinically insignificant additional benefits. This practice is inherently anti-competitive and is designed to outright block or challenge the legitimate market entry of generic competitors, raising drug costs for seniors. For example, Forest Laboratories' Namenda (memantine HCl) is indicated for the treatment of moderate to severe Alzheimer's disease. When the 5/10 mg tablets were scheduled to go off patent in April 2015, Forest responded by creating a "new" version marketed as Namenda XR (an extended release version of the drug) and obtained a new patent, providing the manufacturer with an additional 14 years without generic competition.[12] In 2015, the first year with generic memantine HCl tablets, the annual per-user cost decreased 23.8 percent in Part D, consistent with Calendar Year (CY) 2011 levels. In contrast, the per-user cost of patent-protected Namenda XR increased 52.2 percent from CY 2014 to CY 2015.

There are numerous additional examples where a brand drug manufacturer has delayed competition to preserve its monopoly, resulting in astronomically high drug prices:

- Humira, the highest-selling drug in the world, has received six different orphan drug designations since 2005. Its drug price increased by 200 percent from 2012–2018 to $38,000 per patient.[13]
- The REMS for Thalomid, an earlier iteration of Celgene's top-selling cancer drug Revlimid, has been patented over 14 times in order to delay the development of generics. The price for Revlimid rose from $6,195 in 2006 to $16,691 in 2017.[14] The Medicare program spent an average of $88,437 per beneficiary for a year of Revlimid treatment in 2017.[15]
- The price of Evzio, a drug manufactured by Kalèo and utilized for emergency treatment of known or suspected opioid overdoses with a novel delivery mechanism, has risen by approximately 600 percent since 2014.[16]

These actions from brand drug manufacturers weaken the ability of plan sponsors to negotiate lower costs for prescription drugs. Plan sponsors have been most successful negotiating lower drug costs on behalf of beneficiaries when there is suffi-

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[11] *See https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf.*

[12] Michael Carrier and Steve Shadowen, "Pharmaceutical Product Hopping: A Proposed Framework for Antitrust Analysis," *Health Affairs Blog* (June 1, 2017); letter from Patrick G. Boen, Senior Director, Clinical Development at Forest Research Institute, to providers (Feb. 2014) (announcing plans "to discontinue the sale of NAMENDA" (memantine HCl) tablets on August 15, 2014).

[13] FDA, *https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm.*

[14] Alison Kodjak, "How a Drugmaker Gamed the System to Keep Generic Competition Away," NPR, May 17, 2018.

[15] CMS 2017 Part D Drug Spending Dashboard, available here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html.*

[16] Ken Alltucker, "Drug Company Raised Price of Lifesaving Opioid Overdose Antidote More Than 600 Percent," *USA Today,* November 19, 2018.

cient competition in the market. According to the Centers for Medicare and Medicaid Services (CMS) Office of the Actuary (OACT), the:

- *Federal spending on retail prescription drugs is flat:* For the second consecutive year, retail prescription drug growth has decreased; the 0.4 percent growth has been driven by a continued shift to lower-cost generic drugs and declines in generic drug prices.[17]
- *Cost of drugs with limited competition has increased at double the rate:* Conversely, there have been significant price increases for drugs subject to limited or no competition. In 2016, the cost of single-source drugs with no generic alternatives increased at more than double the rate of average annual drug spending.[18]

The trend of increasing list prices for prescription drugs with limited competition is seen for prescription drugs administered in both clinical settings, which are typically covered by Medicare Part B and are generally considered specialty drugs, and dispensed at the pharmacy counter, which are typically covered by Medicare Part D.

- *90 percent of the Medicare B drugs with the highest expenditure have no generic:* A 2017 study performed by the Government Accountability Office (GAO) found that Medicare Part B drugs with the highest expenditures are predominantly single-sourced (84 percent) without a generic option (90 percent).[19] This has resulted in a market where eight of the top ten Part B top-expenditure drugs have an annual cost of $10,000 to $30,000.[20]
- *List prices increase beyond inflation for Part D drugs with fewer than five manufacturers:* An analysis of 2017 Part D prescription drug spending found that prescription drugs with less competition were more likely to have list price increases than drugs with five or more manufacturers.[21]

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[17] "CMS Office of the Actuary Releases 2017 National Health Expenditures," available online at *https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-national-health-expenditures.*

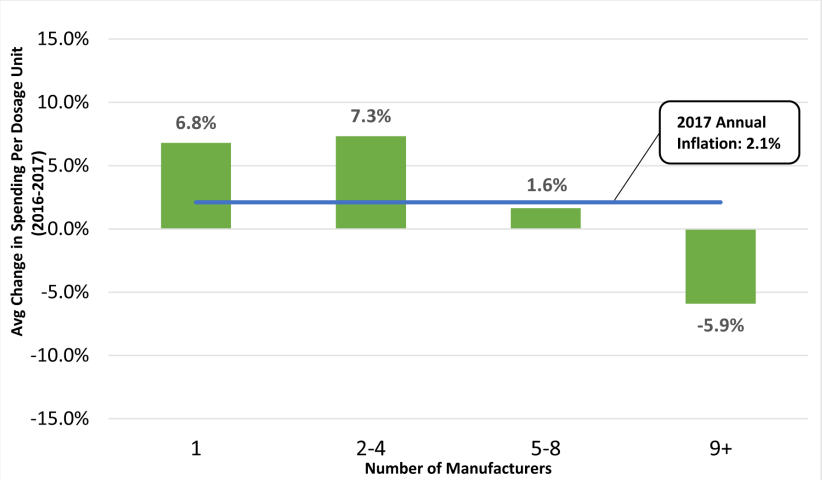
[18] *Ibid.*

[19] GAO, "Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015," GAO–18–83, published December 18, 2017, available online at *https://www.gao.gov/assets/690/689082.pdf.*

[20] MedPAC, "Medicare and the Healthcare Delivery System," available online at *http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0.*

[21] Based on Humana analysis of the CMS 2017 Part D Drug Spending Dashboard and Data, available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html.* The CMS dashboard includes all Part D organizations and plan types. Part D PDE records were summarized by drug by linking National Drug Codes (NDCs) available in the PDE data to a commercially available database and aggregated across all strengths, dosage forms, and routes of administration to the drug brand name and generic name. CMS did not provide NDCs in the public use file. Over-the-counter drugs in the PDE data are excluded as well as NDCs with fewer than 50 claims in the current (2017) or previous year (2016). In addition, NDCs with large variations in reported units from year to year were reviewed by CMS on a case-by-case basis and data anomalies were excluded. Drug spending metrics for Part D drugs are based on the gross drug cost, which includes ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees. Part D drug spending represents total spending for the prescription claim, including amounts paid by the Medicare Part D plan and beneficiary payments. The Part D spending metrics do not reflect any manufacturers' rebates. For purposes of this analysis, we removed Part D covered supplies, such as syringes and alcohol swipes for diabetics, and weighted average change in spending per dosage unit by 2017 claim volume. Average 2017 inflation rate is sourced from the Bureau of Labor Statistics website.

Year over Year Growth in Prescription Drug Costs Decreases with Competition in Part D [22]



HHS OIG Proposed Rule Does Not Address Anti-Competitive Behavior

The recently proposed regulatory changes to the Anti-Kickback Statute's Safe Harbors from the Office of the Inspector General (OIG) at the Department of Health and Human Services (HHS) will not address any of the anti-competitive actions from drug manufacturers detailed above and, in some cases, will only increase the bargaining power of manufacturers. Drug manufacturers alone set the list price of prescription drugs; nothing in the proposed rule compels drug manufacturers to lower the list price of drugs.

Recommended Legislative Actions

The examples of anti-competitive pricing detailed above and the importance of competition require innovative policy approaches to enhance competition in the market, especially for specialty drugs. Humana strongly supports the introduction of S. 340, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, as well as S. 64, the Preserve Access to Affordable Generics and Biosimilars Act, developed under Chairman Grassley's leadership. We believe the enactment of these bills will encourage the development of generic and biosimilar drugs that will infuse additional competition into the market, prevent brand drug manufacturer REMS abuses that block generic competition, and penalize brand drug manufacturers for engaging in pay-for-delay agreements.

The Food and Drug Administration (FDA) Is Taking Proactive Steps Within Its Regulatory Authority

Humana applauds the FDA's efforts to bring additional competition and transparency to the prescription drug market. In particular, Humana supports the FDA's Drug Competition Action Plan and the goal of removing barriers to generic development and market entry to increase competition, improve access, and lower costs.

Policymakers within Congress and the administration have been focused on addressing the rising prices of prescription drugs. In January, the HHS OIG proposed a rule that modifies the current Discount Safe Harbor under the Anti-Kickback Statute to exclude from discounts protected by the Safe Harbor rebates negotiated by PBMs, Part D plan sponsors, and Medicaid managed care plan sponsors.[23] The OIG's proposed rule also establishes a new Safe Harbor allowing those rebates to be applied to reduce the price at the pharmacy counter.

Through the proposed rule, HHS ultimately seeks to reduce out-of-pocket cost of prescription drugs for those currently covered by Medicare and Medicaid and ultimately to reduce the list price of prescription drugs. However, the rule fails to take into account the role of rebates in reducing the price of premiums for all bene-

[22] *Ibid.*
[23] Available here: *https://www.regulations.gov/document?D=HHSIG-2019-0001-0001.*

ficiaries and in reducing costs to the Federal Government. The proposed rule also fails to consider the complexity of operationalizing the new requirements by the proposed January 1, 2020, implementation date and the downstream behavioral impacts of beneficiaries, drug manufacturers, and plan sponsors.

Rebates Are Currently Used to Lower Premiums

Currently, plan sponsors utilize rebates as a tool to ensure that beneficiaries are obtaining the greatest possible value from their Medicare coverage. Savings that are obtained by Humana through rebate negotiations with drug manufacturers are distributed to our entire beneficiary population through reduced premiums for Part D coverage, resulting in lower costs for seniors in PDP and MA plans.

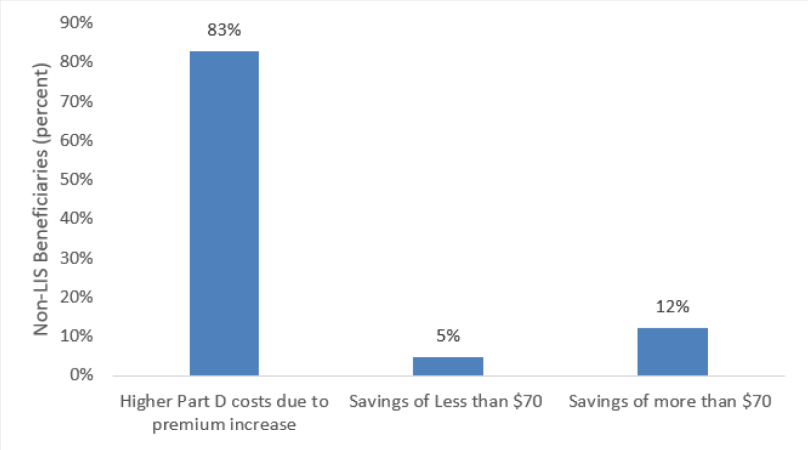
Additionally, rebates have resulted in significant savings to the government. As cited in the Medicare Trustees Report, rebates have played a critical role in keeping the overall cost of Part D lower than projected when the program was first launched in 2006.[24]

The Proposed Rule Will Lead to Higher Premiums and Increase Costs to the Government While Creating a Windfall for Drug Manufacturers

If the proposed rule is finalized as written, all Part D beneficiaries will pay higher premiums. Rebates that have historically been utilized to lower premiums across the program will no longer be applied to the entire population and will instead be utilized to reduce out-of-pocket costs for a small number of seniors. The analysis performed by the CMS OACT indicates that shifting cost savings from rebates to a beneficiary's copay will increase the overall cost of the Part D program for the majority of beneficiaries, the government, and Part D plan sponsors.

Humana's analysis found that approximately 17 percent of beneficiaries would see savings at the pharmacy counter, with only 12 percent saving more than $70 annually.[25] The remaining 83 percent of beneficiaries will see an *increase* in costs for prescription drug coverage due to premium increases that will exceed any potential savings the beneficiary may have experienced at the pharmacy.[26]

Impact of Proposed Rule on Part D Beneficiary Premiums [27]



The small number of beneficiaries who will benefit from the rule will do so at a significant cost to the government. The projections developed by the OACT estimate that government outlays for the Part D program would increase by approximately $200 billion while beneficiaries would save approximately $25 billion; this means

[24] 2018 Medicare Trustees Report: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/ReportsTrustFunds/Downloads/TR2018.pdf.*

[25] Based upon internal analysis of estimated premium impacts for CY 2020 resulting from the proposed rule.

[26] *Ibid.*

[27] Based on internal analysis of estimated premium impacts resulting from the proposed rule.

that government spending will increase approximately $7 for every $1 of savings realized by beneficiaries.[28]

The rule also creates a significant windfall for drug manufacturers through reduced liability in the Coverage Gap Discount Program (CGDP). According to the analysis performed by OACT, drug manufacturers will realize savings of $44 billion over a 10-year period.[29]

The Proposed Rule Will Lower Out-of-Pocket Costs for a Limited Number of Seniors

The proposed rule will have a limited impact on seniors at the pharmacy counter. An analysis based upon 2017 claims data for prescription drugs from CMS found that only 7.8 percent of total prescriptions filled were for drugs for which Humana has a rebate agreement in 2019.[30] This is due to the high utilization of generic drugs, which are not eligible for rebates, and a large number of brand drugs where the manufacturer does not offer rebates.

Put another way, fewer than one in ten prescriptions will have a lower out-of-pocket cost as a result of the proposed rule while premiums for all beneficiaries will increase and costs to the government will rise significantly. Humana believes that there are alternative policy options that could modernize the Part D program and also reduce out-of-pocket spending on prescription drugs. These options are discussed in detail at the end of this testimony.

List Prices for All Brand Drugs Will Need to Decrease by 28 Percent to Keep Beneficiaries Whole

One of the underlying assumptions in the proposed rule is that the changes will result in drug manufacturers lowering their lists prices. However, when asked by Chairman Grassley, "Should the administration finalize this [OIG] rule, would you commit to lowering your drug prices?", the CEOs of AstraZeneca, AbbVie, Bristol-Myers Squibb, Johnson & Johnson, Pfizer, Merck, and Sanofi all testified that they would only lower list prices if the same rules were applied in the commercial sector or they failed to answer the question. The proposed rule only applies to Federal health-care programs and does not extend to ERISA or the Public Health Service Act which governs much of the commercial market.

This will result in increased drug prices that will cause some beneficiaries to pay more out of pocket. Based upon Humana's actuarial analysis, the only way to achieve the same costs for the Part D program and maintain beneficiary premiums comparable to the current system is if all brand drug manufacturers—including those who do not currently offer rebates—elect to decrease their list prices by at least 28 percent. Alternatively, if brand drug manufacturers refuse to reduce their list prices for products not currently rebated, manufacturers of the remaining branded products would need to drop their list prices by at least 45 percent in order to avoid higher costs for CMS, taxpayers, and beneficiaries.

Drug Manufacturers Raise List Prices to Boost Their Revenue

Drug manufacturers alone set the list price of prescription drugs. However, some in the pharmaceutical industry cite rebates and other price concessions as the driver of increasing list prices for all brand drugs. Currently, there are few brand drugs with a rebate agreement in comparison to the total number of drugs in the market. For the 2019 benefit year, Humana will only receive rebates on 255 brand drugs, or seven percent of the potential drugs on its Medicare formulary.

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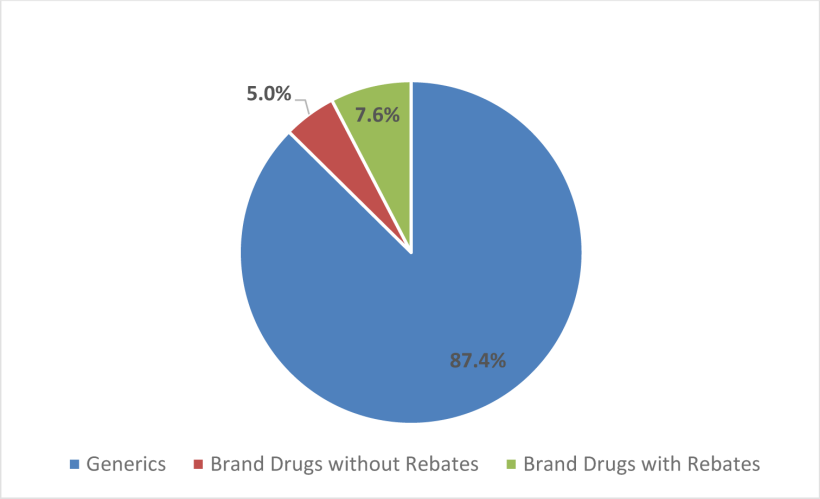
[28] Removal of Safe Harbor Protection for Rebates Involving Prescription Pharmaceuticals and Creation of New Safe Harbor Protection for Certain Point-of-Sale Reductions in Price on Prescription Pharmaceuticals and Certain Pharmacy Benefit Manager Service Fees (RIN 0936–AA08)

[29] *Ibid.*

[30] Based on Humana's analysis of CMS Part D Drug Spending Dashboard and Data, available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html.* Products in the dashboard were categorized as generic if the generic name listed matched the brand name. The remaining products were categorized as brand and then segmented based on whether Humana has a rebate contract for that product in 2019. Finally, "Total Claims" was summed across all products in each category.

Prescriptions Filled by Part D Beneficiaries in 2017 [31]



Additionally, there are many examples of increasing list prices for brand drugs where the manufacturer does not offer rebates. To highlight this, Humana analyzed the historical list prices of three brand drugs—Revlimid, Imbruvica, and Isentress—which accounted for over $4 billion in taxpayer spending in Part D for 2017.[32]

Examples of Brand-Name Drugs With No Rebate

Product	Condition	Manufacturer	Overall Part D Spending in 2017
Revlimid	Cancer	Celgene	$2.3 billion
Imbruvica	Cancer	AbbVie	$1.4 billion
Isentress	HIV	Merck	$320.9 million

None of these drugs were subject to rebate agreements during the 2013–2017 time period examined. However, each drug's list price increased annually by as much as 64 percent. This analysis, utilizing publicly available CMS data, directly refutes the suggestion that rebates are the driver of increasing drug list prices. Ultimately, this is further evidence that the proposed changes to the Anti-Kickback regulations will not result in HHS's desired outcome of lower list prices for prescription drugs and lower out-of-pocket costs for beneficiaries.

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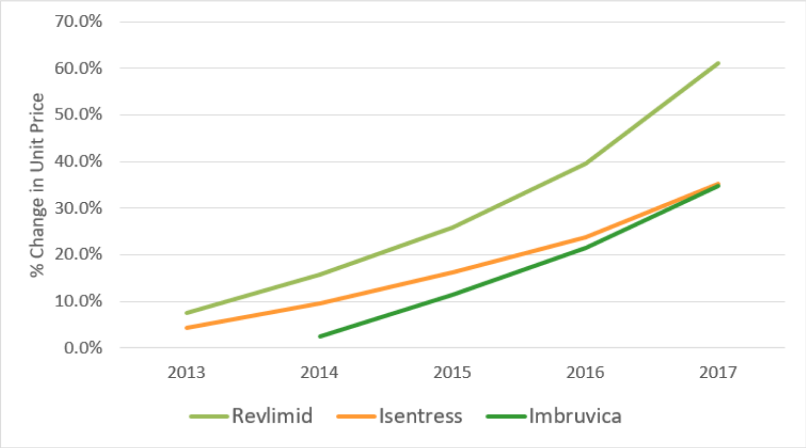
[31] Based on Humana's rebate experience applied to an analysis of the "total claims" in the CMS 2017 Part D Drug Spending Dashboard and Data public use file, available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html*. Note, CMS excludes over-the-counter drugs and National Drug Codes (NDCs) with fewer than 50 claims per year from the public file. Drug spending metrics for Part D drugs are based on the gross drug cost, which includes ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees, but does not reflect any manufacturers' rebates. For purposes of this analysis, we removed Part D covered supplies, such as syringes and alcohol swipes for diabetics.

[32] CMS 2017 Part D Drug Spending Dashboard and Data, available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html.*

Percent Change in Unit List Price Compared to Base Year [33]



THE HHS'S OIG PROPOSED RULE WILL INJECT NEW UNCERTAINTIES INTO THE PART D MARKET THAT WILL PUT UPWARD PRESSURE ON PART D PREMIUMS

Consistent with the administration's own analysis, Humana's actuaries project that Part D premiums will increase for all beneficiaries as a result of the HHS's OIG proposed rule, with out-of-pocket costs reduced for a subset of beneficiaries that utilize rebated brand drugs. We project that those premium increases will lead to changes in beneficiary behavior that will have premium and beneficiary impacts not contemplated in the proposed rule. We have outlined several potential consequences of the OIG HHS proposed rule—none of which are contemplated in the regulation.

- *POS rebates will lead to changes in prescription drug manufacturer pricing and market access behaviors that will be difficult for plan sponsors to project*—POS transparency also impacts prescription drug manufacturer pricing and market access behaviors. Each brand drug manufacturer will naturally seek to develop pricing strategies that maximize market share without deflating their profit margins. Some manufacturers are considering authorized generic drug pricing strategies, while others are examining an average net of rebate pricing strategy with minimal or no price segmentation between Part D plan sponsors. We expect many other variations on these pricing strategies moving forward. The challenge plan sponsors face when preparing 2020 Part D bids is that these constantly evolving market/pricing dynamics further increase the difficulty of projecting Part D plan costs if POS rebates are implemented in 2020. This enhanced unpredictability will either lead to greater pricing misestimates in Part D bids or conservatism in pricing (and thus higher premiums).
- *Some beneficiaries with high drug costs will likely make plan choices based primarily on POS drug costs, which may result in migration to those specific plans, thus increasing the likelihood of adverse risk selection*—We anticipate that beneficiaries shopping for Part D coverage in 2020 and beyond will be choosing a plan based on different criteria than in previous years. With greater transparency of drug prices inclusive of manufacturer rebates, we anticipate that more consumers will be selecting plans based on POS costs versus the traditional focus on premiums, formulary, and pharmacy network. While there are numerous long-term advantages to this change in beneficiary shop-

[33] Based on Humana's analysis of the CMS Part D Drug Spending Dashboard and Data, available online at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html.* Chart reflects the percent change in the unit price of each product in 2013–2017 compared to a base year. Base year is 2012 for Revlimid and Isentress. Base year is 2013 for Imbruvica, which was launched in November 2013.

ping behavior, in the near term, this shift will lead to increased membership movement between plans. Increased beneficiary movement will place further upward pressure on premiums because, historically, newly enrolled beneficiaries are less likely to enroll and engage in clinical programs. In addition, as beneficiaries increasingly select plans based on POS costs, it will place plan sponsors at an increased risk of adverse selection. The current Part D risk adjustment model is not built to sufficiently mitigate this risk, because it assumes that high cost beneficiaries will be evenly spread across all Part D plan sponsors.

PROPOSALS TO MITIGATE BENEFICIARY DISRUPTION IN 2020

Plan sponsors are in the process of preparing Part D bids to CMS for the 2020 benefit year and will be submitted to CMS by June 3rd. If the administration elects to move forward with the proposed changes to the Anti-Kickback Safe Harbor regulations, it is absolutely critical that CMS take immediate steps to mitigate inevitable premium increases and beneficiary disruption. The proposed rule will make it exceedingly difficult for plan sponsors offering Part D coverage to project costs and set accurate beneficiary premiums.[34]

Mandatory point-of-sale rebates would be the most significant regulatory change to the Part D program since its inception. This actuarial uncertainty, coupled with the lack of guidance to date from the CMS OACT, will lead to more conservative (*i.e.,* higher) rate setting, potentially resulting in significant beneficiary disruption.

The following steps would be necessary to help preserve stability and predictability in the Part D market in 2020. We would respectfully suggest members of the committee and other members of Congress to encourage CMS to take the following actions:

- *Implement interim adjustments to the Part D risk adjustment model immediately*—The current Part D risk adjustment model cannot sufficiently mitigate the actuarial uncertainties posed by the Anti-Kickback Safe Harbor proposed regulation. Historically, it has taken CMS multiple years to recalibrate the Part D risk adjustment model to reflect changes in Part D utilization and spending. We strongly urge CMS to work with plan sponsor actuaries immediately on methods for potentially making interim adjustments and to implement a model recalibration as soon as possible to reflect a mandatory point-of-sale rebate market.
- *Require all Part D plan sponsors to offer a plan designed specifically for LIS auto-enrollees as part of a new, fourth plan option*—Part D LIS-eligible beneficiaries will prove to be the most challenging population for plan sponsors to predict pricing and drug utilization for 2020, primarily because LIS beneficiaries are more likely than the general Part D population to utilize rebated brand-name drugs.[35] Our recommendation would encourage population-based formulary design; enhance the value of manufacturer price concessions for CMS; establish parity across the market; and preserve competition and beneficiary choice. We note that there is precedent for this approach; MA dual-eligible special needs plans (D–SNP) are specifically structured for the dual-eligible population both in cost-sharing and formulary design. In order to accommodate the new LIS-only plan, CMS would need to allow plan sponsors to offer a fourth plan, because they are currently limited by CMS sub-regulatory guidance to no more than three plans in any market.
- *Narrow Part D risk corridors for 2020*—In order to manage the transition to the new Part D rebate model contemplated by the HHS OIG proposed rule and mitigate premium increases, we recommend that CMS narrow the Part D risk sharing corridors for 2020 consistent with risk corridors applicable during the first 2 years of the Part D program (2006–2007).[36]

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[34] For a more detailed discussion of the actuarial challenges posed by the HHS OIG proposed rule, please consult public comments submitted by the American Academy of Actuaries, available online at *https://www.actuary.org/sites/default/files/2019-04/Rx_Rebate_Timeline_0403 2019.pdf.*

[35] "MedPAC Report to Congress: Medicare Payment Policy, March 2017," available at *http://www.medpac.gov/docs/default-source/reports/mar17_medpac_ch14.pdf.*

[36] CMS used its demonstration authority to smooth the premium impacts to protect beneficiaries from negative aspects at the start of the Part D benefit. It announced the Medicare Demonstration to Transition Enrollment of Low Income Subsidy Beneficiaries on June 8, 2006 as well as implementing a 1-year payment demonstration, the "Medicare Demonstration to

Continued

- *Increase the 2020 de minimis premium policy for LIS-eligible beneficiaries*—In order to avoid disruption, movement between plans, and confusion for LIS beneficiaries, we recommend that CMS permit plan sponsors to voluntarily waive the portion of the monthly adjusted basic beneficiary premium that is up to a de minimis amount of $10 during the 2020 transition to the new Part D rebate model.[37]
- *Allow plan sponsors to facilitate chargebacks and pharmacy reimbursement*—A 2020 implementation date does not provide sufficient time for stakeholders to develop, test, and deploy the new system for processing chargebacks and pharmacy reimbursement contemplated in the HHS OIG proposed rule. Rather than trying to reinvent the wheel in a matter of months, CMS should continue allowing plan sponsors to process and facilitate chargebacks in order to ensure that pharmacies receive timely and accurate payment for their services.
- *Temporarily exclude Part D from the Total Beneficiary Cost (TBC) calculation for MA–PD plans beginning in 2020*—Because drug formularies may change significantly as a result of the proposed rule, there may be large changes in the Part D component of the TBC calculation. We request that Part D be excluded from the TBC calculation until the impact of formulary changes can be adequately evaluated and quantified.
- *Issue guidance on 2020 bid assumptions as soon as possible*—We strongly encourage CMS to provide guidance on 2020 bid assumptions to ensure consistency in approach among plan sponsors. In particular, because direct subsidy and low-income premium subsidy amounts are a function of plan sponsor bids, there needs to be consistency in bidding approaches to avoid wide swings in plan bids and beneficiary premiums.
- *Preserve the ability for plan sponsors to implement value-based purchasing programs for pharmacies*—Given the extraordinary disruption that could occur in the Part D market in 2020, we recommend that CMS not finalize its proposal. It would add yet another layer of complexity by eliminating pharmacy direct and indirect remuneration (DIR), such as value-based purchasing programs. As CMS's own analysis indicates, prohibiting pharmacy DIR will further increase Part D premiums—amplifying the upward premium trend attributable to POS rebates. In addition, CMS has failed to consider several key unintended consequences of eliminating pharmacy DIR. For example, we anticipate that plan sponsors would respond by lowering pharmacy reimbursement rates and reducing the size of their existing pharmacy networks. All of which would likely result in significant changes in Plan Sponsors' pharmacy networks occurring at the same time as widespread premium increases and formulary changes.
- *Delay the Health Insurance Tax*—In addition to the projected impact of the rebate rule and value-based pharmacy networks rule (DIR), we are also preparing for the potential return of the Health Insurance Tax in 2020. Under both President Obama and President Trump, bipartisan legislation passed delaying the tax, including in the current calendar year (2019). Without congressional action, the tax is scheduled to return in 2020, resulting in tens of millions of seniors with Part D coverage paying higher premiums. We strongly urge congressional action in support of S. 172, the Health Insurance Tax Relief Act of 2019.

MODERNIZING THE PART D PROGRAM TO BETTER SERVE MEDICARE BENEFICIARIES

Given the profound changes that have occurred in the pharmaceutical marketplace since the implementation of Part D, we encourage the committee to examine potential reforms to the Part D program that would both alleviate the burdens seniors face when paying for high cost drugs and leverage market-based reforms to drive down prescription drug prices.

- *Maximum Out-of-Pocket (MOOP) Cost Protection*—In order to better protect non-LIS beneficiaries from high prescription drug costs, we recommend that the committee consider establishing an annual maximum out-of-pocket cap for Part D drugs. It is critical that any proposal to cap out-of-pocket costs in Part

Limit Annual Changes in Part D Premiums Due to Beneficiary Choice of Low-Cost Plans." Those are potential examples of the agency's ability to minimize disruption.

[37] *Ibid.*

D be paired with prescription drug pricing reforms that meaningfully reduce prescription drug costs by improving competition in the pharmaceutical market. Stated another way, the costs of implementing a Part D MOOP should be borne by the pharmaceutical industry.

- *High Cost Specialty Drugs*—As discussed previously, 2 percent of our beneficiaries who utilized specialty drugs comprised 36 percent of total Part D spending in 2018. In 2 years, Humana projects that seniors utilizing specialty drugs could account for as much as 50 percent of total Part D spending. We welcome the opportunity to explore potential solutions for alternative pooling or funding mechanisms for this growing category of products.

PROPOSALS TO INCREASE DRUG MARKET COMPETITION

Humana strongly urges the committee to encourage CMS and other Federal agencies to remove barriers to prescription drug competition and regulations that are abused in anticompetitive ways and are harmful to affordable drug access for beneficiaries. We specifically have recommended to the administration to take the following actions that would address abuses of regulations and anticompetitive behaviors:

- *Finalize CMS's proposed drug pricing rules aimed at increasing competition*—Humana urges CMS to finalize the proposed rules on plan sponsor flexibility for protected classes and the Part B step therapy program in "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses Proposed Rule" [CMS–4180–P]. Humana has long supported these policy changes and has identified opportunities to create competition in the market and lower drug costs for beneficiaries. Internal analysis estimates that the lack of competition due to the protected class policy collectively increased beneficiary premiums by an estimated $2.79 per-beneficiary per-month (PBPM, $34 per-beneficiary-per-year) in 2018. Additionally, 50 percent of Humana's Part B drug spending is attributable to drug classes with multiple clinically equivalent substances where additional competition can be stimulated through utilization management. Additional flexibility with respect to formulary development will enable sponsors to effectively drive competition in the market and lower drug costs for their beneficiaries.
- *Eliminate the requirement that Part D plan sponsors cover at least two drugs in each therapeutic category or class*—CMS currently requires Part D plan sponsor formularies to cover at least two drugs in every Part D covered therapeutic category and class as long as there are at least two drugs available. When two drugs are mandated to be covered in a class, manufacturers of a drug with only one other competitor typically refuse to negotiate rebates or discounts in Medicare Part D because they know their products must be covered. The existing policy increases costs to the plan sponsor, which are passed through not only to individuals in the form of higher premiums, but also to the Federal Government in terms of increased direct subsidy payments.
- *Leverage CMS data to illustrate the cost impacts of anticompetitive behaviors such as patent "evergreening"*—CMS is best-positioned to leverage its claims from Parts A, B, and D to empirically illustrate the Medicare Trust Fund and beneficiary impacts associated with these and other anticompetitive behaviors.
- *Issue information regarding manufacturers' drug pipelines and anticipated drug prices prior to market launch*—It is critical for Part D and Medicare Advantage (MA) plan sponsors and the CMS OACT to be aware of anticipated new drugs, new drug indications, and their potential launch prices. These data are necessary to make critical decisions about MA and Part D bidding parameters, making special updates to the MA and Part D risk adjustments models, and for OACT to perform its long-term program cost estimation duties for the Medicare Trustees. With the right information, this decision-making will have a significant impact on our ability to provide lower drug costs and premiums for beneficiaries. While we understand there are proprietary data provisions and there is general uncertainty about approvals of new therapies, we believe that, between *clinicaltrials.gov* and PubMed, there is a notable opportunity to produce a transparent summary dashboard of the drug pipeline in one place. We ask that HHS ensure that the FDA works toward this goal and provide CMS and plan sponsors with this necessary information.

- *Address anticompetitive actions by drug manufacturers*—Humana strongly supports the administration's continued work to address and prevent anticompetitive actions by drug manufacturers. Again, congressional action through passage of the CREATES Act and S. 64 will limit these actions, bringing more competition to the market and placing downward pressure on beneficiary drug costs.

CONCLUSION

We appreciate the committee's keen interest in working to better understand the root causes of high drug costs. We look forward to working with you on policy solutions to ensure access to affordable prescription drugs and to foster stability in the 2020 benefit year.

QUESTIONS SUBMITTED FOR THE RECORD TO WILLIAM K. FLEMING, PHARM.D.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

COLLECTION, USE, AND SHARING OF PERSONAL HEALTH INFORMATION

Question. Consumers are becoming more and more concerned about the data collection and sharing practices of companies. While these issues have been most prevalent in the social media and tech industry, companies in the pharmaceutical supply chain also have access to tremendous amounts of sensitive, personal health information of the individuals they serve. For example, the company Livongo partners with CVS Caremark to provide low-cost or no-cost blood sugar meters to diabetic patients. The meters are always "connected" to Livongo's "Diabetes Response Specialists." As the company's website states, "When readings are out of range, our Diabetes Response Specialists call or text [the individual] within minutes." While these innovations may be highly beneficial for individuals in managing their health, it's also important for this committee to fully understand what types of information is collected, how or why it's stored or shared, and for what purposes PBMs themselves and other affiliated drug supply chain participants (such as insurers) use the information.

Health information is extremely sensitive. It's the most personal of all the information we share. So I want to know more about each of your companies' data collection, sharing, and protection practices.

Does your company collect and store health information from the end-users of the prescriptions you provide? For example, information or records of a diabetic individual's blood sugar levels.

Answer. Yes. Humana's wholly owned pharmacy benefit manager collects protected health information (PHI), as defined in 45 CFR § 160.103, as necessary to determine if a submitted claim meets the applicable coverage criteria established by CMS and/or Humana's Pharmacy and Therapeutics Committee.

Question. Does your company make any treatment, cost, or coverage decisions based on the health information you collect from an individual?

Answer. In order to ensure compliance with Medicare coverage requirements for certain items and procedures, MAPD and Part D plans must collect health information from the patient and his or her doctor to confirm that the patient meets the applicable coverage criteria established by CMS and Medicare Administrative Contractors (MACs).

Question. Does your company share health information with third parties? And, if so, does your company profit from that sharing?

Answer. Humana shares data with third parties for health care operations, treatment, payment, and other activities as permitted under HIPAA.

Question. Do you believe customers are fully aware of your information collection and sharing practices?

Answer. Yes.

IMPACT OF VERTICAL INTEGRATION BETWEEN PBMS AND INSURANCE COMPANIES

Question. To highlight whether/how vertical integration of PBMs and insurance companies benefits the consumer and taxpayer.

The PBM industry has experienced significant consolidation within the past 10 years, which has contributed to concerns about the potential abuse of market power, barriers to market entry, and exclusionary practices. In 2012, for example, Express Scripts acquired Medco Health Solutions—a nearly $30-billion transaction that merged two of the country's three largest PBMs.[1] More recently, PBMs are also vertically integrating with insurers/payers, reflected by the 2018 acquisitions of Express Scripts Holding Co. (a PBM) by Cigna Corp. (a payer) and of Aetna Inc. (a payer) by CVS Health Corp. As a result, the three largest PBMs are all vertically integrated with insurance companies. According to a report from the Kaiser Family Foundation, the two combined entities, along with UnitedHealth and Humana, will cover 71 percent of all Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.[2] Vertical integration can result in increased efficiencies and consumer benefits. I can also, however, lead to higher barriers to entry for competition, leading to further consolidation. FDA Commissioner Scott Gottlieb recently warned that "consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious. And the very complexity and opacity of these schemes help to conceal their corrosion on our system—and their impact on patients."[3]

I'd like to talk about consolidation, including the recent integration of PBMs with insurance companies. Last year, I wrote to the Justice Department on this issue. It's reported that the three largest PBMs—who are before us today—now cover 71 percent of Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.[4] Such market power has raised concerns. FDA Commissioner Scott Gottlieb said, "the consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious."[5]

I want to hear briefly from each of you on whether the PBM industry is competitive. For example, are there high barriers to entry for new competitors?

Answer. Competition between firms offering pharmacy care services is intense and robust. Such competition helps to spur innovation of new products and technology offerings to preserve the value proposition of Humana's integrated pharmacy care services model. Humana's approach to integrated pharmacy and medical care services allows Humana to deliver a personalized and simplified experience for seniors through a value-based health ecosystem that improves clinical outcomes.

Question. I'm also interested in what effect the most recent consolidations of PBMs and insurers has had on the bottom line for the government and consumer.

Do these arrangements result in a lower cost to the government—as a payer—and the consumer? Please explain.

Answer. Humana's pharmacy care services are fully integrated with our medical service offerings and focused on serving Humana members. This integrated approach to serving seniors delivers a personalized and simplified experience through a value-based health ecosystem that improves clinical outcomes. This ecosystem includes 233 owned, jointly owned, or allied primary care facilities; an ownership interest in the Nation's largest home health and hospice providers; as well as initiatives to address social determinants of health. As a result, the savings to the government and consumers achieved through our pharmacy programs accrue directly to our members through lower premiums and improved benefits.

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[1] *See* "FTC Closes Eight-Month Investigation of Express Scripts, Inc.'s Proposed Acquisition of Pharmacy Benefits Manager Medco Health Solutions, Inc.," Federal Trade Commission (April 2, 2012), *available at https://www.ftc.gov/news-events/press-releases/2012/04/ftc-closes-eight-month-investigation-express-scripts-incs.*

[2] Juliette Cubanski, Anthony Damico, and Tricia Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing" (May 17, 2018), *available at https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.*

[3] FDA Commissioner Scott Gottlieb, M.D., "Capturing the Benefits of Competition for Patients," (March 7, 2018), *available at https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm.*

[4] Juliette Cubanski, Anthony Damico, and Tricia Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing" (May 17, 2018), *available at https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.*

[5] FDA Commissioner Scott Gottlieb, M.D., "Capturing the Benefits of Competition for Patients" (March 7, 2018), *available at https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm.*

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

MANUFACTURER MONEY

Question. What is the total dollar amount that you obtain from pharmaceutical manufacturers in any form such as rebates, fees, etc.?

Answer. Rebates received by Humana for Part D drugs are reported to CMS annually through Direct and Indirect Remuneration (DIR) and reflected in Part D bid submissions. Humana Part D plans reinvest the savings accrued from these rebates in benefit offerings. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers.

Question. What is the total dollar amount that you remit to health plans?

Answer. Rebates received by Humana for Part D drugs are passed through to the Part D plans. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers.

BIOSIMILARS

Question. Managed Care Organizations are on record as widely supportive of the potential of biosimilars. However, most MCOs have continued to support originator brand products and have not preferred and often excluded less expensive biosimilars. For example, most MCOs have kept Remicade (a treatment for rheumatoid arthritis and other diseases) as the preferred agent on their formularies, and in most cases to the exclusion of its biosimilar, Infliximab.

Why do you tout support for biosimilars while, at the same time, inhibiting adoption of these less expensive products?

Answer. We recognize the importance of biosimilars as low-cost alternatives to originator brand products. We have elected to place biosimilars at parity status compared to the originator brand products. Unfortunately, today there are few biosimilar products on the market and the prices of those products are similar to the originator brand products. Our hope is that the market will continue to grow, resulting in lower prices through increased competition. As the market matures and prices begin to drop it is our intent to begin moving biosimilars to lower formulary tiers and to prefer those agents over the originator brand products.

Question. HHS may broaden the scope of its proposed rule and eliminate rebates between Medicare Advantage plans and manufacturers for Part B drugs.

Would this realign incentives to encourage preferred access for lower-cost drugs, such as biosimilars?

Answer. As mentioned previously, Humana recognizes the importance of biosimilars as low-cost alternatives to originator brand products and currently places these products at parity with originator brand products on the formulary. As with generic products, biosimilars frequently launch at prices similar to the originator brand products until there is competition in the market. We support biosimilars that launch at a substantial discount to the originator brand product and specifically prefer the biosimilar Retacrit over the originator brand product Procrit. As such, we encourage the FDA to continue to provide clear guidance, such as the recently released Interchangeability guidelines, that will spur additional biosmiliars to market and increase competition.

Question. What changes can we recommend/make to help you prefer lower-cost drugs, such as biosimilars, without rebates?

Answer. Humana strongly supports the introduction of S. 340, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. We believe the enactment of this bill will encourage the development of generic and biosimilar drugs that will infuse additional competition into the market, prevent brand drug manufacturer REMS abuses that block generic competition, and penalize brand drug manufacturers for engaging in pay-for-delay agreements.

Question. Why is there such a disparity in reimbursed pharmacy prices for specialty generic drugs in Part D? (*e.g.,* Imatinib) Does ownership of specialty pharmacy influence your reimbursement decision?

Answer. Network contracted pharmacies, including Humana owned pharmacies, are predominantly reimbursed based off the same specialty generic drug fee schedule as other pharmacies.

Question. I'm concerned with the recent trend of PBMs allowing brand companies to "pay for position" on insurance formularies, which results in seniors losing access to lower-cost generics and biosimilars.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs?

Answer. We support continued flexibility to determine the cost-sharing structure that is most appropriate for our benefit design, including the ability to mix brand and generic drugs within the non-preferred drug tier (second highest tier on the Humana Part D formulary) or exclude drugs from the formulary. The cost of a brand-name drug is not guaranteed to be lower than a generic. For example, the oral bisphosphonate class of drugs utilized in the treatment of osteoporosis in postmenopausal women illustrates this phenomenon. Alendronate (the generic version of Fosamax) is placed on the lowest tiers (tier 1 or 2), ibandronate (the generic version of Boniva) tablets are placed on tier 2, and risedronate (the generic version of Actonel) is placed on the non-preferred drug tier. This formulary placement allows plans to create behavioral changes that drive members to the more cost-effective medication choice. Generally, an increased number of generic competitors correlates strongly with lower formulary tier placement of a generic and the Food and Drug Administration (FDA) has proven that generic drug prices are reduced with each additional market entry of a generic competitor.

DELAYS AND DENIALS IN CANCER TREATMENT

Question. I have received stories of cancer patients facing delays or denials for their treatment due to PBM actions. Data shows that breast cancer patients who experienced a 3-month or more delay in treatment had a 12 percent lower 5-year survival rate compared with breast cancer patients with only a 0- to 3-month delay.

What percent of patients experience a 14-day or longer delay in receiving an oral oncolytic prescribed by their oncologist?

Answer. Once approved, 84 percent of patients receive their oral oncolytic within 14 days of the initial authorization request submitted by their prescriber. Sixteen percent of patients fill their oral oncolytic more than 14 days after the initial authorization request is submitted and approved. Authorization requests for oral oncolytics are reviewed within 72 hours upon receipt for non-expedited requests and within 24 hours for expedited requests or as quickly as the beneficiary's condition requires in accordance with CMS requirements. Most prescribers will submit the request for approval prior to sending the prescription to the pharmacy for filling.

Question. What are the primary reasons patients experience delays or denials for their treatments?

Answer. Delays for approval are primarily driven by incomplete information provided by the prescriber or his or her office staff. Approximately 30 percent of total requests received are incomplete and require Humana to reach back out to the prescriber for this additional information in order to adequately review the request. Humana provides the specific information needed during the outreach in order to help provide transparency to the prescribers and facilitate receipt of the information needed to complete the review.

Denials for authorization are due primarily to the request not meeting the clinical criteria outlined in the coverage policy for that oral oncolytic or to the requested use not being supported by one of the following: the FDA-approved labeling, the current treatment guidelines or compendia (*e.g.,* NCCN), or there is not adequate available data in the current literature or peer reviewed medical journals.

Question. What percent of determinations to delay or deny treatment for cancer patients are made by an oncologist or healthcare professional with oncology training?

Answer. The clinical criteria for approval that is outlined in the coverage policies which governs authorization requests for oncology therapies are developed by health-care professionals (both pharmacists and physicians) with oncology training and are then reviewed and approved by Humana's Pharmacy and Therapeutics (P&T) Committee which also includes healthcare professionals (both pharmacists and physicians) with oncology training. In addition to P&T Committee approved coverage policies, requests for authorization are reviewed based on the national treatment guidelines and compendia (*e.g.,* NCCN) to see if the use is supported by the

recommendations and these guidelines are developed and reviewed by health-care professionals with oncology training.

Question. Why is a PBM-owned specialty pharmacy better qualified to manage a cancer patient's adherence and side effects than a community cancer clinic with a medically integrated pharmacy?

Answer. A plan-owned specialty pharmacy has access to a patient's entire medication profile and can more completely check for drug interactions and risk for adverse drug events, as well as assess historical adherence in order to identify opportunities to optimize a patient's treatment. In addition, these pharmacies tend to have access to other relevant and rich data elements, such as medical history, and to a vast set of care team resources such as behavioral health clinicians and experts in social determinants of health. These capabilities allow the patient to be treated holistically, with the intent being to reduce costs and improve clinical outcomes while delivering a more integrated experience for the patient.

DIRECT AND INDIRECT REMUNERATION (DIR FEES)

Question. Many community-based cancer clinics have established medically integrated pharmacies so patients can access their oral chemotherapy prescriptions or other medications at the point-of- care. These practices are often assessed large DIR which are based on certain quality measures targeted toward primary care.

Shouldn't pharmacies be evaluated on the type of drug dispensed and disease managed rather than a one-size fits all approach?

Answer. Humana's approach to performance-based contracting with network pharmacies closely aligns with our value-based payment initiatives for providers, hospitals, and other healthcare providers and aims to improve defined quality metrics such as medication adherence in targeted disease states. In all of our performance-based reimbursement programs, we seek to incent our partners to improve the quality of care delivered to our members by more closely aligning reimbursement with beneficiary outcomes and moving away from the traditional FFS reimbursement model. Humana's performance-based pharmacy network is also modeled, in part, on CMS's Star Ratings program. Humana received recommendations regarding the design of the performance-based network from standard-setting organizations that developed metrics for the Star Ratings program to ensure that high-performing pharmacies were rewarded similarly to those plan sponsors in the Star Ratings program.

Question. Does assessing large DIR fees on medically integrated pharmacies drive patients to PBM-owned specialty pharmacies?

Answer. Humana's approach to performance-based contracting with network pharmacies, including our own specialty network pharmacy, closely aligns with our value-based payment initiatives for providers, hospitals, and other healthcare providers and aims to improve defined quality metrics, such as medication adherence in targeted disease states.

Question. Why are pharmacies forced to pay DIR and other fees to PBMs?

Answer. As stated previously, the concept of paying for value and quality, which is at the core of the performance-based pharmacy network, can be seen in numerous value-based payment models including those implemented or proposed by CMS in which the financial incentives are paid after the performance is observed.

Question. According to CMS, PBMs justify DIR fees as adjustments to improve quality. CMS also found that PBMs and PDPs withhold substantially more in reductions in payments than as rewards paid to pharmacies. Aren't so-called "quality adjustments" that collect more for "poor performance" than they pay out for "high performance" just another way for PBMs to collect even more money from pharmacies?

Why do PBMs collect more in quality payment adjustment than they pay pharmacies under Part D?

Answer. Humana's approach to performance-based contracting with network pharmacies closely aligns with our value-based payment initiatives for providers, hospitals, and other healthcare providers. In all of our value-based reimbursement programs, we seek to incent our partners to improve the quality of care delivered to our members by more closely aligning reimbursement with clinical interventions that improve outcomes and moving away from the traditional FFS reimbursement model. The concept of paying for value and quality, which is at the core of the performance-based pharmacy network, can be seen in numerous value-based payment

models including those implemented or proposed by CMS in which the financial incentives are paid after the performance is observed.

FORMULARY PLACEMENT/GENERIC TIERING

Question. In 2011, 71 percent of generic drugs in Part D were on the lowest tier designed for generics; by 2019, that number decreased to only 14 percent of generics. According to an Avalere study, this practice cost seniors $22 billion in higher out-of-pocket costs since 2015, costs that could have been avoided through the proper formulary placement of lower-cost generics. This practice, known as "paying for position," allows brands to block uptake of lower-cost generics and biosimilars, thereby unnecessarily increasing out-of-pocket costs for seniors.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs? Do you ever consider portfolio or bundled rebates with brand manufacturers?

Answer. The use of portfolio or bundled negotiations with drug manufacturers does not align with Humana's Pharmacy and Therapeutics Committee's policy and procedures or the formulary development process. Our coverage decisions are based on treatment guidelines and the evidence base. We prioritize low-cost generic drugs, and if multiple brand name drugs are available to treat the same clinical condition, we negotiate with competing manufacturers to provide access to drug coverage that produces the most value to the member, which includes the lowest out-of-pocket cost over the course of the year and the health outcomes produced.

Question. When you place generics on your formularies, do you place that generic favorably to brand products—in other words, on generic-only tiers?

Answer. The primary drivers of formulary placement are the evidence base, clinical efficacy, and status as a biosimilar. After these factors are considered, the P&T Committee considers the affordability of the drug. A drug's status as a generic or a brand does not always correlate with the affordability of the drug.

Question. When a generic becomes available, do you place it on your formularies immediately?

Answer. Each new-to-market medication, including generics, is reviewed based on the available clinical data for the product, which includes FDA labeling, compendia listing, peer-reviewed literature, real-world evidence, comparative effectiveness data, and nationally recognized treatment guidelines. Evaluation begins with safety and efficacy and the incremental health outcome value in the context of existing treatment options, including brand and generic medications. Generic medications are safe and efficacious, cost-effective alternatives, and the generic utilization rate among Humana's Medicare population is greater than 90 percent among products with currently available FDA AB-rated generic alternatives. This 90 percent generic dispensing rate is driven by Humana not covering higher cost brand medications in classes where a generic equivalent medication is on the market.

It should also be noted that the presence of a single generic does not always result in an immediate decrease in the price of the generic or brand drug. Humana's analysis of 2017 Part D prescription drug spending found that prescription drugs with less competition were more likely to have list price increases than drugs with five or more manufacturers.

Question. According to CMS, from 2012 to 2017 PBMs imposed a 45,000 percent increase in the amount of DIR fees pharmacies had to pay PBMs and PDPs under Part D, and revenues earned from these fees increased 225 percent per year during this period.[6] I thought PDPs and PBMs were supposed to pay pharmacies for dispensing drugs to patients. Why do pharmacies have to pay DIR fees to PBMs at all?

Answer. Humana's approach to performance-based contracting with network pharmacies closely aligns with our value-based payment initiatives for providers, hospitals, and other healthcare providers. In all of our value-based reimbursement programs, we seek to incent our partners to improve the quality of care delivered to our members by more closely aligning reimbursement with clinical interventions that improve outcomes and moving away from the traditional FFS reimbursement model. The concept of paying for value and quality, which is at the core of the

[6] CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of- Pocket Expenses, 83 Fed. Reg. 62152, 62174 (November 30, 2018).

performance-based pharmacy network, can be seen in numerous value-based payment models including those implemented or proposed by CMS in which the financial incentives are paid after the performance is observed.

QUESTION SUBMITTED BY HON. JOHN THUNE

Question. You've all shared your ability to leverage technology such as real-time benefit tools to help patients and providers understand drug costs at the point of prescribing, as well as how technology can be used to help identify opportunities to provide enhanced support and medication management for enrollees. What policies can we consider to incentivize greater uptake of these tools?

Answer. Humana applauds CMS's final rule published on May 23, 2019, which will require all Part D plan sponsors to have a real-time benefit tool by 2021. We believe that there are several current barriers that lessen the effectiveness of these tools. Most importantly, there are currently no regulations requiring EHR vendors to implement open APIs that specifically facilitate the integration of real-time benefit tools. As a result, some EHR vendors have implemented exorbitant "connection fees" in order to enable this integration, while others have refused to partner with plans. On the provider side, there are often insufficient incentives in place to spur provider adoption. In launching our Real Time Benefit Tool (RTBT) IntelligentRx, we found that three functionalities made our tool more attractive for use by providers: cloud-based solution, integration with a point-of-sale claims engine, and electronic prior authorization functionality.

In fact, Humana is the first national health-care insurer to collaborate with Epic to bring together patients, providers, and payers to power value-based care. Humana and Epic are advancing interoperability to promote open communication and information transparency that will give patients and their practitioners integrated and real-time access to the patients' medical history, health insights, and treatment options, which, in turn, enables cost reduction, improves quality, and increases patient satisfaction. To enhance the prescriber's experience, Humana will integrate its RTBT, IntelligentRx, directly into Epic's e-prescribing workflow, delivering real-time pharmacy data throughout its network.

QUESTIONS SUBMITTED BY HON. RICHARD BURR

Question. Pharmacy Benefit Managers (PBMs) offer a variety of contract designs to health insurance plans, allowing the insurer or client to choose the best structure for their customers. During the Finance Committee hearing on April 9, 2019, each witness stated that, in the contracts structured to allow for the pass through of rebate dollars at the point of sale, PBMs do not keep *any* portion of the rebate. If the PBM does not keep a portion of the rebate, what type of revenue do PBMs receive from these contracts? What percent of your contracts are point of sale and what percent utilize a structure providing a percentage of the rebate back to the PBM?

Answer. Currently Humana does not administer any point-of-sale rebate plan designs. Rebates received by Humana for Part D drugs are passed through to the Part D plans. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers.

Question. It is our understanding that contracts with pharmaceutical manufacturers may also take a variety of forms. In calendar years 2016, 2017 and 2018, what was the total dollar amount that you obtained from pharmaceutical manufacturers in any form such as rebates, fees, etc.? What is the total dollar amount that was passed on to health insurance plans with which you have an agreement or contract?

Answer. For all calendar years, rebates received by Humana for Part D drugs are reported to CMS annually through Direct and Indirect Remuneration (DIR) and reflected in Part D bid submissions. Rebates received by Humana for Part D drugs are passed through to the Part D plans. Part D plans reinvest the savings accrued from these rebates in benefit offerings. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. One challenge that I see, when considering the medical treatment marketplace, is that we have a new wave of life-saving treatments—of incredible cures we could never have dreamed of, even 10 or 15 years ago—for which cost, by necessity, is going to be a major issue. You look, for instance, at a condition like sickle cell disease. For the average SCD patient who reaches age 45, lifetime treatment costs are at roughly $1 million—and there are complications that can make that figure even higher. Now that we see therapies coming down the pipeline that could erase those long-term costs and drastically improve the quality of life for sickle cell patients, the question becomes how can our current payment systems adapt to—and absorb—the high costs necessary to bring treatments like these to market and to ensure that we continue to see innovations like these ones moving forward?

Answer. Few interventions are available for sickle cell disease beyond palliative treatment but many therapies are on the horizon, and some are already in late-stage trials. Clinically meaningful outcomes that result in improved quality of life are essential for all new products being reviewed by the FDA. Manufacturers have historically focused drug development on safety and clinical efficacy compared to a placebo for regulatory approval. FDA accelerated approval is often based on surrogate markers as opposed to outcomes data which are directly tied to improvements in patient health. This is a very real issue in the treatment of oncologic diseases where products are approved with limited phase 2 clinical trial data which are not designed to assess outcomes for a broad patient population or long-term. In a review of the 93 cancer drug indications granted accelerated approval since 1992, only 19 drugs (20 percent) had improvement in overall survival while 19 drugs (20 percent) simply met the original surrogate end point used in the accelerated approval. To support better health outcomes, the FDA approval process should be transformed from accelerated approval based on surrogate endpoints to a system based on outcomes and value that improves health. Such a shift in FDA approval of high cost specialty drugs would facilitate payment and reimbursement subject to a Coverage with Evidence Development (CED). CED would allow Medicare Advantage and Part D plans to provide coverage and reimbursement based on shared risk with drug manufacturers with the condition that additional data is systemically produced by manufacturers through prospective registries or additional controlled trials to assess actual health outcomes that may be produced. Once sufficient data is reported, permanent coverage and reimbursement based on longer term health outcomes would be established.

Question. And along the same lines, beyond creating some much-needed clarity around value-based arrangements—which I've been working with Senators Cassidy and Warner to accomplish legislatively—are there steps that Congress could take to facilitate these innovative payment models?

Answer. **Outcomes (or value-based) contracts:** Outcomes-based contracting should be leveraged and reserved for disease states with limited or no competition and serve as a feedback loop to answer the uncertainties that exist around first-in-class agents, accelerated approval drugs, and orphan drugs approved in small populations in order to inform future formulary and coverage decisions. Three disease states account for 70 percent of the pharmaceutical industry's drug pipeline—oncology, infectious diseases, and central nervous system (CNS) disorders. And the proportion of new therapies approved as orphan drugs has ballooned. In 2015, 21 orphan drugs were approved, accounting for 47 percent of all new medicines, up from just 29 percent in 2010; in 2016, nine more orphans won approval, 40 percent of the total. These drugs are typically fast tracked, offered breakthrough status, and approved on phase 2 trials without the rigorous standards other drug classes are held to. These are the areas of focus where outcomes-based contracting would be most helpful.

Manufacturers should take on meaningful risk in outcomes-based contracting: Our experience is that the vast majority of manufacturers are only willing to enter into outcomes-based contract arrangements that align with a product's clinical trial data and FDA approval. As such, the findings from such agreements add little or nothing to the existing evidence base and virtually assure a positive outcome for the manufacturer. In most cases, manufacturers seek outcomes-based contracts for products in drug classes where robust competition already exists, indicating that the manufacturer is more interested in gaining a competitive advantage or preferred formulary access as opposed to advancing the medical evidence around the safety and efficacy of their product in a real-world environment. It is our view that outcomes-based contracting remains the exception—and not the norm—in de-

termining the ultimate value of prescription drugs. They do not produce the best arrangement in every situation. In competitive disease areas where multiple drug manufacturers offer well-established treatments or where generics are prevalent, such as the markets for oral diabetes drugs, multiple sclerosis, and hepatitis C, the ordinary effects of traditional price concession negotiations afforded by robust competition produce the lowest costs.

Medicaid best price is a barrier to outcomes-based contracting: In our negotiations with drug manufacturers, they often cite Medicaid Best Price as the primary reason for refusing to take on more significant downside risk in outcomes-based contracts. Although we cannot empirically validate that Best Price is a limiting barrier—only drug manufacturers can speak to that question—just over 30 percent of our executed outcomes-based contracts apply solely to our Medicare Part D plans, which are statutorily excluded from manufacturers' Best Price calculations. The products associated with these outcomes-based contracts are predominantly high-cost specialty drugs and include therapies for auto-immune/inflammatory conditions (rheumatoid arthritis, psoriasis), cardiovascular disease, diabetes, infectious disease, and cancer. The remaining 70 percent of our outcomes-based contracts apply equally to our commercial and Medicare lines of business. Recently published reports have found that though Medicaid Best Price is an understandable concern for manufacturers determining whether to pursue value-based contracts, particularly in the commercial market, its effect can be mitigated and is not the immutable obstacle to value-based contracting that some manufacturers' claim. We encourage CMS to review this research and determine if additional guidance is necessary to clarify the treatment of outcomes-based agreements relative to manufacturer calculations of Best Price. CMS may also wish to consider using its demonstration authority to explore opportunities to ameliorate manufacturers' concerns regarding the impact of outcomes-based contracting on Medicaid Best Price calculations. For example, CMS could develop a limited pilot program to test whether excluding outcomes-based contracts from Medicaid Best Price results in manufacturers taking on more significant downside risk, and whether that in turn creates net savings for the Federal Government and beneficiaries.

Question. I'm also interested in the role that technology can play in helping to drive down drug costs—as well as to increase medication adherence. Some estimates suggest that between 50 and 75 percent of patients don't take their medications as prescribed, and that one in five new prescriptions go unfilled. And study after study shows that cost is a key factor here. As a consequence, we see roughly 125,000 deaths from non-adherence every year, along with more than $100 billion in excess costs to the health-care system. To what extent can technology help providers and patients to make more informed and cost-effective choices about prescriptions—and to then adhere to these prescriptions?

Answer. Humana was the first Part D plan to provide real-time access to drug cost and formulary information to physicians and their patients through our IntelligentRx tool. IntelligentRx enables physicians and their patients to make joint treatment decisions based upon efficacy and cost for 3.1 million prescriptions annually. The tool is currently available to all 10 million Humana members, including individuals with Medicare, Medicaid, and employer coverage.

Humana applauds CMS's final rule published on May 23, 2019, which will require all Part D plan sponsors to have a real-time benefit tool by 2021. We believe that there are several current barriers that lessen the effectiveness of these tools including the lack of requirements on electronic medical records vendors and creating incentives for increased provider participation. In launching IntelligentRx, we found that three functionalities made our tool more attractive for use by providers: cloud-based solution, integration with a point-of-sale claims engine, and electronic prior authorization functionality.

Question. And maybe more to the point, to the extent that these technological tools are out there, what steps are you and your clients taking to encourage physicians and patients to use them?

Answer. In 2019, Humana plans to launch integrations with additional electronic medical record vendors, including Epic, which is one the largest medical record companies in the country. We believe this will significantly increase provider access to and utilization of our real-time benefit tool.

QUESTIONS SUBMITTED BY HON. BILL CASSIDY

Question. Are there ever cases where a patient in your health plan or one of the health plans for whom you negotiate as a PBM pays more for a medicine than the plan spends on a net basis, when you reimburse the pharmacy for that same medicine? In those cases, what entity receives the benefit of the difference between the amount the patient pays and the net amount the plan pays?

Answer. No. Humana members always pay out-of-pocket costs that are the lowest amount of the benefit defined member cost share, the negotiated rate, and the pharmacy "usual and customary" (U&C) cash price.

Question. In calendar years 2015, 2016, 2017—what percent of your revenue was from fees paid by plans, fees paid by manufacturers, other fees, pharmacy spread or rebates? Same question as to profits. Of all revenue generated from part D contracts, what percent did you retain?

Answer. For all calendar years, rebates received by Humana for Part D drugs are passed through to the Part D plans. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers.

Question. Should a patient ever pay more out of pocket for a medicine than what you pay the pharmacy for that medicine?

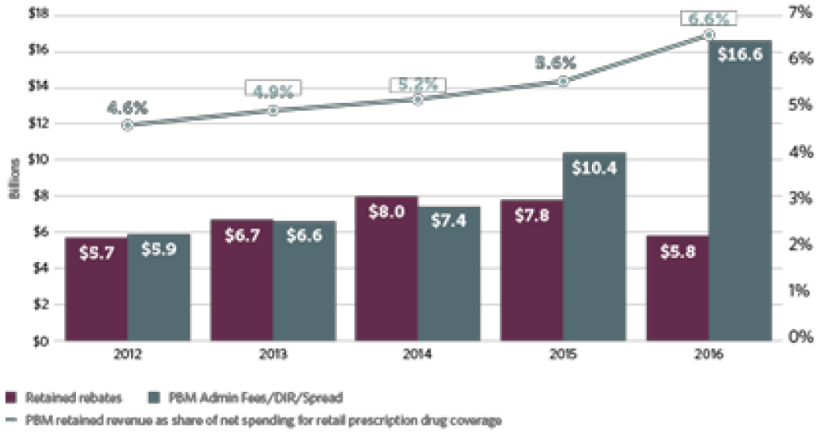
Answer. No. Humana members always pay out-of-pocket costs that are the lowest amount of the benefit defined member cost share, the negotiated rate, and the pharmacy "usual and customary" (U&C) cash price.

Question. PBM revenue from fees has risen, illustrated below. Further, PBM's retained revenue as a percent of net retail drug spend has consistently increased. What do you attribute this increase to?

Answer. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers. Rebates received by Humana for Part D drugs are passed through to the Part D plans. Part D plans reinvest the savings accrued from these rebates in benefit offerings. Additionally, rebates have resulted in significant savings to the government. As cited in the Medicare Trustees Report, rebates have played a critical role in keeping the overall cost of Part D lower than projected when the program was first launched in 2006.

Figure 9

PBM Retained Revenue on Retail Prescription Drugs by Source and Share of Net Spending for Retail Prescription Drug Coverage, 2012-16



Question. How are bona fide service fees established? What was your revenue generated in part D by bona fide fees in 2015, 2016, and 2017?

Answer. For all calendar years, Humana's wholly owned PBM has not had bona fide service fee arrangements with drug manufacturers.

Question. A *Health Affairs* article suggests plans may prefer paying PBMs using rebates instead of fees, as "Using retained rebates to cover PBM costs in lieu of fees could artificially lower reported administrative costs and make it easier to meet government medical loss ratio (MLR) requirements." Is it true that paying the PBM a percent of rebates would keep that revenue from counting towards a plan's MLR?

Answer. Humana is not familiar with this approach. Rebates received by Humana for Part D drugs are passed through to the Part D plans.

Question. Would you support an industry-wide standard set of performance metrics by which a PBM would set its pharmacy contracts, which would be tailored based on regional patient populations, to give certainty for local pharmacies?

Answer. While Humana appreciates the goal of standardizing information, we strongly oppose requiring plans and PBMs to implement a set of universally applicable performance metrics. Mandating a compulsory set of performance/contracting metrics would homogenize value-based payment programs for pharmacies and stifle innovation. Similar to the way in which CMS and other payers are experimenting with a variety of value-based reimbursement for physicians and hospitals, plans need the flexibility to test and learn. Furthermore, the generation of a standard data set in this fashion would be an infringement upon the contractual relationship between the plan sponsors and the pharmacies and could potentially limit future innovation to improve member outcomes.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

Question. In Medicare Part D, beneficiaries' deductible and coinsurance payments are calculated based on the price negotiated between the PBM and the pharmacy.

Does this take into account rebates and discounts the PBM negotiates separately with pharmaceutical manufacturers?

Answer. Currently Humana does not administer any point-of-sale rebate plan designs.

Question. In calendar years 2016, 2017, and 2018, what share of brand prescriptions covered by the Part D plans you contract with were filled in the deductible or required beneficiaries to pay coinsurance? What was the total amount beneficiaries spent out-of-pocket for those prescriptions? What would beneficiaries' total out-of-pocket spending have been under the same cost sharing structure if their payments were based on the net price to the Part D plan, inclusive of rebates and other price concessions, rather than the price negotiated between your PBM and the pharmacy?

Answer. It is important to note that Part D has a very high generic dispensing rate, and plans do not receive rebates on generics. Generic drugs account for the vast majority of Part D program utilization and now approach 90 percent in the Part D Program. In CY 2016, low cost generic drugs accounted for 87 percent of overall prescription drug utilization for Humana. Despite accounting for the vast majority of the utilization, these drugs only contributed to 24 percent of total drug costs in 2016. To illustrate, we calculated the frequency distribution of annual cost sharing savings of the POS rebate construct and the associated percentage of Humana membership that would have received the annual cost sharing savings if rebates at the POS were required during the 2016 plan year (see table below). Seventy-one percent of Humana's membership would receive $0 in cost sharing reduction, 19 percent would receive $100 or less in annual cost sharing reductions, and only 10 percent of membership would receive more than $100 in annual cost sharing savings.

Frequency Distribution of Annual Member Cost Sharing Reductions With POS Rebates

Annual Sum of Cost Sharing Savings	Percentage of Membership
$0	71.3 percent
<$20	8.3 percent

Frequency Distribution of Annual Member Cost Sharing Reductions With POS Rebates—Continued

Annual Sum of Cost Sharing Savings	Percentage of Membership
$21–$40	4.3 percent
$41–$60	3.0 percent
$61–$80	2.0 percent
$81–$100	1.4 percent
$101–$1,000	9.4 percent
>$1,000	0.2 percent

QUESTIONS SUBMITTED BY HON. RON WYDEN

SPREAD PRICING IN MEDICAID

Question. A PBM practice that has come up quite a bit recently is the practice of spread pricing. Spread pricing occurs when PBMs charge health plans more for prescription drugs than they actually reimburse pharmacies, and then pocket the different as profit.

Do you engage in spread pricing practices?

Answer. Humana does not use spread pricing in the Medicare Advantage, Part D PDP, or Managed Medicaid plans. Humana offers the opportunity for employers to select spread pricing. Providing employers a choice in financing preserves the ability for plan sponsors to effectively manage the performance of pharmacy benefit managers through performance-based contracts and creates incentives for stronger price negotiations.

REBATE DEMANDS

Question. The use of rebates as a negotiating tool has led to problematic incentives in the prescription drug supply chain. For example, drug companies have argued that they increase list prices in response to demands from PBMs for high or increasing rebates.

Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that require equivalent rebates, even in the case of a drug for which the list price has been lowered?

Answer. No.

Question. Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that require advance notice of changes in the list price of drugs, including reductions or increases in list price?

Answer. No.

REVENUE SOURCES

Question. Please provide an annual breakdown of the following components of the revenue you received from drug manufacturers from January 1, 2013 through December 31, 2018: dollar amount and percent of revenue from rebates; dollar amount and percent of revenue from administrative fees; dollar amount and percent of revenue from distribution fees; dollar amount and percent of revenue from marketing fees; dollar amount and percent of revenue from clinical case management fees; and all other sources of revenue from manufacturers not listed above.

Answer. For all calendar years, rebates received by Humana for Part D drugs were reported to CMS annually through Direct and Indirect Remuneration (DIR) and reflected in Part D bid submissions. Humana Part D plans reinvest the savings accrued from these rebates in benefit offerings. Humana's wholly owned pharmacy benefit manager did not receive fees from pharmaceutical manufacturers.

PART D NEGOTIATION

Question. The PBM market has changed dramatically over the past several years. Many Part D health plans also operate as PBMs, including your companies. While Part D has done a great job offering Medicare beneficiaries drug coverage they did not have access to before, Part D has not been successful at keeping up with the growing cost of medicines. PBMs and Part D plans claim they bargain to get lower prices, but the HHS Inspector General found that almost 4 in 10 brand name drugs in Part D offered no rebate or discount to Part D plans.

Why have Part D plans been ineffective at bringing down the cost of almost half of brand-name medicines?

Answer. The current challenges in the Part D market are complex. The three major issues that are preventing Part D plans from effectively negotiating with manufacturers on the price of sole-source brand-name drugs are: the introduction of high cost specialty drugs which frequently do not have any competition; the anti-competitive actions taken by manufacturers to delay competition and further prolong monopolies; and the unintended consequences of well-intended drug policies have limited the negotiating power of Part D plan sponsors.

We discuss these challenges and potential solutions to address them in our response to the recent discussion draft on Part D Improvements developed by the House Committees on Ways and Means and Energy and Commerce, which is attached. We welcome additional conversations with the Senate Finance Committee on these policy challenges as well.

Question. At the hearing, witnesses spoke about the ways in which they seek to get the best price for patients. However, behind this is the reality that PBMs are driven by their bottom line. Researchers at Johns Hopkins University found that 72 percent of formularies in Part D charge lower cost-sharing for a brand name drug compared to the cheaper generic equivalent. This occurs because the more expensive brand name drugs are able to give bigger rebates, but we can never know for sure because rebate information is kept secret.

How can the public have confidence that they're getting the lowest price and not the price that gives you the biggest rebate to your business?

Answer. Humana has a history of maintaining low premiums in Part D. Additionally, over 80 percent of seniors have out of pocket costs of less than $275 annually. One of the tools used to ensure that beneficiaries receive the best value from their prescription drug plans is rebates. Savings that are obtained by Humana through rebate negotiations with drug manufacturers are distributed to all Part D beneficiaries through reduced premiums, resulting in lower costs for seniors in PDP and MAPD plans. Additionally, rebates have resulted in significant savings to the government. As cited in the Medicare Trustees Report, rebates have played a critical role in keeping the overall cost of Part D lower than projected when the program was first launched in 2006.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Should the CREATES Act become law, what commitment can your company making to covering generics as soon as they are approved and passing those savings on to patients?

Answer. Humana strongly supports the introduction of S. 340, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. If this bill were to become law, Humana will continue to advance the adoption of generics through our formulary development process. We also believe that the CREATES Act would lead to a more robust market for generics that could be leveraged to increase the utilization rate of generic drugs in Part D (currently 85 percent of the drugs provided to Part D beneficiaries are generic).

Question. What are your concerns with point-of-sale rebates and what alternatives do you propose to such rebates to improve consumer savings at the pharmacy counter?

Answer. We anticipate the Part D rebate model will be changed to one where the rebates that manufacturers are willing to offer will be applied at point-of-sale. This regulatory action will have mixed results. All beneficiaries will pay higher premiums: 83 percent will see higher total costs given the premium increases; 5 percent

will see savings of less than $70 per year; and only 12 percent will see savings of greater than $70 per year.

The only way to achieve the same costs for the Part D program and maintain beneficiary premiums is if all brand drug manufacturers elect to decrease their prices by at least 28 percent, not just the 7 percent of drugs currently receiving rebates—which would require a 45-percent reduction.

We have attached our recent letter to the House Energy and Commerce and Ways and Means Committees, which include policy recommendations for modernizing the Part D program.

Question. What are the specific steps your company is taking to move PCSK9 inhibitors off the specialty tier in Medicare Part D and to fixed copay tiers given that prices went down by 60 percent and are no longer above the specialty tier threshold?

Why haven't your plans moved it already, given that CMS allows plans to make positive mid-year formulary changes that improve patient access and affordability?

Answer. At the time the formulary is developed, Humana formulary placement is determined based on the evidence base, clinical efficacy, and status as a biosimilar. After these factors are considered, the P&T Committee considers the affordability of the drug. In some cases, manufacturers do not share their intention to offer lower costs versions of medications when plans and formularies are being designed. In the case of PCSK9 inhibitors, Humana added the lower priced NDC to its formularies as soon as it launched in 2019 and starting in 2020 PCSK9 inhibitors will be on a lower tier.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

DRUG REBATE RULE AND HIGHER PART D PREMIUMS

Question. In January, the Department of Health and Human Services released a proposal to reform prescription drug rebates paid by pharmaceutical manufacturers to pharmacy benefit managers under Medicare Part D. The OIG proposal attempts to ban most rebates by eliminating their regulatory protections and creating two new safe harbor provisions: one to expressly protect discounts applied directly at the point of sale (POS) for consumers, and another to protect certain service fees that manufacturers pay to PBMs for services furnished to health plans. The only service fees that would be permissible under the proposal are those that are fixed, and not based on a percentage of sales and not based on volume or the value of other business generated between the parties. The proposed rule was designed to address the Department's concerns with the current rebate system, which HHS believes rewards high list prices, discourages the use of generics and biosimilars, and does not reflect patient out-of-pocket costs. For consumers, this proposal may result in lower costs at the pharmacy counter, but Part D premiums may increase as a result.

Could you explain which Part D beneficiaries could see savings on their drug costs at the pharmacy counter and which Part D beneficiaries could not see lower drug costs?

Answer. The implementation of the rebate rule is most likely to reduce POS drug costs for non-LIS seniors who take patent-protected drugs that treat conditions like hepatitis C, diabetes, and various autoimmune disorders. Humana's analysis applying the POS rebate policy to its 2018 benefits found that approximately 17 percent of beneficiaries would see savings at the pharmacy counter, with only 12 percent saving more than $70 annually. The remaining 83 percent of beneficiaries will see an increase in costs for prescription drug coverage due to premium increases that will exceed any potential savings the beneficiary may have experienced at the pharmacy.

PERVERSE INCENTIVE TO PLACE MORE EXPENSIVE DRUGS ON FORMULARIES

Question. In a Senate Finance Committee hearing had a few weeks ago, many pharmaceutical companies argued that the current rebate structure incentivizes high list prices. These companies argue that the higher the list price of the drug, the greater the rebates, and therefore, the more profit the PBM earns. While contracts between PBMs, Part D Plans, and pharmaceutical companies require PBMs to pass through 100 percent of the negotiated rebate back to insurance plans, I

worry that this structure could incentivize PBMs to favor a more expensive drug on the formulary because they could get a higher rebate.

Is there an incentive for a PBM to place a higher cost drug on the Part D formulary because the PBM receives a larger rebate for that more expensive drug? Why or why not?

Answer. Our goal is to ensure that our beneficiaries are receiving the lowest possible price. We prioritize low-cost generic drugs, and if multiple brand name drugs are available to treat the same clinical condition, we negotiate with competing manufacturers to provide access to drug coverage that produces the most value to the member, which includes the lowest out-of-pocket cost over the course of the year and the health outcomes produced. Humana's current formulary design includes 10 percent or less of brand medications on the preferred generic and generic tiers (the lowest tiers on Humana's Part D formulary), with the majority of those two tiers composed of generic medications.

SIX PROTECTED CLASSES PROPOSAL AND ACCESS

Question. This past November, the Centers for Medicare and Medicaid Services released a proposed rule for 2020 to help tackle drug pricing. Among the proposed changes is one, which would alter the current rules, governing the "six protected classes." The concept of the "protected classes" has been around since the launch of the Medicare Part D Program, and it was instituted to ensure that some of our most vulnerable patients would have access to their needed drugs by requiring formularies to cover nearly all protected drugs. These classes are anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Some people have argued that these protected classes have led to higher drug prices because formularies are required to include this prescription coverage, and there are limited tools left to help lower prices. In an effort to increase competition, this proposed new rule would do a couple of different things. The first aspect of the administration's proposal would allow Part D sponsors to implement broader use of prior authorization and step therapy for protected class drugs, including determining use for protected class indications. Any time there is a mention of plans using prior authorization or step therapy there is an immediate concern of restricting patient access to needed drugs or medical services.

Could you explain why your company would favor such utilization management tools like step therapy or prior authorization?

Answer. Humana fully supports the use of utilization management tools such as prior authorization and step therapy—including the expanded use of non-formulary drug status. Plan sponsors utilize their pharmacy and therapeutic (P&T) committees, which make their own assessments of clinical appropriateness and therapeutic alternatives based upon labeling from the Food and Drug Administration (FDA), clinical guidelines, peer-reviewed literature, and the medical compendia, which is a critical component of a well-managed drug plan. Humana's P&T committee evaluates each member case individually to ensure members stable on their drug therapies receive evidence-based quality care. Humana has long supported the use of evidence-based utilization management for Part B drugs to lower out-of-pocket costs for its members and stimulate increased price competition in the Part B drug market. The historic barrier to more efficient management of Part B drug utilization is that existing Medicare policies made it impossible for MA plans to leverage market-based tools to increase competition and lower costs. Without such tools, pharmaceutical companies had nearly unlimited pricing power, as evidenced by the ever-increasing costs of Part B drugs. Since 2009, Medicare Part B drug spending has grown at an average rate of 9 percent per year. Approximately 50 percent of the growth in Part B drug spending from 2009 to 2013 was the result of increased prices for existing products and shifts in the mix of drugs, including the adoption of new drugs.

Question. Do you believe there is a danger that using step therapy or prior authorization could possibly restrict patients from having access to medication that has been successful for them? Why or why not?

Answer. We do not believe there is a danger of restricted access to drugs due to prior authorization or step therapy. The step therapy program was developed with clinical efficacy as the primary requirement. Step therapy policies are reviewed periodically to ensure that all standards are based on the most up-to-date clinical cri-

teria. Furthermore, all patients and providers have the ability to request exceptions and appeals, which can be processed in less than 24 hours if needed.

Question. If you were to use step therapy or prior authorization for drugs in the six protected classes, how would you ensure patients would continue to have access to their needed medications in one of the six protected classes?

Answer. Humana is disappointed in CMS's decision not to finalize the protected class proposals this spring. However, if Congress were to revisit the proposals on protected classes, Humana would use many of the same measures currently in place today in the Part B Step Therapy to ensure that beneficiaries have access to the appropriate medications. This would include the development of clinical policies, communication efforts to beneficiaries and providers, expedited appeals processes as necessary, and savings in the form of reduced premiums.

Question. The second aspect of the administration proposed change to the six protected classes is the proposal to allow drug coverage formularies to exclude a protected class drug from a Part D formulary if the drug represents a new formulation of a single-sourced drug, regardless of whether the older formulation remains on the market. My understanding is that this administration is trying to target pharmaceutical companies who participate in the anticompetitive practice of "evergreening." This is a practice where pharmaceutical companies make slight alterations to a drug's packaging, color, and formulation without an added or new benefit. However, we also understand that seemingly small changes to a drug can still make a big difference to patient well-being. We have heard from Maryland physicians that the creation of combination antiretroviral pills was a huge step forward in the fight against HIV. Even though these combination pills or extended release versions didn't have a new chemical formula, they made a world of difference to the HIV patients taking over a dozen pills a day. These vulnerable patients are obviously very concerned that they could lose coverage for new and better drugs, especially when their old drugs may no longer be available. HIV treatments have come a long way in the last few decades, and proper antiretroviral treatment is vital to ensuring an end to the HIV epidemic.

Do you think the proposed rule anticipates a situation where a pharmaceutical company stops producing an older version of a drug when a new formulation is available, but the newer formulation is not covered by a Part D plan? Why or why not?

Answer. Humana is disappointed in CMS's decision not to finalize the protected class proposals this spring. If Congress were to revisit the proposals on protected classes, Humana does not believe there would be access issues for protected class drugs. However, it should be noted that manufacturers alone make production decisions for the medications that are brought to the market.

Question. What would your company do to ensure that patients continue to have access to their medication in this situation?

Answer. Humana would encourage manufacturers to continue to make novel medications that support beneficiaries but manufacturers alone make production decisions for the medications they bring to market.

APPEALS PROCESS IN GENERAL

Question. Prior authorization and step therapy are some of the most commonly mentioned concerns from patient groups coming to talk to my office, second only patients' concerns about out-of-pocket costs. What has become especially striking in the past few weeks is the number of physicians explaining how they feel stymied by prior authorization restrictions by insurance plans. We have heard from one surgeon who argued for weeks with the insure to appeal a decision that had been made to deny a newer type of less-invasive surgery. Someone who was not a surgical expert made the denial. Eventually, his patient made the decision to stop waiting and opted for a far more invasive and dangerous procedure because it was covered by insurance. Other doctors talk about the hours they spend on the phone waiting to appeal a decision, only to be told they need to write an extensive report justifying their medical decision. While the physicians are waiting for a response, quite often there are patients suffering without their proper medications, without certain tests, or not getting the surgery that the expert recommends.

What is your organization doing to improve the appeals process for patients and physicians, in order to ensure timely medical care and access to their prescription drugs?

Answer. Humana strives to ensure that all of our beneficiaries and their providers have as much information as possible when making decisions about their care. That is why Humana was the first Part D plan to provide physicians and their patients with real-time access to drug cost and formulary information through our IntelligentRx tool. IntelligentRx enables physicians and their patients to make joint treatment decisions based upon efficacy and cost for 3.1 million prescriptions annually. The tool is currently available to all 10 million Humana members, including individuals with Medicare, Medicaid, and employer coverage. One of the elements of this tool is electronic prior authorizations or ePA which instantaneously processes prior authorizations and minimizes the need to file appeals.

Question. What do you think is an appropriate wait limit for emergency medical appeals, and how do you make sure you meet it?

Answer. Humana complies with current CMS requirements to process regular and expedited drug appeals within 72 or 24 hours respectively or as quickly as the beneficiary's condition requires.

Question. Another complaint that I have heard from physician groups is that many formularies do not cover newer drugs that they consider to be necessary for hard-to-treat diseases, even if the drugs are very well-studied.

With technology changing so rapidly, how do your companies ensure that you keep up with the medical and surgical experts and new research, so that your authorization decisions are in line with the most recent medical innovations and physician standards?

Answer. Our coverage decisions are based on treatment guidelines and the clinical evidence base. Our treatment guidelines are generally evaluated quarterly and at least annually to ensure appropriate coverage based on the most recent medical innovations and evidence.

DIRECT AND INDIRECT REMUNERATION FEES

Question. I have heard from independent pharmacies in Maryland that have struggled with Pharmacy Benefit Managers and Direct and Indirect Remuneration (DIR) fees. According to independent pharmacies, there are times when DIR fees are based on performance, and these fees range from $2–$7 for certain types of maintenance prescriptions and are often collected retroactively—weeks or even months after a prescription was filled. A PBM can take money back from the pharmacy when the pharmacies haven not met a PBM's performance standard. In these instances, the PBM claws back money and creates a situation where the pharmacy does not receive adequate reimbursement to cover its costs. As a result, DIR fees can be a significant financial loss to pharmacies and an additional cost burden to patients.

Could you explain what performance measures are considered when determining a DIR fee?

Answer. The highest performing pharmacies in Humana's quality performance network, those that are above the 80th percentile of medication adherence measures, are rewarded at a higher level in order to recognize their superior performance. For example, in 2017 the highest performing pharmacies received up to $6 per eligible claim, pharmacies in the 50th to 80th percentiles received up to $2 per eligible claim, and those below the 50th percentile were not rewarded. The medication adherence measures included:

- **Diabetes (non-insulin agents):** biguanides, sulfonylureas, thiazolidinediones, DPP-IV inhibitors, incretin mimetics, meglitinides, sodium glucose co-transporter2 (SGLT2) inhibitors (Members filling insulin products are excluded).
- **Hypertension/blood pressure (Renin Angiotensin System Antagonists):** Direct Renin Inhibitor, Angiotensin Receptor Blockers (ARBs), Angiotensin Converting Enzyme (ACE) Inhibitors (members filling Entresto (sacubitril/valsartan) are excluded from the measure).
- **Hyperlipidemia/high cholesterol:** All statins.

Question. How is that performance measure communicated to the pharmacy?

Answer. Quality performance measures are contractually laid out, completely transparent and utilize a third party data service platform called EQuIPP (Electronic Quality Improvement Platform for Plans and Pharmacies). EQuIPP was cre-

ated by Pharmacy Quality Solutions (PQS). PQS is a subsidiary of the Pharmacy Quality Alliance (PQA), which has developed, tested, and endorsed numerous measures of medication-use quality. The platform provides a weekly updated list of outlier patients to pharmacies and a monthly performance score. Outlier patients are patients who are non-adherent to their medications or have demonstrated historical non-adherence. Pharmacies can use this information to help coordinate, inform, and monitor their quality improvement efforts, allowing them to deliver high-quality care locally while understanding how their performance compares to other pharmacies in Humana's quality performance network. Performance results are updated monthly with the percentage of Humana patients that are adherent and pharmacy percentile rankings.

Question. How much does your company receive in DIR fees?

Answer. Rebates received by Humana for Part D drugs are reported to CMS annually through Direct and Indirect Remuneration (DIR) and reflected in Part D bid submissions. Humana Part D plans reinvest the savings accrued from these rebates in benefit offerings. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers.

Question. How much does your company receive in performance-related DIR fees?

Answer. Performance-related DIR fees received by Humana for Part D drugs are reported to CMS annually through Direct and Indirect Remuneration (DIR) and reflected in Part D bid submissions. Humana Part D plans reinvest the savings accrued from these fees in benefit offerings.

Question. Are those fees passed on to the consumer? If so, how?

Answer. Humana Part D plans reinvest the savings accrued from these fees in benefit offerings.

DRUG SHORTAGES

Question. Currently there are over 270 drugs in shortage. Drug shortages happen for many reasons such as manufacturing and quality problems, natural disasters, and inventory practices of wholesalers and pharmacies. Drug shortages cause harm to providers, hospitals, and most importantly patients. Pharmacists and providers must spend significant amounts of time on researching alternative drug treatments for the patient, which may not always be the most optimal therapies.

As a pharmacy benefit manager, you have contractual agreements with pharmaceutical companies in order to place their drugs on a plan's formulary. While I understand that drug shortages happening in both the inpatient and outpatient settings, there may be a role PBMs can play in protecting patients.

For the prescription drugs you negotiate to cover on a plan formulary, could you use your negotiating power to ensure a drug is available to a patient? Why or why not?

Answer. Humana is focused on providing seniors with access to the best care possible. As part of that goal, Humana has developed innovative solutions for ensuring that our members are informed when making decisions about their prescription drugs to reduce costs and improve health outcomes. Drug manufacturing is outside of the scope of the service offering of Humana's pharmacy care services.

Question. What do you do to ensure that patients have the drugs they need?

Answer. Humana is focused on providing seniors with the best care possible. As part of that goal, Humana has developed innovative solutions for ensuring that our members are informed when making decisions about their prescription drugs to reduce costs and improve health outcomes. Humana was the first Part D plan to provide real-time access to drug cost and formulary information to physicians and their patients through our IntelligentRx tool. IntelligentRx enables physicians and their patients to make joint treatment decisions based upon efficacy and cost for 3.1 million prescriptions annually. The tool is currently available to all 10 million Humana members, including individuals with Medicare, Medicaid, and employer coverage.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

BIOSIMILARS

Question. During the hearing, each of you expressed support for biosimilars and most of you indicated you try and take advantage of available biosimilars to help lower costs. When I asked each of you to identify solutions to help ensure a robust biosimilar marketplace here in the U.S., most of you mentioned things Congress or the administration could do to help ensure uptake of biosimilars—from lowering the exclusivity period for biologics to finalizing guidance on interchangability at the FDA. However, none of you offered any solutions or ideas for what your company could do to help ensure timely uptake of biosimilars, a robust U.S. biosimilars market, and a resulting cost savings to patients to taxpayers.

Most of the biosimilars currently approved and on the market in the U.S. are reimbursed through the medical benefit. What are the similarities and differences in how rebates are passed onto patients and providers in the medical benefit versus pharmacy benefit. In your answer, please describe these similarities and differences across each of your books of business (*i.e.,* commercial, Medicare, Medicaid).

Answer. Currently Humana does not administer any point-of-sale rebate plan designs.

Question. Do any of your plans require the use of a higher list price, branded product over the use of a therapeutically equivalent lower list price generic or biosimilar product? Why? If a plan restricts the use of a biosimilar or generic product in lieu of an innovator or brand name product, do patients pay more out-of-pocket than they would if the biosimilar was preferred?

Answer. Our position is to negotiate the lowest net cost for any drug, and there are instances where it is beneficial to members to exclude generic competitors from formulary placement. Unfortunately, today there are few biosimilar products on the market and the prices of those products are similar to the originator brand products. Humana places such biosmiliars at parity with the originator brand products.

Question. Recognizing most biosimilars are paid for via medical benefit, please explain whether you use step-therapy to restrict access to biosimilars for your patients in any medical benefit you manage across each of your books of business (*i.e.,* commercial, Medicare, Medicaid). What role do rebates playing in your consideration for patient access to biosimilars in each of these instances?

Answer. As mentioned previously, our position is to negotiate the lowest net cost for any drug, and there are instances where it is beneficial to members to exclude generic competitors from formulary placement. Unfortunately, today there are few biosimilar products on the market and the prices of those products are similar to the originator brand products. Humana places such biosmiliars at parity with the originator brand products.

Question. How can and will your company help ensure a robust biosimilars market here in the U.S.?

Answer. Humana strongly supports the introduction of S. 340, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act. We believe the enactment of this bill will encourage the development of generic and biosimilar drugs that will infuse additional competition into the market prevent brand drug manufacturer REMS abuses that block generic competition, and penalize brand drug manufacturers for engaging in pay-for-delay agreements.

Question. I have heard concerns that "rebate walls" are responsible for keeping new biosimilars off of formularies, where a manufacturer offers conditional rebates on a bundle of their products in order to incentive PBMs to exclude a new biosimilar competitor from their formularies. Have you ever decided to place a drug on a preferred tier because of the rebates you receive for other drugs from that manufacturer? If you do not do this, do you support this practice being carried out by your competitors?

Answer. Our coverage decisions are based on treatment guidelines and the evidence base. We prioritize low-cost generic drugs, and if multiple brand name drugs are available to treat the same clinical condition, we negotiate with competing manufacturers to provide access to drug coverage that produces the most value to the member, which includes the lowest out-of-pocket cost over the course of the year and the health outcomes produced.

Question. What more can and will you do to counteract efforts to rebate-block or bundle rebates to block biosimilar formulary placement? Will you commit to taking these actions as more biosimilars become available in Part D?

Answer. While an increased number of generic competitors generally correlates strongly with lower formulary tier placement of a generic or biosimilar and the Food and Drug Administration (FDA) has proven that generic drug prices are reduced with each additional market entry of a generic competitor, there are numerous examples of generic medications and biosimilars that do not provide cost savings or equivalent therapeutic benefits that would warrant placement on a lower tier. As generic class sizes grow and competition increases, we encourage the continued flexibility to evaluate the cost-effectiveness of each medication in the class in order to determine tier placement. This includes the flexibility to mix brand and generic drugs within the non-preferred drug tier (the second highest tier). Since the cost of a brand name drug is not guaranteed to be lower than the generic alternative, any requirement to name tiers "brand" or "generic" would not help the member understand which tier has a more affordable drug. While moving certain high-cost generic and biosimilar drugs to lower tiers may produce savings for some members through reduced out-of-pocket cost-sharing, it would result in all members experiencing higher monthly premiums.

REBATES VS. FEES

Question. During the hearing, Senator Cassidy asked each of you about the trend in PBM contracting where a larger share of your reimbursement and payment is a result of "fees" which you are able to pocket, as opposed to "rebates" which must be passed back to the plan/consumer.

Please define the word "rebate." As part of your definition, please clarify whether or not you consider administrative fees, inflation payments, product discounts, prospective rebates, care management fees, procurement fees or any other type of fee or payment that isn't a retrospective rebate to be a rebate.

Answer. Payments made from a drug manufacturer to a plan or PBM after the point of sale that change the cost of covered drugs for plan sponsors.

Question. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), a list of each of the different types of rebates, charges, and/or fees that you incorporate into your contracts.

Answer. Rebates received by Humana for Part D drugs are reported to CMS annually through Direct and Indirect Remuneration (DIR) and reflected in Part D bid submissions. Humana's wholly owned pharmacy benefit manager does not receive fees from pharmaceutical manufacturers.

Question. Rebates, by definition, must be passed along to the employer, health plan, or consumer. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), details on which of the rebates/fees detailed in my prior question are passed along to the consumer and/or plan and which are kept by the PBM.

Answer. Rebates received by Humana for Part D drugs are passed through to the Part D plans.

FIDUCIARY DUTY

Question. Each of you have argued that you are the one entity in the drug supply chain that exists to help lower the cost of prescription drugs. You claim that your value comes in saving taxpayers, plans, and consumers money.

Would you be willing to accept a fiduciary standard in your contracts? In other words, do you believe you have a fiduciary duty to the plan or employer you contract with—to act in their best interest and not your own? If not, why not?

Answer. In today's highly competitive market for PBM services, these types of requirements are unnecessary. Many PBM customers, including Part D plan sponsors, receive 100 percent of rebates collected by the PBM under pass-through pricing models. In these cases, the interests of the PBM and its customer are already aligned. Other customers, such as commercial insurers and large employer groups, may receive services under spread pricing models, but they are sophisticated purchasers operating in a highly competitive PBM market. These customers often solicit competitive bids from PBMs before selecting a contracting partner and negotiate "market check" provisions into their contracts, allowing the customer to periodically renegotiate the contract if an independent third party determines that more favorable aggregate pricing terms are available elsewhere in the market. The enti-

ties that purchase PBM services have considerable leverage to obtain competitive pricing from PBMs and pass savings through to consumers. Government regulation in this area is not needed and would interfere with an already highly competitive market.

PAYING PHARMACISTS

Question. Following a series of reports in *The Columbus Dispatch,* Ohio has taken a number of actions over the past year to crack down on several PBM practices. Efforts to date have included investigations, lawsuits, and policy changes to address the egregious use of spread-pricing, alleged breaches of contract, accusations of anti-competitive behavior, a misuse of taxpayer dollars, and a general lack of transparency.

PBMs are responsible for creating pharmacy networks, setting the price patients and health plans pay for prescription drugs, adjudicating claims, and reimbursing pharmacies for dispensed drugs. In addition, nearly all PBMs own proprietary pharmacies that directly compete with the PBM-created retail network. Do you design plans that incentivize or require patients to use a pharmacy owned by your affiliate over a competing retail pharmacy. If yes, do you believe this represents a conflict of interest? If yes, how do you ensure there is no resulting anticompetitive misuse of pharmacy and patient data?

Answer. Under CMS's current requirements for Part D, the beneficiary incentives for use of mail service are limited, which has resulted in relatively low utilization of mail service as compared to other programs. If more flexibility on mail service benefit design were permitted, Medicare beneficiaries would be able to choose a plan that incentivizes use of mail service pharmacy. Savings from increased flexibility in plan design and the increased use of mail service pharmacies in plan networks could significantly reduce Part D costs to both the Medicare program and beneficiaries while simultaneously improving clinical quality through improved medication adherence.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Can you answer the following questions to help us understand the pharmacy benefit manager business model and how you make formulary decisions?

What percent of rebates are passed to the consumer under Medicare Part D?

Answer. Currently, plan sponsors utilize rebates as a tool to ensure that beneficiaries are obtaining the greatest possible value from their Medicare coverage. Rebates received by Humana for Part D drugs are passed through to the Part D plans. Part D plans reinvest the savings accrued from these rebates in benefit offerings and reduced premiums for Part D coverage, resulting in lower costs for seniors in PDP and MAPD plans. Additionally, rebates have resulted in significant savings to the government. As cited in the Medicare Trustees Report, rebates have played a critical role in keeping the overall cost of Part D lower than projected when the program was first launched in 2006.

Question. What percent of rebates are passed to the consumer in the private insurance market?

Answer. Humana does not administer any point-of-sale rebate plan designs.

Question. Do you have any comments on how health plans should use their share of the rebates to lower drug prices for patients with high deductibles?

Answer. Humana utilizes rebates as a tool to ensure that beneficiaries are obtaining the greatest possible value from their Medicare coverage. Rebates that are invoiced and collected from manufacturers are returned to beneficiaries in the form of reduced premiums for Part D coverage, resulting in lower costs for seniors in PDP and MAPD plans.

Question. What is the process of deciding on which tier a generic will be placed in your formularies?

Answer. Each new-to-market brand and generic medication is reviewed based on the available clinical data for the product which includes FDA labeling, compendia listing, peer-reviewed literature, real-world evidence, comparative effectiveness data, and nationally recognized treatment guidelines. Evaluation begins with safety, effi-

cacy, and the incremental health outcome value in the context of existing treatment options.

Question. Are generics always tiered as preferred (versus branded drugs)?

Answer. No. Our mission is to negotiate the lowest net cost for any drug, and there are instances where it is beneficial to members to exclude generic competitors from formulary placement. As generic class sizes grow and competition increases, we encourage the continued flexibility to evaluate the cost-effectiveness of each medication in the class in order to determine tier placement. This includes the flexibility to mix brand and generic drugs within the non-preferred drug tier (second highest tier on the Humana Part D formulary). Since the cost of a brand name drug is not guaranteed to be lower than the generic alternative, any requirement to name tiers "brand" or "generic" would not help the member understand which tier has a more affordable drug. While moving certain high-cost generic drugs to lower tiers may produce savings for some members through reduced out-of-pocket cost-sharing, it would result in all members experiencing higher monthly premiums.

Question. How quickly are generics placed on formularies once FDA clears them?

Answer. Each new-to-market brand and generic medication is reviewed based on the available clinical data for the product which includes FDA labeling, compendia listing, peer-reviewed literature, real-world evidence, comparative effectiveness data, and nationally recognized treatment guidelines. Evaluation begins with safety, efficacy, and the incremental health outcome value in the context of existing treatment options.

Question. Given the struggles we hear about patients accessing insulin, what measures are you taking to ensure that diabetes products and different types of insulin are placed on a preferred tier when establishing a formulary?

Answer. Approximately 26 million Americans living with diabetes are subject to the pharmaceutical industry's price increases, with significant hikes in the cost of the life-saving drug, insulin. More specifically:

- The price of insulin has tripled in the last decade.
- From 2013 to 2016, the average price increase for all insulin products was 28 percent compared to 12 percent for all brand name drugs over the same period.

Answer. Humana covers both a short- and long-acting insulin on its preferred brand drug tier (tier 3 of 5 on the Humana Part D formulary). This provides a significant contribution to stabilizing premiums and reducing financial burden to members.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

TRANSPARENCY, REBATES, AND SPREAD PRICING

Question. During the hearing, I asked an initial question on spread pricing and wanted to follow up here. According to the Centers for Medicare and Medicaid Services (CMS), total gross spending in 2017 on prescription drugs was $154.9 billion in Medicare Part D, $30.4 billion in Part B, and $67.6 billion in Medicaid.

One of the main challenges in lowering the price of prescription drugs is that there is a disturbing lack of transparency all along the supply chain, from research and development to what the patient is expected to pay at the counter. Further, the out-of- pocket costs for drugs varies greatly and unpredictably from patient to patient. That is why Senate Special Committee on Aging Chairwoman Collins and I introduced legislation that would codify the Drug Spending Dashboards at the CMS. The dashboards provide cost and spending information for drugs in the Medicaid, Medicare Part B, and Medicare Part D programs.[7] With regards to transparency in the prescription drug supply chain, please provide answers to the following questions:

Is it the policy and practice of your company to negotiate with drug manufacturers in good faith and obtain the best and lowest prices possible for patients and American taxpayers?

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[7] S. 709, 116th Congress, Prescription Drug Pricing Dashboard Act. Online at: *https://www.congress.gov/bill/116th-congress/senate-bill/709?q=%7B%22search%22%3A%22drug+dashboard%22%7D&s=1&r=1.* Accessed April 23, 2019.

Answer. Yes. As mentioned previously, our mission is to negotiate the lowest net cost for any drug.

Question. Is it the policy and practice of your company that patients, providers, researchers, policymakers, and the American people in general, know how taxpayer dollars are being spent in the Medicare and Medicaid programs?

Answer. Humana supports transparency in the spending of taxpayer dollars and supports legislation providing the Medicare Payment Advisory Commission (MedPAC) with the authority to collect information about rebate agreements as long as the disclosure of the information is protected.

Question. Is it the policy and practice of your company to disclose how much a drug costs?

Answer. As stated previously, Humana supports legislation that would require plan sponsors to provide MedPAC with the authority to collect information about rebate agreements similar to the data elements below as long as the disclosure of the information is protected.

Question. Please provide a list of actions your company has taken to ensure that pharmacists are enabled and allowed to communicate to patients how they can pay the lowest out-of- pocket cost possible for their prescription drugs.

Answer. Humana encourages pharmacies to provide our members with information on the lowest possible price at which they can obtain their prescription drugs. Humana does not currently, and has not in the past, employed gag clauses or any other such limitations. Consistent with Part D regulatory requirements, Humana members pay the lowest amount of applicable member cost sharing, the negotiated price, or the pharmacy "usual and customary" (U&C) cash price. Humana has developed several innovative solutions for ensuring that our members are informed when making decisions about their prescription drugs.

- *IntelligentRx:* Humana was the first Part D plan to provide physicians and their patients real-time access to drug cost and formulary information through our IntelligentRx tool. IntelligentRx enables physicians and their patients to make joint treatment decisions based upon efficacy and cost for 3.1 million prescriptions annually. The tool is currently available to all 10 million Humana members, including individuals with Medicare, Medicaid, and employer coverage.
- *Maximize Your Benefits (MYB) Program:* Humana continuously analyzes our members' prescription drug claims to identify opportunities for them to save money by switching to a lower-cost drug or by utilizing other savings programs, such as foundation-based cost-sharing assistance. Based upon that analysis, we proactively reach out to our members and provide instructions on how to maximize their savings opportunities. We estimate that the program saved our members almost $200 million in 2018.
- *Clinical Pharmacy Programs:* Humana ensures that seniors are taking the right combination of drugs necessary to improve their health through our clinical programs—medication therapy management (MTM) and medication reconciliation during transitions of care from facility to home. Through these programs, we help seniors by eliminating duplicative drugs, identifying lower-cost options, supporting medication adherence, and identifying possible adverse drug interactions. As a result of these initiatives, beneficiaries have increased medication adherence by as much as 13 percent and have experienced reduced emergency room visits, urgent care visits, and hospital admissions.

Attachment: Humana Comments to House Ways and Means and Energy and Commerce Bipartisan Draft on Part D Improvements

June 6, 2019

The Honorable Richard Neal
U.S. House of Representatives
2309 Rayburn House Office Building
Washington, DC 20515

The Honorable Frank Pallone, Jr.
U.S. House of Representatives
2107 Rayburn House Office Building
Washington, DC 20515

The Honorable Kevin Brady
U.S. House of Representatives
1011 Longworth House Office Building
Washington, DC 20515

The Honorable Greg Walden
U.S. House of Representatives
2185 Rayburn House Office Building
Washington, DC 20515

Dear Chairman Neal, Chairman Pallone, Ranking Member Brady, and Ranking Member Walden:

We are pleased to respond to your discussion draft of legislation to reform and improve the Medicare Part D program. We look forward to continuing to work with you on public policy solutions to lower drug costs for Medicare Part D beneficiaries.

Humana is an integrated health and wellness company focused on providing value to seniors by operating a holistic, health outcomes-driven model that is beneficiary-centric, focuses on chronic care and includes locally-integrated health capabilities. Humana currently provides Medicare prescription drug coverage to more than 8.4 million seniors across all 50 States, with approximately 4 million Medicare Advantage (MA) members and 4.4 million Medicare Prescription Drug Plan (PDP) members. We also provide medical coverage for approximately 1.5 million commercial customers, more than 340,000 Medicaid beneficiaries, and 5.9 million TRICARE enrollees in the eastern United States. Humana is unique in that our pharmacy and medical teams are tightly integrated and focused solely on serving our own members—not those of other payers. As a result, the savings achieved by our pharmacy programs, such as through manufacturer rebates and discounts, accrue directly to our members in the form of lower premiums and improved benefits.

Humana's integrated approach to serving seniors delivers a personalized and simplified experience through a value-based health ecosystem that improves clinical outcomes. This ecosystem includes 233 owned, jointly-owned, or allied primary care facilities; an ownership interest in the Nation's largest home health and hospice providers;[8] as well as initiatives to address social determinants of health.

We value this opportunity to provide our views on the Part D Program and the high cost of prescription drugs for a subset of the Medicare population. Your leadership in this area is appreciated, and we stand ready to work with you as a partner on our shared goal of using smart, effective policy changes to lower prescription drug costs.

Our comments on the discussion draft center around three themes:

- ***Part D is highly successful and complex:*** Since its inception, the prescription drug program has played a pivotal role in supporting America's seniors. Currently over 80 percent of seniors have out-of-pocket costs of less than $275 annually, and 85 percent of seniors state that they are satisfied with their prescription drug plan.[9, 10] However, the program and its funding structures are extremely complex. As changes are made, there is risk for unintended consequences that could undermine the success of the benefit, especially when it comes to the potential for increased premiums. As such, it is important to consider the complexities of the Part D program and the unique funding mechanisms that have been established for different populations in each phase of the benefit.
- ***Manufacturers should have accountability for beneficiary costs and government reinsurance:*** At a high level, it is imperative to recognize that drug manufacturers alone set list prices for prescription drugs. Any policies that are implemented to address beneficiary and government costs should address the actions of and incentives for drug manufacturers. This proposal does not attempt to moderate the price setting practices of manufacturers nor does it address the current policies that have created these challenges in the market. The committees should modify manufacturers' pricing incentives by increasing their liability in the catastrophic phase of the benefit and by establishing a maximum-out-of-pocket (MOOP) cap.
- ***Discussion draft will have a minimal impact on committee goals:*** The committees state that the draft legislation will "improve the Medicare Part D

[8] Forty percent stake in Kindred at Home and CURO Health Services.
[9] "10 Essential Facts About Medicare Prescription Drug Spending:" *https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/*.
[10] 2017 CMS Stars Report Card Master Table. Notes: "Rating of Drug Plan."

prescription drug program for beneficiaries and taxpayers alike."[11] An analysis of the proposed policy indicates that it will result in $84 billion in additional government spending while only generating savings for 2.2 percent of Part D beneficiaries through the drug spending cap.[12, 13] Furthermore, beneficiaries will essentially be paying for government reinsurance savings in the catastrophic phase of the benefit through a premium increase of $5.9 billion.[14] While the proposal shifts incentives and protects some seniors, we believe that there are alternative policies that should be explored that will allow for greater savings to the Part D program.

Less than 15 years ago, Americans did not have access to an outpatient prescription drug benefit under Medicare. As the committees have noted, today more than 46 million seniors have access to life-improving medicines through Part D. At the inception of the Medicare Part D program, Congress designed a competitive marketplace where PDP sponsors competed with one another, primarily based on premiums. Seniors enrolled in prescription drug coverage have gained significant value from the program's focus on market competition including:

- Stable premiums through the 13 years of the program, averaging approximately $30 per month negotiating rebates to lower costs for all seniors;[15]
- Generic dispensing rates near 90 percent;[16]
- An average of more than 26 Part D plan sponsor options;[17]
- A 50-percent reduction in medication non-adherence due to affordability;[18] and
- Beneficiary satisfaction rates near 90 percent.[19]

Despite the benefits realized by Part D beneficiaries, there are still seniors who struggle with the increasing cost of prescription drugs. This is especially true for the one million beneficiaries who are not eligible for the low-income subsidy (LIS) and reach the catastrophic phase of the benefit each year. These individuals generally spend an additional $3,041 annually in out-of-pocket costs for their prescription drug needs while in the catastrophic phase.[20]

As the committees contemplate changes to the Part D benefit, we respectfully request an examination of all policy tradeoffs to achieve the goal of reducing drug costs for beneficiaries and taxpayers. It is again imperative to recognize that drug manufacturers alone set list prices. Without robust policy changes that increase competition and provide plans with additional tools and negotiating leverage, as well as the development of new funding mechanisms to address the unsustainable costs of sole source specialty drugs, well-intended components of the discussion draft, aimed at reducing drug costs for beneficiaries and taxpayers, will fall short.

Specifically, while we support the committees' intention to protect beneficiaries from unaffordable out-of-pocket costs by establishing a MOOP in Part D, it is vital that

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[11] Committee Leaders Announce Call for Comments on Bipartisan Medicare Part D Pricing Legislation. House Committee on Energy and Commerce. May 23, 2019. Available here: *https://energycommerce.house.gov/newsroom/press-releases/committee-leaders-announce-call-for-comments-on-bipartisan-medicare-part-d*.

[12] Oliver Wyman. "Part D Catastrophic Coverage—Financial Implications of Restructuring Liability." May 2019. Available here: *https://www.ahip.org/wp-content/uploads/Restructuring-the-CMS-Federal-Reinsurance-Program.pdf*.

[13] MedPAC. "March 2019 Report to the Congress: The Medicare Prescription Drug Program Status Report." March 2019. Available here: *http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0*.

[14] Oliver Wyman. "Part D Catastrophic Coverage—Financial Implications of Restructuring Liability." May 2019. Available here: *https://www.ahip.org/wp-content/uploads/Restructuring-the-CMS-Federal-Reinsurance-Program.pdf*.

[15] "10 Essential Facts About Medicare Prescription Drug Spending:" *https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/*.

[16] *Ibid.*

[17] *Ibid.*

[18] Diebold, Jeffrey. "The Effects of Medicare Part D on Health Outcomes of Newly Covered Medicare Beneficiaries." *The Journals of Gerontology:* Series B, Volume 73, Issue 5, July 2018, pages 890–900: *https://academic.oup.com/psychsocgerontology/article/73/5/890/2631953*.

[19] 2017 CMS Stars Report Card Master Table. Notes: "Rating of Drug Plan."

[20] Kaiser Family Foundation. "No Limit Medicare Part D Enrollees Exposed to High Out-of-Pocket Drug Costs Without a Hard Cap on Spending:" *https://www.kff.org/report-section/no-limit-medicare-part-d-enrollees-exposed-to-high-out-of-pocket-drug-costs-without-a-hard-cap-on-spending-issue-brief/;* Kaiser Family Foundation. "10 Essential Facts About Medicare and Prescription Drug Spending." January 29, 2019: *https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/;* Kaiser Family Foundation. "Medicare Part D in 2016 and Trends Over Time." September 16, 2016: *https://www.kff.org/report-section/medicare-part-d-in-2016-and-trends-over-time-section-4-the-low-income-subsidy-program/*. Part D enrollment figures reflect 2016 enrollment.

this addition is thoughtfully designed. We strongly urge the committees to use earlier well-intended consumer-centric policy changes, such as the protected classes and The Orphan Drug Act, as a frame of reference for potential unintended consequences that could impact the market Both of these policies have limited competition, produced exorbitantly high drug list prices, and resulted in a refusal by manufacturers to entertain negotiated price concessions. Likewise, if manufacturers are not held responsible for the costs associated with establishing a Part D MOOP and restructuring reinsurance, manufacturer pricing strategies related to specialty drugs will continue their upward trajectory.

Humana's Efforts to Support Beneficiaries With Prescription Drug Costs

Humana is focused on providing seniors with the best care possible. As part of that goal, Humana has developed innovative solutions for ensuring that our members are informed when making decisions about their prescription drugs to reduce costs and improve health outcomes including:

- ***IntelligentRx:*** Humana was the first Part D plan to provide real-time access to drug cost and formulary information to physicians and their patients through our IntelligentRx tool. IntelligentRx enables physicians and their patients to make joint treatment decisions based upon efficacy and cost for 3.1 million prescriptions annually. The tool is currently available to all 10 million Humana members, including individuals with Medicare, Medicaid, and employer coverage.
- ***Maximize Your Benefits (MYB) Program:*** Humana continuously analyzes our members' prescription drug claims to identify opportunities for them to save money by switching to a lower-cost drug or by pointing them to other savings programs such as foundation-based cost-sharing assistance. Based upon that analysis, we proactively reach out to our members and provide instructions on how to maximize their savings opportunities. We estimate that the program saved our members almost $200 million in 2018.
- ***Clinical Pharmacy Programs:*** Humana also ensures that seniors are taking the right combination of drugs necessary to improve their health through our clinical programs—medication therapy management (MTM) and medication reconciliation during transitions of care from facility to home. Through these programs, we help seniors by eliminating duplicative drugs, identifying lower-cost options, supporting medication adherence, and identifying possible adverse drug interactions. As a result of these initiatives, beneficiaries have increased medication adherence by as much as 13 percent and have experienced reduced emergency room visits, urgent care visits, and hospital admissions.

In the sections below we provide our assessment of current policy challenges facing Part D, our viewpoints on the specific policy questions and issues on which the committees are seeking feedback, and our recommendations on additional legislative actions the committees should contemplate as part of any proposal to modernize Part D. We look forward to hearing your feedback and to answering any questions you might have.

Sincerely,

Douglas Stoss
Vice President, Federal Affairs
Humana, Inc.

I. The Policy Challenges in Part D and the Prescription Drug Market

Policy Challenge #1: *Impact of High Cost Specialty Drugs in Part D*

The Kaiser Family Foundation analyzed the expected annual cost to beneficiaries related to select specialty drugs for cancer, hepatitis C, multiple sclerosis, and rheumatoid arthritis. Results of the analysis show that out-of-pocket costs to beneficiaries taking these medications could be as high as $16,551 a year.[21]

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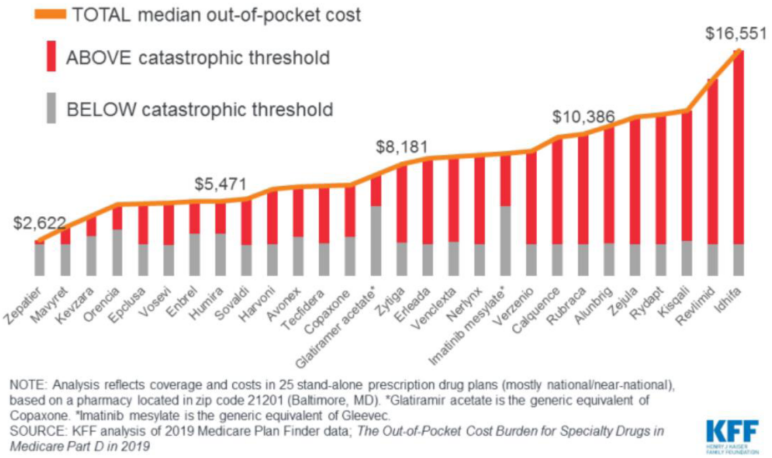
[21] Kaiser Family Foundation. "10 Essential Facts About Medicare and Prescription Drug Spending." January 29, 2019. Available here: *https://www.kff.org/infographic/10-essential-facts-about-medicare-and-prescription-drug-spending/*.

Expected Annual Costs in Part D in 2019 for Select Specialty Drugs[22]



NOTE: Analysis reflects coverage and costs in 25 stand-alone prescription drug plans (mostly national/near-national), based on a pharmacy located in zip code 21201 (Baltimore, MD). *Glatiramir acetate is the generic equivalent of Copaxone. *Imatinib mesylate is the generic equivalent of Gleevec.
SOURCE: KFF analysis of 2019 Medicare Plan Finder data; *The Out-of-Pocket Cost Burden for Specialty Drugs in Medicare Part D in 2019*

KFF

Humana's experience reflects the overall Part D program challenges highlighted in the Kaiser Family Foundation analysis. In 2016, **46 percent of drugs on Humana's specialty tier triggered catastrophic coverage on the first fill.** In 2018, **two percent of Humana beneficiaries who utilized specialty drugs comprised 36 percent of total Part D spending.** In 2 years, Humana projects that seniors utilizing specialty drugs could account for as much as 50 percent of total Part D spending. Additionally, research has demonstrated that the price of oral specialty drugs has increased by 20.6 percent between 2008 and 2016 with 71.1 percent of that increase attributable to drugs that are new to the market.[23] This trend of increasingly high launch prices has further exacerbated the challenges associated with specialty drugs in the Part D program.

Additionally, seniors who reach the catastrophic phase are commonly taking high cost specialty drugs with little to no competition. The most recent Medicare Payment Advisory Commission (MedPAC) Report to the Congress from March 2019 echoed the challenges for the population of seniors with high drug costs:[24]

> ***Ten times the number of seniors reached the catastrophic phase on first fill in 2016:*** The number of seniors who reached the catastrophic phase through a single claim increased from 33,000 in 2010 to 360,000 in 2016. Non-LIS beneficiaries were more likely to have this experience than LIS beneficiaries.
>
> ***Spending on specialty drugs accounted for four times as much of total spend in 2017 compared to 2007:*** Specialty-tier drugs accounted for 25 percent of Part D overall gross spending in 2017, an increase from 6 percent in 2007.

Some observers have suggested that Part D plan sponsors need to have more "skin in the game" through changes such as point-of-sale rebates. Even if point-of-sale rebates were instituted in Part D, there would still be a high degree of reinsurance spend because of the ever-increasing launch prices of specialty drugs.

Policy Challenge #2: *Anti-competitive Behavior by Drug Manufacturers*

As numerous congressional hearings have highlighted, a major factor contributing to the increase in drug spending is the list price of prescription drugs. **Drug manu-**

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[22] *Ibid.*

[23] Hernandez I. et. al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Prescription Drugs." *Health Affairs.* 2019 38:1 available from: *https://www.healthaffairs.org/doi/abs/10.1377/hlthaff.2018.05147.*

[24] "March 2019 Report to the Congress: Medicare Payment Policy:" *http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0.*

facturers alone set the list price of prescription drugs. Drug manufacturers have also historically engaged in a host of tactics meant to delay generic competition, including preventing generic manufacturers from obtaining drug samples, utilizing the Risk Evaluation and Mitigation Strategy (REMS) process to block timely entry of generics, utilizing loopholes in the patent system to delay and thwart the market entry of lower cost competitors, and paying generic manufacturers to delay market entry. According to the Federal Trade Commission (FTC), these anti-competitive "pay-for-delay" actions alone increase costs for seniors and American taxpayers by $3.5 billion annually.[25]

There are numerous additional examples where a brand drug manufacturer has delayed competition to preserve its monopoly, resulting in astronomically high drug prices:

- Humira, the highest-selling drug in the world, has received six different orphan drug designations since 2005. Its price increased by 200 percent from 2012 to 2018, to $38,000 per patient.[26]
- The REMS for Thalomid, an earlier iteration of Celgene's top-selling cancer drug Revlimid, has been patented over 14 times in order to delay the development of generics. The price for Revlimid rose from $6,195 in 2006 to $16,691 in 2017.[27] The Medicare program spent an average of $88,437 per beneficiary for a year of Revlimid treatment in 2017.[28]

These actions by brand drug manufacturers weaken the ability of plan sponsors to negotiate lower costs for prescription drugs. Plan sponsors have been most successful negotiating lower drug costs on behalf of beneficiaries when there is sufficient competition in the market. In the past 2 years:

- ***Federal spending on retail prescription drugs has remained flat:*** For the second consecutive year, retail prescription drug growth has decreased; the 0.4-percent growth has been driven by a continued shift to lower-cost generic drugs and declines in generic drug prices.[29]
- ***Cost of drugs with limited competition has increased at double the rate of all drugs:*** Conversely, there have been significant price increases for drugs subject to limited or no competition. In 2016, the cost of single-source drugs with no generic alternatives increased at more than double the rate of average annual drug spending.[30]

The trend of increasing list prices for prescription drugs with limited competition is seen for prescription drugs administered in both clinical settings, where drugs are typically covered by Medicare Part B and generally considered specialty drugs, and those dispensed at the pharmacy counter, where drugs are typically covered by Medicare Part D.

- ***90 percent of the Medicare B drugs with the highest expenditures have no generic:*** A 2017 study performed by the Government Accountability Office (GAO) found that Medicare Part B drugs with the highest expenditures are predominantly single-sourced (84 percent) without a generic option (90 percent).[31] This has resulted in a market where eight of the top ten high cost Part B drugs have an annual cost of $10,000 to $30,000.[32]
- ***List prices increase beyond inflation for Part D drugs produced by fewer than five manufacturers:*** An analysis of 2017 Part D prescription drug

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[25] *See https://www.ftc.gov/sites/default/files/documents/reports/pay-delay-how-drug-company-pay-offs-cost-consumers-billions-federal-trade-commission-staff-study/100112payfordelayrpt.pdf*.

[26] FDA, *https://www.accessdata.fda.gov/scripts/opdlisting/oopd/listResult.cfm*.

[27] Alison Kodjak, "How a Drugmaker Gamed the System to Keep Generic Competition Away," NPR, May 17, 2018.

[28] CMS 2017 Part D Drug Spending Dashboard, available here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html*.

[29] CMS Office of the Actuary Releases 2017 National Health Expenditures, available online at: *https://www.cms.gov/newsroom/press-releases/cms-office-actuary-releases-2017-national-health-expenditures*.

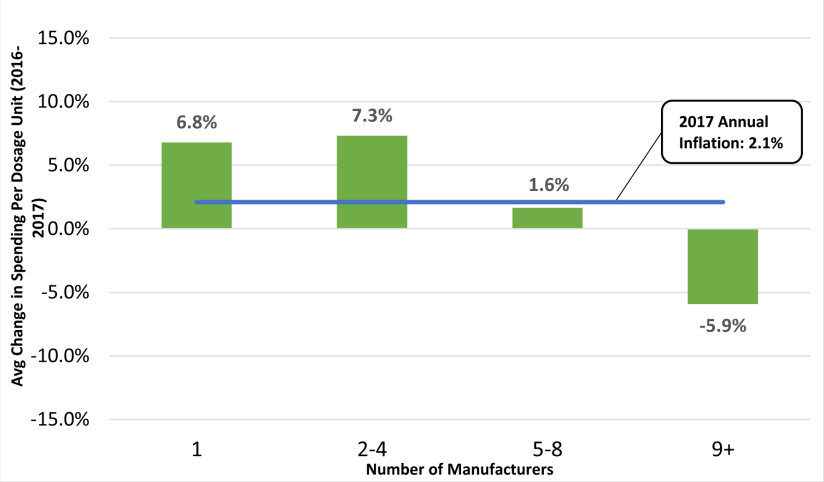
[30] Blue Health Intelligence. "Rising costs for patented drugs drive growth of pharmaceutical spending in the U.S." May 2017. Available here: *https://www.bcbs.com/the-health-of-america/reports/rising-costs-patented-drugs-drive-growth-pharmaceutical-spending-us*.

[31] GAO, "Medicare Represented at Least Half of the Market for 22 of the 84 Most Expensive Drugs in 2015," GAO–18–83: Published: Dec. 18, 2017, available online at: *https://www.gao.gov/assets/690/689082.pdf*.

[32] MedPAC, "Medicare and the Healthcare Delivery System," available online at: *http://www.medpac.gov/docs/default-source/reports/jun17_reporttocongress_sec.pdf?sfvrsn=0*.

spending found that prescription drugs with less competition were more likely to have list price increases than drugs with five or more manufacturers.[33]

Year Over Year Growth in Prescription Drug Costs Decreases With Competition in Part D



Policy Challenge #3: *Unintended Consequences of Well-Intended Drug Policy Decisions That Have Affected Part D*

Price competition for drugs in the Part D market has been inhibited by the unintended consequences of well-intended policy decisions. Policies crafted to maintain access have caused near-market failure for the population of drugs with little to no competition—ultimately providing manufacturers with a licensed monopoly to impose astronomically high prices on the American taxpayer. In these cases manufacturers have no incentive to lower prices, and plan sponsors, who have a mandate to cover the drugs, no longer have the tools to manage the cost of drugs. This is especially true when compared to the commercial market, where there is far more flexibility in formulary development. Some of the policies that contributed to this market reality include:[34]

- **FDA Accelerated Drug Approval:** Due to the increasing costs of specialty drugs, clinically meaningful outcomes that result in actual savings to the health care system are essential for all new products being reviewed by the FDA. Manufacturers have historically focused drug development on safety and clinical efficacy compared to a placebo for regulatory approval. FDA accelerated approval is often based on surrogate markers as opposed to outcomes data which are directly tied to improvements in patient health. This is a very real issue in the

[33] Based on Humana analysis of the CMS 2017 Part D Drug Spending Dashboard and Data, available online at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.html*. The CMS dashboard includes all Part D organizations and plan types. Part D PDE records were summarized by drug by linking National Drug Codes (NDCs) available in the PDE data to a commercially available database and aggregated across all strengths, dosage forms, and routes of administration to the drug brand name and generic name. CMS did not provide NDCs in the public use file. Over-the-counter drugs in the PDE data are excluded as well as NDCs with fewer than 50 claims in the current (2017) or previous year (2016). In addition, NDCs with large variations in reported units from year to year were reviewed by CMS on a case-by-case basis and data anomalies were excluded. Drug spending metrics for Part D drugs are based on the gross drug cost, which includes ingredient cost, dispensing fees, sales tax, and applicable vaccine administration fees. Part D drug spending represents total spending for the prescription claim, including amounts paid by the Medicare Part D plan and beneficiary payments. The Part D spending metrics do not reflect any manufacturers' rebates. For purposes of this analysis, we removed Part D covered supplies, such as syringes and alcohol swipes for diabetics, and weighted average change in spending per dosage unit by 2017 claim volume. Average 2017 inflation rate is sourced from the Bureau of Labor Statistics website.

[34] *Ibid.*

treatment of oncologic diseases where products are approved with limited phase 2 clinical trial data which are not designed to assess outcomes for a broad patient population or long-term. In a review of the 93 cancer drug indications granted accelerated approval since 1992, only 19 drugs (20 percent) had improvement in overall survival while 19 drugs (20 percent) simply met the original surrogate end point used in the accelerated approval.[35] To support better health outcomes, the FDA approval process should be transformed from accelerated approval based on surrogate endpoints to a system based on outcomes and value that improves health. Such a shift in FDA approval of high cost specialty drugs would facilitate payment and reimbursement subject to a Coverage with Evidence Development (CED). CED would allow Medicare Advantage and Part D plans to provide coverage and reimbursement based on shared risk drug manufacturers with the condition that additional data is systemically produced by manufacturers through prospective registries or additional controlled trials to assess actual health outcomes that may be produced. Once sufficient data is reported, permanent coverage and reimbursement based on longer term health outcomes would be established.

- **Orphan Drugs:** In order to incentivize manufacturers to invest in treatments for orphan drugs, longer exclusivity periods are provided as a result of the Orphan Drug Act of 1983. However, this policy has been abused by manufacturers who will obtain multiple orphan drug designations for the same drug in order to delay competition.
- **Requirement of Two Drugs per Class:** The Centers for Medicare and Medicaid Services (CMS) currently requires Part D plan sponsor formularies to cover at least two drugs in every Part D covered therapeutic category and class as long as there are at least two drugs available. When two drugs are mandated to be covered in a class, manufacturers of a drug with only one other competitor typically refuse to negotiate rebates or discounts in Medicare Part D because they know their products must be covered. The existing policy increases costs to the plan sponsor, which are passed through not only to individuals in the form of higher premiums, but also to the Federal Government in terms of increased direct subsidy payments.
- **Protected Classes:** CMS requires that there must be multiple treatment options in the protected classes. When negotiating with manufacturers for drugs in the protected classes, there are few tools that health plans can employ to lower prices. The drugs in the protected classes include treatments for conditions such as cancer and HIV, which are typically treated by high cost specialty drugs like Revlimid.
- **Pharmacy Network Access Standards:** CMS's current network adequacy standards focus on ensuring that beneficiaries have broad access to a wide range of pharmacies within two to fifteen miles of a beneficiary's residence. However, given the consolidation in the retail pharmacy market, the shift to consumers preferring online shopping and delivery, and the shift to the use of mail order pharmacies for convenience, these standards are now over inflating the size of the network due to the need to contract with most major retailers and community pharmacies to meet CMS's defined network access standards. The artificial inflation in pharmacy network size also comes with inflated costs that impact the cost of the program for both beneficiaries and taxpayers.

II. The Committees' Draft Legislative Changes to Improve Part D

Proposal #1: *Establishing a Part D Maximum Out-of-Pocket (MOOP)*

The discussion draft contemplates a new maximum out-of-pocket (MOOP) on prescription drugs costs for Medicare beneficiaries in Part D based on the current catastrophic threshold. This policy is aimed at addressing the high costs created for the 8 percent of seniors who reach the catastrophic phase each year, mainly due to the use of high cost specialty drugs. Of those seniors who reach the catastrophic level, only 2.2 percent are non-LIS beneficiaries who do not currently have a MOOP in the Part D benefit.[36]

The implementation of a MOOP is most likely to help non-LIS seniors who take patent-protected drugs that treat hepatitis C, diabetes, cancer, and various auto-

[35] *JAMA Intern Med.* Published online May 28, 2019. doi:10.1001/jamainternmed.2019.0462.
[36] MedPAC. "March 2019 Report to the Congress: The Medicare Prescription Drug Program Status Report." March 2019. Available here: *http://medpac.gov/docs/default-source/reports/mar19_medpac_ch14_sec.pdf?sfvrsn=0*.

immune disorders. Oliver Wyman modeled the cost implications of the implementation of a MOOP with $0 cost sharing for beneficiaries once they hit the catastrophic phase. The analysis estimates that adding a MOOP to the Part D benefit would result in a $59.3-billion decrease in OOP cost sharing over 10 years for the 2.2 percent of non-LIS beneficiaries who reach the catastrophic phase of the benefit.[37] Offsetting these savings, all beneficiaries would see a premium increase of $20 billion over 10 years resulting in a net $39.3 billion in savings for beneficiaries. Meanwhile, government spending would increase significantly with an additional $84.7 billion in spending over a 10-year period. The MOOP, while beneficial to 2.2 percent of all Part D beneficiaries, will result in government spending over $2 for every $1 in beneficiary savings.

Table 1. Estimated Costs Associated With Part D MOOP [38]

Liability	Change (in Billions)
Premium	$20.0
Cost Sharing	$(59.3)
Total Beneficiary Costs	**$(39.3)**
Direct Subsidy	$63.8
Reinsurance	$34.3
Low-Income Premium Subsidy	$(22.7)
Low-Income Cost Sharing Subsidy	$9.3
Total Government Cost	**$84.7**

Furthermore, according to CMS and HHS OIG guidance drug "manufacturers may sponsor patient assistance programs (PAPs) that provide financial assistance or drug free product (through in-kind product donations) . . . to augment any existing prescription drug coverage." In other words, with some restrictions, PAPs can assist Part D enrollees.[39] While these dollars do not contribute to the technical CMS Part D true-out-of-pocket cost (TrOOP) calculation for plan payment purposes and determining the member's Part D phase progression (*i.e.,* deductible phase vs initial coverage limit, etc.) ***they do shield the beneficiary from literally paying out of their own pocket.***

Available data indicates that manufacturers spend considerable amounts on PAPs. According to the Congressional Research Service, the Abbvie Patient Assistance Foundation received $1 billion in 2015; the Johnson & Johnson Patient Assistance Foundation received $662 million; and the Bristol Myers Squibb Patient Assistance Foundation received $620 million.[40] One independent analysis of tax records indicates that manufacturers spend approximately $7 billion per annum on PAPs.[41] ***Manufacturers must be substantively responsible for financing a Part D MOOP or they will realize a windfall profit by transferring their PAP spending liabilities onto the Medicare Trust Fund, plans, and America's seniors.***

As the committees consider how to fund the MOOP for beneficiaries who exceed the catastrophic threshold, ***it is critical that any proposal is paired with prescrip-***

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[37] Oliver Wyman. "Part D Catastrophic Coverage—Financial Implications of Restructuring Liability." May 2019. Available here: *https://www.ahip.org/wp-content/uploads/Restructuring-the-CMS-Federal-Reinsurance-Program.pdf.*

[38] *Ibid.*

[39] CMS, "Pharmaceutical Manufacturer Patient Assistance Program Information," available online at: *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenIn/PAPData.html;* and HHS OIG Advisory Opinion No. 06–03, available online at: *https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-03F.pdf.*

[40] Congressional Research Service, "Prescription Drug Discount Coupons and Patient Assistance Programs (PAPs) R44264," available online at: *https://crsreports.congress.gov/product/pdf/R/R44264.*

[41] Frerick, Austin. "The Cloak of Social Responsibility: Pharmaceutical Corporate Charity." *Tax Notes* 153.9 (2016): 1151.

tion drug pricing reforms that meaningfully reduce prescription drug costs by improving competition in the pharmaceutical market. Without these types of reforms, it is likely the current trend in inflationary pricing will be exacerbated as there will continue to be fewer incentives for manufacturers to lower prices when beneficiary OOP costs are capped for high costs drugs that progress beneficiaries to the catastrophic phase of the benefit. Stated another way, the costs of implementing a Part D MOOP should be borne by the pharmaceutical industry.

As the committees have stated and we mention previously, the goal of the draft improvements to Part D is to decrease costs for beneficiaries and the Medicare Trust Fund. ***The MOOP proposal adds additional pressure to the Medicare Trust Fund through $84.7 billion in increased expenditures to reduce out-of-pocket costs for 2.2 percent of beneficiaries.***[42] The proposal does not address the true policy challenges in Part D—the role of specialty drugs, anti-competitive practices by manufacturers, and the impacts of past policy decisions. Once again, drug manufacturers alone set the list price of prescription drugs; nothing in the discussion draft compels drug manufacturers to lower the list price of drugs.

Recommended legislative actions to lower list prices and address anti-competitive behavior

The examples of anti-competitive pricing and the importance of competition require innovative policy approaches to enhance competition in the market, especially for specialty drugs. Humana strongly supports the introduction of HR. 965, the Creating and Restoring Equal Access to Equivalent Samples (CREATES) Act, as well as HR. 2375, the Preserve Access to Affordable Generics and Biosimilars Act. We believe the enactment of these bills will encourage the development of generic and biosimilar drugs that will infuse additional competition into the market, prevent brand drug manufacturer REMS abuses that block generic competition, and penalize brand drug manufacturers for engaging in pay-for-delay agreements.

Furthermore, Humana strongly urges the committees to encourage CMS and other Federal agencies to remove barriers to prescription drug competition and regulations that are abused in anticompetitive ways and are harmful to affordable drug access for beneficiaries. We specifically have recommended that the administration take the following actions to address abuses of regulations and anticompetitive behaviors:

- **Leverage CMS data to illustrate the cost impacts of anticompetitive behaviors such as patent "evergreening"**—CMS is best-positioned to leverage its claims from Parts A, B, and D to empirically illustrate the Medicare Trust Fund and beneficiary impacts associated with these and other anticompetitive behaviors.
- **Issue information regarding manufacturers' drug pipelines and anticipated drug prices prior to market launch**—It is critical for Part D and MA plan sponsors and the CMS Office of the Actuary (OACT) to be aware of anticipated new drugs, new drug indications, and their potential launch prices. These data are necessary to make critical decisions about MA and Part D bidding parameters, to make special updates to the MA and Part D risk adjustment models, and for OACT to perform its long-term program cost estimation duties for the Medicare Trustees. With the right information, this decision-making will have a significant impact on our ability to provide lower drug costs and premiums for beneficiaries. While we understand there are proprietary data provisions and general uncertainty around approvals of new therapies, we believe that, between clinicaltrials.gov and PubMed, there is a notable opportunity to produce a transparent summary dashboard of the drug pipeline in one place. We ask that HHS ensure that the FDA works toward this goal and provides CMS and plan sponsors with this necessary information.

Proposal #2: *Changes to Part D Plan Reinsurance Liability*

The discussion draft contemplates a structure for Part D plans to better manage costs by reducing the government's share of catastrophic coverage from 80 percent to 20 percent over four years which has also been recommended by **MedPAC and the President's FY 2019 and 2020 budgets.** These proposals have typically been accompanied by a recommendation to provide Part D plan sponsors with additional negotiating tools to lower costs. We note that the discussion draft does not include such proposals.

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[42] *Ibid.*

We also note a growing misunderstanding that, somehow, Part D plan sponsors are not negotiating with manufacturers to the fullest extent possible because the plans only have 15-percent liability in the catastrophic phase. We want to point out that even 15-percent plan liability in the catastrophic phase is significant. Under the current Part D structure, Humana does not negotiate any less vigorously for the lowest net drug cost because certain drugs may propel a beneficiary into the catastrophic phase of the benefit. Price concessions are negotiated with manufacturers 6 to 12 months in advance of a given plan year and enrollment and drug utilization is uncertain at the time of these negotiations. Nonetheless, plans are competitively motivated to have the lowest premium and we strive for the greatest price concessions that can be achieved to reach that goal regardless of the phase of the benefit in which drug utilization occurs.

Given our earlier comments and the significant role that manufacturers play in creating this issue in the first place, ***manufacturers must bear a significant percentage of the cost if Congress pursues policy changes in Part D reinsurance.*** In particular, if a MOOP is also implemented in the Part D benefit, such a policy is likely to be inflationary for pharmaceutical prices as there is essentially no incentive to lower prices without significant manufacturer liability.

Humana believes this reinsurance policy change would fail to address high cost specialty drugs, the primary Part B and D trend drivers, and would create a significant destabilization of the program, increase beneficiary premiums, and exacerbate incentives to avoid enrollment of high-cost beneficiaries without new tools and levers to manage utilization. Without any meaningful changes to the current Part D program rules to increase plan flexibility, Oliver Wyman estimates this proposal in isolation would increase Part D program costs for the government by $6.90 billion over 10 years.[43] According to the analysis, the increase in spending will primarily be driven by plan sponsors factoring in additional risk margin due to the larger share of liability in the catastrophic phase of the benefit and smaller health plans purchasing private reinsurance to protect from a larger share of new risk. In this scenario, the analysis projects that beneficiary costs would also increase by approximately $5.9 billion over the same period—essentially further cannibalizing any savings incurred by the Part D program.[44] ***In this scenario, beneficiaries are essentially paying for government savings in the catastrophic phase of the benefit through a premium increase of $5.9 billion.***

Table 2. Estimated Costs Associated With Part D Reinsurance Reallocation [45]

Liability	Change (in Billions)
Premium	$5.90
Cost Sharing	$0.00
Total Beneficiary Costs	**$5.90**
Direct Subsidy	$733.70
Reinsurance	$(724.20)
Low-Income Premium Subsidy	$(2.60)
Low-Income Cost Sharing Subsidy	$0.00
Total Government Cost	**$6.90**

While the 4-year phase-in of increased plan liability in the catastrophic phase of the benefit should soften beneficiary premium increases and program disruption, increasing plan reinsurance liability without adding additional tools to manage the benefit will not reduce program costs. The proposed mechanism to offset these increased Part D program costs is increased plan incentive to manage high cost drugs

[43] Oliver Wyman. "Part D Catastrophic Coverage—Financial Implications of Restructuring Liability." May 2019. Available here: *https://www.ahip.org/wp-content/uploads/Restructuring-the-CMS-Federal-Reinsurance-Program.pdf*.
[44] *Ibid.*
[45] *Ibid.*

to remain competitive. ***It is important to note that while the funding mechanism varies through the benefit phases, the benefit itself and the coverage requirements do not.*** For example, the formulary and utilization management policies are not altered when a beneficiary enters the catastrophic phase. ***By changing the reinsurance liability, plan sponsors will not gain any additional flexibility to better manage the use of high cost drugs.*** Many high cost drugs are sole source and required to be covered due to CMS protected class status, must be covered due to Part D formulary outlier rules, and have limited utilization management opportunities. In addition, the LIS population comprises a significant proportion of high cost drug utilization where cost sharing is statutorily limited and cannot be meaningfully used to manage utilization.

As the committees have stated previously, the goal of the proposed improvements to Part D is to decrease costs for beneficiaries and the Medicare Trust Fund. ***The proposed changes to plan reinsurance liability achieve neither of these goals in a substantive way as proposed—they only fuse more risk into the market and shift current government liabilities to seniors.***

Policy Recommendations for Additional Plan Flexibility

Any changes to the allocation of reinsurance should be accompanied by additional tools to support the management of high cost drugs, lessen barriers to outcomes based contracting, and allow for additional formulary flexibility. We recommend the following policy actions:

Providing Seniors With More Options

- **Allow Plan Sponsors to Offer More Than Three PDPs:** Proprietary market research performed on behalf of Humana indicates that beneficiaries are interested in greater variation in the products offered in Part D. The research found that beneficiaries believe the optimal number of choices in Part D would include five different PDPs spanning across health status complexity and customer service variation. An increasing number of seniors have indicated that they are interested in a more convenient and service oriented PDP. Conversely, there was still a significant portion of beneficiaries who were driven by lowest possible cost. These findings were reinforced by market actions in 2019 when 28 percent of PDP enrollees in regions with new products were enrolled in a new PDP offered as a result of elimination of the meaningful difference requirement for enhanced alternative (EA) PDPs.[46]
- **High Cost Specialty Drugs:** As discussed previously, two percent of our beneficiaries who utilized specialty drugs comprised 36 percent of total Part D spending in 2018. In two years, Humana projects that seniors utilizing specialty drugs could account for as much as 50 percent of total Part D spending. We welcome the opportunity to explore potential solutions for alternative pooling or funding mechanisms for this growing category of products.

Lessening Barriers to Outcome-Based Contracting

- **Outcome (or Value-Based) Contracts:** Outcome-based contracting should be leveraged and reserved for disease states with limited or no competion and serve as a feedback loop to answer the uncertainies that exist around first-in-class agents, accelerated approval drugs, and orphan drugs approved in small populations in order to inform future formulary and coverage decisions. Three disease states account for 70 percent of the pharmaceutical industry's drug pipeline—oncology, infectious diseases, and central nervous system (CNS) disorders.[47] And the proportion of new therapies approved as orphan drugs has ballooned. In 2015, 21 orphan drugs were approved, accounting for 47 percent of all new medicines, up from just 29 percent in 2010; in 2016, nine more orphans won approval, 40 percent of the total.[48] These drugs are typically fast tracked, offered breakthrough status, and approved on phase 2 trials without the rigorous standards other drug classes are held to. These are the areas of focus where outcome-based contracting would be most helpful. Lastly, as more and more drugs with $500k–$1M price tags reach the market, there is a need

[46] Humana analysis of CMS State County Contract Enrollment File from January 2019, available here: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDEnrolData/Monthly-PDP-Enrollment-by-State-County-Contract.html*.

[47] *See https://www.clinicalleader.com/doc/top-three-therapy-overall-pharmaceutical-industry-pipeline-gbi-research-0001*.

[48] *See https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/*.

to ensure that the prices of such drugs are commensurate with their benefits. While the reward may be curing a genetic disease or cancer, and failures may be limited (*i.e.,* less than 5 percent), it is critical that payers gather data and identify which specific populations fail to benefit from a given therapy and that manufacturers cover costs where therapies fail to deliver the intended health outcomes.

- **Manufacturers Should Take on Meaningful Risk in Outcome-Based Contracting:** Our experience is that the vast majority of manufacturers are only willing to enter into outcome-based contract arrangements that align with a product's clinical trial data and FDA approval. As such, the findings from such agreements add little or nothing to the existing evidence base and virtually assure a positive outcome for the manufacturer. In most cases, manufacturers seek outcome-based contracts for products in drug classes where robust competition already exists, indicating that the manufacturer is more interested in gaining a competitive advantage or preferred formulary access as opposed to advancing the medical evidence around the safety and efficacy of their product in a real-world environment. It is our view that outcome-based contracting remains the exception—and not the norm—in determining the ultimate value of prescription drugs. They do not produce the best arrangement in every situation. In competitive disease areas where multiple drug manufacturers offer well-established treatments or where generics are prevalent, such as the markets for oral diabetes drugs, multiple sclerosis, and hepatitis C, the ordinary effects of traditional price concession negotiations afforded by robust competition produce the lowest costs.
- **Medicaid Best Price Is a Barrier to Outcome-Based Contracting:** In our negotiations with drug manufacturers, they often cite Medicaid Best Price as the primary reason for refusing to take on more significant downside risk in outcome-based contracts. Although we cannot empirically validate that Best Price is a limiting barrier—only drug manufacturers can speak to that question—just over 30 percent of our executed outcomes-based contracts apply solely to our Medicare Part D plans, which are statutorily excluded from manufacturers' Best Price calculations. The products associated with these outcomes-based contracts are predominantly high-cost specialty drugs and include therapies for auto-immune/inflammatory conditions (rheumatoid arthritis, psoriasis), cardiovascular disease, diabetes, infectious disease, and cancer. The remaining 70 percent of our outcome-based contracts apply equally to our commercial and Medicare lines of business. Recently published reports have found that though Medicaid Best Price is an understandable concern for manufacturers determining whether to pursue value-based contracts, particularly in the commercial market, its effect can be mitigated and is not the immutable obstacle to value-based contracting that some manufacturers' claim.[49] We encourage CMS to review this research and determine if additional guidance is necessary to clarify the treatment of outcome-based agreements relative to manufacturer calculations of Best Price. CMS may also wish to consider using its demonstration authority to explore opportunities to ameliorate manufacturers' concerns regarding the impact of outcome-based contracting on Medicaid Best Price calculations. For example, CMS could develop a limited pilot program to test whether excluding outcome-based contracts from Medicaid Best Price results in manufacturers taking on more significant downside risk, and whether that in turn creates net savings for the Federal Government and beneficiaries.

Providing Additional Formulary Flexibility

- **Modernize Protected Classes:** Humana has long supported these policy changes and has identified opportunities to create competition in the market and lower drug costs for beneficiaries. Internal analysis estimates that the lack of competition due to the protected class policy collectively increased beneficiary premiums by an estimated $2.79 per-beneficiary per-month (PBPM, $34 per-beneficiary-per-year) in 2018. Additional flexibility with respect to formulary de-

[49] Sachs, Bagley, and Lakdawalla, "Innovative Contracting for Pharmaceuticals and Medicaid's Best-Price Rule," *Journal of Health Politics, Policy, and Law* (2018) 43 (1): 5–18, *https://doi.org/10.1215/03616878-4249796;* Duke Margolis Center for Health Policy, "Overcoming the Legal and Regulatory Hurdles to Value-Based Payment Arrangements for Medical Products," White Paper (December 2017), *https://healthpolicy.duke.edu/sites/default/files/atoms/files/overcoming_legal_and_regulatory_hurdles_to_value-based_payment_arrangements_for_medical_products.pdf?_sm_au_=iHV1FMvjM0SN08HN*.

velopment will enable sponsors to effectively drive competition in the market and lower drug costs for their beneficiaries.

- **Eliminate the Requirement That Part D Plan Sponsors Cover at Least Two Drugs in Each Therapeutic Category or Class:** CMS's current policy to cover at least two drugs in every Part D covered therapeutic category and class as long as there are at least two drugs available limits the ability of plan sponsors to negotiate with manufacturers. Since two drugs are mandated to be covered in a class, manufacturers of a drug with only one other competitor typically refuse to negotiate rebates or discounts in Medicare Part D because they know their products must be covered. This policy ultimately increases costs across the system.

III. Committees' Request for Additional Information

Question #1 and #2: *Elimination of the Coverage Gap and Associated Liability in the Catastrophic Phase*

The discussion draft solicits comments on fundamentally changing the structure of the Part D benefit by changing or eliminating the distinction between the initial coverage phase and the coverage gap discount program while reallocating the share of costs attributed to the government, Part D plans, and manufacturers in the catastrophic phase.

As discussed previously, two percent of our beneficiaries who utilized specialty drugs comprised 36 percent of total Part D spending in 2018. In two years, Humana projects that seniors utilizing specialty drugs could account for as much as 50 percent of total Part D spending. In 2018, only 6.9 percent of Humana's total membership reached the catastrophic phase of the benefit (2.5 percent of non-Low-Income Subsidy members and 18.4 percent of Low-Income Subsidy members). We welcome the opportunity to explore potential solutions for alternative pooling or funding mechanisms for this subset of Part D beneficiaries. We recommend that the committees employ the following guiding principles:

- ***Establish a MOOP through policy changes to curb anti-competitive actions:*** Protect beneficiaries from excessive out-of-pocket costs associated with specialty drug costs through a Part D MOOP that is funded from policy changes that curb and eliminate anti-competitive drug manufacturer pricing practices.
- ***Maintain affordable premiums:*** Ensure that changes to improve Part D, mitigate any premium increases, and hold manufacturers accountable by discouraging manufacturer price increases and high specialty drug launch prices.

Additionally, it is important to consider the complexities of the Part D program and the unique funding mechanisms that have been established for different populations in each phase of the benefit. As changes are made—as with all policy decisions—there is risk for unintended consequences that could undermine the success of the benefit for the majority of seniors who participate in the program. Once again, we would welcome the opportunity to have detailed discussions with the committees.

Question #3: *Rewards and Incentives for Low-Income Part D Beneficiaries for Out-of-Pocket Costs Below the Catastrophic Level and All Beneficiaries Above a Part D Maximum Out-of-Pocket*

The Part D program provides "extra help" to dual-eligible and other low-income beneficiaries to make prescription medications more affordable. While the subsidy makes prescription drugs accessible and affordable to a vulnerable population, it has created some disincentives that result in excessive or inefficient utilization of brand name drugs, increasing costs for the Medicare program and beneficiaries who aren't eligible for the low income subsidies. The generous subsidies negate conventional benefit design mechanisms employed by plan sponsors to improve the quality and affordability of care. For example, cost sharing for low income beneficiaries is subsidized based on whether a drug is a brand or generic (in 2020, for a full-benefit dual eligible below 100 percent of the FPL, generic drugs cost $1.30 and brand drugs cost $3.90). While these low member cost shares help patients afford prescription medications, they do little to encourage utilization of lower cost choices. One option for increasing the use of lower cost alternatives is to allow rewards and incentives in Part D for LIS beneficiaries. In some cases, rewards or incentives may be able to reduce financial burdens while also increasing the health and wellness of beneficiaries. Any reward or incentive system must be based on the desired behavior change to be economically feasible. However, generic dispensing rates for LIS members are still above 85 percent. The rewards and incentives would not result in savings if they were applied to the total population that is already taking a generic. In addition, any rewards and incentives tests would need to closely monitor

any initial conversions that subsequently converted back to the higher cost drug. In some cases, this may be warranted, but in general, sponsors should reward based on long term behavior change that results in an increase in medication adherence. Since the LIS program within Part D is unique, and since rewards and incentives are not currently allowed in Part D, there is not a set of baseline data to predict the success of any reward or incentive programs. As such, sponsors could be given the flexibility to test alternate strategies and designs to determine what best drives sustainable, long-term behavior change. Examples of potential reward and incentive programs include:

- **Gift cards at the point of sale:** Gift cards would likely provide the greatest incentive for LIS beneficiaries to switch to lower-cost alternatives. This could either be done at the point of sale (in conjunction with the pharmacy), or administered by plan sponsors by sending the reward to the member soon after claims adjudication. Although this option would likely provide an immediate impact, precautions would need to be taken to assure the system did not drive excess utilization, or could otherwise be manipulated or abused. An OIG waiver would likely be needed to avoid potential violation of inducement regulations.
- **Provide other health-related rewards:** While not as motivating as gift card equivalents, health related rewards still provide meaningful incentives for LIS beneficiaries to utilize lower cost alternatives. In addition, the focus on health items limits exposure to potential abuse. It also allows the flexibility to provide near immediate feedback and maximize the impact to behavior change.
- **Create a point system/rewards program:** In addition to encouraging lower cost alternatives, such a program could also strongly promote other healthy behavior changes such as healthy foods, exercise, etc. Many of these programs are already operational relative to MAPD and commercial business, which may speed up any implementation. The risk of abuse is also low for this model and the focus on longer term goals may mitigate issues related to a one-time action. While a rewards program encourages appropriate behavior change, the delay between the action and the reward may limit the effectiveness of the program relative to other alternatives.

PREPARED STATEMENT OF HON. CHUCK GRASSLEY,
A U.S. SENATOR FROM IOWA

Good morning. This hearing will come to order. Today, the committee continues its look at why prescription drug costs are so high and what can be done to bring them down.

I'd like to welcome our witnesses, who are top executives from major pharmacy benefit managers, or PBMs.

Medicare prescription drug plans hire PBMs to manage Part D benefits. In Medicaid, State and managed care organizations also employ PBMs. We know that drug companies set the list price, and our February hearing with CEOs of major manufacturers focused on those high prices. We now turn our attention to PBMs.

PBMs negotiate with the drug companies, as well as pharmacies, to arrive at a price for a drug and its ultimate cost. This system of private entities negotiating is what I envisioned as an author of the Part D program. I still believe this is absolutely the right approach. I oppose any effort to undue the "non-interference clause" currently in statute. However, it's our duty to understand how the system is working today and what we can do to improve it.

In addition to negotiating prices, PBMs also determine what drugs are covered and what patients pay out of pocket. Despite this vast influence over what often amounts to life and death, many consumers have very little insight into the workings of PBMs. PBMs report rebates and other price concessions to the Centers for Medicare and Medicaid Services (CMS), but the statute severely restricts what can be done with that information. More transparency is needed.

The current system is so opaque that it's easy to see why there are many questions about PBMs' motives and practices. One question we must ask is whether PBMs prefer a high-cost drug with big rebates over a cheaper drug. Some even argue that PBMs force drug companies to raise their list price.

Senator Wyden and I are investigating pricing and rebating practices related to insulin. This will help us more broadly determine whether PBMs and manufacturers

today are focused on patients or their own bottom line. Mergers and vertical integration is another area that has increasingly prompted concern. All of the PBMs here today are owned by or affiliated with an insurance plan. In many cases, the combined company also owns pharmacies and other players in the health industry.

It's important we look to see whether such integration actually helps patients and consumers, or whether it just opens the door for anti-competitive behavior. Last year I sent the Federal Trade Commission a letter on this very issue and asked them to keep me apprised of their work. I am putting my letter and the response into the record.

I realize I've raised many issues. I look forward to hearing the witnesses providing insight and helping us find solutions.

Ranking Member Wyden and I are committed to working on a bipartisan basis to bring drug costs down. Our next step is to work with committee members to develop policies to help Medicare and Medicaid patients and protect the taxpayers.

United States Senate

COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

August 17, 2018

The Honorable Joseph Simons
Chairman
Federal Trade Commission
600 Pennsylvania Ave., NW
Washington, DC 20580

Dear Chairman Simons:

I write with regard to the Federal Trade Commission's recent inquiry into intermediaries in the pharmaceutical supply chain, including pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs). As you know, the pharmaceutical supply chain is currently witnessing significant consolidation and vertical integration, by way of the proposed mergers of Cigna Corp. with Express Scripts Holding Co. and CVS Health Corp. with Aetna Inc. The resulting entities would have considerable market share in the provision and management of prescription drug benefits.

According to a new report from the Kaiser Family Foundation, the two combined entities, along with UnitedHealth and Humana, would cover 71% of all Medicare Part D enrollees and 86% of stand-alone drug plan enrollees.[1] Moreover, these transactions would result in substantial vertical integration within the pharmaceutical supply chain, with the three largest PBMs all vertically integrated with insurance companies. Vertical integration, like the proposed transactions, can often result in increased efficiencies and consumer benefits, and should be evaluated accordingly.

Such integration, however, can also lead to higher barriers to entry for competition in each standalone market, leading to further consolidation. These risks have been highlighted by key administration stakeholders. According to President Trump's Council of Economic Advisers, "[p]olicies to *decrease* concentration in the PBM market and other segments of the supply chain (*i.e.,* wholesalers and pharmacies) can *increase* competition and further reduce the price of drugs paid by consumers."[2] Further, Food and Drug Administration Commissioner Scott Gottlieb recently warned that "consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious. And the very complexity

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[1] Juliette Cubanski, Anthony Damico, and Tricia Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing" (May 17, 2018), *available at https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/*.

[2] The Council of Economic Advisers, "Reforming Biopharmaceutical Pricing at Home and Abroad" (February 2018), *available at https://www.whitehouse.gov/wp-content/uploads/2017/11/CEA-Rx-White-Paper-Final2.pdf.*

and opacity of these schemes help to conceal their corrosion on our system—and their impact on patients."[3]

Accordingly, it is critical for Congress to understand the FTC's perspective on these issues, including the potential impact of concentration on the marketplace, and more broadly, whether the presence of PBMs and other intermediaries in the pharmaceutical supply chain tends to reduce, control, or increase the cost of health care in the United States. In the past, the FTC has asserted that allowing competition among PBMs will yield more benefits than contract terms mandated by government.[4] Further, a 2005 FTC study of PBMs that own mail-order pharmacies found that such ownership arrangements "generally did not disadvantage plan sponsors" and that "competition in this industry can afford plan sponsors with sufficient tools to safeguard their interests."[5]

The pharmaceutical industry, however, has experienced significant changes and consolidation in the intervening years. In light of these changes, and of the Commission's recent roundtable discussion on these complex issues, I respectfully request written answers to the following questions by no later than September 17, 2018.

1. At its November 2017 roundtable entitled "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics," the FTC invited comment on the following question:

   a. What role do intermediaries, such as pharmacy benefit managers (PBMs) and group purchasing organizations (GPOs) play in prescription drug pricing, consumer access, and quality? What are the benefits and costs of intermediaries in the pharmaceutical supply chain? Has consolidation affected price, access, or quality?

   What specific conclusions has the FTC drawn from the comments and dialogue it received in response to the above question?

2. At its November 2017 roundtable, the FTC invited comment on the following question:

   a. How do companies assess the benefits, costs, and risks of contracting with intermediaries? How well do consumers understand intermediaries' roles? Is more information necessary?

   What specific conclusions has the FTC drawn from the comments and dialogue it received in response to the above question?

3. What specific actions does the FTC intend to take as a result of its November 2017 roundtable? Please provide a detailed description of any relevant forthcoming actions—including policy proposals, additional research or roundtable discussions, consumer education efforts, or enforcement actions—that Congress should be aware of at this time.

4. Based on recent market consolidation and integration efforts, does the FTC believe there is sufficient competition in the various markets of the pharmaceutical supply chain?

5. What specific legal or regulatory obstacles, if any, is the FTC currently facing in its efforts to ensure a competitive and transparent marketplace in the pharmaceutical supply chain, including but not limited to the PBM marketplace?

6. What specific legislative actions, if any, should Congress be considering at this time to increase transparency in the pharmaceutical supply chain and to best ensure that cost savings or efficiencies are actually passed onto consumers?

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[3] FDA Commissioner Scott Gottlieb, M.D., "Capturing the Benefits of Competition for Patients" (March 7, 2018), *available at https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm* (emphasis added).

[4] FTC Staff Comment to the Honorable James L. Seward Concerning New York Senate Bill 58 on Pharmacy Benefit Managers (PBMs) (March 31, 2009), *available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-honorable-james-l.seward-conceming-new-york-senate-bill-58-pharmacy-benefit-managers-pbms/v090006newyorkpbm.pdf.*

[5] FTC, "Pharmacy Benefit Managers: Ownership of Mail-Order Pharmacies" ii (August 2005), *available at http://www.ftc.gov/reports/pharmbenefit05/050906pharmbenefitrpt.pdf.*

Thank you for your attention to this matter, and I look forward to your response. If you have any questions, please contact Ryan Dattilo or Kyle McCollum of my Judiciary Committee staff at 202–224–5225.

Sincerely,

Charles E. Grassley
Chairman
Committee on the Judiciary

FEDERAL TRADE COMMISSION
WASHINGTON, DC 20580

September 27, 2018

The Honorable Charles E. Grassley
Chairman
Committee on the Judiciary
U.S. Senate
Washington, DC 20510

Dear Chairman Grassley:

Thank you for your letter regarding the Federal Trade Commission's recent inquiry into intermediaries in the pharmaceutical supply chain, including pharmacy benefit managers ("PBMs") and group purchasing organizations ("GPOs"). As you have recognized, a number of changes are occurring in this sector. I appreciate your concerns about the potential impact on competition and consumers. Although I cannot comment on any particular acquisition or company, I assure you that the Commission continues to examine competition in pharmaceutical markets, and this will remain a high priority under my leadership.

As you mentioned, the Commission hosted a workshop in November 2017, "Understanding Competition in Prescription Drug Markets: Entry and Supply Chain Dynamics." The purpose of that workshop was to identify continuing obstacles to generic competition in prescription drug markets. Thirty years ago, Congress passed the Hatch-Waxman Act to expedite generic entry. In 2010, Congress enacted the Biologics Price Competition and Innovation Act ("BPCIA") to expedite biosimilar drug approval. The Hatch-Waxman Act has largely succeeded in lowering patent-related entry barriers for small-molecule generic drugs, and biosimilars are slowly proceeding through the BPCIA pathway. Still, concerns about rising drug prices have led the FTC and others to question whether other obstacles, beyond patents, are suppressing generic and biosimilar entry.

With this question in mind, participants at the November 2017 workshop examined considerations that may limit entry into generic drug markets after relevant patents have expired. The program included a keynote address by FDA Commissioner Scott Gottlieb, as well as panel discussion featuring a number of academics, researchers, and industry stakeholders. In addition, the FTC received and reviewed more than 600 public comments. Panelists and commenters identified issues related to niche patient populations, complex manufacturing processes, consolidation, drug shortages, and Risk Evaluation and Mitigation Strategies ("REMS") restrictions. They also evaluated how contractual relationships between intermediaries, manufacturers, and health plan sponsors can affect the prices that consumers pay for prescription drugs. Participants discussed the unique market structures through which drugs get to consumers, which include manufacturers, wholesalers, retailers, pharmacy benefit managers, group purchasing organizations, and health plans.

These panel discussions, and review of the related comments, offered the FTC a better understanding of modem competitive dynamics, which in turn has informed the agency's enforcement, policy, and advocacy efforts. For example, the FTC relied on this learning when developing our response to the Department of Health and Human Services' ("HHS") call for public comments on the *Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs.*[1] Among other things, the FTC comment

[1] Statement of the Federal Trade Commission to the Department of Health and Human Services Regarding the HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs (July 16, 2018), *https://www.ftc.gov/system/files/documents/advocacy-documents/statement-federal-*

Continued

identified how branded pharmaceutical manufacturers' misuse of REMS may impede pharmaceutical competition, which was a topic raised at our workshop. We continue to analyze the workshop record and consider next steps.

I particularly appreciate your concerns about market consolidation and the potential for anticompetitive conduct in the health care sector. I share your belief that vigorous antitrust enforcement is critical to ensuring competitive markets and protecting consumers. One of the FTC's highest priorities is enforcing the antitrust laws against anticompetitive mergers and conduct among firms throughout the pharmaceutical supply chain. The FTC has brought many cases challenging mergers among pharmaceutical companies and distributors, and has been at the forefront of challenging anticompetitive conduct—such as reverse payment settlements or sham litigation—that creates obstacles to generic competition.[2]

During my nomination process, I expressed my concerns about whether merger enforcement has been too lax. As I stated then and continue to believe now, the FTC may need to take corrective action if close study reveals that the Commission has indeed been too cautious in challenging mergers, including those involving PBMs that resulted in actual harm.

The Commission therefore is conducting an ambitious program of *Hearings on Competition and Consumer Protection in the 21st Century.* These public hearings are designed to seek input on whether broad-based changes in the economy, business practices, and technology, as well as international developments, require any adjustments to competition and consumer protection enforcement and policy. This effort harkens back to the Global Competition and Innovation Hearings undertaken in 1995 during the Chairmanship of Robert Pitofsky. As part of this project, the Commission is inviting public comment on a broad range of antitrust and consumer protection topics, including evaluating the state of antitrust law and enforcement, evaluating the competitive effects of corporate acquisitions and mergers, best approaches for performing merger retrospective studies, and identifying industries that are conducive to these analyses. We will keep you apprised regarding any recommendations or other initiatives that come out of our hearings project.

Thank you again for your interest in promoting effective competition in U.S. pharmaceutical markets. If you have any questions, please feel free to have your staff call Jeanne Bumpus, the Director of our Office of Congressional Relations, at (202) 326–2195.

Sincerely,

Joseph J. Simons
Chairman

PREPARED STATEMENT OF MIKE KOLAR, INTERIM PRESIDENT AND CEO, PRIME THERAPEUTICS, LLC

Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for the opportunity to discuss how pharmacy benefit managers (PBMs) and, in particular, Prime Therapeutics LLC, provide value to the health-care system.

I am Mike Kolar, and I serve as the Interim President and CEO of Prime. At Prime, our mission is to make health care work better by helping people get the medicine they need to feel better and live well. We do this by managing pharmacy benefits for health insurers, employers, and government programs including Medicare and Medicaid. Our goal is to ensure that the members and beneficiaries of these plans and programs get the medication most appropriate for their condition at a cost that is the most affordable in the context of their overall insurance benefit. This mantra of "right drug, for the right person, at the right time, and at the right cost," guides our actions every day.

We appreciate the committee's efforts to thoroughly examine issues related to the problem of high drug costs. We see firsthand the challenges that these costs cause

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trade-commission-department-health-human-services-regarding-hhs-blueprint-lower/v180008_commission_comment_to_hhs_re_blueprint_for_lower_drug_prices_and_costs.pdf.

[2] For a summary of the FTC's antitrust actions in the pharmaceutical industry, *see* "Overview of FTC Antitrust Actions in Pharmaceutical Products and Distribution" (April 2017), *https://www.ftc.gov/system/files/attachments/competition-policy-guidance/overview_pharma_april_2017.pdf.*

for our plans, for their members and beneficiaries and for taxpayers. In 2018, drug costs represented 27 percent of total health-care costs for our commercial clients. A portion of this increased spend results from newly introduced therapies, which have the potential to improve outcomes and avoid medical costs for payers and individuals. But it is the price and value of these new therapies as well as existing therapies, as set by pharma and pharma alone, that needs to be effectively questioned, checked and balanced. As a unique, transparent pharmacy benefits manager, our value lies in applying our clinical expertise to serve as an effective hedge against otherwise unmitigated pricing behaviors and to make medication more affordable.

We agree that high drug costs present a problem for individuals and society. We look forward to sharing more about our how our unique, transparent approach and the clinical value we provide addresses the problem as it exists today. We will provide our thoughts on how the key issues of transparency and manufacturer rebates should be viewed in framing solutions to the problem of high drug costs. And we will share our views on other effective means of reducing the high cost of prescription drugs for the benefit of plans, employers, patients and taxpayers.

PRIME REPRESENTS A UNIQUE PBM MODEL

Prime Therapeutics was formed in 1998 by two Blue Cross and Blue Shield Plans seeking to more effectively manage plan and member drug costs. Starting with only a few million members, Prime has grown over the last 20 years to provide pharmacy benefits to over 28 million individuals, from 23 Blue Cross Blue Shield plans as well as Federal employees served by the Federal Employee Program (FEP®). Prime's growth has been driven by our ability to effectively manage drug costs for these plans and their members as a trusted, transparent partner. Our integration with our Blue Cross and Blue Shield clients allows us to leverage our view into both pharmacy *and* medical data to improve care and reduce costs. This helps our plans to best serve the specific needs of their respective local communities.

Today Prime is owned and controlled solely by 18 not-for-profit Blue Plan clients. This makes us the only major PBM with a primary mission focused on driving savings instead of margins. We are not beholden to the short term, quarterly need to report earnings to Wall Street shareholders. We are free to focus on delivering the lowest net cost on prescription medicines and driving lowest overall cost of care for our clients and their members. We are driven to get the right drug, for the right person, at the right time, and at a cost that is as affordable as possible in the context of a member's overall insurance benefit to help ensure sustainability and optimal health outcomes.

PRIME APPLIES EXTENSIVE CLINICAL EXPERTISE TO REDUCE DRUG COSTS

The core value we provide our clients and their beneficiaries is based upon our deep clinical pharmacy expertise. We employ pharmacists and physicians and engage an independent Pharmacy and Therapeutics (P&T) Committee made up of 26 actively practicing, nationally recognized medical and pharmacy experts to evaluate the safety, efficacy, and value of existing and emerging drug therapies. This expertise allows us to advise our plan clients regarding drug coverage decisions, utilization policies, and adherence, intervention and therapy management programs to lead to better patient outcomes, ensure quality and patient safety, and manage costs. The common misperception that Prime and other PBM's are simply transactional "middlemen" entirely ignores the immense value we provide in helping to ensure clinically appropriate drug utilization to drive better outcomes.

The retail prices of some of the most popular prescription drugs older Americans take to treat everything from diabetes to high blood pressure to asthma increased by an average of 8.4 percent in 2017, far exceeding the 2.1-percent inflation rate for other consumer goods and service.[1] Rising costs from specialty drugs and high prices of new specialty drugs have had an even more significant impact on overall drug prices. These specialty drugs treat complex, chronic conditions, like multiple sclerosis and rheumatoid arthritis. These drugs are usually injected or infused. They require careful oversight from a health-care provider and require special handling. Over half of all drugs approved by the FDA in 2018 were specialty drugs.[2] According

[1] Bunis, Dena. "Retail Prices of Brand-Name Drugs Continue to Skyrocket," September 26, 2018, AARP, *https://www.aarp.org/health/drugs-supplements/info-2018/prices-rising-for-name-brand-drugs.html.*

[2] Healthinsurance.org "Glossary," *https://www.healthinsurance.org/glossary/specialty-drug/* and *https://www.pcmanet.org/pcma-cardstack/what-is-a-specialty-drug/*.

to a recent report from the Pharmacy Benefit Management Institute, less than 5 percent of commercially insured patients use specialty medications, but they constitute half of overall drug costs.[3] Prime predicts that specialty drugs will be 60 percent of all drug spend by 2021.

While pharmaceutical companies keep introducing new drugs at high prices and raising prices on existing drugs, we work hard to counter these rising costs by appropriately managing utilization and negotiating for lower net reimbursement. Prime's management tools are critical to managing both drug trend and quality. The results of our efforts can be shown by the savings we generate. Despite rising costs overall, Prime's programs delivered nearly $3.4 billion in incremental value to our health plan clients in 2018. In an environment of rising prices and new, high-cost drug introductions, Prime has a long track record of successfully managing overall drug trend. Trend defines the difference of drug spend between one year and the next. It is affected by the number of people using which drugs (utilization) and the prices of those drugs. Prime's commercial clients experienced a drug trend of only 3.3 percent in 2018, and experienced a negative trend in 2017. Prime was similarly successful in managing drug trend in government program markets. Here, where full utilization of our clinical and negotiating tools is significantly limited by current regulations, we achieved a 4.7 percent trend in Medicare and 7.3 percent in Medicaid for 2018, and −0.8 percent and −5.4 percent, respectively for 2017.[4, 5]

We achieve these results by leveraging our clinical expertise to advance quality, optimize utilization and manage net price for our clients and their members and beneficiaries through:

- *Formulary management,* including pipeline management and formulary development. Our P&T Committee evaluates the clinical efficacy and safety of new and existing medications and approves and regularly reviews our clinical recommendations for each drug, including coverage, clinical appropriateness and safety. Our P&T Committee meets quarterly and reviews all drug categories annually. We also make formulary recommendations regarding preference or "tiering" using a lowest net drug cost approach. That occurs only after our initial clinical safety and efficacy determinations, and with an additional concern for minimizing member impacts across any transitions.
- *Utilization management,* including prior authorization, step therapy, and quantity limits.
    - When a provider prescribes a drug that could potentially be misused in an unsafe or ineffective manner, prior authorization serves as an additional check, in collaboration with the care provider, to confirm that the drug is appropriate for the particular patient and their condition. This is done to ensure safety and avoid unnecessary costs for the plan and the patient.
    - Step therapy programs similarly help avoid unnecessary costs for the payer and patient by recommending effective, lower cost, "first line" therapies prior to administration of a costlier alternative.
    - Quantity limits also help avoid waste and manage cost for all parties by recommending limited initial trial quantities of a medication to ensure it achieves the intended outcome and/or does not result in harmful side effects before additional doses are dispensed and paid for by the plan and patient.
- *Our GuidedHealth™ program,* promoting optimal member medication management through retrospective drug utilization reviews. GuidedHealth (GH360) is a population health database and clinical rules engine that uses integrated medical and pharmacy data to identify opportunities to lower drug and medical costs. Prime identifies these opportunities and intervenes with doctors, members and pharmacies through a multi-channel communication strategy (*e.g.,* pharmacist case management, direct messaging to prescribers

[3] Pharmacy Benefit Management Institute, "2019 Trends in Specialty Drug Management," *https://www.pbmi.com/ItemDetail?iProductCode=SPECIALTY_2019&Category=SPECIALTY.*

[4] "Prime Therapeutics Keeps High Drug Cost Trends at Bay: Annual Trend Reports Released," March 19, 2019, *https://www.primetherapeutics.com/en/news/pressreleases/2019/release-2018-drug-trend.html.*

[5] "Prime Releases Proves PBM's Value: Delivers Negative Drug Trend in 2017," February 20, 2018, *https://www.primetherapeutics.com/en/news/pressreleases/2018/drugtrend-2017-release.html.*

via electronic medical records (EMR), phone, text, email, mail) to help guide better drug therapy. Examples of opportunities include medication non-adherence, gaps in care, drug safety concerns, drug/condition management issues, high cost specialty drug management interventions and chronic disease management programs. In our experience, each dollar spent on these types of programs yields up to $8 in cost savings for our plan clients and their members or beneficiaries, totaling more than $350M in savings, and growing, each year.

- *Pharmacy network management,* designed to ensure access, quality and affordability for beneficiaries and plans. Prime maintains contracts with over 60,000 retail pharmacies nationwide representing in aggregate over 91 percent of all pharmacies in the United States. Prime highly values the role of the local pharmacist in serving patients and ensuring appropriate medication therapy, including pharmacists' role in counseling patients on drug administration, interactions, adherence and safety. We partner closely with pharmacists and local pharmacies in these activities. In constructing networks of local pharmacies to serve members and beneficiaries, we drive both higher quality and more affordable costs for the benefit of patient.
- *Fraud, waste, and abuse* (FWA) programs that aggressively combat activities that burden plans, members and taxpayers with costs that are wholly unnecessary, and not infrequently, have a basis in criminal activity. Our activities in rooting out fraud, waste and abuse resulted in $268M in savings in 2018 alone for our clients, their members and beneficiaries.
- *Value-based contracting (VBC),* designed to hold a pharmaceutical manufacturer accountable for the overall effectiveness of its drug. Prime's goal with VBC strategies includes evaluating the effectiveness and value that a drug has on a member's total cost of care, including both pharmacy and medical costs. Our value-based contracts focus on all aspects of care, including channel management, persistency and compliance, health monitoring, diagnostic testing, and health outcomes assessments. We signed our first VBC contract in 2010. Since then, we have contracted with pharmaceutical manufacturers for value-based arrangements in therapeutic areas that affect large groups and gaps in care (*e.g.,* diabetes, cardiovascular disease, chronic migraine) as well as those that are high cost for our clients' members (*e.g.,* hepatitis, rheumatoid arthritis, ulcerative colitis, multiple sclerosis).
    - One example of our value-based contracting is our arrangement with the manufacturer of an oral type 2 diabetes medicine indicated to reduce the risk of cardiovascular death in adults with type 2 diabetes and established cardiovascular disease. Our contract evaluates the incidence and total cost of care for certain cardiac events among patients taking this medication and links payment for the drug to improved outcomes. We believe that this type of evidence-based, outcome-driven reimbursement model underscores the unique value that Prime can bring in the drug market to ensure that prices become more aligned with quality and economic value.

We believe that these capabilities and additional capabilities under development provide significant value for our clients and their members and beneficiaries. We welcome opportunities to expand the application of our programs to drive additional savings in government programs. Specifically, Prime supports the August 2018 CMS change that allows plans to create indication-based formularies—formularies that cover specific drugs for specific indications—for Medicare beginning in 2020. Indication based formularies are currently used in our commercial business. The ability to bring this expertise to Medicare will provide plans additional flexibility and choice in formulary design, and will improve drug affordability for plans and beneficiaries.

Beyond cost control, our clinical expertise plays a key role in patient safety. PBMs are the entities in the health-care system that are best situated to know and to coordinate all the medications that a patient takes. Neither pharmacies nor physicians are currently guaranteed to see the entire spectrum of a patient's prescriptions. A 2012 study found slightly more than one-third of patients use multiple pharmacies

to fill their prescriptions.[6] A more recent study of Part D patients reported that even more—38 percent—used multiple pharmacies.[7] Individual physicians may also not know all the medication their patients use. According to a recent *Consumer Reports* survey, over half (53 percent) of Americans who take prescription drugs get them from more than one health-care provider, which increases the risk of adverse drug effects.[8] PBMs like Prime play an important role in identifying inappropriate utilization and adverse drug interactions. Prime's concurrent drug utilization program screens medicines at the point of sale for potential drug therapy problems such as drug-to-drug interactions, inappropriate refill timing and potential overuse or misuse. If an issue is flagged, Prime collaborates with the local pharmacist to address the issue with the patient and to provide clinically appropriate guidance on how to proceed.

As health care becomes more complicated, and as personalized medicine and companion diagnostics (*i.e.,* a laboratory genomic test whose result determines therapy) become more prevalent, we see additional opportunities to use our clinical expertise to collaborate with physicians and allied health professionals to manage medication therapies. The clinical expertise and tools of a PBM like Prime can help to continue to ensure the right patient gets the right therapy at the right time even as science and research continue to advance.

PRIME BELIEVES IN TRANSPARENCY

From our inception 20 years ago, our business model was built on transparency, and we understand the importance of transparency in the health-care system overall. We believe that the right kind of transparency within the PBM model can improve outcomes and lower costs for members and beneficiaries. We would caution, however, that the wrong kind of transparency will ultimately lead to higher drug prices.

In Prime's view, there are five audiences for the right kind of transparency:

(1) client transparency;
(2) patient transparency;
(3) government transparency;
(4) physician/prescriber transparency; and
(5) pharmacy transparency.

Client Transparency: Client transparency is the hallmark of Prime's unique business model. Unlike the clients of other PBMs, Prime's clients see their respective drug costs at a unit cost level. Prime also shows clients *all* the savings Prime generates on their behalf, including pharmacy savings and rebates. Savings are passed back to clients to offset the cost of services and to help keep premiums affordable. To be clear, Prime's model is to send the *entire* rebate back to our clients.

Enrollee/Patient Transparency: Prime believes it is vitally important that its members make informed choices. Presently, Prime has tools that are available to patients to enable them to more easily understand their pharmacy benefits. We maintain a website at *MyPrime.com* that allows members access to pharmacy benefit information. *MyPrime.com* is a personalized platform where members can find pharmacies, understand coverage and tiering, and find actual prices for prescription drugs, including their applicable cost share. We share information about *MyPrime.com* with members upon plan enrollment and thereafter in other beneficiary communications.

We also support efforts to advance adoption of a real-time benefit tool (RTBT). This provides an easy-to-use, complete view of a beneficiary's prescription benefit information including cost, formulary alternatives, and utilization management requirements at the point of prescribing. This allows both the patient and his or her prescriber to make informed decisions using both clinical and pricing information. To drive rapid adoption and widespread use, we believe that RTBTs should be based upon a standardized platform, such as the in-process standard being finalized by the National Council for Prescription Drug Programs (NCPDP). This standard will pro-

[6] Eder, Rob, "Why Patients Use Multiple Pharmacies," *Drugstore News,* August 28, 2012, *https://www.drugstorenews.com/news/why-patients-use-multiple-pharmacies/*.

[7] Z.A. Marcum et al., "Impact of Multiple Pharmacy Use on Medication Adherence and Drug-drug Interactions in Older Adults With Medicare Part D," *J Am Geriatr Soc.* 2014 Feb.; 62(2): 244–252. Downloaded from *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4115075/*.

[8] "Americans Taking More Prescription Drugs Than Ever," *HealthDay Reporter,* August 3, 2017, *https://www.webmd.com/drug-medication/news/20170803/americans-taking-more-prescription-drugs-than-ever-survey.*

vide the guardrails to ensure consistent, thorough, and quality communication of prescription benefit information. This will aid practitioners and patients in making informed, real-time drug decisions at the point of prescription, eliminating surprises and delays that adversely impact medication utilization and adherence, and, ultimately, health outcomes.

Government Transparency: The Center for Medicare and Medicaid Services (CMS) collects very detailed information from PBMs about Part D transactions through its mandatory Direct and Indirect Remuneration (DIR) reporting. CMS has a thorough line of sight into all rebates, fees, and payment adjustments, which are reported to CMS as DIR on a drug by drug basis. Further, each plan submits bids annually to CMS by the first Monday in June. Those bids reflect the plan's expected benefit payments plus administrative costs after they deduct expected Federal reinsurance subsidies, and the level of CMS payment to plan sponsors is derived from actual plan bids.

Prime supports legislation recently introduced by Senators Cornyn, Cortez Masto, Carper, and Cassidy that would allow the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission access to CMS's DIR data to inform Congress's decision-making on Part D policy. Our support is based upon the important protections for proprietary data included in the legislation that will mitigate the risk of adverse, anti-competitive consequences that could cause drug prices to increase.

Physician and Allied Health Professional Prescriber Transparency: Prime provides prescribers with access to formularies and regularly communicates changes in formularies and other coverage information, and we believe that adoption of RTBTs will provide an enhanced user experience and more rapid transparency to aid prescribers in making informed prescription decisions.

In addition to supporting RTBTs, we also support electronic prescribing directly to patients' pharmacies. This vastly improves efficiency for health-care professionals and pharmacy interactions for patients. We were pleased that last year's SUPPORT Act, Pub. L. 115–271, included a requirement that Part D plans use electronic prior authorization (ePA).

Pharmacy Transparency: In our relationships with pharmacies we seek to ensure quality by scoring pharmacy performance on key metrics as such as medication adherence and generic dispensing rates, which aid in improving a member's health outcomes and reduce costs. Prime provides quarterly results to the pharmacies and includes data for reconciliation. In our quality based networks, pharmacies earn incentives based upon their performance on key metrics that are relevant to the CMS Stars ratings. Prime uses EQUIPP, an industry standard dashboard that allows pharmacists to track their performance and predict their likely results. Prime meets with pharmacies monthly to review their performance and discuss improvement options. Price concessions earned because of underperformance on quality metrics are remitted in full to our plans for member-facing premium reductions and quality programs, and for reporting to CMS.

Misguided Transparency: Many aspects of transparency are laudable. These are already fully present in Prime's business model, and aid in better managing drug spend for clients and their members and beneficiaries. But we believe proposals that would require disclosure or visibility into *actual* negotiated rebates would have an adverse impact and would likely result in an increase in overall drug costs.

Our view is supported by the Federal Trade Commission (FTC), which has studied the issue and found that such disclosure creates a risk for anti-competitive behavior by manufacturers that would increase prices. Currently, manufacturer rebates to PBMs are confidential, and competing manufacturers do not know the rebate offered by their competitors. When rebates are disclosed, the FTC warns that this type of price transparency may "allow competitors to figure out what their rivals are charging, which dampens each competitor's incentive to offer a low price or increases the likelihood that they can coordinate on higher prices."[9] In the brand drug market, where a limited number of manufacturers offer similar products within a therapeutic class, net price transparency may cause these manufacturers to raise prices.

[9] Koslov, TI, Jex, E, "Price transparency or TMI?," Federal Trade Commission, July 2, 2015, *https://www.ftc.gov/news-events/blogs/competition-matters/2015/07/price-transparency-or-tmi.*

REBATES EFFECTIVELY OFFSET, RATHER THAN CAUSE, HIGH LIST PRICES

One of the key PBM levers for creating competition and value is drug rebates. A rebate is an after-the-fact (usually quarterly), percent reduction off the full list price of a drug given to the end purchaser whether that be a government entity, an employer or an insurer. They are a powerful tool used by PBMs to offset the list prices set by pharma. The 2018 Medicare Trustees' report credited PBM-negotiated rebates, in part, for bringing Part D spending lower than in the Trustees' 2017 Report.[10] Similarly, a recent Oliver Wyman study found that Part D plan-negotiated manufacturer rebates have resulted in $34.9 billion in premium savings for enrollees from 2014 to 2018.[11] As rebates are an effective tool to manage and mitigate pharma pricing behaviors for the benefit of plans and members, we strongly believe that they cannot and should not be curtailed or eliminated without viable, concrete and equally effective means of placing similar competitive pressure on manufacturers and holding them accountable for drug pricing.

While rebates are an important savings tool, they are not Prime's first consideration in making formulary recommendations. Prime's formulary selection process is tied to safety and efficacy consideration *before* accounting for competitive pricing. In considering competitive pricing, we take a "low net cost" approach: Prime will often forgo rebates on a certain drug in favor of a clinically equivalent, lower-cost medication. In Medicare Part D, Prime has more than a 90 percent generic dispensing rate, and generic drugs generally do not offer rebates. In situations in which a rebated drug is covered and rebates are earned, Prime's model is to pass back 100 percent of the value of rebates we negotiate to our clients.

The relationship of rebates to drug prices and the role of rebates is very much misunderstood. Prime disputes the idea that rebates are the primary cause of high list prices. Indeed, many drugs have high and significantly increasing list prices *without* offering any rebates. The HHS OIG found that 39 percent of Part D drugs offered no rebates in 2015.[12] Additionally, there are very limited rebates in Part B, and Part B has nonetheless seen significant price increases in the drugs the program covers, including drugs that increased in price from 2012 to 2017 by between 76 and 3,449 percent.[13] Pharmaceutical companies could lower list prices on these drugs today but have generally not chosen to do so. Where pharmaceutical companies have lowered list prices, there is generally little effect on net costs to the payer or the products are "minor."[14]

Instead of rebates making drugs less affordable, the lack of rebates for certain drugs makes them less affordable. In general, pharmaceutical manufacturers do *not* pay rebates on cancer drugs since plans typically do not implement traditional formulary management tools for these therapies. However, we continue to experience increases in price. As an example, in Medicare Part D in 2018, Prime's clients saw the greatest increase in spending for oral cancer drugs stemming from both an increase in price and utilization. The trend grew from 3.3 percent in 2017 to 19.4 percent in in 2018 for this class.

As this cancer example illustrates, there *is no correlation between rebate levels* and manufacturer list prices.[15] The determining factor of whether a given brand drug will offer a rebate is the competitiveness of the therapeutic class.[16] As MedPAC states in its March 2019 report:

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[10] *https://www.cms.gov/newsroom/press-releases/medicare-trustees-report-shows-lower-spending-projections-medicare-part-d.*

[11] Oliver Wyman, "Premium Impact of Removing Manufacturer Rebates From the Medicare Part D program," July 6, 2018, downloaded from *https://www.pcmanet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf.*

[12] HHS OIG, "Increases in Reimbursement for Brand-Name Drugs in Part D," Data Brief OEI–03–15–00080, June 4, 2018, downloaded from *https://oig.hhs.gov/oei/reports/oei-03-15-00080.asp.*

[13] Visante, "Reconsidering Drug Prices, Rebates, and PBMs," downloaded from *https://www.pcmanet.org/wp-content/uploads/2018/08/Reconsidering-Drug-Prices-Rebates-and-PBMs-08-09-18.pdf.*

[14] Thomas, Katie, "Merck Is Lowering Drug Prices. There's a Catch," *New York Times,* July 18, 2018, *https://www.nytimes.com/2018/07/19/health/merck-trump-drug-prices.html.*

[15] Visante, "Reconsidering Drug Prices, Rebates, and PBMs," downloaded from *https://www.pcmanet.org/wp-content/uploads/2018/08/Reconsidering-Drug-Prices-Rebates-and-PBMs-08-09-18.pdf.*

[16] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy,* March 2019, Chapter 14: "The Medicare prescription drug program (Part D): Status report."

> In general, the extent to which a manufacturer of a specific drug can raise its price depends on many factors—for example, whether there are generics or brand therapeutic alternatives, how many competitors there are in the given market, and whether their competitors cover all the same indications. Competition within a therapeutic class can result in restraint in list-price growth or in higher post sale rebates and discounts.

Where there is no competition in a therapeutic class or if a drug demonstrates clinical superiority over existing therapies, there may either be no rebate or just a very small rebate.[17] In Medicare's protected classes, plan sponsors have limited options to not cover or restrict access to certain drugs. When there are limited options to treat a specific disease state, PBMs have little ability to influence pharma pricing. Drugs in high-cost specialty classes like oncology, hemophilia, and hereditary angioedema generally do not have rebates. In classes where products are deemed clinically interchangeable, such as insulins, diabetes medications (SGLT, DPP–IV), and respiratory drugs to treat asthma and COPD, competition drives greater rebates that can be leveraged for the benefit of payers, members and beneficiaries.

One of the concerns over rebates is that patient cost-sharing in certain plan designs is determined by the list price of a drug rather than the net price. Over the past decade, the patient's role in sharing in prescription drug costs has evolved considerably. The advent of high-deductible health plans and greater use of coinsurance has increased the proportion of health-care costs consumers must pay out of pocket. While such benefit designs were intended to give beneficiaries more control, a very real consequence has been increased exposure to the extreme drug pricing behavior of manufacturers. Patients are justifiably frustrated with the unacceptably high drug prices and unjustified price increases set by pharma, which drive up their costs without providing additional health value.

Prime offers commercial health plan clients and employer groups the option to adjust the prices of drugs in their benefit plans to reflect rebate savings, including the option of applying the rebate savings at the point of sale when a member receives a prescription from a pharmacy. This plan offering allows members with high deductibles and coinsurance to benefit from rebates at the point of sale, but there is a trade-off between premiums and a point-of-sale rebates. Point-of-sale rebates help those who face high coinsurance or deductibles but may cause an increase in premium.

In the commercial market, the majority of members served by Prime are not affected by high list price influenced cost-sharing. They pay flat dollar copays rather than coinsurance (*i.e.,* a percentage of the list price). Indeed, only 1 percent of the commercial membership served by Prime is subject to coinsurance with no out-of-pocket maximum, while 56 percent of the members we serve are enrolled in plans with a flat copay without a deductible and 4 percent are in plans with a flat copay with low deductibles. Neither of these latter two groups are meaningfully affected by the list price of a drug.

Similarly, in Medicare Part D, many beneficiaries do not face significant cost-sharing. Cost-sharing is minimized for the 29 percent of Part D beneficiaries that receive low-income subsidies, also called "Extra Help," who pay flat, nominal amounts for drugs including brands.[18] Prime realizes that a small percentage of beneficiaries are challenged by the current Part D benefit design due to the high cost of certain medications. As MedPAC reports, in 2016, approximately 360,000 Part D beneficiaries filled a prescription for which a *single* claim would meet the maximum out-of-pocket threshold, up from 33,000 in 2010.[19] Prime welcomes the opportunities to work with policymakers, beneficiaries and plans to help Part D enrollees who face high cost-sharing. At the same time, we recognize that that Part D enrollees are very premium sensitive, and are generally pleased with their benefit: a recent nationwide survey found that 85 percent of Part D enrollees are satisfied with their Medicare Part D prescription drug coverage, with over 8 out of 10 also saying that their Part D plans provide "good value." The same survey research indicates that 78 percent of seniors feel that their copays and coinsurance are af-

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[17] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy,* March 2019, Chapter 14: "The Medicare prescription drug program (Part D): Status report."

[18] J. Cubanski, A. Damico, and T. Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing," May 17, 2018, downloaded from *https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/*.

[19] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy,* March 2019, Chapter 14: "The Medicare prescription drug program (Part D): Status report."

fordable.[20] Another recent survey of seniors in Part D found that they are satisfied with their out-of-pocket costs by a 67 percent to 30 percent margin.[21]

As we work towards policy solutions to further address high drug costs, we believe that the important role rebates play in managing cost requires careful study. The lack of a proven link between list price and rebates, the need for plan flexibility in designing benefits and keeping premiums low, and the need for an equally effective means of holding pharma accountable must all be considered before enacting measures that would mandate redirection or cause rebates to be curtailed or eliminated.

PRIME OFFERS POLICY SOLUTIONS

Prime welcomes the opportunity to partner with the committee and other Federal policymakers to advance initiatives to lower drug prices and improve health care. For instance, we support changes to anti-kickback law and Medicaid best price that would catalyze further value-based contracting and provide greater regulatory certainty around such contracts.

We believe that high list prices are the central issue driving the drug cost problem, and that PBMs are the most effective organizations capable of bringing down drug costs for payers and patients. An optimally competitive drug marketplace helps us to fully deploy our tools to lower costs for our plans, for their members and beneficiaries and for taxpayers. We therefore support such policies as:

- *Addressing Part D's protected classes:* Designating "classes of clinical concern" in Part D, where all or substantially all drugs in a class must be covered allows drug manufacturers to name their price. CMS already applies careful plan formulary coverage checks to assure proper coverage in all drug classes. Prime supports a CMS proposal to moderate the effect of protected classes—not eliminate them—that would save $2 billion over 10 years.[22]
- *Modify the requirement for two drugs per class.* The requirement that Part D plans cover two drugs per class is outmoded. It has encouraged manufacturers to argue for ever more granular classes and reduced competition, increasing Part D costs. Modifying the requirement by requiring plans to ensure access to therapies based on conditions or disease states instead would reduce costs without reducing access to needed drugs.
- *Apply Part D management tools to Part B drugs.* PBM tools such as value-based formularies, manufacturer negotiation, prior authorization, and step therapy have proven indispensable in improving patient safety and lowering costs in outpatient prescription drug plans like Part D. Adding Part D management tools to the Medicare fee-for-service program and building on efforts in Medicare Advantage for Part B drugs would make drugs more affordable on Medicare's medical side. We also believe policymakers should explore using economic value assessments to ensure that payments for drugs are based on cost savings and quality outcomes for patients.
- *Eliminate pay-for-delay agreements:* Patent settlements involving "pay-for-delay" agreements allow drug patent holders to pay off potential competitors who would otherwise produce a competing generic or biosimilar drug. These anti-competitive agreements should be eliminated.
- *End risk evaluation and mitigation strategy (REMS) abuses.* Brand drug manufacturers have withheld drug samples from would-be generic manufacturers by citing REMS compliance as an excuse. Enacting the CREATES Act or similar legislation would prohibit these abusive practices used by a small minority of brand drug manufacturers to keep competitors off the market.
- *Address orphan drug exclusivity abuses.* Orphan drug exclusivities are meant to encourage research into therapies to address rare diseases. However, the exclusivities afforded by orphan status have been abused. In fact, six of the eight best-selling biologic drugs in 2017 have orphan approvals, but the drugs have been widely used for non-orphan indications. Orphan exclusivity periods

[20] *http://medicaretoday.org/2018/08/85-percent-of-u-s-seniors-are-satisfied-with-their-medicare-part-d-prescription-drug-coverage-according-to-nationwide-survey/.*

[21] North Star Opinion Research, National Survey of Seniors Enrolled in Part D, March 2019, *https://www.pcmanet.org/wp-content/uploads/2019/03/NSO-PCMA-Senior-Part-D-Survey-Memo-March-6.pdf.*

[22] Owermohle, Sarah, *Politico Prescription Pulse,* "CMS Takes on 'Protected Classes in Part D,'" November 27, 2018, *https://www.politico.com/newsletters/prescription-pulse/2018/11/27/cms-takes-on-protected-classes-in-part-d-431017.*

should apply to only those drugs originally approved by FDA under an orphan indication and only for the orphan indication itself.

- *Tackle patent "ever-greening"* or patenting a small change in an existing drug to prevent generic competition. The advent of generic drugs, and particularly multiple generic drugs brings down drug prices, and ever-greening blocks this competition, keeping prices unnecessarily high. Brand patents should not result in near-permanent exclusivity.
- *Encourage faster FDA approval of "me-too" brands:* Increasingly the drugs FDA reviews and approves are reviewed under accelerated approval to address "unmet needs." The imperative for greater competition to lower drug prices should also be considered a type of unmet need.
- *Promote biosimilar interchangeability:* The FDA has yet to finalize guidance on interchangeability. Such guidance would allow substitution of biologics with biosimilars just as pharmacists do today with brand name drugs to lower costs for patients.
- *Eliminate the tax deduction for direct-to-consumer (DTC) drug ads.* While DTC drug ads may encourage some people to see a doctor, they drive up unnecessary utilization and the cost of drug benefits and often encourage patients to demand a brand name over a generic. Tax deductions should end for ads mentioning a specific product.

CONCLUSION

We appreciate the committee's interest in our perspectives on the problem of high drug costs, the role that PBMs and Prime play in helping to manage those costs, and our views on the issues of transparency, rebates and potential policy solutions that can effectively address the drug cost issue.

We believe that the clinical expertise and solutions we offer create significant value for our clients and their members and beneficiaries by ensuring that the right drugs are accessible and affordable, in the context of overall benefit designs, at the right time and for the right patients.

We are a unique PBM. We are owned solely by Blue plans and are designed to serve their needs through a transparent, lowest net cost model to enable them to serve their members and communities. We are hopeful that our perspective is useful in the dialogue and in leading to constructive solutions.

QUESTIONS SUBMITTED FOR THE RECORD TO MIKE KOLAR

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

COLLECTION, USE, AND SHARING OF PERSONAL HEALTH INFORMATION

Question. Consumers are becoming more and more concerned about the data collection and sharing practices of companies. While these issues have been most prevalent in the social media and tech industry, companies in the pharmaceutical supply chain also have access to tremendous amounts of sensitive, personal health information of the individuals they serve. For example, the company Livongo partners with CVS Caremark to provide low-cost or no-cost blood sugar meters to diabetic patients. The meters are always "connected" to Livongo's "Diabetes Response Specialists." As the company's website states, "When readings are out of range, our Diabetes Response Specialists call or text [the individual] within minutes." While these innovations may be highly beneficial for individuals in managing their health, it's also important for this committee to fully understand what types of information is collected, how or why it's stored or shared, and for what purposes PBMs themselves and other affiliated drug supply chain participants (such as insurers) use the information.

Health information is extremely sensitive. It's the most personal of all the information we share. So I want to know more about each of your companies' data collection, sharing, and protection practices.

Does your company collect and store health information from the end-users of the prescriptions you provide? For example, information or records of a diabetic individual's blood sugar levels.

Answer. Yes. While facilitating a patient's pharmacy benefit, Prime may receive and store protected health information about that patient. Prime has policies designed to ensure that any use or disclosure of health information occurs only as permitted by HIPAA and as directed by patients and Prime's health plan clients.

Question. Does your company make any treatment, cost, or coverage decisions based on the health information you collect from an individual?

Answer. Yes, we may make utilization management decisions in accordance with the health plan's pharmacy benefit. Such information can result in approval of a drug that had been subject to prior authorization thereby expediting patient access to appropriate therapy.

Question. Does your company share health information with third parties? And, if so, does your company profit from that sharing?

Answer. Yes to the first question and no to the second. Prime shares health information with third parties only as authorized by HIPAA and as necessary to facilitate services Prime provides to patients and Prime's health plan clients. Prime's customers contractually limit and control the ways in which Prime may use health information. Prime does not sell data, and does not profit from sharing data.

Question. Do you believe customers are fully aware of your information collection and sharing practices?

Answer. Yes. Prime is owned by many of its health plan customers. Prime's customers contractually limit the ways in which Prime may use health information.

IMPACT OF VERTICAL INTEGRATION BETWEEN PBMS AND INSURANCE COMPANIES

Question. The PBM industry has experienced significant consolidation within the past 10 years, which has contributed to concerns about the potential abuse of market power, barriers to market entry, and exclusionary practices. In 2012, for example, Express Scripts acquired Medco Health Solutions—a nearly $30-billion transaction that merged two of the country's three largest PBMs.[1] More recently, PBMs are also vertically integrating with insurers/payers, reflected by the 2018 acquisitions of Express Scripts Holding Co. (a PBM) by Cigna Corp. (a payer) and of Aetna Inc. (a payer) by CVS Health Corp. As a result, the three largest PBMs are all vertically integrated with insurance companies. According to a report from the Kaiser Family Foundation, the two combined entities, along with UnitedHealth and Humana, will cover 71 percent of all Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.[2] Vertical integration can result in increased efficiencies and consumer benefits. I can also, however, lead to higher barriers to entry for competition, leading to further consolidation. FDA Commissioner Scott Gottlieb recently warned that "consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious. And the very complexity and opacity of these schemes help to conceal their corrosion on our system—and their impact on patients."[3]

I'd like to talk about consolidation, including the recent integration of PBMs with insurance companies. Last year, I wrote to the Justice Department on this issue. It's reported that the three largest PBMs—who are before us today—now cover 71 percent of Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.[4] Such market power has raised concerns. FDA Commissioner Scott Gottlieb

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[1] *See* "FTC Closes Eight-Month Investigation of Express Scripts, Inc.'s Proposed Acquisition of Pharmacy Benefits Manager Medco Health Solutions, Inc.," Federal Trade Commission (April 2, 2012), available at *https://www.ftc.gov/news-events/press-releases/2012/04/ftc-closes-eight-month-investigation-express-scripts-incs.*

[2] Juliette Cubanski, Anthony Damico, and Tricia Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing" (May 17, 2018), available at *https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.*

[3] FDA Commissioner Scott Gottlieb, M.D., "Capturing the Benefits of Competition for Patients" (March 7, 2018), available at *https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm.*

[4] Juliette Cubanski, Anthony Damico, and Tricia Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing" (May 17, 2018), available at *https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.*

said, "the consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious."[5]

I want to hear briefly from each of you on whether the PBM industry is competitive. For example, are there high barriers to entry for new competitors?

Answer. Yes, the PBM industry is competitive. Despite consolidation, there continue to be more than 30 PBMs operating today in the U.S.[6] (not including the multitude of other related players, *e.g.,* specialty drug management carve-out vendors.) Additionally, new players regularly enter the market, including recent technology-focused PBMs like RxAdvance and SmithRx, in addition to Flipt in 2019.

Question. I'm also interested in what effect the most recent consolidations of PBMs and insurers has had on the bottom line for the government and consumer.

Do these arrangements result in a lower cost to the government—as a payer—and the consumer? Please explain.

Answer. The health-care industry is facing an unprecedented amount of change via a variety of market trends, all with the potential to both individually and jointly impact government and consumer costs. In addition to consolidation, other key market forces include: rising consumerism in health care, movement towards outcomes-based models, and adoption of new technologies—*e.g.,* artificial intelligence.

Given the varying intertwined market dynamics, it is nearly impossible to isolate the effects of consolidation. However, data shows PBMs have and are expected to continue to leverage strategies, including consolidation, to help control the rising cost of drugs.

Recent drug trend reports show that Prime and several other PBMs are controlling pharmacy costs at low, single-digit levels,[7] while health-care costs overall are inflating.[8]

Integrated Managed Care Organization (MCO) + PBM models are also aimed at creating more efficiency and driving to the lowest net cost of care. The recent wave of MCO + PBM consolidation is essentially aimed at attempting to duplicate the same integrated and cost-efficient Blue + Prime model that Prime pioneered over 20 years ago. Today, through organic growth and strategic alignment with other system players, this model continues to evolve and deliver high quality pharmacy benefit management and care while effectively controlling costs.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

MANUFACTURER MONEY

Question. What is the total dollar amount that you obtain from pharmaceutical manufacturers in any form such as rebates, fees, etc.?

What is the total dollar amount that you remit to health plans?

Answer. Prime's default business model passes through 100 percent of manufacturer rebates and administrative fees to clients, except in instances where clients have negotiated to have Prime retain a portion of manufacturer administrative fees to offset fees that Prime's clients pay it for PBM services.

BIOSIMILARS

Question. Managed Care Organizations are on record as widely supportive of the potential of biosimilars. However, most MCOs have continued to support originator brand products and have not preferred and often excluded less expensive biosimilars. For example, most MCOs have kept Remicade (a treatment for rheumatoid

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[5] FDA Commissioner Scott Gottlieb, M.D., "Capturing the Benefits of Competition for Patients" (March 7, 2018), available at *https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm.*

[6] Drug Channels Institute (2019, March), The 2019 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers.

[7] Drug Channels Institute (May 22, 2019), "Which PBM best managed drug spending in 2018: CVS Health, Express Scripts, MedImpact, or Prime Therapeutics?" Retrieved from *https://www.drugchannels.net/2019/05/which-pbm-best-managed-drug-spending-in.html*.

[8] PwC Health Research Institute (June 2018), "Medical cost trend: behind the numbers." Retrieved from *https://www.pwc.com/us/en/industries/health-industries/library/behind-the-numbers.html.*

arthritis and other diseases) as the preferred agent on their formularies, and in most cases to the exclusion of its biosimilar, Infliximab.

Why do you tout support for biosimilars while, at the same time, inhibiting adoption of these less expensive products?

Answer. Prime has encouraged the use of biosimilars. Prime manages drugs to the lowest net cost for our health plans, and there may be instances where biosimilars will not be the lowest net cost product.

Biosimilars are treated the same way as brands for purposes of formulary consideration (*e.g.,* evaluated for safety, efficacy, and then for lowest net cost and member transition considerations).

Other factors outside a PBM's control often inhibit adoption of less expensive products such as regulations (*e.g.,* interchangeability, step therapy rules), provider buy-and-bill practices, patient acceptance, and prescriber practices.

The FDA has just recently approved final guidance on interchangeability. Only one manufacturer has submitted an application for this designation. Without interchangeability designation, a provider must write a prescription for a specific biosimilar product. This slows adoption of biosimilar use. Furthermore, many biosimilar agents are indicated for chronic conditions, where patients have been stable on the branded product for many years. Patients and physicians, alike, are resistant to the idea of switching stable patients to a different therapy, even biosimilars.

Step Therapy Legislation: If the review of a medical policy or utilization management policy results in an approval of a branded product for a certain timeframe, it can be difficult to switch patients while they are covered under that approval. Without an interchangeability designation, each product must be considered a unique brand and the patient can remain on that therapy for the duration of the policy approval. This too, slows the adoption of biosimilar use. In addition, some States have enacted step therapy mandates that prohibit plans from requiring members to utilize low-cost effective medications prior to being approved on high cost branded medications.

Physician buy-and-bill contracts: Physician groups often have their own contracts with manufacturers. If their billing practices make it more lucrative to dispense the brand, it can be difficult to move market share.

Question. HHS may broaden the scope of its proposed rule and eliminate rebates between Medicare Advantage plans and manufacturers for Part B drugs.

Would this realign incentives to encourage preferred access for lower-cost drugs, such as biosimilars?

Answer. No, the removal of rebates will not encourage access to lower-cost drugs because there is no guarantee that pharma will lower their list prices. Prime will always recommend the lowest net cost drug inclusive of rebates.

Question. What changes can we recommend/make to help you prefer lower-cost drugs, such as biosimilars, without rebates?

Answer. Prime would support the following changes to increase the adoption of lower cost biosimilar drugs by its health plan clients:

(1) Interchangeability: Designation being granted upon biosimilar drug approval.

(2) Removal of the following anti-competitive practices that delay biosimilars from coming to market: (a) pay-for-delay deals between brand and biosimilar manufacturers (currently there are pay-for-delay deals between brand and biosimilar manufacturers; (b) patent thickets; (c) branded manufacturers preventing biosimilar manufacturers from obtaining samples for testing; and (d) sham citizen petitions.

Question. Why is there such a disparity in reimbursed pharmacy prices for specialty generic drugs in Part D (*e.g.,* Imatinib)? Does ownership of specialty pharmacy influence your reimbursement decision?

Answer. Under CMS guidelines there is no current definition of a "specialty pharmacy," which means that any pharmacy regardless of pharmacy type, services offered or accreditation may dispense a specialty medication.

While Medicare guidelines require standard terms and conditions for pharmacies to participate in a Medicare network, the CMS guidelines do not require each pharmacy to agree to the same financial terms. In fact, CMS has acknowledged that

pharmacies may have different financial terms due to their purchasing power or rural location.

Prime has implemented a specialty fee schedule for medications dispensed by participating network pharmacies that aligns with the pricing that Prime negotiated with the specialty pharmacy in which Prime has joint ownership. Many pharmacies in the retail network have refused to agree to the additional specialty drug fee schedule and therefore are reimbursed at their retail rates. Prime's pharmacy agreement outlines reimbursement for any drug dispensed by the pharmacy and not the type of drug (specialty or traditional) in the situation when the pharmacy did not agree to the specialty drug fee schedule. The negotiation schedule also varies with pharmacies based upon each pharmacy's renewal date which can create variability in pricing.

In addition, Prime's agreement with pharmacies establishes that Prime will pay the pharmacy the lesser of the (a) pharmacy's usual and customary price; (b) the pharmacy's submitted cost plus dispensing fee; (c) the maximum allowable cost plus a dispensing fee; or (d) the negotiated price plus a dispensing fee. Prime's goal is to ensure that the member pays the lowest price (amount) possible. Therefore, depending upon how the pharmacy prices the drug and our lesser of logic, the same drug may be reimbursed differently by the pharmacy.

Prime's goal is always to offer the lowest net cost to our clients, members and health plans. Prime implemented a specialty drug fee schedule for medications dispensed by a participating network pharmacy that was in addition to our standard financial terms that would align with the pricing that Prime negotiated with the specialty pharmacy in which Prime has joint ownership. In fact, Prime's joint ownership of a specialty pharmacy enables Prime to have clearer insight into the marketplace pricing of a drug by manufacturers and wholesalers to establish pricing models that are effective for members, health plans and pharmacies.

Question. I'm concerned with the recent trend of PBM's allowing brand companies to "pay for position" on insurance formularies, which results in seniors losing access to lower-cost generics and biosimilars.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs?

Answer. Prime's clients may exclude generic or biosimilar competitors from a formulary if there are safety concerns or the generics or biosimilars are not the lowest net cost relative to the brand or base biologic.

With regards to high-cost generics, formulary evaluation of new-to-market generics is the same as the evaluation for any new drug. The Pharmacy and Therapeutics (P&T) Committee considers safety, efficacy, and uniqueness, and then the drug is evaluated based on cost. In certain circumstances, the net cost of a generic drugs may be significantly higher than the brand because of the lack of generic competition in the market. In these circumstances, the generic may be placed at a higher tier than the brand until more lower cost generic competition is available to avoid an increase in cost to the health plan. Once the generic is available at a lower cost than the brand, the health plan may add the generic to formulary or the drug tier lowered. In these scenarios members pay the lowest net cost, regardless of brand or generic status and the tier placement of the medication. Thus, the plan ensures the most cost-effective medication at the best price is available to the member. With regards to medications with potential safety concerns, brand and generic medications may be excluded to minimize adverse health outcomes and encourage the use of clinically effective safer alternatives available.

DELAYS AND DENIALS IN CANCER TREATMENT

Question. I have received stories of cancer patients facing delays or denials for their treatment due to PBM actions. Data shows that breast cancer patients who experienced a 3-month or more delay in treatment had a 12-percent lower 5-year survival rate compared with breast cancer patients with only a 0- to 3-month delay.

What percent of patients experience a 14-day or longer delay in receiving an oral oncolytic prescribed by their oncologist?

Answer. When medications are subject to prior authorization, reviews are completed and decisions rendered, on average, within 4 days for standard requests and 1 day for request marked as urgent. Outcomes are communicated to the providers

either through electronic prior authorization (ePA) or fax over 95 percent of the time.

Question. What are the primary reasons patients experience delays or denials for their treatments?

Answer. The primary reasons a patient may experience delays include off-label, non-FDA approved use or for use in cancers that are not addressed in guidelines. Our health plan clients' utilization management policies allow for use of oncology medications for indications approved in FDA labeling and/or supported by National Comprehensive Cancer Network (NCCN), Drugs and Biologics compendia with a category 1 or 2A recommendation, AHFS *(http://www.ahfsdruginformation.com/about-us/),* or DrugDex level of evidence of 1 or 2A.

Question. What percent of determinations to delay or deny treatment for cancer patients are made by an oncologist or health-care professional with oncology training?

Answer. Any determination or delay in care is based on the formulary and utilization management for drug safety and efficacy concerns and published FDA appropriate uses for the drug (*i.e.,* either label or recognized compendia). In general, initial reviews are not specifically reviewed by an oncology specialist. A specialist will review any appeal level of review.

Question. Why is a PBM-owned specialty pharmacy better qualified to manage a cancer patient's adherence and side effects than a community cancer clinic with a medically integrated pharmacy?

Answer. The PBM-owned specialty pharmacy has view of all the members medications via data from the PBM; this gives a comprehensive view of the member that may have additional issues other than cancer and seeing multiple physicians. A larger national based pharmacy such as a PBM-owned specialty pharmacy will use clinically reviewed assessment algorithms to address side effects and to track adherence and also work very closely with the drug manufacture in reporting back any trends that may be seen with a broad number of patients. The pharmacy can also update the teaching and training for the member based on new information being reviewed. Oncology centers should have oral oncology medication management practices (education, toxicity management, financial, etc.) in place for these patients, regardless of where care is delivered as part of both nursing and oncologist society quality measures standards. Depending on resources, the extent and quality of those services vary greatly. This is where a specialty pharmacy can consistently delivery these resources to every patient. Increasing touch points and access to healthcare providers for these services to patients, especially education, only enhances the care being delivered.

DIRECT AND INDIRECT REMUNERATION (DIR) FEES

Question. Many community-based cancer clinics have established medically integrated pharmacies so patients can access their oral chemotherapy prescriptions or other medications at the point of care. These practices are often assessed large DIR which are based on certain quality measures targeted toward primary care.

Shouldn't pharmacies be evaluated on the type of drug dispensed and disease managed rather than a one-size fits-all approach?

Answer. Under current law, there is no easy way to distinguish among types of pharmacies. CMS regulations allow any participating pharmacy in a Part D plan's Medicare network to dispense both traditional (non-specialty) and specialty medications. Prime's pharmacy price concessions models (DIR) applies the same metrics to all participating pharmacies in our Medicare networks to be consistent with the CMS any willing provider provisions. Therefore, a specialty pharmacy that participates in Prime's Medicare network must meet the same terms and conditions as a non-specialty pharmacy.

Question. Does assessing large DIR fees on medically integrated pharmacies drive patients to PBM-owned specialty pharmacies?

Answer. No. Most patients pay fixed copayments amounts for the patient cost share portion and these copayments do not vary by pharmacy. In addition, if the patient utilizes an out of network pharmacy, the patient may pay more as there are no contracted negotiated prices with an out of network pharmacy.

Question. According to CMS, from 2012 to 2017 PBMs imposed a 45,000 percent increase in the amount of DIR fees pharmacies had to pay PBMs and PDPs under

Part D, and revenues earned from these fees increased 225 percent per year during this period.[9] I thought PDPs and PBMs were supposed to pay pharmacies for dispensing drugs to patients. Why do pharmacies have to pay DIR fees to PBMs at all?

Why are pharmacies forced to pay DIR and other fees to PBMs?

Answer. DIR is a technical term created by CMS that is specific to the Medicare Part D program to account for performance and quality measures that cannot be reasonably determined at point of sale (POS)—*i.e.,* at the time a medicine is dispensed. DIR is reported to CMS after the contract year to which the DIR relates. As a performance-based assessment program, DIR helps drive high quality clinical and pharmacy performance. Metrics vary but can include generic dispensing rates, medication adherence, reducing inappropriate drug use (such as high-risk medicines *e.g.,* controlled substances), diabetes disease management, audit performance and error rates, cost-effective dispensing rates, and align with Medicare Star Ratings that Part D plans are held to. CMS annually issues DIR reporting guidance and provides careful oversight to the program. DIR fees are utilized for quality programs including lower member premiums by the plan. Prime passes 100 percent of the DIR fee to the health plan and the DIR fee is reported to CMS. DIR fees are part of the larger movement to measure quality across the provider spectrum of care.

Question. According to CMS, PBMs justify DIR fees as adjustments to improve quality. CMS also found that PBMs and PDPs withhold substantially more in reductions in payments than as rewards paid to pharmacies.[10] Aren't so-called "quality adjustments" that collect more for "poor performance" than they pay out for "high performance" just another way for PBMs to collect even more money from pharmacies?

Why do PBMs collect more in quality payment adjustment than they pay pharmacies under Part D?

Answer. For Prime's clients, there are many claims where less is taken in pharmacy adjustments than what the pharmacies are paid under Part D. There are some low-cost claims, where more is collected than they were paid, and lastly, there are some claims paid at Usual and Customary Rates, where no DIR adjustments are made.

DIR fees help to reduce premiums and improve quality. A 2017 Milliman report, "Value of Direct and Indirect Remuneration (DIR): Impact on Medicare Part D Prescription Drug Plan (PDP) Program Stakeholders" found that by encouraging pharmacies to meet contractual "pay-for-performance" standards based on measures such as the generic dispensing rate (GDR), pharmacy DIR can have a significant effect on savings. For instance, a one percentage point increase in the GDR for prescription drug plans would have saved the Part D program and its beneficiaries an estimated $15.3 billion since the inception of the program. Over the next 10 years, that savings increases to an estimated $68.9 billion for a 1 percentage-point improvement in the GDR. Gaps in the standards of quality and treatment patients receive ultimately increases the burden of illness and health costs nationwide.

FORMULARY PLACEMENT/GENERIC TIERING

Question. In 2011, 71 percent of generic drugs in Part D were on the lowest tier designed for generics; by 2019, that number decreased to only 14 percent of generics. According to an Avalere study, this practice cost seniors $22 billion in higher out-of-pocket costs since 2015, costs that could have been avoided through the proper formulary placement of lower-cost generics. This practice, known as "paying for position," allows brands to block uptake of lower-cost generics and biosimilars, thereby unnecessarily increasing out-of-pocket costs for seniors.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs? Do you ever consider portfolio or bundled rebates with brand manufacturers?

Answer. Prime evaluates *all* drugs including new-to-market generics for clinical efficacy, safety, and member transition issues before considering costs. Prime's clients may exclude and/or place drugs on higher tiers based on cost or safety con-

[9] CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152, 62174 (November 30, 2018).
[10] *Id.* at 62174.

cerns. In certain circumstances, generic drugs remain at a higher net cost relative to the brand due to a lack of generic competition. In these instances, Prime may recommend to our clients that the generic be delayed until more lower cost generic competition is available. Once the generic is available at a lower cost than the brand, the generic is added to formulary. In scenarios where the brand is preferred over the generic Prime recommends that the member's cost share for the brand is set equal to the lower generic cost sharing tier. Prime may consider the added incremental benefit from a package of drugs, but this bundling is not a primary driver of decision-making.

Question. When you place generics on your formularies, do you place that generic favorably to brand products—in other words, on generic-only tiers?

Answer. Prime evaluates all drugs including generics for clinical efficacy, safety and member transition issues before considering costs. Generics are generally given a favorable status over their brand counterpart on Prime's clients' formularies assuming that they are the lower net cost products.

Question. When a generic becomes available, do you place it on your formularies immediately?

Answer. Formulary placement of a new generic product will depend on whether or not the brand is currently covered on the formulary. If the branded product is currently on formulary, the generic is immediately added if it is available at a lower net cost to the plan. If the branded product has been excluded or non-formulary, the generic would also not be available until it is reviewed by the P&T Committee. In scenarios where the brand is preferred over the generic Prime recommends that the member's cost share for the brand is set equal to the lower generic cost sharing tier.

QUESTION SUBMITTED BY HON. JOHN THUNE

Question. You've all shared your ability to leverage technology such as real-time benefit tools to help patients and providers understand drug costs at the point of prescribing, as well as how technology can be used to help identify opportunities to provide enhanced support and medication management for enrollees. What policies can we consider to incentivize greater uptake of these tools?

Answer. On May 23, 2019, CMS released a final Part D rule, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out of Pocket Expenses" (CMS–4180–F) requiring all Medicare plans to have a real-time benefit tool in place and connected to one EHR by January 1, 2021. This is a great start for Medicare but many additional steps are necessary to ensure universal access, interoperability, and adoption.

Additional policy is necessary to require accessibility of real time benefit tools across Medicare, Medicaid, Commercial, and Marketplace plans so all citizens can benefit from the technology. The Medicare rule sets a threshold requiring connectivity to one EHR. Members whose providers use other EHRs will not have access to the information. There are no requirements in the rule to ensure access at the members preferred provider or to require provider group connectivity to a solution. This may limit the availability of information at the point of prescribing. Developing these connectivity requirements would ensure that plans are connected to the EHR systems and provider groups that their members use.

Interoperability is a challenge in the current environment because the plan/PBM must establish connectivity with multiple vendors due to exclusivity contracts that are in place between EHRs and vendors that provide real time benefit inquiry solutions. To provide thorough and complete access to all beneficiaries at any physician they choose, PBMs will need to contract and connect to many vendors. Limiting the use of exclusivity agreements and clearly defining connectivity and access requirements is necessary.

The largest barrier to adoption at the provider level is inconsistent and inaccurate information being presented at the point of prescribing. This issue is the result of varying proprietary methods of real time benefit inquiry that exist in the industry. Mandating provider and plan use of the National Council for Prescription Drug Programs, (NCPDP) standard for real time benefit check currently in development would ensure all relevant information is presented in real time including: coverage, pricing for the selected drug, therapeutic alternatives, and alternate pharmacy channels. Standardization would allow the use of real time benefit information to

be measured so providers can be incentivized to act on the information and prescribe the lowest-cost drug.

QUESTIONS SUBMITTED BY HON. RICHARD BURR

Question. Pharmacy benefit managers (PBMs) offer a variety of contract designs to health insurance plans, allowing the insurer or client to choose the best structure for their customers. During the Finance Committee hearing on April 9, 2019, each witness stated that, in the contracts structured to allow for the passthrough of rebate dollars at the point of sale, PBMs do not keep *any* portion of the rebate. If the PBM does not keep a portion of the rebate, what type of revenue do PBMs receive from these contracts? What percent of your contracts are point of sale and what percent utilize a structure providing a percentage of the rebate back to the PBM?

Answer. Prime offers commercial health plan clients and employer groups the option to adjust the prices of drugs in their benefit plans to reflect rebate savings, including the option of applying the rebate savings at the point of sale when a member receives a prescription from a pharmacy. When clients deploy a partial POS rebate, Prime's general practice is to return the remainder of the rebate to the client. As Prime's general business model to pass through all revenue received from manufacturers to clients, Prime's primary source of revenue is client administrative fees. However, in some cases, clients have negotiated to have Prime retain a portion of manufacturer administrative fees to offset fees that Prime's clients pay it for PBM services.

In the commercial market, the majority of members served by Prime are not affected by high list price influenced cost-sharing. They pay flat dollar copays rather than coinsurance (*i.e.,* a percentage of the list price). Indeed, only 1 percent of the commercial membership served by Prime is subject to coinsurance with no out of pocket maximum, while 56 percent of the members we serve are enrolled in plans with a flat copay without a deductible and 4 percent are in plans with a flat copay with low deductibles. Neither of these latter two groups are meaningfully affected by the list price of a drug.

Similarly, in Medicare Part D, many beneficiaries do not face significant cost sharing. Cost sharing is minimized for the 29 percent of Part D beneficiaries that receive low-income subsidies, also called "Extra Help," who pay flat, nominal amounts for drugs including brands.

It is Prime's business model to pass back 100 percent of the manufacturer rebates we negotiate to our health plan clients. For some clients we may retain a portion of the rebates in lieu of a higher administrative fee. Clients use these rebates to help offset premiums. If a client chooses to offer POS rebates directly to all or any subset of their members, that is the client's decision. POS rebates are a newer offering and currently only a couple of our clients have chosen to adopt our POS product. While the majority of plan sponsors continue to use rebates as an effective mechanism to control premium costs or reducing costs for all members through benefit designs such as lower copays, POS rebates are used by approximately 5 percent of our commercial clients' members today. It presents flexibility and an alternative for those who want to do to so. However, it should be noted that not all branded drugs receive rebates, so the reduced pricing is limited to select brand medications and not every member may realize the benefits. Currently, we do not have a POS rebate option in Medicare Part D.

Question. It is our understanding that contracts with pharmaceutical manufacturers may also take a variety of forms. In calendar years 2016, 2017 and 2018, what was the total dollar amount that you obtained from pharmaceutical manufacturers in any form such as rebates, fees, etc.? What is the total dollar amount that was passed on to health insurance plans with which you have an agreement or contract?

Answer. This question requests proprietary data. Prime's default business model passes thru 100 percent of manufacturer rebates and administrative fees to clients, except in instances where clients have negotiated to have Prime retain a portion of manufacturer administrative fees to offset fees that Prime's clients pay it for PBM services.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. One challenge that I see, when considering the medical treatment marketplace, is that we have a new wave of life-saving treatments—of incredible cures we could never have dreamed of, even 10 or 15 years ago—for which cost, by necessity, is going to be a major issue. You look, for instance, at a condition like sickle cell disease. For the average SCD patient who reaches age 45, lifetime treatment costs are at roughly $1 million—and there are complications that can make that figure even higher. Now that we see therapies coming down the pipeline that could erase those long-term costs and drastically improve the quality of life for sickle cell patients, the question becomes, how can our current payment systems adapt to—and absorb—the high costs necessary to bring treatments like these to market and to ensure that we continue to see innovations like these ones moving forward?

Answer. Prime believes value based agreements (VBA) are a promising approach to ensuring high cost treatment, especially one-time treatments like gene therapies, are bringing value commensurate to the price. As these high cost therapies have unknown durability and long-term safety, VBAs that allow for a value warranty ameliorate some of the price to value concern and create acceptability for the up-front high cost. In developing VBAs, Prime engages all aspects of member care such as health monitoring/diagnostic testing, appropriate therapy, adherence, health outcomes, and total cost of care. However, current Medicaid best price rules and limited anti-kickback safe harbors restrain and limit the value of these arrangements. We recommend Congress and/or HHS create a VBA safe harbor to protect innovative, value based arrangements and address the Medicaid best price rules.

A potential adaptation of the current payment system for high cost one-time treatments is to have separate federally subsidized program like those created for End Stage Renal Disease and Vaccination Injury Compensation Program. These programs ensure continued access to life saving vaccines and dialysis, when costs are substantial.

Another potential adaptation is the "Netflix" model, in which a single-source manufacturer is contracted to provide a specific drug to an entire population's utilization in exchange for a monthly capitated payment set using a baseline utilization rate. This model also employs a manufacturer rebate to reimburse the contracting entity for claim payments exceeding the capitated rate. This model is actively being piloted in Medicaid State programs in Louisiana and Washington State. Application outside of Medicaid may require an exemption from Medicaid Best Price calculation.

Question. And along the same lines, beyond creating some much-needed clarity around value-based arrangements—which I've been working with Senators Cassidy and Warner to accomplish legislatively—are there steps that Congress could take to facilitate these innovative payment models?

Answer. Please see response to the previous question. In summary, Prime requests VBAs be exempt from Medicaid Best Price calculations or a Medicaid Best Price Safe Harbor be created. Currently, there is no anti-kickback statue safe harbor or Medicaid Best Price safe harbor for VBA. We urge you to have the HHS create safe harbors, or for Congress to enact legislation allowing exempting VBAs from anti-kickback statutes and Medicaid Best Price calculations.

Question. I'm also interested in the role that technology can play in helping to drive down drug costs—as well as to increase medication adherence. Some estimates suggest that between 50 and 75 percent of patients don't take their medications as prescribed, and that one in five new prescriptions go unfilled. And study after study shows that cost is a key factor here. As a consequence, we see roughly 125,000 deaths from non-adherence every year, along with more than $100 billion in excess costs to the health-care system. To what extent can technology help providers and patients to make more informed and cost-effective choices about prescriptions—and to then adhere to these prescriptions?

Answer. Prime is using technology to provide real time, member-specific benefit coverage and drug cost information to providers, patients and pharmacists, helping all of them make better, more cost-effective decisions. Specifically, for new prescriptions, patients can use smart phone or web sites to access their own benefit plan, see if a particular drug is covered and, if so, at what amount they will have to pay out of pocket and what price they will pay at local pharmacies or via mail order. From this electronic source, patients can evaluate what a drug would cost if it were filled today—and see any other lower cost, covered drugs that might also be available under their benefit plan. When doctors go to start a new prescription for a patient, Real Time Benefit Check (RTBC) will show the member specific coverage and

benefit information for the selected drug, as well as for therapeutic alternatives that may also be covered. By presenting lower cost, covered drugs and the cost associated with each, prescribers can also help save cost for their patients and the insurance payers.

For existing prescriptions, before a scheduled doctor appointment, Prime evaluates the complete list of drugs taken by that patient, looking for lower cost options that are covered by the patient's benefit plan. The doctor is sent a report of drug savings opportunities, based on that member's drug list. Then, during that patient's appointment the doctor can review this with the patient and assess (and make) changes based on the lower cost covered drugs that address the member's condition.

Prime is piloting technology to proactively review long term prescriptions to assess if lower cost options might be available for patients. If a lower cost alternative is found, then the savings opportunity is presented to the patient—who can request their prescription be changed to the new, lower cost drug.

Technology makes it easier for patients and providers to track adherence to medications. One tool Prime is testing shows a member's cost share and any additional steps needed for filling the original or alternative drug, enabling providers to discuss options with members and make informed decisions together at the point of care. This technology helps providers select the most cost-effective drug the first time and helps members better manage their drug spend. Providing everyone in the delivery system with access to real-time prescription cost and benefit information can not only reduce unnecessary cost surprises when filling a prescription, but it can also drive medication adherence.

Question. And maybe more to the point, to the extent that these technological tools are out there, what steps are you and your clients taking to encourage physicians and patients to use them?

Answer. Prime is making prescribers and the health systems aware of the tools we offer, encouraging adoption of the technology. We work with our clients and partners to communicate the technology offerings described in response to Senator Scott's question above. In addition, Prime is training patients and providers on the new technology and the benefits of using the technology, and lastly Prime offers incentives to some provider groups via performance based incentives around medication adherence, lowering cost of care and drug spend. Where applicable, these tools are added incentives for providers to participate and utilize technology cost savings tools like these.

QUESTIONS SUBMITTED BY HON. BILL CASSIDY

Question. Are there ever cases where a patient in your health plan or one of the health plans for whom you negotiate as a PBM pays more for a medicine than the plan spends on a net basis, when you reimburse the pharmacy for that same medicine? In those cases, what entity receives the benefit of the difference between the amount the patient pays and the net amount the plan pays?

Answer. Yes, depending on the benefit design there may be situations where a patient pays more for a medicine than the plan spends on the net basis. In those cases, the health plan receives the full benefit of the difference that can be used to manage premiums, benefit design and member programs.

Question. In calendar years 2015, 2016, and 2017, what percent of your revenue was from fees paid by plans, fees paid by manufacturers, other fees, pharmacy spread, or rebates? Same question as to profits. Of all revenue generated from part D contracts, what percent did you retain?

Answer. Part D regulations require all pharmacy discounts and all rebates be accounted for in what the plan paid the PBM. The pharmacy paid amount, by regulation, matches the amount charge to the plan (pass through). All rebates are reported on the annual DIR report that plans submit to CMS. CMS audits plans' financials, including the administrative fees charged to plan clients.

Question. Should a patient ever pay more out of pocket for a medicine than what you pay the pharmacy for that medicine?

Answer. Depending on the benefit design there may be situations where a patient pays more for a medicine than the plan spends on the net basis. In those cases, the health plan receives the full benefit of the difference that can be used to manage premiums, benefit design and member programs.

Question. PBM revenue from fees has risen, illustrated below. Further, PBM's retained revenue as a percent of net retail drug spend has consistently increased. What do you attribute this increase to?

Answer. As drug costs have risen, PBM fees have generally increased because they are a percent of a higher number. Prime is not focused on generating revenue, but on generating savings, and our default model is to pass 100 percent of rebates back to our owner clients.

Question. How are bona fide service fees established? What was your revenue generated in part D by bona fide fees in 2015, 2016, and 2017?

Answer. Prime does not collect any bona fide services fees in Part D. All manufacturer administrative fees are reported as DIR because they are passed back to clients directly or indirectly in lieu of higher PBM administrative fees.

Question. A *Health Affairs* article suggests plans may prefer paying PBMs using rebates instead of fees, as "Using retained rebates to cover PBM costs in lieu of fees could artificially lower reported administrative costs and make it easier to meet government medical loss ratio (MLR) requirements." Is it true that paying the PBM a percent of rebates would keep that revenue from counting towards a plan's MLR?

Answer. Prime is not a health plan and not in a position to comment on internal MLR accounting matters.

Question. Would you support an industry-wide standard set of performance metrics by which a PBM would set its pharmacy contracts, which would be tailored based on regional patient populations, to give certainty for local pharmacies?

Answer. Prime would support the implementation of a standard set of quality measures using the Pharmacy Quality Alliance as the measure steward. See *https://www.pqaalliance.org/our-story* for more information about PQA and its multi-stakeholder membership. PQA is a public-private partnership with CMS. However, the PQA measures should be considered a standard baseline measure set and not prevent plans from competing on other measures that would encourage plans' development of innovative contracting strategies and experimenting with additional measures that can improve quality.

Prime values measuring a pharmacy's quality performance to determine the pharmacy's effective management of their patients on such metrics as medication adherence, cost management, and health outcomes. We currently utilize the PQA measures for measuring and monitoring a pharmacy's quality performance. The pharmacy performance results on these PQA measures determine the amount of pharmacy price concessions that a pharmacy pays as well as the amount of incentive payments that a pharmacy receives from a plan.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

Question. In Medicare Part D, beneficiaries' deductible and coinsurance payments are calculated based on the price negotiated between the PBM and the pharmacy.

Does this take into account rebates and discounts the PBM negotiates separately with pharmaceutical manufacturers?

If yes, what percentage of the time is this the case?

Answer. No, given the retrospective nature of rebates, the deductible and coinsurance does not take into account rebates and discounts the PBM negotiates separately with pharmaceutical manufacturers.

Question. In calendar years 2016, 2017, and 2018, what share of brand prescriptions covered by the Part D plans you contract with were filled in the deductible or required beneficiaries to pay coinsurance? What was the total amount beneficiaries spent out-of-pocket for those prescriptions? What would beneficiaries' total out-of-pocket spending have been under the same cost sharing structure if their payments were based on the net price to the Part D plan, inclusive of rebates and other price concessions, rather than the price negotiated between your PBM and the pharmacy?

Answer. In calendar year 2016, based on the standard CMS Part D Benefit, 100 percent of brand prescriptions filled required a member to pay a copay or coinsurance. Of all prescriptions filled, 10 percent were brand. The total amount of beneficiaries' out-of-pocket spend for those prescriptions accounted for $635 million in drug spend. The beneficiaries out of pocket spend based on the net price to Prime

would have been $519 million. This accounts for an 18.4-percent decrease in cost per Rx, reducing the cost from $564 to $460.

In calendar year 2017, based on the standard CMS Part D Benefit, 100 percent of brand prescriptions filled required a member to pay a copay or coinsurance. Of all prescriptions filled, 9 percent were brand prescriptions. The total amount of beneficiaries' out-of-pocket spend for those prescriptions accounted for $689 million in drug spend. The beneficiaries out of pocket spend based on the net price to Prime would have been $555 million. This accounts for a 19.5-percent decrease in cost per Rx, reducing the cost from $637 to $513.

In calendar year 2018, based on the standard CMS Part D Benefit, 100 percent of brand prescriptions filled required a member to pay a copay or coinsurance. Of all prescriptions filled, 9 percent were brand prescriptions. The total amount of beneficiaries' out-of-pocket spend for those prescriptions accounted for $724 million in drug spend. The beneficiaries out of pocket spend based on the net price to Prime would have been $562 million. This accounts for a 22.4-percent decrease in cost per Rx, reducing the cost from $698 to $542.

QUESTIONS SUBMITTED BY HON. RON WYDEN

SPREAD PRICING IN MEDICAID

Question. A PBM practice that has come up quite a bit recently is the practice of spread pricing. Spread pricing occurs when PBMs charge health plans more for prescription drugs than they actually reimburse pharmacies, and then pocket the different as profit.

Do you engage in spread pricing practices?

Answer. We do not engage in spread pricing in Medicaid.

REBATE DEMANDS

Question. The use of rebates as a negotiating tool has led to problematic incentives in the prescription drug supply chain. For example, drug companies have argued that they increase list prices in response to demands from PBMs for high or increasing rebates.

Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that:

Require equivalent rebates, even in the case of a drug for which the list price has been lowered.

Answer. No.

Question. Require advance notice of changes in the list price of drugs, including reductions or increases in list price?

Answer. No.

REVENUE SOURCES

Question. Please provide an annual breakdown of the following components of the revenue you received from drug manufacturers from January 1, 2013 through December 31, 2018: dollar amount and percent of revenue from rebates; dollar amount and percent of revenue from administrative fees; dollar amount and percent of revenue from distribution fees; dollar amount and percent of revenue from marketing fees; dollar amount and percent of revenue from clinical case management fees; and all other sources of revenue from manufacturers not listed above.

Answer. The answers to these questions require proprietary data.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Should the CREATES Act become law, what commitment can your company making to covering generics as soon as they are approved and passing those savings on to patients?

Answer. Prime has long supported the CREATES Act. Prime evaluates all drugs including new to market generics for clinical efficacy, safety and member transition

issues before considering costs, in the context of their impact to health plan costs and the premiums their members pay. In certain circumstances, generic drugs remain at a higher tier relative to the brand due to a lack of generic competition and significantly higher price point. In these instances, Prime may recommend to our clients that the generic be maintained at a higher tier or excluded until more lower cost generic competition is available to avoid an increase in member premiums. Once the generic is available at a lower cost than the brand, the generic is added to formulary or the drug tier lowered. In these scenarios members pay the lowest net cost, regardless of brand or generic status and the tier placement of the medication. Thus, the plan ensures the most cost-effective medication at the best price is available to the member. With regards to medications with potential safety concerns, brand and generic medications may be placed on a higher tier or excluded to minimize adverse health outcomes and encourage the use of clinically effective safer alternatives available.

Question. What are your concerns with point-of-sale rebates, and what alternatives do you propose to such rebates to improve consumer savings at the pharmacy counter?

Answer. If the full value of the rebate is passed on, there is the potential for pharmaceutical competitors to determine the value of a rebate given by competitors and create a situation rife with the opportunity for tacit collusion.

Point-of-sale rebates help those who face high coinsurance or deductibles but may cause an increase in premium. In the commercial market, the majority of members served by Prime are not affected by high list price influenced cost-sharing. They pay flat dollar copays rather than coinsurance (*i.e.,* a percentage of the list price). Indeed, only 1 percent of the commercial membership served by Prime is subject to coinsurance with no out-of-pocket maximum, while 56 percent of the members we serve are enrolled in plans with a flat copay without a deductible and 4 percent are in plans with a flat copay with low deductibles. Neither of these latter two groups are meaningfully affected by the list price of a drug.

Question. What are the specific steps your company is taking to move PCSK9 inhibitors off the specialty tier in Medicare Part D and to fixed copay tiers given that prices went down by 60 percent and are no longer above the specialty tier threshold?

Why haven't your plans moved it already, given that CMS allows plans to make positive mid-year formulary changes that improve patient access and affordability?

Answer. Repatha *is* on Prime's clients' Medicare formulary on a preferred brand tier.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

DRUG REBATE RULE AND HIGHER PART D PREMIUMS

Question. In January, the Department of Health and Human Services released a proposal to reform prescription drug rebates paid by pharmaceutical manufacturers to pharmacy benefit managers under Medicare Part D. The OIG proposal attempts to ban most rebates by eliminating their regulatory protections and creating two new safe harbor provisions: one to expressly protect discounts applied directly at the point-of-sale (POS) for consumers, and another to protect certain service fees that manufacturers pay to PBMs for services furnished to health plans. The only service fees that would be permissible under the proposal are those that are fixed, and not based on a percentage of sales and not based on volume or the value of other business generated between the parties. The proposed rule was designed to address the Department's concerns with the current rebate system, which HHS believes rewards high list prices, discourages the use of generics and biosimilars, and does not reflect patient out-of-pocket costs. For consumers, this proposal may result in lower costs at the pharmacy counter, but Part D premiums may increase as a result.

Could you explain which Part D beneficiaries could see savings on their drug costs at the pharmacy counter and which Part D beneficiaries could not see lower drug costs?

Answer. Point-of-sale rebates help those who face high coinsurance or deductibles but may cause an increase in premium.

In Medicare Part D, many beneficiaries do not face significant cost-sharing. Cost-sharing is minimized for the 29 percent of Part D beneficiaries that receive low-income subsidies, also called "Extra Help," who pay flat, nominal amounts for drugs including brands.[11] Prime realizes that a small percentage of beneficiaries are challenged by the current Part D benefit design due to the high cost of certain medications. As MedPAC reports, in 2016, approximately 360,000 Part D beneficiaries filled a prescription for which a single claim would meet the maximum out-of-pocket threshold, up from 33,000 in 2010.[12] Prime welcomes the opportunities to work with policymakers, beneficiaries and plans to help Part D enrollees who face high cost-sharing. At the same time, we recognize that Part D enrollees are very premium sensitive, and are generally pleased with their benefit. A recent nationwide survey found that 85 percent of Part D enrollees are satisfied with their Medicare Part D prescription drug coverage, with over eight out of 10 also saying that their Part D plans provide "good value."

PERVERSE INCENTIVE TO PLACE MORE EXPENSIVE DRUGS ON FORMULARIES

Question. In a Senate Finance Committee hearing had a few weeks ago, many pharmaceutical companies argued that the current rebate structure incentivizes high list prices. These companies argue that the higher the list price of the drug, the greater the rebates, and therefore, the more profit the PBM earns. While contracts between PBMs, Part D Plans, and pharmaceutical companies require PBMs to pass through 100 percent of the negotiated rebate back to insurance plans, I worry that this structure could incentivize PBMs to favor a more expensive drug on the formulary because they could get a higher rebate.

Is there an incentive for a PBM to place a higher cost drug on the Part D formulary because the PBM receives a larger rebate for that more expensive drug? Why or why not?

Answer. No, Prime does not have such an incentive, but we cannot speak for all PBMs. While rebates are an important savings tool, they are not Prime's first consideration in making formulary recommendations. Prime's formulary selection process is tied to safety and efficacy consideration before accounting for competitive pricing. In considering competitive pricing, we take a "low net cost" approach: Prime's clients will often forgo rebates on a certain drug in favor of a clinically equivalent, lower-cost medication. In Medicare Part D, Prime has more than a 90-percent generic dispensing rate, and generic drugs generally do not offer rebates. In situations in which a rebated drug is covered and rebates are earned, Prime's model is to pass back 100 percent of the value of rebates we negotiate to our clients.

DIRECT AND INDIRECT REMUNERATION FEES

Question. I have heard from independent pharmacies in Maryland that have struggled with Pharmacy Benefit Managers and direct and indirect remuneration (DIR) fees. According to independent pharmacies, there are times when DIR fees are based on performance, and these fees range from $2–$7 for certain types of maintenance prescriptions and are often collected retroactively—weeks or even months after a prescription was filled. A PBM can take money back from the pharmacy when the pharmacies haven not met a PBM's performance standard. In these instances, the PBM claws back money and creates a situation where the pharmacy does not receive adequate reimbursement to cover its costs. As a result, DIR fees can be a significant financial loss to pharmacies and an additional cost burden to patients.

Could you explain what performance measures are considered when determining a DIR fee?

Answer. Prime includes performance metrics that are related to CMS Star ratings such as adherence to statin medications, statin use in persons with diabetes, adherence to auto immune medications, adherence to multiple sclerosis medications and metrics relative to cost such as generic dispensing rates and 90-day supply fill rates.

Question. How is that performance measure communicated to the pharmacy?

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[11] J. Cubanski, A. Damico, and T. Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing," May 17, 2018, downloaded from *https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/*.

[12] Medicare Payment Advisory Commission, *Report to the Congress: Medicare Payment Policy, March 2019,* Chapter 14: "The Medicare prescription drug program (Part D): Status report."

Answer. Performance measures are part of Prime's contracts with pharmacies either directly or through their pharmacy service administrative organizations (PSAOs). Prime uses EQUIPP, an industry standard dashboard that allows pharmacists to track their performance. Performance scores are communicated to pharmacies during the quarterly reconciliation process. In addition, Prime utilizes a national pharmacy quality platform that hosts the pharmacy performance score on the adherence metrics, and statin use in person with diabetes on which the pharmacy can view their performance.

Question. How much does your company receive in DIR fees?

Answer. One hundred percent of the collected performance related DIR fees in Part D are passed on to the health plan and reported to CMS.

Question. How much does your company receive in performance-related DIR fees?

Answer. One hundred percent of the collected performance related DIR fees in Part D are passed on to the health plan and reported to CMS.

Question. Are those fees passed on to the consumer? If so, how?

Answer. These fees are used to lower the premiums Medicare beneficiaries pay. A 2017 Milliman report, "Value of Direct and Indirect Remuneration (DIR): Impact on Medicare Part D Prescription Drug Plan (PDP) Program Stakeholders," found that by encouraging pharmacies to meet contractual "pay-for-performance" standards based on measures such as the generic dispensing rate (GDR), pharmacy DIR can have a significant effect on savings. For instance, a one percentage point increase in the GDR for prescription drug plans would have saved the Part D program and its beneficiaries an estimated $15.3 billion since the inception of the program. Over the next 10 years, that savings increases to an estimated $68.9 billion for a one percentage point improvement in the GDR.

DRUG SHORTAGES

Question. Currently there are over 270 drugs in shortage. Drug shortages happen for many reasons such as manufacturing and quality problems, natural disasters, and inventory practices of wholesalers and pharmacies. Drug shortages cause harm to providers, hospitals, and most importantly patients. Pharmacists and providers must spend significant amounts of time on researching alternative drug treatments for the patient, which may not always be the most optimal therapies.

As a Pharmacy Benefit Manager, you have contractual agreements with pharmaceutical companies in order to place their drugs on a plan's formulary. While I understand that drug shortages happening in both the inpatient and outpatient settings, there may be a role PBMs can play in protecting patients.

For the prescription drugs you negotiate to cover on a plan formulary, could you use your negotiating power to ensure a drug is available to a patient? Why or Why not?

Answer. It is Prime's understanding from the FDA fall 2018 meeting on drug shortages that the majority of drug shortages occur in the hospital setting. Prime only negotiates drug discounts for the outpatient setting. Many shortages result from manufacturer deficiencies, which are beyond the reach of the PBM.

Question. What do you do to ensure that patients have the drugs they need?

Answer. When the preferred product is no longer available, we will generally recommend that our health plan clients move a previously non-preferred drug into preferred status.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

BIOSIMILARS

Question. During the hearing, each of you expressed support for biosimilars, and most of you indicated you try to take advantage of available biosimilars to help lower costs. When I asked each of you to identify solutions to help ensure a robust biosimilar marketplace here in the U.S, most of you mentioned things Congress or the administration could do to help ensure uptake of biosimilars—from lowering the exclusivity period for biologics to finalizing guidance on interchangability at the FDA. However, none of you offered any solutions or ideas for what your company

could do to help ensure timely uptake of biosimilars, a robust U.S. biosimilars market, and a resulting cost savings to patients to taxpayers.

Most of the biosimilars currently approved and on the market in the U.S. are reimbursed through the medical benefit. What are the similarities and differences in how rebates are passed onto patients and providers in the medical benefit versus pharmacy benefit. In your answer, please describe these similarities and differences across each of your books of business (*i.e.,* commercial, Medicare, Medicaid).

Answer. Prime has encouraged the use of biosimilars and has placed them in a parity position across our standard formularies. Prime manages drugs to the lowest net cost for our health plans and there may be instances where biosimilars will not be the lowest net cost product. Prime, along with the clients we support, evaluate market dynamics and ability to move market share in determining the lowest net cost products. There is not a significant difference in lines of business. Prime's general business model is to pass 100 percent of the rebates back to our clients regardless of benefit—medical or pharmacy.

Question. Do any of your plans require the use of a higher list price, branded product over the use of a therapeutically equivalent lower list price generic or biosimilar product? Why? If a plan restricts the use of a biosimilar or generic product in lieu of an innovator or brand name product, do patients pay more out-of-pocket than they would if the biosimilar was preferred?

Answer. In certain instances this may occur. Biosimilars may not have the lowest net cost product compared to the branded drug. In addition, moving enough market share to the biosimilar may be difficult and result in monetary losses for the health plan. Simply removing rebates may not result in the overall lowering of drug costs as there are many factors that impact biosimilar adoption in the market place such as interchangeability guidelines, ASP pricing, provider buy-and-bill practices, resistance to migrating patients from stable therapies to a biosimilar and product availability.

Question. Recognizing most biosimilars are paid for via medical benefit, please explain whether you use step-therapy to restrict access to biosimilars for your patients in any medical benefit you manage across each of your books of business (*i.e.,* commercial, Medicare, Medicaid). What role do rebates playing in your consideration for patient access to biosimilars in each of these instances?

Answer. Step therapy is a tool to ensure appropriate use of high-cost therapies where there are potential lower-cost therapeutic alternatives, regardless of whether a drug is a branded biologic or biosimilar. Prime has encouraged the use of biosimilars and has recommended that our client's place them in a parity position across our standard formularies. Prime manages drugs to the lowest net cost for our health plans and there may be instances where biosimilars will not be the lowest net cost product. Prime, along with the plans we support, evaluate market dynamics and ability to move market share in determining the lowest net cost products.

Question. How can and will your company help ensure a robust biosimilars market here in the U.S.?

Answer. Prime is currently supporting the biosimilar market in several ways. We are working with biosimilar manufacturers to help ensure they are aware of our low net cost strategies. Next, we work with our health plans to develop medical policy and utilization management policies that can utilize step therapy as a lever to move market share to preferred products. Prime works with our health plans to manage other strategies that can move utilization to preferred products (*e.g.,* site of care policies, reimbursement solutions). Finally, Prime is actively working to promote legislation that supports interchangeability at the State and Federal level.

Question. I have heard concerns that "rebate walls" are responsible for keeping new biosimilars off of formularies, where a manufacturer offers conditional rebates on a bundle of their products in order to incentive PBMs to exclude a new biosimilar competitor from their formularies. Have you ever decided to place a drug on a preferred tier because of the rebates you receive for other drugs from that manufacturer? If you do not do this, do you support this practice being carried out by your competitors?

Answer. Prime first uses our Pharmacy and Therapeutics Committee to make all clinical recommendations. Only after clinical and safety factors are considered do issues of cost arise. Our clients base decisions on the clinical evaluation of the drug and lowest net cost. We also assess the member disruption effects of making any

formulary change. We consider each drug on its own merits or do not consider drugs in bundles in making financial recommendations.

We cannot speak to our competitors' strategies.

Question. What more can and will you do to counteract efforts to rebate-block or bundle rebates to block biosimilar formulary placement? Will you commit to taking these actions as more biosimilars become available in Part D?

Answer. All decisions are made based on the clinical evaluation of the drug and lowest net cost. We do not consider products in bundles but consider drugs on a drug by drug basis after considering clinical and safety factors and issues of patient disruption first.

REBATES VS. FEES

Question. During the hearing, Senator Cassidy asked each of you about the trend in PBM contracting where a larger share of your reimbursement and payment is a result of "fees" which you are able to pocket, as opposed to "rebates" which must be passed back to the plan/consumer.

Please define the word "rebate." As part of your definition, please clarify whether or not you consider administrative fees, inflation payments, product discounts, prospective rebates, care management fees, procurement fees or any other type of fee or payment that isn't a retrospective rebate to be a rebate.

Answer. "Rebate(s)" means a retrospective discount paid by a pharmaceutical manufacturer to a PBM on behalf of a client for the pharmaceutical manufacturer's products dispensed to a member of a client's plan. Rebates do not include any manufacturer administrative fees paid to a PBM by a pharmaceutical manufacturer. All other remuneration that Prime receives from pharmaceutical manufacturers are included in this definition including inflation protection rebates. "Manufacturer administration fee" means fees paid to a PBM by a pharmaceutical manufacturer for rebate services performed by the PBM on the pharmaceutical manufacturers' behalf.

Question. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), a list of each of the different types of rebates, charges, and/or fees that you incorporate into your contracts.

Answer. In each of these lines of business, Prime receives in the agreements with pharmaceutical manufacturers both Rebates and Manufacturer Administrative Fees as defined in the question above.

Question. Rebates, by definition, must be passed along to the employer, health plan, or consumer. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), details on which of the rebates/fees detailed in my prior question are passed along to the consumer and/or plan and which are kept by the PBM.

Answer. Prime's model is to pass through 100 percent of the rebates to owner clients and retain a portion of the manufacturer admin fees to offset costs for the PBM services provided to clients.

FIDUCIARY DUTY

Question. Each of you have argued that you are the one entity in the drug supply chain that exists to help lower the cost of prescription drugs. You claim that your value comes in saving taxpayers, plans, and consumers money.

Would you be willing to accept a fiduciary standard in your contracts? In other words, do you believe you have a fiduciary duty to the plan or employer you contract with—to act in their best interest and not your own? If not, why not?

Answer. Prime contracts primarily with Blue Cross Blue Shield non-profit insurance companies. Prime provides a variety of services to these and other Clients at their direction through separate contracts. These contracts do not generally provide that Prime will have any fiduciary obligations. Prime does not believe that the law imposes fiduciary duties upon PBMs apart from the written terms of their contracts with clients and, therefore, imposing a blanket fiduciary responsibility on PBMs would be contrary to its contractual agreements with its clients and inconsistent with established law surrounding fiduciaries. Such regulation may also disrupt the reasonable expectations of clients that have contracted with Prime, and potentially increase Prime's costs in providing services to clients and the premiums that individual members pay for insurance.

PAYING PHARMACISTS

Question. Following a series of reports in *The Columbus Dispatch,* Ohio has taken a number of actions over the past year to crack down on several PBM practices. Efforts to date have included investigations, lawsuits, and policy changes to address the egregious use of spread-pricing, alleged breaches of contract, accusations of anticompetitive behavior, a misuse of taxpayer dollars, and a general lack of transparency.

PBMs are responsible for creating pharmacy networks, setting the price patients and health plans pay for prescription drugs, adjudicating claims, and reimbursing pharmacies for dispensed drugs. In addition, nearly all PBMs own proprietary pharmacies that directly compete with the PBM-created retail network. Do you design plans that incentivize or require patients to use a pharmacy owned by your affiliate over a competing retail pharmacy. If yes, do you believe this represents a conflict of interest? If yes, how do you ensure there is no resulting anticompetitive misuse of pharmacy and patient data?

Answer. Some of Prime's clients have adopted benefit plans that offer lower member cost-share for preferred mail order and specialty pharmacies, including AllianceRx Walgreens Prime in which Prime has a 45-percent ownership interest. Prime has policies and controls in place to prevent anticompetitive misuse. We do not believe this is a conflict of interest, and the FTC has concurred. See *https://www.ftc.gov/news-events/press-releases/2005/09/ftc-issues-report-pbm-ownership-mail-order-pharmacies*.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Can you answer the following questions to help us understand the pharmacy benefit manager business model and how you make formulary decisions?

What percent of rebates are passed to the consumer under Medicare Part D?

Answer. Prime passes 100 percent of rebates to its Medicare Part D plan sponsor clients who may use the rebates to lower premiums and benefit the consumer. In Medicare Part D, many beneficiaries do not face significant cost sharing. Cost sharing is minimized for the 29 percent of Part D beneficiaries that receive low-income subsidies, also called "Extra Help," who pay flat, nominal amounts for drugs including brands.

Question. What percent of rebates are passed to the consumer in the private insurance market?

Answer. Prime offers commercial health plan clients and employer groups the option to adjust the prices of drugs in their benefit plans to reflect rebate savings, including the option of applying a portion of the rebate savings at the point of sale when a member receives a prescription from a pharmacy. This plan offering allows members with high deductibles and coinsurance to benefit from rebates at the point-of-sale, but there is a trade-off between premiums and a point-of-sale rebates. Point-of-sale rebates may help those who face high coinsurance or deductibles but may also cause an increase in premium. Whether a member benefits from point-of-sale rebates is highly dependent on the member's specific benefit plan, as well as the member's overall medical and pharmacy expenses.

In the commercial market, the majority of members served by Prime are not affected by high list price influenced cost-sharing. They pay flat dollar copays rather than coinsurance (*i.e.,* a percentage of the list price). Indeed, only 1 percent of the commercial membership served by Prime is subject to coinsurance with no out of pocket maximum, while 56 percent of the members we serve are enrolled in plans with a flat copay without a deductible and 4 percent are in plans with a flat copay with low deductibles. Neither of these latter two groups are meaningfully affected by the list price of a drug.

It is Prime's business model to pass back 100 percent of the manufacturer rebates we negotiate to our health plan clients who may use the rebates to offset premiums. If a client chooses to offer POS rebates directly to all or any subset of their members, that is the client's decision and Prime is indifferent to it. POS rebates are a newer offering and currently only a couple of our clients have chosen to adopt our POS product that passes rebates back through POS to members. While the majority of plan sponsors continue to use rebates as an effective mechanism to control premium costs or reducing costs for all members through benefit designs such as lower

copays, POS rebates is available for approximately 5 percent of our commercial clients' members today. It presents flexibility and an alternative for those who want to do so. However, it should be noted that not all branded drugs receive rebates, so the reduced pricing is limited to select brand medications and not every member may realize the benefits. Currently, we do not have a POS rebate option in Medicare Part D.

Question. Do you have any comments on how health plans should use their share of the rebates to lower drug prices for patients with high deductibles?

Answer. We believe that health plan sponsors should have the flexibility to use rebate dollars in setting benefit designs and premiums in ways that best serve their respective members and market needs.

Question. What is the process of deciding on which tier a generic will be placed in your formularies?

Answer. For all drugs including generics, Prime's formulary selection process is tied to safety and efficacy consideration before accounting for competitive pricing. In considering competitive pricing, we take a "low net cost" approach: Prime will often recommend that clients forgo rebates on a certain drug in favor of a clinically equivalent, lower-cost medication.

Question. Are generics always tiered as preferred (versus branded drugs)?

Answer. In general, generics are given a favorable status on Prime's clients' formularies. However, there are a few exceptions made with regards to high cost generics and those with potential safety concerns.

With regards to high cost generics, Prime evaluates new to market generics in the context of their impact to health plan costs and the premiums their members pay. In certain circumstances, generic drugs remain at a higher tier relative to the brand due to a lack of generic competition and significantly higher price point. In these instances, Prime may recommend to our clients that the generic be maintained at a higher tier or excluded until more lower cost generic competition is available to avoid an increase in member premiums. Once the generic is available at a lower cost than the brand, the generic is added to formulary or the drug tier lowered. In these scenarios members pay the lowest net cost, regardless of brand or generic status and the tier placement of the medication. Thus, ensuring the most cost-effective medication at the best price available to the member. With regards to medications with potential safety concerns, brand and generic medications may be placed on a higher tier or excluded to minimize adverse health outcomes and encourage the use of clinically effective safer alternatives available.

Question. How quickly are generics placed on formularies once FDA clears them?

Answer. Formulary placement of a new generic product will be dependent on if the brand is currently covered on the formulary and available at a lower net cost since patent cliff strategies can add to costs. If the branded product is currently on formulary, the generic is immediately added. If the branded product has been excluded or non-formulary, the generic would also not be available until it is reviewed by the P&T.

Question. Given the struggles we hear about patients accessing insulin, what measures are you taking to ensure that diabetes products and different types of insulin are placed on a preferred tier when establishing a formulary?

Answer. Insulins are highly similar across branded products. Prime's clients ensure that there are adequate formulations available to treat the needs of all diabetic patients. Approving biosimilar insulin products will help provide even more options at a lower cost for these patients.

Through our clinical evaluation process, Prime recommends to our clients that there are adequate formulations available on our formularies. We work towards coverage on health savings account (HSA) preventive drug lists and with pharmaceutical manufacturers to pull through clinical support programs such as free diabetes meter programs. Prime also has a number of adherence programs that ensure continued use.

Prime members have seen relatively flat out of pocket payments over the past 5 years and have generally not been exposed to list prices in the news.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

TRANSPARENCY, REBATES, AND SPREAD PRICING

Question. During the hearing, I asked an initial question on spread pricing and wanted to follow up here. According to the Centers for Medicare and Medicaid Services (CMS), total gross spending in 2017 on prescription drugs was $154.9 billion in Medicare Part D, $30.4 billion in Part B, and $67.6 billion in Medicaid.

One of the main challenges in lowering the price of prescription drugs is that there is a disturbing lack of transparency all along the supply chain, from research and development to what the patient is expected to pay at the counter. Further, the out-of-pocket costs for drugs varies greatly and unpredictably from patient to patient. That is why Senate Special Committee on Aging Chairwoman Collins and I introduced legislation that would codify the Drug Spending Dashboards at the CMS. The dashboards provide cost and spending information for drugs in the Medicaid, Medicare Part B, and Medicare Part D programs.[13] With regards to transparency in the prescription drug supply chain, please provide answers to the following questions.

Is it the policy and practice of your company to negotiate with drug manufacturers in good faith and obtain the best and lowest prices possible for patients and American taxpayers?

Answer. Yes.

Question. Is it the policy and practice of your company that patients, providers, researchers, policymakers, and the American people in general, know how taxpayer dollars are being spent in the Medicare and Medicaid programs?

Answer. Prime supports transparency that is actionable and does not create risk to competition.

CMS collects very detailed information from PBMs about Part D transactions through its mandatory Direct and Indirect Remuneration (DIR) reporting. CMS has a thorough line of sight into all rebates, fees and payment adjustments, which are reported to CMS as DIR on a drug by drug basis. Further, each plan submits bids annually to CMS by the first Monday in June. Those bids reflect the plan's expected benefit payments plus administrative costs after they deduct expected Federal reinsurance subsidies, and the level of CMS payment to plan sponsors is derived from actual plan bids.

Prime supports legislation introduced by Senators Cornyn, Cortez Masto, Carper, and Cassidy that would allow the Medicare Payment Advisory Commission and the Medicaid and CHIP Payment and Access Commission access to CMS's DIR data to inform Congress's decision-making on Part D policy. Our support is based upon the important protections for proprietary data included in the legislation that will mitigate the risk of adverse, anti-competitive consequences that could cause drug prices to increase.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by manufacturer list price?

Answer. Our model is transparent as to rebates and costs, and we provide this information to our clients in the normal course of our business.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by rebate paid by the manufacturer to you (the PBM)?

Answer. Our model is transparent as to rebates and costs, and we provide this information to our clients in the normal course of our business.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by the amount reimbursed to pharmacies by the PBM?

Answer. Our model is transparent as to rebates and costs including pharmacy costs, and we provide this information to our clients in the normal course of our business.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by the amount insured and uninsured patients pay out of

[13] S. 709, 116th Congress, Prescription Drug Pricing Dashboard Act, online at: *https://www.congress.gov/bill/116th-congress/senate-bill/709?q=%7B%22search%22%3A%22drug+dashboard%22%7D&s=1&r=1.* Accessed April 23, 2019.

pocket before coupons, discounts, and other forms of patient assistance offered at the point of sale?

Answer. Patients who have Prime's drug coverage can see what they will pay out of pocket on *MyPrime.com.* Medicare Plan Finder can also be used by Part D members shopping our clients' plans, and we provide accurate price information to help inform beneficiaries' choices. We do not have a relationship with uninsured patients.

Question. If so, please provide useful and easily accessible links to where policymakers and the public can find such information. If not, please disclose how much each drug you work with clients to provide costs, broken down by: manufacturer list price; rebate paid by the manufacturer to you (the PBM); the amount reimbursed to pharmacies by the PBM; and the amount insured and uninsured patients pay out of pocket, before coupons, discounts, and other forms of patient assistance offered at the point of sale.

Answer. As a PBM, we do not have a relationship with uninsured patients, and do not know what they pay. Pharmaceutical companies alone set list prices and could lower them for the benefit of all patients.

Question. Please provide a list of actions your company has taken to ensure that pharmacists are enabled and allowed to communicate to patients how they can pay the lowest out-of- pocket cost possible for their prescription drugs.

Answer. Prime does not currently and has not used gag clauses. Prime assists its clients in the development of the benefit plan so that, at the point of purchase, members pay the lower amount of either the pharmacy's submitted price or the amount of the applicable member cost share, as specified in the member's benefit plan.

PREPARED STATEMENT OF STEVE MILLER, M.D., EXECUTIVE VICE PRESIDENT AND CHIEF CLINICAL OFFICER, CIGNA CORPORATION

Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for inviting me to testify at this hearing. I am Steve Miller, M.D., executive vice president and chief clinical officer at Cigna Corporation.

I am a former transplant nephrologist and former vice president and chief medical officer for Washington University and Barnes Jewish Hospital. From 2005 to 2018, I served as senior vice president and chief medical officer at Express Scripts, leading the company's clinical, policy, quality, and performance efforts. In that role and currently as chief clinical officer at Cigna, I engage with all participants in the supply chain, ensuring that clinical quality and efficacy are a key focus of the company's negotiations with drug manufacturers. I also work closely with many of our clients, which include large employers, small businesses, labor unions, health plans, the Federal Government, and States, to find unique and innovative solutions to enable them to continue providing affordable and high quality coverage options.

The United States drives the most innovation in health services. At Cigna, we believe we can do better by our citizens to achieve better health, with greater choice, affordability, and predictability. We challenge ourselves every day to identify solutions that achieve those goals. I appreciate the opportunity to testify on affordability and access to prescription drugs in the United States. Cigna supports the committee's efforts to make prescription drug prices more affordable, and new innovations more accessible, to all patients and payers in the United States.

Cigna is a global health services company; our subsidiaries are major providers of medical, pharmacy, dental, disability and related products and services in more than 30 countries and jurisdictions around the world, including South Korea, China, India, the Middle East, and Europe. Cigna is also the largest provider of expatriate benefits in the world. In the United States, Cigna is one of the largest health services providers. We emphasize whole-person health and clinical quality to deliver choice, affordability and enhanced quality of life for our customers and clients. Key enablers of our success are collaborative relationships with providers, an emphasis on outcomes- and value-based reimbursement, robust patient support services, and transparency tools for customers and clients to make informed decisions that address their specific needs. We strive to be a constructive participant in public policy discussions and to contribute workable solutions to societal challenges in all of the countries, markets and jurisdictions in which we operate.

Cigna completed its combination with Express Scripts in December 2018. Express Scripts helps more than 80 million Americans achieve better care at a lower cost. We are proud to serve TRICARE, the health program for 9.4 million uniformed service members, retirees and their families, for more than 10 years. Express Scripts' tools include an innovative specialty pharmacy care model for costly and complex drugs; clinically based drug utilization reviews; clinically based formulary management; medical and drug data analysis; and specialized Therapeutic Resource Centers, with pharmacists specially trained on conditions such as diabetes, oncology, inflammatory conditions, multiple sclerosis, and pulmonary hypertension.

The combination brings together industry-leading capabilities that are uniquely positioned to deliver better care, expanded choice, and greater affordability. Our combined company's 74,000 employees come to work every day to enhance the health, well-being and peace of mind of the more than 160 million customer relationships we serve globally.

In an environment where many proposals would narrow or restrict choice in order to drive affordability, Cigna sees an opportunity to further expand customer choice, and to make it easier for people to access the health services they need, whether in a doctor's office, an urgent care center, a retail pharmacy setting, or employer clinic; or, for more acute needs, at a hospital or outpatient center. As customers increasingly choose to access health-care services at home or through digital platforms, we see these expanded, personalized engagement and delivery channels as a tremendous opportunity to expand choice and simplify health care.

Pharmacy is the most frequently consumed aspect of health care for Americans. On average, people use their pharmacy benefit 11 times a year, making it the most widely used benefit employers and health plans offer. For illnesses that were once treated with surgery, prescription drugs have emerged as an effective front-line option. However, prescription drug spending is forecast to grow at 5.5 percent per year, on average, between 2018 and 2027.[1] Over the past 10 years, the Consumer Price Index (CPI) has increased 15 percent.[2] During that same time period, the prices for generic drugs have dropped by an average of 60 percent; conversely, these savings have been subsumed by an astonishing 208 percent increase in the cost of branded drugs.[3]

Innovation can yield exciting and life-changing new therapies and treatments. But innovation often comes with a high price tag, especially in the pharmaceutical sector. At Cigna, we are focused on accelerating solutions that support both innovation and price stability.

We are already making good progress. Cigna and Express Scripts' solutions for driving lower drug spending and fostering the use of lower net cost treatments are making medications more accessible for Americans. In 2018, Express Scripts' clinical-first approach returned $45 billion in savings to our clients—employers, health plans, government programs, unions, and others.[4] Because of our innovative solutions and approach to pharmacy care, our clients achieved the lowest drug trend in 25 years, just 0.4 percent across employer-sponsored plans. Further, we delivered an unprecedented 0.3 percent decline in drug spending across Medicare plans. The average 30-day prescription cost Americans only 6 pennies more than in 2017. All of this was accomplished in an environment where manufacturers raised list prices 7.3 percent. We guide patients to effective, lower-cost therapies, and secure deep discounts from manufacturers and pharmacies.

With that context as background, our statement today focuses on the following topics:

- Our efforts to drive improved affordability, predictability, and accelerate value-based care for patients;
- The role of rebates in prescription drug costs; and
- Legislative and regulatory solutions to lower drug costs for patients and payers.

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[1] *https://www.cms.gov/research-statistics-data-and-systems/statistics-trends-and-reports/nationalhealthexpenddata/downloads/forecastsummary.pdf.*

[2] *https://www.statbureau.org/en/united-states/inflation.*

[3] *http://lab.express-scripts.com/lab/drug-trend-report/~/media/29f13dee4e7842d6881b7e034fc0916a.ashx.*

[4] *http://lab.express-scripts.com/lab/drug-trend-report/2018-drug-trend-report.*

OUR EFFORTS TO DRIVE IMPROVED AFFORDABILITY, PREDICTABILITY, AND ACCELERATE VALUE-BASED CARE FOR PATIENTS

Cigna has a range of world class capabilities that promote clinical quality, reduce costs, and expand access to needed medications. We are focused on accelerating solutions that support both innovation and price stability, including:

- *Treating the Whole Person.* We support our clients in maintaining or improving their health; emphasize early intervention; and focus on treating the whole person through medical, pharmacy, and behavioral health services.
- *Consumer Support and Personalized Choices.* Our combined clinical and care teams support an individual's end-to-end health journey by coordinating care and explaining choices along the way. Our innovative tools allow us to personalize options, simplify care, and expand choice.
- *Partner of choice for providers.* We work closely with physicians and other providers to close gaps in care through real-time information sharing and support that enables better health outcomes.
- *Value-based payment.* Cigna prioritizes payment arrangements with healthcare providers and pharmaceutical manufacturers that are outcomes-based. These arrangements enhance Cigna's value-based provider collaboratives and Express Scripts' value-based manufacturer and retail collaborations, which improve health outcomes at a lower cost.
- *Lower total cost of care.* We provide better tools and information to keep people healthier and ensure they receive efficient and effective care.

At Cigna, we focus on the pursuit of value through integrated offerings that reduce costs and promote improved health outcomes:

- In the United States, *85 percent of our medical customers* are currently in transparent administrative services only relationships.
- Through *value-based arrangements,* Cigna realized medical cost savings of more than $600 million between 2013 and 2017.[5] These efforts have allowed us to maintain the industry's lowest medical trend for the past 6 years.[6]
- The *2018 Cigna Value of Integration Study* shows that clients with Cigna medical, pharmacy, and behavioral benefits reduce annual medical costs by an average of $645 for each person with an identified health improvement opportunity—savings that can increase to nearly $10,000 for individuals with certain chronic conditions.[7]

Express Scripts uses their clinical expertise to negotiate lower drug costs with drug manufacturers, leveraging competition to help drive savings for their clients, which include employers, labor unions, health plans, the Federal Government, and States. These negotiations serve to create competition in the market for prescription drugs. The savings ultimately benefit patients in the form of lower premiums and reduced out-of-pocket costs. Additional savings are realized when clients take advantage of Express Scripts' clinical support services, which enable individuals to lead healthier and more productive lives.

When it comes to prescription drugs, our goal is to achieve improved clinical outcomes at lower costs. Express Scripts offers several innovative programs to help us achieve that goal:

- Our *SafeGuardRx℠* programs allow us to help our clients closely manage high-cost drug classes through a holistic approach that combines clinical care with advanced analytics, and patient engagement supported by technology. Through SafeGuardRx Solutions, we have leveraged value-based arrangements to take on some of the most challenging therapy classes, including hepatitis C, high cholesterol, cancer, inflammatory conditions, pulmonary conditions, and multiple sclerosis.

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[5] Cigna January 2019 analysis of national Accountable Care program groups with effective dates from 2013 through 2017. Reimbursements already paid to groups are subtracted from the savings to reflect overall investment.

[6] Cigna Corporation investor presentation, February, 1, 2019, *https://www.cigna.com/assets/docs/about-cigna/CI-investor-kit.zip.*

[7] *https://www.cigna.com/newsroom/news-releases/2018/cigna-study-shows-improved-health-well-being-and-affordability-for-individuals-with-integrated-medical-behavioral-and-pharmacy-benefits.*

- One of our SafeGuardRx programs—The *Diabetes Care Value Program*—improves pharmacy care while controlling plan costs for people with diabetes. Developed with drug makers and launched in 2017, the program has reduced diabetes drug spending by 19 percent—a total savings of $42.6 million. The program combines specialized diabetes pharmacy care with benefit strategies, such as utilization management and quality pharmacy networks, and improved compliance with recommended treatment guidelines.
- Our *National Preferred Flex Formulary* is a unique approach that provides employers and health plans with the flexibility to take advantage of the possibility of a drug manufacturer choosing to lower the price of a drug by offering an authorized generic alternative. Should the manufacturer offer an authorized generic, that product can be added to the formulary. This is a pathway to help give cash-paying patients immediate access to more affordable medications. In the end, we care most about the lowest net cost of a drug, not the rebate. We welcome manufacturers lowering their list prices so that patients can have greater access to medications.
- *SmartShareRx℠* offers employers and plan sponsors more flexibility in how they use rebate savings. The program was established to share estimated rebate savings on eligible medications to combat patients' primary pain point: cost-sharing in the deductible phase. However, the program has evolved to apply estimated rebate value to eligible medications filled in all phases of the pharmacy benefit to reduce patients' out-of-pocket costs at the pharmacy counter. Despite the availability of point-of-sale rebate benefit designs in the commercial market for years, we have had few employers and plan sponsors take up this option. For more than 10 years, we have offered the option to clients to provide rebate value at the point-of-sale.
- *Inside Rx℠* is a prescription savings program launched in partnership with GoodRx to expand affordable access to brand and generic medications for patients with no insurance, high deductibles, or high out-of-pocket costs, by offering discounts to these patients at the point-of-sale. Since the launch of the program in May 2017, we have helped patients save an estimated $400 million.

Express Scripts builds products that fit a wide variety of use cases, working to uniquely partner across the health-care ecosystem to uncover opportunities, take action, and deliver better outcomes. Real-time clinical alerts that reach physicians through electronic prescribing systems can turn data into actionable patient intelligence, helping people stay on their therapy regimen and avoid dangerous drug-drug interactions. Express Scripts' Real Time Prescription Benefit, launched last November, helps to simplify the patient's experience with their prescriber and improve the transparency of drug costs. We provide patient-specific information and pricing information directly into the physician's Electronic Health Record (EHR) within seconds. Physicians using electronic prescribing can see the following information to inform prescribing decisions:

- Alternative drugs and associated details, such as generic versus brand pricing;
- Coverage information, including electronic prior authorization requirements, step therapy requirements, or quantity limits; and,
- The patient's cost through each pharmacy dispensing channel: retail, home delivery or specialty pharmacy.

By providing drug cost information and reconciling coverage issues at the point of prescribing, we are eliminating confusion and pain points for patients at the pharmacy counter. A 2018 annual report by Surescripts on price transparency found that provider adoption of Real-Time Prescription Benefits has grown by 1,338 percent, with monthly benefit checks growing to over 6 million by December 2018.[8] Surescripts' data shows that Real-Time Prescription Benefits saved patients as much as $8,032 in out-of-pocket costs on a single prescription.[9] These systems are delivering measurable savings to patients at the pharmacy counter, while ensuring providers and patients are communicating to make better-informed medication choices. Electronic prior authorization capabilities are improving as well, allowing

[8] *https://surescripts.com/news-center/press-releases/!content/new-data-from-surescripts-shows-that-patients-are-getting-more-affordable-prescriptions-faster-and-with-less-hassle.*

[9] *https://surescripts.com/news-center/press-releases/!content/price-transparency-at-the-point-of-care-boosts-patient-savings-and-prescriber-efficiency.*

prescribers to switch the drug 28 percent of the time and eliminating over 158,000 hours of potential wait time in December 2018, according to Surescripts' report.

Cigna and Express Scripts also provide patients real-time pricing information, customized to their individual plans, via our websites and mobile apps, so patients can choose the pharmacy that provides the most affordable dispensing option. Our innovations help better inform patients of their cost exposure and treatment options, improving affordability and predictability for patients.

As we look ahead to gene therapies, a growing category of expensive drugs, we are actively developing new value-based payment models. For example, we have periodic payment agreements with manufacturers that are structured as value-based contracts to reward efficacy. Simply put, if a drug is working, the company gets a payment. If not, the payment stops. Similarly, we have worked to develop "discontinuation" payment arrangements that require payment to be returned if a patient does not see a benefit from the drug.

Express Scripts' innovative pharmaceutical and pharmacy solutions position Cigna to offer even greater value to our clients, public health program partners, and patients. The combined company integrates Express Scripts' pharmacy benefit management with Cigna's health-care products and services.

For example, over seven million Americans diagnosed with diabetes use insulin. For some patients, the increasing price of insulin limits access and adherence. When Cigna and Express Scripts announced the merger, we clearly stated we would improve choice, affordability, and predictability. Within the first 100 days of our combination, we were able to launch a new Patient Assurance Program which will bring additional affordability and predictability to customers who rely on insulin to manage their diabetes. Furthering Cigna and Express Scripts' respective historical efforts in diabetes disease management, the Patient Assurance Program establishes a lower fixed out-of-pocket cost for covered insulins, ensuring customers will pay no more than $25 out-of-pocket when filling a 30-day insulin prescription at a retail pharmacy or through home delivery. This is an early example of the accelerated change and innovation our new company is positioned to drive in the financing and delivery of care.

THE ROLE OF REBATES IN THE PRESCRIPTION DRUG SUPPLY CHAIN

Approximately 90 percent of all prescriptions we fill are generics. The remaining 10 percent are branded drugs, which represent 70 percent of the spending on prescription drugs. We believe there are targeted solutions to address this 70 percent. We work to do this through sophisticated, evidence-based negotiations for clinically equivalent therapies.

Solutions for driving lower drug spending and fostering the use of lower net cost treatments often include negotiating discounts or rebates. The role of rebates in prescription drug pricing has been mischaracterized. Rebates are not the cause of increasing drug prices. Rebates are discounts paid by drug manufacturers after a patient receives a manufacturer's drug. In the system today, rebates are used to reduce health-care costs for consumers. Today, employers and others use the value of discounts to help keep premiums affordable, lower out-of-pocket costs, and offer workplace wellness programs, just to name a few ways they put discounts to work.

Most drugs do not involve a rebate structure. For example, rebates are not typically offered for generic medications, for drugs without market competition (*i.e.,* sole-source brand drugs), or for drugs administered by a physician. According to a study of drugs covered under Medicare Part D by the actuarial firm Milliman, 81 percent of all drugs analyzed do not offer rebates and 64 percent of brand drugs analyzed do not offer rebates.[10] Many sole-source, highly expensive specialty drugs, like drugs to treat cancer, do not offer rebates and continue to be priced higher and higher:

- In 2017, non-rebated drugs treating depression, high-cholesterol, infertility, and other conditions all registered price increases of more than 15 percent.[11]

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[10] Milliman, "Prescription Drug Rebates and Part D Drug Costs." July 16, 2018. The Milliman analysis focused on approximately 1,300 drug and therapeutic class combinations, reflecting 97 percent of 2016 Part D gross drug spending.

[11] Express Scripts, "Let's Talk About Rebates," May 15, 2018, *http://lab.express-scripts.com/lab/insights/industry-updates/lets-talk-about-rebates.*

- List prices for oral oncology medications, which are not rebated or discounted to any significant extent, doubled between 2011 and 2016, from $20 per unit to $40 per unit.[12]
- Looking at the 39 oral oncology medications on the market in 2010, six experienced 100–200 percent inflation between 2010 and 2016; one was greater than 300 percent and another one was greater than 800 percent.[13] Rebates are not available on these drugs, but the manufacturers continue to increase list prices. Under the recently proposed rebate rule, beneficiaries using non-preferred and specialty drugs will see premiums increase, and will not see a reduction in cost at the pharmacy counter.

Restricting or eliminating rebates does not assure improved affordability for patients or taxpayers:

- A study by the actuarial firm Oliver Wyman found that rebates reduced overall costs in Medicare Part D by $34.9 billion from 2014 to 2018, and eliminating rebates would have driven Part D premiums higher by 52 percent in 2018 alone.[14] From 2014 to 2018, the national average Part D premium increased less than 2 percent per year. Manufacturer rebates are one of the major contributors to holding premiums relatively flat over the last 5 years.
- The Centers for Medicare and Medicaid Services' (CMS) Office of the Actuary (OACT), in reviewing the Department of Health and Human Services' (HHS) recently proposed rule addressing rebates in Medicare Part D and Medicaid, estimates that Part D premiums will increase by as much as 25 percent and that Federal spending will increase by $196 billion over 10 years.[15]
- Data released by CMS for 2019 Part D premiums, and national average plan bids, show a negative trend for the first time in more than a decade.[16] CMS cites drug manufacturer and pharmacy price concessions as a factor driving lower costs.
- A *Health Affairs* analysis of the most recent National Health Expenditures prescription drug forecast for 2017–2026 concluded that increased rebates "contributed to lower net prices for many prescription drugs in recent years and are expected to have dampened prescription drug spending growth in 2017."[17]
- The actuarial firm Milliman found that on average, the highest cost drugs have the lowest manufacturer rebates (as a percentage of gross drug cost), for brand drugs with rebates.[18]

In the Medicare Part D program, rebate savings are passed to Part D plan sponsors and are responsible for saving enrollees and taxpayers billions of dollars each year since the Part D program began. CMS requires plans to show how they are using rebates to deliver Part D coverage to their members. All Part D plan sponsors must submit to CMS detailed annual reporting of rebate amounts by drug and Part D plan. In addition to reporting individual drug rebates, plan sponsors must also report to CMS how much of the rebate amounts were retained by the pharmacy benefit manager (PBM) rather than being shared with the sponsor, rebate guarantee amounts, rebate amounts reflected at the point-of-sale, third-party payer claim rebate amounts, and any other rebate amounts not already reported. Not only are plan sponsors required to report these rebate amounts to CMS, but they must also report what the rebates are for, such as formulary or tier placement, market share

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[12] Express Scripts, "The Cost of Hope: 5 Things to Know About the Cost of Cancer Drugs." May 30, 2017, *http://lab.express-scripts.com/lab/insights/industry-updates/the-cost-of-hope-5-things-to-know-about-the-cost-of-cancer-drugs.*

[13] *http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter.*

[14] Oliver Wyman, "Premium Impact of Removing Manufacturer Rebates From the Part D Program." July 2018, *https://www.pcmanet.org/wp-content/uploads/2018/07/OW-Part-D-Manufacturer-Rebate-Premium-Impact-FINAL.pdf.*

[15] *https://aspe.hhs.gov/system/files/pdf/260591/OACTProposedSafeHarborRegulationImpacts.pdf.*

[16] 2019 Medicare Advantage ratebook and prescription drug rate information, *https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Ratebooks-and-Supporting-Data-Items/2019Rates.html?DLPage=1&DLEntries=10&DLSort=0&DLSortDir=descending.*

[17] *Health Affairs,* "National Health Expenditure Projections, 2017–26: Despite Uncertainty, Fundamentals Primarily Drive Spending Growth." February 14, 2018, *https://www.healthaffairs.org/doi/10.1377/hlthaff.2017.1655.*

[18] Milliman, "Prescription Drug Rebates and Part D Drug Costs." July 16, 2018.

targets, volume targets, inflation rebates, or rebate guarantees. Finally, plan sponsors must report any administrative fees charged to manufacturers.[19]

In the commercial market, rebates are an effective tool that employers and health plans use to generate more savings for prescription drugs. Employers and other plan sponsors that work with Cigna and Express Scripts choose how rebates are used. Some use them to lower premiums and cost sharing, others choose to expand access, fund wellness programs, or provide discounts to consumers at the point of sale. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates. Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers.

Cigna welcomes the opportunity to work with policymakers to bring down drug costs for patients at the pharmacy counter. There are a number of opportunities to address high list prices and patient exposure at the pharmacy counter that address competition, access to generics, and benefit designs. However, legislative or regulatory efforts to eliminate or restrict the ability of plan sponsors or PBMs to negotiate lower overall costs will lead to higher drug prices not only for Medicare beneficiaries and taxpayers, but also for millions of individuals who access health benefits through their employers.

We believe there are more direct and effective ways to deliver relief to patients most in need without disrupting coverage for millions. For example, in addition to the policy opportunities discussed later, we believe a better way to address patient out-of-pocket costs is to allow payers and their PBMs to use the power of benefit designs to limit beneficiary exposure while ensuring payers continue to have all of the tools at their disposal to negotiate lower costs. For individuals in high-deductible health plans, this could include changes to the tax code to allow coverage of chronic care treatments and other services pre-deductible, for example. Additionally, many have discussed possible changes to the Medicare Part D benefit design to achieve lower patient out-of-pocket costs, and Cigna and Express Scripts welcome the opportunity to be a constructive participant in those efforts for both Medicare Part D beneficiaries and patients in the commercial market.

LEGISLATIVE AND REGULATORY SOLUTIONS TO LOWER DRUG COSTS FOR PATIENTS

We support efforts by Congress and the administration to use market-based solutions that put downward pressure on prescription drug prices through competition, consumer choice, and open and responsible drug pricing. For example, last year we endorsed legislation authored by Senators Stabenow, Cassidy, Ranking Member Wyden, and others to ensure patients are told the lowest cost option available to them at the pharmacy counter. We were pleased the legislation became law, and included a provision to provide more transparency into so-called "pay-for-delay" agreements that prevent biosimilar drugs from entering the marketplace.

Looking to the future, we believe efforts to address out-of-control drug pricing through legislative and regulatory actions should include:

- *Speeding generics and biosimilars to market:*
    - Enacting the Creating and Restoring Access to Equivalent Samples (CREATES) Act, introduced by Chairman Grassley, which aims to lower drug prices by ending restricted access to samples by manufacturers of brand-name drugs, and help to speed generics to market. According to the Congressional Budget Office, its passage would save $3.9 billion over 10 years.[20]
    - Prohibiting patent settlements that include so-called "pay-for-delay" arrangements, which delay the availability of lower-cost generics and biosimilars. Legislation to address these arrangements was recently introduced by Senators Klobuchar and Grassley, and we hope Congress will enact authority to block these anti-competitive agreements, removing barriers to competition and expanding the availability of lower-cost generics and biosimilars. According to a Federal Trade Commission

[19] Final Medicare Part D DIR Reporting Requirements for 2017. Accessed March 4, 2019 at: *https://www.cms.gov/Research-Statistics-Data-and-Systems/Computer-Data-and-Systems/HPMS/HPMS-Memos-Archive-Weekly-Items/SysHPMS-Memo-2018-May-30th.html.*

[20] *https://www.cbo.gov/system/files/2018-09/s974.pdf.*

(FTC) study, these anticompetitive deals cost consumers and taxpayers $3.5 billion in higher drug costs every year.[21]

- Encouraging the FDA to finalize guidance on biosimilar naming standards, improve the efficiency of the biosimilar product development and approval process, and develop effective communication tools to educate providers and patients about the safety and efficacy of biosimilars.
- Preserving the ability of the Inter Partes Review (IPR) process at the U.S. Patent and Trademark Office to invalidate patents that do not represent true innovation. Legislative and regulatory efforts to weaken this process will extend patent monopolies for pharmaceutical and biological products, resulting in higher prices for patients.
- Considering changes to provisions in the United States-Mexico-Canada Agreement (USMCA) that would extend exclusivity for biological products in Mexico and Canada for 10 years. These provisions will limit the ability of Congress to address the 12-year exclusivity period for brand-name biologics.

- *Advancing price transparency for patients and providers in public programs:*
  - We strongly support the concept of providing information about the price of drugs, therapies, and the cost of care to beneficiaries and their providers as a means of improving price transparency, educating consumers, and incentivizing the efficient use of care throughout the health-care system. We support efforts by CMS to move toward a system in which Part D enrollees and their providers have access to real-time benefit check and electronic prior authorization tools, while ensuring appropriate standardization and time frames for implementation.
- *Advancing value-based arrangements in public programs:*
  - It is essential to bring the benefit of value-based payment to spending in public programs. Such arrangements may involve outcomes-based payments that cannot be determined until well after the plan year concludes. Changes to existing laws and/or regulations would allow for such arrangements in all settings and help improve the overall value of national spending for pharmaceuticals. The specific changes Cigna believes are needed include:
    - Modifying Medicaid Best Price (MBP) rules to exclude outcomes-based pharmaceutical contracts from inclusion in MBP calculations in certain situations where failure to achieve a desired outcome leads a manufacturer to refund the full (or majority) cost of the drug, or where payment is contingent on the health outcomes of individual patients;
    - Creating additional flexibility under the Anti-Kickback Statute (AKS) to support value-based contracts and other innovative programs; and,
    - Revising Part D regulations to explicitly permit and provide guidance for how outcomes-based contracting should be accounted for in plan bids or between plan sponsors when the outcome measurement period spans plan years, or when outcomes can only be measured at the end of a plan year.
- *Prioritizing reforms to lower costs and protect patient access in Medicare:*
  - Public programs must have the ability to leverage the commercial market's successful utilization management tools that lower costs while protecting patient access. We support efforts to modify the six protected "classes of clinical concern" in Part D, where all or substantially all drugs in a class must be covered, allowing drug manufacturers to name their price with little negotiation. CMS's plan to only moderate the effect of protected classes—not eliminate them—would save $2 billion over 10 years.
  - There are also clear opportunities to achieve savings in the Medicare Part B program, including introducing Part D utilization management tools into Part B and potentially shifting some Part B drugs to Part D.

[21] *https://www.ftc.gov/news-events/media-resources/mergers-competition/pay-delay.*

Because of the complexity involved with identifying the "candidate" drugs for moving into Part D, along with assessing the consequences and impacts of doing so for both programs, we strongly recommend CMS engage stakeholders through a work group-type process where sample, de-identified data could be shared for mutual evaluation.

- We also support efforts to ensure the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) have access to de-identified information currently submitted by PBMs, Part D sponsors, and Medicare Advantage plans to CMS. Legislation to address this issue was recently introduced by Senators Cortez Masto, Cornyn, Carper, and Cassidy.

- *Stopping Orphan Drug Act abuses:*
  - Pharmaceutical manufacturers have been accused of abusing the Orphan Drug Act, which was introduced to incentivize drug manufacturers to prioritize the development of "orphan drugs," drugs used to treat an illness or disease that affects fewer than 200,000 people. We support efforts to ensure that this pathway is used for true orphan designations, and not, as some observers say, as a legal cover to seek specious orphan drug designations.[22]

Thank you for the opportunity to be here today, and for the consideration of our views. We look forward to working with you and others to ensure medical innovation continues to be a hallmark of the United States. Many of the proposals highlighted in my testimony are achievable if we work collaboratively, throughout the system, to overcome the challenges facing public and private stakeholders, and the health of our Nation.

I welcome the opportunity to discuss these issues with you and look forward to your questions.

QUESTIONS SUBMITTED FOR THE RECORD TO STEVE MILLER, M.D.

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

IMPACT OF VERTICAL INTEGRATION BETWEEN PBMS AND INSURANCE COMPANIES

Question. The PBM industry has experienced significant consolidation within the past 10 years, which has contributed to concerns about the potential abuse of market power, barriers to market entry, and exclusionary practices. In 2012, for example, Express Scripts acquired Medco Health Solutions—a nearly $30-billion transaction that merged two of the country's three largest PBMs. More recently, PBMs are also vertically integrating with insurers/payers, reflected by the 2018 acquisitions of Express Scripts Holding Co. (a PBM) by Cigna Corp. (a payer) and of Aetna Inc. (a payer) by CVS Health Corp. As a result, the three largest PBMs are all vertically integrated with insurance companies. According to a report from the Kaiser Family Foundation, the two combined entities, along with UnitedHealth and Humana, will cover 71 percent of all Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees. Vertical integration can result in increased efficiencies and consumer benefits. It can also, however, lead to higher barriers to entry for competition, leading to further consolidation. FDA Commissioner Scott Gottlieb recently warned that "consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious. And the very complexity and opacity of these schemes help to conceal their corrosion on our system—and their impact on patients."

I'd like to talk about consolidation, including the recent integration of PBMs with insurance companies. Last year, I wrote to the Justice Department on this issue. It's reported that the three largest PBMs—who are before us today—now cover 71 percent of Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees. Such market power has raised concerns. FDA Commissioner Scott Gottlieb said, "the consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious."

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[22] *https://khn.org/news/drugmakers-manipulate-orphan-drug-rules-to-create-prized-monopolies/*.

I want to hear briefly from each of you on whether the PBM industry is competitive. For example, are there high barriers to entry for new competitors?

Answer. As you are aware, Cigna completed a merger with Express Scripts in December 2018. Our combination was premised on our deep belief that while neither company on its own could achieve the change needed to the U.S. health-care system, together we can make significant improvements to current approaches to caregiving, moving from episodic to holistic, disconnected to connected, and—critically—complicated to simple. The combined companies bring together approximately 74,000 employees around the world with a joint mission to drive predictable, affordable, and high-quality care through connected, personalized solutions.

We believe that PBMs operate in an incredibly competitive market, with over 60 [1] different entities competing to deliver cost savings to customers, employers, and health plans. Employers and health plans therefore have a number of choices in contracting and designing pharmacy benefit options in the market, and we are constantly evolving and innovating with our offerings to remain competitive and affordable. Our transaction was subject to the review and approval of the Department of Justice and State regulators.

Question. I'm also interested in what effect the most recent consolidations of PBMs and insurers has had on the bottom line for the government and consumer.

Do these arrangements result in a lower cost to the government—as a payer—and the consumer? Please explain.

Answer. The combination of Cigna and Express Scripts is accelerating the pace of positive changes we are bringing to the system. Together, the combined company is seeking to transform health care service—reducing costs, while improving the customer experience, care quality, and health outcomes. By bringing together the medical, behavioral, and health engagement (wellness) insights of Cigna and the broad pharmacy, specialty pharmacy, and clinical insights of Express Scripts, we can create integrated customer solutions that offer better care, reduce medical and pharmaceutical costs, and flatten the cost curve for health care to be in line with that of other consumer goods.

For example, over 7 million Americans diagnosed with diabetes use insulin. For some patients, the increasing price of insulin limits access and adherence. When Cigna and Express Scripts announced the combination, we clearly stated we would improve choice, affordability, and predictability. Within the first 100 days of our combination we were able to launch a new Patient Assurance Program, which will bring additional affordability and predictability to customers who rely on insulin to manage their diabetes. Furthering Cigna and Express Scripts' respective historical efforts in diabetes disease management, the Patient Assurance Program establishes a lower, fixed out-of-pocket cost for covered insulins, ensuring eligible customers in participating plans will pay no more than $25 out of pocket when filling a 30-day insulin prescription at a retail pharmacy or through home delivery. This is an early example of the accelerated change and innovation our new company is positioned to drive in the financing and delivery of care.

COLLECTION, USE, AND SHARING OF PERSONAL HEALTH INFORMATION

Question. Consumers are becoming more and more concerned about the data collection and sharing practices of companies. While these issues have been most prevalent in the social media and tech industry, companies in the pharmaceutical supply chain also have access to tremendous amounts of sensitive, personal health information of the individuals they serve. For example, the company Livongo partners with CVS Caremark to provide low-cost or no-cost blood sugar meters to diabetic patients. The meters are always "connected" to Livongo's "Diabetes Response Specialists." As the company's website states, "When readings are out of range, our Diabetes Response Specialists call or text [the individual] within minutes." While these innovations may be highly beneficial for individuals in managing their health, it's also important for this committee to fully understand what types of information is collected, how or why it's stored or shared, and for what purposes PBMs themselves and other affiliated drug supply chain participants (such as insurers) use the information.

Health information is extremely sensitive. It's the most personal of all the information we share. So I want to know more about each of your companies' data collection, sharing, and protection practices.

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[1] *https://www.pcmanet.org/wp-content/uploads/2019/04/Competitive-PBM-Marketplace.pdf.*

These are "yes" or "no" questions for all of you. Does your company collect and store health information from the end users of the prescriptions you provide? For example, information or records of a diabetic individual's blood sugar levels.

Answer. The PBM is subject to the requirements of the Health Insurance Portability and Accountability Act (HIPAA) in its role as a HIPAA Business Associate to PBM clients, which are HIPAA Covered Entities. The collection, storage, and use of health information is essential for a variety of services provided to the PBM clients, by way of example, processing claims and appeals; providing services that support safety reviews, such as Drug Utilization Review; and member prescription adherence. For example, to help members manage insulin adherence, the PBM can assist members by monitoring blood sugar levels, as provided by the patient's physician, and then offer tailored support for improved care. For diabetes and other chronic conditions, we look for ways to engage with members and their health-care providers to achieve the best outcomes.

Question. Does your company make any treatment, cost, or coverage decisions based on the health information you collect from an individual?

Answer. Benefit design, including coverage decisions, are determined by the PBM client, whether that is an employer in the private market, a State, a union, or the Federal Government. As mentioned earlier, an individual's health information is necessary to pay claims and decide appeals. In addition, tracking patients' prescription adherence assists Express Scripts in developing tools to prevent or minimize non-adherence. In particular, clinical standards and models, in combination with personalized clinical services and interventions, are used to attempt to prevent or minimize non-adherence. Information, such as geographic location/address, smoking status, drug cost, co-morbidities or potential clinical concerns, and other factors are gathered for the model to anticipate a patient's potential obstacles to prescription adherence and healthy outcomes. Using this data, a tailored approach is developed—through personal clinical services and outreach, for example, via providing consultations with licensed pharmacists—to reduce or prevent the likelihood of non-adherence and support outcomes.

Question. Does your company share health information with third parties? And, if so, does your company profit from that sharing?

Answer. In compliance with HIPAA requirements, health information is shared with HIPAA Business Associates consistent with the HIPAA "minimum necessary" standard and pursuant to the provisions of a written Business Associate Agreement to allow these third parties to support and assist in providing PBM services. Additionally, the PBM shares health information with health care professionals, such as physicians and pharmacies, for purposes of supporting treatment provided by those professionals.

The sharing of protected health information (PHI) with Business Associates does not provide the PBM with a source of revenue; Business Associates are vendors that are compensated for their services. Use disclosure of PHI is limited as agreed to in the Business Associate Agreement and governed by applicable HIPAA requirements.

Question. Do you believe customers are fully aware of your information collection and sharing practices?

Answer. We make individuals aware of their privacy rights via the HIPAA Notice of Privacy Practices, which is available, as required by HIPAA, on our website, where they can learn how to request an accounting of disclosures of their PHI other than for treatment, payment, or health-care operations.

QUESTIONS SUBMITTED BY HON. RON WYDEN

REBATE DEMANDS

Question. The use of rebates as a negotiating tool has led to problematic incentives in the prescription drug supply chain. For example, drug companies have argued that they increase list prices in response to demands from PBMs for high or increasing rebates.

Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that require equivalent rebates, even in the case of a drug for which the list price has been lowered?

Answer. As noted during the hearing, manufacturers alone make and set prices for their products; rebates are retroactive discounts negotiated by PBMs with manufacturers to defray the price of drugs paid by health plans. The availability of any/several competitor brand drugs within a therapeutic class will affect the amount of discount obtainable—if any—by a PBM, among a host of other variables.

Health plans and payers choose how to use rebate value. In Medicare Part D, for example, all of the rebate value is passed through to plan sponsors. In situations where a manufacturer lowers the list price of one of its products, maintaining the "equivalent" rebates for that drug results in an even lower negotiated price for plans and patients. Hence, a PBM negotiating "equivalent" rebates in the face of lower list prices actually helps drive a lower drug cost for payers.

We welcome and encourage manufacturers to lower list prices independent of whatever discounts we negotiate with them.

Question. Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that require advance notice of changes in the list price of drugs, including reductions or increases in list price?

Answer. Many sole-source, high-priced specialty drugs, such as those treating cancer, do not offer rebates and continue to rise in cost over time. For example:

In 2017, non-rebated drugs treating depression, high-cholesterol, infertility, and other conditions all registered price increases of more than 15 percent.[2]

List prices for oral oncology medications, which are not rebated or discounted to any significant extent, doubled between 2011 and 2016, from $20 per unit to $40 per unit.[3] Looking at the 39 oral oncology medications on the market in 2010, six experienced 100–200-percent inflation between 2010 and 2016; one was greater than 300 percent and another one was greater than 800 percent.[4] Rebates are not available on these drugs, but the manufacturers continue to increase list prices. Under the recently proposed rebate rule, beneficiaries using non-preferred and specialty drugs will see premiums increase, and will not see a reduction in cost at the pharmacy counter.[5]

In the end, we focus on the lowest net cost of a drug, not the rebate. Again, we welcome manufacturers lowering their list prices so that patients can have greater access to medications.

Question. If the answer to either of the above is "yes," please provide details regarding each of these requirements in each instance in which they were in place: the required rebate amount or percent; the amount of notice required for list price change notifications, specifically for increases and decreases; any penalties for noncompliance with rebate or notification requirements by the drug manufacturer.

Answer. In situations where a manufacturer lowers the list price of one of its products, maintaining the "equivalent" rebates for that drug results in an even lower negotiated price for plans and patients. Hence, a PBM negotiating "equivalent" rebates in the face of lower list prices actually helps drive a lower drug cost for payers.

REVENUE SOURCES

Question. Please provide an annual breakdown of the following components of the revenue you received from drug manufacturers from January 1, 2013 through December 31, 2018: dollar amount and percent of revenue from rebates; dollar amount and percent of revenue from administrative fees; dollar amount and percent of revenue from distribution fees; dollar amount and percent of revenue from marketing fees; dollar amount and percent of revenue from clinical case management fees; all other sources of revenue from manufacturers not listed above.

Answer. Revenues generated by Express Scripts segments can be classified as either tangible pharmacy revenues or other pharmacy service revenues. We earn tangible pharmacy revenues from the sale of prescription drugs by retail pharmacies in our retail pharmacy networks and from dispensing prescription drugs from our

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[2] Express Scripts, "Let's Talk About Rebates," May 15, 2018, *http://lab.express-scripts.com/lab/insights/industry-updates/lets-talk-about-rebates.*

[3] Express Scripts, "The Cost of Hope: 5 Things to Know About the Cost of Cancer Drugs." May 30, 2017, *http://lab.express-scripts.com/lab/insights/industry-updates/the-cost-of-hope-5-things-to-know-about-the-cost-of-cancer-drugs.*

[4] *http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter.*

[5] *http://lab.express-scripts.com/lab/insights/industry-updates/sharing-smarter.*

home delivery and specialty pharmacies. Other pharmacy service revenues include administrative fees associated with integrated medical benefit management solutions, the administration of retail pharmacy networks contracted by certain clients, informed decision counseling services and certain specialty pharmacy services.

PART D NEGOTIATION

Question. The PBM market has changed dramatically over the past several years. Many Part D health plans also operate as PBMs, including your companies. While Part D has done a great job offering Medicare beneficiaries drug coverage they did not have access to before, Part D has not been successful at keeping up with the growing cost of medicines. PBMs and Part D plans claim they bargain to get lower prices, but the HHS Inspector General found that almost 4 in 10 brand name drugs in Part D offered no rebate or discount to Part D plans.

Why have Part D plans been ineffective at bringing down the cost of almost half of brand-name medicines?

Answer. According to a study of drugs covered under Medicare Part D by the actuarial firm Milliman, 81 percent of all drugs in the program—including 64 percent of brand drugs analyzed—do not offer rebates.[6] In most cases, the reason for this can be traced down to the absence of competitor or therapeutically equivalent (generic) drugs that PBMs can use as negotiating leverage with manufacturers. In other instances, Medicare regulations prevent use of step therapy or prior authorization for drugs that fall within the six protected classes, or are the only drug in a class. In such cases, mandatory coverage requirements remove any negotiating leverage PBMs could otherwise exert on the manufacturer.

Many have discussed possible changes to the Medicare Part D benefit design to achieve lower patient out-of-pocket costs, and our company welcomes the opportunity to be a constructive partner in efforts to address these program shortcomings for Medicare Part D beneficiaries. The testimony provided in front of the Senate Finance Committee on April 9, 2019 included several policy options that inject greater competition into the prescription drug market and also give plans and PBMs further utilization management and negotiation tools to work with in Medicare.

PBM PROFITS

Question. At the hearing, witnesses spoke about the ways in which they seek to get the best price for patients. However, behind this is the reality that PBMs are driven by their bottom line.

Researchers at Johns Hopkins University found that 72 percent of formularies in Part D charge lower cost-sharing for a brand name drug compared to the cheaper generic equivalent.[7] This occurs because the more expensive brand name drugs are able to give bigger rebates, but we can never know for sure because rebate information is kept secret.

How can the public have confidence that they're getting the lowest price and not the price that gives you the biggest rebate to your business?

Answer. Every formulary decision we make is based first and foremost on clinical guidance, not on cost. Our National Preferred Formulary (NPF) is developed by an independent Pharmacy and Therapeutics (P&T) Committee comprised of independent practicing physicians, other clinicians and academics representing multiple areas of clinical expertise. Their decisions are based solely on whether clinical evidence shows that a drug must be covered. Only after products are evaluated from a clinical perspective are net cost and other factors considered. Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process.

Further, we note that plan sponsors are not obligated to adopt our NPF, but can accept, reject, or modify it as they deem fit or even create their own custom drug formulary. A formulary becomes part of a plan sponsor's benefit only after adoption by the client. Like formularies, copay tiers and other elements of benefit design are ultimately determined by our clients. Plan sponsors use PBMs to manage their drug benefits, however, because our services are effective and result in savings to their plans and ultimately, for patients. Competition among PBMs is fierce and clients—

[6] *https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf.*
[7] *https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2728446.*

who are sophisticated and often advised by expert consultants—leverage that dynamic to secure the greatest savings from their bidders.

SPREAD PRICING IN MEDICAID

Question. A PBM practice that has come up quite a bit recently is the practice of spread pricing. Spread pricing occurs when PBMs charge health plans more for prescription drugs than they actually reimburse pharmacies, and then pocket the different as profit.

Do you engage in spread pricing practices?

Answer. Spread pricing is one option Express Scripts' clients—including Medicaid Managed Care Organizations (MCOs) where authorized by a State—may elect in structuring their overall drug pricing arrangement. Certain clients opt to utilize spread pricing, while other clients opt to use pass-through arrangements. It is important to note that our clients (payers) always decide whether or not to use spread pricing.

Spread pricing encourages active and aggressive rate negotiations by harnessing market forces to achieve the lowest drug prices through negotiation. Put more simply, spread pricing allows PBMs to offer client plan sponsors more favorable discounts and reduced administrative costs as compared to "pass-through" or "cost-plus" arrangements. Notably—and contrary to the views of many industry critics—spread pricing is favored by many clients because it represents the greatest alignment of interests between the PBM and client; specifically, that the PBM is compensated for driving the lowest net cost for the plan sponsor.

Question. If yes, do you engage in such practices in Medicaid?

Answer. Yes. Express Scripts has contracts with Medicaid managed care plans in which the client has chosen to utilize spread pricing.

Question. List each State you operate in where you have a contract with a Medicaid managed care plan where you employ spread pricing.

Answer. We have arrangements with clients who operate under rules established by State Medicaid agencies and we encourage the committee to work with States to understand and examine the specifics of contracts within their State.

Question. List each Medicaid managed care plan you have contracts with where you employ spread pricing.

Answer. We have arrangements with clients who operate under rules established by State Medicaid agencies and we encourage the committee to work with States to understand and examine the specifics of contracts within their State.

Question. Describe whether and how you disclose the use of such practices to the plans.

Answer. Our clients decide which pricing structure to select and are provided robust disclosures. Further, we give plans full audit rights to ensure we are performing according to the terms of our contracts with them.

Question. Describe whether you disclose such practices directly to the State.

Answer. Express Scripts does not contract directly with any State Medicaid agencies, but instead the Medicaid Managed Care Organization contracted with the State.

Question. List any States where you have direct contracts with the State Medicaid agency as a PBM for fee-for-service individuals.

Answer. Express Scripts does not contract directly with any State Medicaid agencies as a PBM.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

Question. What is the total dollar amount that you obtain from pharmaceutical manufacturers in any form such as rebates, fees, etc.?

Answer. Manufacturers ultimately decide whether to offer a rebate discount, and if so, what rebate to offer. When there are multiple therapies with similar clinical efficacy, Express Scripts is able to leverage competition to drive lower costs for its clients and customers. Conversely, rebates are not typically offered for drugs with-

out market competition (*i.e.,* sole-source brand drugs), drugs that have obtained "orphan" designation, or drugs administered by a physician. Rebates are typically only offered on brand drugs. The amount of rebate discounts varies significantly based on utilization and a plan's benefit design.

Question. What is the total dollar amount that you remit to health plans?

Answer. In 2018, Express Scripts saved its clients $45 billion. Because of our innovative solutions, our clients achieved the lowest drug trend in decades, just 0.4 percent across employer-sponsored plans. Despite rising list prices, the average 30-day prescription cost only $0.06 more than in the previous year. To Medicare, we delivered an unprecedented 0.3 percent decline in drug spending across the plans we serve.[8]

Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates. In Medicare Part D, 100 percent of the rebate value is passed through to plan sponsors.

Question. Managed Care Organizations are on record as widely supportive of the potential of biosimilars. However, most MCOs have continued to support originator brand products and have not preferred and often excluded less expensive biosimilars. For example, most MCOs have kept Remicade (a treatment for rheumatoid arthritis and other diseases) as the preferred agent on their formularies, and in most cases to the exclusion of its biosimilar, Infliximab.

Why do you tout support for biosimilars while, at the same time, inhibiting adoption of these less expensive products?

Answer. We support the lowest net cost, clinically appropriate option for our clients and members. We fully support efforts to accelerate adoption of specialty generics and biosimilars. In certain situations, our formulary offerings may prefer branded products when doing so results in a lower net cost to our client plan sponsors.

Question. HHS may broaden the scope of its proposed rule and eliminate rebates between Medicare Advantage plans and manufacturers for Part B drugs. Would this realign incentives to encourage preferred access for lower cost drugs, such as biosimilars?

Answer. We believe that part of the cause for escalating drug costs in the Part B program today includes a lack of utilization management tools that exert downward pressure on net costs. There are clear opportunities to achieve savings in the Medicare Part B program, including introducing Part D utilization management tools into Part B and potentially shifting some Part B drugs to Part D. Because of the complexity involved with identifying the "candidate" drugs for moving into Part D, along with assessing the consequences and impacts of doing so for both programs, we strongly recommend CMS engage stakeholders as they develop their policy.

Question. What changes can we recommend/make to help you prefer lower-cost drugs, such as biosimilars, without rebates?

Answer. After clinical factors are evaluated, Express Scripts considers the lowest net cost drugs as part of developing formulary offerings for its clients, where competition exists. Lowest net cost can be achieved through lower list price, rebates, or both. We welcome manufacturers lowering their list prices so that patients can have greater access to medications. Solutions for driving lower drug spending and fostering the use of lower net cost treatments often include negotiating discounts or rebates.

The role of rebates in prescription drug pricing has been mischaracterized. Rebates are not the cause of increasing drug prices. Rebates are discounts paid by drug manufacturers after a patient receives a manufacturer's drug. In the system today, rebates are used to reduce health care costs for consumers. The amount of discount/rebate per drug attainable is affected by the relative bargaining power of the PBM negotiating to drive down costs for its plan sponsor clients.

PBMs compete among themselves to obtain the greatest rebates/discounts for health plan sponsors. The ability to help drive lower net drug costs for plan sponsors, in addition to the quantity and quality of other clinical and administrative

[8] *https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf.*

services provided by the PBM, will determine its success in the marketplace. Today, employers and others use the value of discounts to help keep premiums affordable, lower out-of-pocket costs, and offer workplace wellness programs, just to name a few ways they put discounts to work.

Question. Why is there such a disparity in reimbursed pharmacy prices for specialty generic drugs in Part D (*e.g.,* Imatinib)? Does ownership of specialty pharmacy influence your reimbursement decision?

Answer. Our ownership of Accredo specialty pharmacy does not influence reimbursement decisions with respect to other pharmacies.

Question. I'm concerned with the recent trend of PBM's allowing brand companies to "pay for position" on insurance formularies, which results in seniors losing access to lower-cost generics and biosimilars.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs?

Answer. The process Express Scripts uses to develop formularies has been constructed to ensure that clinical considerations are paramount and fully taken into account before cost considerations. Formulary management is a highly effective strategy that pharmacy plan sponsors can implement to maintain a safe, affordable and meaningful benefit for patients. When a manufacturer launches a lower-cost authorized alternative to a branded medication currently on the market, Express Scripts will evaluate the product for placement on the National Preferred Flex Formulary. If clinically appropriate, the authorized alternative product will be added to the Flex formulary with preferred or possibly non-preferred status. The innovator brand-name product, and potentially other products in the therapy class, then will be excluded from coverage.

In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand. Moreover, until recent changes to current biosimilar interchangeability guidance were released by the FDA, and pending further implementation of those policies, the ability of plan sponsors to make clinically appropriate therapeutic substitutions has been severely limited. We are hopeful as more biosimilars enter the U.S. market that, under these new guidelines, plans will be in a much better position to take full advantage of the potential these products can provide.

FORMULARY PLACEMENT/GENERIC TIERING

Question. In 2011, 71 percent of generic drugs in Part D were on the lowest tier designed for generics; by 2019, that number decreased to only 14 percent of generics. According to an Avalere study, this practice cost seniors $22 billion in higher out-of-pocket costs since 2015, costs that could have been avoided through the proper formulary placement of lower-cost generics. This practice, known as "paying for position," allows brands to block uptake of lower-cost generics and biosimilars, thereby unnecessarily increasing out-of-pocket costs for seniors.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs? Do you ever consider portfolio or bundled rebates with brand manufacturers?

When you place generics on your formularies, do you place that generic favorably to brand products—in other words, on generic-only tiers?

When a generic becomes available, do you place it on your formularies immediately?

Answer. Our formulary is a critical driver of both clinical efficacy and value. Formulary development involves guidance from three distinct committees: the Therapeutic Assessment Committee ("TAC"); the Pharmacy and Therapeutics Committee ("P&T"); and the Value Assessment Committee ("VAC"). Each is described briefly below:

- TAC is an internal clinical review body consisting of clinical pharmacists and physicians, who review specific medications following FDA approval using medical literature and published clinical trial data.

- P&T consists of a group of 15 independent physicians and one pharmacist from active community and academic practices representing a broad range of medical specialties.
- VAC, which consists of Express Scripts' employees from formulary management, product management, finance, human resources, and clinical account management, considers the value of drugs by evaluating the net cost, market share, and drug utilization trends of clinically similar medications.

Our formulary development approach for all medications prioritizes clinical considerations first and foremost before evaluating net cost to clients. Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process. The financial impact to clients, however, is considered by the VAC, but only after all clinical considerations have been taken into account.

When a manufacturer launches a lower-cost authorized alternative to a branded medication currently on the market, Express Scripts will evaluate the product for placement on the National Preferred Flex Formulary. If appropriate, the authorized alternative product will be added to the Flex formulary with preferred or possibly non-preferred status. The innovator brand-name product, and potentially other products in the therapy class, then will be excluded from coverage. In our experience to date, we have not seen manufacturers of authorized alternatives offer a rebate that would result in a net cost lower than that of the brand.

DIRECT AND INDIRECT REMUNERATION (DIR) FEES

Question. Many community-based cancer clinics have established medically integrated pharmacies so patients can access their oral chemotherapy prescriptions or other medications at the point-of- care. These practices are often assessed large DIR which are based on certain quality measures targeted toward primary care.

Shouldn't pharmacies be evaluated on the type of drug dispensed and disease managed rather than a one-size fits all approach?

Answer. CMS Star ratings were created with patient outcomes in mind. That is why Express Scripts chooses to leverage CMS quality standards to measure pharmacy performance. Express Scripts and our plan sponsors believe that pharmacies should be held to the same quality standards as our plan sponsors.

We agree that DIR arrangements should include performance metrics over which pharmacies have meaningful control and an ability to influence. We also believe that they should appropriately take into account whether the pharmacy is a retail pharmacy, specialty pharmacy, or dispensing physician. Express Scripts DIR arrangements take these factors into account.

Question. Does assessing large DIR fees on medically integrated pharmacies drive patients to PBM-owned specialty pharmacies?

Answer. No.

Question. According to CMS, from 2012 to 2017 PBMs imposed a 45,000 percent increase in the amount of DIR fees pharmacies had to pay PBMs and PDPs under Part D, and revenues earned from these fees increased 225 percent per year during this period.[9] I thought PDPs and PBMs were supposed to pay pharmacies for dispensing drugs to patients. Why do pharmacies have to pay DIR fees to PBMs at all?

Why are pharmacies forced to pay DIR and other fees to PBMs?

Answer. Pharmacies are not forced to enter into DIR agreements with Express Scripts. DIR agreements are made between plan sponsors and pharmacies as a way to improve the cost and quality of a Medicare Part D plan. They are part of the contract that is mutually developed and agreed upon by the pharmacy and the Part D plan sponsor.

As part of these arrangements, pharmacies become one of the plan's preferred pharmacies by agreeing to achieve certain performance metrics. These metrics for the pharmacies are typically aligned with the Star ratings metrics that CMS uses to judge the performance of Part D plans. Express Scripts has seen improvement

[9] CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152, 62174 (November 30, 2018).

in quality across all pharmacy types over time, particularly for Pharmacy Services Administrative Organizations (PSAOs) and independent pharmacies.

Pharmacies are increasingly interested in participating in DIR arrangements as a way to become a preferred provider within a Part D plan's retail pharmacy network. Within these narrower pharmacy networks, patients have lower copays when filling prescriptions at their plan's preferred pharmacies, and those pharmacies benefit by gaining access to a larger percentage of the plan's beneficiaries.

Ultimately, it is the decision of the pharmacy whether or not to enter into a DIR agreement.

Question. According to CMS, PBMs justify DIR fees as adjustments to improve quality. CMS also found that PBMs and PDPs withhold substantially more in reductions in payments than as rewards paid to pharmacies.[10] Aren't so-called "quality adjustments" that collect more for "poor performance" than they pay out for "high performance" just another way for PBMs to collect even more money from pharmacies?

Why do PBMs collect more in quality payment adjustment than they pay pharmacies under Part D?

Answer. If a pharmacy does not reach the performance metric to which it agreed to pursue and maintain—*e.g.,* medication adherence rates for a specific disease category—then that pharmacy is assessed the DIR fee detailed in the contract between the plan and pharmacy. It is important to note that all DIR fees go to the Part D plan sponsor and not to the PBM—100 percent of pharmacy network DIR is passed to plan sponsors.

In addition to a variable reimbursement based on quality outcomes, the Express Scripts performance network also includes bonus payments to top performers at the end of the year to further reward achievement of high quality outcomes.

DELAYS AND DENIALS IN CANCER TREATMENT

Question. I have received stories of cancer patients facing delays or denials for their treatment due to PBM actions. Data shows that breast cancer patients who experienced a 3-month or more delay in treatment had a 12-percent lower 5-year survival rate compared with breast cancer patients with only a 0- to 3-month delay.

What percent of patients experience a 14-day or longer delay in receiving an oral oncolytic prescribed by their oncologist?

Answer. At ESI, we use pharmacists and board certified physicians for all of our reviews. We respectfully refer to our answer below with respect to the most common reasons for delays. We are committed to always providing our clients' patients access to clinically appropriate medications as quickly, affordably, and safely as possible.

Question. What are the primary reasons patients experience delays or denials for their treatments?

Answer. A client plan sponsor's formulary design and the utilization management tools—*e.g.,* prior authorization or step therapy, etc.—determines how quickly a patient may access certain prescribed medications. Where there are multiple drugs—both branded or generic—within a therapeutic class that are similarly effective, certain of those drugs may be preferred for initial coverage over others. Formularies are designed based on evidence-based research and established clinical guidelines. Again, plan sponsors alone determine their formularies and which utilization management tools to employ as permitted under applicable law (*i.e.,* Medicare, ERISA, etc.).

Where a prescriber seeks an exception to the plan's preferred drug option, he/she has the right to appeal and request approval of the original prescription. For coverage appeals, prescribers are required to submit all relevant clinical information necessary for the plan to determine if the request is appropriate under the patient's circumstances. In these situations, providers act on behalf of patients when requesting approval of some covered services or medications from health plans before delivering a particular treatment.

When clinical evidence appropriately provides that alternative medicines that are similarly effective and cost less have not been tried first, or additional patient clin-

[10] *Id.* at 62174.

ical information must be provided to support their request for coverage, any delays that arise may be due to any number of factors. The vast majority of any delayed approvals for exception requests are due to prescribers not providing complete information at the time the request was submitted. Or the prescriber does not respond to plan follow-up requests for additional clinical information necessary to complete a review on their submissions.

Cigna and Express Scripts have worked to simplify and improve the prior authorization request experience for prescribers, and have developed and made available to physicians an "App" tool that allows providers using it to submit electronic prior authorization requests directly from their smartphones at the moment the prescription is being ordered, along with possible alternatives that would not require such a request. Details on this product are discussed further in our response to questions addressing "real-time benefit check tools."

Question. What percent of determinations to delay or deny treatment for cancer patients are made by an oncologist or healthcare professional with oncology training?

Answer. We are committed to always providing our clients' patients access to clinically appropriate medications as quickly, affordably, and safely as possible.

Question. Why is a PBM-owned specialty pharmacy better qualified to manage a cancer patient's adherence and side effects than a community cancer clinic with a medically integrated pharmacy?

Answer. Specialty pharmacies are distinct from traditional pharmacies because they coordinate many aspects of patient care to more effectively manage treatment, side effects and interactions with other therapies. Medications dispensed by specialty pharmacies are often subject to strict dispensing rules under the FDA REMS program, and require special storage, handling and packaging prior to dispensing. These products are usually significantly more expensive than conventional medications and require additional controls to assure that patients take them appropriately.

For these reasons, manufacturers of specialty medications frequently enter into limited distribution arrangements with those specialty pharmacies fully capable of addressing the unique needs of their products. This is not a function of whether a specialty pharmacy is owned by a PBM or not; not all specialty pharmacies (even large ones based on prescription volume) are owned by PBMs, and often have their own limited distribution arrangements with manufacturers as well. In fact we also contract with non-PBM owned specialty pharmacies provided they meet the same quality and safety accreditation standards followed by the industry.

At Accredo, our in-house specialty pharmacy, we operate 15 condition-specific Therapeutic Resource Centers (TRCs) that allow us to deliver a level of expertise and individualized care that is unmatched in the market. Our clinical model, developed around the TRCs, allows us to provide patients with the additional resources they need to manage their condition safely and effectively, including:

- Access to 500 specialty pharmacists on the phone and through video;
- 550 field-based infusion nurses who meet patients face-to-face—at home, work, or school—to administer specialty medications for some of the most complex disease states, such as pulmonary arterial hypertension and immune disorders;
- Nutrition counseling and social worker support;
- Therapy management programs to protect patient health and safety; and
- Complete coordination of care between the medical benefit, pharmacy benefit and physicians.

This unique combination of clinical specialization and personalized engagement helps patients make decisions that improve adherence, optimize health outcomes, and reduce costs.

QUESTIONS SUBMITTED BY HON. BILL CASSIDY

Question. In calendar years 2015, 2016, and 2017, what percent of your revenue was from fees paid by plans, fees paid by manufacturers, other fees, pharmacy

spread or rebates? Same question as to profits. Of all revenue generated from part D contracts, what percent did you retain?

Answer. Per our annual 10–K filings with the SEC:

- In 2015, Express Scripts' net profit margin was 2.43 percent.
- In 2016, Express Scripts' net profit margin was 3.39 percent.
- In 2017, Express Scripts' net profit margin was 4.51 percent.

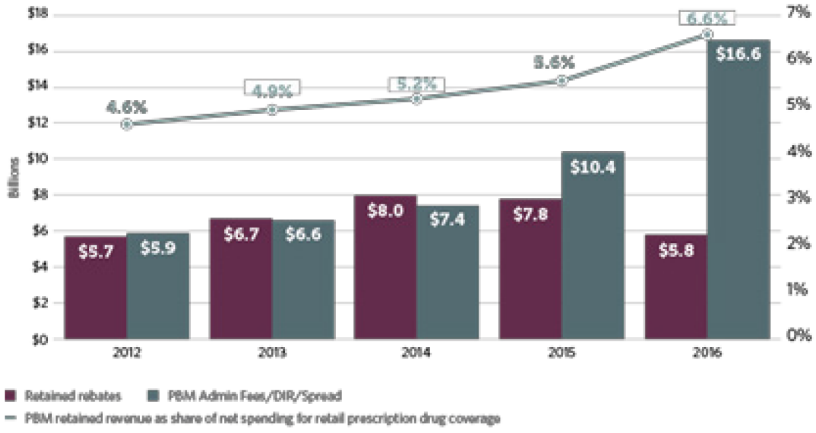
Question. Should a patient ever pay more out of pocket for a medicine than what you pay the pharmacy for that medicine?

Answer. Express Scripts employs a "lesser of logic" approach at the point of sale for patients at the retail pharmacy, and pharmacies in our networks are not permitted to charge a member more for their copay under their benefit than the pharmacy's cash price. Moreover, Express Scripts has never used "gag clauses" and enthusiastically supported legislation—passed in the previous Congress—that banned such practices.

Question. PBM revenue from fees has risen, illustrated below. Further, PBM's retained revenue as a percent of net retail drug spend has consistently increased. What do you attribute this increase to?

Figure 9

PBM Retained Revenue on Retail Prescription Drugs by Source and Share of Net Spending for Retail Prescription Drug Coverage, 2012-16



Answer. We would first note that this is an industry chart and not necessarily indicative of our specific business.

We respectfully refer to our answer for the preceding question to note that while revenues may increase, Express Scripts' profit margin remained consistently around or below the 5-percent range.[11] It is noteworthy that the Express Scripts 2017 margins are roughly a third less than that of the top Fortune 500 drug manufacturers, who averaged 14.6-percent profit from revenues in that same year (2017).

Following Cigna's combination with Express Scripts, the combined organization reported a GAAP margin of 3.61 percent for the first quarter of 2019. We again note the disparity with our counterparts among the top Fortune 500 drug manufacturers, who averaged 23.9 percent profit from revenues in 2018.[12]

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[11] *https://www.drugchannels.net/2018/06/profits-in-2018-fortune-500.html.*
[12] *https://www.drugchannels.net/2019/06/profits-in-2019-fortune-500.html.*

Question. How are bona fide service fees established? What was your revenue generated in part D by bona fide fees in 2015, 2016, and 2017?

Answer. Express Scripts has served and continues to serve thousands of clients, which include Medicare Part D sponsors. Express Scripts' clients, including Medicare Part D sponsors, make benefit design decisions and individually negotiate contractual provisions such as service fees.

Question. A *Health Affairs* article suggests plans may prefer paying PBMs using rebates instead of fees, as "Using retained rebates to cover PBM costs in lieu of fees could artificially lower reported administrative costs and make it easier to meet government medical loss ratio (MLR) requirements." Is it true that paying the PBM a percent of rebates would keep that revenue from counting towards a plan's MLR?

Answer. In the Medicare setting, we pass through 100 percent of the rebate value to our health plan clients.

Question. Would you support an industry-wide standard set of performance metrics by which a PBM would set its pharmacy contracts, which would be tailored based on regional patient populations, to give certainty for local pharmacies?

Answer. We welcome the opportunity to work with you on improving performance metrics standards. We encourage policies that use informed metrics that would improve quality of care for all patients.

Question. Are there ever cases where a patient in your health plan or one of the health plans for whom you negotiate as a PBM pays more for a medicine than the plan spends on a net basis, when you reimburse the pharmacy for that same medicine? In those cases, what entity receives the benefit of the difference between the amount the patient pays and the net amount the plan pays?

Answer. Yes, there are and in those cases where such differences occur, the contracting arrangements with the client will dictate how those amounts are allotted.

QUESTIONS SUBMITTED BY HON. RICHARD BURR

Question. Pharmacy Benefit Managers (PBMs) offer a variety of contract designs to health insurance plans, allowing the insurer or client to choose the best structure for their customers. During the Finance Committee hearing on April 9, 2019, each witness stated that, in the contracts structured to allow for the pass-through of rebate dollars at the point of sale, PBMs do not keep *any* portion of the rebate. If the PBM does not keep a portion of the rebate, what type of revenue do PBMs receive from these contracts? What percent of your contracts are point of sale and what percent utilize a structure providing a percentage of the rebate back to the PBM?

Answer. In a typical rebate pass-through arrangement with clients, we are paid an "administrative fee" (spelled out in our contract with the plan sponsor) for adjudicating a prescription drug claim in lieu of keeping any portion of any rebate dollars remitted to the plan; this is also known as a "cost-plus" arrangement. When selecting between "spread pricing" and "pass-through" arrangements, clients negotiate for pricing terms that best suit their needs from a wide range of options. For more than 10 years, we have offered our clients an option to provide rebate value at the point-of-sale, and to date only a handful of clients have chosen to do so. Instead, most clients elect to use rebate value to offset premiums and offer a more robust benefit.

In Medicare Part D, PBMs are required to pass through all rebates to the plan sponsor. Client contracts contain financial disclosures in which Express Scripts provides a detailed overview of its principal revenue sources, including arrangements with pharmaceutical manufacturers, wholesale distributors, and retail pharmacies. These disclosures explain that some of this revenue relates to utilization of prescription drugs by members of the clients receiving PBM services, and that Express Scripts may pass through certain manufacturer payments to its clients or may retain certain of those payments for itself, depending on the contract terms between Express Scripts and the client. Terms vary across clients and contracts. Express Scripts' contractual terms with its clients are confidential and based on those confidentiality obligations, Express Scripts cannot disclose the individual financial performance of any specific contract.

Our clients, who are sophisticated entities and are often represented by benefit consultants and advisors, negotiate the overall arrangement they believe best suits their pharmacy benefit needs. Terms vary across clients and contracts, and some cli-

ents negotiate to receive a portion of rebates, as well as manufacturer administrative fees collected by Express Scripts. Nearly half of Express Scripts' clients have opted for 100-percent pass-through of rebates.

Question. It is our understanding that contracts with pharmaceutical manufacturers may also take a variety of forms. In calendar years 2016, 2017 and 2018, what was the total dollar amount that you obtained from pharmaceutical manufacturers in any form such as rebates, fees, etc.? What is the total dollar amount that was passed on to health insurance plans with which you have an agreement or contract?

Answer. In 2018, Express Scripts' clinical pharmacy benefit solutions returned $45 billion in savings to our clients,[13] up from $32 billion in 2017.[14] Because of our innovative solutions, our clients achieved the lowest drug trend in decades, just 0.4 percent across employer-sponsored plans. Despite rising list prices, the average 30-day prescription cost only $0.06 more. In Medicare, we delivered an unprecedented 0.3-percent decline in drug spending across the plans we serve.[15]

Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates. In Medicare Part D, 100 percent of the rebate value is passed through within the program.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

Question. In Medicare Part D, beneficiaries' deductible and coinsurance payments are calculated based on the price negotiated between the PBM and the pharmacy.

Does this take into account rebates and discounts the PBM negotiates separately with pharmaceutical manufacturers?

If yes, what percentage of the time is this the case?

Answer. In Medicare Part D, 100 percent of the rebate value is passed through within the program. All beneficiaries benefit from rebates in the form of lower premiums. Most drugs do not involve a rebate structure. According to a study of drugs covered under Medicare Part D by the actuarial firm Milliman, 81 percent of all drugs analyzed do not offer rebates and 64 percent of brand drugs analyzed do not offer rebates.[16] In the case of payments made during the deductible phase of the benefit and when cost-sharing is percentage-based, rebates and discounts are not factored into beneficiaries' payments at the point of sale. However, as noted above, all beneficiaries in Medicare Part D see the value of rebates in the form of lower premiums. This is part of the reason that the Medicare Part D program remains popular among seniors, and why participation remains high.

Question. In calendar years 2016, 2017, and 2018, what share of brand prescriptions covered by the Part D plans you contract with were filled in the deductible or required beneficiaries to pay coinsurance? What was the total amount beneficiaries spent out of pocket for those prescriptions? What would beneficiaries' total out-of-pocket spending have been under the same cost sharing structure if their payments were based on the net price to the Part D plan, inclusive of rebates and other price concessions, rather than the price negotiated between your PBM and the pharmacy?

Answer. We do not maintain information in the form requested.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Should the CREATES Act become law, what commitment can your company making to covering generics as soon as they are approved and passing those savings on to patients?

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[13] *https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf.*

[14] *file:///C:/Users/p067734/Downloads/Express%20Scripts%202017%20Drug%20Trend%20Report.pdf.*

[15] *https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf.*

[16] *https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf.*

Answer. We strongly support the Creating and Restoring Access to Equivalent Samples (CREATES) Act, which aims to lower drug prices by ending restricted access to samples by manufacturers of brand-name drugs, and help to speed generics to market. According to the Congressional Budget Office, its passage would save $3.9 billion over 10 years. Express Scripts is committed to leveraging competition to drive lower drug costs, which is why we support the CREATES Act and other legislative changes that would speed the entry of generic drugs into the market. Express Scripts has long been committed to encouraging generic drug use—including biosimilars where available—as appropriate to preserve patient access to needed medications in the most cost-effective manner without sacrificing safety or efficacy.

Question. What are your concerns with point-of-sale rebates and what alternatives do you propose to such rebates to improve consumer savings at the pharmacy counter?

Answer. When selecting between spread pricing and pass-through arrangements, clients negotiate for pricing terms that best suit their needs from a wide range of options. For more than 10 years, we have offered our clients an option to provide rebate value at the point of sale, and to date only a handful of clients have chosen to do so. Instead, most clients elect to use rebate value to offset premiums and offer a more robust benefit.

Question. What are the specific steps your company is taking to move PCSK9 inhibitors off the specialty tier in Medicare Part D and to fixed copay tiers given that prices went down by 60 percent and are no longer above the specialty tier threshold?

Answer. Express Scripts focuses on the lowest net cost drugs on formulary. Plan sponsors always determine their formulary benefit design including their drug coverage tiers, and always retain the option to make changes accordingly subject to Medicare rules.

Question. Why haven't your plans moved it already, given that CMS allows plans to make positive mid-year formulary changes that improve patient access and affordability?

Answer. Again, we make changes to drug placement on formulary tiers at the direction of our client plan sponsors. Further, we advise clients to prefer lowest net cost drugs within their formularies.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

DRUG REBATE RULE AND HIGHER PART D PREMIUMS

Question. In January, the Department of Health and Human Services released a proposal to reform prescription drug rebates paid by pharmaceutical manufacturers to pharmacy benefit managers under Medicare Part D. The OIG proposal attempts to ban most rebates by eliminating their regulatory protections and creating two new safe harbor provisions: one to expressly protect discounts applied directly at the point of sale (POS) for consumers, and another to protect certain service fees that manufacturers pay to PBMs for services furnished to health plans. The only service fees that would be permissible under the proposal are those that are fixed, and not based on a percentage of sales and not based on volume or the value of other business generated between the parties. The proposed rule was designed to address the Department's concerns with the current rebate system, which HHS believes rewards high list prices, discourages the use of generics and biosimilars, and does not reflect patient out-of-pocket costs. For consumers, this proposal may result in lower costs at the pharmacy counter, but Part D premiums may increase as a result.

Could you explain which Part D beneficiaries could see savings on their drug costs at the pharmacy counter and which Part D beneficiaries could not see lower drug costs?

Answer. According to a study of drugs covered under Medicare Part D by the actuarial firm Milliman, 81 percent of all drugs analyzed do not offer rebates and 64 percent of brand drugs analyzed do not offer rebates.[17] However, the CMS Office of the Actuary's analysis of the proposed rule shows that all beneficiaries would be harmed by the rule in the form of higher Part D premiums. Under the recently proposed rebate rule, many beneficiaries using generic, non-preferred, and specialty

[17] *https://www.ahip.org/wp-content/uploads/2018/07/AHIP-Part-D-Rebates-20180716.pdf.*

drugs will see premiums increase, and not a reduction in costs at the pharmacy counter.

PERVERSE INCENTIVE TO PLACE MORE EXPENSIVE DRUGS ON FORMULARIES

Question. In a Senate Finance Committee hearing had a few weeks ago, many pharmaceutical companies argued that the current rebate structure incentivizes high list prices. These companies argue that the higher the list price of the drug, the greater the rebates, and therefore, the more profit the PBM earns. While contracts between PBMs, Part D Plans, and pharmaceutical companies require PBMs to pass through 100 percent of the negotiated rebate back to insurance plans, I worry that this structure could incentivize PBMs to favor a more expensive drug on the formulary because they could get a higher rebate.

Is there an incentive for a PBM to place a higher cost drug on the Part D formulary because the PBM receives a larger rebate for that more expensive drug? Why or why not?

Answer. No. Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process. Our formulary development approach for all medications prioritizes clinical considerations first and foremost before evaluating net cost to clients. The financial impact to clients, however, is considered, but only after all clinical considerations have been taken into account.

Question. Another complaint that I have heard from physician groups is that many formularies do not cover newer drugs that they consider to be necessary for hard-to-treat diseases, even if the drugs are very well-studied.

With technology changing so rapidly, how do your companies ensure that you keep up with the medical and surgical experts and new research, so that your authorization decisions are in line with the most recent medical innovations and physician standards?

Answer. Express Scripts develops formularies through a four-step process involving the work of distinct committees: the Therapeutic Assessment Committee, National Pharmacy and Therapeutics Committee, Value Assessment Committee, and an annual formulary review by the National Pharmacy and Therapeutics Committee.

The Therapeutic Assessment Committee (TAC) is an internal clinical review body, consisting of clinical pharmacists and physicians who are employed by Express Scripts. From a formulary development perspective, the committee is tasked to review specific medications following approval by the Food and Drug Administration (FDA). Before discussing a new drug at TAC, Express Scripts' clinical team conducts a search of the medical literature, evaluates published data from clinical trials, and develops comprehensive drug evaluation summary documents. The drug evaluation documents include, at a minimum: a summary of the pharmacology, safety, efficacy, dosage, mode of administration, and the relative place in therapy of the medication under review compared to other pharmacologic alternatives. Following a review of the drug evaluation summary document, TAC ultimately provides a formulary placement recommendation that is shared with the Express Scripts' National Pharmacy and Therapeutics (P&T) Committee. TAC formulary recommendations are merely a suggestion and cannot be formally implemented without the approval of the P&T Committee.

Express Scripts' P&T Committee is a group of independent, actively practicing physicians and pharmacists who are not employed by Express Scripts. The P&T Committee is tasked to review medications from a purely clinical perspective. The committee does not have access to, nor does it consider, any information regarding Express Scripts' rebates/negotiated discounts, or the net cost of the drug after application of all discounts. The committee does not use price, in any way, to make formulary placement decisions.

The P&T Committee can establish one of the following three formulary placement designations: include, exclude, or optional from a formulary. Drugs with a designation of include are recommended for placement on all formularies. Drugs may be given an include designation for one or more of the following clinical reasons: unique indication for use addressing a clinically significant unmet treatment need; efficacy superior to that of existing therapy alternatives; a safety profile superior to that of existing therapy alternatives; a unique place in therapy; and/or drugs which treat medical conditions that necessitate individualized therapy and for which there are multiple treatment options. Drugs with an exclude designation are not rec-

ommended for formulary inclusion. Drugs may be given an exclude designation for one or more of the following clinical reasons: efficacy inferior to that of existing therapy alternatives; a safety profile inferior to that of existing therapy alternatives; and/or insufficient data to evaluate the drug. Medications recalled from the market for safety reasons take an automatic exclude status, and are formally reviewed at the next P&T Committee meeting. Drugs may also be designated as optional on a formulary. Drugs may be given an optional designation based on the conclusion that they are clinically similar to other currently available drug alternatives.

Optional medications are forwarded to the Value Assessment Committee (VAC) for further analysis, which considers the value of drugs by evaluating the net cost, market share, and drug utilization trends of clinically similar medications. VAC consists of Express Scripts employees from various areas. No member of VAC can serve in any capacity on TAC (and vice-versa). VAC reviews drugs designated as optional by the P&T Committee, and develops a formulary placement recommendation.

Finally, on an annual basis, the National P&T Committee will review the final formulary recommendations, by drug class, for the upcoming plan year. The committee utilizes this opportunity to ensure adherence to previously established formulary placement recommendations, and to recommend any additional changes to ensure that the formulary is clinically appropriate. The committee also ensures that all Express Scripts national formularies cover a broad distribution of therapeutic classes and categories, and that the formularies neither discourage enrollment by any group of enrollees nor discriminate against certain patient populations.

Question. I have heard from independent pharmacies in Maryland that have struggled with pharmacy benefit managers and direct and indirect remuneration (DIR) fees. According to independent pharmacies, there are times when DIR fees are based on performance, and these fees range from $2–$7 for certain types of maintenance prescriptions and are often collected retroactively—weeks or even months after a prescription was filled. A PBM can take money back from the pharmacy when the pharmacies haven not met a PBM's performance standard. In these instances, the PBM claws back money and creates a situation where the pharmacy does not receive adequate reimbursement to cover its costs. As a result, DIR fees can be a significant financial loss to pharmacies and an additional cost burden to patients.

Could you explain what performance measures are considered when determining a DIR fee?

Answer. The metrics for the pharmacies are aligned with the Star ratings metrics that CMS uses to judge the performance of Part D plans. The metrics are part of the contract that is mutually developed and agreed upon by the pharmacy and the Part D plan sponsor.

Examples of performance metrics include: generic dispensing rate, patient adherence rate, prescription refill rate, counselling services, medication therapy management, dispensing volume, and opioid dispensing oversight.

Question. How is that performance measure communicated to the pharmacy?

Answer. Our performance networks use the EQUIPP portal, an industry standard for quality data, which provides insightful information on performance and potential opportunities for patient intervention.

Pharmacies and plan sponsors can log in to the quality reporting tool EQUIPP, managed by our reporting partner Pharmacy Quality Solutions (PQS), to have visibility into the pharmacy performance and ranking of the key metrics.

Question. How much does your company receive in DIR fees?

Answer. Pharmacy network DIR fees go to the Part D plan sponsor and not to the PBM—100 percent of DIR is passed to plan sponsors, who typically use these fees to help reduce premiums.

If a contracted pharmacy's performance does not meet a mutually agreed-upon quality metric—as defined in their contract, entered into voluntarily with us—Express Scripts does not claw back monies already disbursed to the pharmacy. Again, pharmacies who meet or exceed their performance metric scores receive bonus payments as a reward for providing high-quality care to patients.

Question. How much does your company receive in performance-related DIR fees?

Answer. DIR fees go to the Part D plan sponsor and not to the PBM—100 percent of DIR is passed to plan sponsors, who typically use these fees to reduce premiums.

If a contracted pharmacy's performance does not meet up to a mutually agreed-upon quality metric—as defined in their contract, entered into voluntarily with us—Express Scripts does not claw back monies already disbursed to the pharmacy. Again, pharmacies who meet or exceed their performance metric scores receive bonus payments as a reward for providing high quality care to patients

Question. Are those fees passed on to the consumer? If so, how?

Answer. Medicare Part D beneficiaries benefit from DIR arrangements as these fees not only spur pharmacies to provide them with the highest-quality care and services, but they also lower plan costs in a number of ways. For example, these collected fees are typically used to keep premiums low—and across all plans, well below CBO projections with little increases year-over-year, despite an environment seeing ever-escalating drug prices. Among other metrics, rewarding pharmacies that maintain high medication adherence rates reduces the likelihood of medical interventions and saves the costs of providing such care for both plans and beneficiaries.

DRUG SHORTAGES

Question. Currently there are over 270 drugs in shortage. Drug shortages happen for many reasons such as manufacturing and quality problems, natural disasters, and inventory practices of wholesalers and pharmacies. Drug shortages cause harm to providers, hospitals, and most importantly patients. Pharmacists and providers must spend significant amounts of time on researching alternative drug treatments for the patient, which may not always be the most optimal therapies.

As a pharmacy benefit manager, you have contractual agreements with pharmaceutical companies in order to place their drugs on a plan's formulary. While I understand that drug shortages happening in both the inpatient and outpatient settings, there may be a role PBMs can play in protecting patients.

For the prescription drugs you negotiate to cover on a plan formulary, could you use your negotiating power to ensure a drug is available to a patient? Why or why not?

Answer. We do not manufacture, set the price of, or control the supply of a drug. Our contracts assume products will be available for patients, as it is in our collective interest to have adequate supply and competition to lower costs and improve quality. Further, there is rarely a single, predictable reason behind a drug shortage. In many cases, shortages are the result of disruptions in manufacturing processes, FDA orders to halt productions, etc., matters for which we have no control over—even via contract negotiation.

Question. What do you do to ensure that patients have the drugs they need?

Answer. Preventing drug shortages and ensuring adequate supply of necessary pharmaceutical products is critical to patient health. The majority of drug shortages occur in the hospital setting. We have predictive models that help to show us which drugs might be in short supply and make adjustments as we are able. In the United States, the biggest problems with drug shortages occur when there is a single source manufacturer. Decreasing the amount of time in which generics get to market can also play a key part in solving this problem.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

Question. During the hearing, each of you expressed support for biosimilars and most of you indicated you try and take advantage of available biosimilars to help lower costs. When I asked each of you to identify solutions to help ensure a robust biosimilar marketplace here in the U.S., most of you mentioned things Congress or the administration could do to help ensure uptake of biosimilars—from lowering the exclusivity period for biologics to finalizing guidance on interchange ability at the FDA. However, none of you offered any solutions or ideas for what your company could do to help ensure timely uptake of biosimilars, a robust U.S. biosimilars market, and a resulting cost savings to patients to taxpayers.

Most of the biosimilars currently approved and on the market in the U.S. are reimbursed through the medical benefit. What are the similarities and differences in how rebates are passed onto patients and providers in the medical benefit versus pharmacy benefit. In your answer, please describe these similarities and differences across each of your books of business (*i.e.,* commercial, Medicare, Medicaid).

Answer. We believe that part of the cause for escalating drug costs in the Part B program today includes a lack of utilization management tools that exert downward pressure on net costs. There are clear opportunities to achieve savings in the Medicare Part B program, including introducing Part D utilization management tools into Part B and potentially shifting some Part B drugs to Part D. Because of the complexity involved with identifying the "candidate" drugs for moving into Part D, along with assessing the consequences and impacts of doing so for both programs, we strongly recommend CMS engage stakeholders as they develop their policy.

In addition, for our commercial business, we have fully insured arrangements, in which rebates are generally used to lower premiums, and self-funded arrangements, in which our clients have a choice on how rebate dollars are used, including to lower administrative costs or reduce employee contributions. Most self-funded clients elect lower administrative costs rather than 100 percent pass-through of rebate dollars due to lower prevalence, fewer rebate dollars, and the additional complexity of medical claims. Drug rebates in the medical benefit are typically available only for high-cost specialty drugs. Rebates do not impact provider reimbursement as it is based on a percentage of Average Sales Price (ASP). Finally, point-of-sale capability is not generally an option for drugs covered in the medical benefit given the differences in processing compared to drugs covered under a retail pharmacy benefit.

Question. Do any of your plans require the use of a higher list price, branded product over the use of a therapeutically equivalent lower list price generic or biosimilar product? Why? If a plan restricts the use of a biosimilar or generic product in lieu of an innovator or brand name product, do patients pay more out-of-pocket than they would if the biosimilar was preferred?

Answer. As we have noted in other responses to similar questions, our plan clients alone decide what their formulary benefit design will be for the plan(s). Accordingly, we do not require our client plan sponsors use higher net cost branded products over lower net cost drugs, regardless of whether they are on-brand, generic or biosimilar. While we advise clients to prefer lowest net cost drugs within their formularies, such decisions are ultimately theirs.

Question. Recognizing most biosimilars are paid for via medical benefit, please explain whether you use step-therapy to restrict access to biosimilars for your patients in any medical benefit you manage across each of your books of business (*i.e.,* commercial, Medicare, Medicaid). What role do rebates playing in your consideration for patient access to biosimilars in each of these instances?

Answer. Rebate size is not considered by our P&T Committee when determining tiering/formulary placement for any drug, whether on-brand or biosimilar. We always advise clients to pursue lowest net cost for preferred drug placements in their formularies.

Question. How can and will your company help ensure a robust biosimilars market here in the U.S.?

Answer. With an expected cost of 15 percent to 40 percent less than originator products, biosimilars create a significant savings opportunity across the U.S. health care system. Cigna and Express Scripts are fully supportive of a robust biosimilars market in the United States, and believes important first steps toward ensuring such a market include ending so-called "pay-for-delay" arrangements, which delay the availability of lower-cost generics and biosimilars. We would also encourage the FDA to finalize guidance on biosimilar naming standards, improve the efficiency of the biosimilar product development and approval process, and develop effective communications tools to educate providers and patients about the safety and efficacy of biosimilars.

Question. I have heard concerns that "rebate walls" are responsible for keeping new biosimilars off of formularies, where a manufacturer offers conditional rebates on a bundle of their products in order to incentive PBMs to exclude a new biosimilar competitor from their formularies. Have you ever decided to place a drug on a preferred tier because of the rebates you receive for other drugs from that manufacturer? If you do not do this, do you support this practice being carried out by your competitors?

Answer. We negotiate for lowest net cost. Our formulary development approach for all medications prioritizes clinical considerations first and foremost before evaluating net cost to clients. Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process. The finan-

cial impact to clients, however, is considered only after all clinical considerations have been taken into account.

Question. What more can and will you do to counteract efforts to rebate-block or bundle rebates to block biosimilar formulary placement? Will you commit to taking these actions as more biosimilars become available in Part D?

Answer. We advise clients to prefer lowest net cost drugs within their formularies.

REBATES VS. FEES

Question. During the hearing, Senator Cassidy asked each of you about the trend in PBM contracting where a larger share of your reimbursement and payment is a result of "fees" which you are able to pocket, as opposed to "rebates" which must be passed back to the plan/consumer.

Please define the word "rebate." As part of your definition, please clarify whether or not you consider administrative fees, inflation payments, product discounts, prospective rebates, care management fees, procurement fees or any other type of fee or payment that isn't a retrospective rebate to be a rebate.

Answer. At a most basic level, a rebate is simply a retrospective discount. For over 30 years, Express Scripts has been singularly focused on helping employers, health plans, labor unions, and public programs like Medicare expand access to needed medications without overwhelming payer budgets. In 2018, we helped save employers more than $45 billion on their prescription drug costs.[18] Also, we held prescription drug cost increases for our clients to just 1.5 percent, the lowest growth rate since we started measuring the trend in the early 1990s.

Express Scripts returns on average 95 percent[19] of rebates we negotiate with drug manufacturers directly to our clients. Our clients, 100 percent of the time, decide how rebates will be returned to them. In turn, clients determine how they will use rebates to lower patient premiums, cost-sharing, and/or deductibles.

Ninety-six to 98 percent of our clients are projected to stick with Express Scripts through 2020 because they know the value we bring by not only driving down costs, but also through improving care and creating better outcomes. Better value includes working with our clients to achieve a 90 percent generic-fill rate—and generics are generally not rebated.

Notwithstanding the mistaken blame on rebates as the source of drug price increases, we note many non-rebated drugs continue to see double-digit increases. In 2017, non-rebated drugs treating infertility, depression, high cholesterol, and transplants all registered price increases above 15 percent.

Question. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), a list of each of the different types of rebates, charges, and/or fees that you incorporate into your contracts.

Answer. Our clients—who are sophisticated entities and are often represented by benefit consultants and advisors—determine the overall pricing arrangement they believe best suits their pharmacy benefit management needs. Terms vary across clients and contracts. Express Scripts' contractual terms with its clients are confidential.

Question. Rebates, by definition, must be passed along to the employer, health plan, or consumer. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), details on which of the rebates/fees detailed in my prior question are passed along to the consumer and/or plan and which are kept by the PBM.

Answer. Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers. Nearly half of Express Scripts' clients have opted for 100 percent pass-through of rebates. In Medicare Part D, 100 percent of the rebate value is passed through within the program to plan sponsors. As noted before, employers and other plan sponsors that work with Cigna and Express Scripts choose how any rebates are used. Some use them to lower premiums and cost sharing, others choose to expand access, fund wellness programs, or provide discounts to consumers at the

[18] *https://my.express-scripts.com/rs/809-VGG-836/images/Express%20Scripts%202018%20Drug%20Trend%20Report.pdf.*

[19] *http://lab.express-scripts.com/lab/insights/drug-options/2019-national-preferred-formulary-better-access-better-value.*

point of sale. These decisions are and should be governed by the particular circumstances of the employer, health plan, and patients.

FIDUCIARY DUTY

Question. Each of you has argued that you are the one entity in the drug supply chain that exists to help lower the cost of prescription drugs. You claim that your value comes in saving taxpayers, plans, and consumers' money.

Would you be willing to accept a fiduciary standard in your contracts? In other words, do you believe you have a fiduciary duty to the plan or employer you contract with—to act in their best interest and not your own? If not, why not?

Answer. Fiduciary status for PBMs is not appropriate because the services that PBMs provide are not fiduciary in nature. While PBMs provide claims processing and perform other administrative tasks for plans, they do not make decisions regarding benefit design or exercise any discretionary authority over the plan or plan assets.

PAYING PHARMACISTS

Question. Following a series of reports in *The Columbus Dispatch,* Ohio has taken a number of actions over the past year to crack down on several PBM practices. Efforts to date have included investigations, lawsuits, and policy changes to address the egregious use of spread-pricing, alleged breaches of contract, accusations of anticompetitive behavior, a misuse of taxpayer dollars, and a general lack of transparency.

PBMs are responsible for creating pharmacy networks, setting the price patients and health plans pay for prescription drugs, adjudicating claims, and reimbursing pharmacies for dispensed drugs. In addition, nearly all PBMs own proprietary pharmacies that directly compete with the PBM-created retail network. Do you design plans that incentivize or require patients to use a pharmacy owned by your affiliate over a competing retail pharmacy. If yes, do you believe this represents a conflict of interest? If yes, how do you ensure there is no resulting anticompetitive misuse of pharmacy and patient data?

Answer. Unlike some PBM competitors in the industry, our company does not own or operate a retail pharmacy chain. While we do own and operate both mail-order and specialty pharmacies, we do not exclude from our network of pharmacies competitors both large and small, provided they meet the same industry standard accreditation and safety standards we follow ourselves. We also reiterate that client plan sponsors will determine whether any particular pharmacies are preferred or not.

In the case of specialty pharmacies, however, we note they are distinct from traditional retail pharmacies because they coordinate many aspects of patient care to more effectively manage treatment, side effects, and interactions with other therapies the patient may be receiving. Medications dispensed by specialty pharmacies are often subject to strict dispensing rules under the FDA REMS program, and require special storage, handling, and packaging prior to dispensing. These products are usually significantly more expensive than conventional medications and require additional controls to assure that patients take them appropriately.

For these reasons, manufacturers of specialty medications frequently enter into limited distribution arrangements with specialty pharmacies fully capable of addressing the unique needs accompanying use of their products. This is not a function of whether a specialty pharmacy is owned by a PBM or not; not all specialty pharmacies (even large ones) are owned by PBMs. Again, we also contract with non-PBM owned specialty pharmacies provided they meet the same quality and safety accreditation standards followed by the industry.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Can you answer the following questions to help us understand the pharmacy benefit manager business model and how you make formulary decisions?

What percent of rebates are passed to the consumer under Medicare Part D?

Answer. In Medicare Part D, 100 percent of the rebate value is passed through within the program to Part D plan sponsors. All beneficiaries benefit from rebates in the form of lower premiums.

Question. What percent of rebates are passed to the consumer in the private insurance market?

Answer. Express Scripts passes approximately 95 percent of rebates, discounts, and price reductions back to its core PBM commercial and health plan clients and their customers. Employers and other plan sponsors that work with Cigna and Express Scripts choose how rebates are used. Some use them to lower premiums and cost sharing, others choose to expand access, fund wellness programs, or provide discounts to consumers at the point of sale.

Question. Do you have any comments on how health plans should use their share of the rebates to lower drug prices for patients with high deductibles?

Answer. Employers and other plan sponsors that work with Cigna and Express Scripts choose how rebates are used. Some use them to lower premiums and cost sharing, others choose to expand access, fund wellness programs, or provide discounts to consumers at the point of sale. These decisions are and should be governed by the particular circumstances of the employer, health plan, and patients.

Question. What is the process of deciding on which tier a generic will be placed in your formularies?

Answer. Our formulary development approach for all medications prioritizes clinical considerations first and foremost before evaluating net cost to clients. Financial impact to Express Scripts is expressly excluded and prohibited from consideration in the formulary development process. The financial impact to clients, however, is considered after all clinical considerations have been taken into account. Further, our clients determine, ultimately, the placement of any drug on their formularies as it is our purpose to manage the pharmacy benefit design they select.

Question. Are generics always tiered as preferred (versus branded drugs)?

Answer. Our National Preferred Formulary (NPF) is developed by an independent Pharmacy and Therapeutics (P&T) Committee comprised of independent practicing physicians, other clinicians and academics representing multiple areas of clinical expertise. Their decisions are based solely on whether clinical evidence shows that a drug must be covered. Only after products are evaluated from a clinical perspective are net cost and other factors considered. Again our focus is on the lowest net cost for drugs so we can reduce costs for our clients.

Further, we note that plan sponsors are not obligated to adopt our NPF, but can accept, reject, or modify it as they deem fit or even create their own custom drug formulary. A formulary becomes part of a plan sponsor's benefit only after adoption by the client. Like formularies, copay tiers and other elements of benefit design are ultimately determined by our clients.

Question. How quickly are generics placed on formularies once FDA clears them?

Answer. Where a brand drug already has multiple manufacturers of generic equivalents, no special arrangements need to be made because this occurs frequently for "mature" drugs and the makers of these generic products can and do change. With regard to a newly approved, authorized generic, we will add it to our formulary at the direction of our clients.

Question. Given the struggles we hear about patients accessing insulin, what measures are you taking to ensure that diabetes products and different types of insulin are placed on a preferred tier when establishing a formulary?

Answer. Earlier this year, we were able to launch a new Patient Assurance Program, which will bring additional affordability and predictability to customers who rely on insulin to manage their diabetes. Furthering Cigna and Express Scripts' respective historical efforts in diabetes disease management, the Patient Assurance Program establishes a lower, fixed out-of-pocket cost for covered insulins, ensuring customers will pay no more than $25 out of pocket when filling a 30-day insulin prescription at a retail pharmacy or through home delivery. This is an early example of the accelerated change and innovation our new company is positioned to drive in the financing and delivery of care.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. During the hearing, I asked an initial question on spread pricing and wanted to follow up here. According to the Centers for Medicare and Medicaid Serv-

ices (CMS), total gross spending in 2017 on prescription drugs was $154.9 billion in Medicare Part D, $30.4 billion in Part B, and $67.6 billion in Medicaid.

One of the main challenges in lowering the price of prescription drugs is that there is a disturbing lack of transparency all along the supply chain, from research and development to what the patient is expected to pay at the counter. Further, the out-of- pocket costs for drugs varies greatly and unpredictably from patient to patient. That is why Senate Special Committee on Aging Chairwoman Collins and I introduced legislation that would codify the Drug Spending Dashboards at the CMS. The dashboards provide cost and spending information for drugs in the Medicaid, Medicare Part B, and Medicare Part D programs.[20] With regards to transparency in the prescription drug supply chain, please provide answers to the following questions.

Is it the policy and practice of your company to negotiate with drug manufacturers in good faith and obtain the best and lowest prices possible for patients and American taxpayers?

Answer. We negotiate with manufacturers to achieve the lowest net cost of prescription drugs for our customers, regardless of whether they are employers in the commercial market or health plan sponsors offering Medicare Advantage or Medicaid coverage.

Question. Is it the policy and practice of your company that patients, providers, researchers, policymakers, and the American people in general, know how taxpayer dollars are being spent in the Medicare and Medicaid programs?

Answer. We strongly support the concept of providing information about the price of drugs, therapies, and the cost of care to beneficiaries and their providers as a means of improving price transparency, educating consumers, and incentivizing the efficient use of care throughout the health care system. We support efforts by CMS to move toward a system in which Part D enrollees and their providers have access to real-time benefit check and electronic prior authorization tools, while ensuring appropriate standardization and timeframes for implementation. We also support efforts to ensure the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC) have access to de-identified information currently submitted by PBMs, Part D sponsors, and Medicare Advantage plans to CMS. Legislation to address this issue was recently introduced by Senators Cortez Masto, Cornyn, Carper, and Cassidy.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by manufacturer list price; rebate paid by the manufacturer to you (the PBM); the amount reimbursed to pharmacies by the PBM; and the amount insured and uninsured patients pay out of pocket, before coupons, discounts, and other forms of patient assistance offered at the point of sale?

If so, please provide useful and easily accessible links to where policymakers and the public can find such information. If not, please disclose how much each drug you work with clients to provide costs, broken down by manufacturer list price; rebate paid by the manufacturer to you (the PBM); the amount reimbursed to pharmacies by the PBM; and the amount insured and uninsured patients pay out of pocket, before coupons, discounts, and other forms of patient assistance offered at the point of sale.

Answer. We are committed to providing transparency and audit rights to our clients. However, making this information available to the public involves releasing both proprietary and trade secret information, the disclosure of which would require us to breach contracts and harm our ability to negotiate discounts and lower prices for our clients—and ultimately reduce competition in the marketplace.

Question. Please provide a list of actions your company has taken to ensure that pharmacists are enabled and allowed to communicate to patients how they can pay the lowest out-of-pocket cost possible for their prescription drugs.

Answer. Last Congress, Express Scripts endorsed bipartisan Senate legislation aimed at stopping so-called PBM "gag clauses" that prohibit a pharmacy from informing a patient that the retail cash price may be lower than his or her copayment. Express Scripts does not engage in this anti-consumer practice. We believe our members should be informed about any out-of-pocket costs in advance. We provide

[20] S. 709, 116th Congress, Prescription Drug Pricing Dashboard Act, online at: *https://www.congress.gov/bill/116th-congress/senate-bill/709?q=%7B%22search%22%3A%22drug+dashboard%22%7D&s=1&r=1.* Accessed April 23, 2019.

members real-time pricing information, customized to their individual plans, via our website and mobile app. Pharmacies participating in our retail networks are not permitted to charge a member more for their copay under their benefit than the pharmacy's cash price.

Additionally, our Real Time Prescription Benefit tool, launched last November, helps to simplify the patient's experience with their prescriber and improve the price transparency. Real-time clinical alerts that reach physicians through electronic prescribing systems can turn data into actionable patient intelligence, helping people stay on their therapy and avoid dangerous drug-drug interactions. We provide patient-specific information and pricing information directly into the physician's electronic health record within seconds. By providing drug cost information and reconciling coverage issues at the point of prescribing, we are eliminating confusion and pain points for patients at the pharmacy counter.

These systems are delivering measurable savings to patients at the pharmacy counter, while ensuring providers and patients are communicating to make better-informed medication choices. Electronic prior authorization capabilities are improving as well, eliminating hours of potential wait time for prescribers and patients.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

REAL-TIME BENEFIT CHECK

Question. You've all shared your ability to leverage technology such as real-time benefit tools to help patients and providers understand drug costs at the point of prescribing, as well as how technology can be used to help identify opportunities to provide enhanced support and medication management for enrollees. What policies can we consider to incentivize greater uptake of these tools?

Answer. Thank you for this question and for your continued willingness to work toward policies that will harness technology to improve health outcomes and control costs. We would welcome the opportunity to work with you and your staff on additional policies, but wanted to highlight the following proposals.

We strongly support the concept of providing information about the price of drugs, therapies, and the cost of care to beneficiaries and their providers as a means of improving price transparency, educating consumers, and incentivizing the efficient use of care throughout the health-care system. We support efforts by CMS to move toward a system in which Part D enrollees and their providers have access to real-time benefit check and electronic prior authorization tools, while ensuring appropriate standardization and time frames for implementation.

Greater uptake of these tools in public programs, through policies promulgated by CMS, will lead to greater uptake in commercial markets, so that all patients and prescribers have the information needed to improve affordability and predictability.

Question. You referenced legislation in your testimony that I've worked on with Senator Carper to apply value-based insurance design to high-deductible health plans for chronic disease management. If enacted, how do you expect plans to utilize this tool and what will be the impact on drug prices and health-care spending more broadly?

Answer. This legislation addresses a key affordability issue for consumers, and for the health-care system, as prevention is a critical tool to managing future health-care costs. As plan sponsors turn to CDHPs as a way manage costs and encourage patients to take a more active role in their health care purchasing decisions, we welcome more flexibility through health savings accounts (HSAs) to help patients manage the growth in spending generally, but on chronic conditions in particular. The ability to cover care related to chronic disease management prior to a beneficiary reaching their plan deductible through an HSA could mitigate the financial deterrent posed by expensive prescriptions and services. If enacted, this legislation would enable increased patient engagement to improve health outcomes and potentially reduce costs.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. One challenge that I see, when considering the medical treatment marketplace, is that we have a new wave of life-saving treatments—of incredible cures

we could never have dreamed of, even 10 or 15 years ago—for which cost, by necessity, is going to be a major issue. You look, for instance, at a condition like sickle cell disease. For the average SCD patient who reaches age 45, lifetime treatment costs are at roughly $1 million—and there are complications that can make that figure even higher. Now that we see therapies coming down the pipeline that could erase those long-term costs and drastically improve the quality of life for sickle cell patients, the question becomes, how can our current payment systems adapt to—and absorb—the high costs necessary to bring treatments like these to market and to ensure that we continue to see innovations like these ones moving forward?

Answer. The current health-care system is built to address chronic illnesses treated over time, and not built for one-time potentially curative therapies. We are focused on building a future ecosystem that helps ensure payers and patients get the most value from new breakthrough gene and cell therapies. We are focused on providing appropriate clinical and financial management for gene therapies and other curative and transformative therapies coming to market. Our company is working with drug makers, policymakers, patient groups and payers on innovative approaches to make gene therapies accessible for patients. Innovative contracting can ensure that payers and patients are not on the hook when a treatment isn't effective, and discussions with policymakers can help set an appropriate regulatory framework.

Ultimately, we believe gene therapies will require payment and patient care systems which are as novel as the medications themselves. Ideas on the table include paying for a treatment over time, establishing insurer risk pools and financing one-time payments. A successful model must address patients who change insurers or employers, and tracking their health outcomes over time to ensure treatments are effective.

Question. And along the same lines, beyond creating some much-needed clarity around value-based arrangements—which I've been working with Senators Cassidy and Warner to accomplish legislatively—are there steps that Congress could take to facilitate these innovative payment models?

Answer. We urge Congress to take steps establishing additional flexibility under the Anti-Kickback Statute (AKS) to support value-based contracts and other innovative programs in public programs.

SIX PROTECTED CLASSES PROPOSAL AND ACCESS

Question. This past November, the Centers for Medicare and Medicaid Services released a proposed rule for 2020 to help tackle drug pricing. Among the proposed changes is one, which would alter the current rules, governing the "six protected classes." The concept of the protected classes has been around since the launch of the Medicare Part D program, and it was instituted to ensure that some of our most vulnerable patients would have access to their needed drugs by requiring formularies to cover nearly all protected drugs. These classes are anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Some people have argued that these protected classes have led to higher drug prices because formularies are required to include this prescription coverage, and there are limited tools left to help lower prices. In an effort to increase competition, this proposed new rule would do a couple of different things. The first aspect of the administration's proposal would allow Part D sponsors to implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications. Any time there is a mention of plans using prior authorization or step therapy there is an immediate concern of restricting patient access to needed drugs or medical services.

Could you explain why your company would favor such utilization management tools like step therapy or prior authorization?

Answer. We offer an option for plans not implementing exclusions to utilize step therapies requiring the trial of a clinically appropriate preferred product before the patient can try a non-preferred drug. Like formularies, step therapies and other elements of benefit design are ultimately determined by our clients. Prior authorization is designed to help prevent individuals from being prescribed medications that are either clinically inappropriate or that lack evidence demonstrating that they are safe and effective for a specific condition. It is also a highly effective tool for health insurance companies to manage costs for otherwise expensive medications without

sacrificing access to clinically appropriate, lower-net cost, but similarly effective options for patients.

Question. Do you believe there is a danger that using step therapy or prior authorization could possibly restrict patients from having access to medication that has been successful for them? Why or why not?

Answer. Properly managed, they should not. A medical exception process is always available for the prescribing physician to pursue if a patient's unique health situation requires a non-preferred product to be the only option.

Question. If you were to use step therapy or prior authorization for drugs in the six protected classes, how would you ensure patients would continue to have access to their needed medications in one of the six protected classes?

Answer. Cigna supports changes to the six protected classes, in part because the Part D program includes strong patient protections that enable beneficiaries to gain access to any drugs subject to utilization management (UM), when clinically appropriate. Existing coverage review processes—both standard and expedited—have proven workable, and plans have demonstrated the use of UM tools can provide safe access to the most appropriate medications while reducing member and plan costs. This additional opportunity for interaction and education with patients and prescribers, and the assessment of the appropriateness of a prescribed therapy based on either cost or clinical efficacy, may avoid unnecessary or inappropriate utilization and should not come at the expense of access.

Question. The second aspect of the administration proposed change to the six protected classes is the proposal to allow drug coverage formularies to exclude a protected class drug from a Part D formulary if the drug represents a new formulation of a single-sourced drug, regardless of whether the older formulation remains on the market. My understanding is that this administration is trying to target pharmaceutical companies who participate in the anticompetitive practice of "ever-greening." This is a practice where pharmaceutical companies make slight alterations to a drug's packaging, color, and formulation without an added or new benefit. However, we also understand that seemingly small changes to a drug can still make a big difference to patient well-being. We have heard from Maryland physicians that the creation of combination antiretroviral pills was a huge step forward in the fight against HIV. Even though these combination pills or extended release versions didn't have a new chemical formula, they made a world of difference to the HIV patients taking over a dozen pills a day. These vulnerable patients are obviously very concerned that they could lose coverage for new and better drugs, especially when their old drugs may no longer be available. HIV treatments have come a long way in the last few decades, and proper antiretroviral treatment is vital to ensuring an end to the HIV epidemic.

Do you think the proposed rule anticipates a situation where a pharmaceutical company stops producing an older version of a drug when a new formulation is available, but the newer formulation is not covered by a Part D plan? Why or Why not?

Answer. Provided that existing formulations of drugs set for "ever-greening" by a manufacturer are off-patent, generic manufacturers should be able to offer alternatives to the "new" formulation. It is common practice for manufacturers of the "brand" drug to begin offering a new formulation for an existing product near the end of its patent protection cycle, precisely because it will likely be facing generic competition. That said, no current statutes prevent a manufacturer from halting production of an older formulation in favor of a new, ever-greened version of the same drug.

Question. What would your company do to ensure that patients continue to have access to their medication in this situation?

Answer. To the extent possible, we will work to provide our clients' patients with all available supply of such products, and if necessary, help them find therapeutically similar alternative therapies that can best approach the clinical efficacy of the discontinued drug.

APPEALS PROCESS IN GENERAL

Question. Prior authorization and step therapy are some of the most commonly mentioned concerns from patient groups coming to talk to my office, second only patients' concerns about out-of-pocket costs. What has become especially striking in the past few weeks is the number of physicians explaining how they feel stymied

by prior authorization restrictions by insurance plans. We have heard from one surgeon who argued for weeks with the insurer to appeal a decision that had been made to deny a newer type of less-invasive surgery. Someone who was not a surgical expert made the denial. Eventually, his patient made the decision to stop waiting and opted for a far more invasive and dangerous procedure because it was covered by insurance. Other doctors talk about the hours they spend on the phone waiting to appeal a decision, only to be told they need to write an extensive report justifying their medical decision. While the physicians are waiting for a response, quite often there are patients suffering without their proper medications, without certain tests, or not getting the surgery that the expert recommends.

What is your organization doing to improve the appeals process for patients and physicians, in order to ensure timely medical care and access to their prescription drugs?

Answer. We work collaboratively with physician partners to identify where they see opportunities for improvement and we are always looking to balance timely access with patient safety and effective utilization. Moreover, we have worked to simplify and improve the prior authorization request experience for prescribers, and have developed and made available to physicians an "App" tool that allows providers using it to submit electronic prior authorization requests directly from their smartphones at the moment the prescription is being ordered, along with identifying possible alternatives that would not require such a request. Details on this product are discussed further in our response to questions addressing "real-time benefit check tools."

Question. What do you think is an appropriate wait limit for emergency medical appeals, and how do you make sure you meet it?

Answer. One way to improve the appeals process and reduce wait times is increased use of electronic prior authorizations. Currently, 60 percent of our prior authorizations are done electronically and we aim for that to be even higher. It's faster for the patient and it's more convenient for the prescriber. Electronic prior authorization capabilities are improving as well, eliminating over 158,000 hours of potential wait time in December 2018. As noted in our response above, we have worked to simplify and improve the prior authorization request experience for prescribers, and have developed and made available to physicians an "App" tool that allows providers using it to submit electronic prior authorization requests directly from their smartphones at the moment the prescription is being ordered, along with possible alternatives that would not require such a request. Details on this product are discussed further in our response to questions addressing "real-time benefit check tools."

PREPARED STATEMENT OF JOHN M. PRINCE,
CHIEF EXECUTIVE OFFICER, OPTUMRX

Chairman Grassley, Ranking Member Wyden, and members of the committee, I am honored to be here today on behalf of OptumRx. Our company has 28,000 dedicated employees—including 5,000 pharmacists and pharmacy technicians—working every day to deliver value to society, improve the quality of pharmacy care services, simplify the health-care experience, and ensure that the individuals we are privileged to serve have affordable access to the drugs they need.

We reduce the costs of prescription drugs. We negotiate substantial discounts from drug manufacturers on behalf of our customers. And we are leading the way to ensure that those discounts directly benefit consumers. We recently announced that soon all of our new employer-sponsored drug plans must provide point-of-sale drug discounts to their employees at the pharmacy counter. This builds on a similar initiative we launched at scale last year for millions of members in fully insured employer plans.

Manufacturers are increasing drug prices for one simple reason: a lack of meaningful competition allows them to. In the absence of competition, manufacturers often set exceptionally high prices. There is a vital role for Congress and the administration to play in addressing this important issue.

I look forward to discussing this issue with the committee. I will focus on the following points:

1. OptumRx's pharmacy care services business is achieving better health outcomes for patients, lowering costs for the system, and improving the health-care experience for consumers.
2. OptumRx negotiates better prices with drug manufacturers for our customers and for consumers.
3. Drug manufacturers are solely responsible for the high cost of prescription drugs.
4. Drug manufacturers are not helping solve the problem by blaming others in the supply chain and offering so-called "authorized generics" that often result in net prices higher than the brand drugs they replace.
5. Sensible policy reforms that promote competition and value-based payment models will help make drugs more affordable.

Let me address these points in order.

1. OPTUMRX'S PHARMACY CARE SERVICES BUSINESS IS ACHIEVING BETTER HEALTH OUTCOMES FOR PATIENTS, LOWERING COSTS FOR THE SYSTEM, AND IMPROVING THE HEALTH-CARE EXPERIENCE FOR CONSUMERS

Our team delivers pharmacy care services to 250,000 patients each day. These services improve health outcomes for patients and reduce costs in the system. Here are some examples:

- We communicate with patients (and their physicians) about how to take their medications, avoid harmful drug interactions, and access convenient home-delivery services.
- We provide drug infusion services directly in patients' homes, so they do not need to visit a hospital to obtain the same, high-quality care, which improves medication adherence and reduces costs.
- We have more than 450 pharmacies embedded in community mental health centers to serve the behavioral health medication needs of patients receiving care there. Our ability to deploy those on-site services has improved medication adherence, reduced emergency room visits and hospitalizations, and reduced overall costs by $700 per patient.
- We provide special assistance for patients who need help managing their chronic conditions, including real-time video consultations with pharmacists.
- We are helping to address the opioid crisis by developing evidence-based programs that help prevent overprescribing by physicians and detect suspected opioid misuse, as well as offering medication-assisted treatment to patients with opioid use disorder. Our customers who have adopted our opioid management program have achieved a 96 percent adherence rate by prescribers with the Centers for Disease Control and Prevention's prescribing guidelines.

Our pharmacy care services business is doing important work to improve health outcomes and lower costs. We are not stopping with those efforts. We are also developing consumer-friendly tools to make the health care experience more satisfying and effective for patients. For example, one of these tools, PreCheck MyScript®, is a digital platform that simplifies the drug prescribing experience by showing the prescribing physician what the patient's true out-of-pocket cost would be while the patient is still in the physician's office. PreCheck MyScript® has helped lower consumer out-of-pocket costs by an average of $135 per prescription filled. This is just one of the ways we are working to simplify the system.

2. OPTUMRX NEGOTIATES BETTER PRICES WITH DRUG MANUFACTURERS FOR OUR CUSTOMERS AND CONSUMERS

OptumRx manages pharmacy benefits on behalf of our customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and Federal and State government employee plans. In that role, we promote use of clinically effective, lowest net-cost prescription drugs for consumers when medications are needed.

This work starts with an independent, clinically based formulary design process. OptumRx's Pharmacy and Therapeutics (P&T) Committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an unbiased

and evidence-based way. The P&T Committee meets regularly, and its deliberations are open and transparent to OptumRx's customers and prospective customers.

A drug's cost plays no role in the P&T Committee's clinical review. Cost only becomes relevant after the P&T Committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered. If there is more than one drug in a particular class, OptumRx gives preferable placement on its formulary to the lowest-net-cost drug. For about 90 percent of prescriptions processed, OptumRx can identify a generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug. If there is no generic product available, there may still be other therapeutically equivalent branded alternatives. If so, OptumRx negotiates with those competing brand manufacturers to obtain discounts, and places the drug with the lowest overall net cost in a preferred position on the formulary.

OptumRx has been effective in driving utilization of clinically effective low-cost medications. OptumRx's negotiated network discounts and clinical tools are reducing annual drug costs, on average, by $1,600 per person for our customers. Even greater savings are achieved by customers who implement evidence-based utilization management and other OptumRx clinical programs.

OptumRx also ensures that these cost-savings go to our customers and consumers. Our customers receive approximately 98 percent of the value of the discounts we negotiate from drug manufacturers. The application of discounts is subject to audit and verification by an independent third-party on behalf of any of our customers. In those limited instances in which we retain some of the discount, it is because our customers have chosen to pay us that way.

We have heeded the call for change by taking direct action to ensure that the discounts we obtain directly lower consumers' out-of-pocket costs at the pharmacy counter. Last year, we implemented a point-of-sale discount solution at scale for fully insured group customers so that consumers receive the benefit of discounts at the pharmacy counter. This action has already made nearly six million consumers eligible for point-of-sale discounts. Eligible consumers filling prescriptions on discounted brand drugs are seeing average savings of $130 per eligible prescription. We believe it will also improve prescription drug adherence by as much as 16 percent. By the end of 2019 we expect more than nine million consumers will be eligible for these point-of-sale discounts. Last month, we announced a decision to expand this point-of-sale discount solution to all new employer-sponsored plans beginning in January 2020.

It is important to recognize that pharmacy benefit managers are the only stakeholders in the prescription drug supply chain working to reduce costs for their customers and the only ones able to effectively negotiate with drug companies. In fact, studies have shown that pharmacy benefit managers will save the Medicare Part D program over $900 billion in the next 10 years.[1] If States fully utilized those same tools and capabilities, Medicaid could save more than $100 billion over the next 10 years.[2]

3. DRUG MANUFACTURERS ARE RESPONSIBLE FOR THE HIGH COST OF PRESCRIPTION DRUGS

Drug manufacturers have continued to increase the prices of their branded drugs. List prices have increased on the twenty most-prescribed brand drugs for seniors by an average of 12 percent for each of the past 5 years.[3] And from 2017 to 2018, drug manufacturers raised the list prices on twenty drugs by more than 200 percent.[4] In January 2019, manufacturers increased prices yet again on 15 of the top 20 most utilized brand drugs. There appears to be no end in sight. The Centers for Medicare and Medicaid Services (CMS) estimates a faster rate of growth in prescription drugs than all other health care expenditures.[5]

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[1] Oliver Wyman, *Savings Generated by Pharmacy Benefit Managers in the Part D Program,* June 2017. Available at: *http://www.affordableprescriptiondrugs.org/app/uploads/2018/05/resources_medicarepartd_report.pdf.*

[2] UnitedHealth Group, *Pharmacy Benefit Management Can Save Medicaid Drug Programs Over $100 Billion,* March 2018. Available at: *https://www.unitedhealthgroup.com/content/dam/UHG/PDF/2018/PBM-Medicaid-Savings-Study040418.pdf.*

[3] U.S. Committee on Homeland Security and Governmental Affairs, "Manufactured Crisis: How Devastating Drug Price Increases Are Harming America's Seniors," March 2018.

[4] Pharmacy Benefit Consultants Analysis, AWP Price Increases (12–2016 to 12–2017), January 2017–March 2018.

[5] American Academy of Actuaries, March 2018.

Drug manufacturers alone decide what list price to set for their branded products. If market conditions permit OptumRx to negotiate better prices for a particular branded product, then we do so. As a matter of economics, where there is no competition over a branded drug, or where a drug's "exclusivity period" is extended by anti-competitive tactics, it is difficult to control price-gouging by manufacturers.

There is no better example of the economic calculus driving manufacturers' drug-pricing decisions than "specialty" drugs. These drugs treat complex conditions like cancer, HIV, rheumatoid arthritis, immune disorders, and multiple sclerosis, and they often lack therapeutic equivalents. If a manufacturer sets a very high price for a specialty drug, it is very difficult to negotiate a better price, since that drug has no competing therapeutic equivalent.

As a result, the prices of specialty drugs are spiraling out of control. At least 26 non-discounted specialty drugs cost in excess of $200,000 per year.[6] These include Elaprase at $985,000 per year, Myalept at $889,000 per year, and Cinryze at $626,000 per year.[7] Today, less than 2 percent of the population takes specialty drugs, yet those drugs will account for approximately 50 percent of total drug spending by 2022.[8]

Drug manufacturers not only set high prices for branded drugs; they regularly extend the lives of those patented products by using aggressive, anti-competitive tactics to delay the entry of cheaper generic alternatives into the marketplace. One such tactic involves obtaining new patents for products that are not actually new drugs. A recent academic paper found that "78 percent of the drugs associated with new patents were not new drugs, but existing ones, and extending protection is particularly pronounced among blockbuster drugs."[9] The study further found that "Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70 percent had their protection extended at least once, with almost 50 percent having the protection cliff extended more than once."[10]

Drug manufacturers have also engaged in "pay-for-delay" tactics to avoid competition. For example, in November 2018, AbbVie entered into an agreement with Pfizer to keep Pfizer from marketing a generic version of AbbVie's top-selling Humira in the U.S. until 2023.[11] This agreement represented AbbVie's seventh pay-for-delay deal with a would-be competitor.[12] This means that patients in the U.S. will continue to pay much higher prices for an additional 6 years after Humira's patent expires before a lower-priced, therapeutically equivalent drug is available. AbbVie has also secured more than 100 patents on this one drug.[13] As a result of these tactics, the list price of Humira—a drug that was introduced in 2003—has increased by 78 percent over the last 4 years alone.[14] Humira is now projected to generate annual revenues of nearly $20 billion—16 years after its launch.[15]

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[6] OptumRx Book of Business, January–March 2019.

[7] *Ibid.*

[8] IQVIA, *Medicine Use and Spending in the U.S.*, April 2018. Available at: *https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022.*

[9] Professor Robin Feldman, "May Your Drug Price Be Evergreen." *Journal of Law and the Biosciences,* December 2018. Available at: *https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsy022/5232981.*

[10] *Ibid.*

[11] Eric Sagonowsky, "AbbVie inks Humira patent deal No. 7, delaying Pfizer's U.S. biosim launch until late 2023." *Fierce Pharma,* November 30, 2018. Available at: *https://www.fiercepharma.com/pharma/abbvie-inks-humira-patent-deal-no-7-delaying-pfizer-s-u-s-biosim-launch-until-late-2023.*

[12] *Ibid.*

[13] Cynthia Koons, "This Shield of Patents Protects the World's Best-Selling Drug." *Bloomberg,* September 7, 2017. Available at: *https://www.bloomberg.com/news/articles/2017-09-07/this-shield-of-patents-protects-the-world-s-best-selling-drug.*

[14] OptumRx Book of Business, 2015–2019.

[15] Bob Herman, "Humira sales approach $20 billion." *Axios,* January 25, 2019. Available at: *https://www.axios.com/abbvie-humira-2018-sales-20-billion-e4039176-baeb-44ff-b4fe-1b63005283b9.html.*

4. DRUG MANUFACTURERS ARE NOT HELPING SOLVE THE PROBLEM BY BLAMING OTHERS IN THE SUPPLY CHAIN AND OFFERING SO-CALLED "AUTHORIZED GENERICS" THAT OFTEN RESULT IN NET PRICES HIGHER THAN THE BRAND DRUGS THEY REPLACE

Manufacturers have blamed pharmacy benefit managers, health plans, and hospitals for high drug costs. They contend that the discounts or rebates we negotiate with them are the root cause of the problem. That is simply untrue.

We have a proven track record of reducing net costs to our customers. We negotiate a discount when there are two or more competing brand drugs in the same therapeutic class. In those circumstances, we take advantage of the competitive market. We negotiate better prices with manufacturers, give preferred formulary status to the drug that offers the best price, and then we provide those savings to our customers and consumers. That is a formula for reducing costs, not increasing them.

The data simply does not support the manufacturers' contrary assertion. If they were right, drug prices would be rising more steeply for the drugs on which we negotiate discounts. But the opposite is true. In fact, drug prices are rising the fastest in the area of specialty drugs, where due to the importance of the drugs and the lack of clinical alternatives, manufacturers are unwilling to negotiate a discount. It is no surprise, then, that CMS recently reported that in 2016 and 2017 drug manufacturers raised prices the most on those drugs that have no discounts.[16] The related assertion by brand manufacturers that discounts force them to increase list prices is simply an attempt to avoid accountability. If market conditions permit it, OptumRx harnesses the purchasing power of its customers to negotiate discounts.

Drug manufacturers have also responded to criticisms of the high prices they set for their products by introducing so-called "authorized generic" versions of their higher-priced brand products. To be clear, these are not generic drugs. Their marketing and production is exclusively controlled and directed by the brand drug manufacturers. They do nothing to promote competition. Rather, in our experience, these so-called "generics" often result in higher overall cost when compared to the discounted price of the original brand drug.

As an example, consider a hypothetical brand manufacturer that has set the list price for its brand drug at $100. OptumRx has successfully negotiated a $70 discount off that list price, resulting in a net overall cost of $30 for the brand drug. If the brand manufacturer announces a so-called "authorized generic" at a list price of $50, the list price may be lower, but the overall net price of the "generic" is $20 higher than the brand drug. This may result in a lower cost-sharing obligation for some plan members in the short-term, but in the long-term it will be more expensive for plans and lead to higher overall drug costs for everyone, benefiting no one other than the manufacturers.

5. SENSIBLE POLICY REFORMS THAT PROMOTE COMPETITION AND VALUE-BASED PAYMENT MODELS WILL HELP MAKE DRUGS MORE AFFORDABLE

An effective intellectual property environment plays an indispensable role in both promoting drug discovery and ensuring innovations are affordable and sustainable. Today's intellectual property system does not work as intended. The most important step Congress can take to address the high cost of prescription drugs is to modernize the intellectual property system for the 21st century and eliminate drug manufacturers' ability to manipulate the patent and regulatory system and thereby prevent lower-cost generics and biosimilars from reaching consumers more quickly. Specifically, Congress should:

- Pass the bipartisan CREATES Act to end the manipulation by drug manufacturers of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generic competition.
- Prohibit "pay-for-delay" settlements between manufacturers that delay the market entry of lower-cost alternatives.
- Restrict "ever-greening" of patents in which drug manufacturers make minor changes to their product, or to the delivery technology for their product, to extend the patent exclusivity period.
- Reduce the exclusivity period for brand and specialty drugs.

[16] Sarah Karlin-Smith, Sarah Owermohle, and Janie Boschma, "Drugs with a single manufacturer drive Medicare, Medicaid spending increases, CMS says." *Politico,* March 14, 2019.

- Increase patent transparency for biologics (which are essentially generic equivalents for expensive specialty drugs), promote biosimilar competition, and bring needed biosimilar treatments to market faster and at lower cost.

Beyond patent law reform, there are also other policy solutions that will help lower the net price of drugs, eliminate market barriers, increase transparency, and promote true competition. In particular, the Federal Government should:

- Continue to support Food and Drug Administration (FDA) reforms around biosimilars. Specifically, the FDA should adopt reforms to release these products to the market more quickly and should finalize guidance to promote substitution of these products over expensive branded specialty products. As other countries have shown, these two measures have been proven to increase competition and lower drug prices.
- Finalize Proposed Rules that would modernize the Medicare Part B and Part D programs by implementing utilization management tools in Medicare Part B and enabling negotiation in the six protected classes in Medicare Part D.
- Finalize a Proposed Rule that would enable Medicare and Medicaid to use real-time benefits tools at the point of prescribing to allow beneficiaries to have meaningful and actionable information about out-of-pocket drug costs.
- Evaluate the entire prescription drug regulatory structure to identify opportunities to advance value-based payments and promote comparative effectiveness.

The administration's proposed Safe Harbor Rule does not address the root cause of rising drug prices. In fact, according to actuaries at CMS, the Proposed Rule would increase premiums up to 25 percent for seniors and create a $40 billion windfall for drug manufacturers.

If the administration intends to finalize the Proposed Rule, it should prevent the disruption of the existing and proven supply chain, and ensure that pharmacy benefit managers are explicitly authorized to facilitate discounts at the point of sale for seniors. Today, pharmacy benefit managers administer point-of-sale discounts, including for Medicare Part D, through proven, stable, secure, and highly efficient systems that have evolved through three decades of investment, innovation, and partnership with key stakeholders. Unless pharmacy benefit managers facilitate point-of-sale discounts, existing, negotiated drug discounts will be jeopardized, net prices will increase, and consumers will experience disruption.

The Proposed Rule potentially would allow these discounts to be administered by wholesalers. A new, unregulated, and unproven system of wholesaler-based discounts and service fees to local pharmacies would be unworkable because:

- Wholesalers get paid more if drug prices are high.
- It would create a standing conflict of interest for wholesalers whose subsidiaries help drug manufacturers *undermine* formularies.
- There is no current Federal structure to regulate wholesalers' administration of discounts, nor will CMS have visibility to these discounts and service fees as it currently does.
- Wholesalers lack the underlying claims data to facilitate these transactions.
- Unlike Part D plans and pharmacy benefit managers, wholesalers and drug manufacturers are not subject to prompt pay laws.

It is critically important to understand that drug manufacturers pay wholesalers based on list prices and are not subject to the U.S. Department of Health and Human Services' proposed Safe Harbor reforms. Because they are paid based on list prices, allowing wholesalers to begin administering point-of-sale discounts will recreate the very concern that Congress and the administration are attempting to address.

We appreciate the opportunity to address the committee today, and share with you the meaningful solutions we are advancing to deliver value for consumers and bring down prescription drug costs. We are committed to doing our part to make prescription drugs more affordable for people and sustainable for the country. I would be pleased to answer any questions you have.

QUESTIONS SUBMITTED FOR THE RECORD TO JOHN M. PRINCE

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

COLLECTION, USE, AND SHARING OF PERSONAL HEALTH INFORMATION

Question. Consumers are becoming more and more concerned about the data collection and sharing practices of companies. While these issues have been most prevalent in the social media and tech industry, companies in the pharmaceutical supply chain also have access to tremendous amounts of sensitive, personal health information of the individuals they serve. For example, the company Livongo partners with CVS Caremark to provide low-cost or no-cost blood sugar meters to diabetic patients. The meters are always "connected" to Livongo's "Diabetes Response Specialists." As the company's website states, "When readings are out of range, our Diabetes Response Specialists call or text [the individual] within minutes." While these innovations may be highly beneficial for individuals in managing their health, it's also important for this committee to fully understand what types of information is collected, how or why it's stored or shared, and for what purposes PBMs themselves and other affiliated drug supply chain participants (such as insurers) use the information.

Health information is extremely sensitive. It's the most personal of all the information we share. So I want to know more about each of your companies' data collection, sharing, and protection practices.

Does your company collect and store health information from the end-users of the prescriptions you provide? For example, information or records of a diabetic individual's blood sugar levels.

Answer. Yes, OptumRx collects and stores health information, consistent with applicable privacy laws, related to an individual's prescriptions when a pharmacy submits a claim for processing to our PBM or a member or provider submits a prior authorization for a prescription. Additionally, as part of certain clinical programs offered to customers by the PBM, and with the member's consent, OptumRx may also access information from an individual, such as a diabetic individual's glucose testing results.

Question. Does your company make any treatment, cost, or coverage decisions based on the health information you collect from an individual?

Answer. OptumRx does not make treatment decisions. Coverage decisions are made, on behalf of OptumRx's customers, based on the adjudication of the health information submitted by a pharmacy and also may be made based on health information submitted by an individual or their provider when a prior authorization is required by a health plan for a particular prescription.

Answer. Does your company share health information with third parties? And, if so, does your company profit from that sharing?

Answer. OptumRx, as a business associate to its customers, uses and shares data only as authorized by applicable law and its customer contracts. In addition to sharing data with and on behalf of its customers, OptumRx shares claims-related health information with providers about their patients as part of clinical programs. Health information may be shared with third party vendors of OptumRx in support of our PBM services pursuant to business associate agreements. OptumRx does not profit from the sharing of information with its vendors. OptumRx does have some arrangements to license de-identified data. Additionally, our pharmacies have service agreements with drug manufacturers that may involve the sharing of certain data in accordance with applicable law.

Question. Do you believe customers are fully aware of your information collection and sharing practices?

Answer. Yes.

IMPACT OF VERTICAL INTEGRATION BETWEEN PBMS AND INSURANCE COMPANIES

Question. The PBM industry has experienced significant consolidation within the past 10 years, which has contributed to concerns about the potential abuse of market power, barriers to market entry, and exclusionary practices. In 2012, for example, Express Scripts acquired Medco Health Solutions—a nearly $30 billion transaction that merged two of the country's three largest PBMs. More recently, PBMs are also vertically integrating with insurers/payers, reflected by the 2018 acquisi-

tions of Express Scripts Holding Co. (a PBM) by Cigna Corp. (a payer) and of Aetna Inc. (a payer) by CVS Health Corp. As a result, the three largest PBMs are all vertically integrated with insurance companies. According to a report from the Kaiser Family Foundation, the two combined entities, along with UnitedHealth and Humana, will cover 71 percent of all Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees. Vertical integration can result in increased efficiencies and consumer benefits. I can also, however, lead to higher barriers to entry for competition, leading to further consolidation. FDA Commissioner Scott Gottlieb recently warned that "consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious. And the very complexity and opacity of these schemes help to conceal their corrosion on our system—and their impact on patients."

I'd like to talk about consolidation, including the recent integration of PBMs with insurance companies. Last year, I wrote to the Justice Department on this issue. It's reported that the three largest PBMs—who are before us today—now cover 71 percent of Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.4 Such market power has raised concerns. FDA Commissioner Scott Gottlieb said, "the consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious."

I want to hear briefly from each of you on whether the PBM industry is competitive. For example, are there high barriers to entry for new competitors?

Answer. The PBM industry is and will remain highly competitive. There are currently more than 60 PBMs actively competing for business from governments, Medicare Part D beneficiaries, unions, health plans, and large and small employers, and more players are entering the market on a regular basis.[1] For example, Anthem started IngenioRx on March 2, 2019, to replace its contract with Express Scripts.[2] In April 2018, Diplomat Pharmacy launched CastiaRx, a PBM with specialty pharmacy experience to manage pharmacy and medical benefit plans for small and midsize payers.[3] New ventures such as WithMe Health, Amazon, and Haven have entered or are planning to enter the health benefits industry with disruptive business models.[4] Not only can customers choose from numerous external PBM options, but some government payers and health plans also can (and do) perform their own PBM services internally.[5]

At least eight PBMs serve major health plans and large employers, while others serve regional and smaller customers.[6] It is OptumRx's experience when competing for business there are regularly at least 3-5 competitors bidding for the same business.

Question. I'm also interested in what effect the most recent consolidations of PBMs and insurers has had on the bottom line for the government and consumer.

Do these arrangements result in a lower cost to the government—as a payer—and the consumer? Please explain.

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[1] "Drug Pricing in America: A Prescription for Change, Part III," hearing before the Senate Committee on Finance, 116th Congress, video at 57:22–27, 57:48–54 (April 9, 2019) (live testimony of Steve Miller, M.D., executive vice president and chief clinical officer, Cigna Corporation; live testimony of Derica Rice, executive vice president, CVS Health and president, CVS Caremark), video available at *https://www.finance.senate.gov/hearings/drug-pricing-in-america-a-prescription-for-change-part-iii.*

[2] Anthem, Inc., "Anthem Reports Fourth Quarter and Full Year 2018 Results Reflecting Strong Core Performance" (January 3, 2019), available at *https://ir.antheminc.com/news-releases/news-release-details/anthem-reports-fourth-quarter-and-full-year-2018-results?field_nir_news_date_value[min]=2019;* Anthem, Inc., "Anthem Launches IngenioRx, New Pharmacy Benefits Manager" (October 18, 2017), available at *https://ir.antheminc.com/news-releases/news-release-details/anthem-launches-ingeniorx-new-pharmacy-benefits-manager?field_nir_news_date_value[min]=2019.*

[3] Diplomat Pharmacy, Inc., "Diplomat Launches CastiaRx, Industry-Leading Specialty Benefit Manager," PR Newswire (April 30, 2018), *https://www.prnewswire.com/news-releases/diplomat-launches-castiarx-industry-leading-specialty-benefit-manager-300638735.html.*

[4] Withme.health; Kevin Truong, "Why a VC Frustrated by the PBM Industry Decided to Start an Alternative," *MedCityNews.com* (January 6, 2019), *https://medcitynews.com/2019/01/why-a-vc-frustrated-by-the-pbm-industry-decided-to-start-an-alternative/?rf=1.*

[5] *Id.* at 107 ("The various functions of pharmacy benefit management can be performed by different entities within the drug channel system: an employer, a health plan, the government, and an independent PBM company."); *id.* at 115 ("Humana Pharmacy Solutions is the internal PBM of health insurer Humana. It manages traditional prescription drug coverage for Humana's individual and employer groups.").

[6] Adam J. Fein, "The 2018 Economic Report on U.S. Pharmacies and Pharmacy Benefit Managers" (February 2018) at p. 112 Ex. 75.

Answer. OptumRx operates in a competitive industry where we must continually innovate, reduce the total cost of care, and improve outcomes to win new business and retain existing customers. Our synchronization of disparate, uncoordinated areas in health care allows us to focus on these goals. This results in lower costs to government and consumer payers, on average saving $1,600 per person annually.

Over the next decade, PBMs project that they will save the Medicare Part D program over $900 billion.[7] If States fully utilized those same tools and capabilities, over the same period, Medicaid could save more than $100 billion.[8] This adds up to $1 trillion in savings for Federal and State governments and taxpayers as a direct result of PBMs.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

MANUFACTURER MONEY

Question. What is the total dollar amount that you obtain from pharmaceutical manufacturers in any form such as rebates, fees, etc.?

What is the total dollar amount that you remit to health plans?

Answer. OptumRx does not collect an administrative fee from manufacturers for Medicare or Medicaid plans, or for drugs for which manufacturers provide no discount. The drugs in this latter category—the majority of which are generics—constitute approximately 90 percent of all prescriptions processed by OptumRx. OptumRx's PBM business does not receive distribution, marketing or clinical case management fees.

OptumRx makes pricing and rebate information available to customers, and reimbursement and out-of-pocket information available to pharmacies, subject to appropriate confidentiality provisions. The information is subject to independent audit by our customers. At the consumer level, OptumRx provides solutions to help consumers make better decisions, including our MyScript Finder solution, which provides members with easy to understand price and benefit transparency. OptumRx shares with its customers approximately 98 percent of the discounts it obtains from manufacturers. We pass through an even greater percentage of the discounts we negotiate with manufacturers to our Medicare Part D and Medicaid plan customers. Discounts collected on behalf of Medicare Part D customers are reported to CMS, and discounts collected on behalf of Medicaid customers are disclosed to those customers for their reporting purposes.

BIOSIMILARS

Question. Managed Care Organizations are on record as widely supportive of the potential of biosimilars. However, most MCOs have continued to support originator brand products and have not preferred and often excluded less expensive biosimilars. For example, most MCOs have kept Remicade (a treatment for Rheumatoid Arthritis and other diseases) as the preferred agent on their formularies, and in most cases to the exclusion of its biosimilar, Infliximab.

Why do you tout support for biosimilars while, at the same time, inhibiting adoption of these less expensive products?

Answer. OptumRx urges action to increase the availability and adoption of biosimilars and promote true competition. Specifically, Congress should modernize the intellectual property system for the 21st century and eliminate drug manufacturers' ability to manipulate the patent and regulatory system to prevent lower-cost generics and biosimilars from reaching consumers more quickly. We applaud the FDA's recent release of interchangeability guidance to promote substitution of these products over expensive branded specialty products. The FDA should continue to adopt reforms to release biosimilars to the market more quickly and promote adoption with prescribers and patients. As other countries' experiences have shown, these two measures have proven to increase competition and lower drug prices.

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[7] "Drug Pricing in America: A Prescription for Change, Part III," hearing before the Senate Committee on Finance, 116th Congress (April 9, 2019) (prepared testimony of John M Prince, CEO, OptumRx) (citing Oliver Wyman, "Savings Generated by Pharmacy Benefit Managers in the Medicare Part D Program" (June 26, 2017), available at *http://www.affordableprescriptiondrugs.org/app/uploads/2018/05/resources_medicarepartd_report.pdf.*

[8] *Id.*

There are 51 approved biosimilars in Europe. To date, however, in the U.S. the FDA has only approved 19 biosimilars, and of those only seven have launched to market.

Not all biosimilars are less expensive products, but OptumRx promotes the inclusion of those biosimilars that are less expensive and that drive lower net costs on its standard formularies. On our Premium formulary effective July 1, 2019, for example, we prefer the Infliximab biosimilars Renflexis and Inflectra, and exclude Remicade; we also prefer the biosimilar Zarzio, a biosimilar that treats blood disorders, and exclude Amgen's biologic Neupogen.

Question. HHS may broaden the scope of its proposed rule and eliminate rebates between Medicare Advantage plans and manufacturers for Part B drugs.

Would this realign incentives to encourage preferred access for lower-cost drugs, such as biosimilars?

What changes can we recommend/make to help you prefer lower-cost drugs, such as biosimilars, without rebates?

Answer. We have heard the bipartisan call for reform and have taken strong action to reduce drug prices for millions of consumers. Last year, our company led the way in voluntarily making negotiated prescription drug discounts available at the point of sale for UnitedHealthcare's fully insured customers.

Earlier this year, we took action to ensure the prescription drug discounts we negotiate with drug manufacturers will be passed directly to consumers at the point of sale for all new employer customers starting in 2020. Eligible consumers filling prescriptions on discounted brand drugs are seeing average savings of $130 per eligible prescription and increased drug adherence by as much as 16 percent. This action means real out-of-pocket savings for consumers who take brand drugs with discounts.

These actions underscore that only PBMs have the capability to both negotiate meaningful discounts from drug manufacturers and ensure those savings flow directly to consumers at the pharmacy counter.

Our action to provide point-of-sale discounts to employer-sponsored health plans demonstrates that the private sector is responsive and is taking a leadership role with its customers to reform the market. Legislation to eliminate rebates is unnecessary and could put at risk the ability to negotiate significant discounts from drug manufacturers. In fact, according to actuaries at CMS, even without broadening its scope, the CMS' Proposed Rebates Rule would increase premiums up to 25 percent for seniors and create a $40 billion windfall for drug manufacturers. Broadening it to Medicare Advantage plans would likely exacerbate this problem.

Congress should take action in ways that promote real competition to drive down the list prices of prescription drugs. The most important step Congress can take to address the high cost of prescription drugs is to modernize the intellectual property system for the 21st century and eliminate drug manufacturers' ability to manipulate the patent and regulatory system and prevent lower-cost generics and biosimilars from reaching consumers more quickly. Specifically, Congress should:

- Pass the bipartisan CREATES Act to end the manipulation by drug manufacturers of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generic competition.
- Prohibit "pay-for-delay" settlements between drug manufacturers that delay the market entry of lower-cost alternatives.
- Restrict "ever-greening" of patents in which drug manufacturers make minor changes to their product, or to the delivery technology for their product, to extend the patent exclusivity period.
- Reduce the exclusivity period for brand and specialty drugs.
- Increase patent transparency for biologics.
- Continue additional FDA reforms, such as the recently issued interchangeability guidance, to promote biosimilar competition to bring needed lower cost biosimilar treatments to market faster and promote broader adoption with prescribers and patients.

Question. Why is there such a disparity in reimbursed pharmacy prices for specialty generic drugs in Part D (*e.g.,* Imatinib)? Does ownership of specialty pharmacy influence your reimbursement decision?

Answer. Preferred network pharmacy options deliver greater drug cost savings and value to customers and their members through our pharmacy care services model that is integrated with pharmacies that we operate. OptumRx is transparent to customers by disclosing our ownership of pharmacies, and customers ultimately choose the pharmacy network plan design that best meet their needs.

We offer reasonable terms and conditions for participation in the various networks we offer on behalf of our Part D customers. While pricing may differ across networks, we seek to pay all of our Part D providers market competitive rates. All of our Part D plan customers have chosen pass-through pricing arrangements. We are not aware of any reimbursement anomalies related to Imatinib.

Question. I'm concerned with the recent trend of PBM's allowing brand companies to "pay for position" on insurance formularies, which results in seniors losing access to lower-cost generics and biosimilars.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs?

Answer. OptumRx manages pharmacy benefits on behalf of our customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and Federal and State government employee plans. In that role, we promote the use of clinically effective, low net-cost prescription drugs for consumers when medications are needed.

This work starts with an independent, clinically based formulary design process. OptumRx's Pharmacy and Therapeutics (P&T) committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence and review and appraise those drugs in an unbiased and evidence-based way. The P&T committee meets regularly, and its deliberations are open and transparent to OptumRx's customers and prospective customers.

A drug's cost plays no role in the P&T committee's clinical review. Cost only becomes relevant after the P&T committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered. If the P&T committee determines that more than one drug in a particular class is clinically effective, OptumRx will consider net cost—among other factors such as improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees—when negotiating formulary placement for that therapeutic category.

For about 90 percent of prescriptions processed, OptumRx can identify a generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug. If there is no generic product available, there may still be other therapeutically equivalent branded alternatives. If so, OptumRx negotiates with those competing brand manufacturers to obtain discounts, and generally places the drugs that drive the lowest overall net cost for the therapeutic category in a preferred position on the formulary.

OptumRx has been effective in driving utilization of clinically effective low-cost medications. OptumRx's negotiated network discounts and clinical tools are reducing annual drug costs, on average, by $1,600 per person for our customers. Even greater savings can be achieved by customers who implement evidence-based utilization management and other OptumRx clinical programs.

OptumRx also ensures that these cost-savings go to our customers. Our customers receive approximately 98 percent of the value of the discounts we negotiate from drug manufacturers. The application of discounts is subject to audit and verification by an independent third-party on behalf of any of our customers. In those limited instances where we retain some of the discount, it is because our customers have chosen to pay us that way. Additionally, as noted above, we have led the industry in promoting point-of-sale discounts for consumers.

DELAYS AND DENIALS IN CANCER TREATMENT

Question. I have received stories of cancer patients facing delays or denials for their treatment due to PBM actions. Data shows that breast cancer patients who experienced a 3-month or more delay in treatment had a 12-percent lower 5-year survival rate compared with breast cancer patients with only a 0- to 3-month delay.

What percent of patients experience a 14-day or longer delay in receiving an oral oncolytic prescribed by their oncologist?

Answer. All of our prior authorization and step therapy criteria are evidence-based and approved by our or the applicable customer's independent P&T committee process. Step therapies are used to aid in affordability by encouraging patients to choose clinically appropriate lower net cost alternative therapies when such therapies exist. Prior authorizations help ensure treatment is clinically appropriate and aligned with FDA labeling, and assist in minimizing potential safety concerns. Time limits for completing the prior authorization process vary depending upon regulatory and contractual provisions and line of business. Once the member has initiated the prior authorization process, OptumRx renders and communicates its decision to the prescribing physician, utilizing criteria approved by OptumRx's or our customer's independent P&T committee, within 12 hours, on average. Delays in actually receiving the prescriptions may be caused by a number of factors outside of OptumRx's control.

Question. What are the primary reasons patients experience delays or denials for their treatments?

Answer. OptumRx strives to avoid all unnecessary delays, and maintains a streamlined process for seeking and obtaining necessary approvals for a course of treatment. When there are delays in this process, we have found the primary factor to be that the patient's physician fails to provide the necessary clinical information in a timely manner during a prior authorization review. The primary reason OptumRx, as the plan's administrator, would not approve coverage for a treatment is that the requested drug is deemed not clinically appropriate for treatment based on clinical criteria reviewed and approved by the independent physicians and pharmacists of OptumRx or the customer's independent P&T committee.

Question. What percent of determinations to delay or deny treatment for cancer patients are made by an oncologist or health-care professional with oncology training?

Answer. All criteria used to determine coverage of oncology therapies are reviewed and approved by the OptumRx independent P&T committee inclusive of practicing oncologists considered experts in the field or the customer's P&T committee.

Question. Why is a PBM-owned specialty pharmacy better qualified to manage a cancer patient's adherence and side effects than a community cancer clinic with a medically integrated pharmacy?

Answer. OptumRx has 67,000 pharmacies in our networks, including 24,000 independent pharmacies. Our network pharmacies play a valuable role in providing convenient network access to our customers and their members. A customer may select a preferred network to help drive greater drug cost savings and improved outcomes. Our specialty pharmacies use a multi-faceted approach to clinical management which we have seen drive higher medication adherence rates and lower medical costs. OptumRx discloses its ownership of pharmacies, and customers ultimately choose the pharmacy network plan design that best meets their needs. In addition, a pharmacy that is connected and integrated with access to a more complete range of PBM data related to a patient's therapeutic regimen is able to identify additional opportunities to improve outcomes and lower health care costs.

DIRECT AND INDIRECT REMUNERATION (DIR) FEES

Question. Many community-based cancer clinics have established medically integrated pharmacies so patients can access their oral chemotherapy prescriptions or other medications at the point of care. These practices are often assessed large DIR which are based on certain quality measures targeted toward primary care.

Shouldn't pharmacies be evaluated on the type of drug dispensed and disease managed rather than a one-size-fits-all approach?

Answer. OptumRx operates a performance-based pharmacy network for Medicare Part D that rewards pharmacies with contingent compensation based on performance across quality metrics designed to improve outcomes in disease States including diabetes, hypertension and cholesterol. These metrics align with measures used by CMS to evaluate Part D plan performance under the CMS STAR ratings program.

Question. Does assessing large DIR fees on medically integrated pharmacies drive patients to PBM-owned specialty pharmacies?

Answer. Performance-based compensation structures for network pharmacies do not incentivize the patient to select any particular pharmacy.

Question. According to CMS, from 2012 to 2017 PBMs imposed a 45,000 percent increase in the amount of DIR fees pharmacies had to pay PBMs and PDPs under Part D, and revenues earned from these fees increased 225 percent per year during this period. I thought PDPs and PBMs were supposed to pay pharmacies for dispensing drugs to patients. Why do pharmacies have to pay DIR fees to PBMs at all?

Why are pharmacies forced to pay DIR and other fees to PBMs?

Answer. Pharmacies are able to agree or decline to participate in performance-based pharmacy networks.

Question. According to CMS, PBMs justify DIR fees as adjustments to improve quality. CMS also found that PBMs and PDPs withhold substantially more in reductions in payments than as rewards paid to pharmacies. Aren't so-called "quality adjustments" that collect more for "poor performance" than they pay out for "high performance" just another way for PBMs to collect even more money from pharmacies?

Why do PBMs collect more in quality payment adjustment than they pay pharmacies under Part D?

Answer. OptumRx does not retain the contingent performance amounts withheld from payments to pharmacies as part of its performance-based pharmacy network. Instead, all contingent performance amounts are either paid to the high performing pharmacies or are used by the Part D client to reduce the drug cost for pharmacies that do not meet the specified quality metrics.

FORMULARY PLACEMENT/GENERIC TIERING

Question. In 2011, 71 percent of generic drugs in Part D were on the lowest tier designed for generics; by 2019, that number decreased to only 14 percent of generics. According to an Avalere study, this practice cost seniors $22 billion in higher out-of-pocket costs since 2015, costs that could have been avoided through the proper formulary placement of lower-cost generics. This practice, known as "paying for position," allows brands to block uptake of lower-cost generics and biosimilars, thereby unnecessarily increasing out-of-pocket costs for seniors.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs? Do you ever consider portfolio or bundled rebates with brand manufacturers?

When you place generics on your formularies, do you place that generic favorably to brand products—in other words, on generic-only tiers?

When a generic becomes available, do you place it on your formularies immediately?

Answer. OptumRx manages pharmacy benefits on behalf of our customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and Federal and State government employee plans. In that role, we promote use of clinically effective, low net-cost prescription drugs for consumers when medications are needed.

This work starts with an independent, clinically based formulary design process. Our customers may adopt OptumRx's standard formulary or choose instead to utilize their own custom formularies. OptumRx's Pharmacy and Therapeutics (P&T) committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an unbiased and evidence-based way. The P&T committee meets regularly, and its deliberations are open and transparent to OptumRx's customers and prospective customers. Part D customers may designate OptumRx's P&T committee or leverage their own committees for such purposes.

A drug's cost plays no role in the P&T committee's clinical review. Cost only becomes relevant after the P&T committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered. If the P&T committee determines that more than one drug in a particular class is clinically effective, OptumRx will consider net cost—among other factors such as improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees—when negotiating formulary placement for that therapeutic category.

For approximately 90 percent of prescriptions processed, OptumRx can identify a generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug. If there is no generic product available, there may still be other therapeutically equivalent branded alternatives. If so, OptumRx negotiates with those competing brand manufacturers to obtain discounts, and generally places the drugs that drive the lowest overall net cost for the therapeutic category in a preferred position on the formulary.

OptumRx has been effective in driving utilization of clinically effective low-cost medications. OptumRx's negotiated network discounts and clinical tools are reducing annual drug costs, on average, by $1,600 per person for our customers. Even greater savings can be achieved by customers who implement evidence-based utilization management and other OptumRx clinical programs.

OPTUMRX SPECIFIC

Question. Attached is a new contract for 2020 that OptumRx sent to a community oncology practice in my State. It States that if CMS requires "100 percent of pharmacy price concessions to be reported at the point of sale" then OptumRx will reimburse pharmacy providers 10 percent less for the drugs they dispense.

Please tell me how and why OptumRx justifies reducing reimbursement on critical cancer drugs if CMS takes away your rebates?

Answer. There is no relationship between drug manufacturer rebates and what OptumRx pays a participating network pharmacy for dispensing a particular drug.

Question. What's the valid connection between rebates, which have been linked to fueling higher drug prices, and reimbursement to pharmacy providers of cancer medicines?

Answer. There is no relationship between drug manufacturer rebates and what OptumRx pays a participating network pharmacy for dispensing a particular drug.

March 15, 2019

NOTICE AMENDMENT 2020 MEDICARE PART D PRESCRIPTION DRUG COMPENSATION RATE

Effective Date: January 1, 2020

OptumRx Retail Pharmacy Network Compensation Exhibit to the Medicare Addendum

OptumRx appreciates your pharmacy's current participation in our Medicare pharmacy networks administered by OptumRx. In accordance with your Pharmacy Network Agreement ("Agreement"), OptumRx is providing the 2020 Medicare Part D network prescription drug compensation rates pursuant to this notice amendment.

Effective January 1, 2020, we are modifying the current particular Medicare Prescription Drug Compensation to the Agreement with the enclosed Retail Pharmacy Network Compensation Exhibit to the Medicare Addendum.

The Agreement allows the Administrator to modify Prescription Drug Compensation.

The modified Medicare Prescription Drug Compensation will become effective January 1, 2020. No further action is required by your pharmacy to be active in the 2020 Retail Medicare Part D network administered by OptumRx.

If you have any questions, please contact the Provider Relations Department Monday through Friday, 8 AM – 5 PM CT at **(877) 633-4701**.

Please distribute immediately.
For questions regarding communications, contact the Pharmacy Provider Communications team: pharmacyprovidercommunications@optum.com

2020 M&R NETWORK NOTICE AMENDMENT TO THE MEDICARE PART D ADDENDUM TO THE PHARMACY NETWORK AGREEMENT

Effective January 1, 2020, this 2020 Medicare Advantage Prescription Drug and Medicare Part D Prescription Drug (including Group Retirees) Network Amendment (hereinafter "M&R Amendment") amends the Medicare Part D Addendum to the Pharmacy Network Agreement ("Agreement") by and between OptumRx, Inc. and each of its affiliates that provides pharmacy benefit management services (collectively, the "Administrator"), and Company and its Company Pharmacies, ("Company"). In consideration of Company participating and providing Covered Prescription Services in the M&R Network, Administrator agrees to pay Company the following Prescription Drug Compensation, subject to the other terms and conditions herein.

A. Company and Administrator entered into the Agreement , pursuant to which Company has agreed to arrange for Company Pharmacies to furnish Covered Prescription Services to Members in connection with the Benefit Plans offered by Administrator's Clients;

B. The Agreement allows for Administrator to amend the Agreement by providing a notice amendment.

[redacted]

NOW, THEREFORE, in consideration of the foregoing premises and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereto agree as follows:

1. The following provisions defined in this M&R Amendment are strictly limited and only applicable to Medicare Advantage Prescription Drug and Medicare Part D Prescription Drug (including Group Retiree) Benefit Plans:

1.1. **Network Applicability**. The M&R Networks are strictly limited and only applicable to Medicare Advantage Prescription Drug and Medicare Part D Prescription Drug (including Group Retiree) Benefit Plans. Therefore, the M&R Networks do not, in any manner, support any ERISA Benefit Plans, Commercial, or Medicaid Benefit Plans.

[redacted]

3. **United Healthcare Contingent Medication Adherence Performance Fee**. The Contingent Medication Adherence Performance Fee (CPF) for the United Healthcare M & R Network is defined in the attached Exhibit A-2a of this M&R Amendment, as applicable. If as of the Effective Date CMS requires one hundred percent (100%) of pharmacy price concessions to be reported at the point of sale, both parties agree that the CPF and Prescription Drug Compensation described in Exhibit A-2a will no longer apply and the Prescription Drug Compensation described in Exhibit A-2b shall apply as of the Effective Date for the United Healthcare M&R Networks.

4. **Term and Termination**. In addition to the terms and conditions of the Agreement, the following terms also apply to the term and termination of this M&R Amendment.

41. **Term**. The term of this M&R Amendment shall continue through the term established in the Agreement.

42. **Termination of this M&R Amendment**. This M&R Amendment may be terminated in accordance with the same notice requirements of the Agreement except that, Company shall provide Administrator with written notification prior to April 1st of the current year should Company desire to terminate without cause this M&R Amendment. Any such termination shall only become effective January 1st of the following year. Termination of this M&R Amendment shall not automatically result in a termination of the Medicare Part D Addendum or the Agreement.

5. In the event of any conflict between the terms set forth in this M&R Amendment and the terms of the Agreement, the terms set forth in this M&R Amendment shall supersede and control. Capitalized terms used in this M&R Amendment and not otherwise defined herein shall have the meaning given to them in the Agreement.

OptumRx, Inc.

DocuSigned by:
Denise Van Keulen
8DDDB555D707C484...

Denise M. Van Keulen
Vice President Network Relatio 2020 MPD8 Notice Amendment 1

EXHIBIT A-2a

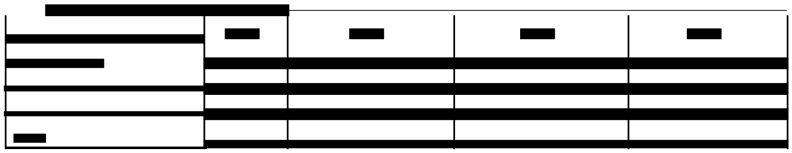
[redacted]

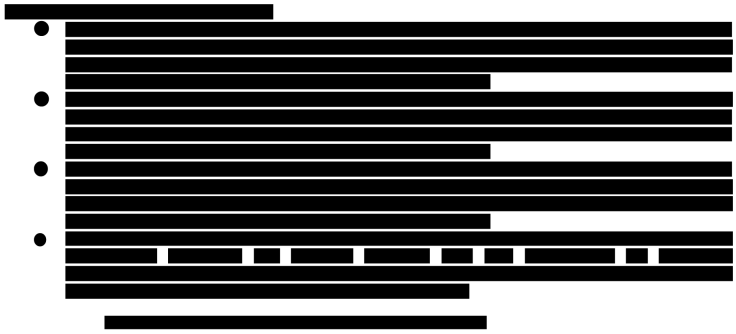
COMPENSATIO N AND

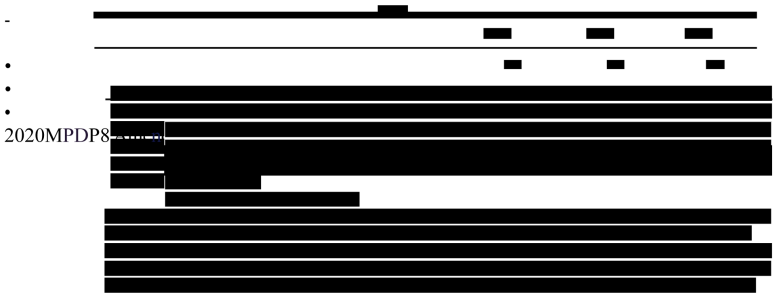
1. **Prescription Drug Compensation.** The Prescription Drug Compensation shall mean the lesser of (i) Company's Usual and Customary Charge or (ii) the Submitted Cost Amount or (iii) the contracted rate defined in Chart 1.1 below as "Prescription Drug Contracted Rate".

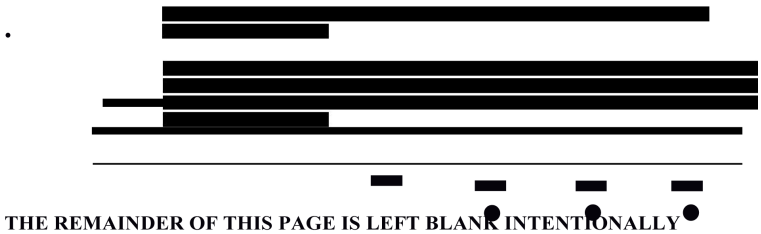
Chart: 1.1 Prescription Drug Contracted Rate

	[redacted]						
				[redacted]			
		Networ	Day	Brand	Dispens e Fee	Generic Rate lesser	Dispens e Fee
MAPD individual, PDP Preferred.							
MAPD individual, PDP Preferred.							









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[redacted]

EXHIBIT A-2b

1. **Prescription Drug Compensation**. The Prescription Drug Compensation shall mean the lesser of (i) Company's Usual and Customary Charge or (ii) the Submitted Cost Amount or (iii) the contracted rate defined in Chart 1.1 below as "Prescription Drug Contracted Rate".

Chart: 1.1 Prescription Drug

	[redacted]						
				[redacted]		[redacted]	
		Network	Day	Brand	Dispens	Generic Rate lesser	Dispens
MAPD individual, PDP Preferred.							
MAPD individual, PDP Preferred.							

[redacted]

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QUESTION SUBMITTED BY HON. JOHN THUNE

Question. You've shared your ability to leverage technology such as real-time benefit tools to help patients and providers understand drug costs at the point of prescribing, as well as how technology can be used to help identify opportunities to provide enhanced support and medication management for enrollees. What policies can we consider to incentivize greater uptake of these tools?

Answer. We have a long history of developing consumer-friendly tools to lower out-of-pocket costs and make the health-care experience more satisfying and effective for patients. For example, one of these tools, PreCheck MyScript®, is a digital platform that simplifies the drug prescribing experience by showing the prescribing physician what the patient's true out-of-pocket cost would be while the patient is

still in the physician's office. PreCheck MyScript® has helped lower consumer out-of-pocket costs by an average of $135 per prescription filled. This is just one of the ways we are working to simplify the system.

OptumRx recently introduced another transparency tool for use by consumers directly. MyScriptFinder provides drug pricing, coverage, and therapeutic alternatives information for consumers to discuss with their physician through a mobile application or the Internet. The information includes point-of-sale drug pricing information for consumers filling prescriptions at an OptumRx network pharmacy.

We recommend the committee advance solutions that provide meaningful transparency to consumers, providers, and customers while preserving the role of health plans and PBMs to reduce overall net costs by harnessing the competitive marketplace, including:

- Drive interoperability and end information blocking to enable seamless integration of data into the clinical workflow;
- Advance technology solutions for consumers and providers that promote visibility to the lowest price for any given medication; and
- Support business practices that ensure consumers pay low, transparent out-of-pocket costs at the pharmacy counter.

QUESTIONS SUBMITTED BY HON. RICHARD BURR

Question. Pharmacy benefit managers (PBMs) offer a variety of contract designs to health insurance plans, allowing the insurer or client to choose the best structure for their customers. During the Finance Committee hearing on April 9, 2019 each witness stated that, in the contracts structured to allow for the passthrough of rebate dollars at the point of sale, PBMs do not keep *any* portion of the rebate. If the PBM does not keep a portion of the rebate, what type of revenue do PBMs receive from these contracts? What percent of your contracts are point of sale and what percent utilize a structure providing a percentage of the rebate back to the PBM?

Answer. To meet varying customer needs, we offer flexibility in how we are compensated for our services. For example, customers can choose to compensate us through per-member per-month fees, administrative fees, or they may require us to retain a certain percentage of discounts we negotiate with drug manufacturers. If a customer allows us to retain a certain percentage of rebates, the specific amount we retain will be governed by the terms set forth in our customer agreement. Already today, approximately 98 percent of discounts we collect from drug manufacturers are passed on to our customers. Additionally, for years we have offered the capability to enable point-of-sale discount solutions and in 2018 we were the first PBM to launch the solution at scale to ensure that consumers also directly benefit from our negotiations with drug manufacturers. By the end of 2019 we expect more than 9 million consumers will be eligible for these point-of-sale discounts, and beginning January 1, 2020, we will expand this point-of-sale discount solution to all new employer-sponsored plans.

Question. It is our understanding that contracts with pharmaceutical manufacturers may also take a variety of forms. In calendar years 2016, 2017 and 2018, what was the total dollar amount that you obtained from pharmaceutical manufacturers in any form such as rebates, fees, etc.? What is the total dollar amount that was passed on to health insurance plans with which you have an agreement or contract?

Answer. OptumRx does not collect an administrative fee from manufacturers for Medicare or Medicaid plans, or for drugs for which manufacturers provide no discount. The drugs in this latter category—the majority of which are generics—constitute approximately 90 percent of all prescriptions processed by OptumRx. OptumRx's PBM business does not receive distribution, marketing or clinical case management fees.

OptumRx makes pricing and rebate information available to customers, and reimbursement and out-of-pocket information available to pharmacies, subject to appropriate confidentiality provisions. The information is subject to independent audit by our customers. At the consumer level, OptumRx provides solutions to help consumers make better decisions, including our MyScript Finder solution, which provides members with easy to understand price and benefit transparency. OptumRx shares with its clients approximately 98 percent of the discounts it obtains from manufacturers. We pass through an even greater percentage of the discounts we ne-

gotiate with manufacturers to our Medicare Part D and Medicaid plan customers. Discounts collected on behalf of Medicare Part D customers are reported to CMS, and discounts collected on behalf of Medicaid customers are disclosed to those customers for their reporting purposes.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. One challenge that I see, when considering the medical treatment marketplace, is that we have a new wave of life-saving treatments—of incredible cures we could never have dreamed of, even 10 or 15 years ago—for which cost, by necessity, is going to be a major issue. You look, for instance, at a condition like sickle cell disease. For the average SCD patient who reaches age 45, lifetime treatment costs are at roughly $1 million—and there are complications that can make that figure even higher. Now that we see therapies coming down the pipeline that could erase those long-term costs and drastically improve the quality of life for sickle cell patients, the question becomes, how can our current payment systems adapt to—and absorb—the high costs necessary to bring treatments like these to market and to ensure that we continue to see innovations like these ones moving forward?

And along the same lines, beyond creating some much-needed clarity around value-based arrangements—which I've been working with Senators Cassidy and Warner to accomplish legislatively—are there steps that Congress could take to facilitate these innovative payment models?

Answer. We understand how important these treatments are for patients facing life-threatening illness. The availability of high cost gene therapies and cures are increasing, with list prices averaging $850,000 for such therapies. To date, five gene therapies have been approved by the Food and Drug Administration, and 20–45 additional gene therapies will be launched in the U.S. over the next 5 years. Thirty million Americans have some form of rare disease. If just five percent are treated at an average list price of $850,000, this would equal $1.275 trillion—four times the $330 billion the U.S. spends on all prescription drugs today.

We recommend the committee advance the following policies to stem this approaching crisis:

- Require the Centers for Medicare and Medicaid Services to issue a National Coverage Determination on each high-cost therapy or cure.
- Use registries to assess the long-term health outcomes of each high-cost therapy or cure.
- Introduce a drug price inflation penalty tied to the Consumer Price Index, medical cost, or the Medicare growth rate in the catastrophic phase for all brand, biosimilar, and generic drug covered in Medicare Part B and Part D.
- Study risk mitigation options, such as stop loss programs, for extremely high-cost products.
- Modify Medicaid Best Price, Anti-Kickback Statute, and Stark requirements that currently impede the full use of value-based contracting for all drugs and devices.

Question. I'm also interested in the role that technology can play in helping to drive down drug costs—as well as to increase medication adherence. Some estimates suggest that between 50 and 75 percent of patients don't take their medications as prescribed, and that one in five new prescriptions go unfilled. And study after study shows that cost is a key factor here. As a consequence, we see roughly 125,000 deaths from non-adherence every year, along with more than $100 billion in excess costs to the health-care system.

To what extent can technology help providers and patients to make more informed and cost-effective choices about prescriptions—and to then adhere to these prescriptions?

Answer. New and emerging technology tools, such as real-time benefit check (OptumRx's version is known as PreCheck MyScript), are now delivering the most accurate cost information at one of the most critical stages of the prescription process—the provider's issuance of the prescription. These tools enable patients to have a much better understanding of the costs they will be facing when they go to get their medication at the pharmacy counter. More importantly, these tools can drive a critical conversation between patients and their provider about the cost of medica-

tion and the treatment options (*e.g.,* switch to generics or therapeutic equivalent brands) that will best position the patient for long-term adherence and optimal condition treatment.

Question. And maybe more to the point, to the extent that these technological tools are out there, what steps are you and your clients taking to encourage physicians and patients to use them?

Answer. OptumRx is actively working with prescribers and other relevant stakeholders across the health-care system to promote adoption of these new tools. We are also working directly with providers to: (1) educate on the objectives of these tools; (2) understand how to best integrate these tools into prescriber's existing work flows; and (3) assess what further enhancements are needed to ensure maximum clarity and value for the provider/patient experience. Lastly, OptumRx is making similar tools available to patients. These patient-facing tools focus on price comparisons and the different options available for obtaining medications when patients directly inquire about medication costs. Information about medication choice is available to patients who contact OptumRx by phone, web, or mobile applications. We work to measure and manage adoption of these tools to ensure they are generating value and lowering cost.

QUESTIONS SUBMITTED BY HON. BILL CASSIDY

Question. Are there ever cases where a patient in your health plan or one of the health plans for whom you negotiate as a PBM pays more for a medicine than the plan spends on a net basis, when you reimburse the pharmacy for that same medicine? In those cases, what entity receives the benefit of the difference between the amount the patient pays and the net amount the plan pays?

Answer. OptumRx does not believe this is currently taking place. OptumRx encourages its customers to give their members the benefit of its contracted network reimbursement rates if they are lower than the members' copayment amounts. However, if there are cases where the member copayment exceeds the contracted reimbursement rate, the pharmacy, not OptumRx as the PBM, generally retains the excess.

Question. In calendar years 2015, 2016, and 2017, what percent of your revenue was from fees paid by plans, fees paid by manufacturers, other fees, pharmacy spread, or rebates? Same question as to profits. Of all revenue generated from part D contracts, what percent did you retain?

Answer. OptumRx does not collect an administrative fee from manufacturers for Medicare or Medicaid plans, or for drugs for which manufacturers provide no discount. The drugs in this latter category—the majority of which are generics—constitute approximately 90 percent of all prescriptions processed by OptumRx. OptumRx's PBM business does not receive distribution, marketing or clinical case management fees.

OptumRx makes pricing and rebate information available to customers, and reimbursement and out-of-pocket information available to pharmacies, subject to appropriate confidentiality provisions. The information is subject to independent audit by our customers. At the consumer level, OptumRx provides solutions to help consumers make better decisions, including our MyScript Finder solution, which provides members with easy to understand price and benefit transparency. OptumRx shares with its clients approximately 98 percent of the discounts it obtains from manufacturers. We pass through an even greater percentage of the discounts we negotiate with manufacturers to our Medicare Part D and Medicaid plan customers. Discounts collected on behalf of Medicare Part D customers are reported to CMS, and discounts collected on behalf of Medicaid customers are disclosed to those customers for their reporting purposes.

Part D revenue and retention information is reported to CMS. OptumRx does not generate any revenue in Part D via service fees.

Question. Should a patient ever pay more out of pocket for a medicine than what you pay the pharmacy for that medicine?

Answer. OptumRx encourages its customers to give their members the benefit of its contracted network reimbursement rates if they are lower than the members' copayment amounts. However, if there are cases where the member copayment ex-

ceeds the contracted reimbursement rate, the pharmacy, not OptumRx as the PBM, generally retains the excess.

Question. A recent study shows that PBM revenue from fees has risen. Further, PBM's retained revenue as a percent of net retail drug spend has consistently increased. What do you attribute this increase to?

Answer. OptumRx did not prepare or participate in the study referenced, nor can it comment on the data sources that formed the basis for the study. However, the increase in fee revenue may be attributable to customers increasingly choosing to keep all or a greater percentage of discounts, or deciding to move to a pass-through network arrangement and paying PBMs through administrative fees.

Question. How are bona fide service fees established? What was your revenue generated in part D by bona fide fees in 2015, 2016, and 2017?

Answer. OptumRx does not generate any revenue in Part D via service fees.

Question. A *Health Affairs* article suggests plans may prefer paying PBMs using rebates instead of fees, as "Using retained rebates to cover PBM costs in lieu of fees could artificially lower reported administrative costs and make it easier to meet government medical loss ratio (MLR) requirements." Is it true that paying the PBM a percent of rebates would keep that revenue from counting towards a plan's MLR?

Answer. OptumRx reports 100 percent of rebates received on behalf of Part D plans so that Part D plans can accurately complete DIR reports filed with CMS. In the limited instances that a Part D plan allows OptumRx to retain a portion of rebates as compensation for services, the Part D plan must still report 100 percent of the rebates received on its DIR reports. While we do not have visibility to our Part D plan customers' MLR filings, we are not aware of any situations where a Part D plan has reported a PBM's retained rebates as administrative costs.

Question. Would you support an industry-wide standard set of performance metrics by which a PBM would set its pharmacy contracts, which would be tailored based on regional patient populations, to give certainty for local pharmacies?

Answer. OptumRx is open to evaluating proposals, with a focus on approaches that reduce health care costs, incentivize improved health outcomes and improve quality.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

Question. In Medicare Part D, beneficiaries' deductible and coinsurance payments are calculated based on the price negotiated between the PBM and the pharmacy.

Does this take into account rebates and discounts the PBM negotiates separately with pharmaceutical manufacturers?

If yes, what percentage of the time is this the case?

In calendar years 2016, 2017, and 2018, what share of brand prescriptions covered by the Part D plans you contract with were filled in the deductible or required beneficiaries to pay coinsurance? What was the total amount beneficiaries spent out of pocket for those prescriptions? What would beneficiaries' total out-of-pocket spending have been under the same cost sharing structure if their payments were based on the net price to the Part D plan, inclusive of rebates and other price concessions, rather than the price negotiated between your PBM and the pharmacy?

Answer. Virtually all brand prescriptions include a member cost share. CMS has specific requirements and processes to obtain appropriate data on beneficiary cost sharing. Plan sponsors, working with their PBM, submit the required data and information to CMS annually and as requested. We are not able to determine the amount of member cost share under hypothetical scenarios retroactively.

QUESTIONS SUBMITTED BY HON. RON WYDEN

SPREAD PRICING IN MEDICAID

Question. A PBM practice that has come up quite a bit recently is the practice of spread pricing. Spread pricing occurs when PBMs charge health plans more for prescription drugs than they actually reimburse pharmacies, and then pocket the different as profit.

Do you engage in spread pricing practices?

Answer. Clients choose how they want to pay OptumRx for its services. Some choose a pass-through model in which the client pays us an administrative fee for managing prescription claims. If our customers choose a traditional model, OptumRx bears the risk. Our clients pay us based on agreed-upon negotiated market rates, which may or may not be the same as the prices we have negotiated with our network pharmacies. Some customers prefer the certainty and stability that a traditional (or spread) model offers.

Question. If yes, do you engage in such practices in Medicaid?

Answer. Yes, when allowed by State law and if the customer chooses it.

Question. If so, please list each State you operate in where you have a contract with a Medicaid managed care plan where you employ spread pricing.

Answer. Arizona, California, Florida, Hawaii, Maryland, Massachusetts, Nebraska, New Mexico, New York, New Jersey, Oregon, Pennsylvania, Utah, Virginia, and Washington. State Medicaid plans are increasingly choosing to move to pass-through pricing arrangements.

Question. List each Medicaid managed care plan you have contracts with where you employ spread pricing.

Answer. See above.

Question. Describe whether and how you disclose the use of such practices to the plans.

Answer. OptumRx's contracts with customers describe the financial model the customer has chosen, whether traditional (spread) or pass-through.

Question. Describe whether you disclose such practices directly to the State.

Answer. Except when contracting to provide services to a State's Medicaid Fee-for-Service program (as noted in the next response), OptumRx contracts with the various States' Medicaid Managed Care Organizations, rather than with State Medicaid departments directly. However, State Medicaid programs have access to those contracts.

Question. List any States where you have direct contracts with the State Medicaid agency as a PBM for fee-for-service individuals.

Answer. Arizona, Georgia, Indiana, Nevada, South Dakota, and Washington.

REBATE DEMANDS

Question. The use of rebates as a negotiating tool has led to problematic incentives in the prescription drug supply chain. For example, drug companies have argued that they increase list prices in response to demands from PBMs for high or increasing rebates.

Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that:

Require equivalent rebates, even in the case of a drug for which the list price has been lowered?

Answer. See explanation below.

Question. Require advance notice of changes in the list price of drugs, including reductions or increases in list price?

Answer. See explanation below.

Question. If the answer to either of the above is yes, please provide details regarding each of these requirements in each instance in which they were in place: the required rebate amount or percent; the amount of notice required for list price change notifications, specifically for increases and decreases; and any penalties for noncompliance with rebate or notification requirements by the drug manufacturer.

Answer. Our customers that are Part D plan sponsors consider contracted-for discounts when setting their premiums. Those premiums must be submitted with their bids to CMS seven months before each plan year starts. CMS holds plan sponsors to those premiums for the duration of their contracts. We believe it is important for plans to be able to calculate premiums with confidence. For this reason, OptumRx proposed a Part D contract amendment requesting either advance notice from a

drug manufacturer of list price decreases in the middle of a plan year or, in the absence of advance notice, a commitment by the manufacturer to honor its contracted-for discounts for the entire plan year.

If a manufacturer agreed to the terms of the proposed amendment, and then failed to provide the requested notice, it would be expected to maintain its contracted-for discounts for the duration of the plan year for which the discounts were negotiated to provide premium continuity and stability in the Part D market.

REVENUE SOURCES

Question. Please provide an annual breakdown of the following components of the revenue you received from drug manufacturers from January 1, 2013 through December 31, 2018: dollar amount and percent of revenue from rebates; dollar amount and percent of revenue from administrative fees; dollar amount and percent of revenue from distribution fees; dollar amount and percent of revenue from marketing fees; dollar amount and percent of revenue from clinical case management fees; and all other sources of revenue from manufacturers not listed above.

Answer. OptumRx does not collect an administrative fee from manufacturers for Medicare or Medicaid plans, or for drugs for which manufacturers provide no discount. The drugs in this latter category—the majority of which are generics—constitute approximately 90 percent of all prescriptions processed by OptumRx. OptumRx's PBM business does not receive distribution, marketing or clinical case management fees.

OptumRx makes pricing and rebate information available to customers, and reimbursement and out-of-pocket information available to pharmacies, subject to appropriate confidentiality provisions. The information is subject to independent audit by our customers. At the consumer level, OptumRx provides solutions to help consumers make better decisions, including our MyScript Finder solution, which provides members with easy to understand price and benefit transparency. OptumRx shares with its customers approximately 98 percent of the discounts it obtains from manufacturers. We pass through an even greater percentage of the discounts we negotiate with manufacturers to our Medicare Part D and Medicaid plan customers. Discounts collected on behalf of Medicare Part D customers are reported to CMS, and discounts collected on behalf of Medicaid customers are disclosed to those customers for their reporting purposes.

PART D NEGOTIATION

Question. The PBM market has changed dramatically over the past several years. Many Part D health plans also operate as PBMs, including your companies. While Part D has done a great job offering Medicare beneficiaries drug coverage they did not have access to before, Part D has not been successful at keeping up with the growing cost of medicines. PBMs and Part D plans claim they bargain to get lower prices, but the HHS Inspector General found that almost 4 in 10 brand name drugs in Part D offered no rebate or discount to Part D plans.

Why have Part D plans been ineffective at bringing down the cost of almost half of brand-name medicines?

Answer. Drug manufacturers alone set the price of prescription drugs. A 2018 research study from Visante found that for drugs that have no or decreasing rebates, prescription drug prices, set by drug manufacturers, continue to skyrocket. In Medicare Part D, prescription drugs with no rebates (roughly 40 percent of those prescribed) saw significant price hikes between 2012 and 2017. In Medicare Part B, where there are no PBM-negotiated rebates, drug manufacturers increased the prices of the 10 most-used drugs by a range of 16 to 74 percent.

This research comes on the heels of a study by the Department of Health and Human Services (HHS) Office of the Inspector General, which similarly found that even after accounting for rebates, the prices of prescription drugs increased by 62 percent—a dramatic increase from 2011 to 2015.

CBO continues to conclude that the government would not be able to lower drug prices more effectively than the private sector. Drug manufacturers are increasing drug prices for one simple reason: a lack of meaningful competition allows them to do so. In the absence of competition, drug manufacturers often set exceptionally high prices. There is a vital role for Congress and the administration to play in addressing this important issue.

OptumRx supports providing Part D plans with greater flexibility to negotiate discounts for drugs in the protected classes. Currently, Part D plans must cover substantially all drugs in six protected classes, including all drugs to treat cancer, depression, and HIV, many of which are costly specialty medicines. The current protected class policy limits the private sector's ability to negotiate meaningful savings on protected class brand drugs. Today in the commercial market, discounts for the same protected class drugs can have a negotiated discount of up to 30 percent compared to an average of a six percent discount on protected class drugs in Part D. Without sacrificing the availability of appropriate clinical alternatives, increased flexibility will better position Part D plans to derive cost savings for the Medicare program and for beneficiaries, not only through discounts, but also through the use of biosimilars and generic alternatives. We estimate these flexibilities specific to protected class drugs could drive savings of up to 50 percent.[9]

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Should the CREATES Act become law, what commitment can your company making to covering generics as soon as they are approved and passing those savings on to patients?

Answer. OptumRx urges action to increase the availability of generics and promote true competition. The most important step Congress can take to address the high cost of prescription drugs is to modernize the intellectual property system for the 21st century and eliminate drug manufacturers' ability to manipulate the patent and regulatory system and thereby prevent lower-cost generics and biosimilars from reaching consumers more quickly. We support the CREATES Act becoming law to end the manipulation by drug manufacturers of the Risk Evaluation and Management Strategies (REMS) program to block timely entry of generic competition.

Question. What are your concerns with point-of-sale rebates and what alternatives do you propose to such rebates to improve consumer savings at the pharmacy counter?

Answer. We have heeded the call for change by taking direct action to ensure that the discounts we obtain directly lower consumers' out-of-pocket costs at the pharmacy counter. Last year, we implemented a point-of-sale discount solution at scale for fully insured group customers so that consumers receive the benefit of discounts at the pharmacy counter. This action has already made nearly 6 million consumers eligible for point-of-sale discounts. Eligible consumers filling prescriptions on discounted brand drugs are seeing average savings of $130 per eligible prescription. We believe it can also improve prescription drug adherence by as much as 16 percent. By the end of 2019 we expect more than nine million consumers will be eligible for these point-of-sale discounts. In March of this year, we announced a decision to expand this point-of-sale discount solution to all new employer-sponsored plans beginning in January 2020. This action means real out-of-pocket savings for consumers at the pharmacy counter who take brand drugs with discounts.

Question. What are the specific steps your company is taking to move PCSK9 inhibitors off the specialty tier in Medicare Part D and to fixed copay tiers given that prices went down by 60 percent and are no longer above the specialty tier threshold?

Why haven't your plans moved it already, given that CMS allows plans to make positive mid-year formulary changes that improve patient access and affordability?

Answer. After the independent P&T Committee assessment, OptumRx seeks to prefer the drugs that drive to the lowest net cost for the therapeutic category on its standard formularies. In addition to net cost, OptumRx considers other factors such as improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees.

Tiering of PCSK9 inhibitors is complicated by the fact that newer and older formulations may share unique coding attributes required by CMS that make differentiation in claims adjudication systems difficult. OptumRx expects that, given ongoing market price changes in the PCSK9 category, tiering of PCSK9 inhibitors will change in the future.

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[9] UnitedHealth Group, Comment Letter on Contract Year (CY) 2020 Medicare Advantage and Part D Drug Pricing Proposed Rule (CMS–4180–P) (January 25, 2019).

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

DRUG REBATE RULE AND HIGHER PART D PREMIUMS

Question. In January, the Department of Health and Human Services released a proposal to reform prescription drug rebates paid by pharmaceutical manufacturers to pharmacy benefit managers under Medicare Part D. The OIG proposal attempts to ban most rebates by eliminating their regulatory protections and creating two new safe harbor provisions: one to expressly protect discounts applied directly at the point-of-sale (POS) for consumers, and another to protect certain service fees that manufacturers pay to PBMs for services furnished to health plans. The only service fees that would be permissible under the proposal are those that are fixed, and not based on a percentage of sales and not based on volume or the value of other business generated between the parties. The proposed rule was designed to address the Department's concerns with the current rebate system, which HHS believes rewards high list prices, discourages the use of generics and biosimilars, and does not reflect patient out-of-pocket costs. For consumers, this proposal may result in lower costs at the pharmacy counter, but Part D premiums may increase as a result.

Could you explain which Part D beneficiaries could see savings on their drug costs at the pharmacy counter and which Part D beneficiaries could not see lower drug costs?

Answer. Part D beneficiaries who are not currently taking medications, who take generic drugs, or who take non-rebated brand drugs would not be expected to benefit from the shift to point-of-sale discounts, although premiums would increase for all seniors in Medicare Part D. Further, CBO and OACT estimate that net prices in Part D for rebated products would increase.[10]

PERVERSE INCENTIVE TO PLACE MORE EXPENSIVE DRUGS ON FORMULARIES

Question. In a Senate Finance Committee hearing had a few weeks ago, many pharmaceutical companies argued that the current rebate structure incentivizes high list prices. These companies argue that the higher the list price of the drug, the greater the rebates, and therefore, the more profit the PBM earns. While contracts between PBMs, Part D Plans, and pharmaceutical companies require PBMs to pass through 100 percent of the negotiated rebate back to insurance plans, I worry that this structure could incentivize PBMs to favor a more expensive drug on the formulary because they could get a higher rebate.

Is there an incentive for a PBM to place a higher cost drug on the Part D formulary because the PBM receives a larger rebate for that more expensive drug? Why or why not?

Answer. OptumRx promotes the use of clinically effective, low net-cost prescription drugs. For Part D consumers electing an OptumRx standard formulary, this work starts with an independent, clinically based formulary design process. OptumRx's P&T committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an evidence-based way. A drug's cost plays no role in the P&T committee's clinical review. Cost only becomes relevant after the P&T committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered.

If the P&T committee determines that more than one drug in a particular class is clinically effective, OptumRx will consider net cost—among other factors such as improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees—when negotiating formulary placement for that therapeutic category.

For about 90 percent of prescriptions processed, OptumRx can identify a generic drug in a particular therapeutic class and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug. If there is no generic product available, there may still be other therapeutically equivalent branded

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[10] Congressional Budget Office, "Incorporating the Effects of the Proposed Rule on Safe Harbors for Pharmaceutical Rebates in CBO's Budget Projections—Supplemental Material for Updated Budget Projections: 2019 to 2029" (May 2019), available at *https://www.cbo.gov/system/files/2019-05/55151-SupplementalMaterial.pdf;* Centers for Medicare and Medicaid Services, Office of the Actuary Analysis on Proposed Safe Harbor Regulation (August 30, 2018), available at *https://www.cms.gov/Research-Statistics-Data-and-Systems/Research/ActuarialStudies/Downloads/ProposedSafeHarborRegulationImpact.pdf*.

alternatives. If so, OptumRx negotiates with those competing brand manufacturers to obtain discounts, and generally places the drugs that drive the lowest overall net cost for the therapeutic category in a preferred position on the formulary.

OptumRx has been effective in driving utilization of clinically effective low-cost medications. OptumRx's negotiated network discounts and clinical tools are reducing annual drug costs, on average, by $1,600 per person for our customers. Even greater savings can be achieved by customers who implement evidence-based utilization management and other OptumRx clinical programs.

SIX PROTECTED CLASSES PROPOSAL AND ACCESS

Question. This past November, the Centers for Medicare and Medicaid Services released a proposed rule for 2020 to help tackle drug pricing. Among the proposed changes is one, which would alter the current rules, governing the "six protected classes." The concept of the protected classes has been around since the launch of the Medicare Part D Program, and it was instituted to ensure that some of our most vulnerable patients would have access to their needed drugs by requiring formularies to cover nearly all protected drugs. These classes are anticonvulsants, antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Some people have argued that these protected classes have led to higher drug prices because formularies are required to include this prescription coverage, and there are limited tools left to help lower prices. In an effort to increase competition, this proposed new rule would do a couple of different things. The first aspect of the administration's proposal would allow Part D sponsors to implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications. Any time there is a mention of plans using prior authorization or step therapy, there is an immediate concern of restricting patient access to needed drugs or medical services.

Could you explain why your company would favor such utilization management tools like step therapy or prior authorization?

Answer. All of our prior authorization and step therapy criteria are evidence-based and approved by our or the applicable customer's independent P&T committee process. Step therapies are used to aid in affordability by encouraging patients to choose clinically appropriate lower net cost alternative therapies when such therapies exist. Prior authorizations help ensure treatment is clinically appropriate and aligned with FDA labeling, and assist in minimizing potential safety concerns.

Question. Do you believe there is a danger that using step therapy or prior authorization could possibly restrict patients from having access to medication that has been successful for them? Why or why not?

Answer. All of our prior authorization and step therapy criteria are evidence-based and approved by our or the applicable customer's independent P&T committee process. The committee's assessment takes into account the risks associated with abrupt changes or switching of medications. Our formulary management program includes a formulary exception process and prior authorization process that allows a prescriber to request an alternate, appropriate medication when the medication identified as first line on the formulary is not appropriate for an individual patient. This process allows for a case-by-case review for individual patients.

Question. If you were to use step therapy or prior authorization for drugs in the six protected classes, how would you ensure patients would continue to have access to their needed medications in one of the six protected classes?

Answer. We would utilize our independent P&T committee to evaluate step therapy or prior authorization protocols in the six protected classes.

Question. The second aspect of the administration proposed change to the six protected classes is the proposal to allow drug coverage formularies to exclude a protected class drug from a Part D formulary if the drug represents a new formulation of a single-sourced drug, regardless of whether the older formulation remains on the market. My understanding is that this administration is trying to target pharmaceutical companies who participate in the anticompetitive practice of "evergreening." This is a practice where pharmaceutical companies make slight alterations to a drug's packaging, color, and formulation without an added or new benefit. However, we also understand that seemingly small changes to a drug can still make a big difference to patient well-being. We have heard from Maryland physicians that the creation of combination antiretroviral pills was a huge step forward in the fight

against HIV. Even though these combination pills or extended release versions didn't have a new chemical formula, they made a world of difference to the HIV patients taking over a dozen pills a day. These vulnerable patients are obviously very concerned that they could lose coverage for new and better drugs, especially when their old drugs may no longer be available. HIV treatments have come a long way in the last few decades, and proper antiretroviral treatment is vital to ensuring an end to the HIV epidemic.

Do you think the proposed rule anticipates a situation where a pharmaceutical company stops producing an older version of a drug when a new formulation is available, but the newer formulation is not covered by a Part D plan? Why or why not?

Answer. In situations where no therapeutically equivalent alternatives were available, the new formulation would likely be put on formulary through the OptumRx P&T process, which would require formulary options for treatment of a condition. As such, the proposed rule should not lead to a situation where patients did not have access to a unique treatment option on formulary.

Question. What would your company do to ensure that patients continue to have access to their medication in this situation?

Answer. OptumRx would recommend a formulary that met CMS requirements and provided for good and appropriate treatment of a condition as validated by OptumRx's independent P&T committee. In a situation where an older formulation was no longer available and no therapeutic alternatives exist, the new formulation will be placed on formulary.

APPEALS PROCESS IN GENERAL

Question. Prior authorization and step therapy are some of the most commonly mentioned concerns from patient groups coming to talk to my office, second only patients' concerns about out-of-pocket costs. What has become especially striking in the past few weeks is the number of physicians explaining how they feel stymied by prior authorization restrictions by insurance plans. We have heard from one surgeon who argued for weeks with the insure to appeal a decision that had been made to deny a newer type of less-invasive surgery. Someone who was not a surgical expert made the denial. Eventually, his patient made the decision to stop waiting and opted for a far more invasive and dangerous procedure because it was covered by insurance. Other doctors talk about the hours they spend on the phone waiting to appeal a decision, only to be told they need to write an extensive report justifying their medical decision. While the physicians are waiting for a response, quite often there are patients suffering without their proper medications, without certain tests, or not getting the surgery that the expert recommends.

With technology changing so rapidly, how do your companies ensure that you keep up with the medical and surgical experts and new research, so that your authorization decisions are in line with the most recent medical innovations and physician standards?

Answer. All criteria used to make therapy authorization decisions are reviewed by the independent physicians and pharmacists who comprise OptumRx's or the applicable customer's independent P&T committee. These professionals evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an unbiased and evidence-based way. The P&T committee conducts an annual review to ensure that its evaluation criteria are in line with the most recent medical innovations and clinical standards. The annual review process also engages additional independent external physician specialists to provide additional clinical insights and recommendations for the P&T committee to consider when making clinical determinations.

DIRECT AND INDIRECT REMUNERATION FEES

Question. I have heard from independent pharmacies in Maryland that have struggled with Pharmacy Benefit Managers and direct and indirect remuneration (DIR) fees. According to independent pharmacies, there are times when DIR fees are based on performance, and these fees range from $2–$7 for certain types of maintenance prescriptions and are often collected retroactively—weeks or even months after a prescription was filled. A PBM can take money back from the pharmacy when the pharmacies haven not met a PBM's performance standard. In these instances, the PBM claws back money and creates a situation where the pharmacy does not receive adequate reimbursement to cover its costs. As a result, DIR fees

can be a significant financial loss to pharmacies and an additional cost burden to patients.

Could you explain what performance measures are considered when determining a DIR fee?

Answer. Our Medicare Part D health plan customers identify DIR strategies to improve clinical outcomes and affordability. We have the administrative flexibility to implement the strategies our customers identify. Performance measures generally include quality metrics designed to improve outcomes in disease States, including diabetes, hypertension, and cholesterol, which align with measures used by CMS to evaluate Part D plan performance under the CMS STAR ratings program.

Question. How is that performance measure communicated to the pharmacy?

Answer. Performance measures are communicated in writing as part of the Pharmacy Network Agreement between OptumRx and participating pharmacies, either directly or through their contracting entity such as a Pharmacy Services Administrative Organization (PSAO). In addition, OptumRx provides quarterly and year-end reporting about performance to improve quality to participating pharmacies.

Question. How much does your company receive in DIR fees?

Answer. With respect to OptumRx's performance-based pharmacy network, OptumRx does not retain any of the contingent performance amounts withheld from payments to pharmacies. All such contingent performance amounts are either paid to the high performing pharmacies, or are used by the Part D customers to reduce the drug cost for pharmacies that do not meet the specified quality metrics.

Question. How much does your company receive in performance-related DIR fees?

Answer. See response above.

Question. Are those fees passed on to the consumer? If so, how?

Answer. OptumRx's performance networks focus on activities that benefit consumers (such as increased adherence) and the health system as a whole by improving health outcomes and lowering health-care costs. Our Part D plan customers determine how to best use DIR amounts to lower overall costs and improve health outcomes.

DRUG SHORTAGES

Question. Currently there are over 270 drugs in shortage. Drug shortages happen for many reasons such as manufacturing and quality problems, natural disasters, and inventory practices of wholesalers and pharmacies. Drug shortages cause harm to providers, hospitals, and most importantly patients. Pharmacists and providers must spend significant amounts of time on researching alternative drug treatments for the patient, which may not always be the most optimal therapies.

As a pharmacy benefit manager, you have contractual agreements with pharmaceutical companies in order to place their drugs on a plan's formulary. While I understand that drug shortages happening in both the inpatient and outpatient settings, there may be a role PBMs can play in protecting patients.

For the prescription drugs you negotiate to cover on a plan formulary, could you use your negotiating power to ensure a drug is available to a patient? Why or Why not?

Answer. Drug shortages are often related to manufacturing and quality problems, natural disasters, and inventory practices of wholesalers and pharmacies. In these situations, drug availability is outside of OptumRx's control.

Question. What do you do to ensure that patients have the drugs they need?

Answer. OptumRx works closely with various suppliers to ensure that they have the supply needed to meet patient demand for prescriptions dispensed by affiliated pharmacies. Additionally, when drug shortages take place, OptumRx evaluates the medications and, if necessary, identifies clinically appropriate alternatives and communicates with consumers about the availability of those alternatives. This may take the form of suppressing utilization management criteria, such as step therapy or prior authorization, and/or moving alternative drugs to a more favorable tier until the shortage is resolved.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

BIOSIMILARS

Question. During the hearing, each of you expressed support for biosimilars and most of you indicated you try and take advantage of available biosimilars to help lower costs. When I asked each of you to identify solutions to help ensure a robust biosimilar marketplace here in the U.S., most of you mentioned things Congress or the administration could do to help ensure uptake of biosimilars—from lowering the exclusivity period for biologics to finalizing guidance on interchangability at the FDA. However, none of you offered any solutions or ideas for what your company could do to help ensure timely uptake of biosimilars, a robust U.S. biosimilars market, and a resulting cost savings to patients to taxpayers.

Most of the biosimilars currently approved and on the market in the U.S. are reimbursed through the medical benefit. What are the similarities and differences in how rebates are passed onto patients and providers in the medical benefit versus pharmacy benefit. In your answer, please describe these similarities and differences across each of your books of business (*i.e.,* commercial, Medicare, Medicaid).

Do any of your plans require the use of a higher list price, branded product over the use of a therapeutically equivalent lower list price generic or biosimilar product? Why? If a plan restricts the use of a biosimilar or generic product in lieu of an innovator or brand name product, do patients pay more out-of- pocket than they would if the biosimilar was preferred?

Recognizing most biosimilars are paid for via medical benefit, please explain whether you use step-therapy to restrict access to biosimilars for your patients in any medical benefit you manage across each of your books of business (*i.e.,* commercial, Medicare, Medicaid). What role do rebates playing in your consideration for patient access to biosimilars in each of these instances?

How can and will your company help ensure a robust biosimilars market here in the U.S.?

I have heard concerns that "rebate walls" are responsible for keeping new biosimilars off of formularies, where a manufacturer offers conditional rebates on a bundle of their products in order to incentive PBMs to exclude a new biosimilar competitor from their formularies. Have you ever decided to place a drug on a preferred tier because of the rebates you receive for other drugs from that manufacturer? If you do not do this, do you support this practice being carried out by your competitors?

What more can and will you do to counteract efforts to rebate-block or bundle rebates to block biosimilar formulary placement? Will you commit to taking these actions as more biosimilars become available in Part D?

Answer. OptumRx promotes the use of clinically effective, low net-cost prescription drugs for consumers when medications are needed. This work starts with an independent, clinically based formulary design process. OptumRx's customers may adopt OptumRx's standard formulary or choose instead to utilize their own custom formularies.

OptumRx's P&T committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence, and review and appraise those drugs in an evidence-based way. A drug's cost plays no role in the P&T committee's clinical review. Cost only becomes relevant after the P&T committee has identified drugs in a particular therapeutic class that are clinically equivalent and should be covered.

If the P&T committee determines that more than one drug in a particular class is clinically effective, OptumRx will consider net cost—among other factors such as improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees—when negotiating formulary placement for that therapeutic category.

For about 90 percent of prescriptions processed, OptumRx can identify a generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug.

OptumRx has been effective in driving utilization of clinically effective low-cost medications. OptumRx's negotiated network discounts and clinical tools are reducing annual drug costs, on average, by $1,600 per person for our customers. Even

greater savings can be achieved by customers who implement evidence-based utilization management and other OptumRx clinical programs.

Increasing the number of generic and biosimilars alternatives to branded drugs is key to increasing competition and lowering drug prices. OptumRx urges action to increase the availability of biosimilars and promote true competition. Specifically, Congress should modernize the intellectual property system for the 21st century and eliminate drug manufacturers' ability to manipulate the patent and regulatory system and thereby prevent lower-cost generics and biosimilars from reaching consumers more quickly. OptumRx applauds the FDA's recent release of interchangeability guidance to promote substitution of these products over expensive branded specialty products. The FDA should adopt reforms to release biosimilars to the market more quickly and to promote adoption by prescribers and consumers. As has been successfully done in many therapeutic categories outside of the U.S., these two measures have been proven to increase competition in the market and lead to lower drug prices provided that biosimilars are available and priced competitively, similar to generic drugs. There are 51 approved biosimilars in Europe. To date, however, in the U.S. the FDA has only approved 19 biosimilars, and of those only seven have launched to market.

Not all biosimilars are less expensive products, but OptumRx promotes the inclusion of those biosimilars that are less expensive and drive lower net costs on its standard formularies, which can be adopted by our customers. On our Premium formulary effective July 1, 2019, for example, we prefer the Infliximab biosimilars Renflexis and Inflectra, and exclude Remicade; we also prefer the biosimilar Zarzio, a biosimilar that treats blood disorders, and exclude Amgen's biologic Neupogen.

REBATES VS. FEES

Question. During the hearing, Senator Cassidy asked each of you about the trend in PBM contracting where a larger share of your reimbursement and payment is a result of "fees" which you are able to pocket, as opposed to "rebates" which must be passed back to the plan/consumer.

Please define the word "rebate." As part of your definition, please clarify whether or not you consider administrative fees, inflation payments, product discounts, prospective rebates, care management fees, procurement fees or any other type of fee or payment that isn't a retrospective rebate to be a rebate.

Answer. The definition of "rebate" is negotiated and documented in each customer agreement. Such negotiated definitions typically either expressly include or exclude manufacturer administrative fees or price protection guarantee amounts (*i.e.,* inflation payments) paid by drug manufacturers. They generally expressly exclude (i) any purchase discounts or concessions related to the purchase of pharmaceutical products to be dispensed by our pharmacies and (ii) fees paid by drug manufacturers for services or other products we provide directly to those drug manufacturers.

Question. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), a list of each of the different types of rebates, charges, and/or fees that you incorporate into your contracts.

Answer. The following discounts, fees, or other payments are contemplated by the rebate agreements we have negotiated with drug manufacturers on behalf of our payer customers: rebates or discounts; price protection guarantee or inflation payments; and manufacturer administrative fees.

No manufacturer administrative fees are billed or collected on Medicare Part D, Medicaid Managed Care, CHIP, and QRPDP utilization.

Additionally, certain rebate agreements contemplate the drug manufacturer reimbursing OptumRx for expenses incurred in notifying health care providers and impacted consumers in the event of a manufacturer drug recall (*e.g.,* printing or postage costs) and payment of interest penalties for late rebate payments.

Question. Rebates, by definition, must be passed along to the employer, health plan, or consumer. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), details on which of the rebates/fees detailed in my prior question are passed along to the consumer and/or plan and which are kept by the PBM.

Answer. For all customers, the definition of "rebates," and any rights we have to retain a portion of such rebates collected on behalf of our customers as compensation for our services to such customer, is negotiated and documented in each customer agreement. In some but not all of our agreements, customers may require

that the value of any administrative fees paid by drug manufacturers to the PBMs for services provided by the PBM to the drug manufacturers be passed through, just like rebates, to the customer and/or directly to the member through point-of-sale discounts. Based on our agreements with our customers, our customers have chosen to receive approximately 98 percent of the value of the discounts we negotiate from drug manufacturers. The balance is used to compensate OptumRx for its services.

FIDUCIARY DUTY

Question. Each of you have argued that you are the one entity in the drug supply chain that exists to help lower the cost of prescription drugs. You claim that your value comes in saving taxpayers, plans, and consumers money.

Would you be willing to accept a fiduciary standard in your contracts? In other words, do you believe you have a fiduciary duty to the plan or employer you contract with—to act in their best interest and not your own? If not, why not?

Answer. OptumRx operates in a highly competitive industry where we must continually innovate, reduce the total cost of care, and improve clinical care to win new business and retain existing customers. We serve highly sophisticated customers that hold us accountable for delivering results and the lowest net cost.

PAYING PHARMACISTS

Question. Following a series of reports in *The Columbus Dispatch,* Ohio has taken a number of actions over the past year to crack down on several PBM practices. Efforts to date have included investigations, lawsuits, and policy changes to address the egregious use of spread-pricing, alleged breaches of contract, accusations of anticompetitive behavior, a misuse of taxpayer dollars, and a general lack of transparency.

PBMs are responsible for creating pharmacy networks, setting the price patients and health plans pay for prescription drugs, adjudicating claims, and reimbursing pharmacies for dispensed drugs. In addition, nearly all PBMs own proprietary pharmacies that directly compete with the PBM-created retail network. Do you design plans that incentivize or require patients to use a pharmacy owned by your affiliate over a competing retail pharmacy. If yes, do you believe this represents a conflict of interest? If yes, how do you ensure there is no resulting anticompetitive misuse of pharmacy and patient data?

Answer. OptumRx does not believe its ownership of affiliated pharmacies creates a conflict of interest. Preferred network pharmacy options deliver greater drug cost savings and value to plans and their members through our pharmacy care services model that is integrated with pharmacies that we operate. OptumRx discloses its ownership of pharmacies to customers, and customers ultimately choose the pharmacy network plan design that best meets their needs.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Can you answer the following questions to help us understand the pharmacy benefit manager business model and how you make formulary decisions?

What percent of rebates are passed to the consumer under Medicare Part D?

Answer. OptumRx shares with its customers approximately 98 percent of the discounts it obtains from manufacturers based on the agreements we have negotiated with our customers. We pass through an even greater percentage of the discounts we negotiate with manufacturers to our Medicare Part D plan customers. Part D plans in turn use those discounts to help reduce premiums for consumers.

Question. What percent of rebates are passed to the consumer in the private insurance market?

Answer. We have heeded the call for change by taking direct action to ensure that the discounts we obtain directly lower consumers' out-of-pocket costs at the pharmacy counter. Last year, we implemented a point-of-sale discount solution at scale for fully insured group customers so that consumers receive the benefit of discounts at the pharmacy counter. This action has already made nearly 6 million consumers eligible for point-of-sale discounts. Eligible consumers filling prescriptions on discounted brand drugs are seeing average savings of $130 per eligible prescription. We believe it can also improve prescription drug adherence by as much as 16 percent. By the end of 2019 we expect more than nine million consumers will be eligible

for these point-of-sale discounts. In March of this year, we announced a decision to expand this point-of-sale discount solution to all new employer-sponsored plans beginning in January 2020. This action means real out-of-pocket savings for consumers at the pharmacy counter who take brand drugs with discounts.

Question. Do you have any comments on how health plans should use their share of the rebates to lower drug prices for patients with high deductibles?

Answer. We encourage our customers to make negotiated prescription drug discounts available at the point-of-sale, and indeed beginning January 1, 2020, we will not write new employer-based coverage that does not provide for point-of-sale discounts.

Question. What is the process of deciding on which tier a generic will be placed in your formularies?

Answer. OptumRx manages pharmacy benefits on behalf of our customers, including self-insured employer groups, fully insured health plans, union funds, Medicare, Medicaid, and Federal and State government employee plans. In that role, we promote use of clinically effective, low net-cost prescription drugs for consumers when medications are needed.

This work starts with an independent, clinically based formulary design process. OptumRx's Pharmacy and Therapeutics (P&T) committee is comprised of independent physicians and pharmacists who evaluate existing and emerging drugs based on scientific evidence and review and appraise those drugs in an unbiased and evidence-based way. The P&T committee meets regularly, and its deliberations are open and transparent to OptumRx's customers and prospective customers.

A drug's cost plays no role in the P&T committee's clinical review. Cost only becomes relevant after the P&T committee has identified drugs in a particular therapeutic class that are clinically effective and should be covered. If the P&T committee determines that more than one drug in a particular class is clinically effective, OptumRx will consider net cost—among other factors such as improving adherence, product availability, market share, potential disruption to patients, and negotiated price protection guarantees—when negotiating formulary placement for that therapeutic category.

For approximately 90 percent of prescriptions processed, OptumRx can identify a generic drug in a particular therapeutic class, and give that drug preferred placement on its formulary over the more expensive branded (or "on-patent") drug. If there is no generic product available, there may still be other therapeutically equivalent branded alternatives. If so, OptumRx negotiates with those competing brand manufacturers to obtain discounts, and generally places the drugs that drive the lowest overall net cost for the therapeutic category in a preferred position on the formulary.

OptumRx has been effective in driving utilization of clinically effective low-cost medications. OptumRx's negotiated network discounts and clinical tools are reducing annual drug costs, on average, by $1,600 per person for our customers. Even greater savings can be achieved by customers who implement evidence-based utilization management and other OptumRx clinical programs.

OptumRx also ensures that these cost-savings go to our customers. Our customers receive approximately 98 percent of the value of the discounts we negotiate from drug manufacturers. The application of discounts is subject to audit and verification by an independent third-party on behalf of any of our customers. In those limited instances in which we retain some of the discount, it is because our customers have chosen to pay us that way. Additionally, we have led the industry in promoting point-of-sale discounts for consumers.

Question. Are generics always tiered as preferred (versus branded drugs)?

Answer. For approximately 90 percent of prescriptions processed, OptumRx can identify a low-cost generic drug in a particular therapeutic class and give that drug preferred placement on its formulary over a more expensive branded (or "on-patent") drug. There are a small number of instances in which OptumRx may achieve a lower net cost for its customers and consumers by preferring a branded drug over its generic alternative. When that occurs, OptumRx works to ensure that these cost-savings go to our customers. Our customers receive approximately 98 percent of the value of the discounts we negotiate from drug manufacturers.

Question. How quickly are generics placed on formularies once FDA clears them?

Answer. Generics are generally added to our standard formularies shortly after launch. Generics do not get reviewed by OptumRx's P&T committee since the FDA's approval signifies that it has determined that the generic has the same active ingredients as the brand and is determined to be a bioequivalent of the brand. There are a small number of instances in which OptumRx may achieve a lower net cost for its customers and consumers by preferring a branded drug over its generic alternative. When that occurs, OptumRx works to ensures that these cost-savings go to our customers. Our customers receive approximately 98 percent of the value of the discounts we negotiate from drug manufacturers.

Question. Given the struggles we hear about patients accessing insulin, what measures are you taking to ensure that diabetes products and different types of insulin are placed on a preferred tier when establishing a formulary?

Answer. In large part because OptumRx has insulin on its High Deductible Health Plan (HDHP) preventive drug list, and encourages its customers to do the same, we have helped our customers keep Out-of-Pocket (OOP) costs low for insulin products. Indeed, 76 percent of our customers' enrollees who need insulin pay nothing at the pharmacy counter, or pay only a fixed copay. Due to policy terms, including the fact that insulin is on OptumRx's HDHP preventive drug list, the average OOP cost for a 30-day supply of insulin is approximately $41 per month for our commercial plan and Medicare enrollees, which is less than eight percent of the average list price for major insulin products.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

TRANSPARENCY, REBATES, AND SPREAD PRICING

Question. During the hearing, I asked an initial question on spread pricing and wanted to follow up here. According to the Centers for Medicare and Medicaid Services (CMS), total gross spending in 2017 on prescription drugs was $154.9 billion in Medicare Part D, $30.4 billion in Part B, and $67.6 billion in Medicaid.

One of the main challenges in lowering the price of prescription drugs is that there is a disturbing lack of transparency all along the supply chain, from research and development to what the patient is expected to pay at the counter. Further, the out-of-pocket costs for drugs varies greatly and unpredictably from patient to patient. That is why Senate Special Committee on Aging Chairwoman Collins and I introduced legislation that would codify the Drug Spending Dashboards at the CMS. The dashboards provide cost and spending information for drugs in the Medicaid, Medicare Part B, and Medicare Part D programs. With regards to transparency in the prescription drug supply chain, please provide answers to the following questions.

Is it the policy and practice of your company to negotiate with drug manufacturers in good faith and obtain the best and lowest prices possible for patients and American taxpayers?

Answer. Yes. We would not win new business or retain current customers if we did not negotiate the best possible prices. PBMs are the only entity in the supply chain working to drive down costs for patients and American taxpayers.

Question. Is it the policy and practice of your company that patients, providers, researchers, policymakers, and the American people in general, know how taxpayer dollars are being spent in the Medicare and Medicaid programs?

Answer. Yes.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by manufacturer list price; rebate paid by the manufacturer to you (the PBM); the amount reimbursed to pharmacies by the PBM; and the amount insured and uninsured patients pay out of pocket, before coupons, discounts, and other forms of patient assistance offered at the point of sale?

If so, please provide useful and easily accessible links to where policymakers and the public can find such information. If not, please disclose how much each drug you work with clients to provide costs, broken down by manufacturer list price; rebate paid by the manufacturer to you (the PBM); the amount reimbursed to pharmacies by the PBM; and the amount insured and uninsured patients pay out of pocket, before coupons, discounts, and other forms of patient assistance offered at the point of sale

Answer. OptumRx makes pricing and discount information available to customers, and reimbursement and out-of-pocket information available to pharmacies, subject to appropriate confidentiality provisions. At the consumer level, OptumRx provides solutions to help consumers make better decisions, including our MyScript Finder solution, which provides members with easy to understand price and benefit transparency. OptumRx shares approximately 98 percent of all discounts it negotiates with its customers in accordance with the applicable agreements. Pharmacy reimbursement figures vary widely based upon the drugs at issue and applicable pharmacy network provisions. Dollars paid via patient assistance programs such as discount cards and coupons are often not known to OptumRx.

Question. Please provide a list of actions your company has taken to ensure that pharmacists are enabled and allowed to communicate to patients how they can pay the lowest out-of-pocket cost possible for their prescription drugs.

Answer. OptumRx does not have gag clauses in pharmacy contracts that prevent a pharmacist from communicating with patients how they can pay the lowest out-of-pocket cost possible for their prescription drugs. Our pharmacy contracts require pharmacies to accurately submit their usual and customary cash prices to OptumRx. We use this information when the claim is processed to help ensure the beneficiary is paying the lowest cost at the pharmacy. OptumRx complies with the "Patient Right to Know Drug Prices Act" and the "Know the Lowest Price Act of 2018."

PREPARED STATEMENT OF DERICA RICE, EXECUTIVE VICE PRESIDENT, CVS HEALTH; AND PRESIDENT, CVS CAREMARK

Chairman Grassley, Ranking Member Wyden, and members of the committee, thank you for the opportunity to join you today.

My name is Derica Rice, and I am an executive vice president at CVS Health and president of CVS Caremark. I joined CVS Health because I believe in the company's vision of helping patients on their path to better health. We want to make health care more accessible, more affordable and improve health outcomes for the communities we serve.

We have long been at the forefront of putting our patients' health first and improving the public health of our communities, through company-wide initiatives such as removing tobacco from our stores and waging a multi-front fight against the opioid epidemic. We provide millions of dollars in charitable support to free clinics and community health centers—the organizations reaching our Nation's most vulnerable populations with the care that they need. And it is why, at CVS Health, we decided to stop selling tobacco products more than 4 years ago—even at the cost of $2 billion in annual sales revenue.

And our purpose—helping people on their path to better health—is what drives us to provide more affordable, accessible, and effective health care, and to deliver better health outcomes, at a lower cost. Never has our work been more important than today. The rising cost of health care and prescription drugs affects every household in this Nation and are critical issues for consumers and policy makers. Our job is to work with the employers, unions, and government programs we serve to ensure that when their members get to the pharmacy counter, they get medicines they need at the lowest possible cost. As drug prices increase and consumers shoulder more of the burden, we believe we can, and we must, do more to ensure affordable care.

In the spirit of our common goal of reducing health-care costs for consumers and the overall system, I'm here today to share what we, as CVS Caremark, are doing to directly reduce consumers' out-of-pocket costs at the pharmacy counter, and to discuss polices that would help further advance that agenda. Our goal as a pharmacy benefit manager (PBM) is simple: to reduce costs and improve health outcomes. We do this by negotiating discounts with manufacturers, designing formularies that encourage the use of generics and biosimilars, and creating new tools to help bring escalating drug prices under control.

Our work on behalf of our clients to deliver the lowest cost medicines and the best possible outcomes helps them maintain a healthy workforce at an affordable price. Over the last 3 years (2016–2018), we have saved our clients $141 billion in drug costs. At the same time, in 2018 alone, 44 percent of our clients saw their net prescription drug prices decline and 85 percent of our members utilizing their prescription benefit spent less than $300 on their prescriptions.

Despite this, we recognize that consumers are often faced with challenging out-of-pocket costs, so we at CVS Health continue to develop solutions to help lower how much they spend on prescription drugs. Manufacturers alone set the price of their medications. What we do is create value for the employers, health plans and government programs we serve in four key ways:

First, we negotiate the lowest cost possible on behalf of our clients and foster competition among drug manufacturers when more than one clinically equivalent drug is available.

Second, we encourage the use of generics and lower-cost biosimilars because they are proven to improve adherence and outcomes, while also lowering costs. Our research shows that use of generics actually improves outcomes and saves lives, largely because they are more affordable for patients and therefore increase patient adherence to their medicines.

Third, we help reduce drug costs by providing physicians with information that enables them to prescribe the most cost-effective and clinically appropriate medications for their patients. That means prescribers can see the actual cost of the drug to the member and up to five potentially lower-cost options, and make informed decisions that can help save their patients money. We have also made dramatic strides in reducing the administrative burden for providers and patients by broadening availability of electronic tools to help with prescription management like mobile and online prescription scheduling and reminders on refills.

Fourth, we have developed additional tools to help bring escalating drug prices under control. We recently announced our Guaranteed Net Cost pricing model, a new pricing option that provides our clients with a guaranteed price for retail, mail and specialty drug products, regardless of product or price inflation. This heightens our focus on the lowest actual cost of the drug and under this model 100 percent of the rebates are passed through.

Rebates are not secret or hidden payments to PBMs—our clients have full visibility into the amount of the rebates we secure. Over ninety-eight percent of these discounts are passed directly to plan sponsors, who typically use them to reduce premiums and other costs for their members.

Pharmaceutical manufacturers insist that drug price increases are driven by rebates. This is simply not true. If that was the case, rebates and list prices should be highly correlated. To the contrary, data show that in many cases list prices are increasing faster for drugs with smaller rebates than for medications with substantial rebates.

We believe strongly that our PBM tools bring tremendous savings and value to the clients we serve. We focus every day on delivering the value our clients expect and easing the burden of high drug prices for their members. To help consumers manage their out-of-pocket costs, we were among the first to introduce rebates at the point-of-sale in the commercial market, enabling our clients to pass along the value of negotiated rebates on branded drugs to their members at the pharmacy counter. Currently, almost 10 million of our clients' members are in plans offering these savings.

Two years ago, the administration raised the idea of point-of-sale rebates in the Medicare Part D program. Given our goal of keeping out-of-pocket costs lower for American seniors, we were the first Medicare Part D plan to offer point-of-sale rebates through our SilverScript Allure plan—which leaves the choice to individual beneficiaries as to what plan best serves their needs.

We have encouraged clients, particularly those who offer a high-deductible health plan, to offer benefit plans similar to what we at CVS Health provide our own employees. Our covered employees have point-of-sale rebates while they are in the deductible phase, in addition to zero-dollar copays for medications that prevent disease. This includes not only generic medications that may prevent the onset of chronic conditions but also some key brand drugs like insulin. We believe point-of-sale rebates combined with a zero-dollar copay preventive drug list are effective in reducing high out-of-pocket costs for members in high deductible health plans and help increase adherence which improves health outcomes and keeps costs down. At the end of the day, however, we believe in the value of providing choices. A one-size-fits-all approach that limits choice would not be appropriate for every health plan and their beneficiaries.

For patients in high-deductible plans with a health savings account, using a preventive drug list to make medications for common chronic conditions available at

a zero-dollar copay can lead to better adherence and significant cost savings. As I mentioned, we take this approach with our own employees. CVS Health fully pays for certain drugs, including a number of generic medications, for its covered employees and dependents under the preventive drug list even before they meet their deductible. This has improved our generic dispensing rate, reducing costs for both our employees and CVS Health.

As a health-care company, we place a high priority on preventive care, and medication adherence is a key component of achieving better health outcomes for patients. Our metrics for preventive drug regimens for conditions such as hypertension, hyperlipidemia, heart failure, diabetes, asthma/COPD and depression show that health-care costs for patients with these conditions are reduced when they take their medications as prescribed. For example, for patients with congestive heart failure, CVS Health found that they spend nearly $8,000 less per year by adhering to their medication.

We continue to develop additional innovations to help bring escalating drug prices and costs under control, especially for chronic conditions.

CVS Health has taken a condition-specific approach through our Transform Care programs to help manage chronic conditions effectively, preventing wherever possible more serious adverse events, and improving clinical outcomes, reducing hospitalizations, emergency care and overall costs. We also have announced an initiative to improve chronic kidney disease and dialysis. Not only are we creating new tools to better identify and manage kidney disease, we are also working to provide more home dialysis, which studies have shown leads to increased satisfaction and better outcomes in appropriate patients.

And most recently, we opened our new HealthHUB locations to help elevate the store into a convenient neighborhood health care destination that brings easier access to better care at a lower cost. With personalized support programs and MinuteClinic services, the HealthHUB teams are focused on improving care for patients managing chronic conditions, with a focus on recommending next best clinical actions and driving medical cost savings. This concept combines the best of today's CVS Pharmacy with the future of accessible, low-cost health services and offers trusted advice.

In addition to developing these unique and innovative delivery system reforms, we have launched patient-centered programs to help consumers save money and increase price transparency across multiple points of care, thus giving our members far greater access to more affordable drugs.

As we've interacted with consumers, they have told us that they want to know whether their drug is covered and what their out-of-pocket costs are going to be. So, we now provide member-specific information in the doctor's office, at the pharmacy counter and directly to consumers on their phones and online. We call this real-time benefits. That means prescribers can see the actual cost of the drug to the member based on their current coverage, and up to five potentially lower-cost options, enabling them to make informed decisions and help patients save money while improving their care.

Real-time prescription benefits information is integrated directly into the pharmacist's existing workflow, making it easy for them to engage CVS Caremark members about potentially lower-cost alternatives, based on the member's specific formulary coverage. Additionally, our approximately 30,000 CVS pharmacists can use our proprietary search tool, Rx Savings Finder, to quickly identify available savings opportunities for customers.

And customers can use our app and online tool, which lets members check and compare prescription drug prices on their computer, phone or other devices. In addition to being able to request refills and view their prescription history, members are able to use the app to see what their out-of-pocket costs for a specific medication will be and find lower-cost alternatives to talk about with their doctor or pharmacist. More than 230,000 searches per month are conducted in this tool.

But as much as we have been able to accomplish, we also understand that more must be done. Because of the rise of high deductible health plans without adequate coverage for preventive drugs, consumers sometimes do not see the benefit of the discounts PBMs negotiate from manufacturers at the pharmacy counter, especially in their deductible phase if they are enrolled in a plan without point-of-sale rebates.

As many of you noted in the last hearing, often there is limited to no competition on drugs because of the myriad manipulative practices in our patent system that

prevent competition from coming to market and restrict the FDA from advancing policies that can speed adoption of biosimilars and generics. We support the FDA's focus on bringing more lower-cost alternatives to market faster. We also support many of the policies proposed by members of this committee, including the chairman and Ranking Member Wyden, that would bring more competition to the market, create more transparency, and limit out-of-pocket expenses for seniors.

We have identified specific policy solutions that could lower drug costs as Congress and the administration consider the range of solutions and next steps.

First, we believe Medicare and Medicaid programs should be able to utilize the full breadth of tools that are used in the private marketplace, including for the plans that cover members of Congress and Federal employees.

We also believe Congress should require the adoption of real-time benefits to give doctors and patients transparency and information on lower-cost options when the prescription is written.

We support transparency proposals, such as the one recently introduced by a bipartisan group of Senators on this committee to make the amount of rebates collected and passed through that is now shared with CMS available to MedPAC and MACPAC as well.

We think Medicare should also encourage Part D providers to include a point-of-sale rebate option in their plan bids. Point-of-sale rebate plans do not make sense for everyone, which is why we oppose mandating it for all plans. But it should be an available option for the seniors who are facing higher drug costs, so they have the opportunity to choose a point-of-sale rebate plan if it works for them.

We believe Congress should enact an out-of-pocket spending cap for Medicare beneficiaries and change the reinsurance component of Medicare Part D in keeping with what MedPAC has recommended.

Changing the rules governing health savings accounts, or HSAs, by giving plans the ability to offer more coverage prior to the deductible being met would make a big difference for consumers. Currently, plans paired with HSAs are unable to offer first-dollar coverage of services such as chronic condition management. Medications may only be covered prior to the deductible being met if they are preventive, and the government has taken a very limited position on what is considered preventive.

We support policies, including legislation led by members of this committee, to allow first-dollar coverage of all preventive medications, as well as treatment for chronic disease. This one change could immediately lower out-of-pocket costs for millions of Americans, while saving the health care system billions of dollars by improving medication adherence and preventing future costs.

We support increased access to generics and biosimilars. Biosimilars have the potential to save the health system $54 billion over 10 years, but we need more of them on the market. In the European Union, 53 biosimilars have been approved, while only 17 have been approved in the United States and most of them are not on the market. We encourage the administration to finalize interchangeability guidance to improve competition in the biologic market.

Additionally, we support efforts to address anti-competitive behavior. CVS Health is a longstanding supporter of the CREATES Act, and we thank Chairman Grassley for his leadership on this issue. The CREATES Act would address cases where brand manufacturers abuse safety protocols to keep generic and biosimilar competitors off the market.

We also support ending "pay-for-delay," a tactic that allows brand manufacturers to pay generic competitors to keep products off the market and extend market exclusivity.

As you know, the Office of Inspector General at HHS recently proposed a rule that would require any discount we negotiate for Medicare Part D plans and Medicaid Managed Care Organizations to be applied at the pharmacy counter, in effect, providing 100-percent point-of-sale rebates. We fully support the administration's objectives to lower drug prices and out-of-pocket costs for consumers. However, we found that under the proposed rule, if finalized, approximately 15 percent of beneficiaries would benefit, approximately another 15 percent may benefit, and approximately 70 percent of beneficiaries would have higher costs in increased premiums—increases that would be higher than any savings they see at the pharmacy counter.

At a time when consumers want more choices, this rule mandates 100-percent point-of-sale rebates as the only option. It might be right for some patients, but it will raise health-care costs across the board while only benefiting a small minority of patients. The question for policymakers is whether the positives of such a system outweigh the negatives. From our perspective, they do not.

Today, we pass along effectively 100 percent of the rebates to Medicare Part D plans, which use them, in general, to lower plan premiums, reducing costs for both beneficiaries and the government. This is a tremendously successful program in not only providing a needed benefit to seniors but keeping premium costs to beneficiaries stable. The CMS actuaries indicate that the proposed rule would upend this stability by increasing premiums by 19 percent initially and by 25 percent after the impacts have been fully incorporated into the plans' costs. If these changes are implemented some seniors will either decide to drop current Part D coverage or sign up for coverage only when they are faced with high costs, thereby incurring a penalty.

If rebates are forced at point-of-sale only, it could also undercut the negotiating power of PBMs to advocate for lower prices from the drug manufacturers by making competitively sensitive discount information widely available, therefore reducing manufacturer willingness to provide deep, differentiated discounts. This will likely lead to higher net drug prices.

Unfortunately, nothing in this proposal would require drug manufacturers to lower drug prices by the rebate amounts that exist today. In fact, the proposed rule provides drug manufacturers with two windfalls. The CMS actuaries' analysis estimates that manufacturers will keep 15 percent of the rebates they currently pass along as higher net drug prices, and second, that manufacturers will pay as much as $39.8 billion less over 10 years in lower discount payments in the coverage gap of Part D.

While we oppose the proposed rule, CVS Health is proactively working with pharmaceutical manufacturers to ensure that the potential effects of this rule would not have a negative financial impact on Part D plans and beneficiaries. In March 2019, we sent a letter to leading drug companies asking them not to increase their net prices for prescription drugs as a result of the rule, which could cause increases in premiums and out-of-pockets costs for Part D beneficiaries.

We appreciate this committee's attention and work on the challenging issue of drug pricing. And, Mr. Chairman, aligned with your leadership, we continue to advocate for policies that foster competition, lower consumer costs and restrain anticompetitive behavior. We look forward to continuing to work with you and every member of this committee.

Thank you again for the opportunity to testify, and I am happy to answer any questions.

QUESTIONS SUBMITTED FOR THE RECORD TO DERICA RICE

QUESTIONS SUBMITTED BY HON. CHUCK GRASSLEY

COLLECTION, USE, AND SHARING OF PERSONAL HEALTH INFORMATION

Question. Consumers are becoming more and more concerned about the data collection and sharing practices of companies. While these issues have been most prevalent in the social media and tech industry, companies in the pharmaceutical supply chain also have access to tremendous amounts of sensitive, personal health information of the individuals they serve. For example, the company Livongo partners with CVS Caremark to provide low-cost or no-cost blood sugar meters to diabetic patients. The meters are always "connected" to Livongo's "Diabetes Response Specialists." As the company's website states, "When readings are out of range, our Diabetes Response Specialists call or text [the individual] within minutes." While these innovations may be highly beneficial for individuals in managing their health, it's also important for this committee to fully understand what types of information is collected, how or why it's stored or shared, and for what purposes PBMs themselves and other affiliated drug supply chain participants (such as insurers) use the information.

Health information is extremely sensitive. It's the most personal of all the information we share. So I want to know more about each of your companies' data collection, sharing, and protection practices.

Does your company collect and store health information from the end-users of the prescriptions you provide? For example, information or records of a diabetic individual's blood sugar levels.

Answer. We do collect limited data on members' drug utilization and outcomes in order to help our members manage their health. This can include adherence data and other forms of patient tracking to ensure that prescribed medicines are having their intended effects.

Question. Does your company make any treatment, cost, or coverage decisions based on the health information you collect from an individual?

Answer. We do not. We occasionally have prior authorization or step therapy requirements that a patient must meet before being authorized for costly medications, and we may retain that data.

Question. Does your company share health information with third parties? And, if so, does your company profit from that sharing?

Answer. CVS Caremark does share information with business associates in compliance with the Health Insurance Portability and Accountability Act (HIPAA) and applicable State laws. We do not monetize Personally Identifiable Health Information (PHI), but do monetize some anonymized data similar to other companies that cannot be used to identify or track individuals.

Question. Do you believe customers are fully aware of your information collection and sharing practices?

Answer. We inform all CVS Caremark clients of our data collection and sharing practices. Individual members have access to and receive CVS Caremark's Notice of Privacy Practices. For CVS Caremark websites and mobile applications, the applicable Privacy Policy is available to all users.

IMPACT OF VERTICAL INTEGRATION BETWEEN PBMS AND INSURANCE COMPANIES

Question. The PBM industry has experienced significant consolidation within the past 10 years, which has contributed to concerns about the potential abuse of market power, barriers to market entry, and exclusionary practices. In 2012, for example, Express Scripts acquired Medco Health Solutions—a nearly $30 billion transaction that merged two of the country's three largest PBMs.[1] More recently, PBMs are also vertically integrating with insurers/payers, reflected by the 2018 acquisitions of Express Scripts Holding Co. (a PBM) by Cigna Corp. (a payer) and of Aetna Inc. (a payer) by CVS Health Corp. As a result, the three largest PBMs are all vertically integrated with insurance companies. According to a report from the Kaiser Family Foundation, the two combined entities, along with UnitedHealth and Humana, will cover 71 percent of all Medicare Part D enrollees and 86 percent of stand-alone drug plan enrollees.[2] Vertical integration can result in increased efficiencies and consumer benefits. I can also, however, lead to higher barriers to entry for competition, leading to further consolidation. FDA Commissioner Scott Gottlieb recently warned that "consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious. And the very complexity and opacity of these schemes help to conceal their corrosion on our system—and their impact on patients."[3]

I'd like to talk about consolidation, including the recent integration of PBMs with insurance companies. Last year, I wrote to the Justice Department on this issue. It's reported that the three largest PBMs—who are before us today—now cover 71 percent of Medicare Part D enrollees and 86 percent of stand-alone drug plan enroll-

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[1] *See* "FTC Closes Eight-Month Investigation of Express Scripts, Inc.'s Proposed Acquisition of Pharmacy Benefits Manager Medco Health Solutions, Inc.," Federal Trade Commission (April 2, 2012), available at *https://www.ftc.gov/news-events/press-releases/2012/04/ftc-closes-eight-month-investigation-express-scripts-incs.*

[2] Juliette Cubanski, Anthony Damico, and Tricia Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing" (May 17, 2018), available at *https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/.*

[3] FDA Commissioner Scott Gottlieb, M.D., "Capturing the Benefits of Competition for Patients" (Mar. 7, 2018), available at *https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm.*

ees.[4] Such market power has raised concerns. FDA Commissioner Scott Gottlieb said, "the consolidation and market concentration make the rebating and contracting schemes [of PBMs] all that more pernicious."[5]

I want to hear briefly from you on whether the PBM industry is competitive. For example, are there high barriers to entry for new competitors?

Answer. The PBM industry is an intensely competitive market which has driven down prices for millions of Americans and for the businesses, unions and government programs that PBMs serve. PBMs compete against one another to obtain the lowest prices possible from the drug manufacturers and promote access to generic drugs and biosimilars which helps to keep costs down. In addition to providing services on the client side, they also build competing pharmacy networks and work to reduce wasteful spending, fraud and abuse within the system. As a result, PBMs save money for patients on prescription drug and related medical costs—an average of $941 annually. In fact, the FTC has described the market in which PBMs operate as "competitive . . . characterized by numerous, vigorous competitors who are expanding and winning business from traditional market leaders." A variety of different PBMs offer businesses, labor, consumers and government a variety of choices when considering options for best managing their pharmacy benefit. HHS recently indicated that the estimate there are approximately 60 PBMs currently operating in the United States.

Question. I'm also interested in what effect the most recent consolidations of PBMs and insurers has had on the bottom line for the government and consumer.

Do these arrangements result in a lower cost to the government—as a payer—and the consumer? Please explain.

Answer. In terms of what the CVS Health acquisition of Aetna has set out to do for the consumer experience, as a combined company we are working to connect consumers with the powerful health resources of CVS Health in communities across the country and Aetna's network of providers to help remove barriers to high quality care. We are also building a lasting relationship with consumers, making it easier for consumers to access the information, resources and services they need to achieve their best health.

We believe that access is a critical component of building a simpler and more responsive and affordable health care experience for consumers. We have already seen that new products and services developed by the combined company are becoming available to the health care marketplace, regardless of one's insurer, pharmacy benefit manager (PBM) or pharmacy of choice. While we cannot speak to every transaction in the health space, we believe that by fully integrating Aetna and CVS Health, we can develop new ways to engage consumers in their total health and wellness through personal contacts and deeper collaboration with their primary care physicians. As a result, we expect patients will benefit from earlier interventions and better-connected care, leading to improved health outcomes and lower medical costs.

QUESTIONS SUBMITTED BY HON. JOHN CORNYN

MANUFACTURER MONEY

Question. What is the total dollar amount that you obtain from pharmaceutical manufacturers in any form such as rebates, fees, etc.?

Answer. Through negotiations with drug manufacturers and other PBM programs, from 2016–2018, CVS Caremark has saved its clients more than $141 billion in pharmacy spend, including the delivery of $67 billion in rebates to clients and their members. We pass through 100 percent of rebates for Medicare and about 98 percent of rebates for clients in our other lines of business.

Question. What is the total dollar amount that you remit to health plans?

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[4] Juliette Cubanski, Anthony Damico, and Tricia Neuman, "Medicare Part D in 2018: The Latest on Enrollment, Premiums, and Cost Sharing" (May 17, 2018), available at *https://www.kff.org/medicare/issue-brief/medicare-part-d-in-2018-the-latest-on-enrollment-premiums-and-cost-sharing/*.

[5] FDA Commissioner Scott Gottlieb, M.D., "Capturing the Benefits of Competition for Patients" (Mar. 7, 2018), available at *https://www.fda.gov/NewsEvents/Speeches/ucm599833.htm.*

Answer. From 2016–2018, CVS Caremark has saved its clients more than $141 billion in pharmacy spend, including the delivery of $67 billion in rebates to clients and their members. Over the last 3 years we've kept drug price growth nearly flat, saving our clients and their members more than $141 billion as a result of PBM management, a 30-percent cost avoidance on pharmacy spend. Last year, 44 percent of our clients saw a decline in their prescription drug prices. Our client arrangements typically include additional fees for services that the client asks us to provide, in particular, managing and improving patient adherence since improving adherence to medication is one of the best ways to manage chronic conditions and keep costs down. In 2018, Caremark passed through $300 million to our clients in the form of rebates.

BIOSIMILARS

Question. Managed Care Organizations are on record as widely supportive of the potential of biosimilars. However, most MCOs have continued to support originator brand products and have not preferred and often excluded less expensive biosimilars. For example, most MCOs have kept Remicade (a treatment for rheumatoid arthritis and other diseases) as the preferred agent on their formularies, and in most cases to the exclusion of its biosimilar, Infliximab.

Why do you tout support for biosimilars while, at the same time, inhibiting adoption of these less expensive products?

Answer. We support the development of biosimilars, and believe they are a critical piece of lowering drug costs for patients and our clients. With regards to specific formulary decisions, we prefer products that provide the lowest net cost for our clients. While a biosimilar may have a lower list price, it is important that they compete on total costs with the brand to create savings for patients and plans.

Question. HHS may broaden the scope of its proposed rule and eliminate rebates between Medicare Advantage plans and manufacturers for Part B drugs.

Would this realign incentives to encourage preferred access for lower-cost drugs, such as biosimilars?

Answer. We do not believe this would advantage biosimilars. Eliminating rebates would not lower the net cost of the drug, and may, in fact, increase drug costs.

Question. What changes can we recommend/make to help you prefer lower-cost drugs, such as biosimilars, without rebates?

Answer. Creating an environment that allows for biosimilars to provide a lower net cost than their competitors is critical. We therefore urge you to focus on barriers to entry of biosimilars, such as brand evergreening that make the development of generics and biosimilars more costly. If it is less costly to bring a competitor to market generics and biosimilars will have the flexibility to provide larger discounts on their products.

Question. Why is there such a disparity in reimbursed pharmacy prices for specialty generic drugs in Part D (*e.g.,* Imatinib)? Does ownership of specialty pharmacy influence your reimbursement decision?

Answer. Reimbursement for specific products varies by client based on their contract with Caremark. However, CVS's ownership of our specialty pharmacy does not influence our reimbursement decisions. All plans in Part D use transparent pricing with their PBMs for pharmacy reimbursement.

Question. I'm concerned with the recent trend of PBM's allowing brand companies to "pay for position" on insurance formularies, which results in seniors losing access to lower-cost generics and biosimilars.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs?

Answer. We may exclude a generic or biosimilar if it is not the lowest net cost product. This practice allows us to provide the lowest costs to our clients and patients.

DELAYS AND DENIALS IN CANCER TREATMENT

Question. I have received stories of cancer patients facing delays or denials for their treatment due to PBM actions. Data shows that breast cancer patients who

experienced a 3-month or more delay in treatment had a 12-percent lower 5-year survival rate compared with breast cancer patients with only a 0- to 3-month delay.

What percent of patients experience a 14-day or longer delay in receiving an oral oncolytic prescribed by their oncologist?

Answer. Less than 3 percent of members experience a 14-day or longer delay in receiving an oral oncolytic prescribed by their oncologist.

Question. What are the primary reasons patients experience delays or denials for their treatments?

Answer. Most frequently, members experience an initial denial of coverage when a treatment is requested for a diagnosis for which the treatment is not indicated in the labeling approved by the U.S. Food and Drug Administration and for which there is no support in the recognized compendia and clinical practice guidelines (*e.g.,* National Comprehensive Cancer Network Clinical Practice Guidelines) or when the members' clinical characteristics do not meet the criteria or guidelines for coverage of the requested treatment (*e.g.,* no confirmation of HER2-positive breast cancer). Members may also experience a delay or denial when the initial request does not include all of the required clinical information.

Question. What percent of determinations to delay or deny treatment for cancer patients are made by an oncologist or healthcare professional with oncology training?

Answer. Initial denials of coverage are based on coverage criteria that have been reviewed by an oncologist or healthcare professional with oncology training and approved by the CVS Caremark National Pharmacy and Therapeutics Committee. Generally, appeals of initial denials are reviewed by an oncologist or healthcare professional with oncology training.

Question. Why is a PBM-owned specialty pharmacy better qualified to manage a cancer patient's adherence and side effects than a community cancer clinic with a medically integrated pharmacy?

Answer. Cancer patients are managed by their treating physicians—whether it's in a cancer clinic or elsewhere—and much of their treatments are covered under the medical benefit and not the pharmacy benefit. We think both entities provide services within their expertise. Specialty pharmacies lead efforts to coordinate patient care with physicians and other health professionals to avoid gaps in care and assure that patients are receiving and taking the proper medications. CVS Health helps make it easier for patients and their providers to start and stay on specialty therapies. Our high-touch care management offers patients embedded nurse support through CareTeam Choice and a seamless patient experience across a continuum of care, including convenient retail access and digital tools. This whole-patient management goes beyond the specialty drug regimen to help improve clinical outcomes while also helping to reduce total health-care costs.

DIRECT AND INDIRECT REMUNERATION (DIR) FEES

Question. Many community-based cancer clinics have established medically integrated pharmacies so patients can access their oral chemotherapy prescriptions or other medications at the point-of-care. These practices are often assessed large DIR which are based on certain quality measures targeted toward primary care.

Shouldn't pharmacies be evaluated on the type of drug dispensed and disease managed rather than a one-size fits all approach?

Does assessing large DIR fees on medically integrated pharmacies drive patients to PBM-owned specialty pharmacies?

Answer. CVS Health believes that performance criteria should be meaningful to the practice of retail pharmacy and actionable toward meeting achievable goals.

Specialty pharmacies have a different set of measurements under our pay-for-performance program than retail pharmacies, and all specialty pharmacies that participate in our networks, whether PBM-owned or not, have equal opportunities to achieve their goals.

Question. According to CMS, from 2012 to 2017 PBMs imposed a 45,000 percent increase in the amount of DIR fees pharmacies had to pay PBMs and PDPs under Part D, and revenues earned from these fees increased 225 percent per year during

this period.[6] I thought PDPs and PBMs were supposed to pay pharmacies for dispensing drugs to patients. Why do pharmacies have to pay DIR fees to PBMs at all?

Why are pharmacies forced to pay DIR and other fees to PBMs?

Answer. Spending under pharmacy pay-for-performance programs in Medicare Part D are accounted for under the Direct and Indirect Remuneration (DIR) form Part D plans have to submit to CMS. Given the structure of Part D, fees paid by pharmacies to PBMs under pay-for-performance are passed along to the PBM who then passes along the fees to the Part D plan. The Part D plans use these fees to reduce premiums. This is why the CMS actuaries indicated that accounting for these fees at the point-of-sale would increase Federal spending by $16.6 billion over 10 years and increase beneficiary premium costs by $5.7 billion over 10 years. Pay-for-performance is used throughout Medicare including for hospital, physician and Medicare Advantage payments. CVS Health believes that pharmacy pay-for-performance programs increase value for Medicare beneficiaries by incentivizing pharmacies to improve performance and lower costs.

Question. According to CMS, PBMs justify DIR fees as adjustments to improve quality. CMS also found that PBMs and PDPs withhold substantially more in reductions in payments than as rewards paid to pharmacies.[7] Aren't so-called "quality adjustments" that" collect more for "poor performance" than they pay out for "high performance" just another way for PBMs to collect even more money from pharmacies?

Why do PBMs collect more in quality payment adjustment than they pay pharmacies under Part D?

Answer. PBMs do not collect more in quality payments than what they pay pharmacies. Fees associated with pay-for-performance are a small percentage of overall pharmacy reimbursement. Any pay-for-performance fees paid by pharmacies are directly passed to Medicare Part D plan sponsors who use them to lower beneficiary premiums.

FORMULARY PLACEMENT/GENERIC TIERING

Question. In 2011, 71 percent of generic drugs in Part D were on the lowest tier designed for generics; by 2019, that number decreased to only 14 percent of generics. According to an Avalere study, this practice cost seniors $22 billion in higher out-of-pocket costs since 2015, costs that could have been avoided through the proper formulary placement of lower-cost generics. This practice, known as "paying for position," allows brands to block uptake of lower-cost generics and biosimilars, thereby unnecessarily increasing out-of-pocket costs for seniors.

Do you ever exclude generic or biosimilar competitors from formulary placement, or place these lower-cost drugs in higher cost-sharing tiers that are generally reserved for non-preferred or brand drugs? Do you ever consider portfolio or bundled rebates with brand manufacturers?

Answer. We may exclude a generic or biosimilar if it is not the lowest net cost product. This practice allows us to provide the lowest costs to our clients and patients. We do not bundle rebates across multiple products for a manufacturer.

Question. When you place generics on your formularies, do you place that generic favorably to brand products—in other words, on generic-only tiers?

Answer. We strive to place generics on the lowest possible tier when they provide the lowest net cost. We place products in relation to their higher-cost counterparts in a manner to provide savings to patients and give them an economic incentive to choose lower-cost options.

Question. When a generic becomes available, do you place it on your formularies immediately?

Answer. The time frame for adding generic drugs to a formulary varies depending on the type of plan and the plan sponsor's formulary strategy. For CVS Caremark template formularies with an "open" formulary strategy, a generic drug may be added to the formulary as soon as it becomes available in the market and is added to our adjudication drug file. For template formularies with a "closed" formulary

[6] CMS Proposed Rule: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses, 83 Fed. Reg. 62152, 62174 (November 30, 2018).
[7] *Id.* at 62174.

strategy, generally generic drugs will be reviewed soon after their availability in the market. In most cases, a generic drug will be added to the closed template formularies. However, a generic drug may not be added to the closed template formularies when the net cost to clients exceeds the net cost of the reference brand drug or other alternatives in the same therapeutic class.

QUESTIONS SUBMITTED BY HON. JOHN THUNE

Question. You referenced legislation in your testimony that I've worked on with Senator Carper to apply value-based insurance design to high-deductible health plans for chronic disease management. If enacted, how do you expect plans to utilize this tool and what will be the impact on drug prices and health care spending more broadly?

Answer. We encourage Congress to enact proposals to allow high deductible plans with a health savings account (HSA) more options at providing first dollar drug coverage, especially for those with chronic diseases. Currently, HSA rules allow employers to cover prescription drugs at little or no cost under a preventative drug list—this coverage is allowed outside the patient's deductible. However, once the patient actually gets sick, the patient has to start paying for drugs as part of the deductible in their high-deductible plan. CVS Health supports the Chronic Disease Management Act (S. 2410, 115th Congress), legislation led by Senator John Thune and Senator Tom Carper, which would give high deductible health plans paired with HSAs the ability to offer first dollar coverage for chronic disease management. If this legislation was enacted, health plans will structure their benefits differently, and we would foresee plans covering prescription drugs and some health-care services before the deductible has been met. We anticipate this could lower health care costs overall and improve patient outcomes by ensuring access to care and medications for costly chronic conditions.

Question. You've shared your ability to leverage technology such as real-time benefit tools to help patients and providers understand drug costs at the point of prescribing, as well as how technology can be used to help identify opportunities to provide enhanced support and medication management for enrollees. What policies can we consider to incentivize greater uptake of these tools?

Answer. Caremark uses real-time benefits technology to provide member-specific drug pricing information in the doctor's office, at the pharmacy counter, and directly to patients through digital tools. Prescribers using the tool have visibility into a patient's covered benefits, where they are in their deductible phase, what they will pay out of pocket for a specific drug, and any lower cost, clinically appropriate alternatives. Through the Check Drug Cost Tool on the Caremark member portal and app, patients are using this real-time benefits information to identify savings. Medicare should drive the adoption of real time benefits to give beneficiaries and physicians meaningful, actionable transparency to lower costs. This can be done by mandating that prescribers use e-prescribing and real-time benefit tools, or otherwise incentivizing its use.

QUESTIONS SUBMITTED BY HON. RICHARD BURR

Question. Pharmacy benefit managers (PBMs) offer a variety of contract designs to health insurance plans, allowing the insurer or client to choose the best structure for their customers. During the Finance Committee hearing on April 9, 2019, each witness stated that, in the contracts structured to allow for the passthrough of rebate dollars at the point of sale, PBMs do not keep *any* portion of the rebate. If the PBM does not keep a portion of the rebate, what type of revenue do PBMs receive from these contracts? What percent of your contracts are point of sale and what percent utilize a structure providing a percentage of the rebate back to the PBM?

Answer. We cover approximately 10 million lives in the commercial sector with point-of-sale rebates, out of approximately 60 million lives covered on the commercial side. In aggregate, we pass along 98 percent of our rebates to clients, and in Medicare Part D effectively 100 percent of the rebates are passed through. Overall, the vast majority of our clients are receiving 100 percent of the rebates we collect, and a small number compensate us by allowing us to retain a portion of rebates. Clients that receive 100 percent of rebates compensate us for our services in other ways, including per member per month fees or the use of spread pricing.

Question. It is our understanding that contracts with pharmaceutical manufacturers may also take a variety of forms. In calendar years 2016, 2017 and 2018, what was the total dollar amount that you obtained from pharmaceutical manufacturers in any form such as rebates, fees, etc.? What is the total dollar amount that was passed on to health insurance plans with which you have an agreement or contract?

Answer. Over the last 3 years, we've kept drug price growth nearly flat, saving our clients and their members $142B as a result of PBM management, a 30-percent cost avoidance on pharmacy spend. Last year, 44 percent of our clients saw a decline in their prescription drug prices. Our client arrangements typically include additional fees for services that the client asks us to provide, in particular, managing and improving patient adherence since improving adherence to medication is one of the best ways to manage chronic conditions and keep costs down. In 2018, Caremark passed through $300 million to our clients.

QUESTIONS SUBMITTED BY HON. TIM SCOTT

Question. One challenge that I see, when considering the medical treatment marketplace, is that we have a new wave of life-saving treatments—of incredible cures we could never have dreamed of, even 10 or 15 years ago—for which cost, by necessity, is going to be a major issue. You look, for instance, at a condition like sickle cell disease. For the average SCD patient who reaches age 45, lifetime treatment costs are at roughly $1 million—and there are complications that can make that figure even higher. Now that we see therapies coming down the pipeline that could erase those long-term costs and drastically improve the quality of life for sickle cell patients, the question becomes, how can our current payment systems adapt to—and absorb—the high costs necessary to bring treatments like these to market and to ensure that we continue to see innovations like these ones moving forward?

Answer. We believe the best way to absorb the costs of treatment in the system is by promoting competition to incent manufacturers to continue to innovate and bring new treatments to market. Therefore, we believe policies that would lower barriers to entry for generic and biosimilars provide the best way to mitigate growing costs, and ensure long-term innovation. These include eliminating gamesmanship of the FDA REMS program, preventing brand manufacturer "evergreening" and "product hopping," ending pay-for-delay settlements, and modernizing the Orange and Purple Books. All of these improvements would prevent brand manufacturers from artificially maintaining monopolies and lower-costs long term.

Question. And along the same lines, beyond creating some much-needed clarity around value-based arrangements—which I've been working with Senators Cassidy and Warner to accomplish legislatively—are there steps that Congress could take to facilitate these innovative payment models?

Answer. Among the most cost-effective ways to improve health outcomes that involve beneficiaries in their care is to improve medication adherence and access to preventive care services. However, current laws, such as the anti-kickback statute (AKS) and civil monetary penalties (CMP) law, often inhibit these types of activities because of their overly broad reach and severe penalties. As a result, many patient engagement activities that could lead to better health, including helping with medication adherence and health management, have been unintentionally limited. To address this, Congress could allow for broader CMP exceptions and corresponding AKS safe harbors that would permit incentives for: (1) activities that prevent the exacerbation of a current condition or illness by recognizing these as a form of "preventive care," and (2) activities that promote compliance with a treatment regimen by recognizing these as promoting access to care just as do activities that improve a beneficiary's ability to obtain medical items and services.

Question. I'm also interested in the role that technology can play in helping to drive down drug costs—as well as to increase medication adherence. Some estimates suggest that between 50 and 75 percent of patients don't take their medications as prescribed, and that one in five new prescriptions go unfilled. And study after study shows that cost is a key factor here. As a consequence, we see roughly 125,000 deaths from non-adherence every year, along with more than $100 billion in excess costs to the health-care system.

To what extent can technology help providers and patients to make more informed and cost-effective choices about prescriptions—and to then adhere to these prescriptions?

And maybe more to the point, to the extent that these technological tools are out there, what steps are you and your clients taking to encourage physicians and patients to use them?

Answer. Caremark uses real-time benefits technology to provide member-specific drug pricing information in the doctor's office, at the pharmacy counter, and directly to patients through digital tools. Prescribers using the tool have visibility into a patient's covered benefits, where they are in their deductible phase, what they will pay out of pocket for a specific drug, and any lower cost, clinically-appropriate alternatives. Through the Check Drug Cost Tool on the Caremark member portal and app, patients are using this real-time benefits information to identify savings. Medicare should drive the adoption of real time benefits to give beneficiaries and physicians meaningful, actionable transparency to lower costs. This can be done by mandating that prescribers use e-prescribing and real-time benefit tools, or otherwise incentivizing its use.

QUESTIONS SUBMITTED BY HON. BILL CASSIDY

Question. Are there ever cases where a patient in your health plan or one of the health plans for whom you negotiate as a PBM pays more for a medicine than the plan spends on a net basis, when you reimburse the pharmacy for that same medicine? In those cases, what entity receives the benefit of the difference between the amount the patient pays and the net amount the plan pays?

Answer. Our contracts with all dispensing pharmacies in our network require that CVS Caremark members always get the benefit of at least the lower of the pharmacy's cash price and the plan's copay. If a CVS Caremark plan member's copay for a drug is greater than the dispensing pharmacy's contracted rate, it is not our practice to collect that difference from the pharmacy.

Question. In calendar years 2015, 2016, and 2017, what percent of your revenue was from fees paid by plans, fees paid by manufacturers, other fees, pharmacy spread or rebates? Same question as to profits. Of all revenue generated from part D contracts, what percent did you retain?

Answer. We do not break down our revenue in this manner. Rather, our financials are tracked by business sector—retail pharmacy, pharmacy services, and health-care benefits. The PBM and Part D businesses are a part of the pharmacy services segment, which also includes mail and specialty pharmacies. Overall revenues in our pharmacy services sector increased by 2.7 percent. The company's number of pharmacy network claims processed increased 5.6 percent compared to 2017. But the comparable average revenue per pharmacy network claim processed decreased by 2.7 percent during that same period.

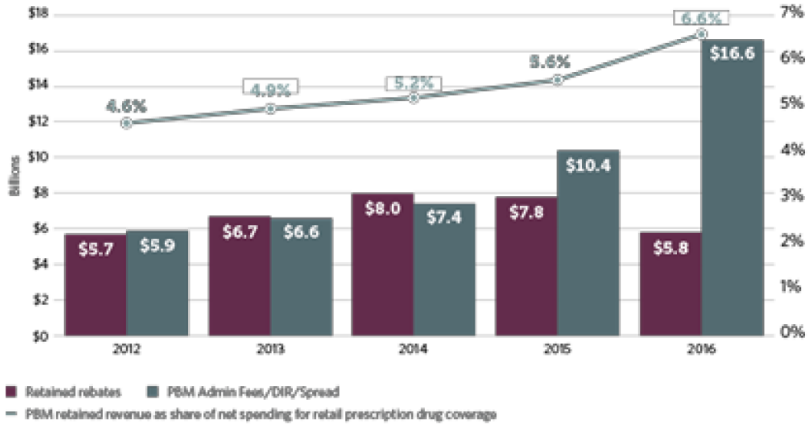
Question. Should a patient ever pay more out of pocket for a medicine than what you pay the pharmacy for that medicine?

Answer. Patient out-of-pocket costs are dictated by the insurance plans. As a PBM, however, we do encourage our clients with high deductible health plans to use point-of-sale rebates—and now cover approximately 10 million lives under point-of-sale rebates. We also encourage our clients to use a preventive drug list and cover many drugs on that list at a zero copay as we do in our own health plan. Moreover, we support expanding the ability of high deductible health plans to offer first dollar coverage for certain drugs and chronic conditions, and have worked with Congress and the administration to advance a change to the rules around high deductible health plans and health savings accounts.

Question. PBM revenue from fees has risen, illustrated below. Further, PBM's retained revenue as a percent of net retail drug spend has consistently increased. What do you attribute this increase to?

Figure 9

PBM Retained Revenue on Retail Prescription Drugs by Source and Share of Net Spending for Retail Prescription Drug Coverage, 2012-16



Answer. Over the last 3 years we've kept drug price growth nearly flat, saving our clients and their members $142B as a result of PBM management, a 30-percent cost avoidance on pharmacy spend. Last year, 44 percent of our clients saw a decline in their prescription drug prices. Our client arrangements typically include additional fees for services that the client asks us to provide, in particular, managing and improving patient adherence since improving adherence to medication is one of the best ways to manage chronic conditions and keep costs down. In the Medicare space, we pass 100 percent of the rebates and any administrative fees to our Part D plan clients.

Question. How are bona fide service fees established? What was your revenue generated in part D by bona fide fees in 2015, 2016, and 2017?

Answer. PBMs provide services to the Part D plan sponsor for which they are paid fees. Manufacturers have also historically paid a service fee to PBMs for the provision of some or all of the following services: calculating the amount of rebates payable for products dispensed to the beneficiaries of each plan sponsor and invoicing the manufacturer for rebates; providing the manufacturer with reports on product utilization and rebate calculations; utilizing internal control measures to protect against payment of unearned rebates, etc. In the Medicare space, we pass 100 percent of the rebates and any administrative fees to our Part D plan clients.

Question. A *Health Affairs* article suggests plans may prefer paying PBMs using rebates instead of fees, as "Using retained rebates to cover PBM costs in lieu of fees could artificially lower reported administrative costs and make it easier to meet government medical loss ratio (MLR) requirements." Is it true that paying the PBM a percent of rebates would keep that revenue from counting towards a plan's MLR?

Answer. Based on CMS guidance, this cannot happen. CMS requires all retained rebates be reported as a reduction in drug spend and are incorporated into the bid premium.

Question. Would you support an industry-wide standard set of performance metrics by which a PBM would set its pharmacy contracts, which would be tailored based on regional patient populations, to give certainty for local pharmacies?

Answer. CVS Health supports a pay-for-performance pharmacy model that allows pharmacies to execute using set performance criteria aligned with Medicare Part D plans' objectives, such as meeting/exceeding acceptable star ratings for drug adherence as set and agreed upon by CMS each plan year (health outcomes focused), and

also aligned with benefit plan designs (cost containment focus). We believe such measures should be actionable by the pharmacy.

QUESTIONS SUBMITTED BY HON. STEVE DAINES

Question. In Medicare Part D, beneficiaries' deductible and coinsurance payments are calculated based on the price negotiated between the PBM and the pharmacy.

Does this take into account rebates and discounts the PBM negotiates separately with pharmaceutical manufacturers?

If yes, what percentage of the time is this the case?

Answer. Other than CVS Health's current Allure plan option (where some rebates are shared with beneficiaries directly at the pharmacy counter), rebate dollars are used to reduce premiums in Part D rather than to reduce deductibles and coinsurance payments.

Question. In calendar years 2016, 2017, and 2018, what share of brand prescriptions covered by the Part D plans you contract with were filled in the deductible or required beneficiaries to pay coinsurance? What was the total amount beneficiaries spent out of pocket for those prescriptions? What would beneficiaries' total out-of-pocket spending have been under the same cost sharing structure if their payments were based on the net price to the Part D plan, inclusive of rebates and other price concessions, rather than the price negotiated between your PBM and the pharmacy?

Answer. The Medicare Part D program has been successful in providing beneficiaries with broad access to pharmacy services and prescription drugs—all while keeping premiums low, customer satisfaction high, and consistently operating under budget. We pass along effectively 100 percent of rebates to Part D plan sponsors. Research firm Oliver Wyman projected that over the next decade, PBM-negotiated rebates will save the program more than $600 billion. While the program is successful, CVS Health has proven to be a leader in supporting comprehensive Part D reform, like what MedPAC has recommended, particularly to address beneficiaries' out of pocket spending. We recommend Congress evaluate the potential benefit of shifting manufacturer liability to the catastrophic phase from the current coverage gap discount phase. This will incentivize manufacturers around their drug costs as they will face liability when the beneficiary enters the catastrophic phase. We also believe Congress should establish a true out-of-pocket cap to protect high cost beneficiaries—similar to the protections afford by MA plans—and increase plan liability in the catastrophic phase. This type of reform would realign and improve incentives for plans and manufacturers while simplifying the benefit structure. To maximize savings, it should be done as part of a package that enhances PBM formulary tools.

QUESTIONS SUBMITTED BY HON. RON WYDEN

SPREAD PRICING IN MEDICAID

Question. A PBM practice that has come up quite a bit recently is the practice of spread pricing. Spread pricing occurs when PBMs charge health plans more for prescription drugs than they actually reimburse pharmacies, and then pocket the different as profit.

Do you engage in spread pricing practices?

If yes, do you engage in such practices in Medicaid? If so, please list each State you operate in where you have a contract with a Medicaid managed care plan where you employ spread pricing; list each Medicaid managed care plan you have contracts with where you employ spread pricing; describe whether and how you disclose the use of such practices to the plans; describe whether you disclose such practices directly to the State; and list any States where you have direct contracts with the State Medicaid agency as a PBM for fee-for-service individuals.

Answer. CVS Caremark contracts with 39 managed care organizations (MCOs) to help manage Medicaid drug benefits across 35 States and the District of Columbia. Our PBM does not contract with Medicaid MCOs in States where all Medicaid benefits (medical and pharmacy) are managed exclusively under the fee-for-service model, or in States where Medicaid drug benefits are carved out of MCO coverage. CVS Caremark does not currently choose to operate solely as a pharmacy benefits

administrator (PBA) for State fee-for-service programs, but could potentially do so in the future.

While a majority of our Medicaid MCO contracts are "pass-through," where all PBM services and network costs are paid for through an administrative fee, CVS Caremark may also contract with an MCO using the traditional, or spread pricing methodology. "Spread pricing" is simply the term used to describe the difference in pricing from what a PBM is paid from its clients for claims for their enrollees to what a PBM reimburses its contracted pharmacies for those claims—no different than what any business pays its suppliers vs. what it is paid by its end users. This compensation model is often requested by PBM clients, including many of the commercial, employer and government plans PBMs support, because it provides them with stability and certainty around their drug costs. In its June 2018 report on MCOs and PBMs operating in Medicaid, following a review of nearly 40 million claims, the Ohio Department of Medicaid found that MCOs that were using this traditional pricing model were saving the State $145 million annually.

Clients, based on the region, State or population they serve, may choose a distinct contracting model over another, or use a combination of the two. In every case, the MCO always chooses the model as part of the RFP and procurement process and dictates the level of pricing transparency included in the contract, consistent with State and Federal Medicaid contract and reporting requirements.

MCOs maintain the right to audit PBMs based on contract terms and conditions, including pricing, and Medicaid MCOs and their subcontractors, including PBMs, must also comply with State Medicaid model contracting requirements as well as State and Federal Medicaid disclosure and reporting requirements, including the 2016 Medicaid and CHIP Managed Care Final Rule.

REBATE DEMANDS

Question. The use of rebates as a negotiating tool has led to problematic incentives in the prescription drug supply chain. For example, drug companies have argued that they increase list prices in response to demands from PBMs for high or increasing rebates.

Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that require equivalent rebates, even in the case of a drug for which the list price has been lowered?

Answer. No.

Question. Does your company currently have, or has your company had since January 2013, any agreements with drug manufacturers that require advance notice of changes in the list price of drugs, including reductions or increases in list price?

Answer. No.

REVENUE SOURCES

Question. Please provide an annual breakdown of the following components of the revenue you received from drug manufacturers from January 1, 2013 through December 31, 2018: dollar amount and percent of revenue from rebates; dollar amount and percent of revenue from administrative fees; dollar amount and percent of revenue from distribution fees; dollar amount and percent of revenue from marketing fees; dollar amount and percent of revenue from clinical case management fees; and all other sources of revenue from manufacturers not listed above.

Answer. Our financial disclosures are in Forms 10–Q and 10–K and can be found on the CVS Health investor relations website *(https://investors.cvshealth.com/investors/sec-filings/default.aspx).*

PART D NEGOTIATION

Question. The PBM market has changed dramatically over the past several years. Many Part D health plans also operate as PBMs, including your companies. While Part D has done a great job offering Medicare beneficiaries drug coverage they did not have access to before, Part D has not been successful at keeping up with the growing cost of medicines. PBMs and Part D plans claim they bargain to get lower prices, but the HHS Inspector General found that almost 4 in 10 brand name drugs in Part D offered no rebate or discount to Part D plans.

Why have Part D plans been ineffective at bringing down the cost of almost half of brand-name medicines?

Answer. Pharmaceutical manufacturers set the price of their drugs. Once they set the price, we negotiate to try to lower those costs. PBMs are effective managers of drug costs and we kept our overall client drug price growth trend in 2018 to 1.2 percent. A number of restrictions on Part D plans contribute to findings of the HHS Inspector General, including requirements that Medicare Part D plans cover two drugs from every category or class, and that they cover all or substantially drugs in the six protected classes.

The mandatory coverage of two drugs in each category or class has negative effects on a PBM's ability to drive competition between drugs to gain the largest discounts, and fundamentally undermines the development of evidence-based formularies. The mandate overrides the activities of Pharmacy and Therapeutic (P&T) Committees, which make their own assessments on clinical appropriateness and therapeutic alternatives. CMS requires Part D plans to have a robust P&T Committee process in place and should rely on that system to determine the appropriate medications to be placed on formulary. The protected class policy increases net drug costs in the program, as it eliminates manufacturers' incentives to offer discounts—thus removing any form of price competition for these drugs. The tiering exceptions process also drug manufacturers to work with physicians to degrade the effectiveness of PBMs and Part D plans to control drug costs through effective formulary management. In areas where Part D plans have formulary flexibility similar to the commercial market, they drive savings comparable to or even greater than what is done on the commercial side.

QUESTIONS SUBMITTED BY HON. ROBERT MENENDEZ

Question. Should the CREATES Act become law, what commitment can your company making to covering generics as soon as they are approved and passing those savings on to patients?

Answer. The CREATES Act would prohibit brand manufacturers from abusing the FDA Risk Evaluation and Mitigation Strategies Program and other restrictive distribution schemes to delay generic development. Currently brand manufacturers can use these tricks to keep generic firms from acquiring the necessary samples to develop generics or biosimilars. Passing the CREATES Act would get lower cost products to the market faster and save patients money.

The time frame for adding generic drugs to a formulary varies depending on the type of plan and the plan sponsor's formulary strategy. For CVS Caremark template formularies with an "open" formulary strategy, a generic drug may be added to the formulary as soon as it becomes available in the market and is added to our adjudication drug file. For template formularies with a "closed" formulary strategy, generally generic drugs will be reviewed soon after their availability in the market. In most cases, a generic drug will be added to the closed template formularies. However, a generic drug may not be added to the closed template formularies when the net cost to clients exceeds the net cost of the reference brand drug or other alternatives in the same therapeutic class.

Question. What are your concerns with point-of-sale rebates and what alternatives do you propose to such rebates to improve consumer savings at the pharmacy counter?

Answer. Caremark encourages our commercial clients to use point-of-sale rebates, as CVS Health does in our own employee health plan. Our Part D plan, SilverScript also offers a Part D plan with POS rebates for 2019 (Allure, the only Part D plan sponsor with such an offering). Caremark covers approximately 10 million lives under point-of-sale rebates in its commercial business.

We believe that Part D plans should be required to offer a third option that provides for partial point-of-sale rebates such as our Allure plan, but this should be an option rather than a mandate. While it may benefit some patients, it increases premium costs for all beneficiaries. The unique structure of Part D does not make mandating point-of-sale rebates the only option for a preferred policy choice. Such a policy would only benefit approximately 15 to 30 percent of beneficiaries while making 70 percent of beneficiaries worse off, raise premiums by 20 to 30 percent, and cost the government close to $200 billion over 10 years in new spending.

Question. What are the specific steps your company is taking to move PCSK9 inhibitors off the specialty tier in Medicare Part D and to fixed copay tiers given that

prices went down by 60 percent and are no longer above the specialty tier threshold?

Why haven't your plans moved it already, given that CMS allows plans to make positive mid-year formulary changes that improve patient access and affordability?

Answer. CMS generally will not approve mid-year changes that will cost the plan, and potentially CMS, money.

QUESTIONS SUBMITTED BY HON. BENJAMIN L. CARDIN

DRUG REBATE RULE AND HIGHER PART D PREMIUMS

Question. In January, the Department of Health and Human Services released a proposal to reform prescription drug rebates paid by pharmaceutical manufacturers to pharmacy benefit managers under Medicare Part D. The OIG proposal attempts to ban most rebates by eliminating their regulatory protections and creating two new safe harbor provisions: one to expressly protect discounts applied directly at the point-of-sale (POS) for consumers, and another to protect certain service fees that manufacturers pay to PBMs for services furnished to health plans. The only service fees that would be permissible under the proposal are those that are fixed, and not based on a percentage of sales and not based on volume or the value of other business generated between the parties. The proposed rule was designed to address the Department's concerns with the current rebate system, which HHS believes rewards high list prices, discourages the use of generics and biosimilars, and does not reflect patient out-of-pocket costs. For consumers, this proposal may result in lower costs at the pharmacy counter, but Part D premiums may increase as a result.

Could you explain which Part D beneficiaries could see savings on their drug costs at the pharmacy counter and which Part D beneficiaries could not see lower drug costs?

Answer. As the CMS actuaries point out in the preamble to the HHS OIG rebate proposed rule, a majority of beneficiaries will face higher costs under the proposal, as their premium increase will be greater than any savings they see at the pharmacy counter. Our own estimates indicate that 70 percent of beneficiaries will likely be financially worse off if this proposal is adopted, only 15 percent of beneficiaries would benefit, and another 15 percent may benefit. The beneficiaries who would benefit are those who take expense drugs that have rebates, the beneficiaries who would not benefit are those who are taking few to now drugs, or taking drugs without rebates (such as generics and many specialty medications).

PERVERSE INCENTIVE TO PLACE MORE EXPENSIVE DRUGS ON FORMULARIES

Question. In a Senate Finance Committee hearing had a few weeks ago, many pharmaceutical companies argued that the current rebate structure incentivizes high list prices. These companies argue that the higher the list price of the drug, the greater the rebates, and therefore, the more profit the PBM earns. While contracts between PBMs, Part D Plans, and pharmaceutical companies require PBMs to pass through 100 percent of the negotiated rebate back to insurance plans, I worry that this structure could incentivize PBMs to favor a more expensive drug on the formulary because they could get a higher rebate.

Is there an incentive for a PBM to place a higher cost drug on the Part D formulary because the PBM receives a larger rebate for that more expensive drug? Why or why not?

Answer. No, there is not an incentive because of the rebate. It is not the size of the rebate that drives the decision making, but whether the product has the lowest net cost for our clients.

SIX PROTECTED CLASSES PROPOSAL AND ACCESS

Question. This past November, the Centers for Medicare and Medicaid Services released a proposed rule for 2020 to help tackle drug pricing. Among the proposed changes is one, which would alter the current rules, governing the "six protected classes." The concept of the protected classes has been around since the launch of the Medicare Part D program, and it was instituted to ensure that some of our most vulnerable patients would have access to their needed drugs by requiring formularies to cover nearly all protected drugs. These classes are anticonvulsants,

antidepressants, antipsychotics, immunosuppressants, antiretrovirals, and antineoplastics.

Some people have argued that these protected classes have led to higher drug prices because formularies are required to include this prescription coverage, and there are limited tools left to help lower prices. In an effort to increase competition, this proposed new rule would do a couple of different things. The first aspect of the administration's proposal would allow Part D sponsors to implement broader use of prior authorization and step therapy for protected class drugs, including to determine use for protected class indications. Any time there is a mention of plans using prior authorization or step therapy there is an immediate concern of restricting patient access to needed drugs or medical services.

Could you explain why your company would favor such utilization management tools like step therapy or prior authorization?

Answer. Step therapy is a successful and clinically evidence-based technique used by nearly all Medicare, Medicaid, self-insured companies, and health insurance plans nationally. It is used by plans to manage the utilization of drugs that are very high in cost. Pharmacy benefit programs frequently implement a variety of guidelines and programs that are designed to ensure that patients receive clinically appropriate and cost-effective therapies. Sometimes this can involve programs that promote a generic drug or lower-cost brand-name alternative drug before higher cost non-preferred drugs are covered. Without these programs in place, the cost of the benefit will increase with no corresponding increase in quality.

Question. Do you believe there is a danger that using step therapy or prior authorization could possibly restrict patients from having access to medication that has been successful for them? Why or why not?

Answer. No, because exceptions policies are in place to allow beneficiaries to receive needed drugs.

Question. If you were to use step therapy or prior authorization for drugs in the six protected classes, how would you ensure patients would continue to have access to their needed medications in one of the six protected classes?

Answer. In most of the protected classes there are several alternatives—for example, there is a wide variety of drugs in the immunosuppressant class and numerous generics in the antidepressant and antipsychotic classes. We believe Part D plans' Pharmacy and Therapeutics (P&T) Committees are well-qualified and structured to ensure that beneficiaries have an appropriate choice of drugs in these classes on the plan's formulary. Furthermore, the current exceptions processes would remain in place.

Question. The second aspect of the administration's proposed change to the six protected classes is the proposal to allow drug coverage formularies to exclude a protected class drug from a Part D formulary if the drug represents a new formulation of a single-sourced drug, regardless of whether the older formulation remains on the market. My understanding is that this administration is trying to target pharmaceutical companies who participate in the anticompetitive practice of "evergreening." This is a practice where pharmaceutical companies make slight alterations to a drug's packaging, color, and formulation without an added or new benefit. However, we also understand that seemingly small changes to a drug can still make a big difference to patient well-being. We have heard from Maryland physicians that the creation of combination antiretroviral pills was a huge step forward in the fight against HIV. Even though these combination pills or extended release versions didn't have a new chemical formula, they made a world of difference to the HIV patients taking over a dozen pills a day. These vulnerable patients are obviously very concerned that they could lose coverage for new and better drugs, especially when their old drugs may no longer be available. HIV treatments have come a long way in the last few decades, and proper antiretroviral treatment is vital to ensuring an end to the HIV epidemic.

Question. Do you think the proposed rule anticipates a situation where a pharmaceutical company stops producing an older version of a drug when a new formulation is available, but the newer formulation is not covered by a Part D plan? Why or why not?

Answer. Brands will sometimes cease production of an older version of a product in the interest of promoting a new formulation and preventing uptake of impending generic competition for the old formulation. This is commonly referred to as "product hopping" and allows them to keep prices artificially high. In instances that you are

describing, if the newer product provides a genuine benefit to patients we would work to get such products on formulary. Otherwise we would use traditional utilization management tools to ensure patients have access to the appropriate drugs.

Question. What would your company do to ensure that patients continue to have access to their medication in this situation?

Answer. Transition fills are permitted in Part D for those established on a therapy, and the exceptions process is always in place for those who require an off-formulary medication.

APPEALS PROCESS IN GENERAL

Question. Another complaint that I have heard from physician groups is that many formularies do not cover newer drugs that they consider to be necessary for hard-to-treat diseases, even if the drugs are very well-studied.

With technology changing so rapidly, how do your companies ensure that you keep up with the medical and surgical experts and new research, so that your authorization decisions are in line with the most recent medical innovations and physician standards?

Answer. CVS Caremark has a National Pharmacy and Therapeutics Committee (P&T) Committee that ensures the appropriate use of utilization management tools, including step therapy and prior authorization programs.

The CVS Caremark P&T Committee is an external advisory body of experts from across the country, composed of 21 independent health care professionals, including physicians and pharmacists, all of whom have broad clinical backgrounds and/or academic expertise regarding prescription drugs. Included in this committee is a physician who is a medical ethicist that is responsible for assisting in the decision-making process by facilitating the discussion, as needed, and to provide unbiased feedback with respect to the logic and appropriateness of the conclusions drawn and the decisions reached.

The committee meets face-to-face on a quarterly basis, and, as needed, on an ad hoc basis. It is responsible for formulary development, reviewing all existing standard formularies, and reviewing and approving all utilization management criteria (*i.e.,* prior authorization, step therapy, etc.). It bases its decisions on scientific evidence, standards of practice, peer-reviewed medical literature, accepted clinical practice guidelines and other appropriate information.

DIRECT AND INDIRECT REMUNERATION FEES

Question. I have heard from independent pharmacies in Maryland that have struggled with Pharmacy Benefit Managers and direct and indirect remuneration (DIR) fees. According to independent pharmacies, there are times when DIR fees are based on performance, and these fees range from $2–$7 for certain types of maintenance prescriptions and are often collected retroactively—weeks or even months after a prescription was filled. A PBM can take money back from the pharmacy when the pharmacies haven not met a PBM's performance standard. In these instances, the PBM claws back money and creates a situation where the pharmacy does not receive adequate reimbursement to cover its costs. As a result, DIR fees can be a significant financial loss to pharmacies and an additional cost burden to patients.

Could you explain what performance measures are considered when determining a DIR fee?

How is that performance measure communicated to the pharmacy?

How much does your company receive in DIR fees?

How much does your company receive in performance-related DIR fees?

Are those fees passed on to the consumer? If so, how?

Answer. Our performance metrics address certain activities such as: increasing patient participation in Medicare medication therapy management consultations; comprehensive medication reviews; engaging and reporting metrics related to diabetes disease management programs; appropriately reducing high-risk medications in the senior population; and actively engaging customer satisfaction and service programs.

Under Medicare Part D, financial flows that may be either positive or negative that cannot be accurately approximated at the point-of-sale are accounted for under Direct and Indirect Remuneration (DIR) reporting to CMS. These amounts are factored into CMS's calculation of final Medicare payments to Part D plans. CVS Caremark provides pharmacy pay-for-performance metrics clearly in our contracts with pharmacies and provides informational support to pharmacies to help them understand the program and achieve their goals.

Pharmacy pay-for-performance fees accounted for under DIR are directly passed to Medicare Part D plan sponsors who use them to lower beneficiary premiums. This is why the CMS actuaries indicated that accounting for these fees at the point-of-sale would increase Federal spending by $16.6 billion over 10 years and increase beneficiary premium costs by $5.7 billion over 10 years.

DRUG SHORTAGES

Question. Currently there are over 270 drugs in shortage. Drug shortages happen for many reasons such as manufacturing and quality problems, natural disasters, and inventory practices of wholesalers and pharmacies. Drug shortages cause harm to providers, hospitals, and most importantly patients. Pharmacists and providers must spend significant amounts of time on researching alternative drug treatments for the patient, which may not always be the most optimal therapies.

As a pharmacy benefit manager, you have contractual agreements with pharmaceutical companies in order to place their drugs on a plan's formulary. While I understand that drug shortages happening in both the inpatient and outpatient settings, there may be a role PBMs can play in protecting patients.

For the prescription drugs you negotiate to cover on a plan formulary, could you use your negotiating power to ensure a drug is available to a patient? Why or why not?

Answer. The PBM's role is strictly related to making the lowest cost available to our plans.

Question. What do you do to ensure that patients have the drugs they need?

Answer. As a broader enterprise, CVS Health is dedicated to using its purchasing power to ensure a consistent supply of drugs for patients across all of our health care entities, by negotiating with multiple suppliers to protect against unpredictable manufacturing interruptions.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

BIOSIMILARS

Question. During the hearing, each of you expressed support for biosimilars and most of you indicated you try and take advantage of available biosimilars to help lower costs. When I asked each of you to identify solutions to help ensure a robust biosimilar marketplace here in the U.S., most of you mentioned things Congress or the administration could do to help ensure uptake of biosimilars—from lowering the exclusivity period for biologics to finalizing guidance on interchangability at the FDA. However, none of you offered any solutions or ideas for what your company could do to help ensure timely uptake of biosimilars, a robust U.S. biosimilars market, and a resulting cost savings to patients to taxpayers.

Most of the biosimilars currently approved and on the market in the U.S. are reimbursed through the medical benefit. What are the similarities and differences in how rebates are passed onto patients and providers in the medical benefit versus pharmacy benefit. In your answer, please describe these similarities and differences across each of your books of business (*i.e.,* commercial, Medicare, Medicaid).

Answer. CVS Caremark offers services to manage drug utilization within the medical benefit for clients.

To the extent that rebates are paid for drug claims processed through the medical benefit, they are treated in a similar fashion to rebates paid for claims under the pharmacy benefit. That is 100 percent of the rebates are passed through to some clients, and other clients may allow us to retain some an agreed-upon portion of rebates as compensation for our services. The client who determines how those rebate dollars are used, often either to reduce premiums or to lower costs at the point of sale.

As a result of a recent CMS rule that will allow in 2020 limited use of step therapy in Medicare Advantage plans for Part B covered drugs, medical rebates may become a consideration for MA plans.

Question. Do any of your plans require the use of a higher list price, branded product over the use of a therapeutically equivalent lower list price generic or biosimilar product? Why? If a plan restricts the use of a biosimilar or generic product in lieu of an innovator or brand name product, do patients pay more out of pocket than they would if the biosimilar was preferred?

Answer. CVS Caremark offers services to manage drug utilization within the medical benefit for clients. In these instances we use similar strategies to those seen in the commercial benefit (patient and physician education and communication, prior authorization, preferred products, etc.). Similar to the pharmacy benefit, we prefer products to target lower cost strategies for clients for each therapeutic class in the context of clinical appropriateness and market factors. Rebates can play a role to the extent that the lowest net cost product may provide a rebate to the plan sponsor that reduces cost for the plan and patients.

However, we believe a bigger driver of biosimilar adoption are the incentives for providers that often lead them to higher-cost products, such as the ASP+6 percent model in Medicare Part B that pays doctors more for the use of high cost products with not penalty for forgoing lower-cost, equally effective treatments.

Question. Recognizing most biosimilars are paid for via medical benefit, please explain whether you use step-therapy to restrict access to biosimilars for your patients in any medical benefit you manage across each of your books of business (*i.e.,* commercial, Medicare, Medicaid). What role do rebates playing in your consideration for patient access to biosimilars in each of these instances?

Answer. CVS Caremark offers services to manage drug utilization within the medical benefit for clients. In these instances, we use similar strategies to those seen in the commercial benefit (patient and physician education and communication, prior authorization, preferred products, etc.). Similar to the pharmacy benefit, we prefer products that provide the lowest net cost for clients. Rebates can play a role to the extent that the lowest net cost product may provide a rebate to the plan sponsor that reduces cost for the plan and patients.

Question. How can and will your company help ensure a robust biosimilars market here in the U.S.?

Answer. We continue to support the development of a robust biosimilars marketplace. We support policies such as ending abuses of FDA's REMS program, eliminating pay-for-delay settlements, and ending patent "evergreening" to get competition to market faster. Additionally, we will continue to aggressively negotiate on behalf of our clients and their patients in order to get access to the lowest net-cost therapies, which we believe will be biosimilars in the long term.

Question. I have heard concerns that "rebate walls" are responsible for keeping new biosimilars off of formularies, where a manufacturer offers conditional rebates on a bundle of their products in order to incentive PBMs to exclude a new biosimilar competitor from their formularies. Have you ever decided to place a drug on a preferred tier because of the rebates you receive for other drugs from that manufacturer? If you do not do this, do you support this practice being carried out by your competitors?

Answer. CVS Caremark does not negotiate with manufacturers to obtain rebates that are bundled across multiple products. However, insulin manufacturers have sometimes offered rebates for an insulin product that would vary, in part, depending on the formulary coverage of another insulin product produced by the same manufacturer. For example, if two insulin products offered by a manufacturer were both covered on a formulary, then the manufacturer might offer a higher rebate amount than if only one of the products was covered on a formulary. The rebate amounts applied would depend on the formulary that a client chose to utilize.

Question. What more can and will you do to counteract efforts to rebate-block or bundle rebates to block biosimilar formulary placement? Will you commit to taking these actions as more biosimilars become available in Part D?

Answer. We remain committed to biosimilars as an important tool in reducing costs for our clients and their members. When engaged in negotiations on competing products we remain committed to providing our clients with the lowest net cost op-

tion, and believe that as more biosimilars enter the market those negotiations will serve to lower costs for clients and their members.

REBATES VS. FEES

Question. During the hearing, Senator Cassidy asked each of you about the trend in PBM contracting where a larger share of your reimbursement and payment is a result of "fees" which you are able to pocket, as opposed to "rebates" which must be passed back to the plan/consumer.

Please define the word "rebate." As part of your definition, please clarify whether or not you consider administrative fees, inflation payments, product discounts, prospective rebates, care management fees, procurement fees or any other type of fee or payment that isn't a retrospective rebate to be a rebate.

Answer. Rebates are simply negotiated discounts off the manufacturer selected list price of the product. The size or amount of rebates is based on the formulary placement and plan design features that are selected by the PBM client. We do include inflation payments as part of "rebates." Under rebate agreements, we may earn an administrative fee from manufacturers for the services we provide to them in connection with rebate billing, collection and distribution. In the Medicare space, we pass 100 percent of the rebates and any administrative fees to our Part D plan clients.

Question. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), a list of each of the different types of rebates, charges, and/or fees that you incorporate into your contracts.

Answer. Our contracts include formulary rebates, rebates that are tied to drug inflation, and administrative fees, as are described in question seven.

Question. Rebates, by definition, must be passed along to the employer, health plan, or consumer. Please provide, across your books of business (*i.e.,* commercial, Medicare, Medicaid), details on which of the rebates/fees detailed in my prior question are passed along to the consumer and/or plan and which are kept by the PBM.

Answer. As mentioned in question seven, we pass 98 percent of rebates along to plan sponsors, and at every level these rebates are typically being used to reduce premium costs to benefit consumers in accessing coverage. In Medicare Part D, we pass along effectively 100 percent.

FIDUCIARY DUTY

Question. Each of you has argued that you are the one entity in the drug supply chain that exists to help lower the cost of prescription drugs. You claim that your value comes in saving taxpayers, plans, and consumers money.

Would you be willing to accept a fiduciary standard in your contracts? In other words, do you believe you have a fiduciary duty to the plan or employer you contract with—to act in their best interest and not your own? If not, why not?

Answer. CVS Health believes that including a fiduciary standard in our contracts with our clients is inappropriate standard, would create many challenges to creating an drug benefit, and would likely increase costs for our clients. ERISA defines the term "fiduciary" as a person who (i) exercises any discretionary control respecting management of such plan or exercises any authority or control respecting management or disposition of its assets or (ii) has any discretionary authority or discretionary responsibility in the administration of such plan.[8]

The U.S. Supreme Court has ruled that a person is a fiduciary for an ERISA plan only "to the extent" a person has or exercises such discretionary authority or control on behalf of a plan. Following this decision, multiple Federal courts have ruled that the PBM was not acting in a fiduciary capacity in managing its PBM-related services (*e.g.,* negotiating with drug manufacturers or retail pharmacies or managing its formulary), but rather managing its own business which did not involve the discretionary control of plan assets.

In light of this well-settled law, there are many concerns about the effect that imposing a fiduciary duty on PBMs on behalf of the ultimate payer would have on the PBMs' ability to negotiate drug prices. Such a requirement may impact how PBMs interact with their clients and their beneficiaries depending upon how the fiduciary duty is defined, and who it applies to (sponsor or beneficiary). Overall, imposing a

[8] 29 U.S.C. § 1002(21)(A).

fiduciary duty on a PBM would pose a challenge for payers trying to control costs while the payer is providing a sustainable benefit to their plan members in an era of rising launch prices for drugs and ongoing, annual increases in drug prices.

The imposition of a fiduciary duty may reduce the flexibility that a plan sponsor has with regards to structuring their financial arrangement with their PBM and could lead to one-size-fits-all solutions. There may be only one way of contracting that would meet the definition of a fiduciary without some potential for incurring legal liability. Additionally, it could restrict payers' ability to uniquely design their benefit to meet their beneficiaries' specific needs while implementing ways to provide cost savings, including formulary preferences, exclusions, and utilization management techniques. There is also the possibility that it would prevent payers from having their PBM obtain better pricing from retail pharmacies through use of managed networks. The reality of the marketplace is that one-size-fits-all plan designs would not work for everyone because not all payers have the same level of economic resources or the same size and type of patient populations.

PAYING PHARMACISTS

Question. Following a series of reports in *The Columbus Dispatch,* Ohio has taken a number of actions over the past year to crack down on several PBM practices. Efforts to date have included investigations, lawsuits, and policy changes to address the egregious use of spread-pricing, alleged breaches of contract, accusations of anticompetitive behavior, a misuse of taxpayer dollars, and a general lack of transparency.

PBMs are responsible for creating pharmacy networks, setting the price patients and health plans pay for prescription drugs, adjudicating claims, and reimbursing pharmacies for dispensed drugs. In addition, nearly all PBMs own proprietary pharmacies that directly compete with the PBM-created retail network. Do you design plans that incentivize or require patients to use a pharmacy owned by your affiliate over a competing retail pharmacy. If yes, do you believe this represents a conflict of interest? If yes, how do you ensure there is no resulting anticompetitive misuse of pharmacy and patient data?

Answer. CVS Caremark is the pharmacy benefit management (PBM) business of CVS Health. As a PBM, CVS Caremark administers prescription drug benefits for our clients who include large employers, health plans, State government employee plans, and government payors (*e.g.,* Medicare and Medicaid), and others. As a PBM, CVS Caremark also manages the development and maintenance of a vast network of retail pharmacies across the United States. We're proud of our extensive pharmacy network, which has nearly 68,000 participating pharmacies, including independently-owned, community-based pharmacies, other local pharmacies in grocery stores and mass merchants, as well as regional and national chains. The pharmacists serving our members are trusted health-care providers and their interventions help patients take their medications as directed by their physicians, ultimately improving outcomes and managing overall health-care costs.

CVS Pharmacy is the retail pharmacy chain of CVS Health and is probably the most recognizable part of the broader enterprise due to our presence in 10,000 communities across the U.S. CVS Pharmacy is focused on providing our customers with convenient access to their medications as well as other products and services they need to stay healthy. In addition, CVS Pharmacy participates in pharmacy networks for health plans and PBMs other than CVS Caremark.

CVS Caremark also partners with pharmacies that directly compete with CVS Pharmacy. For example, Caremark considers independently-owned pharmacies to be important partners in creating the networks we offer our PBM clients to ensure their members have convenient access to their medications. Independent pharmacies account for about 40 percent of the CVS Caremark's network of more than 68,000 pharmacies, and the number of independent pharmacies in our network has remained consistent for the past 25 years.

Question. After investigating the issues brought to light by *The Columbus Dispatch,* Ohio's Medicaid report found that CVS Caremark often paid CVS pharmacies substantially more than unaffiliated pharmacies for the same generic drugs under the Medicaid program. An investigation by the State legislature in Arkansas also found that CVS Caremark was paying CVS pharmacies a significantly higher price for medications than they were paying independent pharmacies. You have mentioned that there is a firewall between the two sides of the company; however, the results of the State's investigation seem to be less clear. How will CVS Caremark

ensure taxpayers that it isn't using their money to pay its own stores more to drive competitors out of business in Medicaid or the Part D program?

Answer. Since CVS Pharmacy and Caremark merged, CVS Health has maintained stringent firewall protections between our CVS Pharmacy retail business and our CVS Caremark PBM business. We take these protections very seriously.

The question regarding whether an effective firewall exists between CVS's retail and PBM businesses was fully reviewed by the Federal Trade Commission. The FTC and Federal regulators were satisfied that the two companies are indeed kept separate. The firewall has detailed and elaborate privacy and security policies and procedures in place that ensure that the protected health information (PHI) of each covered entity (including each health plan) is only accessed and disclosed as permitted by that covered entity and in accordance with the standards set forth in the Health Insurance Portability and Accountability Act (HIPAA) and its implementing regulations.

There are many safeguards in place to do this, technical, physical and administrative as HIPAA requires, preventing the inappropriate sharing of PHI between the PBM CVS/Caremark and CVS Health, and the inappropriate use or sharing of PHI generally. The firewall also prohibits CVS/Caremark from sharing other confidential and competitive information, such as the reimbursement rates for its pharmacy networks, with the CVS/pharmacy segment.

Further, a June 2018 report from the Ohio Department of Medicaid found after a review of over 35 million Medicaid claims adjudicated by CVS Caremark in 2017–2018 that there was no evidence of anti-competitive behavior between the retail and PBM business units and that CVS Caremark reimbursed independent pharmacies at a higher rate than chains, including CVS Pharmacy.

As with any PBM, overall average reimbursement will vary based on the mix of drugs being dispensed by a pharmacy. A pharmacy's drug mix impacts the weighted volume of higher and lower discounted drugs being dispensed, and therefore the overall average reimbursement levels across a PBM's pharmacy provider network.

For example, a pharmacy dispensing a greater volume of drugs that is more deeply discounted (*e.g.,* certain generics) based on its patient population's disease prevalence would have a reimbursement rate that reflects its average discount.

SETTING DRUG PRICES

Question. All of you helped me establish a few basic facts during the hearing on April 9th. First, we established that PBMs *do not* set drug prices. Second, we established that nothing in the administration's proposed rebate rule would require any PhRMA company to lower the price any drug. And—in fact—no PhRMA company is willing to commit to lowering the price of their drugs if this rule goes into effect. We know this because of the answers to QFRs each of the PhRMA representatives gave to Chairman Grassley and Ranking Member Wyden as a follow-up to a prior Finance Committee hearing.

Following the administration's proposed rebate rule, CVS Caremark wrote to several pharmaceutical manufacturers to ask them to commit to not INCREASING their prices if the Trump rebate rule is finalized. Has any manufacturer responded to your letter and made a commitment to keeping their prices at or below where they are today?

Answer. The overwhelming majority of manufacturers who responded to the survey could not agree without qualifications or caveats. A handful of smaller pharmaceutical companies did commit.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Can you answer the following questions to help us understand the Pharmacy Benefit Manager business model and how you make formulary decisions?

What percent of rebates are passed to the consumer under Medicare Part D?

Answer. Effectively 100 percent of rebates are passed on to the Part D plan sponsor, where they are used to lower premiums for beneficiaries. This is why the CMS actuaries estimated that costs to the government would increase by $196 billion over 10 years if rebates are passed at the point of sale, and that beneficiary premiums would ultimately increase by 25 percent.

Question. What percent of rebates are passed to the consumer in the private insurance market?

Answer. In aggregate, we pass along 98 percent of all rebates to our clients.

Question. Do you have any comments on how health plans should use their share of the rebates to lower drug prices for patients with high deductibles?

Answer. We encourage our commercial clients, especially those that use high-deductible plans, to use our point-of-sale (POS) rebate option to lower drug costs at the pharmacy counter for their beneficiaries. CVS Health's own health plan for our employees uses POS rebates, and across all our clients we cover approximately 10 million lives under POS rebates.

Question. What is the process of deciding on which tier a generic will be placed in your formularies?

Answer. Tier placement for generic products varies depending on the type of plan (*e.g.,* Medicare, managed Medicaid, fully-insured, self-funded, etc.) and the plan sponsor's formulary strategy. Generally, for CVS Caremark template formularies, tier placement is guided by established business rules appropriate for the type of plan and formulary strategy. Often generic drugs will be placed on the lowest cost sharing tier. In some instances, generic drugs may be placed on higher tiers based on cost or clinical considerations. CVS Caremark template formularies, including tier placement, are reviewed by the CVS Caremark National Pharmacy and Therapeutics Committee.

Question. Are generics always tiered as preferred (versus branded drugs)?

Answer. No. In some instances, generics may be higher cost and we look to provide the lowest net cost to our clients.

Question. How quickly are generics placed on formularies once FDA clears them?

Answer. The time frame for adding generic drugs to a formulary varies depending on the type of plan and the plan sponsor's formulary strategy. For CVS Caremark template formularies with an "open" formulary strategy, a generic drug may be added to the formulary as soon as it becomes available in the market and is added to our adjudication drug file. For template formularies with a "closed" formulary strategy, generally generic drugs will be reviewed soon after their availability in the market. In most cases, a generic drug will be added to the closed template formularies. However, a generic drug may not be added to the closed template formularies when the net cost to clients exceeds the net cost of the reference brand drug or other alternatives in the same therapeutic class.

Question. Given the struggles we hear about patients accessing insulin, what measures are you taking to ensure that diabetes products and different types of insulin are placed on a preferred tier when establishing a formulary?

Answer. Although tier placement of particular products may vary by formulary, all of the CVS Caremark template formularies include at least one product of each type of insulin (rapid acting, short acting, intermediate acting, long acting and mixes) on a preferred tier. We also recognize that rising insulin prices are deeply concerning. Over the last 3 years, we've see the list price for insulin increase 47 percent. Our job as a PBM is to help blunt the impact of these prices increases for our clients. When possible we use competition in a drug category to help drive down costs.

We also offer a clinical program called Transform Diabetes Care that helps members better monitor and manage their diabetes between doctor's visits. The program has helped members achieve and maintain a 1-point improvement in A1C over 12 months. To put this result into perspective, every 1 percentage point improvement in A1C among patients with uncontrolled diabetes is estimated to save $1,400 per member per year in medical savings. Fifty percent of patients with uncontrolled diabetes in the program were moved to controlled status.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

TRANSPARENCY, REBATES, AND SPREAD PRICING

Question. During the hearing, I asked an initial question on spread pricing and wanted to follow up here. According to the Centers for Medicare and Medicaid Serv-

ices (CMS), total gross spending in 2017 on prescription drugs was $154.9 billion in Medicare Part D, $30.4 billion in Part B, and $67.6 billion in Medicaid.

One of the main challenges in lowering the price of prescription drugs is that there is a disturbing lack of transparency all along the supply chain, from research and development to what the patient is expected to pay at the counter. Further, the out-of-pocket costs for drugs varies greatly and unpredictably from patient to patient. That is why Senate Special Committee on Aging Chairwoman Collins and I introduced legislation that would codify the Drug Spending Dashboards at the CMS. The dashboards provide cost and spending information for drugs in the Medicaid, Medicare Part B, and Medicare Part D programs.[9] With regards to transparency in the prescription drug supply chain, please provide answers to the following questions.

Is it the policy and practice of your company to negotiate with drug manufacturers in good faith and obtain the best and lowest prices possible for patients and American taxpayers?

Answer. Yes. Part D is highly competitive and incentivizes Part D plans to get the best deals possible.

Question. Is it the policy and practice of your company that patients, providers, researchers, policymakers, and the American people in general, know how taxpayer dollars are being spent in the Medicare and Medicaid programs?

Answer. Both Medicare Part D and Medicaid require extensive reporting requirements that we comply with, that allow CMS to understand how the program is working. CVS Health supports legislation to give MedPAC and MACPAC access to appropriate data. Reporting to CMS and health plan clients in Part D is very granular as it is done at the NDC level.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by manufacturer list price?

Answer. No, but it is tracked and reported in aggregate to CMS for Part D plans.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by rebate paid by the manufacturer to you (the PBM)?

Answer. Yes, for Part D.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by the amount reimbursed to pharmacies by the PBM?

Answer. Yes, for Part D.

Question. Is it the policy and practice of your company to disclose how much a drug costs, broken down by the amount insured and uninsured patients pay out of pocket, before coupons, discounts, and other forms of patient assistance offered at the point of sale?

Answer. Yes, for Part D.

Question. If so, please provide useful and easily accessible links to where policymakers and the public can find such information. If not, please disclose how for each drug you work with clients to provide costs, broken down by manufacturer list price.

Answer. PBMs do not set the manufacturer list price. We negotiate with manufacturers only after they have set the price. PBM reimbursement to pharmacies is not based upon the manufacturer list price either.

Question. If so, please provide useful and easily accessible links to where policymakers and the public can find such information. If not, please disclose how for each drug you work with clients to provide costs, broken down by rebate paid by the manufacturer to you (the PBM); the amount reimbursed to pharmacies by the PBM; and the amount insured and uninsured patients pay out of pocket, before coupons, discounts, and other forms of patient assistance offered at the point of sale.

Answer. The information in the questions above is provided to CMS and health plans via the prescription drug events (PDE) reports and Direct and Indirect Remuneration (DIR) reports in Medicare Part D. These are reported retrospectively. The granular information is not available to the public; however, the public can and ex-

[9] S. 709, 116th Congres, Prescription Drug Pricing Dashboard Act. Online at: *https://www.congress.gov/bill/116th-congress/senate-bill/709?q=%7B%22search%22%3A%22drug+dashboard%22%7D&s=1&r=1.* Accessed April 23, 2019.

tensively does use the CMS Plan Finder tool. Plan finder details the members monthly out-of-pocket costs for the specific drugs the member takes by month. Plan finder pricing is updated every two weeks, so the public has access to current pricing data. Furthermore, members get monthly explanation of benefits statements detailing their out of pocket spending.

Coupons and patient assistance programs are generally not allowed in Medicare Part D. In any case, PBMs have no insight into those dollar flows as they are done at the pharmacy counter outside the claim's process. PBMs do not cover uninsured patients and do not have insight to their pharmacy costs.

Question. Please provide a list of actions your company has taken to ensure that pharmacists are enabled and allowed to communicate to patients how they can pay the lowest out-of-pocket cost possible for their prescription drugs.

Answer. CVS Caremark does not use so-called "gag clauses," and CVS Health supported Federal legislation to ban them.

PREPARED STATEMENT OF HON. RON WYDEN,
A U.S. SENATOR FROM OREGON

This morning, the Finance Committee continues our work on pharmaceutical price-gouging, which does enormous harm to consumers and taxpayers. There's a lot of work to do in the days ahead, but this committee has already put points on the board. Just last week, Congress passed our bipartisan legislation that stopped a blatant scheme big pharmaceutical companies had used to rip off Medicaid and taxpayers.

This morning, the committee is joined by executives from several pharmacy benefit managers. I see this hearing as a chance to examine one of the most gnarled, confounding riddles in American health care today. Pharmacy benefit managers are among the most profitable companies in the Nation. What PBMs do to earn all those profits is a mystery.

The deals they strike with drug makers and insurers are a mystery. How much they're pocketing out of the rebates they negotiate is a mystery. With Americans learning about schemes like "spread pricing" in Medicaid, whether PBMs bring any real value to taxpayers is a mystery.

PBMs are supposed to be negotiators who get better deals on prescription drugs for patients. What they are is middlemen who've raked in profits while drug prices have shot into the stratosphere. And as most people will tell you, there are already too many middlemen taking a cut in the American health-care system.

Let's run through a little history and some basic facts with PBM 101. PBMs first showed up decades ago, back when prescription drugs were becoming more common. They told insurers, "We're the ones who know drug pricing, so we'll handle the negotiations for you." But there is scant evidence PBMs have held drug prices down in a meaningful way. In fact, most of the evidence shows the opposite.

Pharmacy benefit managers make more money when they pick a higher-priced drug over a lower-priced drug. The logic on this issue isn't exactly graduate-level. PBM profits are based on taking their slice of the prescription drug pie. More expensive drugs mean there's a bigger pie. When there's a bigger pie, there's a bigger slice for PBMs.

Pharmacy benefit managers guard their operations with greater secrecy than HBO is guarding the ending of "Game of Thrones." There has never been more outrage in America over the rising costs of prescription drugs. If PBMs had clear, hard evidence proving that they're getting patients a better deal on prescription drugs, they'd be leafleting the countryside and shouting it from rooftops. Instead, they work overtime to keep patients and taxpayers in the dark.

Today the committee will be told a thousand different versions of the same talking point: "We're all about getting the best possible price for patients." But there won't be actual proof. Bottom line, PBMs are middlemen who strike deals with drug makers in secret. In my experience, that kind of negotiation rarely results in an act of charity for consumers.

Now, because of this committee's special jurisdiction, I want to look at a few specifics with respect to our Federal health-care programs.

First on Medicaid: a PBM scheme known as "spread pricing" to rip off taxpayers via Medicaid set off alarm bells in States nationwide. It's got nothing to do with the cost of cream cheese. Here's how it works. PBMs are paying one set price to pharmacies for a particular drug, but they're turning around and charging Medicaid and other health-care payers far more for that same prescription.

Chairman Grassley and I are digging into this. We've asked the Health Department Inspector General to take a hard look. If there are changes that can be made to clamp down on this exploitation of Medicaid, I hope the committee will consider them. In my view, it's as clear a middleman rip-off as you're going to find.

Now let's look at Medicare, where there are a few issues to examine. First, Part D is one of the few health benefits in America today that does not have an out-of-pocket cap. That means seniors with catastrophic illnesses could be facing costs of thousands and thousands of dollars. These are mostly people on fixed incomes, and growing old in America is already too expensive. This is a flaw that needs to be fixed, and I've proposed legislation to fix it.

Next, Medicare Part D encourages drug makers and PBMs to push seniors onto more expensive drugs. That's because, after a certain amount of spending on drugs, seniors and Medicare are on the hook for 85 percent of the costs. After that point, PBMs pay only 15 percent, and drug makers are off the hook entirely. So it's good business for the drug industry when seniors cross that threshold as fast as possible.

Second, rebates are working against the seniors who need the benefit most. Drug rebates in Part D get sent straight to insurance companies. In theory, they use the rebates to lower premiums, which sounds good if you're healthy. It's not such a great deal for seniors who are battling illnesses. The amounts they pay for their prescriptions are based on list prices, not on the prices factoring in rebates.

That's why I introduced the C–THRU Act, so that patients can finally see whether these rebates are worth that trade-off. If they aren't, C–THRU makes sure that the benefit of the rebate goes directly to seniors at the pharmacy window.

The administration has also proposed new rule changes having to do with this issue. I'm concerned its solution could produce a windfall for drug makers and that the administration is unprepared to take the next steps that rein in drug makers and bring down list prices.

Very briefly in closing, I want to thank Chairman Grassley for bringing this hearing together. I already mentioned the work he and I are doing with respect to Medicaid and so-called spread pricing. He and I are also working together to investigate the role PBMs played in sending insulin prices through the roof. We sent detailed letters to several of the witnesses here this morning. We're looking forward to seeing their responses and the associated documents. And I'm also looking forward to Q&A today.

Member Name: DOB: PA Number:

CVS caremark™

Repatha
Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of thr prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-866-249-6155.** If you have questions regarding the prior authorization, please contact CVS Caremark at 1-866-814-5506. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

PATIENT INFORMATION
Date:
Name:
ID: **********
Date of Birth:
Request Initiated For: REPATHA

PRESCRIBER INFORMATION
Name:
Office Telephone:
Office Fax:
Specialty: _____
NPI#: _____

CRITERIA QUESTIONS

1. What is the patient's diagnosis? _____
2. What is the ICD-10 code? _____
3. The preferred Repatha product for your patient's health plan are the products whose NDC starts with 555. *The products whose NDC starts with 725 are not available. Please note that the two products are the exact same and are made in the same manufacturing facility but have different NDCs.* Can the patient's treatment by switched to the other formulation of Repatha? ***If Yes, fax a new prescription to the pharmacy and skip to #5.***
   ☐Yes ☐No - Continue request for Repatha (NDC: 725)
   ☐Not applicable - Repatha (NDC: 555) is being prescribed, *skip to #5*
4. Given that the two Repatha products are the same, is there a documented clinical reason that the patient must use one over the other? ***ACTION REQUIRED: If Yes, attach supporting chart note(s).*** ☐Yes ☐No
5. Is this a request for a continuation of therapy? *If Yes, no further questions.* ☐Yes ☐No
6. Does the patient meet all of the following? *If Yes, no further questions.* ☐Yes ☐No
   a. The patient has a prior history of clinical atherosclerotic cardiovascular disease (ASCVD) or has experienced a cardiovascular event
   b. The patient has an LDL-C level of greater than or equal to 70 mg/dL
   c. The patient is receiving maximally tolerated statin therapy or is statin intolerant
7. Does the patient meet all of the following? ☐Yes ☐No
   a. The patient has an untreated (before any lipid-lowering therapy) LDL-C level greater than or equal to 190 mg/dL
   b. The patient has a treated LDL-C level of greater than or equal to 100 mg/dL
   c. The patient is receiving maximally tolerated statin therapy or is statin intolerant

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X_____
Prescriber or Authorized Signature **Date (mm/dd/yy)**

Send completed form to: Case Review Unit, CVS Caremark Prior Authorization Fax: 1-866-249-6155

CVS Caremark Prior Authorization • 2211 Sanders Road NBT-6 • Northbrook, IL 60062
Phone: 1-866-814-5506 • Fax: 1-866-249-6155 • www.caremark.com

From *FiercePharma*

UNITEDHEALTHCARE DEMANDS DRUG REBATES EVEN IF PHARMA CUTS LIST PRICES: ANALYST

By Eric Sagonowsky

February 11, 2019

If drugmakers think they can save on rebates if they cut list prices as politicians and public opinion are demanding—well, forget it, says UnitedHealthcare, which sent new demands to pharma companies, an analyst wrote.

The insurance and pharmacy benefits giant is demanding long notices ahead of any drug price cuts, according to the letter, which two drugmakers confirmed to Bernstein analyst Ronny Gal. And UnitedHealthcare expects equivalent rebates whenever list prices are cut, the analyst wrote in a Friday note to investors.

The news comes as drug companies look to price reductions as a new strategy to fight high rebates and gain goodwill with lawmakers and the Trump administration. On Monday, Sanofi announced that it is cutting its Praluent price by 60%, following Amgen's move to chop Repatha's list price by the same percentage. The PCSK9 cholesterol drugs are among many that have a large "gross-to-net" price gap, or high list prices—and high rebates and discounts paid out to the supply chain.

Lowering list prices means smaller costs for patients, but the strategy would also mean lower revenues for PBMs.

UnitedHealthcare asked for seven quarters' notice—a full 21 months—when companies intend to lower prices, Gal wrote. The "drug companies are not too happy about" the UnitedHealthcare letter, he added, as many are considering price reductions.

Gal published another note Monday with UnitedHealthcare's response. The insurance giant's investor relations team reached out to the analyst and said they believed the original report on the letter was misleading. For one, UnitedHealthcare's OptumRx sent the letters in late December and early January, before the administration's recent rebate proposal, Gal wrote, adding that they relate only to rebates in Medicare Part D.

The company explained that Part D contracts "are done on an annual basis and must be submitted to CMS six months ahead of coming into effect," Gal wrote. UnitedHealthcare needs the time to calculate drug cost structures, Gal wrote, summarizing the discussion. And on maintaining rebates, UnitedHealthcare told the analyst patient premiums would rise with lower rebates.

An OptumRx spokesman told FiercePharma the company in April 2018 "led the way in providing prescription drug discounts at the point of sale for millions of consumers and OptumRx negotiates with pharmaceutical manufacturers every day to reduce the prices they charge, including list prices."

"Our goal in asking for advance notice of price changes in the lengthy Part D bid process is to achieve greater transparency and predictability in consumer premiums and out-of-pocket costs," he said. Plus, the company "passes the vast majority of Medicare Part D rebates back to health plans, so our negotiations regarding rebates have virtually no impact on our bottom line."

Drug rebates and high list prices have come under growing fire, and the Trump administration recently unveiled a plan to shake up pricing in Medicare Part D and Medicaid. The plan involves outlawing rebates and instead allowing discounts for patients and fee-for-service deals for PBMs. The PBM industry pushed back, but pharma companies support the idea. Quickly after rolling out the plan, HHS secretary Alex Azar called on Congress to extend the proposal to commercial markets.

The letters have not been made public; Gal wrote that he heard of its existence through conversations with pharma executives.

The new Trump plan is only one out of many in a heated debate over pricing in recent years. Last week, five pharma CEOs and a top executive at Johnson & Johnson agreed to testify at an upcoming Senate committee hearing on drug prices.

Meanwhile, at least one drugmaker is taking a different tack to lower costs for patients. Gilead Sciences, facing huge rebates in hepatitis C, previously unveiled a plan to launch authorized generics to its big-selling drugs Epclusa and Harvoni, rather than cut list prices.

COMMUNICATIONS

AMERICAN PHARMACISTS ASSOCIATION

Chairman Grassley, Ranking Member Wyden, and Members of the Committee, the American Pharmacists Association (APhA) is pleased to submit the following Statement for the Record for the U.S. Senate Finance Committee Hearing "Drug Pricing in America: A Prescription for Change, Part III."

APhA, founded in 1852 as the American Pharmaceutical Association, represents nearly 60,000 pharmacists, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in improving medication use and advancing patient care. APhA members provide care in all practice settings, including community pharmacies, physicians' offices, hospitals, long-term care facilities, specialty pharmacy, community health centers, managed care organizations, hospice settings and the uniformed services.

Both Congress and the Administration have pointed out ongoing pharmaceutical benefit manager (PBM) practices in the Medicare program negatively impacting patient costs, care and access. Additional proposals from the Administration have emphasized PBMs operate in a consolidated, opaque space and pose a barrier to pharmaceutical companies lowering their prices [1] and spend a significant amount of effort trying to rectify the negative impact certain PBM practices have had on patients and pharmacies.

Build Off a Good Start

APhA appreciates the strong bipartisan support of the Committee for recent legislation signed into law that prohibits PBMs' use of so-called pharmacist "gag clauses" in Medicare and private health plans, to support the flow of information between pharmacists and their patients. These laws increase patients' access to more affordable and cost-effective medicines by empowering pharmacists to inform patients that a medication may be less expensive if purchased at the "cash price," rather than through their insurance plan. For years, pharmacists have been frustrated by their inability to help their patients who they knew were struggling with high copayments. APhA also looks forward to working with the Committee to lower patients' out-of-pocket costs.

Similarly, APhA hopes the Committee will build off these bipartisan results to pass legislation prohibiting Medicare Part D plan sponsors/PBMs from retroactively reducing payment on clean claims submitted by pharmacies which would, in turn, increase transparency in drug pricing, decrease beneficiaries' out-of-pocket costs and Medicare catastrophic coverage costs.

Address Retroactive DIR Fees

In 2018, APhA's House of Delegates passed a resolution stating "APhA opposes retroactive direct and indirect remuneration (DIR) fees and supports initiatives to prohibit such fees on pharmacies."[2] APhA has long had policy supporting the pharmaceutical industry's adoption of a "transparent pricing" system which would eliminate

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[1] HHS. American Patients First—The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs. May 2018, available at: *https://www.hhs.gov/sites/default/files/AmericanPatientsFirst.pdf.*

[2] APhA. House of Delegates. Current Adopted Policy Statements 1963–2018. (JAPhA 58(4):356 July/August 2018). Pg. 115. Available at: *https://media.pharmacist.com/hod/APhA_Policy_and_Procedures_2018.pdf.*

hidden discounts, free goods, and other subtle economic devices,[3] like rebates between manufacturers and PBMs. As recognized by the Centers for Medicare and Medicaid Services (CMS), certain PBM practices, can result in higher prices at point-of-sale and consequently, higher beneficiary copays. DIR fees were originally designed to capture rebates and other mechanisms not included at the point-of-sale. However, DIR fees by PBMs are now being used beyond their original purpose to retroactively adjust pharmacies' payment months after the sale, sometimes below the price paid by the pharmacy. As stated by CMS in the November 2017 proposed Medicare Part D rule, "[b]etween 2010 and 2015, the amount of all forms of price concessions received by Part D sponsors and their PBMs increased nearly 24 percent per year, about twice as fast as total Part D gross drug costs, according to the cost and price concession data Part D sponsors submitted to CMS for payment purposes."[4]

Retroactive DIR Fees Increase Costs for Pharmacies and Patients

There is simply no connection between price concessions given by manufacturers to PBMs and the prices paid by pharmacies to their wholesalers. Thus, DIR fees "recovered" from pharmacies by PBMs are totally illogical (*i.e.,* recovering money from pharmacies that pharmacies did not "receive" in the first place). Because current point-of-sale prices or copays paid by beneficiaries can be based on the contracted price before DIR is extracted, many beneficiaries actually pay higher out-of-pocket costs. CMS has cited numerous research that further suggest higher cost sharing can impede beneficiary access to necessary medications, which leads to poorer health outcomes and higher medical care costs for beneficiaries and Medicare. Therefore, APhA strongly urges the Committee to prohibit PBMs' use of such fees as part of their payment methodology for pharmacies.

Retroactive DIR Fees Increase Medicare Catastrophic Coverage Costs

As you know, Medicare-enrolled seniors pay pharmacies a copay for medications, while the full price of the drug is credited against the patient's coverage limit. The PBM administering Medicare's prescription benefit decides to use retroactive DIR fees to take back a portion of the pharmacy's reimbursement for the actual costs of the patient's medication, often causing pharmacies to ultimately dispense a medication below cost, which jeopardizes maintenance of patient access. In addition, the original higher price—not the DIR adjusted price—is still counted against the patient, pushing them more quickly into Medicare's "doughnut hole" coverage gap in which they become responsible for a much greater portion of their prescription costs. Even after the coverage gap closes in 2020, the use of DIR fees significantly increases costs as these patients enter Medicare's catastrophic coverage phase, in which taxpayers are now on the hook for 80% of each patient's health care expenses.

Focus on Patient Care Services: Pharmacists Stand Ready to Help

APhA continues to remind HHS when developing mechanisms to lower drug costs to separately consider the reimbursement of the product cost, which is fixed for pharmacists, from the cost of dispensing and any related patient care service or performance incentive payment to provide adequate reimbursement under a business sustainable model that improves and does not disrupt our nation's pharmacy distribution system. Unfortunately, the current system still fails to provide a specific payment incentive for pharmacies to provide needed patient care services. A situation the Committee could remedy by passing legislation enabling beneficiaries to access pharmacist-provided patient care services under Medicare Part B. Last year, 56 Senators signed onto S. 109, the *Pharmacy and Medically Underserved Areas Enhancement,* a bill that enjoyed the support of many members of the Finance Committee. Such legislation would help improve health outcomes, increase quality, reduce costs and consequently, increase the viability and longevity of the Medicare program. In addition, this legislation aligns with team-based and cost effective health care by facilitating opportunities for early intervention so as to minimize long term health care costs, such as those associated with preventable higher-cost conditions. Providing coverage for patient care services by pharmacists, the medication

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[3] APhA. House of Delegates. Current Adopted Policy Statements 1963–2018 (JAPhA NS8:362 July 1968) (JAPhA NS44(5):551 September/October 2004) (Reviewed 2006) (Reviewed 2011) (Reviewed 2016). Pg. 31. Available at: *https://www.pharmacist.com/sites/default/files/files/16898%20CURRENT%20ADOPTED%20POLICY%20MANUAL%20-%20FINAL.pdf.*

[4] CMS. Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program. Proposed Rule. November 28, 2017. Available at: *https://www.federalregister.gov/documents/2017/11/28/2017-25068/medicare-program-contract-year-2019-policy-and-technical-changes-to-the-medicare-advantage-medicare.*

expert on the health care team, would be a major step forward in making sure medications are appropriate and taken/ used correctly which would begin to address the $672 billion spent annually on medication-related problems and nonoptimized medication therapy, including nonadherence,[5] and maximize the federal government's significant investment in Medicare patients' medications.

APhA would like to thank the Committee for continuing to work with us and other pharmacy stakeholders to increase transparency of PBM practices for pharmacies and patients. We appreciate your ongoing leadership addressing the barriers to innovation which continue to increase America's rising health care costs. Please contact Alicia Kerry J. Mica, Senior Lobbyist, at AMica@aphanet.org or by phone to (202) 429–7507 to arrange a meeting with us to discuss the many services pharmacists provide to improve patient care, outcomes and reduce costs.

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April 9, 2019

The Honorable Chuck Grassley
Chair
U.S. Senate
Committee on Finance
Washington, DC 20510

The Honorable Ron Wyden
Ranking Member
U.S. Senate
Committee on Finance
Washington, DC 20510

Dear Chairman Grassley and Ranking Member Wyden,

The American Society of Clinical Oncology (ASCO) appreciates the committee's ongoing efforts to examine prescription drug pricing and consider solutions to lower costs for patients. ASCO shares your concern about the rising cost of prescription drugs and stands ready to work with you on real solutions that address the affordability of cancer drugs.

ASCO is the national organization representing more than 45,000 physicians and other health care professionals specializing in cancer treatment, diagnosis, and prevention. We are committed to ensuring that evidence-based practices for the treatment of cancer are available to all Americans.

As the committee continues its "Drug Pricing in America: A Prescription for Change" series of hearings with today's hearing focused on pharmacy benefit managers (PBMs), ASCO offers for your review the "ASCO Position Statement: Pharmacy Benefit Managers and Their Impact on Cancer Care."

We hear serious concerns from our members about the negative effects of certain PBM practices on patients and the cancer care system. These include errors in filling prescriptions, treatment doses being altered without consultation with oncology care providers, duplicate patient copays due to incomplete dispensing, and drug waste resulting from incorrect doses or treatments being sent directly to a patient's home. ASCO members also express frustration with utilization management techniques used by PBMs, especially prior authorization and step therapy. ASCO's "Policy Statement on the Impact of Utilization Management Policies for Cancer Drug Therapies" goes into further detail on ASCO's recommendations around prior authorization and step therapy.

If you have questions on any issue involving the care of individuals with cancer or would like to be directed to ASCO's thoughts on a specific issue related to drug pricing, please contact Jennifer Brunelle at Jennifer.brunelle@asco.org.

Sincerely,

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[5] Watanabe , Jonathan H. et al. Cost of Prescription Drug-Related Morbidity and Mortality. Annals of Pharmacology. First published March 26, 2018. Available at: *http://journals.sagepub.com/eprint/ic2iH2maTdI5zfN5iUay/full.*

Monica M. Bertagnolli, M.D., FACS, FASCO
President, American Society of Clinical Oncology

American Society of Clinical Oncology Position Statement: Pharmacy Benefit Managers and Their Impact on Cancer Care

Introduction

Cancer drugs are a critical component of treatment for many cancer types as well as for the prevention and control of symptoms. They also represent an increasing component of cancer care cost. Prescription drugs now account for 10% to 17% of national healthcare spending.[1, 2] Spending on cancer drugs in the United States has increased substantially over the last 5 years, from $28 billion in 2013 to $51 billion in 2017, and is expected to continue this upward trend.[3] The arrival of new, more expensive prescription drugs has contributed to this increase, a trend that is likely to continue. ASCO has weighed in on the rising cost of cancer care several times, including position statements on the affordability of cancer drugs and utilization management.[4, 5]

With cancer care costs rising, new strategies have emerged in the public and private sectors to curb spending while also aiming to preserve and improve quality. One such strategy is utilization of pharmacy benefit manager companies (PBMs), third-party administrators of prescription drug programs used by a variety of sponsors including commercial health plans, self-insured employer plans, Medicare Part D plans, the Federal Employees Health Benefits Program, and others. The PBM industry has grown exponentially since its inception in the 1980s and has become highly concentrated. The three largest PBMs (Express Scripts, OptumRx, and CVS Caremark) collect more than $200 billion a year to manage prescription services for 266 million Americans in both public and private plans. They cover 85% of the market.[6] Additionally, each of these PBMs own a specialty pharmacy company.

PBMs were originally created to serve as third-party administrators of pharmacy claims, but now leverage their market power to obtain lower prices on drugs. Employers and other plan sponsors also use PBMs to outsource the complicated work of designing and maintaining formularies to those with more specialized expertise. Although PBMs have the potential to generate cost savings for payers and plan sponsors, it is not clear those savings necessarily accrue to patients.[7] Stakeholders have been challenged in achieving detailed understanding of this issue because of the proprietary and confidential environment in which PBMs operate.[8]

ASCO members and others in the oncology community have also shared experiences and voiced concerns about a potentially negative role PBMs can have on patient care. Members of ASCO's State Affiliate Council and other ASCO members have expressed concern that, while employing certain cost containing practices, PBMs may in some cases be interfering with the doctor-patient relationship and lowering the quality of care.

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[1] Sood N, Shih T, Van Nuys K, Goldman D. The Flow of Money Through the Pharmaceutical Distribution System. USC Shaeffer—Leanord D. Schaeffer Center for Health Policy and Economics. June 2017, *http://healthpolicy.usc.edu/documents/USC%20Schaeffer_Flow%20of%20Money_2017.pdf.*

[2] National Academy of Sciences, Engineering and Medicine. 2017. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press, *https://doi.org/10.17226/24946.*

[3] IMS Institute for Healthcare Informatics. Medicines Use and Spending in the U.S. April 2018, *https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf.*

[4] American Society of Clinical Oncology. American Society of Clinical Oncology position statement on addressing the affordability of cancer drugs. J Oncol Pract 14(3): 187–192, 2017.

[5] American Society of Clinical Oncology. American Society of Clinical Oncology policy statement on the impact of utilization management policies for cancer drug therapies. J Oncol Pract 13:758–762, 2017.

[6] National Academy of Sciences, Engineering and Medicine. 2017. Making Medicines Affordable: A National Imperative. Washington, DC: The National Academies Press. Available at *https://doi.org/10.17226/24946.*

[7] Robert Goldberg. Drug Costs Driven by Rebates. Center for Medicine in the Public Interest, *http://bionj.org/wp-content/uploads/2015/11/drug-costs-driven-by-rebates.pdf.*

[8] Centers for Medicare and Medicaid Services. Medicare Part D—Direct and Indirect Remuneration (DIR). 2017, *https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html.*

As the leading organization for physicians and oncology professionals caring for people with cancer, ASCO is committed to promoting access to high quality, high value cancer care. Given the enormous leverage PBMs have over the delivery of cancer care—and in view of concerns raised by leaders of state hematology oncology societies across the country—the ASCO Board of Directors has placed a priority on understanding and addressing the role of PBMs in oncology and its effect on patient care.

The purpose of this ASCO Position Statement is to provide a summary of issues our members have raised about the role of PBMs in oncology, to share questions that have surfaced about PBM practices and their impact on physicians and patients, to assert ASCO's immediate position on key issues, and to highlight areas of concern the Society plans to explore more deeply as part of a focused policy effort.

The recommendations put forth in this statement are as follows:

- PBMs and the payers with whom they work for should take immediate steps to address quality of care concerns related to the cancer patients they serve, including assuring that changes to prescribed therapy for patients with cancer are made only in the context of prior consultation and approval of their physician.
- Pharmacies should not be prevented from sharing with patients their most cost-effective option for purchasing needed medications (*i.e.,* gag clauses). To this end, CMS should eliminate contractual requirements that prevent pharmacists from sharing with patients their most cost-effective option for purchasing required medications.
- CMS should leverage its regulatory authority to: (1) require that PBMs provide detailed accounting of DIR fees, and (2) instruct contractors and PBMs to discontinue application of current Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies, instead relying on measures and standards that are more appropriate to the specialty.
- CMS should enforce its "Any Willing Provider" provision in Medicare Part D, preventing PBMs from excluding qualified in-office dispensing or provider led pharmacies from its networks.
- CMS should consider extending use of the JW modifier to better identify sources and cost of waste related to chemotherapy drugs in both Part B and Part D. Such data should be made public. Private payers should consider similar strategies.
- Pharmacy and Therapeutics committees should include full and meaningful participation by oncology specialists.

PBMs and Cancer Care: Overview of the Issues

PBMs are responsible for developing and managing prescription drug benefits in the public and private insurance sectors. Their role includes processing prescription drug claims and negotiating contracts with pharmacies and pharmaceutical manufacturers. The expansion of prescription drug benefits, particularly with implementation of Medicare Part D, has created a higher demand for management and administration of prescription drugs for health plans, employers, and government entities (referred to in this statement collectively as "plan sponsors"). PBMs also own and operate specialty and mail-order pharmacies.

Because PBMs now participate in plans that cover so many lives, they naturally have significant influence over the way patients access their medications.[9] Recently two major PBMs announced plans to merge with large insurers. Pending approval by the federal government, CVS Health is set to acquire Aetna Inc. and Cigna is set to acquire Express Scripts. If approved, this will lead to greater market integration and an ever-increasing role of PBMs.

As for-profit companies, PBMs generate revenue in various ways from pharmaceutical manufacturers, pharmacies and plan sponsors. PBMs obtain revenue from pharmaceutical manufacturers in the form of rebate payments for "preferred" formulary status, which results in increased market-share by encouraging utilization of the drugs chosen.

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[9] PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues. Prepared by Frier Levitt, LLC. Commissioned by the Community Oncology Alliance. January 2017.

Negotiated contracts defining reimbursement to pharmacy network providers (including chain and community pharmacies, physician dispensers and physician practices with on-site pharmacies) also serve as a source of revenue for PBMs. The "spread" or price difference generated by what is charged to plan sponsors and reimbursed to pharmacies for the same prescription has resulted in significant revenue for PBMs.

From plan sponsors, PBMs generate revenue through contracts for administration of prescription drug benefits within the health plans. PBMs charge administration and service fees to plan sponsors for processing prescriptions, creating and managing formularies, and processing claims. These are often managed separately from the rest of an employer's health plan.

PBMs assert there is no link between drug price growth and the rebates they are receiving.[10] The lack of transparency around rebate arrangements prevents verification of such claims. Regardless, the impact of PBMs on oncology care providers and patient quality of care is increasingly apparent. The American Medical Association (AMA) has adopted Resolution 225–A–18 which asks the AMA to assess the impact PBMs have on patient's timely access to medications, patient outcomes, and the "erosion of physician-led medication therapy management."[11]

The Role of PBMs in Utilization Management

As PBMs have grown, so have their restrictions and requirements on pharmacies, providers and patients. ASCO previously identified concerns about certain utilization management practices, the burden they often represent to both physicians and patients, and their potential to erode access and quality of care.These include: (i) prior authorization requirements, (ii) restrictive formularies, (iii) step therapy (fail-first) requirements, and (iv) specialty tiers.[12] While PBMs are more of an intermediary or agent for payers, ASCO's concerns about—and opposition to—certain utilization management practices also apply to PBMs that employ these same policies. ASCO members have reported that some patients have had their medication or dosage changed by PBMs without prior approval by—or consultation with—the treating physician. They have also reported increasing administrative burdens that require additional staff and resources—solely to navigate prior authorization requirements and patient financial assistance programs. The issue has drawn attention across the medical community: the American Medical Association (AMA) has identified this as a priority and has issued prior authorization and utilization management principles, which broadly align with ASCO's recommendations.[13]

Restricted Networks and Distribution

ASCO has previously stated its concerns about payer policies that require oncologists to administer chemotherapy agents that have been prepared outside the physician's office by an entity under contract with the payer (so called "brown bagging" and "white bagging").[14] "Brown bagging" refers to arrangements in which the drug is purchased through a specialty pharmacy and shipped directly to the patient; the patient then takes the drug to the physician's office for administration. "White bagging" refers to arrangements in which the drug is purchased through a specialty pharmacy and shipped to the provider's office for administration. "Brown bagging" is especially concerning, as there is little control over how hazardous or unstable medications are stored and handled prior to administration in the physician's office. Concerns about "white bagging" and "brown bagging" carry the same concerns about medication access and quality whether they are used by payers or PBMs.

As well, PBMs increasingly are shifting drug dispensing away from physicians and toward pharmacies they own or with which they are affiliated, which can negatively

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[10] Pharmaceutical Care Management Association. No Correlation Between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories, *https://www.pcmanet.org/wp-content/uploads/2017/04/Visante-Study-on-Prices-vs.-Rebates-By-Category-FINAL-3.pdf*.

[11] American Medical Association. House of Delegates Resolution 225–A–18, *https://policysearch.ama-assn.org/policyfinder/detail/pharmacy%20benefit%20manager?uri=%2FAMADoc%2Fdirectives.xml-D-120.933.xml*

[12] American Society of Clinical Oncology. American Society of Clinical Oncology policy statement on the impact of utilization management policies for cancer drug therapies. J Oncol Pract 13:758–762, 2017.

[13] American Medical Association. 2016. Prior Authorization and Utilization Management Reform Principles, *https://www.ama-assn.org/sites/default/files/media-browser/principles-with-signatory-page-for-slsc.pdf*.

[14] American Society of Clinical Oncology. "Brown Bagging" and "White Bagging" of Chemotherapy Drugs. 2016, *https://www.asco.org/sites/new-www.asco.org/files/content-files/advocacy-and-policy/documents/2016-ASCO-Brown-Bagging-White-Bagging-Brief.pdf*.

impact patient care and access.[15] PBMs actively incentivize—and in some cases require—patients to use mail order or specialty pharmacies in lieu of a dispensing physician. Such actions are problematic, as it means PBMs are both competing and determining reimbursement rates for pharmacists.[16] Certain states do not allow in-office dispensing or provider-led pharmacies, and such arrangements may not be appropriate in every practice setting. However, some studies have suggested that practices with medically integrated services may improve patient adherence to treatment regimens.[17]

Rebates and Discounts

The lack of transparency in which PBMs operate has caught the attention of many stakeholders in the healthcare community, including plan sponsors who are employers. The National Pharmaceutical Council (NPC) has affirmed that employers are increasingly concerned with pharmacy benefit transparency, complexity, and rebates. A recent NPC survey revealed that a large percentage of employers agree PBMs lack transparency and are overly complicated. Skepticism about the role of rebates in achieving an "aligned and effective health care supply chain" has also been expressed. More than 69% of large employer's surveyed report their organizations would welcome an alternative to rebate-driven approaches to managing pharmacy benefit costs.[18]

Numerous states have passed bills requiring greater transparency from PBMs, including Maximum Allowable Cost (MAC) list mandates and more. Scarce information is available about the size and frequency of rebates PBMs receive from manufacturers, nor is it understood the extent to which patients experience actual benefits of these rebates and discounts.

At the federal level, several legislative proposals call for greater transparency.[19, 20] The 2018 HHS Blueprint for American Patients First also addresses PBM transparency.[21] The Blueprint requests comments on different approaches to learning more about the complex financial dealings of the pharmaceutical industry-at-large. In addition to elimination of gag clauses, it also suggests modification of the Anti-Kickback Statute (AKS) Safe Harbor that allows for rebates.

Gag Clauses

According to the National Conference of State Legislatures, at least 26 states have passed legislation that would prohibit a practice known as a "gag clause" on pharmacists.[22] Gag clauses, increasingly used by PBMs, are contractual requirements that bar a pharmacist from informing patients about lower-cost drug options. These options could include simply purchasing the drug for cash, rather than using insurance. In these circumstances, patients could pay cash at the pharmacy, rather than go through their insurance coverage, thereby avoiding costs that may be solely due to the PBM payment structure. CMS recently issued a letter to Part D plan administrators, reminding them that such clauses are considered "unacceptable."[23] Pa-

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[15] Pharmacy Benefit Managers' Attack on Physician Dispensing and Impact on Patient Care: Case Study of CVS Caremark's Efforts to Restrict Access to Cancer Care Prepared by Frier Levitt, LLC Commissioned by the Community Oncology Alliance. August 2016, *https://www.communityoncology.org/wp-content/uploads/2016/08/PBMs_Physician_Dispensing-White Paper_COA FL.pdf.*

[16] National Community Pharmacists Association. Letter to Senate Judiciary Committee. April 4, 2018, *https://www.ncpanet.org/newsroom/news-releases/2018/04/09/pharmacy-associations-urge-senate-judiciary-committee-to-hold-hearing-on-pbms.*

[17] Egerton, Nancy. In-Office Dispensing of Oral Oncolytics: A Continuity of Care and Cost Mitigation Model for Cancer Patients. American Journal of Managed Care, 22, 4.

[18] National Pharmaceutical Council. Toward Better Value: Employer perspectives on what's wrong with the management of prescription drug benefits and how to fix it. 2017, *http://www.npcnow.org/system/files/research/download/npc-employer-pbm-survey-final.pdf.*

[19] Senate Bill 413/H.R. 1038, Improving Transparency and Accuracy in Medicare Part D Spending Act, *https://www.congress.gov/bill/115th-congress/senate-bill/413.*

[20] House Resolution 1316, Prescription Drug Price Transparency Act, *https://www.congress.gov/bill/115th-congress/house-bill/1316.*

[21] U.S. Department of Health and Human Services. 2018. American Patients First Blueprint, *https://www.hhs.gov/about/news/2018/05/11/trump-administration-releases-blueprint-lower-drug-prices-and-reduce-out-pocket-costs.html.*

[22] National Conference of State Legislatures. Prohibiting PBM "Gag Clauses" that Restrict Pharmacists from Disclosing Price Options: Recent State Legislation 2016–2018, *http://www.ncsl.org/Portals/1/Documents/Health/Pharmacist_Gag_clauses-2018-14523.pdf*

[23] Centers for Medicare and Medicaid Services. CMS Sends Clear Message to Plans: Stop Hiding Information from Patients. May 17, 2018, *https://www.cms.gov/Newsroom/MediaRelease Database/Press-releases/2018-Press-releases-items/2018-05-17.html.*

tients with insurance coverage are still challenged by high copays for prescriptions and out-of-pocket deductibles. Pharmacies should not be prevented from sharing with patients their most cost-effective option for purchasing needed medications (*i.e.,* gag clauses).

Direct and Indirect Remuneration Fees

As a means of setting drug reimbursement at the lowest price, CMS implemented direct and indirect remuneration (DIR) fees, which are intended to determine actual net cost of drugs covered under Part D. DIR fees were initially authorized as part of the Medicare Modernization Act of 2003. CMS defines DIR as additional compensation received after the point-of-sale that serves to change the final cost of the drug for the payer, or the price paid to the pharmacy for the drug.[24] Through DIR fees, plan sponsors and PBMs are required to report all "direct" and "indirect" remuneration received from third-parties, including drug manufacturers.[25] Because manufacturer rebates paid to PBMs are not known until a prescription has been dispensed to the patient and a claim processed at the point-of-sale, such remuneration is calculated and reconciled *after* Medicare pays the PBM. In this way, CMS ensures that taxpayers are only paying PBMs what the drugs ultimately cost. However, it can also mean that dispensing pharmacies discover—after reconciliation—they owe additional money to the PBM.

A 2017 CMS report found that DIR fees used by PBMs do not decrease point-of-sale cost for patients and can, in fact, increase patient out-of-pocket costs. Patients incur cost-sharing based on the price at their pharmacy, rather than the final, post-DIR reconciled price paid by CMS to the PBM. This can push a patient more rapidly into the "donut hole" where they have higher out-of-pocket costs. At the same time, DIR fees can reduce patient premiums and some government costs by shifting costs to the catastrophic phase of the benefit.[26] CMS has proposed several ways to improve the administration of DIR fees in the Medicare program, but has yet to implement significant changes.

Recently, PBMs have created a separate—and additional—DIR fee structure, known among pharmacists and physicians with in-office dispensing and pharmacies as "claw backs." This involves retroactive collection of fees by PBMs, the amounts of which are based on physicians' and pharmacists' performance according to certain metrics. PBMs justify imposition of these performance-based DIR fees by referencing CMS' Star Rating System. The Star Rating System is used by CMS in Medicare Advantage and Medicare Part D to measure performance on plans covering drug services. The Star Rating System measures relate largely to medication adherence for conditions such as diabetes, hypertension, and cholesterol; and was designed to apply to Part D plan sponsors, not pharmacies. No such measures exist for medication management in oncology.[27]

Despite lacking oncology measures and its misapplication on pharmacies instead of plan sponsors, these fees are nevertheless charged directly to oncology pharmacy providers, who assert this is done in a way that that lacks transparency and is highly profitable for PBMs. These performance-based fees are not required by HHS or CMS regulations, and appear to have no basis in statute.[28]

Addressing Key Concerns: Transparency, Drug Waste, and Benefit Design

Key concerns that impact ASCO members and their patients with cancer fall primarily into four categories:

- Quality and access to care.
- Transparency of PBM operations and pricing.
- Impact on drug waste and/or cost.
- Benefit design.

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[24] Medicare Modernization Act of 2003. 42 CFR 423.308.

[25] Centers for Medicare and Medicaid Services. Medicare Part D—Direct and Indirect Remuneration (DIR). 2017, *https://www.cms.gov/newsroom/mediareleasedatabase/fact-sheets/2017-fact-sheet-items/2017-01-19-2.html.*

[26] Centers for Medicare and Medicaid Services. Medicare Part D—Direct and Indirect Remuneration (DIR). 2017, *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2017-Fact-Sheet-items/2017-01-19-2.html.*

[27] Centers for Medicare and Medicaid Services. 2018 Part C and D Star Ratings Measures, *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovGenin/Downloads/2018MeasureList.pdf.*

[28] PBM DIR Fees Costing Medicare and Beneficiaries: Investigative White Paper on Background, Cost Impact, and Legal Issues. Prepared by Frier Levitt, LLC. Commissioned by the Community Oncology Alliance. January 2017.

Quality and Access to Care

ASCO members have expressed several concerns about PBMs and their impact on care. These include mistakes in filling prescriptions, altering treatment dosages for patients without consulting their oncology care provider, incomplete dispensing resulting in duplicate patient copays, and delays in treatment related to prior authorization demands and other problems.

Many of the practices employed by PBMs are utilization management strategies. ASCO has previously asserted its position against policies that attempt to incentivize, force, or coerce patients to accept anti-cancer therapy alternatives that are not recommended by their oncologist. Such practices can threaten both the outcomes for patients and the well-being of their families or care takers. Utilization management processes—whether directed by a health plan or PBM—should result in timely and clear determinations that are consistent with the health insurer's coverage and other policies; decisions should reflect evidence-based practice; and payers should implement utilization management policies in a way that minimizes administrative burdens on both providers and patients.[29] Public and private payers should take immediate steps to assure that changes to prescribed therapy for patients with cancer are made only in the context of prior consultation and approval by their physician.

Timely access to therapies may be harmed by PBM-imposed network restrictions. Some PBMs require that patients use only their proprietary specialty pharmacy for certain drugs, despite the possibility that the patient could access the drug more cheaply and quickly from a different pharmacy. It is not uncommon that PBMs allow the first fill of an oral oncology drug to be carried out at the local or practice pharmacy. Thereafter, all other prescription refills are often required to go through the PBM-associated specialty pharmacy. Because the largest administrative burden and staff time commitment are attached to the first prescription—which includes preauthorization, peer-to-peer review, patient education, enrollment into copay assistance, and seeking foundation support to fill the financial gap—this puts the PBM-associated specialty pharmacy at an unfair advantage. ASCO is opposed to requirements that limit patients to exclusive use of PBM-owned or affiliated pharmacies.

Additionally, PBM accreditation standards required for participating pharmacies are costly and do not have relevance for oncology care. They often are applied in a manner that inappropriately limits the dispensing of specialty drugs. CMS has stated that it has received complaints from pharmacies that Part D plan sponsors have begun to require accreditation of pharmacies, including accreditation by multiple organizations or additional Part D plan-/PBM-specific credentialing criteria for network participation. In a final rule, CMS clearly stated that it does not support the use of a PBM-specific credentialing criteria that inappropriately limits dispensing of specialty drugs to certain pharmacies.[30]

Some oncology practices that provide in-office dispensing have been excluded from PBM networks entirely, despite Medicare's Any Willing Provider (AWP) requirements. CMS has received many complaints from pharmacies expressing concern with the process PBMs have adopted for complying with the AWP requirements. To address these concerns, CMS issued a final rule clarifying that Part D plan sponsors must contract with any pharmacy that meets the Part D plan sponsor's standard terms and conditions for network participation. They also may not exclude pharmacies with unique or innovative business or care delivery models from participating in their contracted pharmacy network solely because they do not fit in a Part D plan sponsor's particular pharmacy type classification.[31] CMS should enforce its "Any Willing Provider" provision in Medicare Part D, preventing PBMs from excluding qualified in-office dispensing or provider led pharmacies from its networks. This enforcement would also prevent PBMs from enacting disproportionate incentives for

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[29] American Society of Clinical Oncology. American Society of Clinical Oncology policy statement on the impact of utilization management policies for cancer drug therapies. J Oncol Pract 13:758–762, 2017.

[30] Centers for Medicare and Medicaid Services. Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program.

[31] Centers for Medicare and Medicaid Services. CMS Finalizes Policy Changes and Updates for Medicare Advantage and the Prescription Drug Benefit Program for Contract Year 2019 (CMS–4182–F), *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2018-Fact-sheets-items/2018-04-02.html.*

patients to only access PBM-operated specialty pharmacies, thus preserving patients' ability to choose the most appropriate pharmacy that meets their needs.

Additionally, CMS should instruct contractors and PBMs to discontinue application of current Star performance ratings and related DIR claw backs on oncology dispensing physicians and practice-based pharmacies, instead relying on measures and standards that are more appropriate to the specialty. Star performance ratings were not intended for this purpose and, as currently structured, are not appropriate for oncology practice. Both flat and percentage-based fees unfairly disadvantage cancer care providers without demonstrably improving quality or patient outcomes.

ASCO remains committed to ensuring that patients are able to obtain timely, high-quality treatment and services at the lowest cost possible. Fragmentation of medication management, which occurs when cancer drug dispensing and distribution are operated by third parties such as PBMs, has the potential to place cancer patients at higher risk for errors and life-threatening toxicities unless additional steps are taken to ensure patient safety and quality standards are met. When managed at the clinic site, the pharmacy has direct access to the patient's electronic records. Forty-seven states offer some degree of in-office dispensing of drugs or provider-led closed pharmacies. In general, specialty pharmacy certifications are readily achievable and can be used to assure appropriate patient safety standards in this setting. ASCO is opposed to increasingly narrow networks that limit patient choice by excluding pharmacy options such as in-office or provider-led closed pharmacies that are convenient, cost effective, and safe for patient care.

Transparency of PBM Operations and Pricing

In contrast to expanding efforts by the federal government to make healthcare prices more public, little is known about PBM financial arrangements.[32] Scarce information is available about the size and frequency of rebates PBMs receive from manufacturers, nor is it understood the extent to which patients experience actual benefits of these rebates and discounts. The ever-changing mix of rebates, discounts and performance-based DIR fees make it nearly impossible for cancer care professionals to anticipate how much prescribed treatments will cost their patients. New and different terms are introduced by PBMs to refer to the same financial arrangements, which adds to the confusion.

Numerous states have passed bills requiring greater transparency from PBMs, including Maximum Allowable Cost (MAC) list mandates and more. As mentioned earlier, 26 states have passed bills to prevent gag clauses, to encourage pharmacists and dispensing physicians to feel empowered to talk to patients about the best possible price for their drugs.

CMS, specifically the Medicare program, should build on these efforts by leveraging its regulatory authority. For example, CMS should make clear the prohibition on gag clauses and should require a more stringent and detailed accounting of DIR fees. Collecting and ultimately publishing such data would help plan sponsors, employers and providers understand the financial arrangements for which they are being asked to contract, ultimately helping to ensure patients are able to be fully informed about price differences and ways to obtain their drugs at the lowest cost.

Impact on Drug Waste and/or Cost

A 2016 article by researchers at Memorial Sloan Kettering Cancer Center found that nearly $3 billion was being lost annually in waste of cancer drugs.[33] Cancer care providers and patients have common interest in reducing the amount of waste in the healthcare system. Providers seek to restrain costs and growth in expenditures in their practice, through quality improvement and efficient scheduling practices that help reduce waste.[34] Patients have a natural interest in reducing their out of pocket costs. There is growing concern that PBMs may be contributing to the costly waste in cancer care. ASCO members have described situations in which a PBM sent the wrong dosage or type of medication or sent medication directly to a patient's home, only to have it expire before they are able to get to their physician's

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[32] Centers for Medicare and Medicaid Services. 2016, *https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Medicare-Provider-Charge-Data/Physician-and-Other-Supplier.html.*

[33] Bach, Peter et al. (2016). Overspending driven by oversized single dose vials of cancer drugs. BMJ 2016; 352 doi: *https://doi.org/10.1136/bmj.i788.*

[34] Leung, Caitlyn, Cheung, MC, Charbonneau, LF, Price, A, Ng, P, Chan, KKW. (2017). Financial impact of cancer drug wastage and potential cost savings from mitigation strategies. Journal of Oncology Practice, 13, 7, *https://doi.org/10.1200/JOP.2017.022905.*

office. Each mistake and wasted vial of cancer medication represents an important expense for a cancer patient and a lost opportunity for appropriate treatment.

Since January 2017, CMS has been requiring attachment of a "JW modifier" to Part B drug billing when an office is submitting a claim for waste.[35] Such claims are limited to times where a physician is required to discard an unused portion of a single dose vial or container, and do not include a patient who does not show up for an appointment. While these instances do not cover the full scope of waste that affects patients in the Medicare program, this is an area worth exploring to better identify cost and sources of waste. ASCO supports increased use of the JW modifier, along with similar mechanisms in commercial plans, to document waste in Part D and private plans. Making these data publicly available would highlight opportunities to reduce waste, lower costs, and enhance care. CMS should consider extending use of the JW modifier to better identify sources and cost of waste related to chemotherapy drugs in both Part B and Part D. Such data should be made public. Private payers should consider similar strategies.

Benefit Design

ASCO members have noted a variety of ways in which PBMs use of the benefit design process—including network size and formulary design—can increase cost for providers and patients. Increased costs have also resulted in oncology practice staff spending more time to locate copay assistance for patients. A recent Kaiser Family Foundation survey highlights the increasing role of separate prescription deductibles within employer plans. Fifteen percent of workers with employer-sponsored coverage now face separate prescription drug deductibles, which shift 100% of the prescription cost to the patient until the deductible is met.[36]

There are also growing concerns about novel strategies imposed by PBMs on benefit design plans, including a relatively new element known as "copay accumulator programs." These programs target specialty drugs for which manufacturers typically provide copay assistance. With a copay accumulator program in place, a manufacturer's assistance no longer applies to a patient's copay or out-of-pocket maximum. Therefore, while they are described as a benefit for patients, these programs in effect prevent patients from reaching their deductibles sooner. Copay accumulator programs generate large savings for employers and PBMs while increasing cost-sharing for patients. There is no standardized naming for these programs, and formal names created by payers can be ambiguous and confusing.[37] PBMs are using copay accumulator programs to shift more healthcare costs away from plan sponsors and employers, and onto patients.

At the heart of PBM administration of drug plans is formulary design, a process that is normally managed by Pharmacy and Therapeutics (P&T) Committees. Used by a range of organizations including PBMs, health plans, hospitals and other health systems, P&Ts develop and manage policies related to formulary management, including prior authorizations, step therapies, quantity limitations, generic substitutions, and other drug utilization management activities affecting access.[38] P&Ts are composed of physicians and pharmacists from a variety of different specialties, but may also include different healthcare practitioners as well as individuals with legal, contract, administrative, and ethics expertise. P&Ts review the strength of scientific evidence when making formulary management decisions. Plans are often designed with several tiers; the highest tier (with the highest copays) often include specialty drugs. The American Cancer Society has found that PBMs regularly place cancer drugs on the highest tier of their formularies, requiring the largest amount of cost-sharing from patients.[39] While CMS has public policy regarding

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[35] Centers for Medicare and Medicaid Services. 2016, *https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/Downloads/JW-Modifier-FAQs.pdf.*

[36] Kaiser Family Foundation. 2017. Employer Health Benefits Survey, *https://www.kff.org/health-costs/report/2017-employer-health-benefits-survey/*.

[37] Drug Channels. Copay Accumulators: Costly Consequence of a New Cost-Shifting Pharmacy Benefit. January 3, 2018, *http://www.drugchannels.net/2018/01/copay-accumulators-costly-conseguences.html.*

[38] International Society for Pharmacoeconomics and Outcomes. Drug Information Used in the Managed Care Pharmacy P&T Decision Making Process: Current Practice and Insights. Retrieved from: *https://www.ispor.org/meetings/baltimore0511/presentations/ISPOR-AMCP-presentation-FINAL-5-10-11.pdf.*

[39] American Cancer Society Cancer Action Network. ACS CAN Examination of Cancer Drug Coverage and Transparency in the Health Insurance Marketplaces. February 22, 2017, *https://www.acscan.org/sites/default/files/National%20Documents/QHP%20Formularies%20Analysis%20-%202017%20FINAL.pdf.*

the creation of Part D drug formularies, this same guidance is not necessarily followed in the private sector by all plan sponsors.[40] A lack of oncology specific specialization on a P&T committee can lead to mistakes and omissions for cutting-edge and complex cancer medications, leading to inferior care for cancer patients. Pharmacy and Therapeutics committees should include full and meaningful participation by oncology specialists.

Conclusion

Promoting delivery of high value care to every patient with cancer is central to ASCO's mission. ASCO understands and shares concerns about escalating costs and their impact on patients—and we have been actively engaged in addressing that issue. However, strategies for controlling cost must not compromise oncologists' ability to provide the right care, at the right time, for all their cancer patients.

ASCO remains committed to principles and recommendations previously conveyed in policy statements addressing utilization management. The opaque nature of PBM practices and policies—and their uncertain impact on cost and quality of cancer care—warrant special attention. ASCO has established a focused effort to obtain greater insight on specific PBM practices, their impact on patients and on cost, and appropriate remedies. A dedicated group of ASCO volunteers will pursue an in-depth analysis of PBM impact on cost and waste, their role and impact on quality of care, and the impact of benefit design on patients' ability to access the care they need.

In the meantime, ASCO is deeply concerned that the practices highlighted within this statement have the near-term potential to erode quality and access to care and should be addressed immediately.

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ASHP (American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Senate Committee on Finance hearing on "Drug Pricing in America: A Prescription for Change, Part III."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's nearly 50,000 members include pharmacists, student pharmacists, and pharmacy technicians. For more than 75 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP's vision is that medication use will be optimal, safe, and effective for all people all of the time. A primary tenet of that vision includes access to affordable medications needed to save or sustain lives. Addressing the issue of skyrocketing drug prices, including excessive price increases on commonly used generic medications, is one of ASHP's highest and longstanding public policy priorities.

Poor access to medications can lead to increased morbidity and mortality, and can cause healthcare costs to increase. According to a recent Kaiser Health Tracking Poll, 29% of adults report that they are not taking their medications as prescribed due to increased cost with 8% of those individuals reporting that their condition has worsened as a result of poor medication adherence.[1]

ASHP has been proactively addressing challenges related to the rapid increase of prescription drug pricing on several fronts, including working with like-minded stakeholders and educating members of Congress about the unsustainable burdens faced by patients, healthcare providers, and the entire healthcare system.

ASHP is a lead member of the Steering Committee of the Campaign for Sustainable Rx Pricing (CSRxP), a coalition of prominent national organizations representing physicians, consumers, payers, hospitals health systems, and patient advocacy

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[40] Centers for Medicare and Medicaid Services. Medicare Prescription Drug Manual. Chapter 6—Part D Drugs and Formulary Requirements (v.01.19.16), *https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/PartDManuals.html.*

[1] Kirzinger, A., Lopes, L., Wu, B., and Brodie, M. (2019, March 15). KFF Health Tracking Poll—February 2019: Prescription Drugs. Retrieved March 8, 2019, from *https://www.kff.org/health-costs/pol1-finding/kff-health-tracking-poll-february-2019-prescription-drugs/*.

groups. CSRxP has developed a policy platform promoting market based solutions supported by three pillars: competition, value, and transparency.

The goal of the campaign is to identify policy options that have bipartisan support and, therefore, a greater likelihood of passage. To that end, CSRxP focuses on policies to incentivize a more competitive marketplace to help stimulate lower drug prices. The campaign has also expressed support for efforts to loosen restrictions that prevent generic drug companies from obtaining the samples necessary to manufacture a competing product.

ASHP does not collect, store, or report drug pricing information. However, we continually hear from pharmacy leaders in hospitals and health systems that sudden, inexplicable, and unpredictable price increases in connection with some of the most commonly used, longstanding generic medications are becoming more prevalent—and are occurring on a nationwide basis.

In January, ASHP, along with the American Hospital Association (AHA) and the Federation of American Hospitals (FAH), released a report on the impact that the cost of and access to prescription drugs are having on hospital budgets and operations.

Specifically, the report showed that:

- Average total drug spending per hospital admission increased by 18.5% between fiscal year (FY) 2015 and FY 2017.
- Outpatient drug spending per admission increased by 28.7%, while inpatient drug spending per admission increased by 9.6% between FY 2015 and FY 2017.
- Hospitals experienced price increases of over 80% across different classes of drugs, including those for anesthetics, parenteral solutions, and chemotherapy.
- Over 90% of surveyed hospitals reported having to identify alternative therapies to manage spending.
- One in 4 hospitals had to cut staff to mitigate budget pressures.[2]

ASHP is committed to continuing to advance policy and other solutions that will improve transparency in drug pricing and promote competition in the market place.

NEED FOR TRANSPARENCY

Addressing the problem of high drug prices is complicated by a lack of transparency in the system, from drug manufacturer price-setting to pharmacy benefit manager (PBM) rebate s. ASHP respects the need to protect trade secrets, but we also believe the system can benefit from transparency related to costs. Thus, we encourage the Committee to explore options for increasing transparency within the pharmacy benefit managers (PBMs) rebates system. Specifically, rebates on drugs should be disclosed to participants in the system, including plan sponsors.

Direct and Indirect Remuneration Fees (DIR Fees), which are negotiated by PBMs, also make it difficult to determine the actual cost of a drug. DIR fees are a growing nationwide concern among pharmacies that dispense medications in a community pharmacy or outpatient clinic setting. Created under the Medicare Part D Program, DIR fees were originally intended as a way for the Centers for Medicare and Medicaid Services (CMS) to account for the true cost of the drug dispensed, including any manufacturer rebates.

Often DIR fees are unknown until the drug is dispensed and the claim adjudicated. Moreover, the fees themselves, which are often arbitrary in nature, have mushroomed over the past decade, to the point that pharmacies regularly see annual DIR totals in the tens of thousands to hundreds of thousands of dollars.

In addition, PBMs are now inappropriately applying their own plan performance measures as a way to assess fees on pharmacies. This is problematic for the following reasons:

- It is an arbitrary and unintended application of quality measures meant for total plan performance as opposed to pharmacy-level metrics.
- The quality measures applied tend to be based on maintenance medications such as blood pressure medications or medications used to treat diabetes. These

[2] NORC at the University of Chicago. Recent Trends in Hospital Drug Spending and Manufacturer Shortages (2019), *https://www.aha.org/system/files/2019-01/aha-drug-pricing-study-report-01152019.pdf.* Accessed February 25, 2019.

measures were never intended to be applied to specialty medications or to other specialized disease states such as oncology, yet PBMs assess DIR fees against the gross reimbursement for all prescriptions received by pharmacy providers, not just maintenance medications.

- Pharmacy providers are essentially being penalized with backdoor fees without any requirement that PBMs define, justify, or explain these charges to providers and to CM S.

Due to the fee structure, DIR fees assessed on pharmacies providing specialty medications have been especially problematic. Fees range from a flat rate of per dollar per claim or a percentage (typically 3–9%) of the total reimbursement per claim. Additionally, these fees are assessed retroactively, sometimes months after the claim has been adjudicated, providing no recourse for the pharmacy impacted by the assessment.

The result of imposing DIR fees has led to higher cost-sharing responsibilities for Medicare beneficiaries. This has, in turn, caused more of these beneficiaries to enter the Part D donut hole where the patient is solely responsible for the cost of the drug. Along with the higher costs absorbed by patients, adherence rates tend to be lower among Medicare beneficiaries who are in the donut hole and may not have the financial resources to pay for their medications. This stands in stark contrast to passing on savings to patients—the very reason DIR fees targeting manufacturer rebates were created.

Pharmacies are not alone in their concern. In January 2017, CMS published a fact sheet expressing concern over DIR fees and cited those fees as contributing to increased drug costs, which, in turn, increased patients' out-of-pocket spending and Medicare spending overall.[3] Additionally, questions remain as to whether Part D plan sponsors have the authority to assess these fees on pharmacies. There are no references to DIR fees collected on pharmacies in either the Part D statute or corresponding CMS regulations.

CONCLUSION

ASHP thanks the Committee on Finance for holding this important hearing. ASHP remains committed to working with Congress and industry stakeholders to ensure that patients have affordable access to lifesaving and life-sustaining medications.

CAMPAIGN FOR SUSTAINABLE RX PRICING

Chairman Grassley, Ranking Member Wyden, and members of the Senate Committee on Finance, the Campaign for Sustainable Rx Pricing (CSRxP) thanks you for the opportunity to submit testimony for the record on the critically important issue of the unsustainable and out-of-control growth in prescription drug prices and the essential role that pharmacy benefit managers (PBMs) play in lowering drug costs for U.S. consumers and taxpayers.

CSRxP is a nonpartisan coalition of organizations committed to fostering an informed discussion on sustainable drug pricing and to developing bipartisan, market-based solutions that promote competition, transparency, and value to improve affordability while maintaining patient access to innovative prescription drugs that can improve health outcomes and save lives. Our members represent organizations including consumers, hospitals, physicians, nurses, pharmacists, employers, pharmacy benefit managers and insurance providers.

Prescription drug prices are out of control and continue to grow at unsustainable rates. Twenty-three cents of every health care dollar goes toward prescription drugs.[1] One in four Americans cannot afford their medications. Excessively high prices unfairly threaten the financial security, health and well-being of U.S. patients and their families every day, as well as strain Federal and state health budgets and the taxpayers who fund them. Too often patients are faced with the unfortunate and unfair choice of purchasing the medications they need to get well and stay healthy and paying their bills. Patients simply should never be presented with such a choice and deserve affordable access to prescription drugs.

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[3] Fact sheet. Medicare Part D—Direct and Indirect Remuneration (DIR). Centers for Medicare and Medicaid Services, January 19, 2017, *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir.* Accessed February 10, 2019

[1] AHIP. "Where Does Your Healthcare Dollar Go?" May 22, 2018.

Given the critical drug pricing crisis facing U.S. consumers and taxpayers today, CSRxP ardently believes it is imperative to rein in the out-of-control drug prices that put patient access to affordable life-saving drugs at risk. We share and applaud the Committee's commitment to lowering drug prices and very much appreciate your leadership in tackling this serious issue that affects U.S. patients and taxpayers every day.

That said, however, as policies are considered to reduce drug costs, CSRxP strongly objects to the notion that PBMs are merely "middlemen" in the drug supply chain not working hard on behalf of patients to make prescription drugs more affordable, as the pharmaceutical industry and Administration suggest. Rather, just the opposite is true: PBMs function as the only real check on the pharmaceutical industry's unilateral ability to set high drug prices and raise them at excessively high rates. Without PBMs negotiating on behalf of patients, drug costs would be significantly higher and even more unaffordable for patients and taxpayers, In this vein, CSRxP wishes to underscore the following as the Committee considers how best to address this critical drug pricing problem:

I. Brand drug companies—and brand drug companies alone—set and increase drug prices at unsustainably high rates.

II. PBMs effectively deploy commercial tools in negotiations with drug companies on behalf of patients to lower drug costs—saving patients and payers an average of $941 per person per year and 40 to 50 percent annually on their prescription drug and medical costs.[2]

III. Purported changes to the current rebate system under consideration by the U.S. Department of Health and Human Services (HHS) will serve only to raise, not lower, drug costs while at the same time perversely increase the profitability of the brand drug industry—the very industry entirely responsible for the drug pricing problem.

CSRxP firmly believes that without major actions by this Committee and others, the pharmaceutical industry will continue to excessively profit from the anti-competitive and unsustainable pricing practices that make prescription drugs unaffordable and jeopardize access for the patients who need them. We look forward to continuing our work with the Committee to implement bipartisan, market-based solutions that effectively leverage private sector negotiating power to curb unfair price gouging practices by drug companies and blunt the unsustainable growth in prescription drug costs.

I. Brand Drug Companies Are Responsible for Setting Needlessly High Drug Prices

Despite efforts from the brand drug industry to suggest otherwise, the drug industry is the driver of the high prescription drug prices that American consumers and taxpayers face today. Brand manufacturers set high launch prices for their products and typically increase those prices at rates that far exceed inflation. As healthcare expert Avik Roy recently said: "[I]n the absence of competition, manufacturers frequently charge the highest prices they believe they can justify in the court of public opinion."[3]

Demonstrating this point, one recent analysis concluded that the increasing costs of prescription drugs were due largely to price increases imposed by manufacturers of drugs already on the market. From 2008 to 2016, the analysis found costs of oral and injectable drugs increased by 9.2 percent and 15.1 percent, respectively, on an annual basis with existing drugs contributing to much of the growth.[4, 5] Costs increased for specialty oral and injectable drugs by 20.6 percent and 12.5 percent, respectively, with 71.1 percent and 52.4 percent of these increases attributable to new drugs.[6] A separate recent study from AARP found that retail prices for 87 percent of the most widely used brand name drugs by older Americans increased from 2016

[2] Visante. "The Return on Investment (ROI) on PBM Services." Prepared for PCMA. November 2016.

[3] Roy Avik. "Drug Companies, 'Not Middlemen,' Are Responsible for High Drug Prices." *The Apothecary.* October 22, 2018.

[4] Hernandez et al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." *Health Affairs.* Vol. 38, No. 1. January 2019.

[5] Kodjak, Alison. "Prescription Drug Costs Driven By Manufacturer Price Hikes, Not Innovation." *National Public Radio.* January 7, 2019.

[6] Hernandez et al. "The Contribution of New Product Entry Versus Existing Product Inflation in the Rising Cost of Drugs." *Health Affairs.* Vol. 38, No. 1. January 2019.

to 2017, with 30 percent having price increases of 10 percent or higher.[7] Overall, prices for prescription drugs in the AARP study increased by an average of 8.4 percent from 2016 to 2017—or four times the 2.1 percent rate of general inflation for the period.[8] These 2017 price increases followed average double-digit annual price increases every year from 2012 to 2016.[9]

High-cost specialty medications in particular are driving much of this unsustainable growth in prescription drug prices and spending. Pharmacy benefit manager Express Scripts reported, for example, that even with strategies in place to lower costs for consumers on specialty medications, growth in commercial spending on high-cost specialty products far outpaced growth in overall prescription drug spending in 2017: 11.3 percent versus 1.5 percent.[10] Similarly, a separate AARP analysis found that retail prices for 101 widely used specialty drugs increased by 9.6 percent in 2015, continuing the increasing trend of specialty product price increases seen since 2006.[11] In 2015, the average annual cost of a single specialty medication used on a chronic basis exceeded $52,000, with the annual cost of these therapies growing by almost $35,000 from 2006 to 2015.[12]

Simply put, data clearly demonstrate pharmaceutical companies unilaterally set high drug prices and impose high price increases that needlessly increase costs for consumers and taxpayers. The unfair pricing practices of the drug industry make prescription drugs unaffordable for patients, putting them at risk for not being able to obtain the medications they need to get well and stay healthy.

II. PBMs Lower Drug Costs for Patients and Taxpayers

Rather than merely serving as "middlemen" in the drug supply chain as the Administration and brand drug industry claim, PBMs play a critical role in lowering the prices that brand drug makers impose on patients. The rebates, price concessions, and other discounts negotiated by PBMs on behalf of more than 266 Americans significantly reduce prescription drugs costs for consumers and taxpayers—between 31 and 36 percent in savings through rebates and discounts and an additional 11 to 15 percent in savings through encouraging increased utilization generics and preferred brands.[13] Such reductions have translated into substantial overall cost savings, lowering costs for patients and payers by an average of $941 per person per year and 40 to SO percent annually on drug and medical costs.[14]

Importantly, Medicare Part D, its enrollees, and the taxpayers who fund it have benefitted significantly from PBM negotiations with drug manufacturers, as well. PBMs have produced nearly $90 billion in savings since the inception of Part D in 2006 to 2016 and are projected to generate $300 billion in savings from 2017 to 2026, according to one recent analysis.[15] The Medicare Trustees generally confirmed this analysis in their most recent report, estimating significantly slower growth in Part D spending in part due to higher manufacturer rebates negotiated by PBMs.[16]

Indeed, HHS Secretary Azar and Centers for Medicare and Medicaid Services (CMS) Administrator Verma both have touted the essential role PBMs play in lowering prescription drug costs for consumers and taxpayers. Secretary Azar told Congress: "The President has generally spoken about the desire to ensure that Medicare is negotiating and getting the best deal possible for drugs. Part D actually has negotiation through the 3 or 4 biggest pharmacy benefit managers that negotiate and actually secure the best net pricing of any players in the commercial system. I sat on the other side of that. I can assure you of this."[17] Likewise, Administrator Verma

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[7] AARP Public Policy Institute. "Trends in Retail Prices of Brand Name Prescription Drugs Widely Used by Older Americans: 2017 Year-End Update," page 8. September 2018.
[8] *Ibid.,* page 5.
[9] *Ibid.,* page 6.
[10] Express Scripts. "2017 Drug Trend Report," page 4.
[11] AARP. "Trends in Retail Prices of Specialty Prescription Drugs Widely Used by Older Americans, 2006 to 2015," page 1. September 2017.
[12] *Ibid.*
[13] Visante. "The Return on Investment (ROI) on PBM Services." Prepared for PCMA. November 2016.
[14] Visante. "The Return on Investment (ROI) on PBM Services." Prepared for PCMA. November 2016.
[15] Milliman. "Value of Direct and Indirect Remuneration: Impact on Part D Prescription Drug Plan (PDP) Stakeholders." July 2017.
[16] The Board of Trustees, Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds. "2018 Annual Report of the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Insurance Trust Funds," page 112.
[17] Azar, Alex. U.S. Senate Committee on Health, Education, Labor, and Pensions. Hearing. November 29, 2017.

said to Congress: "I think that we need to do everything that we can to make drugs more affordable for seniors. . . . I'm thankful that we have the PBMs in the Part D program that are performing that negotiation on behalf of seniors."[18]

In fact, even drug companies themselves acting as large employers contract with PBMs to negotiate lower drug prices for their own employees.[19] Eli Lilly Chief Executive Officer (CEO) Dave Ricks explained: "We hire a PBM by the way for our employee benefits. I provide insurance for 70,000 Americans who work for [Eli] Lilly or their beneficiaries and retirees to negotiate lower drug prices. . . . That's how the system work; it's a marketplace and we're for that."[20]

In other words, those claiming that PBMs merely function as "middlemen" in the drug supply chain have stated just the opposite: Secretary Azar, CMS Administrator Verma and a CEO of a major pharmaceutical company all have touted the value of PBMs bring in reducing prescription drug costs for consumers and taxpayers. CSRxP therefore strongly objects to the notion that PBMs are just "middlemen" and instead urges the pursuit of bipartisan, market-based policies that strongly support and foster the ability of PBMs to negotiate lower prescription drug costs on behalf of patients.

III. HHS's Rebate Rule Substantially Increases Costs for Consumers and Taxpayers While Perversely Raises the Profitability of the Pharmaceutical Industry

CSRxP agrees that the current rebate system can be significantly improved as, in many cases, the system has not adequately addressed the high prices set and controlled entirely by the brand pharmaceutical industry. That said, however, we strongly oppose the HHS Office of Inspector General's proposed rule (OIG–0936–P) that the Administration purports would reform the system. Rather than reform the system, the proposed rule will lead to the drug industry's imposition of higher—not lower—prices on patients and, perversely, will result in raising the profitability of the brand drug industry—the very industry that is solely responsible for this dire drug pricing problem.[21] In particular, CSRxP wishes to emphasize the following highly problematic issues with HHS's rebate rule:

- **Drug companies increase prices regardless of rebate levels and the rebate rule does nothing to stop drug companies from continuing to unilaterally set high drug prices.** The Administration contends that rebate reform is necessary to encourage drug makers to lower their list prices; without the pressure to provide substantial rebates, manufacturers will not set list prices so high, the argument goes. Research, however, definitively demonstrates that rebate levels are not tied to price. Specifically, one recent analysis concluded that there is no correlation between the prices drug companies set and the rebates they negotiate with PBMs and, importantly, that drug companies increase prices regardless of rebate levels.[22] The study found prominent cases of higher-than-average price increases in drug categories where manufacturers negotiated relatively low rebates and, conversely, prominent cases of lower-than-average price increases in drug categories where manufacturers negotiate relatively high rebates.[23] In other words, rebates negotiated by PBMs do not correlate with or necessarily lead to higher list prices—rather drug makers entirely set and control high list prices imposed on consumers and taxpayers. For further evidence that the rebate rule will not result in lower list prices, seven pharmaceutical executives testified to the Senate Finance Committee and said that their respective companies will not reduce list prices unless rebates are no longer used in the commercial market.[24]
- **The rebate rule does not combat the drug industry's abusive price gouging practices for high priced drugs without competition.** Everyone agrees that prescription drugs without competition—often high-cost specialty

[18] Verma, Seema. U.S. Senate Committee on Finance. Hearing. February 16, 2017.
[19] Herman, Bob. Axios. "Phama Companies Hire Drug Pricing Middlemen, Too." March 7, 2019.
[20] CBS. May 8, 2017.
[21] 84 FR 2356.
[22] Visante. "No Correlation between Increasing Drug Prices and Manufacturer Rebates in Major Drug Categories." April 2017.
[23] *Ibid.*
[24] Rowland, Christopher. "Drug executives grilled in Senate over high prices." *The Washington Post.* February 26, 2019, *https://www.washingtonpost.com/business/economy/drug-executives-grilled-in-senate-over-high-prices/2019/02/25/abc89c04-393f-11e9-aaae-69364b2ed137_story.html?utm_term=.e57d10e05667.*

biologic products—pose especially significant cost challenges for federal health programs and the U.S. healthcare system as a whole. The HHS Assistant Secretary for Planning and Evaluation (ASPE) found, for example, that Medicare Part B spending on prescription drugs increased at a rapid average annual rate of 7.7 percent from 2005 to 2014; during that period, specialty biologic medicines (often without significant competition) grew at a particularly fast rate, climbing from 39 percent to 62 percent of total spending, with a substantial share of the growth due to price increases rather than number of patients using the medications.[25] Separately, a large PBM recently found that its clients' spending on specialty medications increased 9.4 percent while spending on traditional, non-specialty medications decreased 5.8 percent in 2017.[26]

Humira, the best-selling pharmaceutical product in the world today with nearly $20 billion in sales in 2018, illustrates the critical problem posed by high-priced medications without competition. Humira has over 100 patents that potentially could extend its market protection as far as 2034 in the U.S., but likely at least through 2022.[27, 28, 29, 30] As a result of the anti-competitive and unfair patent "thicket" and "pay-for-delay" deals reached between the manufacturers of Humira and its biosimilars, U.S. patients taking Humira will continue paying a high price for this drug for at least the next three years and likely will face significant price increases throughout this time.

It is of critical concern, therefore, that pricing reforms tackle drugs with limited or no competition. Unfortunately, the changes to the system in HHS's rebate rule do nothing to address this serious problem. Rather, under the proposed rule, manufacturers retain complete control in price setting and have increased leverage over PBMs that no longer can use commercial negotiating tools to lower costs for patients and taxpayers. Instead of weakening the bargaining power of PBMs on behalf of patients, CSRxP urges the Committee to discourage HHS from adopting this rule and instead take steps to enhance the ability of PBMs to employ even stronger bargaining tools with drug makers so that drug makers actually feel more pressure to lower prescription drug prices for patients.

- **Medicare Part D premiums will increase for all enrollees if HHS adopts the rebate rule—making prescription drug coverage more costly for all Part D beneficiaries.** CSRxP lauds the Department's overarching goal to reduce prescription drug costs for patients. Hence, we do not understand why HHS seeks to implement policies in the rebate rule that will raise—not lower—Part D premiums for patients. Indeed, *all* Medicare Part D enrollees will face substantial premium increases of roughly 19 percent per month in 2020 and 25 percent overall as a result of this proposed rule, according to the Department's Office of the Actuary.[31] Clearly, significantly raising premiums for all Part D beneficiaries will not make prescription drug coverage more affordable and will be particularly problematic for the many Medicare beneficiaries who live on fixed incomes and simply cannot afford unnecessary increases to their monthly Part D premiums.

  In fact, since the inception of the Part D program, rebates and other discounts negotiated by PBMs and health insurers have saved Part D beneficiaries an estimated 21.5 percent on their premiums—or more than $12 billion savings.[32] Assuming HHS does not implement this proposed rule, health insurer and PBM bargaining tools are projected to save beneficiaries 33.2 percent on premiums—or nearly $50 billion—from 2017 through 2026.[33] CSRxP firmly believes that patients should continue to benefit from the significant premium savings that PBMs and health insurers have negotiated on their behalf. Clearly raising Part D premiums through implementation of the rebate rule would not advance this

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[25] HHS Assistant Secretary for Planning and Evaluation. "Medicare Part B Drugs: Pricing and Incentives," page 6. March 8, 2016.
[26] Express Scripts. "2018 Drug Trend Report."
[27] Gonzalez, Richard. "Abbvie Long-Term Strategy." October 30, 2015. Slides 14–16.
[28] Pollack, Andrew. "Makers of Humira and Enbrel Using New Drug Patents to Delay Generic Versions." *The New York Times.* July 15, 2016.
[29] Slide presentation by Michael Carrier at FTC November 8, 2017 workshop. Slide 48.
[30] AbbVie. "AbbVie Reports Full-Year and Fourth-Quarter 2018 Financial Results." January 25, 2019.
[31] 84 FR 2358.
[32] Milliman. "Value of Direct and Indirect Remuneration: Impact on Part D Prescription Drug Plan (PDP) Stakeholders." July 2017.
[33] *Ibid.*

very important goal and we strongly urge the Committee to discourage HHS from adopting the rule.

- **The profitability of the brand drug industry—the industry solely responsible for this critical drug pricing problem—will increase if HHS implements the rebate rule, all unfairly at the expense of taxpayers, Medicare beneficiaries, and Medicare.** CSRxP is extremely concerned that brand drug makers' profitability will significantly improve at the substantial expense of taxpayers and federal health programs if HHS adopts the rebate rule. One estimate projects brand drug makers will pay out nearly $40 billion less in price discounts in the Part D coverage gap over 2020–2029 as a result of the proposed rule.[34] In other words, brand drug makers that alone caused this dire drug pricing problem will profit from the very changes the Administration purports will solve it. At the same time, the HHS Office of the Actuary projects that Medicare Part D spending will increase by $196 billion over 10 years if this rule is implemented.[35] This enormous increase in Medicare Part D spending hurts beneficiaries and taxpayers, making the program substantially less financially stable for its enrollees and the taxpayers who fund it.

  Put another way, taxpayers and Medicare beneficiaries perversely will pay out nearly $200 billion to subsidize the profitability of the brand drug industry—the very industry solely and entirely responsible for the drug pricing problem—if HHS implements this rule. To be very clear, implementation of this proposed rule wrongly and inappropriately will: (1) put Medicare on less sound financial footing for current and future beneficiaries, which is particularly problematic for those seniors on limited, fixed incomes who depend on the program to provide them health security as they age; and (2) require taxpayers and Medicare beneficiaries to pad the bottom lines of the brand pharmaceutical industry—a perverse and adverse outcome that will financially benefit the very industry that has caused the drug pricing problem that this proposed rule ostensibly seeks to address. CSRxP therefore urges on behalf of Medicare beneficiaries and taxpayers that the Committee dissuade HHS from adopting this proposed rule and instead consider bipartisan, market-based alternatives that will increase competition and lower prescription drug prices for consumers.

IV. Conclusion

In conclusion, CSRxP again wishes to express appreciation for your leadership and the Committee's clear commitment to lowering prescription drug prices for all Americans. We wish to underscore that PBMs play a critically important role in lowering drug costs for patients and taxpayers by serving as the only true check on drug companies' unilateral ability to set high prices and raise them at unsustainably high rates. The Administration's reforms to the current rebate system will not stop drug makers from engaging in these unfair pricing practices. Rather than improving prescription drug affordability, these proposed changes will take away the very important tools that PBMs leverage in negotiations with drug makers to lower costs for patients. As a result, this rule will further jeopardize patient access to affordable prescription drugs—all at the expense of taxpayers who perversely would have to fund higher profits for the drug industry. Most importantly, these ostensible reforms do nothing to address the root cause of the problem: brand drug companies—and brand drug companies alone—set list prices way too high and raise those prices at unsustainably high rates.

CSRxP firmly believes that without major actions by this Committee and others, the brand pharmaceutical industry will continue to excessively profit from their unfair and unsustainable pricing practices that increase drugs costs and risk access for the patients who need them. CSRxP looks forward to continue working with the Committee to develop alternative bipartisan, market-based policies that promote transparency, foster competition, and incentivize value to improve affordability for consumers while at the same time maintaining access to the treatments that can improve health outcomes and save lives.

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[34] 84 FR 2362.
[35] 84 FR 2359.

COALITION FOR AFFORDABLE PRESCRIPTION DRUGS
www.affordableprescriptiondrugs.org

Top Reasons Employers Partner With PBMs

Healthy employees are critical to American businesses. More than half of all Americans get health insurance through their job, putting employers on the frontlines of managing health care costs. That is why the majority of employers across the country partner with PBMs to help their employees get the medications they need at a price they can afford.

(1) Help manage overall health care costs

PBMs design personalized drug benefit programs to help each employer provide coverage that is suited for their employees' needs. PBMs drive savings to lower premiums and out-of-pocket costs, so employees can get the prescriptions they need to get and stay healthy.

(2) Help make the complicated simple

With over *4 billion* prescriptions filled each year, PBMs help employers ensure their employees get the medicines they need at a price they can afford.

(3) Negotiate lower prices from drug companies

PBMs leverage the combined purchasing power of all the employers they work with to negotiate deep discounts from drug makers to drive savings for employers and consumers. PBMs are expected to save employer-sponsored plans *$349.6 billion* over the next decade.

(4) Save patients money at the pharmacy counter by reducing out-of-pocket costs

PBMs offer discounts available to patients at the pharmacy counter, saving up to $130 per eligible medication.

(5) Provide patients and their doctors with real-time Rx information

PBMs provide physicians with coverage information at the point of prescribing and provide consumers with convenient access to drug prices so they are aware of their out-of-pocket costs. Using these tools, consumers save $80 on average per prescription fill.

(6) Help make it easier for patients to access and adhere to their prescriptions

PBMs build national networks of pharmacies and offer prescriptions by mail to ensure that employees have easy, convenient access to the medications they need no matter where they live.

(7) Use generic drugs to help lower costs

PBMs identify when there is a lower-cost clinically-equivalent drug. PBM tools to encourage generic utilization can help reduce drug spending by up to 19%.

(8) Improve patient safety

PBMs help prevent *100 million* medication errors each year by checking for potentially dangerous drug interactions and sharing this information with doctors, pharmacists and patients.

(9) Help patients manage chronic conditions

Chronic and mental health conditions drive 90% of health care spending in the U.S. PBMs have developed disease-specific programs to help manage and treat chronic conditions, helping doctors and pharmacists deliver a more seamless patient care experience and improve outcomes. For example, research has shown that PBMs improve adherence in diabetes patients, helping to prevent some 480,000 heart failures and 230,000 incidents of kidney disease each year.

STATEMENT SUBMITTED BY CHRISTINE KASISKY, RPH
Eaglescripts Apothecary

Thank you, Chairman Grassley, Ranking Member Wyden, and Finance Committee members, for having this hearing. My husband and I are pharmacists and own a small independent pharmacy in Pennsylvania. Being practicing pharmacists for over 25 years, we have seen many changes in healthcare. Sadly, it's not for the best. We fully agree with ALL of Chairman Grassley's opening remarks. We have

filled out paperwork online a long time ago to the Federal Trade Commission on insurances and agencies working for insurances becoming providers. This is clearly a conflict of interest for the patient. As you can see, how can Derica Rice be the Executive Vice President of CVS Health and President of CVS Caremark? Our personal example: Why is it when CVS Caremark billing is not working for our independent pharmacy, the CVS helpline says to send our patients to a CVS pharmacy; CVS is able to process prescriptions. We also agree with ALL the comments by Ranking Member Wyden. In our case, we can no longer afford health insurance for us and our 3 children. We are healthy individuals whose monthly premium went up to $1,700.00 per month with a $7,000.00 deductible on each of us so our family no longer has health insurance coverage. Rebates did not lower insurance premiums and do not help patients. I will give some examples of PBM practices in this letter based on personal experiences with PBMs and evidence used in articles to state facts. If there are any further questions, please do not hesitate to call me.

These issues are not new; they have gotten worse. Many bills have been proposed, but due to payouts and threats nothing is done. See *Forbes,* April 9, 2019, "These Senators Received the Biggest Checks from CVS, Humana and Other Drug Middlemen Testifying Tuesday," by Michela Tindera. Also, PBMs have groups such as Drug Benefit Solutions to stop new laws. Jonah Houts, the head of government affairs at Express Scripts said, "We were designed to create tension. We're successful at what we do, and that's why we want to make sure the lawmakers who are considering legislation that affects us understand that." Another article: "Was the HHS Drug Pricing Czar Daniel Best's Death Ruled a Suicide Despite Evidence of Foul Play?" by David Emery. Was the 49-year-old PBM insider a victim of foul play? Recently, my husband and I have been very vocal about PBM practices and January 29, 2019 he received a phoned death threat at closing time in our pharmacy stating, if he doesn't shut his mouth, they were going to kill him. Who do you report the wrongful PBM practices to? They need transparency, regulation and oversight.

Pharmacies have tried taking PBMs to court for their many unfair practices, but we cannot provide enough information of proof. "Pharmacy Loses a Patient Poaching Lawsuit to ESI," by Natalia Mazina, March 19, 2019, lists these practices but with unreasonable contracts and lack of transparency, there is nothing we can do. "The Court dismissed the claim holding that pharmacies failed to plead enough facts to establish this claim." We need fair contracts and laws to support fair business practices.

We keep hearing how PBMs are a BENEFIT manager. There are a huge amount of social media sites showing examples of the opposite. I just got off the phone with Robin Agar a CVS patient who I was able to listen to her calls and frustration with CVS Caremark. Calls and story can be heard at *Tarbell.org,* April 8, 2019, "Sorry, Wrong Number: Patient Fights Back After CVS Caremark Denies Her the Drug She Needs and Records Her Calls," by Michael Corcoran. It tells a sad story of how Robin was dispensed the wrong frequency of a drug, and she couldn't talk to anyone except the help desk who was not a pharmacist or healthcare professional. It is the same with our independent pharmacy when we have questions about a prescription. We can only talk to a "help desk" who is not a healthcare professional—how is this being a good middleman? In another instance, she was denied a medication because CVS Caremark wanted her on a newer more expensive drug. She went through multiple appeals. In the second appeal, CVS stated her doctor was unreachable but if you dialed the number they called, it was for Playtex Corporation. They had called the wrong number despite having the correct number on her prescription and denied the claim. Couldn't CVS Caremark realize it was not a doctor's office? This is a BENEFIT manager? According to Pennsylvania Law, a generic must be substituted for a brand name unless the doctor or patient wants the brand. Why is it the PBMs insist on CERTAIN brands? The much cheaper generic drug is denied; the brand is on formulary, but the pharmacies get reimbursed for the generic drug price. Who wins in this scenario? Only the PBM.

At the hearing, every PBM wanted more competition. This is so untrue. For example, I know of a patient complaining that CVS Pharmacy wouldn't get a different manufacturer of a generic drug in for them. The patient had an allergy to the red dye in the generic drug CVS Pharmacy had in stock so the patient went to a chain competitor. Then, the patient receives a "nasty-gram" from CVS Caremark to use CVS Pharmacy. The patient had to waste their time and call to explain their allergy to the stocked CVS medication and how CVS wouldn't order in another manufacturer that was safe. This is a BENEFIT to the patient?

I recently spoke to Richard Stevens of West Virginia Pharmacists Association who has many great articles including "Update on PBMs," December 26, 2017. He states, "It is a fact based on the following evidence in this summary that PBMs drive up the cost of prescription benefits which in turn drive up healthcare costs." "PBMs are for-profit middlemen working to increase their profits at the expense of payers." He writes, "mandate PBM transparency will give payers across the public and private spectrum access to more information such as, the PBM actual reimbursement paid to their pharmacy network. . . ." "PBMs generate profits by hiding spreads on generic and branded drugs by using different reimbursement methodologies for 'reimbursing' pharmacies versus what they 'bill' payers, and multiple contracts allow PBMs to protect information they consider proprietary." Do you realize, as an independent pharmacy, we don't negotiate any drug prices? Another middle man called a PSAO (Pharmacy Services Administration Organization) negotiates our reimbursement rates. When we asked our PSAO why we are getting below cost on our medicines we dispense they replied, the PBMs only deal with a few PSAOs so if they want to remain in business, they just accept the contract from the PBM. It's a take it or leave it contract. PBMs do not reimburse us correctly even though we submit our cost for the drug. Where is our proprietary information? Please have laws for transparency. The article explains "tricks" by PBMs. "Pay the pharmacy according to the PBMs MAC list yet bill payer according to an AWP Reference Price which allows for hidden 'spreads' on generic drugs which mean profit for the PBM." "PBMs exploit a loophole in the federal law to inflate the AWP value by 25% or more (false AWP.) PBMs use 'false' AWPs when they bill payers." "Numerous court cases have revealed that as a rule PBMs retain some rebate revenues by re-naming them as 'administrative fees.' For example, the New York State Attorney General's lawsuit against Express Scripts on behalf of the state employees' Empire Plan." West Virginia looked into their state program and decided to save taxpayer money and have better patient care by eliminating PBMs in their state programs. See "West Virginia Medicaid saves $54.4 million with prescription drug carve-out," by NCPA, March 13, 2019. Despite West Virginia paying the pharmacies at CORRECT COST of the drug AND a $10.49 dispensing fee, the state saved $54,400,000.00 in one year! In PA we don't even get reimbursed correctly due to spread pricing and claw backs. How much are PBMs taking in? Ohio is following West Virginia and I'm reading other states are investigating PBMs: Arkansas, Kentucky, Louisiana etc. Please help out all states and create laws of transparency and oversite. It is estimated a pharmacy needs between $10 and $11 for liabilities, utilities, staffing, rent supplies etc. in addition to the cost of the drug. If West Virginia can do this and still save why can't a PBM? We don't even get enough reimbursement for the drug we dispense and if there is a fee its well below the $10 to $11 needed. Sometimes there is no dispensing fee or its pennies.

Our Pennsylvania Pharmacist Association in December of 2018 showed how "CVS Caremark uses federal tax money to pay itself and others more than independent pharmacies." See "PPA Capsule Why haven't the chains been joining us in complaining to the world about reimbursement pricing?" A thirty-day supply of the same drug was billed across the state of PA. CVS Caremark reimbursed CVS Pharmacy the highest $63.05. Independent pharmacies all over the state got reimbursed $14.24. How is this fair? Should an insurance or PBM be a provider? How is this fair to all the other pharmacies? CVS Caremark lies and keeps saying they reimburse independents more than CVS pharmacies. This isn't even counting the claw backs. Help! They lied to U.S. Senators under oath!

Our PA Auditor General had hearings about PBMs in which we testified. I am hoping our state follows Ohio. Their auditor general became attorney general, Dave Yost. He stated, "Our review of PBM practices throughout state government is still ongoing. These are the first raindrops, but there's a storm coming." You can read the full article "Ohio Attorney General Takes Pharmacy Benefit Manager to Court," by Catherine Candisky, March 18, 2019. Do you realize in one year the Ohio Department of Medicaid found OptumRx and CVS Caremark charged the state $224,000,000.00 more a YEAR for drugs than they were reimbursing pharmacies? They are a BENEFIT manager who BENEFITED themselves—not the patient, not the pharmacy, not the taxpayer!

Patients need their correct medicine based on their doctor. We need paid fairly as pharmacies and need to worry about counseling our patients not how much we lose on filling a prescription. Healthcare is getting worse, but let's start now and make it better. Patients deserve better healthcare than what is in place now. I think we all agree on that!

MORNING CONSULT

Retired Teachers on the Front Lines of the Drug Pricing Debate

By Jane Gilbert

More than two-thirds of Americans report that they are very concerned about the high cost of prescription drugs. So, as eyes turn to this week's State of the Union and the 116th Congress focuses on its work in Washington, drug pricing undoubtedly will be a top priority for lawmakers who are looking to create meaningful change for patients.

As steward of retiree health care for the Teachers' Retirement System of the State of Kentucky, I help ensure the integrity of the retirement benefits for more than 48,000 of our state's former teachers. Our voice—and that of other purchasers who provide health care and drug benefits to millions of other Americans—sometimes is lost in the noise around the drug pricing debate in Washington.

The teachers I work on behalf of paid into this retirement system throughout their careers, and it's my job to do everything possible to see that these benefits are there for them in their retirement years. This includes their access to affordable, quality health care, including their prescription drugs.

However, my job has become increasingly difficult as drug prices continue to rise with no end in sight. Recent studies show that over the last five years, the price of the 20 most prescribed drugs to seniors increased by an average of 12 percent each year—outpacing the average annual rate of inflation by 10 times. These rising drug prices have dire effects not just for retired teachers in Kentucky, but for retired Medicare beneficiaries across the country with fixed incomes.

To help manage retirees' costs in the face of ever-rising drug prices, TRS relies on pharmacy benefit managers to negotiate with drug manufacturers and drive down the prices of prescription drugs through both discounts and rebates. The PBM that TRS partners with helps TRS keep prescription drug costs in check by ensuring our retirees have access to lower-cost generic alternatives and by providing patient-focused programs and tools, such as medication management tools for chronic conditions of diabetes and heart disease. Eliminating rebates in Medicare Part D is a distraction from the real problem. The real problem is the drug list price that is not established by PBMs.

These programs and tools are critical to keeping TRS' health care costs from increasing at an unsustainable rate while also improving health outcomes and avoiding unnecessary, significant medical costs such as hospital admissions due to adverse drug events. TRS' PBM works hard to keep health care and drug costs affordable for Kentucky's retired teachers. In fact, PBMs are expected to save Kentucky patients and health care purchasers $9.4 billion over the next 10 years.

As policy makers in Washington look for ways to ease the burden of high drug prices on patients and their families, solutions should be found that expand and enhance the tools PBMs use on behalf of purchasers and patients and increase timely competition to improve access. Congress should focus on public/private partnerships, other market-based or federal solutions that will put downward pressure on the rising prescription drug prices set by drug companies and preserve affordable options for patients.

Retired Kentucky teachers, who dedicated their lives to educating future generations, shouldn't have to choose between paying for the prescription drugs they need to get to stay healthy and putting food on their tables. The stakes are too high to get this wrong.

Jane Gilbert is the director for retiree health care for the Teachers' Retirement System of the State of Kentucky, which represents more than 120,000 active and retired teachers in the State of Kentucky.

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(1) Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Grassley, Ranking Member Wyden, and the Members of the United States Committee on Finance for the opportunity to submit a statement on "Drug Pricing in America: A Prescription for Change, Part III."

NACDS and the chain pharmacy industry are committed to partnering with Congress, HHS, patients, and other healthcare providers to find solutions to lower the cost of prescription drugs and improve access to quality, affordable healthcare services. NACDS represents traditional drug stores, supermarkets and mass merchants with pharmacies. Chains operate over 40,000 pharmacies, and NACDS' over 80 chain member companies include regional chains, with a minimum of four stores, and national companies. Chains employ nearly 3 million individuals, including 157,000 pharmacists. They fill over 3 billion prescriptions yearly, and help patients use medicines correctly and safely, while offering innovative services that improve patient health and healthcare affordability. NACDS members also include more than 900 supplier partners and over 70 international members representing 21 countries. Please visit *nacds.org*.

As this Committee examines the rising costs of prescription drugs, we offer the following for your consideration.

(2) Lowering Costs Through Pharmacy DIR Reform

(a) CMS Proposed Rule

On November 30, 2018, the Centers for Medicare and Medicaid Services (CMS) issued a proposed rule, "Modernizing Part D and Medicare Advantage to Lower Prices and Reduce Out-of-Pocket Expenses" that included policy reforms that would increase competition in the Medicare Part D program and lower beneficiary out-of-pocket costs by reforming pharmacy direct and indirect remuneration (DIR) fees.[1] Specifically, these reforms would lower beneficiary costs by:

- **Redefining the "negotiated price" to include all pharmacy price concessions.** Including all pharmacy price concessions in the negotiated price would reduce its amount and result in lower beneficiary cost sharing;
- **Developing a broad definition of "price concession" to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce costs incurred by Part D sponsors.** Again, this would help ensure the lowest negotiated price and thus) lower beneficiary cost-sharing; and
- **Developing standardized pharmacy performance metrics for 2020. NACDS believes such metrics would be a good first step toward the development of Medicare Part D pharmacy quality incentive program.** HHS needs to develop a pharmacy quality incentive program to align incentives between plans, pharmacies and beneficiaries. Pharmacy incentive payments would support higher quality health outcomes. Examples are medication optimization and improved medication adherence, which would improve patient outcomes and reduce healthcare costs.

CMS has recognized the harms caused by pharmacy DIR fees for years.[2] The use of pharmacy DIR fees grew an 45,000 percent between 2010 and 2017.[3] Because of this, Medicare beneficiaries are paying more in out-of-pocket costs, the federal government is not fully understanding what it is paying for prescription drugs, and retail pharmacies are conducting business in an environment where they are unsure whether a payment will be clawed back at some later date as "DIR."

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[1] 83 Fed. Reg. 62152, 62190–92 (November 30, 2018).

[2] *See, e.g.,* 82 Fed. Reg. 56336, 56420–21 (November 28, 2017) (explaining how pharmacy DIR fees increase beneficiary costs and decrease drug price transparency necessary for competition among plans); CMS, Medicare Part D—Direct and Indirect Remuneration (DIR) (January 19, 2017) (noting the negative impact of pharmacy DIR fees on beneficiary drug costs, taxpayer subsidies and plan cost-avoidance); CMS, "Fact Sheet—Medicare Part D—Direct and Indirect Remuneration (DIR)" (January 19, 2017), available at *https://www.cms.gov/newsroom/fact-sheets/medicare-part-d-direct-and-indirect-remuneration-dir*.

[3] *Id.* at 62147.

CMS also recognizes that pharmacy DIR fees harm pharmacies by reducing transparency and predictability of reimbursement.[4] More broadly, pharmacy DIR fees undermine drug price transparency, which is necessary for efficient market competition that would reduce prescription drug costs.[5] Pharmacy DIR fees undermine the transparency needed to allow all stakeholders, notably patients and providers, to make informed decisions about how to best meet healthcare needs. As CMS also points out, "consumers cannot efficiently minimize both their costs and costs to the taxpayers by seeking and finding the lowest-cost drug or a plan that offers them the lowest-cost drug and pharmacy combinations."[6]

Beneficiaries are likely unaware that the increasing use of pharmacy DIR fees has led to inflated drug costs, and thus higher cost-sharing. The impact of higher cost-sharing for beneficiaries also negatively impacts medication adherence, leading to increased total cost of care and poorer health outcomes.

Moreover, finalizing pharmacy DIR reform needs to be coupled with the development of standardized pharmacy quality metrics and a pharmacy quality incentive program. Without a standard set of metrics, beneficiaries, pharmacies and plans are unable to make comparisons of pharmacy quality. As a result, there is not an effective means for consumers to compare plans and pharmacies within the Part D program, undercutting market competition, which can contribute to higher costs.

(b) Better Medication Adherence and Medication Optimization Reduce Healthcare Costs

Pharmacy DIR fee reform and the development of a standardized pharmacy quality incentive program will save taxpayers billions of dollars by aligning incentives for the entire Medicare program, which will encourage a more systematic investment in pharmacy quality programs designed to facilitate care coordination, reduce medical errors, advance population health, and empower and motivate beneficiaries to achieve better health outcomes through medication optimization services and improved medication adherence.

Medication optimization services encompass patient-centered activities that improve health outcomes by addressing medication appropriateness, effectiveness, safety, adherence, and access. Medication optimization services delivered by community pharmacies are central to the care of beneficiaries. Nearly all Americans (91.7 percent) live within 5 miles of a community retail pharmacy and in 2017 nearly 73 percent of prescriptions dispensed in the U.S. were filled at retail pharmacies. Face-to-face interactions with beneficiaries at the point-of-dispensing allow the pharmacist to counsel and educate the patient and are critical to achieving national-scale improvements in health outcomes and lowered costs.[7]

The better use of medicines will also reduce medication non-adherence—that is, patients not taking their medications as prescribed by their healthcare provider. Medication non-adherence contributes to $100–290 billion in unnecessary healthcare expenditures every year as a result of increased hospitalizations and other avoidable,

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[4] *Id.* at 62191.
[5] *Id.* at 62176.
[6] *Id.* at 62176.
[7] Patients who participated in brief face-to-face counseling sessions with a community pharmacist at the beginning of statin therapy demonstrated greater medication adherence and persistency than a comparison group who did not receive face-to-face counseling. The intervention group had statistically greater Medication Possession Ratio (MPR) than the control group every month measured. Taitel M, Jiang J, Rudkin K, Ewing S, Duncan I; "The impact of pharmacist face-to-face counseling to improve medication adherence among patients initiating statin therapy;" *Patient Prefer Adherence;* 2012;6:323–9, *https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3340117/*. Likewise, a systematic review was conducted using 51 studies determining the optimal modes of delivery for interventions to improve adherence to cardiovascular medications. Among person-dependent interventions (nonautomated phone calls, in-person interventions), phone calls showed low success rates (38%). In-person pharmacist interventions were effective when held in a pharmacy (83% successful) but were less effective in clinics (38%). Cutrona SL, Chaudhry NK, et al.; "Modes of Delivery for Interventions to Improve Cardiovascular Medication Adherence;" *AJMC;* December 2010, *https://www.ajmc.com/journals/issue/2010/2010-12-vol16-n12/ajmc_10dec_cutrona929to942?p=l*

expensive medical services.[8, 9, 10] Numerous studies have shown that reducing patient drug costs increases medication adherence, which, in turn, reduces overall healthcare costs. For example, a recent study found that medication nonadherence for diabetes, heart failure, hyperlipidemia, and hypertension resulted in billions of dollars in Medicare fee-for-service expenditures, millions of hospital days, and thousands of emergency department visits that could have been avoided.[11] Specifically, the study estimated that avoidable costs from medication nonadherence of four chronic conditions is $28.9 billion, representing 8 percent of the total expenditures. A 2017 white paper found that the direct medical costs and consequences related to not taking medication as prescribed is estimated to be 7 to 13 percent of national health spending annually—approximately $250 billion to $460 billion in 2017, translated to a potential cost to taxpayers of $6 trillion over 10 years.[12] And a 2016 cost-benefit analysis concluded that between one and two thirds of medicine related hospitalizations are caused by poor adherence. Improving adherence could result in annual per-person savings ranging from $1,000 to $7,000, depending on the disease state.[13] Multiple, credible sources have drawn the same conclusion: medication nonadherence is a costly, preventable problem that dramatically affects total cost of care.

(c) Committee Support

As detailed above, pharmacy DIR reform as proposed by CMS would lead to lower prescription drug costs for both Medicare Part D beneficiaries and federal taxpayers. In addition, pharmacy DIR reform would lead to better medication adherence among Part D beneficiaries, which would lead to further healthcare cost savings. With these cost saving benefits in mind, we urge the Committee to communicate support to CMS in favor of finalizing pharmacy DIR reform, including the development of standardized pharmacy quality metrics that would lead to a pharmacy quality incentive program.

(3) Reform to Manufacturer Rebates

(a) NACDS Supports Goals of Proposed Rule but Changes and Clarifications are Needed

The Department of Health and Human Services (HHS) and the Office of Inspector General (OIG) recently released a proposed rule with the goal of lowering the cost of prescription drugs by requiring that manufacturer reductions in prescription drug prices to health plans/PBMs be passed on to the patient at the pharmacy counter. We support the goals of the proposed rule and believe the changes could lead to reduced patient out-of-pocket costs and could lower government program costs by improving medication adherence. However, we believe HHS and OIG must include specific revisions to the final version, as well as issue other regulatory or sub regulatory guidance to maximize the impacts of passing manufacturer reductions in price to patients at the point-of-sale, reduce costs for all stakeholders, and increase efficiencies by utilizing and leveraging current capabilities and technologies. Below we summarize the changes and clarifications that are needed in the final rule or in concurrent guidance:

- **Timeliness of payments**—Payment of discounts to pharmacies under the HHS/OIG proposal must follow current prompt payment requirements. Without prompt pay requirements applying to all elements of pharmacy claims, pharmacies would face devastating cash flow challenges resulting from having to wait months after dispensing medications before receiving payment of manufacturer reductions in price.
- **Transparency**—The total reimbursement due to the pharmacy, including the amount of any payment related to manufacturer reductions in price, must be known by the pharmacy at the point-of-sale at the time of dispensing. Failure

[8] Rosenbaum L, Shrank WH; "Taking Our Medicine—Improving Adherence in the Accountability Era;" *New England Journal of Medicine;* August 22, 2013.

[9] Network for Excellence in Health Innovation; "Bend the Curve: A Health Care Leader's Guide to High Value Health Care;" 2011.

[10] The NCPIE Coalition; "Enhancing Prescription Medicine Adherence: A National Action Plan;" 2007.

[11] Lloyd, Jennifer T, Maresh, Sha, Powers, Christopher, Shrank, WH, Alley, Dawn E; "How Much Does Medication Nonadherence Cost the Medicare Fee-for-Service Program?"; *Medical Care,* January 2019.

[12] "A Treatable Problem: Addressing Medication Nonadherence by Reforming Government Barriers to Care Coordination;" *Prescriptions for a Healthy America;* October 2017.

[13] Patterson JA, et al.; "Cost-Benefit of Appointment-based Medication Synchronization in Community Pharmacies;" *American Journal of Managed Care;* 2016.

to account for the manufacturer reductions in price at the point-of-sale claim adjudication would make it nearly impossible for pharmacies to track the collection of open receivables and could put pharmacies at substantial financial risk.

- **Protection from Unnecessary Fees**—Pharmacies should not be responsible for fees or other costs associated with administering manufacturer reductions in price. Specifically, pharmacies should not pay additional transaction, administrative, or other fees either directly, or indirectly through reduced reimbursements. The total and final reimbursement to the pharmacy must consist of the full contracted reimbursement from the plan/PBM, the reduction in price negotiated between the manufacturer and the plan/PBM, and the cost-sharing payment from the beneficiary and shall not be affected by the reduction in price negotiated between the PBM and the manufacturer.
- **Maximize Efficiency and Minimize Additional Costs**—The final rule should maximize the use of existing technology, standards, systems, and business relationships. A new system potentially requiring the development of new capacities and technologies for data sharing, processing and auditing of payments to pharmacies, as well as new financial relationships, will only add unnecessary cost and complexity into the healthcare system.

(b) HHS Must Address Pharmacy DIR First

HHS must finalize reforms in the use of pharmacy DIR fees in the Medicare Part D program (as discussed in detail above) before moving forward with finalizing changes to the treatment of manufacturer rebates. Moving forward with reforms to manufacturer rebates without reforming the use of pharmacy DIR fees could incentivize even more aggressive use of pharmacy DIR fees, which would increase beneficiary and taxpayer costs, and lead to poorer medication adherence and worsening overall beneficiary health. We ask the Committee to communicate with HHS the importance of finalizing the proposed CMS rule that reforms pharmacy DIR before finalizing manufacturer rebate reform.

(4) Electronic Prescribing and the Part D Prescription Drug Plan

NACDS supports the efforts of HHS and CMS in integrating a patient-specific real-time benefit tool (RTBT) into the Part D benefit to drive lower prescription drug spending and minimize beneficiary out-of-pocket costs. Beneficiaries often arrive at the pharmacy counter with little or no insight as to what a medication will cost them, which can lead to overuse of unnecessarily expensive medications and the underuse of essential medications. We strongly agree with CMS that "reducing medication cost also yields benefits in patients' medication adherence" and that "increasing patient cost-share for a medication [is] associated with a significant decrease in medication adherence."[14] The integration of a RTBT into the Part D benefit will give providers and beneficiaries the information needed to make better informed choices on their healthcare treatment.

NACDS cautions that policies utilizing RTBTs must be designed in a manner that allows the prescriber to make a determination about whether a prescribed drug is covered by the beneficiary's insurance plan without fear of "steering" a beneficiary to certain pharmacies or to mail order. This could be accomplished by requiring the beneficiary to select his or her pharmacy of choice prior to the prescriber utilizing the RTBT to access the enrollee cost-sharing information. Moreover, we believe that the RTBT must provide sufficient information to the prescriber and pharmacy to facilitate clinical decision making and assist in determining optimal patient medication regimens.

RTBTs must also be able to take into consideration pharmacy-level cost-containment programs, such as $4.00 generic programs, or patient assistance programs. Moreover, absent system safeguards, RTBTs can inadvertently drive physician prescribing of expensive, therapeutically alternatives that are subject to high rebate arrangements between PBMs and manufacturers. Such results would negate the goal of using a RTBT and needlessly drive up overall spending in the Part D program. Policies utilizing RTBTs must:

1. Preserve patient's right to pharmacy selection at the outset;
2. Ensure accurate and complete patient's out-of-pocket costs at formulary and pharmacy levels;

[14] 83 Fed. Reg. 62152, 62165 (November 30, 2018).

3. Avoid unintended economic costs to taxpayers and beneficiaries associated with steering patients to therapeutic alternatives that are subject to "spread pricing" due to excessive list prices and rebates;
4. No commercial messaging within RTBT transmissions; and
5. Ensure information integrity, fairness and accuracy.

We ask members of the Committee to communicate to HHS the need for RTBTs to be implemented in a way that serves its goals of providing timely information that would lower prescription drug costs.

(5) Prohibition Against Gag Clauses in Pharmacy Contracts

NACDS applauds Congress for passing the "Know the Lowest Price Act of 2018" (Pub. L. 115–262) that prohibits plans from restricting their network pharmacies from informing their plan enrollees of the availability of prescription drugs at a cash price that is below what that the enrollee would be charged (either the cost sharing amount or the negotiated price when it is less than the enrollee's cost sharing amount) for the same drug under the enrollee's plan. We are encouraged that CMS states that the measure will become effective with the plan year starting January 1, 2020. The prohibition of gag clauses in contracts among plans, Medicare Advantage plans, PBMs, and pharmacies will enhance patient access to medications, enable pharmacists to have improved relationships with patients, and keep prescription drug costs for patients to a minimum.

(6) Conclusion

NACDS thanks the Committee for your consideration of our comments. We urge members of the Committee to ask HHS to use their authority to include pharmacy DIR fee reform, the development of standardized pharmacy quality metrics, and movement toward the implementation of a pharmacy quality incentive program in the Final Part D Rule for FY2020. We also urge the Committee to communicate to HHS support for moving forward with requiring manufacturer reduction in prices be passed on to patients at the pharmacy counter in a manner that does not unnecessarily burden the prescription drug supply chain or jeopardize patient access to their medications, and that doing so should occur following efforts to finalize pharmacy DIR reform. Finally, we ask members of the Committee to communicate to HHS the benefit of incorporating a RTBT into the Medicare Part D program in a manner that will drive lower spending on prescription drugs while protecting patient choice.

NATIONAL ASSOCIATION OF SPECIALTY PHARMACY
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The National Association of Specialty Pharmacy {NASP) thanks Chairman Grassley, Ran king Member Wyden, and the members of the United States Committee on Finance for the opportunity to submit a statement for the hearing record for "Drug Pricing in America: A Prescription for Change, Part III." NASP strongly shares the Committee's goals of lowering out of-pocket costs for Medicare beneficiaries, improving price transparency, and ensuring patients have continued and affordable access to needed medications. We thank the Committee for its ongoing focus and dialogue on these and other key issues that affect specialty patients and the specialty pharmacies that work to address their complex health care needs.

NASP and its members are committed to the practice of specialty pharmacy with a focus on the patients served to ensure better clinical outcomes while reducing overall healthcare costs. NASP defines a specialty pharmacy as a state licensed and registered pharmacy that is accredited by, or in the process of specialty pharmacy accreditation by an independent, third-party accreditor and solely or largely provides medications and patient medication management services to patients with serious health conditions requiring treatment with complex medication therapies. NASP represents the entire spectrum of the specialty pharmacy industry from the nation's leading independent specialty pharmacies and practicing pharmacists to small and mid-size pharmacy benefit managers (PBMs), pharmaceutical and biotechnology manufacturers of specialty drugs; group purchasing organizations; wholesalers and distributors; integrated delivery systems and health plans; and technology and data management companies. With over 100 corporate members and 1,500 individual members, NASP is the unified voice of specialty pharmacy in the United States.

As this Committee seeks to consider changes to the ways patients access prescription medications in the United States, we offer the following comments for your consideration, with a specific focus on the need to reduce patient costs by ensuring a competitive market of specialty pharmacies and allowing patients with complex medical conditions to have transparent and affordable access to specialty medications.

Lowering Medicare Part D Beneficiary Out-of-Pocket Costs—DIR Reform

Amending the Definition of Negotiated Price and Providing Pharmacy Price Concessions at the Point-of-Sale

Specialty pharmacies have seen dramatic growth in the collection of non-transparent pharmacy direct and indirect remuneration fees {DIR fees) by Pharmacy Benefit Managers (PBMs) since 2012. The Centers for Medicare and Medicaid Services {CMS) has determined that DIR fees issued as pharmacy price concessions grew more than 45,000 percent between 2010 and 2017,[1] with much of that growth occurring after Part D plan sponsors or their PBMs stood up so-called "performance-based" pharmacy payment arrangements that served to institute sizeable reductions in pharmacy reimbursement and zero savings for beneficiaries. In fact, plan sponsors sometimes opt for higher negotiated drug prices in exchange for higher DIR and, in some cases, even prefer a higher net cost drug over a cheaper alternative because any DIR received on the back end that exceeds the projections factored into the plan's bid contributes primarily to plan profits—not lower premiums for beneficiaries.[2]

In its review of this concern, CMS has also highlighted the growing disparity between gross Part D drug costs calculated based on costs of drugs at the point-of-sale, and net Part D drug costs that account for all DIR.[3] This disparity is in large part due to the post sale adjudication of so called "performance-related" DIR fees that many PBMs collect from pharmacies months after claims are submitted and reimbursed. As pharmacy price concessions increase on gross drug costs and are applied after the point-of-sale, specialty patients are paying higher and higher cost-sharing (copays and coinsurance). As a result, specialty beneficiaries are forced into the catastrophic phase of Part D much sooner than if pharmacy price concessions were accounted for at the point-of-sale. Specialty pharmacies know first-hand how this higher cost-sharing impedes beneficiary access to medications. For specialty patients, missing doses or stopping therapy altogether often results in serious setbacks in treatment, and may increase visits to emergency departments or necessitate more costly therapeutic interventions.

NASP agrees with the administration's position that DIR fees ultimately increase costs across the Part D program shifting financial liability away from the Part D Plan sponsor to the beneficiary, to the Medicare program and ultimately, to taxpayers. In late 2018, CMS issue d a proposed regulation, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses,"[4] which included a proposal to amend the definition of negotiated price and move all pharmacy price concessions, including direct and indirect remuneration (DIR) fees to the point-of-sale as soon as calendar year 2020. NASP strongly supports the administration's proposal and has valued the opportunity to work with the Department of Health as well as the broad pharmacy stakeholder community to encourage these efforts and offer recommendations on how to successfully implement pharmacy reimbursement reforms in a way that is most beneficial to the specialty patients served by the Part D program. Addressing this needed reform can be done via regulation or by passing legislation. NASP has endorsed bipartisan and companion legislation, S. 640 and H.R. 1034, the PHAIR Pricing Act of 2019 that would seek to eliminate DIR fees and implement a system of fairly assessing pharmacy quality. NASP specifically recommends the following legislative or regulatory actions be taken:

- **Redefine "negotiated price" at 42 CFR § 423.100 to include all pharmacy price concessions and to reflect the "lowest possible price" at the point-of-sale.** Making this change will reduce beneficiary cost sharing and eliminate retroactive pharmacy price concessions, providing increased price transparency for patients and pharmacies.

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[1] 83 Fed. Reg. 62174.
[2] 82 Fed. Reg. 56420.
[3] 82 Fed. Reg. 56419–56428.
[4] 83 Fed. Reg. No. 231, November 30, 2018; CMS–4180–P; RIN 0938–AT92.

- **Develop a broad definition of "price concession" to include all forms of discounts, direct or indirect subsidies, or rebates that serve to reduce costs incurred by Part D sponsors.** NASP believes codifying a definition is necessary to support consistent accounting of amounts that are pharmacy price concessions by Part D sponsors.
- **Ensure reasonable reimbursement to pharmacies participating in the Medicare Part D program so that the payment received is not less than a pharmacy's cost to dispense.** Reimbursement below cost can force pharmacies out of networks and even out of business, limiting beneficiary access to the pharmacy of their choice and needed for their specialty conditions.

Establishing Standardized Pharmacy Quality Metrics and Defining Specialty Pharmacy

Specialty medications are more clinically complex than most other prescription medications and are used to treat patients with serious and often life threatening conditions including cancer, hepatitis C, rheumatoid arthritis, HIV/AIDS, multiple sclerosis, cystic fibrosis, organ transplantation, human growth hormone deficiencies, and hemophilia. Current statute and regulations do not define specialty drugs, but regulations instead classify specialty drugs as those exceeding a threshold of $670. The cost of a drug should NOT be the basis on which a medication therapy is classified as "specialty." In fact, there are many low-cost medications that are considered by clinicians to be specialty medications because of the complexity of the patient and diseases the medications are used to treat and the unique and labor-intensive services required to assure proper utilization and maximize a patient's clinical outcome.

A specialty pharmacy is needed to support the dispensing of specialty drugs, particularly for drugs that are not routinely available, as well as the extensive patient engagement needed to support clinical management of a patient on specialty therapies. Current statute and regulations do not define specialty pharmacy, which contributes to problems in ensuring network adequacy for patients to access specialty drugs and the specialty pharmacy of their clinician's and personal choice. It also creates unnecessary but fixable challenges in the effort to establish a quality-based payment system for specialty pharmacies. Specialty pharmacies provide:

- *High-touch patient education.* Specialty pharmacies serve as an extension of a physician's office, educating the patient on both the disease and the prescribed therapy. Many specialty pharmacists have specialized areas of clinical expertise, which the prescribing physician relies upon to help manage the patient and their disease.
- *Patient-centric medication management.* Many specialty therapies require in-depth patient/caregiver therapy education, assistance with medication administration, counseling regarding side effects, and continuous monitoring.
- *Navigating coverage and payment issues.* Plan sponsors and PBMs typically utilize significant formulary management tools to ensure medically necessary utilization of specialty drugs, including prior authorization, step therapy, quantity limits and therapeutic switching. In response, specialty pharmacies work with prescribing physicians and payers to facilitate the coverage process, and as needed, determine options for patients to afford their medications.

Specialty pharmacies are severely impacted by "performance based" DIR fees as these fees are assessed using wholly inapplicable performance or quality metrics for drugs that are NOT dispensed by specialty pharmacies and disease states not being managed by specialty pharmacies. Often times, such broader pharmacy measures created by plan sponsors and PBMs are not even appropriate for specialty pharmacy evaluation, as the specialty pharmacy cannot influence the measure (*e.g.,* generic pricing performance). When a specialty pharmacy receives retroactive financial penalties for not meeting PBM-applied DIR performance metrics that are unrelated to the drugs the pharmacy dispenses and the disease states these pharmacies are helping to manage, the pharmacy faces significant financial uncertainty, as their actual reimbursement rate cannot be determined until well after they have dispensed the medication. Oftentimes when the reimbursement is reconciled, it is far less than the actual cost of the drug, which is further complicated by the cost of the requisite services provided by specialty pharmacies to support the patient's journey on the drug. This situation threatens the ability for specialty pharmacies—particularly independent specialty pharmacies that simply do not have the ability to offset lost revenues or costs with other portions of their businesses—to remain network providers, risking access and satisfaction for beneficiaries.

NASP specifically recommends the following regulatory or legislative actions be taken to address concerns with the current DIR performance metrics:

- **Have the Department of Health and Human Services work with stakeholders to establish and have HHS oversee the creation of standardized pharmacy performance metrics that are calculated and reimbursed separate and apart from the negotiated drug price at the point of sale** to ensure any incentive payments tied to metrics: (1) do not increase costs for beneficiaries; and (2) appropriately assess the actual quality performance of a pharmacy in a manner that is specific to the pharmacy type, drugs dispensed, and disease states being managed.
- **Establish a definition of specialty pharmacy** to ensure that performance metrics are appropriate by pharmacy type—with specialty pharmacy defined as a type, similar to how retail is defined in regulation.

These recommendations are both included in the pending Proposed Medicare Part D regulation and included in the bipartisan companion bills S. 640 and H.R. 1034, the Phair Pricing Act of 2019.

Protecting Access to Specialty Drugs and Services and Market Competition

The Medicare Part D Program requires plan sponsors to offer any willing pharmacy (AWP) an in network pharmacy contract with standard terms and conditions that are **reasonable and relevant.**[5] Congress created the AWP requirements to ensure a competitive marketplace in order to lower costs and improve beneficiary access to all types of pharmacies. NASP has serious concerns that Part D plans and their PBMs that own their own specialty pharmacies continue to find opportunities to circumvent statute and exclude other specialty pharmacies from network participation. They look at regulatory definition of "pharmacy type" referenced by the AWP statute and see that specialty pharmacy is not defined in statute or regulation, and they use that to circumvent AWP requirements in place today. Efforts to exclude network access for specialty pharmacies include: offering contracts to specialty pharmacies with unreasonably low and non-negotiable reimbursement rates and requiring PBM accreditation (w/fees) for already accredited specialty pharmacies.

By excluding other specialty pharmacies from its network, the PBM therefore drives more distribution revenue to its own subsidiary specialty pharmacy such that PBM is using its status as a "gatekeeper" in one line of business to drive business to another line of business that it owns, which is a specialty pharmacy. The PBM that owns its own specialty pharmacy is therefore incentivized to exclude other competitor specialty pharmacies. In doing so, the PBM that owns a specialty pharmacy achieves two important financial goals. First, to drive greater revenue and profit to its own specialty pharmacy given that the PBM-owned specialty pharmacy is obviously in network with its parent corporate entity. Second, to create greater leverage in its purchasing power against manufacturers and wholesalers as a result of its greater influence in the network.

NASP urges protections to ensure that plan sponsors and PBMs that own their own specialty pharmacy business cannot provide more advantageous pricing to their own entities in an effort to limit a pharmacy network and gain greater market share. The exclusion of qualified specialty pharmacies from payer networks has negative effects on specialty pharmacy care for patients. Due to a smaller number of choices, patients with complex and rare disorders may lack access to beneficial clinical programs specific to their disease state. Networks that include a limited number of pharmacies create confusion for beneficiaries and medical providers and routinely result in significant delays in treatment, may worsen health conditions and increase hospitalizations and patient health care costs.

As the administration and Congress contemplate regulatory and statutory changes that would require that rebates between manufacturers and PBMs be moved to the point of sale, NASP urges careful consideration over loopholes that could serve to the advantage of PBMs. for example, some large specialty pharmacies are under common ownership and control by PBMs and/or plan sponsors. NASP is concerned that a PBM/plan sponsor could potentially offer a manufacturer favorable formularies or other coverage support for its products in exchange for a purchase discount, instead of a rebate. There must be protections to ensure that arrangements for manufacturer price concessions are not more favorable for PBM/plan affiliated specialty pharmacies than they would be when the same drug is dispensed by a network specialty pharmacy. Reforms to the system must not result in a deliberate pricing dis-

[5] Social Security Act (SSA) § 1860D–4(b)(1)(A).

advantage for network specialty pharmacies that are unable to influence formulary placement, allowing PBM/plan-owned specialty pharmacies to gain a market advantage. Providing statutory or regulatory protections against such practices is all the more important when addressing pricing for drugs where there are limited drug alternatives for patients, such as those with rare and other specialized conditions. Specialty pharmacies provide medication and services that are tailored to managing these unique populations. Network adequacy and ensuring that the contracting negotiations and practices that result from reforms to the system do not violate any willing pharmacy requirements is essential to ensuring access to these medications for patients.

NASP specifically recommends the following regulatory or legislative act ions be taken to protect market competition for specialty pharmacies:

- **Establish a definition of specialty pharmacy** to eliminate loopholes in current AWP statutory requirements and ensure that plan sponsors do not limit network opportunities for non-PBM owned specialty pharmacies.
- **Require regulatory protections against anticompetitive market efforts** to ensure that plan sponsors and PBMs that own their own specialty pharmacy business cannot provide more advantageous pricing to their own entities in an effort to limit a pharmacy network and gain greater market share.
- **Require regulatory protections by codifying provisions in existing CMS guidance and manuals** to protect pharmacies against reimbursement that is below a pharmacy's drug acquisition cost.
- **Establish a pharmacy appeal process** during the plan sponsor bid process that allow pharmacies to appeal when reimbursement is below a pharmacy's drug acquisition cost.

Conclusion

NASP thanks the Committee for consideration of our comments. The recommendations provided can help meet the Committee's goals of decreasing out-of-pocket beneficiary costs for prescribed medications, improving transparency in the drug pricing channel, and ensuring a competitive specialty pharmacy marketplace. NASP looks forward to working with the Committee as it continues to address drug pricing policy reforms.

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April 19, 2019

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Honorable Members of the Senate Finance Committee,

On Tuesday April 9th and Wednesday April 10th the Senate Finance Committee and House Energy and Commerce Committee respectively convened hearings to question pharmacy benefit managers (PBMs) about their role in the high cost of prescription drugs. Despite attempts by both the Senate and House to obtain straight answers to straightforward questions, the PBMs responses were limited to a handful of tired talking points about "saving clients' money" and "passing 100% of rebates through to their clients."

While neither hearing resulted in transparency or even a clear definition of "client," we applaud Rep. Buddy Carter for calling attention to the relationship between PBM-negotiated rebates and insurance companies—notably the ones that own PBMs and those that are PBM-owned. That is to say, PBMs with financial ties to insurance companies are very often negotiating and keeping rebates and fees extracted from those rebates for their parent company. This is another way for them to use the rebate to benefit their own bottom line and continue to cut the public out of these "savings."

America's prescription drug system is irreparably broken and the "fixes" that have been proposed and implemented so far have only made the situation worse. These fixes include turning state- and federally-funded Medicaid and Medicare programs

over to private contractors in the name of saving beneficiaries (patients) money. But thanks to recent state investigations, we now know PBMs can game the system to drive small pharmacies out of business while bilking taxpayers out of hundreds of millions of dollars.

Only full regulatory oversight of PBMs and complete transparency among members of the prescription drug supply chain will enable us to fix our broken system. Independent pharmacists know this includes but is not limited to:

- Ending the practice of manufacturer rebates to PBMs, which increases drug list price and ultimately drives prices up for the patient.
- Eliminating the practice of spread pricing.
- Eliminating Direct and Indirect Remuneration (DIR) fees that are charged back to pharmacies months after the patient's initial transaction and which increased an average *per store* in the U.S. from $74,711 in 2017 to $129,614 *per store* in 2018. There is no evidence these DIR fees have lowered costs or premiums for Medicare Part D beneficiaries.
- Eliminating the use of multiple reimbursement reference points for the same drug including maximum allowable cost (MAC) lists, generic effective rate (GER) and brand effective rate (BER), which vary by pharmacy and financial affiliation to the PBM. It ultimately prevents pharmacies from being able to recoup the costs to purchase the drug. Pharmacies losing money will close, thereby threatening patients' access to their medications especially in the rural and underserved communities.
- Standardizing drug acquisition costs for pharmacies via Centers for Medicaid and Medicare National Average Drug Acquisition Cost (NADAC) database plus a professional dispensing fee indexed to state Medicaid and/or NACDS/NCPA survey for state and federally-funded plans. This would allow for price predictability for patients and their pharmacies and end the stressful and embarrassing "how much does this cost" guessing game.
- Eliminating per-prescription commissions and other per-prescription, per-month fees paid to insurance plan brokers who shuttle the largest PBMs to the largest plan sponsors ensuring competition at the top is limited to a few multi-billion dollar players. Per-prescription per-month broker commissions add hundreds of millions of extra costs to patient and end-payer premiums.
- Prohibiting PBMs from owning pharmacies and steering patients to those pharmacies through fear tactics, misleading propaganda and/or financial incentives not also available to other pharmacies in the PBM network.
- Eliminating the practice of "self-dealing" to PBM-owned pharmacies in order to pay those pharmacies a higher reimbursement than non-PBM owned pharmacies.
- Eliminating restrictive practices that result in a "distribution monopoly" that includes, but is not limited to, mandatory mail order, specialty drugs, biosimilars and restricting the right of other pharmacies to provide patients with a 90-day supply. These practices create conditions for rampant price gouging as well as limit patient accessibility and choice and are blatantly anti-competitive.
- Further eliminating monopolization by protecting pharmacies from excessive PBM-imposed credentialing requirements to hamper their ability to mail medications or dispense certain drugs.
- Eliminating transactions fees charged to pharmacies for everyday business tasks including submitting patient claims for reimbursement, which can amount to as much as $1,500 per month in service of patients.

PBMs are fighting VERY hard to protect their privacy, defaulting to tired claims of "proprietary information" and "trade secrets" when asked the most basic questions about their pricing practices. They use a tired scare tactic by making ominous and nonsensical threats about "drug prices going up" if transparency is mandated.

America's high drug price crisis can be fixed, and Americans should be the ones to fix it. We call on our country's legislators, healthcare providers and healthcare business leaders to work together to resolve the problem together to make American prescription drugs affordable again.

Respectfully,

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PHARMACISTS UNITED FOR TRUTH AND TRANSPARENCY—ILLINOIS

April 19, 2019

U.S. Senate
Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Honorable Members of the Senate Finance Committee,

I am writing to you on behalf of the community and independent pharmacies in Illinois to express our collective frustration and concern at the lack of accountability in the answers the pharmacy benefit manager (PBMs) representatives provided during the April 9th hearing.

It is disconcerting to hear the spokespersons of these Fortune 100 corporations, who themselves represent an industry grossing more than $300 billion annually, make claims of transparency, fair payment practices, and passing on rebates to their clients. We know from direct, everyday experience that many of the statements they made were misleading at best.

Between the various hearings, Congress has spoken to patients, drug manufacturers, pharmacy benefit managers and insurers. To the best of our knowledge, Congress has never asked a pharmacist to share their view—how we handle situations in which patients discover they can't afford their medication; or what we must deal with when PBMs refuse to reimburse the acquisition cost of a medication but justifying charging us exorbitant Direct and Indirect Remuneration (DIR) fees. *In Illinois, community pharmacies were charged an average of $61,300 per store in 2017. In 2018, community pharmacies were charged an average of $104,658 per store at the same time reimbursements back to pharmacies for dispensed prescriptions were cut.*

In the words of a pharmacy owner in southeastern Illinois, whose pharmacy also serves a town with a population of less than 650:

> "We have been open for 25 years and very established. We average 200–225 rxs/day. I also own a telepharmacy. . . . My reimbursements are so poor that the cost of the vial, label, drug, electricity, tech time, and registered pharmacist's time puts me in the negative for most generic drugs. Our local state senator told some other local independents that we should find other sources to buy cheaper. But when we get paid cents on the dollar . . . that doesn't even cover basic expenses. My relief pharmacist (who only works 1 day per week average) made more than I took home last year. . . . I have been cutting back on extra expenses. . . . I just wish the Execs from PBMs would answer as to why they are taking premiums from the patients, rebates from the manufacturers and DIR fees from the pharmacy. And how they can sleep at night knowing they are killing small independent pharmacies like myself. This is just not right! They say they are for transparency . . . explain why they have to have DIR fees. I would also like to be paid the same as any chain is, that way the patient not the PBM can decide which pharmacy they go to."

For non-PBM owned pharmacies, DIR fees, transaction fees, network certification fees—even fees for calling the PBM help desk—are the reality. Excessive fees result in an unsustainable system that ultimately limits choice and access to medications for patients by forcing the closure of small business pharmacies. *Last year, 90 pharmacies were forced to close their doors in Illinois.*

PBMs, on the other hand, are a growing business. Their "volume power" is enormous, never more so since acquiring or being acquired by larger insurers (CVS/Aetna; Cigna/Express Scripts). PBMs are money makers—there's no other reason an insurer would seek to acquire a PBM other than to gain more of an already almost closed market. *Some 80% of all prescriptions processed in the United States go through CVS Caremark, Express Scripts or OptumRx.*

In the words of a pharmacy owner in central Illinois:

> The PBM execs kept focusing on specialty meds, which of course are the highest priced items. They probably do help to some extent to keep those prices in check (while most of the time shutting out the independents from filling these prescriptions). However, if I had had an opportunity to ask them one question, it would have been: "Do you think reimbursing a pharmacy under a dollar (total reimbursement) for a 30 day supply of ANY medication is considered egregious and predatory pricing?" We have exam-

> ples day in and day out of these predatory claims (priced by our main competitor, CVS Caremark). Here are a few: #30 Lisinopril 10mg Tab—$0.57; #30 Amlodipine 5mg Tab—$0.42; #30 Lisinopril 40mg Tab—$1.07; #60 Lorazepam 0.5mg Tab—$1.25; #30 Citalopram 40mg Tab—$0.57; #30 Amlodipine 10mg Tab—$0.33. My concern, along with all of the independents, is with this type of predatory pricing, patients will lose access to care once the independents are gone. *I am unaware of any other retail business ill which the business' main competitor is allowed to set their competitor's retail price.* The highest percent of the drug spend is brand and specialty, but the highest percent of prescriptions filled is in generic drugs, for which their pricing is predatory.

The PBM system is rigged in favor of the real client—the insurance company that owns the PBM. These are the "clients" who benefit from receipt of manufacturer rebates. The constant comment that drug prices will go up if rebates disappear is just another way of saying, "We will raise our prices to account for the loss of the rebate revenue stream."

This letter addresses only a few anti-competitive practices PBMs use in their daily interface with pharmacies. There are many more you don't hear about, and wouldn't because pharmacies are subject to confidentiality agreements beyond the ability to disclose cheaper-priced drug options to patients. Some of these other practices involve the use of multiple Maximum Allowable Cost (MAC) lists, which allows the PBM to reimburse a pharmacy for the same drug at a variety of different reimbursement levels; audit abuses, in which PBMs can withhold reimbursement and penalize a pharmacy literally hundreds or thousands of dollars for simple mistakes such as a typo on a submission claim; and avoiding responsibility for paying local sales or other tax, forcing pharmacies to pick up those charges instead.

It would be difficult to know these practices are taking place if you didn't know what questions to ask. A former pharmacy owner from Illinois asked that we include his list of questions and commentary, in hopes these questions might be helpful in the future. The questions are attached for your reference.

Pharmacists who speak up about PBM abuse are often called "self-serving" and "greedy" by PBMs. Nothing could be further from the truth. *An attack on pharmacy is an attack on the patient.* Patients depend on their pharmacies for access to their medication but also look to their pharmacists for help and guidance in medication therapy. The relationship between pharmacists and patients is truly a sacred trust, especially in communities where there are few available options for filling a prescription.

Senators, no one goes into pharmacy because it's a good business idea or to get rich—it's too complex, too tipped in favor of giant corporations to be a typical small business startup. Pharmacies are here because pharmacists are called to be here, because they are carrying on generations of family tradition taking care of neighbors and doing right by the people in their community.

America's community pharmacies are the "canary in the coalmine" of the prescription drug system. Pharmacies and patients have a special relationship built on trust and communication. They may be the only part of the health care team that stays with the patient for generations, not just years, so they have a very good perspective on issues facing patients today.

We ask you to protect patients and their pharmacies by implementing legislation that mandates full regulatory oversight of PBMs, similar to how insurance companies are regulated.

We applaud the work you're doing to investigate the high drug pricing crisis and protect patients, because to us, they aren't just customers, they are our reason for being here.

Respectfully,

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