OPEN EXECUTIVE SESSION TO CONSIDER AN ORIGINAL BILL ENTITLED THE "BETTER MENTAL HEALTH CARE, LOWER-COST DRUGS, AND EXTENDERS ACT"

WEDNESDAY, NOVEMBER 8, 2023
U.S. Senate,
Committee on Finance,
Washington, DC.

The meeting was convened, pursuant to notice, at 10:03 a.m., in Room 215, Dirksen Senate Office Building, Hon. Ron Wyden (chairman of the committee) presiding.

Present: Senators Stabenow, Cantwell, Menendez, Carper, Cardin, Brown, Bennet, Casey, Warner, Whitehouse, Hassan, Cortez Masto, Warren, Crapo, Grassley, Cornyn, Thune, Cassidy, Lankford, Daines, Barrasso, Johnson, Tillis, and Blackburn.

Also present: Democratic staff: Shawn Bishop, Chief Health Advisor; Eva DuGoff, Senior Health Advisor; Janice Lepore, Fellow; Joshua Sheinkman, Staff Director; Tiffany Smith, Deputy Staff Director and Chief Counsel; and Kripa Sreepada, Senior Health Advisor. Republican staff: Becky Cole, Chief Economist; Erin Dempsey, Deputy Health Policy Director; Brady Gable, Senior Health Policy Advisor; Kellie McConnell, Health Policy

Director; Gregg Richard, Staff Director; and Charlotte Rock, Health Policy Advisor.

OPENING STATEMENT OF HON. RON WYDEN, A U.S. SENATOR FROM OREGON, CHAIRMAN, COMMITTEE ON FINANCE

The Chairman. The Committee will come to order. We meet today to consider the Better Mental Health Care Lower Cost Drugs and Extenders Act. This is a busy day in the Senate, with many other committees also conducting business. So for the information of Senators and staff, let me explain how I and Ranking Member Crapo would like to proceed.

We each are going to deliver an opening statement. Other Members are then welcome to deliver opening statements of up to two minutes. Once opening statements have been given, we will introduce the panel and allow Members to ask questions of the Committee staff. After that, we will consider amendments to the mark.

We are then going to vote on whether to report the mark. If a quorum for a vote is not present, we will vote when we have a quorum. We will let offices know the time of the vote, to make sure that we do have a quorum. With that, we are going to turn to opening statements. I will give mine. We will turn to Senator Crapo's and then to colleagues.

Today, we look at a package of health proposals

that represents important bipartisan initiatives undertaken by the Committee, and we work on several goals: expanding access to mental health care and mental health parity for Americans with Medicare and Medicaid; further reining in the shadowy tactics by pharmacy benefit managers that hurt community pharmacies and drive up prescription drug costs for seniors and taxpayers; we extend essential Medicare and Medicaid provisions that expire this year; and we shore up Medicare payments to physicians.

I want to thank Senator Crapo. We have been partners in this every step of the way, and our colleagues. First with this package, the Committee is going to tackle unfinished business, working to guarantee that Americans everywhere can get the mental health care they need when they need it.

As I travel my home state, holding open to all town meetings, I continue to hear firsthand how badly people and particularly young people are struggling and they are not alone. One-third of Americans have suffered or have a family member who has suffered a mental health crisis.

Yet the U.S. Surgeon General, Dr. Vivek Murthy, testified in our Committee that Americans experience an 11-year gap between the time they first experience

symptoms from mental health condition and when they finally get treatment.

And then there is the substance use disorder crisis in our country. Overdose deaths in America hit a new high in 2022, fueled by the COVID-19 pandemic and the rise of fentanyl use. In response, the Committee started in with hearings, requests for proposals and a strong focus on bipartisanship.

Last year, nearly 20 mental health proposals developed in the Committee, were passed and signed into law. The proposals we authored included measures to get more mental health counselors for kids in both schools and through telemedicine; more resources for community behavioral health centers, where my seat mate has done so much good, thank you, Senator Stabenow; new benefits that cover family therapists in Medicare; and funding to train new doctors, including psychiatrists.

Today, the Finance Committee builds on our record with additional mental health measures. For example, we have been working now to stamp out one of the worst rip-offs I have heard in a long time, and that is this question of ghost networks.

Essentially what happens, I want to thank Senator Bennet in particular. I know Senator Tillis and others have been working on this. This is outrageous, because

what happens is after people pay money to get a good mental health policy, essentially they cannot get services, they cannot talk to providers, they cannot really get much of anything.

There is really no "there" there, and to really give you an idea how outrageous this is, when a person who has bought this coverage is in urgent need of care and goes somewhere else and has to pay extra, they get stuck with the bill rather than the people they originally contracted to get services with.

So, I am really pleased. Senator Bennet, Senator Tillis, my colleagues on both sides of the aisle are joining us and saying that these ghost networks are going to be a thing of the past. There are going to be real consumer protections in this bill. Insurers are going to actually have to cover what people have contracted for. That is what this is all about, honoring a contract, and it is high time.

We have also made it easier for states to provide continuity in mental health and substance use disorder, care for people in the justice system who have not been convicted of a crime. We have included several provisions to help states work with neighboring states to expand telemedicine for mental health care providers.

This is basically bringing services into the 21st

century, because we all know that if you cross over just a little ways into another state, you ought to be able to work something out in order to get some services, and this bill is going to help do that.

We increase the kinds of providers servicing seniors to Medicare as well, and counseling services to them in the mental health area will be more widely available. The package builds on the markup that we had in July. We voted 26 to 1 to modernize the prescription drug programs and stop these PBM middlemen, stop them cold from heaping extra costs on seniors and taxpayers.

I want to thank particularly Senator Crapo. We have worked with all the colleagues on the Committee and I think now we really have a first-rate bill that is going to send the message for the first time in this $4 trillion health care system that we have got in America, that we are cracking down on middlemen. I think that too is long overdue.

So, we have got additional work to do in terms of scores from the Congressional Budget Office. I want to thank Dr. Swagel. He has been very helpful. We are going to consider proposals today, ground-breaking efforts that protect community pharmacies, for example. This is long overdue because they have been singled out for predatory PBM tactics and lower out-of-pocket costs

for chronic disease drugs.

The package is going to further root out the middlemen, and that is going to help steer America's prescription drug market towards a state of rationality and common sense, where the initiatives are always to focus on lower costs for patients and taxpayers. That is what we focused on, lower costs.

Senator Crapo and I also have agreed to continue to work with the Budget Office on a proposal that is not in today's package. It is a proposal from Senators Lankford and Menendez that would make lower cost biosimilars more accessible to seniors under Medicare Part D. We want to thank Dr. Swagel. We continue to work with his office on getting the scores of the proposal, and we will have more to say about that during the markup.

Third, the package extends provisions of law that are set to expire this year. It makes no sense to wait until the last minute. The safety net, hospitals and others, they are doing so much good work for low income folks, who obviously depend on it.

We have also got another year of bonus payments to physicians who move away from the practice of fee for service medicine towards value-based care. A number of our colleagues have done good work on that. Senator

Whitehouse is not here, Senator Barrasso. But they have teamed up in a bipartisan way to promote those sensible payments that encourage quality and value-based care.

Finally, the package provides a one-year increase to Medicare physician payment. Our goal is to shore up Medicare's effort in 2024 to boost payment for primary care. Next year, the Finance Committee will take a deeper look at Medicare physician payment, as several provisions in current law have to be re-examined.

In doing so, we again are going to always come back to this lodestar, where we are spending $4 trillion a year in health care. We have got 330 million of us. Divide 330 million into this four trillion, and you could send every family of four an enormous check, well over $40,000.

So we are spending a lot of money. We are not spending it in the right places, and too much is frittered away on middlemen. We are not doing enough to address chronic diseases, and we will talk about that in today's markup.

Now I am going to turn it over to Senator Crapo. I want to thank him for his cooperation and all our Members, all our Members have been involved in this effort, and we are going to hear from our colleagues after Senator Crapo.

OPENING STATEMENT OF HON. MIKE CRAPO, A U.S. SENATOR FROM IDAHO

Senator Crapo. Well, thank you, Mr. Chairman. Three months ago, this Committee took crucial steps toward improving health care access and affordability for Americans in all walks of life. In advancing the Modernizing and Assuring PBM Accountability Act, we demonstrated the bipartisan conviction and momentum needed to move good policy from concept into law.

At that time, the Chairman and I committed to continuing our work on this prescription, on prescription drug benefits and with this markup, we honor that commitment.

I want to thank Senator Wyden again for the partnership we have been able to develop, and as he has already said, this was a partnership with every Member of this Committee working the way that a Committee ought to work to resolve differences and find common sense bipartisan paths towards solutions that are needed in this country.

I also want to give a shout-out to our staff, and I do not just mean the Committee staff. I mean the staff of every Member of this Committee, who have been working tirelessly to try to do what is now being done

in this Committee, and get that bipartisan agreement put together. This is the way Congress ought to work, and I appreciate the opportunity to work with you Mr. Chairman on this legislation.

Today, we are taking up common sense, comprehensive proposals championed by Members across the dais to strengthen our federal health care programs. For two decades, Medicare Part D has served as a lifeline for countless seniors and Americans with disabilities, ensuring coverage for a wide range of safe and effective medications.

However, market dynamics has shifted. Consolidation has constrained competition, compromised plan quality and heightened the potential for conflicts of interest across the supply chain. Vertically integrated insurers merged with pharmacy benefit manufacturers or PBMs, now account for more than 80 percent of the Part D market, up from just 30 percent in 2010.

Four PBMs manage benefits for 90 percent of enrollees. The three largest specialty pharmacies are all PBM affiliates, controlling more than two-thirds of specialty drug dispensing. In short, the market-driven dynamism envisioned with Medicare Part D's enactment has given way to an opaque, highly concentrated and

distorted pharmacy benefit landscape.

This situation demands oversight and legislative improvement. Taxpayers and seniors finance the program. We are the client. We have a responsibility to promote accountability and improvement, particularly for the most vulnerable and highly in need Americans. Over the past five years, out of pocket costs for Medicare seniors have risen at nearly three times the rate for commercially-insured consumers.

According to a recent report from the Government Accountability Office, Part D beneficiaries pay more than their insurers for 79 of the 100 most highly rebated drugs under the program. The warped, distorted rebate system that dominates the program curbs access to lower-cost medications.

It instead exposes patients to cost sharing based on inflated sticker prices. In a perverse form of reverse insurance, this counts on medications used by the highest need enrollees cross-subsidize the healthiest seniors, with no direct savings at the pharmacy counter.

Thanks to the tireless efforts of Senator Cornyn and Senator Tillis, among others, the legislation before us today would chip away at this outdated model, providing relief to patients with chronic conditions and

capping cost-sharing for all Part D enrollees at the net price of any given drug, inclusive of rebates.

Beneficiaries would save on countless prescriptions, importantly without premium hikes. Under policies led by Senators Blackburn and Lankford, seniors would also see increased pharmacy choice. Our bipartisan bill shores up the enforcement of pharmacy access protections. It would provide for a much-needed focus on independent community sites in medically underserved areas.

With these updates, the Committee's PBM reform legislation would adapt Medicare Part D to address these and other challenges facing today's seniors. Importantly, this comprehensive proposal would also pay for itself, upholding our bipartisan commitment to fiscal responsibility.

Senator Cassidy's continued investment in cost transparency has proven crucial here. In fact, our legislation generates net savings which we have reserved to account for any costs incurred under Senator Lankford's targeted biosimilar access policy, which we remain committed to advancing.

Beyond prescription drug access and affordability, the bill before us reaffirms this Committee's consensus-driven approach to health care improvements on

a wide range of fronts. Mental health provisions crafted by Senators Cornyn, Thune and Daines would drive care integration, improve telehealth access and help to address workforce strain, based on bipartisan proposals developed last year.

Today's legislation also extends key flexibilities for states, to ensure appropriate sites of care for behavioral health needs, thanks to leadership from Senators Thune and Blackburn. Under a policy led by Senator Barrasso, front-line health care providers would retain incentives to enter into value-based payment models.

Clinicians would also receive targeted relief from reimbursement cuts triggered by the volatility of the physician fee schedule. Another vital policy extension championed by Senator Grassley would avert further cuts to doctors across our states, which could otherwise exacerbate ongoing shortages.

Outlining every provision today would take more time than we have. Virtually all Members of this Committee have contributed in meaningful, essential ways to the patient-focused, fiscally sound and evidence-driven financial product, final product.

Senators across the dais have also produced a range of compelling amendments, creating a robust road

map for further collaborative work moving forward, from enhancing access to ground-breaking early cancer screening technologies, to strengthening the physician fee schedule through sustainable structural reforms, we have endless opportunities for meaningful, Member-driven policymaking in the future.

Specifically, one such amendment, the Medicare Multi-Cancer Early Detection Screening Coverage Act, which I lead along with Senators Bennet, Cardin and Scott, has support from a majority of the Senate, including 19 co-sponsors on this Committee, as well as from a majority of the House members, and from more than 700 local and national stakeholder groups representing all 50 states.

Given this rare and broad bipartisan support, I look forward to working together to move this policy through this Committee. This markup, along with our successful markup from July, provides an optimistic blueprint for this type of work. Today, I look forward to advancing this comprehensive deficit-cutting bipartisan legislation, and working to pursue its full Senate passage and enactment.

Thank you, Mr. Chairman.

The Chairman. Well said, Senator Crapo. In just listening to you, I am also struck by the fact that, you

know, the history, particularly of programs like Medicare and Medicaid when you innovate, almost always the private sector wants to pick up on it. So I thank you very much for your leadership and to all our colleagues.

Senator Stabenow, you are next.

OPENING STATEMENT OF HON. DEBBIE STABENOW, A U.S. SENATOR FROM MICHIGAN

Senator Stabenow. Well, thank you very much, Mr. Chairman and Ranking Member Crapo, and I am really pleased and excited at another bipartisan markup that is really, I think, setting a wonderful tone for the Senate and for Congress. So thank you for working together and working with all of us.

I am also really pleased that we are continuing the Committee's important work to address behavioral health, and the behavioral health workforce crisis. As we add more opportunities for people to get care in the community, we need more people providing the services, and so this is really important.

I also very much appreciate Senator Daines. He and I co-chaired the Workforce Working Group last year, and we put forward a draft that contained a number of provisions to expand behavioral health workforce and increase support for critical providers.

And last year, we did some of it. Our bipartisan legislation contained some of the policies, about 200 additional graduate medical education slots. I know Senator Menendez has another amendment that would expand that even further, which I think would be absolutely

wonderful to do.

But we also expanded coverage in Medicare for licensed professional counselors and marriage and family therapists, meaning more access to care for seniors. Today's legislation contains more of our provisions, including improving access to clinical social workers for seniors, increasing Medicare payments for behavioral health providers in areas facing shortages, and requiring Medicaid guidance on how to increase provider capacity in rural and under-served areas.

I also, Mr. Chairman, want to thank you so much for including our amendment, Senator Cornyn and I, to add permanently a definition for certified community behavioral health clinics in the Medicaid program. So we added the funding last year to fully fund it, but it was still called a demonstration project. Now it is fully part of the definitions in Medicaid.

These clinics are transforming the way we provide behavioral health care in the community, treating health care above the neck the same as health care below the neck, and including this definition is another important step forward in making sure that this is permanent.

Many provisions in this legislation are excellent steps toward expanding access to behavioral health services in Medicare and Medicaid. I look forward to

continuing to work with colleagues on expanding access to care, supporting our behavioral health providers, including ensuring that we have licensed clinical social workers properly compensated for their care that they provide, and that CCBHCs are also covered under the Medicare program.

I have filed amendments related to these policies. We are not moving forward, Mr. Chairman, but look forward to working with you in the future on all of these. So, thank you again for holding this really important markup today.

The Chairman. Thank you, Senator Stabenow, and as the former Chair of our Health Subcommittee, we know you are going to run to the finish line of this Congress, and I look forward to working with you.

Senator Cornyn's next.

OPENING STATEMENT OF HON. JOHN CORNYN, A U.S. SENATOR FROM TEXAS

Senator Cornyn. Let me thank you, Mr. Chairman and Senator Crapo, for your leadership in putting together this important package. The Better Mental Health Care/Lower Cost Drugs and Extenders Acts contains provisions that will improve the quality and availability of mental health services, lower the out of pocket costs for consumers, and provide relief for safety net hospitals.

I am pleased to see the inclusion of the Complete Care Act, which Senator Cortez Masto and I have introduced. This policy will help improve access to mental health care in primary care settings by helping providers implement integrated care models like the collaborative care model.

The collaborative care model has shown tremendous results in my state, with multiple health systems like Baylor, Scott and White and JPS Health Network, utilizing it to detect mental health needs of patients earlier and begin critical interventions.

Additionally, the bill contains policies to help lower the out of pocket costs for seniors, as we all know, especially those with chronic health conditions,

mirroring the Share the Savings With Seniors Act that I introduced with Senators Carper, Tillis, and Brown.

I understand there were limitations to how broad this policy could be, but it is a crucial first step to lowering costs and better aligning incentives under Part D. So I want to thank you again Mr. Chairman, you and Ranking Member Crapo, for your support in including those provisions, and hope they will commit -- you will commit to continue to working with us to provide lower costs for our seniors, which I trust you will.

I am also appreciative of the Chairman and Ranking Member for their willingness to continue working on policies to improve access to lower cost biosimilars, something Senator Lankford and Senator Menendez have championed. I am hopeful we can see this finalized before the Senate passes this package, so let me again thank both of you, Mr. Chairman and Ranking Member Crapo for supporting this legislation.

The Chairman. I thank my colleague for his good work.

Next will be Senator Cantwell.

OPENING STATEMENT OF HON. MARIA CANTWELL, A U.S. SENATOR FROM WASHINGTON

Senator Cantwell. Thank you, Mr. Chairman, and thank you for this important markup on the Better Mental Health Care and Lower Cost Drug and Extenders Act. I want to thank all my colleagues for again working collaboratively and focusing on mental health.

I very much support the Stabenow-Cornyn amendment that was part of this package on certified community behavioral health clinics. I think this has been a winning concept in the state of Washington, where I have visited, along with Senator Stabenow, the increase in capacity for mental health and behavioral health coverage by just adding capacity to already-existing clinics.

So cannot get any better than that, and I am glad that we are making that a more permanent program under this amendment. Second, I applaud my colleagues, Senator Crapo and Senator Wyden, for their continued focus on PBMs and PBM transparency. Could not ask for anything better than that, right now when literally pharmacies are being shut down by clawback considerations by PBMs and putting pharmacists out of business. So glad that the Committee is continuing to

focus on that.

And then lastly, over the last six months I have held many roundtables on the pressing fentanyl problem in our state. So I am glad to see that this legislation will also provide a little help in that regard, in the pre-trial detainees to receive treatment for substance abuse.

So very much appreciate that, and look forward to working with my colleagues on an amendment that we filed but we will not offer, that would continue to help us deal with that issue of getting people in treatment faster. But look forward to working with my colleagues on that in the future.

But unfortunately Washington has the dubious distinction right now of having the highest increase in fentanyl deaths over the last year. I think we are part of a border. Texas and Washington had the highest increases in fentanyl deaths in the country.

We are both border states. We have a lot of transportation with our ports, but the fact that these, I was looking for the statistic here, these fentanyl deaths are just -- Washington had the highest increase in 2022, roughly 500 additional deaths. The CDC reports that 109,000 people died of the drug overdose last year.

So, we have to do more to address the fentanyl

crisis in America. So, I thank our colleagues for at least this small help in the fight.

The Chairman. And I also want to thank my colleague for her role in the PBM effort, because as chair of the Commerce Committee, you have been instrumental in terms of the transparency provisions. That is critical. What we have tried to do in this Committee is deal with those programs, where there is a substantial amount of federal spending, Medicare and Medicaid, in order to drive behavior in the health care system.

But this is a team effort, and we thank you for all your leadership.

Okay, Senator Thune is next.

OPENING STATEMENT OF HON. JOHN THUNE, A U.S. SENATOR FROM SOUTH DAKOTA

Senator Thune. Thank you, Mr. Chairman, and to you and Ranking Member Crapo for putting together this bipartisan package. This legislation builds on our previous work on PBMs, and will help ensure that patients have access to community pharmacies and lower prescription drug costs, and it will extend a number of expiring policies in Medicare and Medicaid.

I am pleased to see several bipartisan bills that I championed, including in the modified mark, including policies that will improve access to tele-mental health care, ensure patient access to durable medical equipment, and remove barriers for states to offer individuals access to substance use disorder treatment.

The Support Act, which Congress passed on a bipartisan basis in 2018, included an option for states to provide substance use disorder treatment in institutions for mental disease or IMD. Unfortunately, this option expired on September 30th of this year.

I introduced the Save IMD Options Act with Senators Hassan and Blackburn, to make permanent a state plan option in Medicaid to provide patients access to substance use disorder treatment in IMD. Individuals

across the country continue to struggle with opioid and substance use disorders, and inpatient treatment can be life-saving. South Dakota and Tennessee have leveraged this state option to provide this critical treatment, and more states are likely to opt into this option if it is made permanent.

So, Chairman Wyden and Ranking Member Crapo, will you commit to including this IMD policy in the next vehicle that addresses expiring health provisions and prevent individuals from losing access to substance use disorder care in states that currently offer these services?

The Chairman. I intend to work very closely with my colleague, and we have several colleagues interested in this. This is a very important issue I was just going over with Senator Crapo. We've got a long history with Families First, and I just want to thank my colleague for being willing to work with us, and both I and Senator Crapo want to work with the several members of this Committee who are interested, and I will yield to Senator Crapo.

Senator Crapo. I would just echo the Chairman's remarks. We will work hard to get this done.

Senator Thune. Okay, thank you. I have also filed an amendment this markup that would make long-term

reforms of the Medicare physician fee schedule. The underlying bill that we are considering today includes a one-year payment update for physicians in Medicare.

In recent years, Congress has provided a payment update to physicians after CMS finalized across-the-board cuts. When CMS makes changes to coding policies, it often triggers cuts due to budget neutrality requirements. Unfortunately, CMS's assumptions used for some of these changes often depend on incorrect utilization data, and may not account for the fluctuation in the cost of equipment or staffing.

Instead of Congress making payment adjustments every year, it is time we address the underlying issues and make long-term reforms of this physician fee schedule to ensure there is stability for physicians and the Medicare program for the future. Reforms to the fee schedule should be coupled with updates to incentivize quality, and I am happy to join my colleagues, Senators Whitehouse and Barrasso today, in an amendment to extend the incentives for alternative payment models.

But Congress needs to also make long-term reforms to encourage a greater move toward value-based care. So Chairman Wyden and Ranking Member Crapo, I ask a second question. That is, will you commit to work with me and my colleagues to pass long-term reforms to the physician

fee schedule and incentivize value-based care?

The Chairman. Senator Thune once again is being way too logical for some of these kind of debates. You have got to get at this long-term, and I think, Senator Thune, you made the point that doctors are the backbone of the system.

In other words, we can fuss all we want about various things, but you have got to have doctors, and absolutely we are going to work very closely with you, and as you know, this also connects with an area that we have worked on for a number of years in terms of chronic illness, and Chairman Hatch was terrific in terms of leading us to protecting the Medicare guarantee and doing it by addressing chronic illness, and you have got to have doctors to do it.

So absolutely we will work closely with you, and I yield to Senator Crapo.

Senator Crapo. Thank you. Again, I agree with Senator Wyden's comments. The physicians fee schedule has been broken for years. We have got to quit limping along and lurching and stopping and starting again and getting it fixed. I completely agree with the need for a permanent solution.

We will work with you to get that done. Thank you. Mr. Chairman, I look forward to continuing to work

with you on these policies and seeing them enacted into law, and I thank you.

The Chairman. Very good.

Senator Cassidy is next.

OPENING STATEMENT OF HON. BILL CASSIDY, A U.S. SENATOR FROM LOUISIANA

Senator Cassidy. I am going to speak to the due process/continuity of care provision, and I am going to say although I am glad it is a first step, I am frequently hoping that it is only a first step. I will also say every now and then one of us, in this case me, your like life work meets for public policy hits the road in this sentence, and I would like to think we are going to do something good.

Why? My life's work as a physician has been working with the Medicaid population, those who are in jail and those who are either homeless or at risk of homelessness. And it comes to mind because there is about 430,000 Americans in jail every day who are not yet adjudicated. Which means that they may be found innocent and be allowed to go home.

But as soon as they are booked, they lose their Medicaid. So even though they are not guilty ultimately, they lose Medicaid. Why is that important? Because when you enter a jail, and this is where my life's work comes to bear, they have a formulary of typically lower cost drugs.

When somebody is mentally ill and 44 percent of

those in jail are mentally ill, when they go into jail and they are on a regimen that through trial and error has been found to control their mental illness, if those drugs are not on the jail formulary, they put them on an alternative and they are at risk of decompensating.

Why does that matter? Because one, they are not guilty in some cases. They get discharged to the street and instead of being reasonably well compensated they are now on an ineffective drug regimen. They have sign back up for Medicaid. They are at risk of becoming homeless. If you look at the homeless population, it is indeed a mentally ill population in large measure.

So what does the provision do today? I am glad we have it, but I hope it is only a first step. It says that for the first seven days after somebody is put in jail, before they are adjudicated, when they are still technically innocent, they can maintain their Medicaid benefits, that they do not have to change their formulary and if they are released within two to three days, which is very common, they do not have to re-sign up for Medicaid.

But we limit it to those who have a substance abuse disorder. Now about three-fourths of those with mental illness are co-diagnosed. That leaves about a quarter of the mentally ill who will not qualify for

this continued therapy. It does other good things. The substance use disorder if you also have heart disease, well you do not lose your Medicaid and you can go out and still get your heart disease, and it does not cost very much.

Over ten years, can you believe it, it is only $547 million, which I wish I was worth $547 million. I am not, but around here that is just not very much money. But I think it will actually save a lot of money, because folks will not decompensate, go to the street and/or be rehospitalized because they have lost their Medicaid coverage.

Again, I hope next time we bring this up, it will include mental illness even for those who are not substance abuse. But I appreciate this today. I think it is a good first step, that someone who is innocent until proven guilty does not lose their medical benefits.

The Chairman. Thank you, Senator Cassidy. I would go beyond your statement. I think it is more than a good first step. This is establishing an important due process precedent, that we are going to have coverage in effect pre-trial. I look forward to working with you, and I think we ought to try to expand it in the days ahead, and let me yield to Senator Crapo.

Senator Crapo. I agree once again with the Chairman and with Senator Cassidy. There are a lot of provisions, very good provisions that every Member of this dais wanted to get into this bill, that simply could not be fit in because of different considerations. Sometimes cost, sometimes policy disagreements that could not be resolved. But this is one we need to resolve. I agree to work with you.

The Chairman. And one to build on. I have had conversations with a number of colleagues on both sides of the aisle and, you know, all of us try to focus on one area, and since Gray Panthers I have always said this is the most important.

If we can get these new policies in place, so we can build on them in a bipartisan way in the years ahead, that will be a real statement about making a contribution on our watch. So thank you, Dr. Cassidy.

Our next speaker will be Senator Bennet.

OPENING STATEMENT OF HON. MICHAEL F. BENNET, A U.S. SENATOR FROM COLORADO

Senator Bennet. Well, thank you, Senator Cassidy, for your bill as well. I think that is an important step forward. Thank you, Mr. Chairman, and thank you, Ranking Member Crapo, for holding this markup on really important legislation, to address our mental and behavioral health challenges and high drug costs.

I am pleased the underlying legislation includes my bill with Senator Tillis and Senator -- and Chair Wyden, the Real Health Providers Act. As the mental and behavioral health crisis ravages our communities, Coloradans tell me they struggle to find the mental health services they need.

This crisis is especially prevalent among seniors covered by Medicare, a quarter of whom live with mental illness, and less than half of whom receive treatment. Too often, Coloradans enrolled in Medicare Advantage plans rely on the plan provider directory to find a doctor covered by their plan.

But out of state directories make it -- out of date directories make it impossible to find active providers. These inaccurate directories are known as ghost networks, because doctors listed in them are

either out of network, not accepting new patients, or in some cases no longer in business.

For seniors and in particular for seniors living in rural areas, ghost networks make it more difficult for patients to find in-network health care providers, an issue that is more acute in the mental and behavioral health fields than in any other field that we face.

These outdated networks can lead to unexpected cost or in some cases delayed patient care or no patient care. My Real Health Providers Act will strengthen requirements for private Medicare Advantage plans to maintain accurate provider directories. It also ensures seniors do not pay out of network costs for appointments with doctors who are inaccurately listed as in-network in these directories.

In the richest country in the world, seniors should be able to make informed decisions about their health insurance, and the Real Health Providers Act takes common sense steps toward transparency in the Medicare Advantage program.

I want to thank Senator Tillis again for his bipartisan work on this. I think it is going to make, bring us a huge step forward, and Chairman Wyden, thank you for your leadership on this.

I want to mention one other thing. The underlying

legislation we are considering today also addresses the critical issue of hospital reimbursements by extending DSH payments for two more years. DSH payments are critical to safety net hospitals across Colorado, especially those serving the uninsured and under-insured populations, and again those in rural areas.

While these payments are important, I continue to hear -- and what the work we are doing is important, I continue to hear, as I have mentioned Mr. Chairman from Colorado's safety net hospitals, that they are struggling to stay afloat.

One hospital in Colorado told me that it faces $30 million of uncompensated care because they are willing to take patients that other hospitals are unwilling to take, because it has few, it has more expenditures as a super-safety net hospital that other hospitals do not.

Our current DSH program does not cover those expenditures. I have heard similar things from rural hospitals as well, and I just want to thank you, Mr. Chairman, for your attention to this, your willingness to have conversations about this. I think we need to find an imaginative, bipartisan way forward on this.

So I thank you for that, and I look forward to supporting this legislation.

The Chairman. Thanks very much, Senator Bennet,

and you are highlighting such an important issue. I mean it really starts with insurance companies burying the hospitals and doctors and patients in mounds and mounds of red tape, and then we go into other areas, the denials, the ghost networks and the like. In my state, in the eye of the COVID epidemic, we saw a tremendous increase in the number of claims that were denied.

And finally it got to the point where I actually just put out a press release saying I was investigating it, and then suddenly all the claims got paid. We have got to have a better payment process than getting bills paid when a Member of Congress starts screaming about it.

So I really appreciate what you and Senator Tillis have done. We are going to build on it in the days ahead, and I thank you for your leadership.

Let us see. Senator Menendez would be next in line. He was out of the room.

Senator Menendez. Mr. Chair, I will reserve my time for my amendments.

The Chairman. Very good. So next would be Senator Lankford.

OPENING STATEMENT OF HON. JAMES LANKFORD, A U.S. SENATOR FROM OKLAHOMA

Senator Lankford. Mr. Chairman, thank you. To the Chairman and the Ranking Member, thanks for all the work that you have done and your staff. There has been a lot that has gone into this. There are quite a few what I would call radically helpful policies that are into this.

As we walk through it, we have issues on reducing the cost of drugs at the pharmacy counter for seniors. We have items here that provide a lifeline for independent pharmacies, to make sure they actually stay afloat and stay in our rural communities.

We have issues in here that deal with some of the reimbursement cuts for providers, to be able to make sure we maintain providers. As my colleague Senator Bennet just mentioned, the disproportionate share hospitals that provide for some of our folks most at need, making sure that we actually keep those afloat, and then also increasing access for mental health.

Those are all incredibly important things that need to be covered, that this has been a long time coming to this. I do thank, thank the team as well for all the work on so many different types of issues.

There has also been an ongoing conversation about the issue of one of my bills, ensuring access to lower cost medicines for seniors. I appreciate the Committee for including that in the discussion draft. I will talk more about that later on as we walk through this.

Senator Menendez and I and our teams have worked extensively on this literally for years, to be able to get this done. We have worked with CBO extensively on some of the scoring issues to try to get there. We are not quite there to be able to get final scores. It is a complicated issue, but it is not complicated for the people at the counter.

This will ensure lower costs for individuals that are purchasing drugs, and an increased number of biosimilars that are coming out to again drive down the cost at the counter. So there is no question it will increase the benefit to Americans all across the country, and we are grateful that that has been included in the discussion draft today.

I am also really encouraged to be able to see us add the policies from my bill, Protecting Patient Access to Pharmacies Act. This deals with the DIR fees that most Americans know nothing about, but this Committee spent quite a bit of time digging into and the real detriment that that is getting these unpredictable fees,

which has literally driven many independent pharmacies out of business.

So the work that is happening today will not only ensure independent pharmacies exist, but it will also make sure that some independent pharmacies are actually listed as independent pharmacies. They get a chance to be able to be on that list. It also protects different pharmacies from midyear changes, and there is current policy there where they cannot make a complaint.

If the PBM makes a change in the middle of the year, they just cannot complain about it until the next year. Well, this allows that communication to be able to flow, and then also deals with multiple different issues on the reimbursement side. Right now, literally pharmacies can be reimbursed for less than their actual cost for a drug, based on the pressure from PBMs.

So the PBMs are successful and pharmacies are not. We have got to allow them to be able to survive and thrive. So I appreciate all the work that has gone into many complex issues.

The Chairman. Thanks very much, Senator Lankford, for how you have worked in such a constructive way with Senator Crapo and I. We are going to have a broader discussion on the colloquy issue that we have worked out. But I also want to thank you for standing up for

these small independent pharmacies, because all over the country, we are seeing lines at pharmacies now, where there were not pharmacy lines before, and it is because the PBMs ran these little guys out.

So I really thank you for your leadership, and we will have your colloquy here in a bit, and that will start moving us again to final resolution. I appreciate it.

Next is Senator Hassan.

OPENING STATEMENT OF HON. MAGGIE HASSAN, A U.S. SENATOR FROM NEW HAMPSHIRE

Senator Hassan. Well, thank you very much, Mr. Chair and Ranking Member Crapo. Thank you for holding this markup today on critical issues facing our constituents all across the country. We appreciate your leadership on these and other issues.

And before I speak to Hassan-Blackburn Amendment 1, and while it is not within the scope of this markup, I will say that I look forward to continuing to work with both of you on our shared goal of restoring critical research and development tax incentives, while also expanding the child tax credit, in ways that both encourage work and reduce the number of children living in poverty.

Now regarding today's agenda, I will speak to the Hassan-Blackburn Amendment No. 1 now, and later this morning to the Hassan Amendment No. 2. On Hassan-Blackburn No. 1, the evidence is clear that medication-assisted treatment, otherwise known as MAT, is the single best, most effective option for treating patients with substance use disorders, the gold standard of treatment.

But guaranteed coverage of this essential form of

treatment through Medicaid expires in 2025, unless we take action. My bipartisan amendment with Senator Blackburn would address this cutoff by continuing to require state Medicaid programs to cover medication-assisted treatment beyond the current 2025 expiration. This amendment does not expand the kinds of treatments that we currently use to address opioid use disorder. It does not require anything new of states.

It simply maintains current coverage of life-saving medications, medications that have been used safely by thousands of patients and their doctors for years. Our conversations about this policy over the past few weeks have been positive, and I understand that Members of this Committee are aligned in continuing this policy and ensuring that it does not expire in 2025.

But the Committee has requested that we hold off on voting on this policy for now, and continue to work on it together, something I am amenable to doing with appropriate assurances, to help ensure that we can do this and do it right. So Chair Wyden and Ranking Member Crapo, if I agree to withdraw this amendment today, will you commit to working with me to expand this essential coverage for medication-assisted treatment before it expires in 2025?

The Chairman. The answer is, I will continue to

work with you, and let me give a joint "thank you" to you and Senator Blackburn, who is also here, because both of you have worked very closely with Senator Crapo and I, and you have shown, I think, the right kind of leadership on medication-assisted treatment for opioid use disorders.

We know that medication-assisted treatment is one of the most effective tools that is out there to fight the opioid epidemic. It is not just a New Hampshire issue or an Oregon issue or a Tennessee issue. It is a national issue, a national issue, and making access to this treatment permanent in Medicaid, in my view, is going to save lives.

So I want you to know we are going to keep working very closely with you and with Senator Blackburn, and I gather that this involves your first proposal, and I wanted to get a joint thank you to both of you now because you deserve it, and we are going to keep working with you.

Senator Hassan. Thank you.

The Chairman. Senator Crapo, do you want to add anything?

Senator Crapo. Again, I agree with the Chairman, and I just want to add that, as I said earlier, there are a lot of proposals. There were 56 amendments to

this bill, and every one of them was something that we really wanted to look at.

We just did not have the ability to fit everything in with the cost constraints, as well as with the, some of the, as I said before, some of the policy disagreements that we needed to resolve. The bottom line here is, your proposal is one we need to take a very hard look at, and we will be working on it as we move forward.

Senator Hassan. Thank you.

The Chairman. I thank my colleague.

Senator Tillis is next.

OPENING STATEMENT OF HON. THOM TILLIS, A U.S. SENATOR FROM NORTH CAROLINA

Senator Tillis. Thank you, Mr. Chairman, Ranking Member Crapo, Members of the Committee, for working together on this, and again a special thanks to the staff. You know, every time that we say "I" up here we really mean "we," because we know the lion's share of the work is done by so many of you on the Committee and in our offices.

But this is a great opportunity. We are going to move forward on advancing mental health, PBM reform and the traditional health extenders. Senator Bennet has already talked about the Real Health Providers Act. I tell you, I am watching all these commercials right now. I know everybody is on annual enrollment, and I just wonder how many millions of people are going into ghost networks, not getting an accurate picture of their provider choices.

We need to make sure that they need to. We have got to make progress there, but we have got consumers right now that are making those choices. So it would be great to see this get into place. Also, the Share the Savings With Seniors Act, something that I have worked on with Cornyn and Carper and Brown. I am glad to see

that in there, along with the Caring proposal from Senator Lankford.

You know we -- I am glad to say that we are -- we are going to avoid some drastic cuts, maybe mitigate or prevent some drastic cuts, particularly interested in progress we are making on clinical laboratories, physicians, disproportionate share hospitals, to name a few. The package builds on the progress this Committee has made over the summer with the Modernizing and Ensuring PBM Accountability Act. We have got a lot more work to do.

But I am also looking forward in the future. I am not going to look for a commitment, because Mr. Chair, you have impressed me working on a bipartisan basis that we have got to work through the thorny issues. I do not need a commitment from you. I have seen it evidenced by this markup, and I expect to see other ones.

But we do have to work on other priorities, such as permanent clinical lab fee schedule mix, structural reform to the physician fee schedule, and increased flexibilities to allow foster care children to receive mental health care. I will look forward to working with you on it. I think if we work together, we will come up with bipartisan progress and thanks again for the work you have done to produce this markup.

The Chairman. Well, well said, colleague, and ever since you got on this Committee, you made it clear that you want to be part of this effort, particularly to tackle health care in a bipartisan way. It is so important, because that is how we are really going to make major progress. I thank my colleague for his kind words and especially for working with us, and we are going to continue this bipartisan tradition.

Next is, let us see, Senator Cortez Masto.

OPENING STATEMENT OF HON. CATHERINE CORTEZ MASTO, A U.S. SENATOR FROM NEVADA

Senator Cortez Masto. Thank you. I too want to thank both the Chairman and Ranking Member, and my colleagues and all the staff for all the hard work that you have done in putting this incredible package together. This Committee clearly is taking another important step forward today in our ongoing bipartisan mental health work, by addressing challenges with workforce and service access.

I appreciate the inclusion of the Complete Care Act, legislation that Senator Cornyn and I worked on together. It is in the Chairman's mark, thank you. I am proud of that bipartisan work, as well as the work that has gone into this package as a whole.

On behavioral health integration, the fact is our current specialty mental health care delivery service cannot meet the service demands of the pandemic and beyond. Many people cannot get in to see a specialist for their mental health care, and that is increasingly made primary care the place people turn to get the help they need.

In Nevada and across the country, access challenges have been exacerbated by ongoing shortages

and a general lack of care coordination. That is why Senator Cornyn and I introduced the Complete Care Act, bipartisan legislation that would expand behavioral health care available to Medicare beneficiaries in primary care settings. By incentivizing primary care to adopt and implement integrated care models, the provisions in our bill will improve access to timely and effective behavioral health care.

Integrated models like the collaborative care and primary care behavioral health are incredible tools to support coordination. But we have seen costs associated with implementation limiting the uptake of these models by primary care practices. The Complete Care Act provision in today's mark addresses this issue by enhancing Medicare payment rates for collaborative care and behavioral health integration services.

Importantly, these integrated models are proven workforce extenders. When mental health specialists join a primary care setting, they can share their mental health expertise with even more patients seeking care, and that patient is backed by a team of specialists.

So I thank the Committee for the attention to this issue. I also, I have to do a shout out to our mental health providers, our patients and advocates who have been tremendously supportive of this legislation, and

who helped us get here today.

I hope also that as we make progress on the Committee's broader bipartisan discussion draft, we also continue including the efforts that Senator Cornyn and I have worked on to expand access to crisis stabilization services. And then finally before I close Mr. Chairman, I will, I want to mention I have also filed an amendment along joining me with Senator Cornyn, to improve Medicare's reimbursement of mobile crisis teams and enable peer support specialists to provide that crisis care.

I am not calling for the vote today. The policy is a priority for the coming year. I look forward to working with the Chairman and Ranking Member. I hope there is a commitment to continue to address the crisis side of this. It is just as important, and to that end, I am actually seeking CBO score of this provision, so that we can better understand the cost of Medicare reimbursement for mobile crisis teams. So thank you.

The Chairman. Three cheers for bringing up Medicare and this mobile crisis debate, because as you know, we got started with Medicaid. We have got a lot more to do, because all over this country this question of mobile crisis units is increasingly serious, on homeless and related, a whole array of mental health

issues. I look forward to working with my colleague in Medicare crisis, absolutely.

Let us go to Senator Blackburn, and let me tell my colleagues where I believe we are, having consulted with Senator Crapo. We have got votes coming up at 11:30. With a little bit of luck, we can finish this bill, even with all of our colleagues getting both their opening statements and the colloquies we are going to have. We can get it all done before we go vote. So I thank my colleagues for their patience.

Senator Blackburn is next.

OPENING STATEMENT OF HON. MARSHA BLACKBURN, A U.S. SENATOR FROM TENNESSEE

Senator Blackburn. Well, and I thank you, Mr. Chairman and Senator Crapo, for the markup, and I think it is significant that once we vote today, we will have passed the most significant PBM reform legislation of Congress. So we thank you for that.

As you know, I have led on the bipartisan PBM Act, which will finally delink that middleman compensation from drug prices, ensuring that the PBMs prioritize our seniors. And I would like to submit three documents for the record.

The Chairman. Without objection, so ordered.

[The documents appear at the end of the transcript.]

Senator Blackburn. Thank you. The first is a letter from the National Association of Manufacturers, endorsing this critical delinking proposal. The second, Blue Shield of California, showing payor support for the common-sense policy, and third is a study that from respected researchers, underscoring the importance of these reforms, which will save millions in taxpayer dollars.

I also want to express appreciation for the Better

Act's inclusion of my bipartisan PBM legislation. Pardon me, and that will transform basic pharmacy access protections into more than just a piece of paper, a good thing.

As PBM affiliates dominate the pharmacy sector, community providers across Tennessee are struggling to keep their doors open. They are buried in abysmal payment rates and bureaucratic paperwork. This proposal would bring much-needed certainty and relief to pharmacies across our state, in rural communities that are plagued by cartel-like PBM practices.

Medicare Part D should serve seniors and Americans with disabilities, not consolidated contractors that have moved us closer to single payor health care. I look forward to continuing to work on these critical reforms. I also thank the Chair and Ranking Member for including a much-needed payment increase for our doctors.

With that said, I would like to emphasize that these annual interventions by Congress to provide short-term payment increases are unsustainable. Mr. Chairman, I was pleased to hear you echo that in your remarks. I would also ask the Chair and Ranking Member to work with me on common sense solutions to create payment certainty for providers, and put Medicare on a

sustainable path forward.

Last, I commend the necessary steps the legislation takes to strengthen mental health care and address the ongoing opioid abuse crisis touching every community in my state. This includes the bipartisan Safe IMD Act, that would permanently reinstate the Support Act's SBA option for states, to provide patients with substance use treatment in an IMD, and I thank you for your response to Senator Thune on that as we keep working on this issue.

I look forward to continuing to work on these, and I appreciate today's markup.

The Chairman. Thank you, Senator Blackburn, and thank you especially for all your help with the PBMs. I remember our early conversations on the floor, and your leadership has been much appreciated.

Here is where we are. We have got to finish our opening statements. We have got several colleagues on that.

There is a Lankford question for the Congressional Budget Office, five colloquies, and we will vote, and the goal is to get all of this done before we have votes on the floor.

Senator Daines is next.

OPENING STATEMENT OF HON. STEVE DAINES, A U.S. SENATOR FROM MONTANA

Senator Daines. Chairman Wyden, thanks for your great play-by-play leadership here today. It is appreciated, and thank you for facilitating today's markup, as well as Ranking Member Crapo.

Well, we are all aware of the devastating mental health crisis that our country is experiencing. Caring for our mental health has received increased national recognition in recent years following COVID-19, but it deserved widespread attention long before the COVID pandemic.

Today, the mental health challenges in America are exacerbated by rising levels of isolation, of loneliness, of substance abuse disorders, of addiction, depression, anxiety, and perhaps most notably the lack of access to care, especially in our rural areas and rural states. In Montana, we are seeing one of the largest increases in suicides nationwide.

Fentanyl use in the state has claimed hundreds of lives over the past few years. Attention to mental health is needed now more than ever. The legislation we are considering today explicitly targets the lack of access in several ways, including bolstering telehealth,

addressing coverage gaps and strengthening the mental and behavioral health workforce shortages.

I am grateful to say that a number of policies in today's markup build upon the work that Senator Stabenow and I began last Congress with our colleagues in the Senate Finance Workforce Working Group.

Those policies and a number of others reflected in this legislation are the direct result of intentional, bipartisan efforts to expand mental health and substance use disorder access and services within our federal health care programs. I am glad for this Committee's continued focus on these most important priorities.

Also in today's markup are policies that build on this Committee's previous work on pharmacy benefit manager reforms, as well as addressing certain provisions and funding within the Medicare program. I am glad to say the package is entirely offset. I would like to thank the Chairman and the Ranking Member for their fiscal responsibility in ensuring that the policies are paid for. Not an easy task, and thank you for your work there.

With that, I look forward to moving this legislation out of Committee.

Mr. Chairman, thank you.

The Chairman. Very good. Thanks so much for

working closely with us.

Next will be Senator Carper.

OPENING STATEMENT OF HON. THOMAS R. CARPER, A U.S. SENATOR FROM DELAWARE

Senator Carper. Thanks, Mr. Chairman. I want to thank you and I want to thank Senator Crapo for bringing us together, holding this markup, and especially for continuing to focus on lowering prescription costs through PBM reforms, as well as continuing our work to improve mental health care across the country.

As my colleagues know, Mr. Chairman, I go home almost every night, usually take the train. But early this week I had to drive because it was late, and I stopped at a Wawa just before I went over the bridge between, that connects Delaware and Maryland.

A fella who was from Maryland said to me, he said -- he recognized me, and he said, even though he is not a Delawarean, he said "Why can't you guys just work together? Why can't you guys just work together and get something done?" I wish, I hope that guy is watching today, because every single initiative that we have been talking about here has bipartisan support.

I think that flows from actually the way that, the kind of leadership that Mr. Chairman, that you and Senator Crapo are providing. So thank you for that. I am grateful for the several proposals that I have

offered have been included in the Chairman's mark, including a provision with Senator Cornyn, Senator Brown, Senator Tillis, that will protect seniors from excessive cost sharing for chronic condition medications. For far too long, pharmacy benefit managers have also been left unchecked, pocketing rebates from manufacturers rather than passing them on to patients.

One of my guiding principles is, particularly when it comes to drug pricing policies, make sure, as others have said, that the cost, the low costs are actually passed onto consumers. This important provision that I mentioned will do just that by ensuring seniors with chronic conditions directly see the savings that PBMs negotiate on their behalf.

I would also like to thank our Chairman and Ranking Member for the inclusion of several proposals that I have offered with Senator Cassidy, relating to improving youth mental health. Senator Cassidy and I co-led the youth mental health working group, where many of those ideas originated. So I am delighted that they are going to be moving forward today.

We are currently facing a national youth mental health crisis. The work is yet to be done on these provisions, to take an important step in improving the

health of our children. Mr. Chairman, I have got to go back and finish chairing the Environment and Public Works. If I could just with respect to -- Senators Sullivan and I have an amendment that is going to be offered later today, the Kid's Health Act, an amendment that would take, I think, important steps to improve the health and well-being of children and youth by addressing non-medical factors that influence health, social drivers of health such as access to nutrition, food, mental health services, transportation are particularly profound for our children and are linked to disease burdens across adolescence and adulthood.

The amendment would support states' efforts to establish whole child health models that integrate the social drivers of health and mental health, supports in the health and care delivery for children under Medicaid and CHIP.

And while I am withdrawing this amendment, I look forward to working with Senator Wyden and Senator Crapo to advance this important provision. With that I yield back whatever time I might have. Thank you for letting me go on and on. Thank you.

And to our staffs, our staffs and everybody that has worked so much on this, God bless you. You are doing the Lord's work. Thank you.

The Chairman. I thank my colleague.

Next is Senator Grassley.

OPENING STATEMENT OF HON. CHUCK GRASSLEY, A U.S. SENATOR FROM IOWA

Senator Grassley. Thank you, Chairman and Ranking Member, for holding this meeting. There are several priorities of mine in this package, most importantly the extension of the Medicare Geographic Practice Cost Index IV, that goes by the acronym GPCI for short, that supports the physicians in rural states.

While not in this bill, I hope this Committee will keep working to ensure that CMS uses the most recent physician labor data for GPCI updates. We also need to take a hard look at the existing 36 states that have state-wide regions for physician payments. We need to make sure that the state-wide regions reflect their current cost of physician labor in our rural states.

I am glad that we are advancing mental health provisions, but I urge the Chairman and Ranking Member to consider provisions in my bipartisan Healthy Moms and Babies Act. Addressing the mental health needs of moms can improve our maternal and infant mortality rates, which are going in the wrong direction, as has been recently reported.

We can also improve the mental health of kids with complex medical needs and their families, by passing the

Accelerating Kids Access to Care Act. I am also glad that this Committee is advancing the additional PBM accountability and transparency provisions. This Committee included five of my PBM provisions in the July PBM markup, and I look forward to advancing that on the Senate floor.

While the Committee continues to get technical feedback on my delinking compliance amendment, I want to reiterate my priority for including this in the final package. It is critical that someone in the prescription drug supply chain, like the pharmacist, can report non-compliance directly to CMS.

I have heard firsthand from rural pharmacies about the looming cash flow challenges that they face next year. Without rural pharmacies, seniors will be facing access issues for their medications. This is a situation that I am sure everybody knows. Pharmacies are going to face direct and indirect reimbursement clawback fees from PBMs for calendar year `23, just after January 1st of the coming New Year.

At the same time, pharmacists are also going to face lower post-point of sale reimbursement from PBMs, beginning that very same day, January 1st of our coming New Year. I spoke about these cash flow problems at our July markup, on the Senate floor, and thirdly in two

letters to CMS. I ask unanimous consent to put both of my letters into the record.

The Chairman. Without objection, so ordered.

[The letters appear at the end of the transcript.]

Senator Grassley. I have also spoken to the CMS Administrator and arranged for the Iowa Pharmacy Association to speak with the agency. CMS said that they were, these are their words, "particularly attuned to the cash flow problems." Until this last Monday, we have seen no action to match those words.

I am glad that CMS finally used its bully pulpit and issued a memo to all Part D sponsors and PBMs, that acknowledges the cash flow issues rural pharmacies face next year. CMS reminded Part D plans of prompt payment requirements and pharmacy access standards. I am glad that CMS wrote that they -- these are their words -- "strongly encouraged" Part D plan sponsors to provide payment plans. This is what I have been asking the agency to do for many, many months.

Despite all this, CMS continued oversight and engagement with Congress is critical. CMS cannot sit on the sidelines and let rural pharmacies go out of business. I am glad my amendments to conduct this oversight over CMS and hold PBMs accountable was included in the Chairman's mark.

Finally, I have filed several amendments today on establishing price transparency in prescription drug ads, improving maternal mental health, establishing pharmacy provider status, and supporting kids with complex medical needs. I hope the Chairman and Ranking Member will keep working with me to advance these priorities. Thank you.

The Chairman. I thank my colleague. Thanks for the really good work on PBMs.

I just tell colleagues, we are really sprinting to get this done before we vote. So if we can stay with the 3 minutes, that would be great.

Senator Brown, you are next.

OPENING STATEMENT OF HON. SHERROD BROWN, A U.S. SENATOR FROM OHIO

Senator Brown. Thank you, Mr. Chairman; I will do that. Thanks to the Affordable Care Act and other more recent laws like the IRA, the American Rescue Plan, we made a lot of progress in improving access to health care. Despite this, we know insurance companies, PBMs, Big Pharma continue to engage in harmful practices and price gouge consumers, whether driving up the cost of prescription drug cost, creating barriers to mental health services, causing unnecessary losses of health care coverage.

As a result, many people continue to struggle when it comes to accessing timely, affordable health care and those serving them, from doctors to every pharmacy are hurt too. I am pleased that Senator Wyden and the Finance Committee have been committed to addressing many of these issues bipartisanly.

I look forward to working with the Committee. A number of my priorities are included in the markup, such as helping to lower the cost of prescription drugs, protecting rural independent pharmacies and holding PBMs accountable. I would like to thank the Chair and Ranking Member for incorporating four of my amendments.

I will briefly go over them.

I will not ask for a vote on either, on those priorities today. I would like to continue to work with you to advance these bipartisan policies, Mr. Chair. First amendment, Brown Amendment No. 3, would ensure that vulnerable individuals do not unnecessarily lose access to their Medicaid and CHIP coverage. Each year, millions of Medicaid CHIP beneficiaries are at risk of losing coverage because they take an extra shift working overtime and their income fluctuates, certainly not honoring the dignity of work.

For nearly one in five Americans on Medicaid who have a substance use disorder and may need access to timely care, they cannot afford a disruption. Last year we were able to work in a bipartisan way, to make it possible for children eligible for Medicaid and CHIP to remain covered for 12 months at a time. My amendment would build on the bipartisan work we did at the end of last year.

The second amendment, Brown Amendment No. 4 is a priority for law enforcement. We know that individuals reentering society after incarceration are extremely vulnerable to experiencing struggles. Believe it or not, 129, 129 times more likely to die from an overdose post-release.

We can prevent these individuals from overdosing if they have access to health care coverage upon release. We can start up on treatment as they start their reentry process. That is really the key. The Medicaid Reentry bill, a bill I have worked on Senator Baldwin, is bipartisan legislation that would restate, that would restart Medicaid coverage for eligible individuals 30 days, think about this, 30 days prior to the release, ensuring that individuals have smoother transitions into the communities.

The amendments would break down real barriers to accessing mental health and substance use disorder treatment. Chairman Wyden and Ranking Member Crapo, thank you. I look forward to continuing to work with you on a path forward for these priorities. Thanks so much.

The Chairman. Thank you for your good work for working families, Senator Brown.

Senator Casey is next.

OPENING STATEMENT OF HON. ROBERT P. CASEY, JR., A U.S. SENATOR FROM PENNSYLVANIA

Senator Casey. Mr. Chairman, thank you, and thank you to Ranking Member Crapo for your work to produce a bipartisan bill for the markup. This bill demonstrates that the Committee and the Senate itself is continuing to do the work of the American people by lowering drug costs for seniors, protecting access to care and increasing education assistance for lower income Medicare beneficiaries.

I will support the legislation and I would also like to highlight some of the provisions that I worked on. I was pleased to see the bill included an amended version of Senate Bill 2456, the Protecting Seniors From High Drug Cost Act, which I introduced with Senator Cornyn earlier this year.

The provision would prohibit plans from charging patients cost sharing that is more than the negotiated net price of a covered drug in Medicare Part D, saving money for seniors. I want to thank, Mr. Chairman, you and the Ranking Member and Senator Cornyn for your commitment and your work on this important issue.

This bill also includes a two-year delay of the Medicaid disproportionate share hospital cut, so-called

DSH cuts, which Senator Lankford and I led 49 of our colleagues to support, and we both pushed Senate leadership on this issue as well.

This will help to ensure the financial viability of many of our nation's safety net hospitals. Without the provision, access to care for some of the most vulnerable Americans would be threatened.

Finally, the bill includes funding for the State Health Insurance and Assistance Programs, the so-called SHIPS, S-H-I-P-S. It is also, which are also crucial to ensure that Medicare beneficiaries are empowered to make the best decisions for their health care needs.

I raised this issue during our last hearing on Medicare Advantage marketing, and I appreciate this funding cliff will be addressed. Thank you, Mr. Chairman.

The Chairman. I thank my colleague for his good work. Let us see.

We are now at Senator Cardin.

OPENING STATEMENT OF HON. BENJAMIN L. CARDIN, A U.S. SENATOR FROM MARYLAND

Senator Cardin. Thank you, Mr. Chairman. I also want to throw in my thanks to you and Senator Crapo for advancing this bill. It continues our Committee's responsible actions to deal with the high cost of drugs, which is critically important. It is one of the largest parts of our health care system and certainly this is growing.

And improvements in mental health and behavioral health, which is so needed, comes out of the work of our working Subcommittees for Mental Health. I want to thank all those that were involved in it. The Medicare, the extenders that are in this package is also important.

Thank you for including the recommendations of our Subcommittee on Telehealth. That is important, the experiences we learned from COVID-19 show us that telehealth is an important part of a more accessible, affordable health care, and I was pleased that we were able to incorporate many changes into this bill.

I have an amendment that would add the permanency of the exemption provided for in-person, for telehealth services. It does not expire currently until 2024,

which I understand the reason it was not included in the Chairman's mark. But I would hope that we would make sure that we deal with the permanency of that exemption, because it is important for the advancement of telehealth services, particularly in mental health.

And then, Mr. Chairman, I was disappointed the bill that we are considering here today cut the Medicare Advance Alternative Model in half. My home state in Maryland has one of the highest rates of physicians participating in value-based care. If we do not correct this cut, more than 5,000 Maryland providers will lose resources to continue providing innovative care models to their constituents.

So I am disappointed. I hope we can find a way to advance that, and lastly let me say I join with Senator Bennet and Senator Crapo in offering an amendment to provide Medicare coverage and payment for multiple cancers early detection screening test that are approved by the Food and Drug Administration, that are used to screen for cancers across many cancer types.

This is ground-breaking. We will be able to get early detection for cancers today are basically death sentences that will give hope, and I hope that we will be able to get that legislation to the finish line, in order to be able to save lives. Thank you again for

your courtesies.

The Chairman. We will continue to work with you on the very constructive suggestions you are making for going forward. We tried to get as much money for the alternative payment programs in as we could, and we will be back in the next Congress.

Okay. Senator Johnson, I understand you would like to make an opening statement. Colleagues, that will conclude opening statements then.

OPENING STATEMENT OF HON. RON JOHNSON, A U.S. SENATOR FROM WISCONSIN

Senator Johnson. Thank you, Mr. Chairman. First of all, I want to thank Ranking Member Crapo. He has been doing an excellent job, he and his staff, at providing us very detailed weekly updates in terms of, you know, all the things being discussed here in the Finance Committee, either in Committee or behind the scenes.

But I, you know, I am new to the Committee. Maybe this is a different way of doing business, but as I was made aware this week, we got the Chairman's mark Monday morning. We got an update to it yesterday. Again, it is very detailed but it is not legislative language. I do not have a whole lot of time to go through all this detail, and these are complex issues.

I realize that during our markup on PBM reform I am the only one that voted no, and I think it is as I stated at time it is because (a), we have got to take the Hippocratic Oath here and first do no harm. Plus, and this also further talks with, you know, deals with PBMs, not necessarily in a helpful way.

But I pointed out at that point in time that, you know, PBMs were initially the solution. That was going

to lower drug costs, and we had a very interesting discussion in Republican lunch where Senator Rick Scott, who knows something about this, ran Hospital Corporation of America, said that there was -- he had no negotiating power with drug companies until he was large enough to do it.

So that is what PBMs are doing. They are large enough to actually negotiate a lower price. I think the proof is in the pudding that to some extent they are working, because Big Pharma is all for the PBM reforms we are pushing. So again, these are complex issues. There is a lot that is being passed here.

I do not have the legislative language, but again shout out to Senator Crapo for providing a lot of detail. But I just have to say that I just cannot vote on this. I will either, you know, abstain or I will just vote present. This is just kind of a strange way of doing business here.

I hate to say that, but -- and again, I have got real doubts about what this Committee is trying to do in terms of PBM reforms. Again, first do no harm. I do not know how else you are going to start bringing negotiating power into drug pricing until we actually introduce real consumerism, which we are not doing.

It is just one big group after another big group,

and in this case with the PBM reforms being suggested by this Committee, the fact that Big Pharma is all for them speaks volumes. That is not saying that the smaller pharmacies are not getting hosed in this process, but to me it is almost, it is just -- it is determinative that if Big Pharma is for the PBM reform, there is something wrong with that PBM reform then. Thanks.

The Chairman. So I just want to make one quick point, because time is short. We put out, colleague, a full legislative discussion draft next week on everything we are talking about today. So there has been plenty of time to get into it.

Now we are going to go to the period for colleagues to be able to ask questions. We have got multiple Committee staffers available to answer questions.

For the Senate Finance Majority we have Ms. Marissa Salemi, Ms. Mariel Kraft and Ms. Eva Goff. For Senate Finance Minority staff we have Connor Sheehey, Mr. Stewart Pottman, Ms. Erin Dempsey, Ms. Gabel Brady. We also have Dr. Phil Swagel from the Congressional Budget Office and Asha Savos.

Members have received the modification of the marks. We will dispense with the description. Senators are welcome to ask any questions of the panel that they

choose. Any Senators wish to ask questions of our very talented panel?

Senator Lankford. Mr. Chairman?

The Chairman. Senator Lankford.

Senator Lankford. One quick question for CBO, if I may. Dr. Swagel, thank you. Thanks for all your team and for all the work that you all have done, working on the tiering aspect that we have tried to be able to work through. It is incredibly complicated, but it is focused on how do we actually get lower priced drugs to the consumer to the counter.

I appreciate this. This is the first time you have tried to be able to score something like this on this, so it is a lot of complications as we worked on this for years. I know this has been a top priority of the Chairman and the Ranking Member. They have said it over and over again.

I also understand you are working to be able to get some final scoring on it by the end of this month. I would ask for the opportunity to be able to interact and we are going through all the final scoring on it, to see if there are tweaks, if there are things that you observe and see hey, here is a problem, here is the issue, whatever it may be so we can try to get this right at the end.

Time is of the essence to be able to move this. I am just asking for a commitment that when you get to that point, we have the opportunity to be able to have more than just a score, but also a dialogue to try to figure out and be able to make sure it works.

Dr. Swagel. Senator Lankford, you have that commitment. We will have our analysis ready by the end of this month, and when we have it, we will come to you and we will be happy to go back and forth and make any adjustments.

Senator Lankford. Great, thank you. Thank you, Mr. Chairman.

The Chairman. And I just want to say to my colleague, Senator Crapo and I are going to continue to work with you on this, so we are clear on that. Okay. At this point we have --

Senator Johnson. Mr. Chairman, I have got a question if we have got some time here. The question I posed --

The Chairman. We do not have time, but we are going to make time for your question.

Senator Johnson. I appreciate that. So again, the question I posed, if this PBM reform that this Committee is considering and that we passed earlier, is going to lower drug prices, and if you are really

lowering drug prices, you are going to be taking something out of Big Pharma, right? Why is Big Pharma so supportive of these reforms?

Mr. Sheehey. Well, Senator, thank you for the question. I think, I cannot speak to a stakeholder group's perspective on this. I will say we have received a good deal of support from, as you mentioned the pharmacy community, from the patient community.

What I will say from a substantive reform standpoint, nothing in this bill would in any way undercut or undermine a pharmacy benefit manager's ability to negotiate discounts, negotiate price concessions or rebates. I think it is worth noting, for instance, Section 2 or 3 says the PBM and the plan sponsor simply need to allow the senior at the pharmacy counter to share in some of that discount.

So from a patient perspective, you would be paying less at the pharmacy counter. The plan would still receive the majority of that rebate. They would still be able to negotiate that in private. They are able to adjust it at the margins. I think from a manufacturer perspective, what you would see is a more transparent price point.

So insulin, for instance, you would see an 80 or 90 percent gap between the list price and the net price

for years, and yet the list price was the basis for beneficiary cost sharing. I think this is a shift to a more transparent pricing model, and frankly one where seniors could save in some cases hundreds of dollars at the pharmacy counter.

So, I think folks in general, as we worked on this legislation on our Committee staffs and on the staffs of folks around this room, appreciated the value of trying to bring more transparency. I think they looked at cases where you would see an 80 or 90 percent gap between the untransparent proprietary net price, and the gross cost that we used as the basis for co-insurance, where seniors are actually paying a percentage of this inflated cost.

I think a lot of folks agree, we want to move to a more transparent model that is cheaper at the point of sale and that curbs incentives, as Senator Lankford mentioned, for these plans to prioritize high risk price, high rebate products, but not allow seniors to share in those rebates. I would refer to, for instance, a recent GAO study that suggested that plans by and large, now there are exceptions; Kaiser Permanente is an exception, that use a net cost-based model.

They also prioritize low cost biosimilars. They saved $300 million this year.

The Chairman. Mr. Sheehey --

Mr. Sheehey. Oh, I am sorry sir.

The Chairman. You have made an eloquent case for what --

Mr. Sheehey. I apologize, Mr. Chairman.

Senator Johnson. But he did not answer my question.

The Chairman. He did. He said specifically, Senator Johnson, he talked about the hundreds of dollars that consumers, seniors, and others would save. So we are going to move on now.

A quorum for the purpose of conducting business under Committee Rule 4 is present. That being the case, the modification is hereby incorporated in the Chairman's mark, and the Chairman's mark is modified as open to amendment.

We are going to go back and forth, colleagues, Republican and Democrat. We will start with a Republican amendment or a colloquy. Does any Senator wish to offer an amendment on the Republican side?

Senator Lankford. I do actually, Mr. Chairman. This is the one that Senator Menendez and I have worked on for years on this. This is with the issue of tiering. This is the issue of how you actually get access to biosimilars. What Senator Menendez and I had

actually started with was generics, biosimilar, specialty drugs, to get all that included.

That went through a CBO process. We have then gone through the process to be able to narrow that and tailor that down to just the biosimilars. As they are quickly going on the market, many of them are dramatically cheaper, and we want to make sure they actually end up on the formularies.

Mr. Chairman, I would like to add in a few items for the record. Civica, in a letter that they have submitted to the Biosimilar Forum, what they have submitted, and then the HHS Office of Inspector General did a report in 2022, how the Medicare Part D and beneficiaries could realize significant spending reductions with increased biosimilar use. I would like to add all these to the record.

The Chairman. Without objection, so ordered.

[The submitted materials appear at the end of the transcript.]

Senator Lankford. The amendments that we have, we understand that this is going to be included if at all possible on it. What we are trying to do is to be able to drive down the actual cost to consumers at the counter, as well as the cost to the federal government and the taxpayers as well. I do appreciate all the

staff's commitment to this. This has been a very long process to be able to work through this.

But based on the evidence that we have seen going through this from the HHS OIG and from other that have examined this, I expect this policy to actually come back and save the government money, because it drives down patient costs and it continues to drive down net prices as the branded price has to compete with a lower cost biosimilar.

Simply stated, this would allow for when a new biosimilar comes on board, if it is the net price is significantly cheaper, and we are basing that off what is called the wholesale acquisition cost, it allows that to be able to be on the formulary. So we are actually increasing competition, rather than biosimilars being forced out into the benefit of branded higher priced drugs that we actually increase competition.

It is the basic principle of we want more competition, not less. We want more options for seniors, not less in this. And so we are submitting this as an amendment today. I understand that it is still working through the final process with CBO to get final scoring, so I am not going to ask for a vote on this today. But we think it is essential to be able to get this policy out.

The Chairman. You have been doing very good work on this. Let us recognize Senator Menendez and then Senator Crapo, and I will respond about how we are going to be working with you.

Senator Menendez?

Senator Menendez. Well thank you Mr. Chair, and during the Committee's PBM markup in July, I along with Senator Lankford spoke about our legislation that would address unfair pricing gimmicks that only hurt patients at the pharmacy counter.

At the markup you, Mr. Chairman and the Ranking Member committed to working with us on this policy, and I very much appreciate both of your support and partnership, as well as that of the Committee staffs, that we work together to modify these provisions based on feedback from CBO.

Under the current PBM and Medicare Part D plan structure, often a biosimilar drug, which should come with a lower price tag at the pharmacy counter, actually costs us much or more than the brand name drug product. That is if the drug is even covered insurance at all. Currently, many contracts explicitly block coverage for the most affordable biosimilars. That is just simply not right.

This policy will ensure seniors can financially,

can finally benefit and financially from lower cost biosimilars, instead of being forced to pay for higher-priced drugs solely because of pricing tactics used by the drug pricing minimum.

So I appreciate the Chair and Ranking Member's commitment to seek to include these provisions in the PBM package the Committee moves to the floor, and I have enjoyed working with Senator Lankford in this regard.

The Chairman. And let me just be clear on this. We support the proposal that is being made by our two colleagues, to break the PBM logjam and increase access to lower cost biosimilars, and I am going to recognize Senator Crapo for anything he would like to say.

Senator Crapo. Yeah. I would just like to thank Senators Lankford and Menendez for your leadership on promoting patient access to biosimilars. Economists broadly agree that without this type of pro-competitive policy, low cost biosimilars will continue to face coverage and placement barriers.

This short-termism and gamesmanship of the annual PBM contracting bolsters preferences for higher-priced products, forcing both seniors and taxpayers to carry the burden. Senator Wyden and I have reserved savings in this bill as needed to ensure that we can advance this proposal. But I concur with OIG and a host of

experts. This policy is a savings driver and a game changer. We are committed to getting this done.

The Chairman. I thank my colleague, and we are going to get this done. Let us go now on the Democratic side to either an amendment or a colloquy.

Senator Stabenow, did you have an offering?

Senator Stabenow. I do have something briefly, Mr. Chairman. First, I have two amendments that I will not offer, but one would make sure going forward that the certified community behavioral health clinics are defined in Medicare. We did it in Medicaid today, but not Medicare. I understand there were some reasons for not doing it today, but it is very important we get it done.

The other amendment, which is so important. I want to -- I really want to work, Mr. Chairman, with you and our Ranking Member next year on it as well, to ensure stability in payments for home health agencies in Medicare. This amendment that I have would provide a one-year pause to payment cuts currently facing the home health industry.

We have heard in testimony before this Committee about the challenges facing providers and patients in the home health care sector. We know that when people have the opportunity to get care in their home, that is

their preference. So I am hopeful, Mr. Chairman, that we can work together to address access to home health care and the cuts that have been proposed.

The Chairman. Senator Stabenow, you have been our champ on community mental health programs and also on home health, and we will be working closely with you on both issues.

Senator Stabenow. Thank you.

The Chairman. Okay. No more colloquies apparently on the Republican side.

I am going to Democratic side, and Senator Menendez will be next.

Senator Menendez. Well, thank you Mr. Chairman. In the interest of time, I want to call up and block two amendments, Menendez 1 and Menendez-Stabenow No. 2, and speak to them briefly.

The Chairman. The Senator is recognized.

Senator Menendez. Menendez-Stabenow No. 2 is regarding resident physician shortage reductions. Patients and family members, communities throughout the country, doctors, nurses, providers are all grappling with the reality of the depletion of the physician workforce in our nation's health care system.

By 2034, according to the Association of American Medical Colleges, the demand from primary and specialty

care physicians will exceed supply by a range of anywhere between 37,000 and 124,000 physicians. Growing concerns about physician burnout, pandemic-related trauma, stress, anxiety, frustration, suggests that many physicians may accelerate rather than delay their retirement. Given the considerable time it takes to train a doctor, coupled with the aging physician workforce, the time to invest in training more doctors is now.

I have long-championed legislation to address the physician shortage by increasing the number of Medicare-funded graduate medical education slots. This bipartisan policy would support critical training opportunities needed to alleviate the physician shortage and improve access to health care, particularly in rural or under-served communities, which in turn promotes healthier lives.

I want to urge the Committee to prioritize addressing the physician shortage. I know the Chairman has worked with me in the past on this, and increasing the number of GME slots in any end of the year package.

Lastly, family to family health information resource centers are indispensable for families and children with complex care needs. As implied in the name, these centers provide families with the support,

help and assistance they need to overcome adversity. Without them, parents can be left to struggle alone, unsure of whether to turn -- where to turn for the information of guidance they need to manage their child's health care.

Importantly, the staff of these centers are often parents themselves, so they understand the unique needs of parents who want to best support and navigate for their children. Among the services they provide, family to family centers offer greater access to early and continuous screening, education, technical assistance and peer support.

The funding is the foundation for these essential centers in every state and territory, which is why we must extend their funding this year. I look forward to working with the Chairman and the Ranking Member on both of these items.

The Chairman. I look forward to working with my colleagues. So here is where we are. We have a quorum to get this bill out of Committee. We have four colleagues on the Democratic side who would like to offer colloquies. I am available to listen to all of them. We can also vote and have your colloquies after the vote. Is that agreeable to colleagues? Okay.

We have got at least 15 members present. I move

that the Chairman's mark as modified and amended, be reported favorably. Is there a second?

Voices. Second.

The Chairman. The Clerk will call the roll.

The Clerk. Ms. Stabenow?

Senator Stabenow. Aye.

The Clerk. Ms. Stabenow aye. Ms. Cantwell?

Senator Cantwell. Aye.

The Clerk. Ms. Cantwell aye. Mr. Menendez?

Senator Menendez. Aye.

The Clerk. Mr. Menendez Aye. Mr. Carper?

The Chairman. Aye by proxy.

The Clerk. Mr. Carper, aye by proxy. Mr. Cardin?

The Chairman. Aye by proxy.

The Clerk. Mr. Cardin, aye by proxy. Mr. Brown?

The Chairman. Aye by proxy.

The Clerk. Mr. Brown, aye by proxy. Mr. Bennet?

The Chairman. Aye by proxy.

The Clerk. Mr. Bennet, aye by proxy. Mr. Casey?

Senator Casey. Aye.

The Clerk. Mr. Casey aye. Mr. Warner?

Senator Warner. Aye.

The Clerk. Mr. Warner aye. Mr. Whitehouse?

Senator Whitehouse. Aye.

The Clerk. Mr. Whitehouse aye. Ms. Hassan?

Senator Hassan. Aye.

The Clerk. Ms. Hassan aye. Ms. Cortez Masto?

Senator Cortez Masto. Aye.

The Clerk. Ms. Cortez Masto aye. Ms. Warren?

Senator Warren. Aye.

The Clerk. Ms. Warren aye. Mr. Crapo?

Senator Crapo. Aye.

The Clerk. Mr. Crapo aye. Mr. Grassley?

Senator Crapo. Grassley is on his way. Can we skip him for now?

The Clerk. Mr. Cornyn?

Senator Crapo. Aye by proxy.

The Clerk. Mr. Cornyn, aye by proxy. Mr. Thune?

Senator Crapo. Aye by proxy.

The Clerk. Mr. Thune, aye by proxy. Mr. Scott?

Senator Crapo. Aye by proxy.

The Clerk. Mr. Scott, aye by proxy. Mr. Cassidy?

Senator Crapo. Aye by proxy.

The Clerk. Mr. Cassidy, aye by proxy. Mr. Lankford?

Senator Lankford. Aye.

The Clerk. Mr. Daines?

Senator Daines. Aye.

The Clerk. Mr. Daines aye. Mr. Young?

Senator Crapo. Aye by proxy.

The Clerk. Mr. Young, aye by proxy. Mr. Barrasso?

Senator Crapo. Aye by proxy.

The Clerk. Mr. Barrasso, aye by proxy. Mr. Johnson.

Senator Johnson. No instruction.

The Clerk. Mr. Tillis.

Senator Tillis. Aye.

The Clerk. Mr. Tillis aye. Mrs. Blackburn?

Senator Blackburn. Aye.

The Clerk. Mrs. Blackburn aye. Mr. Chairman?

The Chairman. Aye.

The Clerk. The Chairman votes aye.

Senator Crapo. Grassley will be aye by proxy.

The Clerk. Mr. Grassley, aye by proxy.

The Chairman. The Clerk will report.

The Clerk. Mr. Chairman, the final tally is 26 ayes and zero nays.

The Chairman. The bill is reported favorably. I ask unanimous consent that the staff have the customary authority to make appropriate technical, conforming, and budgetary changes. Without objection.

I am going to stay to hear the colloquies of all four Democrats, and Senator Crapo will stay too.

We will begin with Senator Warner.

Senator Warner. Thank you, Mr. Chairman.

The Chairman. And I thank my colleagues for all their patience. Senator Warner, and right on down the line.

Senator Warner. Thank you, Mr. Chairman, and I thank the Ranking Member and thank the staff, because I know you are anxious to hang on every word that we are about to lay out here. If I had had to do an opening, I would have congratulated you on the PBM work. I am not going to do that. I was going to also talk about the advanced alternative payment model, to make sure we get that bonus payment right to incent the right kind of behavior.

But moving to my amendment, Warner-Scott No. 1, which would include in the underlying bill a definition in statute of long-term care pharmacy. It would mean in the future, Congress can tailor policies specific to long-term care pharmacies when necessary.

It is based on legislation that Senator Scott and I had. We had 21 co-sponsors, 11 who were Finance Members. I am grateful for the Chair and Ranking Member's support for the bill over the last year. We tried to get it in last year, but it did not clear the House. Chairman Wyden, your staff has worked closely with mine this year on updated language, and I know we

are close to finalizing it.

It was not ready for the markup, so I will be withdrawing the amendment. But knowing we are close and this has been a multi, multi-year process. We are just trying to get a definition on long-term care pharmacies in. I hope you can prioritize it to be in this year's end of year package.

The Chairman. I thank my colleague, and I want my colleague to know I think your idea of trying to bring consistency to how these pharmacies are being regulated is just common sense. I will look forward to working closely with you.

Senator Warner. I am going to take that as a yes, to get in your package.

The Chairman. That is as much a "yes" as I can make.

Senator Warner. And I withdraw my amendment. Thank you, Mr. Chairman.

The Chairman. At this point, Senator Carper, I believe you would like to be recorded formally.

Senator Carper. I would ask unanimous consent that I be recorded formally, yes.

The Chairman. Great, terrific.

Senator Whitehouse, right down the line.

Senator Whitehouse. Thanks, thanks very much

Chairman Wyden. I would call up Whitehouse Amendment 1, co-sponsored by Senators Barrasso, Cardin, Thune, Warner and Cassidy. This bipartisan amendment supports the innovative providers in alternative payment models, referred to as APMs.

My favorite one happens to be the Accountable Care Organization because we have had outstanding success with ACOs in Rhode Island through the world of Integra and Coastal Medical. But it is not just Rhode Island. In 2022, ACOs generated $5.2 billion in gross savings, and $22.4 billion in gross savings over the last decade.

So it is a very significant efficiency for Medicare and CMS. But there is much more that needs to be done, because the real benefit of an ACO is not measured in its savings to Medicare. It is measured in its improvement of the quality of care for the patients of the ACO. The reason you are seeing these savings is because patients are healthier, and in many, many respects their lives are made better.

We have seen firsthand in Rhode Island what a remarkable transformation it is when doctors get off the fee for service treadmill and deal with patients as real people and have the flexibility to find ways to make them healthier, whether it is home visits from social workers, whether it is replacement of slippery carpeting

on the stairs, whether it is home telehealth facilities installed.

Whatever it takes, overview of their multiple pharmaceutical needs and better coordination of those. All of these things make the patient experience better, make the patient's health better, and we can do more to support the ACOs. They have, they have not been given the full support that they deserve.

So knowing that APMs can improve patient care and lower costs, while financially rewarding chronic care coordinators, primary care providers and nurse care managers who really represent the backbone of our health care delivery system, before we make significant changes to structure of APM bonus payments we first must have a conversation in the short-term about how we can continue to incentivize providers to participate in value-based care arrangements.

Will you work with me and Senator Barrasso and our multiple bipartisan co-sponsors, to see that this gets done?

The Chairman. This is an easy yes, Senator Whitehouse. The fact is you have been toiling on these alternative payment models for ages, and dollar for dollar they are one of the smartest investments we make in American health care. They fit very well with

chronic care.

As you know, we got the amount up by $700 million for 2024. We are going to keep working with you to increase it. I thank my colleague.

Senator Whitehouse. I thank you, Chairman, and look forward to success as this moves to the floor. Congratulations on your success with this bill today.

The Chairman. Thank you for your good work.

Senator Hassan?

Senator Hassan. Well again, thank you, Mr. Chair and Ranking Member Crapo. I would like to offer my amendment Hassan No. 2, which would end the practice of charging patients unfair hospital facility fees for care provided in the off-campus outpatient setting, like at a regular doctor's office.

Health care costs are too high, and this is in part due to unchecked consolidation of hospitals and physician practices. Increasingly, hospitals have been buying primary care and other community-based practices, and right now hospitals and doctor's offices can charge higher fees than independent doctor's offices.

As a result, some patients have found even though that they are visiting the same facility, receiving the same treatments and even seeing the same doctors before, they are being billed double overnight. This burdens

patients and the Medicare program with unfair steep costs for routine, every day care.

In theory, Congress already banned the practice of charging hospital rates in a community setting. But a loophole in the prior law has meant that it does not help as many patients as Congress intended. My amendment would close this loophole and save taxpayers tens of billions of dollars over the next decade.

With this amendment, we can lower costs for patients and invest in substantial bipartisan health care priorities, including building the nursing and physician workforce. Chair Wyden, Ranking Member Crapo, I understand that you would like more time to work through the technical aspects of this policy, and I am certainly willing to withdraw this amendment for now.

But as I do so, I hope you will commit to facilitating a bipartisan committee process, including discussions, briefings or roundtables with experts to consider and advance site-neutral payment policies that end unfair facility fees.

The Chairman. We will both be working closely with you Senator Hassan, and we have had experts telling us, people that we respect saying hospitals are charging higher prices for services based on where a service is delivered. So there is credible evidence of this kind

of issue and it leads to higher costs, and you do not get better outcomes, so you get kind of a double whammy.

So we are going to be working with you to look at the evidence, to see how to proceed. Senator Crapo.

Senator Hassan. Thank you.

Senator Crapo. I agree. This is one of those issues I mentioned earlier that we need to get done. We will work with you.

Senator Hassan. Thank you very much.

The Chairman. Thank my colleague.

Senator Cortez Masto?

Senator Cortez Masto. I am looking for the same response. [Laughter.]

I call up Cortez-Masto-Cassidy-Warren No. 1. It is the inclusion of certain information in Medicare Advantage encounter data. As we have all talked about this, the issue of a transparency in Medicare Advantage is increasingly important to all of us. I know for so many Nevadans, this is a popular program for my seniors in Nevada. They like it. They also should have the freedom to choose, because quite frankly there are thousands of seniors in Nevada who rely on the traditional fee for service Medicare program that they need.

That is why it is, I think, a priority for many of

us to make sure that the entire Medicare program is sustainable and solvent. I am concerned, however, that we are paying more for Medicare Advantage than for similar benefits delivered under traditional Medicare.

In 2023, $450 billion or 54 percent of total federal Medicare spending went to Medicare Advantage. These are billions of federal dollars flowing to private health plans, and we need to be conducting better oversight if we are going to make policy changes that support all Medicare beneficiaries.

That is why I am offering this amendment that supports transparency and MA plan provider directory oversight. While CMS already requires MA plans to submit encounter data, there is little transparency about plan performance in that existing data. My amendment requires the MA plans to submit encounter data that includes information on payments to providers, cost-sharing for beneficiaries and services provided by companies that are vertically integrated with those MA plans.

It includes several recommendations from OIG to make encounter data more useful, so we can actually follow the federal dollars and how they are being spent by MA organizations. It would also, this policy would strengthen what CMS is collecting in encounter data to

expand what is publicly available to policymakers and research.

Now I understand from the Chairman and Ranking Member you would like more time to work through the policy and the amendment. So I plan to withdraw my amendment today, but I intend to introduce bipartisan legislation, again with the support of my colleagues, and I hope that both the Chairman and Ranking Member can get a commitment to continuing to working forward on this issue, and I understand your concerns.

The Chairman. Look, there is so much that needs to be done to shake up these MA plans, and certainly making sure that Medicare has the information to determine whether seniors are getting what they need is critical. We have been looking at these middlemen. We got a big chunk of the proposals made by Members of this Committee. There is still more to do.

So the answer to your question with respect to having Medicare get the information so we can make sure that the Medicare guarantee is really being, you know, honored is key. So the answer is yes. Senator Crapo.

Senator Crapo. And I agree with Senator Wyden. I will be committed to working with you to advance this proposal in a fiscally responsible and bipartisan way.

The Chairman. Okay.

Senator Warren?

Senator Warren. Down to me? So I would like to call up two amendments today. First, Warren-Grassley --

The Chairman. Without objection, so ordered.

Senator Warren. But I am going to still talk about it further.

The Chairman. Yes. That was not to stop you.

Senator Warren. This is important though, because what this is about is removing the outdated rules in Medicare that prevent seniors and people from disabilities from accessing the full range of hearing and balanced health care services provided by licensed audiologists.

My bill with Senator Paul and Senator Grassley called the Medicare Audiology Access Improvement Act would allow audiologists to provide all the services that are already covered by Medicare, that are also within an audiologist's scope of practice.

It would also remove the barriers to care that currently force Medicare beneficiaries to jump through more hoops than people who receive their health care coverage through the VA, or the Federal Employees Health Benefit Program, or commercial insurance.

This matters because adequate care for hearing loss is an important part of supporting our seniors.

This is substantial research linking hearing health with mental health. Untreated hearing loss has been shown to lead to depression, anxiety, loneliness and social isolation. Studies also suggest that hearing loss may be one of the greatest risk factors for developing dementia.

Seniors with hearing loss experience cognitive decline up to 40 percent faster than those with normal hearing, and older adults with moderate or severe hearing loss are three to five times more likely, respectively, to develop dementia. If we are working to strengthen support for seniors' mental health and mental acuity, then we should include access to health care aimed at treating hearing and balance disorders.

Now I am going to withdraw my amendment, because it does not meet the germaneness standard that the Committee has adopted for this markup. But Mr. Chairman and Mr. Ranking Member, I am asking for your commitment to work with me and with Senator Grassley, to advance this common sense, bipartisan bill in future legislation.

The Chairman. Thoroughly, and you know, I was just trying to get from the staff a little bit of an update on sort of what is actually out there now, and I mean other than the cochlear implants there is, you

know, very little.

And I will just tell my colleague a ten-second story. When I taught Gerontology and got a few hundred dollars coming in to do the Gray Panthers, I would give on an exam what Medicare covered, and people would always say it is only half a loaf, because it does not cover hearing and many other kinds of services.

So you are spot-on and the answer is "yes," and Senator Crapo has indicated to me, and I will let him speak, that he wants to work with us too.

Senator Crapo. Definitely. As we mentioned yesterday when we spoke, I completely agree with your observations about the need to deal with this issue, and I look forward to working with you to see if we can get this done.

Senator Warren. Good. I so appreciate this, and I just want to say, frankly I think we should do more to prioritize hearing health for our seniors, including by expanding Medicare hearing coverage. But I am sticking with the subject that we are talking about today, and at a minimum we should ensure that Medicare beneficiaries can readily access the full range of hearing services that Medicare already covers.

So next I would like to turn to the Medicare Advantage program. I want to echo Senator Cortez

Masto's support for our amendment with Senator Cassidy, to improve Medicare Advantage encounter data, and I hope we can keep working on this in future packages. I appreciate her leadership on this.

But I would also like to offer Warren-Cassidy No. 2, which would require CMS to collect and publish data for Medicare Advantage plans on their prior authorization practices. You know, currently there are no data on the number of prior authorization requests, denials or appeals by type of service, including mental health and substance use disorder services.

This means that we cannot answer basic questions like are denials more common for certain kinds of services, or certain Medicare Advantage plans are improperly denying care more than others. Let me be clear: I strongly believe these data should be available for all types of services, both physical health and behavioral health.

But as the Committee rightly focuses on behavioral health in this markup, I hope we can all agree that this is a step in the right direction. While I am withdrawing this amendment, I look forward to working with the Committee, working with our Chairman and our Ranking Member, to close these data gaps in Medicare Advantage, so that seniors have the information they

need to get the coverage that works best for them.

The Chairman. So my colleague is talking about a very important issue. I mean we talked a little bit about related matters when Senator Bennet's issue came up with respect to the ghosts, and I know you have been going after them rightfully, in my view, as I have been.

The insurance companies are just burying the hospitals and the doctors and patients in mounds of red tape, and I am actually doing an investigation now on how insurers are overusing prior authorizations in Medicaid, and the Inspector General has reported on some very serious practices going on in these government programs.

So I want to work closely with you to deal with what are very obviously barriers to care for vulnerable people. Senator Crapo.

Senator Crapo. Well, thank you, and I agree. I will also be glad to work with you on this. As you know, I am a big proponent of Medicare Advantage, but that does not mean that I like the prior authorization process and that I do not see some problems here that need to be solved. So I will be glad to work with you on that.

Senator Warren. Thank you.

The Chairman. All right.

My colleague, anything else?

Senator Warren. No. That is it for me.

The Chairman. All right. Well, we are now adjourned.

[Whereupon, at 11:57 a.m., the meeting was concluded.]

SUBMITTED BY SENATOR BLACKBURN

Annals of Internal Medicine

IDEAS AND OPINIONS

Insulins and the Evolving Landscape of U.S. Prescription Drug Pricing

Mariana P. Socal, MD, PhD; and Ge Bai, PhD, CPA

The pricing of U.S. prescription drugs is complex. A drug's list price, determined by its manufacturer, is generally higher than its net price, the amount ultimately collected by the manufacturer. This is because manufacturers usually provide price concessions (rebates, discounts, and fees) to pharmacy benefit managers (PBMs), health insurers, and other supply chain entities (1). For cash-paying patients and insured patients in the deductible phase, list prices typically are aligned with their out-of-pocket expenditures (OOPs); for insured patients subject to coinsurance, list prices usually serve as the basis for calculating patients' OOPs (2, 3). Because price concessions are not passed on to patients, patients rarely benefit from lower net prices negotiated by insurers and PBMs (1, 2). The opaque pricing structure of drugs in the United States penalizes patients by exposing them to higher OOPs, limiting treatment affordability and access which, in turn, places patients at risk for poorer health outcomes and potentially higher downstream health care spending (4).

Recently, 3 major insulin manufacturers–Sanofi-Aventis, Eli Lilly, and Novo Nordisk–announced steep cuts to the list prices of their insulin products. Before this, list prices of insulin glargine were up to 5 times higher than its net prices (5). Therefore, a patient in the deductible phase would pay OOPs 5 times more than the net price that their insurance plan pays after rebates; a patient paying 20% coinsurance based on the list price would in effect pay the entire net price. For example, at a list price of about $28 per 100 U for glargine, a patient paying 20% coinsurance would pay $5.60 OOP when the net price to the insurer was approximately $4 (5). Because the insurer and/or the associated PBMs gets and keeps the rebate, in this case, the insurer and/or PBM makes a profit of $1.60 per each 100 U from the patient's OOP ($5.60 minus $4), a profit of about 40% over the net price ultimately due to the drug manufacturer.

Drug manufacturers have long been questioned as to why they maintain high list prices despite decreasing net prices. During congressional testimonies, drug manufacturers pointed to the critical role of PBMs in incentivizing this phenomenon (6). Drug manufacturers rely on PBMs for market access because PBMs negotiate prices with manufacturers on behalf of health insurers and influence which drugs an insurance plan will cover. Health insurers typically pay PBMs a small fee or no fee at all for managing their prescription drug benefits, with the understanding that PBMs cover costs and generate profit primarily from retaining rebates and other price concessions. This revenue structure incentivizes PBMs to favor drugs with high list prices and high rebates, such as insulin glargine (5, 7). Although PBMs also attribute high drug prices to drug manufacturers, both parties benefit from high list prices and high rebates (6). This dynamic explains why list prices of many prescription drugs have been stable or increasing even when net prices decrease. Unfortunately, this nontransparent pricing practice penalizes and shifts costs to patients through higher OOPs.

Against this backdrop, recent reductions in list price implemented by insulin manufacturers may seem counterintuitive. One potential driver is the recent passage of federal legislation capping Medicare beneficiaries' OOPs for insulin products at $35 per month, which–together with OOP caps for insulin for commercially insured patients implemented by several states–has restricted PBMs' ability to shift insulin costs to patients. This disincentivizes PBMs to cover insulin products with high list prices. This decision may have also been influenced by the lifting of the Medicaid rebate cap (to take effect in January 2024). Medicaid rebates are calculated through a complex formula that, among other factors, accounts for how rapidly drug list prices increase relative to inflation. Under certain scenarios, increases in drug prices that outpace the rate of inflation can result in rebates that exceed the average price of the drug (8). The rebate cap ensures that rebates to Medicaid cannot be greater than 100% of the average drug price. Given the historical trajectory of insulin prices, removing the Medicaid rebate cap might lead to insulin manufacturers having to pay state Medicaid programs substantial sums, negatively affecting manufacturers' revenues (8). Lowering list prices could help insulin manufacturers avoid paying such high rebates after the cap is lifted. Moreover, biosimilar insulin options, including some with low list prices and low or no rebates, are increasingly available. Assuming net prices remain stable, this strategy of reducing list prices would translate to insulin manufacturers paying lower rebates to PBMs and state Medicaid programs while potentially increasing manufacturers' total net revenues (through a potential increase in volume) without necessarily jeopardizing the likelihood of having their products covered.

Insulin list price reductions and reductions in rebates could disrupt the revenue and business practices of PBMs. Lower list prices align with the interests of plan sponsors. Although plan sponsors theoretically benefit from rebates passed on by PBMs, their concern is that PBMs may retain too much of the rebates. Pharmacy benefit managers rarely provide transparency on transaction details or allow insurers auditing rights, exacerbating this concern. Lower list prices and lower rebate amounts help mitigate this concern. Most importantly, lower list prices would improve drug affordability and lower OOP burden among cash-paying patients, insured patients during the deductible phase, and those subject to coinsurance. The insulin market has some unique features that may not apply to other drug markets, including a large patient population, high public

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awareness of pricing issues, and OOP caps. However, similar progress has also been seen for some other high-cost drugs, such as proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitors and hepatitis C treatments.

Lower list prices should be welcomed news for prescribing clinicians, as affordability for the patients whose OOP expenditures are tied to drug list prices is likely to improve. However, high list price and high rebates are not changing for all drugs, especially not for most high-cost specialty drugs. The effect of this pricing model on patient OOP may not be fundamentally resolved until drug list prices are delinked from PBMs' compensation. The recently introduced bipartisan Patients Before Middlemen Act in the U.S. Senate Committee on Finance aims to accomplish this goal for the Medicare Part D program (9). Achieving a similar policy in the commercial market can be politically challenging, but a fee-based PBM business model—in which PBM compensation is disconnected to list prices—is emerging. Several other bills recently introduced in the House and Senate focus on improving transparency in the contracting process between PBMs and plan sponsors in the commercial market (10). Although these transparency proposals do not directly delink PBM compensation from drug list prices, they have the potential to enhance plan sponsors' ability to compare options, reduce entry barriers for fee-based PBMs, and encourage incumbent PBMs to adapt to the new model. Ultimately, if the fee-based PBM model gains market share by delivering value to employers and patients, it can mitigate PBMs' preference for high rebates and manufacturers' incentive to maintain high list prices.

Reforming the current opaque and rebate-based pricing structure of the U.S. pharmaceutical market should benefit patients by protecting them from cost shifting; improving medication affordability, treatment adherence, and health outcomes; and reducing preventable downstream health care spending and use.

From Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (M.P.S.); and Johns Hopkins Carey Business School and Johns Hopkins Bloomberg School of Public Health, Baltimore, Maryland (G.B.).

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Corresponding Author: Mariana P. Socal, MD, PhD, Johns Hopkins Bloomberg School of Public Health, 624 North Broadway, Suite 301, Baltimore, MD 21224; e-mail, msocal1@jhu.edu.

Author contributions are available at Annals.org.

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10. Pharmacy Benefit Manager Transparency Act of 2023, S.127, 118th Cong (2023). Accessed at www.congress.gov/bill/118th-congress/senate-bill/127/text on 1 July 2023.

Author Contributions: Conception and design: G. Bai, M.P. Socal.
Analysis and interpretation of the data: M.P. Socal.
Drafting of the article: G. Bai, M.P. Socal.
Critical revision of the article for important intellectual content: G. Bai, M.P. Socal.
Final approval of the article: G. Bai, M.P. Socal.
Administrative, technical, or logistic support: G. Bai.

blue of california

November 6, 2023

Dear Senate Finance Committee:

I am writing to offer Blue Shield of California's support for your efforts to provide more transparency and accountability to the opaque and inefficient market for pharmacy services.

Policymakers and consumers understand that the complex supply chain unnecessarily drives up the cost of drugs while obfuscating the real price charged by manufacturers. The constellation of rebates, spread pricing, mark-ups, vertically integrated specialty pharmacies, and even offshore Group Purchasing Organizations (GPOs) owned by Pharmaceutical Benefit Managers (PBMs) enables finger pointing on high prices and uncertainty on how much, if any, cost savings are passed on to consumers and payers. The true price of drugs remains hidden behind rebates and a smokescreen of acronyms like AWP (Average Wholesale Price), AMP (Average Manufacturer Price), MAC (Maximum Allowable Cost), WAC (Wholesale Acquisition Cost), and ASP (Average Sales Price).

Blue Shield of California is a non-profit health plan serving 4.8 million members. We pay billions of dollars for prescription drugs every year, but even as a sophisticated purchaser we are in the same place as most Americans: questioning whether we are getting a good value for our money.[1] For that reason, Blue Shield of California recently announced a new pharmacy care model designed to fix problems in today's broken system.

Ultimately PBMs—like every part of the health care system—should be paid fair market value for services delivered. The Senate Finance Committee's Modernizing and Ensuring PBM Accountability Act (S. 2973) takes an important step towards fixing the market by going beyond transparency to advance policy reforms that will save consumers and the government money. This includes a policy "de-linking" PBM remuneration from the cost of drugs—including rebates, fees, and discounts. This policy must apply to the PBMs, aligned vertically-integrated specialty pharmacies, and their offshore "Group Purchasing Organizations" (GPOs). Basing reimbursement on rebates and fees tied to the price of a drug or other non-transparent side-deals drives up costs for our members and the government.

While we commend the work of the Finance Committee in addressing these behaviors in Medicare, we hope that when the issue is considered beyond your committee, it also will address the perverse financial incentives for pharmacy services in the commercial insurance markets as well as in Medicare. Addressing de-linking only in Medicare raises the possibility that costs will simply be passed on to the commercial market where the vast majority of Americans receive coverage through their employer.

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[1] Blue Shield experienced these challenges firsthand while working with Civica Script to bring a low-cost version of a critical prostate cancer drug to market. Subsequent reporting revealed that unjustified mark-ups—up to 100 *times* the cost—for specialty generic medications are widespread among the major PBMs. *Wall Street Journal*, "Generic Drugs Should Be Cheap, but Insurers Are Charging Thousands of Dollars for Them," Sept. 11, 2023.

Finally, in addition to retaining the de-linking policy in any legislative package that moves this year, Blue Shield would encourage policymakers to scrutinize the failing market for lower-cost biosimilar drugs and consider additional measures to force changes to the "rebate wall" blocking a competitive market from emerging.[2]

We appreciate your continued work and attention to these issues.

Sincerely,

Andy Chasin
Vice President, Federal Policy and Advocacy
Blue Shield of California

[2] *See* Kaiser Health News, "Drug brokers steer Americans to the costly choice," ("For real competition to take hold, the big pharmacy benefit managers, or PBMs, the companies that negotiate prices and set the prescription drug menu for 80% of insured patients in the United States, would have to position the new drugs favorably in health plans. They haven't, though the logic for doing so seems plain.").

NATIONAL ASSOCIATION OF Manufacturers

Jay Timmons
President and CEO

November 7, 2023

The Honorable Ron Wyden
Chairman
Committee on Finance,
United States Senate
Washington, DC 20510

The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate
Washington, DC 20510

Dear Chairman Wyden and Ranking Member Crapo:

The National Association of Manufacturers is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs 13 million Americans and contributes $2.9 trillion to the U.S. economy annually. Manufacturers pay workers more than 18% above the average for all businesses, and 91% of manufacturing employees were eligible for health insurance benefits in 2022.[1] Manufacturers are committed to providing health benefits, even as health care costs are a top challenge for the industry.[2]

Pharmacy benefit managers contribute to the skyrocketing cost of health care and drive up the cost of medicines. We appreciate the work Congress has done to address PBM reform and encourage continued efforts to achieve cost savings for America's workers and the prescription drug plans managed by employers. Accordingly, the NAM respectfully requests that members of Congress take timely action and advance legislation aimed at needed reforms to the PBM marketplace.

Manufacturers support reforms to the PBM model that achieve these goals:

- Increase transparency
- Ensure pharmaceutical savings are passed from the PBM to workers and plan sponsors
- Delink PBM compensation from the list price of medication

Congress must reform the PBM system so that employers and their employees can negotiate, compete and achieve profits and savings. Currently, the PBM market is rife with misaligned incentives and suffers from a lack of transparency as just three corporations control 80% of the marketplace.

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[1] Kaiser Family Foundation, 2023 Employer Health Benefits Survey (Oct. 18, 2023), *available at* https://www.kff.org/report-section/ehbs-2023-section-3-employee-coverage-eligibility-and-participation/
[2] National Association of Manufacturers, Q3 2023 Manufacturers' Outlook Survey (Sept. 13, 2023), *available at* https://nam.org/2023-third-quarter-manufacturers-outlook-survey/

The NAM supports a market that rewards robust competition and innovation so plan sponsors and consumers fully understand their plan design and benefit from available savings.

Manufacturers look forward to working with you to build on these efforts.

Sincerely,

Jay Timmons
President and CEO
National Association of Manufacturers

Cc: Senate Leadership
House Leadership
Senate Committee on Health, Education, Labor and Pensions
Senate Committee on Commerce, Science and Transportation
House Committee on Ways and Means
House Committee on Energy and Commerce
House Committee on Education and the Workforce

SUBMITTED BY SENATOR GRASSLEY

United States Senate
COMMITTEE ON THE BUDGET
WASHINGTON, DC 20510–6100
TELEPHONE: (202) 224–0642

July 25, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Administrator Brooks-LaSure,

I have heard first-hand from rural and independent pharmacies in Iowa about the looming cash flow challenges created by changes to Medicare Part D post-point-of-sale compensation that begin on January 1, 2024.[1] Pharmacies will be faced with direct and indirect remuneration (DIR) clawback fees for calendar year (CY) 2023 while also accepting a lower point-of-sale reimbursement starting in CY 2024 in response to Centers for Medicare & Medicaid Services (CMS) final rule-making. I am writing you to ask how your agency is ensuring compliance with pharmacy access standards and prompt payment requirements under Medicare Part D throughout these changes to ensure our nation's seniors do not lose access to a local pharmacy, especially in rural communities. In Iowa, our independent pharmacies serve nearly as many communities as large chains and are typically located in more rural communities that are providing vital health care services.[2] It is critical that CMS utilize its oversight authority of Part D plan sponsors and their pharmacy benefit managers (PBMs) to ensure seniors do not lose access to their local pharmacy.

For years, I have been concerned about the growing Part D plan sponsor and PBM practice of applying DIR fees through a clawback of payments made after the point-of-sale.[3] In a 2019 letter to CMS I wrote, "The retroactive extraction of such fees is straining the viability of pharmacy operations. Pharmacy closures harm our communities and have adverse health consequences for patients."[4] This is why I was committed in a Finance Committee mark-up process on prohibiting retrospective recoupment of payments to pharmacies by Part D plan

[1] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).
[2] Iowa Health Professions Tracking Center, Office of Statewide Clinical Education Programs, University of Iowa Carver College of Medicine, "IOWA COMMUNITY PHARMACISTS By Activity 2022"; Chain pharmacies serve: 121 communities; Independent pharmacies serve: 114 communities.
[3] Letter to Health and Human Services (HHS) Secretary Alex Azar and CMS Administrator Seema Verma from 23 Senators, September 2019, https://www.grassley.senate.gov/news/news-releases/grassley-wyden-bipartisan-senators-push-hhs-pharmacy-dir-reforms-medicare-part-d.
[4] *Id.*

sponsors and PBMs.[5] In the 116th Congress, I helped enable MedPAC to analyze Medicare prescription drug payment information including DIR fees.[6] MedPAC has subsequently reported on their findings over three public hearings shedding light on the growth of DIR fee clawbacks, how DIR fees vary widely, and how DIR fee clawbacks impact patient and taxpayer costs.[7]

While shedding light on DIR fee clawbacks is welcomed news, we need more action. This is why I was pleased to support CMS's rule that discontinued DIR fee clawbacks.[8] Pharmacy DIR fees have grown more than 107,400% between 2010 and 2020.[9] This has caused increased costs for seniors at the pharmacy counter, and negatively impacted many rural and independent pharmacists.[10] By ending DIR fee clawbacks, the final rule is expected to reduce seniors' net out-of-pocket prescription drug costs by $21.3 billion over 10 years.[11] This is good news, but seniors should not lose access to their local pharmacy throughout these changes. In the final rule, CMS stated in response to concerns about "pharmacy cash flow during the first quarter of 2023" that "CMS will be particularly attuned to plan compliance with pharmacy access standards under §423.120 to ensure that all Medicare Part D beneficiaries have convenient access to pharmacies and medications."[12] The final rule also stated "that the prompt payment requirements for Part D, as described in §423.520, will continue to apply and that Part D sponsors must pay clean claims in accordance with the prompt pay regulation."[13] I am interested in your agency's recent efforts on these two matters to ensure our nation's seniors do not lose access to a local pharmacy.

In order to better understand how CMS is conducting oversight over DIR fee clawback changes, including potential pharmacy cash flow challenges, I ask you respond to the following questions by August 31, 2023:

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[5] Office of Senator Chuck Grassley, "Grassley, Wyden Release Updated Prescription Drug Pricing Reduction Act, Reach Agreement On Health Extenders," press release, December 6, 2019, https://www.grassley.senate.gov/news/news-releases/grassley-wyden-release-updated-prescription-drug-pricing-reduction-act-reach; Office of Senator Chuck Grassley, "Grassley Introduces The Updated Prescription Drug Pricing Reduction Act Of 2020," press release, July 2, 2020, https://www.grassley.senate.gov/news/news-releases/grassley-introduces-updated-prescription-drug-pricing-reduction-act-2020.

[6] Consolidated Appropriations Act, 2021, Public Law 116-260, Division CC, Title I, Subtitle B, Section 112.

[7] MedPAC, "Initial Findings form MedPAC's analysis of Part D data on drug rebates and discounts," April 7, 2022, https://www.medpac.gov/wp-content/uploads/2021/10/MedPAC-DIR-data-slides-April-2022.pdf; MedPAC, "Analysis of Part D data on drug rebates and discounts," September 30, 2022, https://www.medpac.gov/wp-content/uploads/2021/10/MedPAC-DIR-data-slides-April-2022.pdf; MedPAC, "Assessing postsale rebates for prescription drugs in Medicare Part D," April 13, 2023, https://www.medpac.gov/wp-content/uploads/2022/07/Tab-F-DIR-data-April-2023-SEC.pdf.

[8] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).

[9] *Id.*

[10] Kaiser Family Foundation, "How Rural Communities Are Losing Their Pharmacies, Markian Hawryluk, November 15, 2021, https://khn.org/news/article/last-drugstore-how-rural-communities-lose-independent-pharmacies/.

[11] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).

[12] *Id.*

[13] *Id.*

1. CMS stated in the final rule it would be "particularly attuned" to pharmacy cash flow concerns and pharmacy network access.[14] In preparation for CY 2024 DIR fee clawback changes, what actions has CMS taken to ensure pharmacy access standards under §423.120 are met?

2. In preparation for CY 2024 DIR fee clawback changes, what actions has CMS taken to ensure prompt pay regulations under §423.520 are met?

3. Has CMS conducted, or is prepared to conduct, additional oversight to ensure pharmacy access standards and prompt pay regulations are met in light of concerns about pharmacy cash flow issues?

4. CMS stated in the final rule that it "encourage Part D sponsors to consider options, such as payment plans or alternate payment arrangements, to minimize impacts to vulnerable pharmacies and the patients they serve."[15] Besides stating this in the final rule, has CMS taken action to encourage the use of payment plans or alternative payment arrangements to minimize the final rule's impact on vulnerable pharmacies? Please provide a detailed list of actions.

5. CMS stated in its final rule that the DIR fee clawback changes applicability date of January 1, 2024, instead of January 1, 2023 would provide "extra implementation time" and "Part D sponsors and pharmacies will now have adequate time to implement payment plans or make other arrangements to address these cash flow concerns at the beginning of 2024."[16] Is CMS aware of the amount of DIR fee clawbacks charged to pharmacies so far in CY 2023 and if those amounts are greater than CY 2022?

6. Has CMS conducted or plan to conduct audits of Part D plan sponsors or PBMs in preparation for the CY 2024 DIR fee clawback changes? Please provide audit details.

7. Has CMS engaged with stakeholder groups, or directly with rural and independent pharmacies, in CY 2023 to better understand how DIR fee clawback changes are impacting cash flow challenges going into CY 2024? What has your agency learned?

I look forward to your update on how CMS is ensuring pharmacy network access and prompt payment policies are followed with the coming implementation of post-point-of-sale compensation changes in January 2024.

Sincerely,

Chuck Grassley

Charles E. Grassley
Ranking Member

[14] *Id.*
[15] *Id.*
[16] *Id.*

United States Senate
COMMITTEE ON THE BUDGET
WASHINGTON, DC 20510–6100
TELEPHONE: (202) 224–0642

October 26, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health & Human Services
200 Independence Avenue S.W.
Washington, D.C. 20201

Dear Administrator Brooks-LaSure,

Thank you for talking with me on September 22, 2023, to discuss the looming cash flow challenges I have heard about from rural Iowa pharmacies.[1] On our phone call, you committed to having the Centers for Medicare and Medicaid Services (CMS) meet with the Iowa Pharmacy Association (IPA), determine whether CMS can encourage payment plans between rural pharmacies and PBMs, and determine if the agency can convene stakeholders (rural pharmacies, PBMs, and others) to ensure seniors do not lose access to rural pharmacies. To date, your agency has satisfied one of these three commitments. I am glad CMS took the time to speak with IPA on October 12, 2023, and learn from their valuable insights. However, I expect a response on how CMS can encourage payment plans and convene stakeholders to address this problem for rural pharmacies.

Iowa rural pharmacies are facing these cash flow challenges due to changes in Medicare Part D post-point-of-sale compensation that begin on January 1, 2024.[2] While these changes to direct and indirect remuneration (DIR) clawback fees were much needed, the lower point-of-sale reimbursement in calendar year (CY) 2024 coupled with DIR clawback fees for CY 2023 is going to create cash flow issues for rural pharmacies. These cash flow challenges put pharmacy access at risk in rural America.[3, 4] Rural pharmacists in Iowa are considering closing or going without pay for some time, so that they keep their staff employed and the lights on. To protect seniors' access to rural pharmacies, CMS must conduct robust oversight in the coming months and next year of Part D plans and their pharmacy benefit managers (PBMs) to ensure pharmacy access standards, prompt payment requirements, and other compliance standards are being met.

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[1] Senator Charles E. Grassley Letter to CMS Administrator Chiquita Brooks-LaSure, July 25, 2023, https://www.grassley.senate.gov/imo/media/doc/grassley_to_cms_-_oversight_of_dir_fee_clawback_changes.pdf.
[2] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).
[3] Aaron Gregg and Jaclyn Peiser, *The Washington Post*, "Drugstore closures are leaving millions without easy access to a pharmacy," October 22, 2023, https://www.washingtonpost.com/business/2023/10/22/drugstore-close-pharmacy-deserts/.
[4] Iowa Pharmacy Association, "State of Community Pharmacy in Iowa," October 2023, https://www.iarx.org/files/State%20of%20Community%20Pharmacy%20in%20Iowa.pdf.

Currently, three PBMs control nearly 80 percent of the prescription drug market.[5] These PBMs have significant influence over whether a rural pharmacy remains in business or not. I have urged PBMs to work with rural pharmacies so they can avoid cash flow challenges. I am not asking the PBMs to give up a single dollar that they are entitled to, but I have called on them to work with pharmacists to give extra time to pay back the 2023 DIR fees.[6] While some PBMs have indicated they offer solutions to help rural pharmacies,[7] the rural pharmacies in Iowa report they have not heard from PBMs about these programs, they are not eligible to participate, and that the programs are ineffective in addressing the looming rural pharmacy financial challenges.[8] This is why CMS must conduct robust oversight as Part D plans and PBMs have a lot of power over what prescription drugs patients can access, how much prescription drugs cost to the patient, and the level of reimbursement and administrative burden to the pharmacy.

Without robust CMS oversight, I am concerned we will see reduced access to rural pharmacies for seniors. While CMS has provided pharmacies an additional year to prepare for the final rule's implementation, the financial challenges that rural pharmacies face have not gone away and the agency has the power to conduct robust oversight. In the agency's final rule, CMS stated in response to concerns about "pharmacy cash flow during the first quarter" of the rule's implementation that "CMS will be particularly attuned to plan compliance with pharmacy access standards under §423.120 to ensure that all Part D beneficiaries have convenient access to pharmacies and medications."[9] The final rule also stated, "that the prompt payment requirements for Part D, as described in §423.520, will continue to apply and that Part D sponsors must pay clean claims in accordance with the prompt pay regulation."[10] Also, CMS can review PBM contracting logs to ensure compliance with pharmacy access requirements.[11] Despite CMS's acknowledgment of the cash flow challenges, I have not seen action by the agency to conduct oversight.

In addition to CMS encouraging payment plans and convening stakeholders, I urge the agency to take proactive action to enforce compliance of pharmacy access standards and prompt payment requirements. I also ask you to consider establishing a direct line (e.g., toll-free phone number, email address) for rural pharmacies to report issues about DIR fee clawback changes, so

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[5] U.S. Senate Finance Committee Report, "Insulin: Examining the Factors Driving the Rising Cost of a Century Old Drug," January 14, 2021, https://www.finance.senate.gov/imo/media/doc/Grassley-Wyden%20Insulin%20Report%20(FINAL%201).pdf.

[6] Senator Charles E. Grassley, "Pharmacy Benefit Managers," Vol. 169, No. 158, September 27, 2023, S4735-S4736, https://www.congress.gov/118/crec/2023/09/28/169/158/CREC-2023-09-28-pt1-PgS4733.pdf.

[7] United Health Group, "Optum Rx launches pharmacy wellness programs to support underserved and rural communities," May 30, 2023, https://www.unitedhealthgroup.com/newsroom/posts/2023/2023-05-30-optum-rx-launches-pharmacy-wellness-programs.html; Express Scripts, "Express Scripts® Launches New Initiative to Expand Rural Health Care Access Through Partnerships With Independent Pharmacies," April 20, 2023, https://www.prnewswire.com/news-releases/express-scripts-launches-new-initiative-to-expand-rural-health-care-access-through-partnerships-with-independent-pharmacies-301802608.html.

[8] Iowa Pharmacy Association to the Office of Senator Charles E. Grassley, October 10, 2023.

[9] Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency; Additional Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency, 42 Fed. Reg. 27843 (to be codified at C.F.R. Parts 417, 422, and 423).

[10] *Id.*

[11] Centers for Medicare & Medicaid Services, "Medicare Prescription Drug Benefit Manual – Chapter 5," https://www.cms.gov/medicare/prescription-drug-coverage/prescriptiondrugcovcontra/downloads/memopdbmanualchapter5_093011.pdf.

CMS's enforcement powers on network access, prompt payment standards, and other compliance standards are utilized effectively. CMS should also thoroughly review Part D plan year 2024 contracts to ensure compliance with the availability, accessibility, and acceptability of services, especially in rural and medically underserved areas.[12] CMS conducted extensive outreach to pharmacies during the implementation of Part D along with using administrative resources to ensure Part D plans are complying with federal regulations and statute. [13] CMS should take similar actions.

CMS cannot sit on the sidelines and let rural pharmacies go out of business. I ask for prompt oversight action and a response on how CMS will protect seniors' access to rural pharmacies.

Sincerely,

Charles E. Grassley
Ranking Member

[12] Validation of Part D reporting requirements, U.S.C. § 423.514.
[13] Testimony from Centers for Medicare and Medicaid Services Administrator Dr. Mark McClellan Mark, Implementation of the Medicare Prescription Drug Benefit, 109th Cong (2006), https://www.finance.senate.gov/imo/media/doc/31519.pdf.

SUBMITTED BY SENATOR LANKFORD

U.S. Department of Health and Human Services

Office of Inspector General

Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use

Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
March 2022, OEI-05-20-00480

U.S. Department of Health and Human Services
Office of Inspector General
Report in Brief
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Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use

Why OIG Did This Review

Biologics—usually large, complex molecules produced in a living system—are some of the most expensive drugs available, and spending for biologics is growing in Medicare Part D because they treat diseases common among Medicare beneficiaries. Biologics are estimated to cost Part D upwards of $12 billion annually.

A biosimilar is a lower-cost biologic that is highly similar to an existing biologic approved by the Food and Drug Administration (FDA (i.e., the biosimilar's "reference product").

Although a limited number of biosimilars are currently available for Part-D-covered reference products, multiple biosimilars for Humira—the best-selling prescription drug in the world—are expected to be available in 2023, thereby presenting an opportunity to significantly decrease Part D drug costs.

How OIG Did This Review

We analyzed biosimilar utilization and spending in Part D from 2015 to 2019. We also calculated multiple estimates to explore how Part D and beneficiary spending in 2019 could have changed with increased utilization of biosimilars.

Lastly, we determined the extent to which Part D plan formularies encouraged the use of biosimilars rather than reference products. Specifically, we examined whether biosimilars were included on Part D plan formularies and, if so, whether they were on a less preferential tier or were subject to different utilization management requirements than their reference products.

Key Takeaway

Medicare Part D and its beneficiaries could realize significant spending reductions if biosimilar use becomes more widespread, but the lack of biosimilar coverage on Part D formularies may limit increased utilization.

What OIG Found

Since biosimilars were introduced in 2015, use of and spending on these drugs in Part D has steadily increased. However, they are still used far less frequently than their higher-cost reference product alternatives. In 2019, biosimilars' reference products were still prescribed about five times more frequently than biosimilars in Part D.

We estimated that with increased use of biosimilars instead of reference products, Part D and beneficiary spending could have been considerably reduced in 2019. Specifically, Part D spending on biologics with available biosimilars could have decreased by $84 million, or 18 percent, if *all* biosimilars had been used as frequently as the most-used biosimilars. Additionally, beneficiaries' out-of-pocket costs for these drugs could have decreased by $1.8 million, or 12 percent. Although these amounts are modest in the context of overall Part D spending, far greater spending reductions will be possible as additional biosimilars become available.

Biosimilars have the potential to significantly reduce costs for Part D and beneficiaries if their use becomes more widespread, particularly with the expected launches of biosimilars for blockbuster drugs Humira and Enbrel. However, a lack of biosimilar coverage on Part D formularies could limit this wider utilization. In 2019, not all plan formularies covered available biosimilars. Moreover, those formularies that *did* cover biosimilars rarely encouraged their use over reference products through preferential formulary tier placement and utilization management tools.

What OIG Recommends and How the Agency Responded

Without further changes to the Part D program, the impact of limited coverage and promotion of biosimilars on formularies may be magnified as biosimilars for blockbuster drugs become available. To help ensure that Part D and beneficiaries can capitalize on potential savings, we recommend that the Centers for Medicare & Medicaid Services (CMS) encourage plans to increase access to and use of biosimilars in Part D. We also recommend that CMS monitor biosimilar coverage on formularies to identify concerning trends. CMS concurred with our first recommendation and neither concurred nor nonconcurred with our second recommendation.

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BACKGROUND

Objectives

1. To identify trends in biosimilar utilization and spending in the Medicare Part D program for 2015–2019.
2. To estimate how increased use of biosimilars could have changed Part D spending and beneficiary spending in 2019.
3. To examine the extent to which Part D formularies were designed to encourage the use of biosimilars rather than reference products in 2019.

Biological products—usually large, complex molecules produced in a living system—are among the most expensive prescription drugs in the United States. Although less than 2 percent of Americans used biologics in 2018, they accounted for 40 percent of the total spending on prescription drugs.[1] Biologics cost Medicare Part D and beneficiaries nearly $12 billion in 2019.[2] Because biologics are often used to treat diseases common among the Medicare population (e.g., rheumatoid arthritis, cancer), Part D spending on biologics likely will continue to rise as more beneficiaries benefit from these expensive drugs.[3]

A biosimilar is a biological product that is highly similar to and has no clinically meaningful difference from what is known as its "reference product"—i.e., an existing biologic approved by the Food and Drug Administration (FDA).[4] In 2010, Congress

[1] Scott Gottlieb, M.D., Commissioner of Food and Drugs, remarks as prepared for delivery at the Brookings Institution on the release of the Food and Drug Administration's (FDA's) Biosimilars Action Plan, July 18, 2018. Accessed at https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas on June 15, 2021.

[2] OIG analysis of the Centers for Medicare & Medicaid Services (CMS) Part D Dashboard for calendar year (CY) 2019 spending. This figure excludes insulin and vaccines. On March 23, 2020, FDA began regulating insulin as a biologic product, allowing for biosimilar and interchangeable versions. Until July 2021, FDA had not approved any insulin biosimilars. FDA, "Insulin Gains New Pathway to Increased Competition," March 23, 2020. Accessed at https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition on June 15, 2021. See also FDA, "FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes," July 28, 2021. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes on October 2, 2021.

[3] The Medicare Payment Advisory Commission (MedPAC), "Chapter 14: The Medicare prescription drug program (Part D): Status report," *Report to the Congress: Medicare Payment Policy*, March 2018. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch14_sec.pdf on February 4, 2022.

[4] A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared. 42 U.S.C. § 262(i)(4).

created an abbreviated approval pathway for biosimilars to increase competition and to lower prices for biosimilars in comparison to their reference products. However, in the subsequent 11 years, competition and savings largely have not been realized.[5]

Most Medicare spending on biosimilars and their reference products currently occurs in Part B,[6] but Part D spending on biosimilars is expected to grow in the coming years. Specifically, biosimilars for two blockbuster drugs covered only under Part D—Humira and Enbrel—have been approved but are not yet available to U.S. consumers.[7] When biosimilars for these drugs become available—expected in 2023 and 2029, respectively—they present an opportunity to significantly decrease Part D drug costs.[8, 9] Humira and Enbrel accounted for more than $5 billion in Part D spending and nearly half of Part D spending on biological products in 2019.

This study is part of a larger strategy by the Office of Inspector General (OIG) to address one of the top management and performance challenges facing the Department of Health and Human Services (HHS)—namely, ensuring the financial integrity of HHS programs.[10] More broadly, the objectives of this study align with the Administration's strategies to reduce U.S. prescription drug spending by increasing access to and utilization of lower-cost biosimilars.[11] It also forms a foundation for future work on this topic as Part D spending on biosimilars grows and as the

[5] Mike Z. Zhai, Ameet Sarpatwari, and Aaron Kesselheim, "Why Are Biosimilars Not Living up to Their Promise in the US?," *AMA Journal of Ethics*, August 2019, p. 669. Accessed at https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08 on June 15, 2021.

[6] Most biosimilars are typically administered by a physician and therefore billed under Part B, which is Medicare's medical benefit. Although insulin is primarily billed under Part D, FDA did not regulate insulin as a biologic product—or allow for biosimilar versions—until March 23, 2020. FDA, "Insulin Gains New Pathway to Increased Competition," March 23, 2020. Accessed at https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition on June 15, 2021.

[7] FDA had approved 34 biosimilars as of March 2022; however, some of these biosimilars were not available to consumers because of ongoing patent litigation or patent settlement agreements or because manufacturers had not yet launched them.

[8] Mike Z. Zhai, Ameet Sarpatwari, and Aaron Kesselheim, "Why Are Biosimilars Not Living up to Their Promise in the US?," *AMA Journal of Ethics*, August 2019, p. 671. Accessed at https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08 on June 15, 2021.

[9] Eric Sagonowsky, "Sandoz's Enbrel biosim case turned away at SCOTUS, giving Amgen's blockbuster 8 more years of free rein," *Fierce Pharma*, May 17, 2021. Accessed at https://www.fiercepharma.com/pharma/sandoz-s-enbrel-biosim-case-turned-away-at-supreme-court-giving-amgen-s-blockbuster-many on August 17, 2021.

[10] OIG, *Top Management and Performance Challenges Facing HHS*, 2020. Accessed at https://oig.hhs.gov/reports-and-publications/top-challenges/2020/index.asp on June 15, 2021.

[11] HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, September 9, 2021. Executive Order No. 14036, 86 Fed. Reg. 36987 (July 14, 2021).

biosimilar market matures. Additional OIG work will examine biosimilar utilization and spending in Part B.[12]

Biological Products

Spending for biological products—which are usually large, complex molecules produced in a living system, such as a microorganism, plant cell, or animal cell—is growing.[13] Recent analysis indicates that biologic spending has grown more than twice as quickly as overall drug spending since 2015 and totaled $211 billion in 2019.[14] List prices for Humira and Enbrel—two biologics that accounted for nearly half of the $12 billion in Part D biologic spending—doubled between 2012 and 2017.[15] Because biologics are used to treat diseases common among Medicare beneficiaries (e.g., rheumatoid arthritis), Part D spending on biologics will continue to increase as additional beneficiaries benefit from these expensive therapies.[16]

Biosimilars

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing biologic (known as the biosimilar's "reference product") that has already been approved by the FDA. In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) as part of the Patient Protection and Affordable Care Act, creating an abbreviated approval pathway for biosimilars to introduce competition and lower prices for these drug products.[17] Under the BPCIA, FDA may approve a biosimilar once the drug manufacturer demonstrates that the biosimilar is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the reference product and

[12] OIG, *Biosimilar Trends in Medicare Part B*, OEI-05-22-00140. Accessed at https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000659.asp on February 16, 2022.

[13] FDA, "Biological Product Definitions." Accessed at https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf on June 15, 2021.

[14] IQVIA, "Biosimilars in the United States 2020-2024: Competition, Savings, and Sustainability," October 2020.

[15] Nathan E. Wineinger, Yunyue Zhang, and Eric J. Topol, "Trends in Prices of Popular Brand-Name Prescription Drugs in the United States," *JAMA Network Open*, May 31, 2019, pp. 4–5.

[16] MedPAC, "Chapter 14: The Medicare prescription drug program (Part D): Status report," *Report to the Congress: Medicare Payment Policy*, March 2018. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch14_sec.pdf on February 4, 2022.

[17] P.L. No. 111–148, Title VII, §§ 7001-7003.

the biosimilar. The first biosimilar—Zarxio—was approved under the BPCIA by FDA in 2015.[18]

As of March 2022, 20 of the 34 FDA-approved biosimilars were available in the United States.[19] Ongoing patent litigation and patent dispute settlements prevented many of the remaining biosimilars from launching in the U.S. market.[20] For example, as a result of patent dispute settlements, manufacturers of multiple FDA-approved biosimilars for the blockbuster reference product Humira are not expected to launch their products in the United States until 2023.[21] Similarly, approved biosimilars for another blockbuster drug, Enbrel, are not expected to launch until 2029.[22]

A biosimilar can be deemed "interchangeable" if the manufacturer can demonstrate that the biosimilar produces the same clinical result as its reference product in any given patient.[23] The interchangeability designation allows pharmacists to substitute an interchangeable biosimilar for its reference product without involving the prescriber.[24] Meeting the BPCIA-established threshold for interchangeability requires additional data, such as results of clinical trials in which patients are switched from the reference product to the biosimilar.[25, 26] As of November 2021, only two biosimilars—one for an insulin product and one for Humira—had been deemed

[18] Lisa A. Raedler, "Zarxio (Filgrastim-sndz): First Biosimilar Approved in the United States," *Journal of Hematology Oncology Pharmacy*, June 2020, vol. 10, no. 3. Accessed at http://jhoponline.com/2016-first-annual-oncology-guide-to-new-fda-approvals/16744-zarxio-filgrastim-sndz-first-biosimilar-approved-in-the-united-states on June 15, 2021.

[19] FDA, "Biosimilar Product Information: FDA-Approved Biosimilar Products," July 2021. Accessed at https://www.fda.gov/drugs/biosimilars/biosimilar-product-information on August 2, 2021.

[20] Mike Z. Zhai, Ameet Sarpatwari, and Aaron Kesselheim, "Why Are Biosimilars Not Living up to Their Promise in the US?," *AMA Journal of Ethics*, August 2019, p. 670. Accessed at https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08 on June 15, 2021.

[21] Ibid, p. 671.

[22] Eric Sagonowsky, "Sandoz's Enbrel biosim case turned away at SCOTUS, giving Amgen's blockbuster 8 more years of free rein," *Fierce Pharma*, May 17, 2021. Accessed at https://www.fiercepharma.com/pharma/sandoz-s-enbrel-biosim-case-turned-away-at-supreme-court-giving-amgen-s-blockbuster-many on August 17, 2021.

[23] 42 U.S.C. § 262(k)(4).

[24] Forty-seven States have passed laws allowing pharmacists to substitute interchangeable biosimilars for their reference products unless a prescriber indicates that the prescription should be dispensed as written. Cardinal Health, "Biosimilar Interchangeability Laws by State," July 2021. Accessed at https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf on September 27, 2021.

[25] 42 U.S.C. § 262(k)(4)(B).

[26] Mike Z. Zhai, Ameet Sarpatwari, and Aaron Kesselheim, "Why Are Biosimilars Not Living up to Their Promise in the US?," *AMA Journal of Ethics*, August 2019, p. 669. Accessed at https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08 on June 15, 2021.

"interchangeable."[27, 28, 29] Without interchangeability status, currently a prescriber must proactively write or approve a prescription for a biosimilar.

In 2019, eight biosimilars were available and approved as alternatives to four reference products in Part D. These biosimilars can be self-administered or administered by a caregiver. They treat autoimmune diseases like ulcerative colitis; anemia due to chronic kidney disease; and neutropenia, when the body makes too few white blood cells as a result of chemotherapy. Part D and beneficiary spending on these biosimilars and their reference products was about $466 million.[30] Exhibit 1 lists the biosimilars covered under Part D in 2019 and their reference products.

Exhibit 1: Eight Biosimilars for Four Reference Products Were Covered Under Part D in 2019

Drug Group	Biosimilar	Approval Date	Reference Product(s)
Filgrastims	Zarxio	March 2015	Neupogen
	Nivestym	July 2018	
	Granix	August 2012[31]	
Infliximabs	Inflectra	April 2016	Remicade
	Renflexis	May 2017	
Pegfilgrastims	Fulphila	June 2018	Neulasta
	Udenyca	November 2018	
Epoetin alfas	Retacrit	May 2018	Epogen/Procrit

Source: OIG research, 2021.

[27] An interchangeable product is a biosimilar product that meets additional requirements. FDA, "Biological Product Definitions." Accessed at https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf on June 15, 2021.

[28] FDA, "FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes," July 28, 2021. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes on July 29, 2021.

[29] FDA, "FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira," October 18, 2021. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira on October 18, 2021.

[30] OIG analysis of the CMS Medicare Part D Drug Spending Dashboard. Dashboard available at https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD.

[31] Although Granix was approved under a Biologic License Application before the BPCIA created an abbreviated approval pathway for biosimilars, it is considered a filgrastim biosimilar alternative.

A number of barriers potentially limit the use of available biosimilars. Research shows that many prescribers and patients are not well informed about—and sometimes not even aware of—biosimilar alternatives.[32, 33] Furthermore, some prescribers are hesitant to switch patients who are already successfully using a reference product to its biosimilar—even when the prescribers have a high degree of confidence in the biosimilar's safety and effectiveness.[34] Industry stakeholders argue that confusion among prescribers, patients, and plans results in part from differences in FDA naming conventions for biosimilars and their reference products that may make biosimilars appear inferior.[35, 36, 37] Additional research indicates that low biosimilar use, particularly in Part D, may be attributed to a variety of causes, such as formulary exclusion, unfavorable formulary tier placement, and rebates for preferential formulary treatment of reference products.[38, 39, 40]

Part D Drug Coverage and Formulary Design

Part D sponsors contract with the Centers for Medicare & Medicaid Services (CMS) to administer the Part D benefit through prescription drug plans. Each plan has a formulary, or a list of covered drugs. CMS reviews the formularies submitted by plan sponsors to ensure they align with best practices and provide sufficient access to

[32] John W. Cook et al., "Academic oncology clinicians' understanding of biosimilars and information needed before prescribing," *Therapeutic Advances in Medical Oncology*, vol. 22, Jan. 6, 2019.

[33] Ira Jacobs et al., "Patient attitudes and understanding about biosimilars: an international cross-sectional survey," *Patient Preference and Adherence*, May 26, 2016.

[34] NORC, "Understanding Stakeholder Perception of Biosimilars," April 2021. Accessed at https://www.norc.org/Research/Projects/Pages/understanding-stakeholder-perception-of-biosimilars.aspx on October 5, 2021.

[35] Biospace, "In an Attempt at Clarity, FDA Makes the Biosimilar Naming Convention Even More Confusing," March 8, 2019. Accessed at https://www.biospace.com/article/fda-abandons-biosimilar-naming-convention/ on October 30, 2019.

[36] Biosimilars Council, "Naming Advocacy." Accessed at https://www.biosimilarscouncil.org/advocacy/ on October 28, 2019.

[37] Biosimilars' nonproprietary names follow a standard naming convention: the reference product's nonproprietary name plus a four-letter suffix (e.g., pegfilgrastim-jmdb).

[38] Mike Z. Zhai, Ameet Sarpatwari, and Aaron Kesselheim, "Why Are Biosimilars Not Living up to Their Promise in the US?," *AMA Journal of Ethics*, August 2019, p. 671. Accessed at https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08 on June 15, 2021.

[39] Jinoos Yazdany et al., "Out-of-Pocket Costs for Infliximab and Its Biosimilar for Rheumatoid Arthritis Under Medicare Part D," *JAMA*, Vol. 320, No. 9, September 2018, pp. 931-933. Accessed at https://jamanetwork.com/journals/jama/fullarticle/2698912 on June 15, 2021.

[40] Biosimilars Council, *Failure to Launch: Barriers to Biosimilar Market Adoption*, September 2019. Accessed at https://www.biosimilarscouncil.org/wp-content/uploads/2019/09/AAM-Biosimilars-Council-Failure-to-Launch-2-web.pdf on June 15, 2021. p. 6.

a range of drugs.[41] At a minimum, formularies must cover commonly needed drugs and generally must offer at least two different drugs in each drug class and category.[42] Formularies allow Part D plans to negotiate lower drug prices with manufacturers in exchange for giving the drugs preferential tier placement on a plan's formulary.[43]

Tier Placement

Part D plan formularies organize the drugs they cover into tiers with different beneficiary cost-sharing requirements.[44] Beneficiaries typically pay less for drugs on lower formulary tiers and more for drugs on higher formulary tiers.[45] Part D plans can use preferential tier placement to encourage utilization of certain drugs. Many Part D plans use five-tier formularies that include one specialty tier for very high-priced drugs.[46, 47]

Utilization management tools

In addition to using formulary tier placement to control costs and utilization of specific drugs, Part D plans may implement utilization management tools. These tools include prior authorization and step therapy. Prior authorization requires prescribers to obtain approval from the Part D plan before it will cover a specific drug.

[41] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.7. Accessed at https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf on June 15, 2021.

[42] 42 CFR § 423.120(b)(2).

[43] Health Affairs, Prescription Drug Pricing, September 2017, p. 1. Accessed at https://www.healthaffairs.org/do/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies.pdf on June 15, 2021.

[44] Beneficiaries can request coverage for drugs not included on their plan's formulary by submitting formulary exception requests—with provider documentation—to their Part D plan. CMS, *Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*, §§ 40.5.2, 40.5.3. Accessed at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf on August 16, 2021.

[45] According to CMS, tier 1 should be the lowest cost-sharing tier available to beneficiaries, and any subsequent tiers should be higher cost-sharing tiers in ascending order. CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.7.

[46] MedPAC, "Chapter 14: The Medicare prescription drug program (Part D): Status report," *Report to the Congress: Medicare Payment Policy*, March 2019. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_ch14_sec.pdf on February 4, 2022.

[47] In 2022, Part D plan sponsors may establish a second, "preferred" specialty tier on their formularies. 42 CFR § 423.104(d)(2)(iv)(D). CMS gave sponsors flexibility to determine which drugs are placed on the two specialty tiers. For example, CMS noted that the second specialty tier may impact Part D drug costs by allowing sponsors to encourage use of biosimilars on the preferred specialty tier or by giving them additional negotiating power with brand drug manufacturers. 86 Fed. Reg. 6077 (January 19, 2021).

Step therapy typically requires beneficiaries to first try a less expensive drug before moving to a more expensive drug.

Drug rebates

Part D plan sponsors may negotiate rebates from drug manufacturers in exchange for encouraging greater utilization of a manufacturer's drug. For example, manufacturers may offer rebates to plan sponsors in exchange for placing their drugs on preferred formulary tiers with lower beneficiary cost-sharing or for exclusive coverage of their drugs.[48, 49] In some cases, a manufacturer's rebates for biologic reference products may be high enough that they reduce the cost of these products so much that the biosimilars—despite their typically lower list price—are more expensive for the Part D plan than their reference products.[50] However, manufacturer rebates generally do not directly lower Part D drug costs for beneficiaries.

Beneficiary cost-sharing

Beneficiaries' cost-sharing obligations shift over the course of the annual Part D benefit. As their drug spending increases, beneficiaries move through the phases of the standard Part D drug benefit—deductible, initial coverage, coverage gap, and catastrophic coverage. Cost-sharing amounts for beneficiaries, known as "out-of-pocket costs," vary from one phase to another. Beneficiaries pay for all drug costs until they meet their Part D plan's deductible. During the initial coverage and coverage gap phases, beneficiaries pay copayments (fixed payment amounts) and coinsurance amounts (payments based on a percentage of the drug's cost). Beneficiaries then pay no more than 5-percent coinsurance during catastrophic coverage.

Contributions from other sources can reduce beneficiaries' out-of-pocket costs. Beneficiaries who meet certain income and asset thresholds may qualify for reduced cost-sharing under Medicare's Low-Income Subsidy (LIS) program. In some cases, beneficiaries may receive financial assistance from other sources, such as charities or other government healthcare programs.

Recent legal and policy changes to the Part D drug benefit have decreased beneficiary cost-sharing for biosimilars; however, these changes affect only select Part D coverage phases or beneficiaries. Beginning in 2019, biosimilar manufacturers provided

[48] Congressional Research Service, "Negotiation of Drug Prices in Medicare Part D," October 2019, p. 1. Accessed at https://crsreports.congress.gov/product/pdf/IF/IF11318 on June 15, 2021.

[49] MedPAC, "Chapter 14: The Medicare prescription drug program (Part D): Status Report," *Report to the Congress: Medicare Payment Policy,* March 2020, p. 431. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_medpac_ch14_sec.pdf on February 4, 2022.

[50] Jinoos Yazdany, "Failure to Launch: Biosimilar Sales Continue to Fall Flat in the United States," *Arthritis Rheumatology*, Vol. 72, No. 6, pp. 870-873, September 2019.

beneficiaries with a 70-percent discount on biosimilars in the coverage gap by participating in the Medicare Coverage Gap Program.[51, 52] Prior to this, when beneficiaries were in the coverage gap, they received the 70-percent manufacturer discount only on biologics (i.e., reference products and biologics without biosimilar competitors).[53] Additionally, CMS finalized a rule in 2018 that reduced cost-sharing for LIS beneficiaries, allowing biosimilars to be covered at the copayment level for generic drugs rather than for brand-name drugs for these beneficiaries.[54] As a result, LIS beneficiaries paid very little—between $0 and $3.40—for biosimilar drugs in 2019.[55]

Methodology

This study analyzed trends in biosimilar utilization and spending in Part D using information about prescription drug costs and beneficiary spending from calendar years (CYs) 2015 to 2019. We calculated multiple estimates to explore how Part D and beneficiary spending in CY 2019 could have changed had there been increased biosimilar use.

This study also analyzed 2019 Part D plan formularies to examine how formulary coverage, placement, and utilization management requirements for biosimilars compared to those for their reference products.

Data Analysis

Analysis of total utilization and spending over time. To analyze total Part D biosimilar utilization and spending over time, we identified all Prescription Drug Event (PDE) records for biosimilars and reference products from January 1, 2015,

[51] The Bipartisan Budget Act of 2018 required that manufacturers provide a 70-percent discount for biosimilars. Section 53116 of Bipartisan Budget Act of 2018, P.L. No. 115-123 (February 9, 2018). See also Kaiser Family Foundation, "Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What's Ahead," August 21, 2018. Accessed at https://www.kff.org/medicare/issue-brief/closing-the-medicare-part-d-coverage-gap-trends-recent-changes-and-whats-ahead/ on June 15, 2021.

[52] Although the Part D coverage gap (the so-called "doughnut hole") closed in 2019, beneficiaries still face high cost-sharing for biologics and biosimilars after the initial coverage phase. Beneficiaries still pay for 25 percent of brand-name drug costs after initial coverage ends. Bipartisan Budget Act of 2018, P.L. No. 115-123 (February 9, 2018).

[53] Kaiser Family Foundation, "Summary of Recent and Proposed Changes to Medicare Prescription Drug Coverage and Reimbursement," February 15, 2018. Accessed at https://www.kff.org/medicare/issue-brief/summary-of-recent-and-proposed-changes-to-medicare-prescription-drug-coverage-and-reimbursement/ on June 15, 2021.

[54] 42 CFR §§ 423.782(a)(2)(iii)(A) and 423.782(b)(3).

[55] CMS, "Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 2, 2018. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf on June 15, 2021.

to December 31, 2019.[56] We considered all biosimilars approved for the same reference product to belong to one biosimilar drug group. For each year and quarter, we summed the number of records for each biosimilar drug group and reference product. We calculated annual and quarterly utilization rates for all biosimilars and for each biosimilar drug group by dividing the number of biosimilar prescriptions by the total number of biosimilar and reference product prescriptions. We calculated Part D gross spending by summing the ingredient cost, sales tax, and dispensing fee PDE variables.[57]

To analyze total beneficiary spending on biosimilars over time, we summed the patient payment amount from PDE records.[58] This amount represents the out-of-pocket copayment or coinsurance paid by a beneficiary for a prescription.

We also calculated 2019 Part D and beneficiary spending for two reference products—Humira and Enbrel—expected to have biosimilars available on the U.S. market in 2023 and 2029, respectively.

Analysis of average spending in 2019. For each biosimilar drug group and reference product, we calculated average Part D and beneficiary spending amounts for CY 2019 by dividing the Part D and beneficiary spending by the total drug weight dispensed.

We then used the average spending amounts to illustrate spending differences for typical prescriptions for biosimilars and reference products. First, to define a typical prescription, we calculated the median drug weight dispensed for each biosimilar drug group and its reference product. We then multiplied the average spending amounts for each biosimilar drug group and reference product by the amount dispensed for the typical prescription.

Analysis of changes in 2019 spending with increased biosimilar use. We calculated multiple estimates for changes in Part D and beneficiary spending had biosimilars been used at higher rates in 2019.

We took two steps to estimate how any increase in biosimilar utilization could have changed Part D and beneficiary spending.[59] We first estimated how much Part D and beneficiaries could have spent if all CY 2019 prescriptions for reference products had been for biosimilars instead, using the average biosimilar spending amounts described above. We used average spending at the biosimilar drug group level to

[56] We excluded insulin from this analysis because FDA did not regulate insulin as a biologic product until March 23, 2020.

[57] This represents the total amount paid for drugs covered by the Medicare benefit before rebates are taken into account.

[58] To better approximate most beneficiaries' cost-sharing obligations, we excluded beneficiaries who were receiving other sources of support (e.g., group health plans, governmental programs) from the analysis of beneficiary spending, as well as beneficiaries enrolled in PACE (Program of All-Inclusive Care for the Elderly) plans.

[59] We analyzed changes in spending by beneficiaries receiving the low-income subsidy (LIS) separately.

avoid making assumptions about prescribing practices (e.g., which brand or strength of a biosimilar would be prescribed). Based on this—and the actual spending and utilization for biosimilars in 2019—we then estimated how any increase in biosimilar utilization could have changed Part D and beneficiary spending.

We then used these estimates to assess 2019 Part D and beneficiary spending at various utilization rates, two of which we focused on in the report. We included conservative estimates of what Part D and beneficiary spending could have been if total biosimilar utilization had matched the 60-percent utilization rate of the most used biosimilar group (i.e., filgrastim biosimilars). We also included optimistic estimates of what Part D and beneficiary spending could have been if biosimilar utilization in 2019 had matched the 90-percent utilization rate for Part D generic drugs (i.e., approved generic versions of small-molecule, nonbiologic drugs).[60] The total difference between the actual and estimated spending amounts represented the potential reductions in Part D and beneficiary spending if biosimilar use had increased in 2019.

We used the same methodology to estimate how increased biosimilar use could have changed Part D net spending—that is, Part D spending after adjusting for rebates. To arrive at net spending calculations, we used Direct and Indirect Remuneration (DIR) data about manufacturer rebates from CMS's Health Plan Management System (HPMS).[61] We did not adjust beneficiary spending to reflect rebates because rebates typically do not affect beneficiary out-of-pocket costs.

Analysis of biosimilar formulary coverage and placement. We analyzed formulary coverage and placement separately for each biosimilar drug group. To determine whether Part D plan formularies encouraged biosimilars, we used data from HPMS to calculate the percentage of formularies that included both biosimilars and their reference products; included only biosimilars; or included only the reference products for biosimilars. For formularies that covered both biosimilars and their reference products, we calculated the percentages that (1) placed biosimilars on lower, higher, or the same formulary tiers as their reference products and (2) had different requirements for step therapy and prior authorization for biosimilars than they had for those biosimilars' reference products.

See the Detailed Methodology section for more information.

[60] In an analysis of Part D prescriptions that could have been filled with an approved generic version of a small-molecule drug, CMS found that the generic drug was used 90.8 percent of the time. CMS, "Increasing Access to Generics and Biosimilars in Medicare," February 5, 2020.

[61] Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

Limitations

Changes in Part D and beneficiary spending are estimates and do not represent the exact spending changes that would have resulted from increased biosimilar use in 2019. For instance, these estimates do not account for how drug manufacturers might have responded to greater biosimilar utilization, such as by renegotiating rebates with plans or changing pricing for reference products or biosimilars in response to greater biosimilar use. These estimates also do not account for how increased use of biosimilars could have shifted beneficiaries through the Part D benefit phases or the resulting impacts on beneficiary spending.

This study did not assess whether the increased utilization rates used to estimate spending reductions are achievable. For example, this report does not include an analysis of additional barriers and challenges—such as prescriber preferences—that may prevent greater use of biosimilars. Unlike generic drugs, the biosimilars in this study cannot be substituted for their reference products by a pharmacist because FDA has not deemed them "interchangeable."

Standards

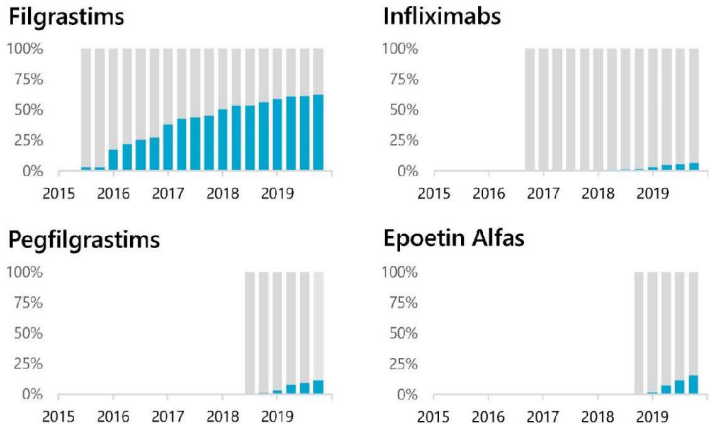
We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

Use of biosimilars in Part D increased every year, but most biosimilars were still used far less than their reference products in 2019

Since biosimilars were first introduced in 2015, use of these drugs in Part D has steadily grown—yet remains low compared to use of their reference products. In nearly 5 years, the total number of biosimilar prescriptions increased substantially; however, biosimilars accounted for only 17 percent of all prescriptions for biosimilars and their reference products in 2019. Among the four drug groups, only filgrastim biosimilars were used more frequently than their reference products. From 2015 to 2019, filgrastim biosimilars grew from 3 percent to 62 percent of quarterly filgrastim prescriptions, driven largely by increased use of Zarxio. In contrast, newer biosimilars in the other three drug groups were used to a much lesser extent than their reference products. Specifically, in the fourth quarter of 2019, biosimilars made up 16 percent of epoetin alfa prescriptions, 12 percent of pegfilgrastim prescriptions, and 7 percent of infliximab prescriptions. Exhibit 2 shows that most biosimilars were used much less frequently than their reference products.

Exhibit 2: For most biosimilars, use remained low compared to their reference products.

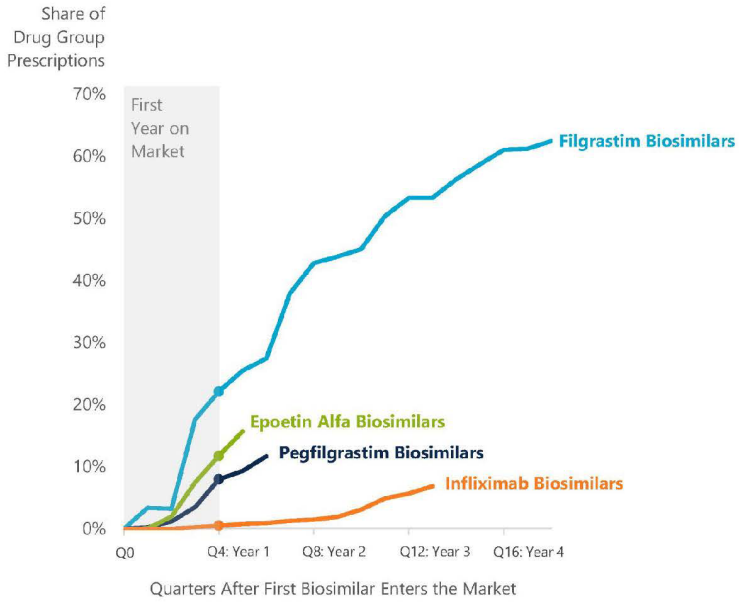


Note: We analyzed the biosimilar share of prescriptions starting in the quarter when a biosimilar alternative first became available on the U.S. market.

Source: OIG analysis of Part D PDE data from 2015–2019.

While biosimilar filgrastim use in Part D increased substantially after a year on the market, subsequent biosimilars have been adopted more slowly. Filgrastim biosimilars grew from 3 percent to 22 percent of all filgrastim prescriptions within a year of their introduction. In contrast, after the same amount of time on the market, newer biosimilars accounted for smaller proportions of their respective drug groups' prescriptions than did filgrastim biosimilars. By the end of their respective first years on the market, biosimilars made up less than 1 percent of total infliximab prescriptions, 8 percent of pegfilgrastim prescriptions, and 12 percent of epoetin alfa prescriptions. In addition to being affected by time on the market, utilization of newer biosimilars may have been affected by other factors, such as the purpose of the drug, providers' prescribing preferences, or the number of available biosimilars. Exhibit 3 illustrates the slower adoption of these biosimilars when compared with filgrastim biosimilars.

Exhibit 3: Newer biosimilars have been adopted more slowly than filgrastim biosimilars—both at the end of their first year on the market and after.



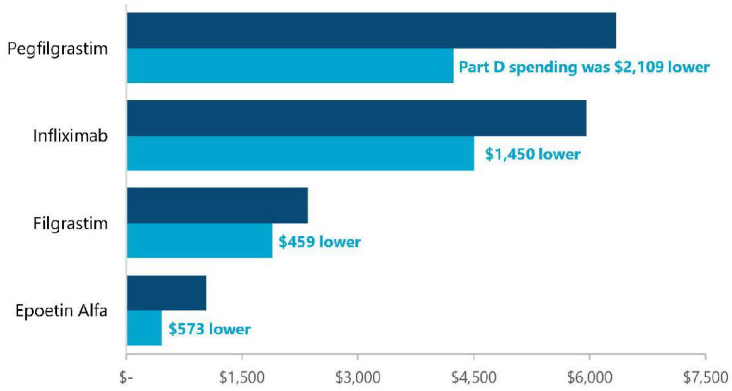
Source: OIG analysis of Part D PDE data from 2015–2019.

Part D spending. As biosimilar utilization increased, Part D spending for these drugs rose but still accounted for a small portion of overall Part D spending on biosimilars and their reference products combined. From 2015 to 2019, total spending on

biosimilars rose from $1.7 million to $60.8 million. In 2019, however, this amounted to only 13 percent of the overall $466 million that Part D paid for biosimilars and their reference products combined.

Although Part D spending on biosimilars has increased, the program paid less on average for biosimilars than for their reference products, which contributed to biosimilars' small share of overall spending. Additionally, Part D spending adjusted for rebates was lower on average for biosimilars than for their reference products.[62] See Exhibit 4 for average Part D gross spending differences for typical reference product and biosimilar prescriptions in 2019.

Exhibit 4: Part D spending for typical prescriptions was lower for biosimilars than for the biosimilars' reference products.



Source: OIG analysis of Part D PDE data from 2019.

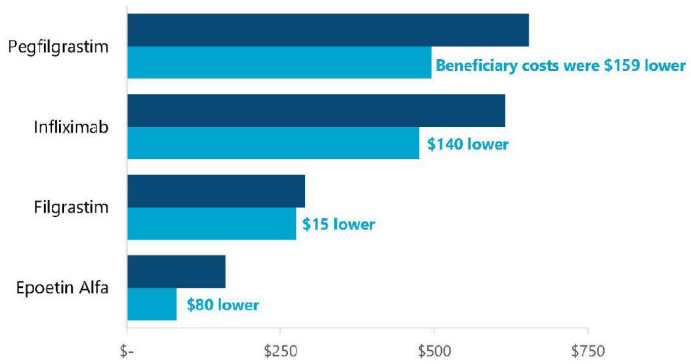
Beneficiary spending. As with the share of biosimilars in Part D spending, beneficiaries' total out-of-pocket spending on biosimilars constituted a small share of their spending on reference products and biosimilars combined. Beneficiaries' total out-of-pocket costs for biosimilars increased from $152,000 in 2015 to $2.8 million in 2019. This accounted for less than 20 percent of the $14.5 million that beneficiaries spent on biosimilars and their reference products in 2019.

On average, beneficiaries paid less for most biosimilars than for their reference products. See Exhibit 5, on the next page, for an illustration of how lower average beneficiary spending for biosimilars would translate to lower out-of-pocket costs for

[62] Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

typical biosimilar prescriptions in 2019. Additionally, Low-Income Subsidy (LIS) beneficiaries typically paid $2.55 less for most biosimilars than for their reference products.

Exhibit 5: Beneficiary out-of-pocket costs for typical prescriptions were lower for biosimilars than for the biosimilars' reference products.



Note: The analysis of beneficiaries' typical prescription spending does not include spending by beneficiaries whose cost-sharing contributions were reduced by Medicare's LIS program.

Source: OIG analysis of Part D PDE data from 2019.

Increased biosimilar use could have reduced Part D and beneficiary spending considerably in 2019, suggesting the potential for far greater spending reductions when biosimilars for blockbuster drugs become available

Drug spending on biologics with available biosimilars could have been reduced considerably for the Part D program and its beneficiaries if all biosimilars had been used at higher rates. This is true both for gross spending and for net spending, which takes into account the rebates that manufacturers pay to Part D plan sponsors. The estimated net spending reductions for the Part D program from increased biosimilar use are comparable to reductions based on gross spending.[63] Further, rebates generally have no effect on beneficiary out-of-pocket costs and therefore do not change the estimated reductions in beneficiary spending. Although the estimated spending decreases are modest in the context of overall Part D spending, far greater

[63] Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

spending reductions may be possible as biosimilars for blockbuster drugs Humira and Enbrel come on the U.S. market—expected in 2023 and 2029, respectively.

Part D spending on biosimilars and their reference products could have been reduced between 18 percent and 31 percent if biosimilars had been used at higher rates

Part D gross spending on biosimilars and their reference products could have decreased $84 million in 2019 if all available biosimilars had been used at the same 60-percent utilization rate as filgrastim biosimilars. This amounts to 18 percent of the $466 million that Part D spent on all biosimilars and their reference products in 2019. We estimated utilization for all biosimilars at 60 percent because filgrastim biosimilars had achieved this utilization rate after nearly 5 years on the market. Furthermore, if biosimilars had been used at a 90-percent utilization rate—the utilization rate of generic, nonbiologic drugs—Part D gross spending on these drugs could have decreased by $143 million, or 31 percent of actual 2019 gross spending.

Part D spending could have decreased by **$84 million** if biosimilars had been used at a higher rate.

In both estimates, the largest spending reductions would have come from increased utilization of the biosimilar for epoetin alfa. Epoetin alfa products were widely used in Part D in 2019, but use of the biosimilar was low compared to use of its more expensive reference product.

Beneficiaries' out-of-pocket costs for biosimilars and their reference products could have been reduced between 12 percent and 22 percent if biosimilars had been used at higher rates

Overall beneficiary spending on biosimilars and their reference products could have decreased by nearly $1.8 million if all biosimilars had been used at the same 60-percent utilization rate at which filgrastim biosimilars were used. This is 12 percent less than the $14.3 million spent by these beneficiaries on all biosimilars and reference products in 2019. If all biosimilars had been used at the same rate as generic drugs (90 percent), overall beneficiary spending on these drugs could have decreased by $3.1 million—22 percent.

For some individual beneficiaries, using a biosimilar rather than a reference product had the potential to markedly reduce the beneficiary's out-of-pocket spending for these expensive drugs. The extent to which a beneficiary could have reduced this out-of-pocket spending by using a biosimilar depends on multiple factors, such as the

type of drug prescribed, the benefit phase in which the prescription was filled, and the cost-sharing structure of the beneficiary's Part D plan. For example, beneficiaries may have greater reductions in their out-of-pocket costs when using biosimilars during the initial coverage phase, rather than during the catastrophic coverage phase, because beneficiary cost-sharing is capped at 5 percent during the latter. Exhibit 6 illustrates the differences in cost-sharing between reference product and biosimilar epoetin alfa for two beneficiaries in the same Part D plan.

Exhibit 6: Beneficiaries may have significantly different out-of-pocket costs when using reference products and biosimilars—even when they are enrolled in the same Part D plan and during the same benefit phase.

Note: We selected claims for reference product prescriptions and biosimilar prescriptions that were for the same quantity and strength of drug and that occurred in the initial coverage phase of the Part D benefit.

Source: OIG analysis of Part D PDE data from 2019.

Although out-of-pocket costs are low for LIS beneficiaries, these beneficiaries also could have realized spending reductions with increased utilization of biosimilars in 2019.[64] Spending by these beneficiaries could have decreased by 15 percent or nearly $34,000 if all biosimilars had been used at the same utilization rate (60 percent) at which filgrastim biosimilars were used. If all biosimilars had been used at the same rate as generic drugs (90 percent), spending could have decreased 25 percent—more than $55,000.

[64] LIS beneficiaries generally paid very little for prescription drugs in 2019—between $0 and $8.50 for a brand-name drug or reference product and between $0 and $3.40 for a generic or biosimilar. CMS, "Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter," April 2, 2018. Accessed at https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf on June 15, 2021.

Substantial reductions in both Part D and beneficiary spending may be possible when biosimilars for blockbuster drugs become available

The potential for even greater spending reductions is possible as more biosimilars come on the market. Nine biosimilars for two blockbuster drugs—Humira and Enbrel—have been approved but are not yet available to U.S. consumers. Unlike with the drugs we analyzed for this study, which are also covered under Medicare's Part B, Humira and Enbrel are covered solely by Part D. As a result, all savings on biosimilars for these drugs will accrue to Part D and its beneficiaries. Further, many Part D beneficiaries likely will continue to take drugs such as Humira and Enbrel because they treat diseases like rheumatoid arthritis that are prevalent among the Medicare population. Finally, these drugs are typically administered more frequently—as often as weekly or every other week—than the drugs included in this study.

Together, Humira and Enbrel accounted in 2019 for more than $5.7 billion in Part D spending—more than 14 times the $405 million that Part D spent that year for reference products with available biosimilars. In 2019, beneficiary spending for Humira and Enbrel totaled more than $70 million. When biosimilars for Humira and Enbrel become available—expected in 2023 and 2029, respectively—they present an opportunity to dramatically decrease spending if there is significant use of the biosimilars. Furthermore, at least seven biosimilars for Humira—including one designated as interchangeable—may be available and could bring even greater spending reductions. For instance, one recent study indicates that with each additional biosimilar alternative that enters the market, the average price decreases for the entire group of biosimilars and their corresponding reference product.[65] With numerous biosimilars available as alternatives to Humira, they may have a greater impact on the market than if a single biosimilar alternative were available. Additionally, Humira may see increased competition from the biosimilar alternative that has been designated as interchangeable, which means that pharmacists can substitute it for the reference product without consulting with the prescriber.[66]

Not all Part D plan formularies covered available biosimilars in 2019, and those that did rarely encouraged their use

The Part D program and its beneficiaries would have seen spending reductions with more widespread biosimilar use, but biosimilar use may have been limited by Part D formularies' lack of biosimilar coverage. As of 2019, not all plan formularies that covered reference products also covered their biosimilar alternatives. Those that covered both reference products and biosimilars usually treated them equally—

[65] Richard G. Frank et al., "Biosimilar Competition: Early Learning," National Bureau of Economic Research Working Paper Series, March 2021. Accessed at http://www.nber.org/papers/w28460 on July 26, 2021.

[66] Biosimilar substitution by pharmacists is subject to State pharmacy laws, which vary by State.

in other words, they did not use formulary design or utilization management tools to encourage the use of biosimilars instead of reference products.

When biosimilars for Humira and Enbrel become available, plans may have strong incentives to exclude them from formularies or otherwise discourage their use. Humira and Enbrel account for billions—rather than millions—of dollars in Part D spending. To maintain their market share, manufacturers may provide substantial rebates to Part D plan sponsors in exchange for exclusive coverage or preferred placement of these drugs—either of which would discourage the use of biosimilars.[67] These rebates typically would not lower out-of-pocket costs for beneficiaries using the reference products.

In 2019, plan formularies did not always include biosimilars—particularly those that had been more recently introduced

Biosimilars—especially those that were newer on the market—were not always included on plan formularies in 2019.[68] The plan formularies that covered only reference products in effect discouraged biosimilar utilization by preventing beneficiaries from using their Part D coverage for biosimilars instead of reference products. Specifically, in 2019, 38 percent of plan formularies that covered an epoetin alfa reference product did not cover the biosimilar and 32 percent of formularies that covered the pegfilgrastim reference product did not cover a biosimilar. These coverage decisions occurred despite the biosimilars costing Part D less on average than their reference products, even when accounting for rebates. Although nearly all plan formularies covered at least one filgrastim biosimilar, 40 percent did not cover Zarxio—the most widely used filgrastim biosimilar and the primary competitor to the reference product.[69]

Few plan formularies covered biosimilars without also covering their corresponding reference products, and thereby actively encouraged the use of biosimilars. Filgrastim biosimilars were the only biosimilars that a considerable number of plan formularies—

[67] MedPAC, "Chapter 14: The Medicare prescription drug program (Part D): Status Report," *Report to the Congress: Medicare Payment Policy,* March 2020, p. 431. Accessed at http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf on October 5, 2021.

[68] In 2019, Part D plans did not include infliximab products on their formularies because of a change that CMS made to its list of drugs that may be included on formularies. (CMS had removed some drugs primarily covered under Part B, like infliximab products, from this list.) Although infliximab reference products and biosimilars were not explicitly included on Part D formularies, they were still covered and paid for by Part D. Any beneficiary who needed an infliximab product had to submit a formulary exception request—with provider documentation—to the beneficiary's Part D plan. CMS, "Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance," § 40.5. Accessed at https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf on October 4, 2021.

[69] Zarxio is considered the primary competitor to Neupogen—the reference product for filgrastim biosimilars—because it was approved for all five of the filgrastim indications and has gained a larger market share in Part D than other filgrastim biosimilars.

18 percent—covered *instead* of the reference product. In contrast, no plan formularies covered only the epoetin alfa biosimilar rather than the reference products. Similarly, only one plan formulary covered only a pegfilgrastim biosimilar without also covering the reference product.

Most plan formularies that included biosimilars did not use tools to encourage biosimilar use

Plan formularies rarely used formulary tools—such as preferential tier placement or utilization management—to encourage the use of biosimilars instead of their reference products.

Tier placement. Tier placement plays a key role in whether prescribers decide to prescribe biosimilars. For example, in addition to affecting beneficiary cost-sharing, tier placement on a plan formulary can influence prescribers' preferences. Specifically, a recent survey (conducted from December 2019 through January 2020) found that when both the biosimilar and its reference product are available on the formulary, prescribers will choose the reference product unless the biosimilar is in a preferred position on the formulary.[70]

Most plan formularies that covered both biosimilars and reference products did not encourage biosimilar use by placing these drugs in preferred positions on the formulary relative to the positions of their reference products. Instead, most placed biosimilars on the same formulary tier as their reference products. Specifically, more than 97 percent of these plan formularies placed all covered biosimilar and reference product filgrastims or pegfilgrastims on the same formulary tier. Less than 3 percent of these formularies placed either a filgrastim biosimilar or a pegfilgrastim biosimilar on a lower tier than its reference product. Additionally, more than 60 percent of these plan formularies placed all epoetin alfa biosimilars and reference products on the same formulary tiers. Only 12 percent of these formularies placed all epoetin alfa biosimilars on lower tiers than their reference product.

When plan formularies place a biosimilar and its reference product on the same tier, beneficiaries have fewer financial incentives to use the biosimilar. As drugs on lower (i.e., preferential) formulary tiers typically have lower out-of-pocket costs, placing a biosimilar and its reference product on the same tier limits the potential cost savings for beneficiaries using the biosimilar.[71] Notably, when a biosimilar and its reference product are on the same tier, with a fixed copayment, using the biosimilar may not reduce beneficiary cost-sharing at all.

Utilization management tools. Similarly, most plan formularies used the same utilization management tools for biosimilars and their reference products—meaning

[70] Allison R. Kolbe et al., "Physician Understanding and Willingness to Prescribe Biosimilars: Findings from a US National Survey," *BioDrugs*, Vol. 35, Issue 3, pp. 363-372, 370.

[71] CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.7.

they neither actively encouraged nor discouraged biosimilar use. For newer biosimilars, most 2019 plan formularies that covered both biosimilars and their reference products used the same prior authorization or step therapy requirements for these drugs. More than 95 percent of these plan formularies had the same prior authorization or step therapy requirements for pegfilgrastim or epoetin alfa biosimilars and their reference products. For filgrastims, more than 85 percent of plan formularies had the same utilization management requirements for biosimilars and for their reference product.

There were some exceptions—a small number of plan formularies used utilization management tools to encourage use of the most used biosimilars, particularly the filgrastim biosimilar Zarxio. Specifically, 13 percent of plan formularies did not require prior authorization for at least one filgrastim biosimilar but did for the reference product. Also, 8 percent of plan formularies used step therapy in a way that would encourage the use of these biosimilars—usually requiring that beneficiaries try the biosimilar Zarxio before other filgrastims.

CONCLUSION AND RECOMMENDATIONS

Biosimilars have the potential to reduce costs for the Part D program and its beneficiaries, both now and in the future. Although use of these drugs has steadily increased, most are still used far less often than their reference products. We estimated that even a conservative increase in the use of currently available biosimilars could have greatly reduced spending for the Part D program and its beneficiaries in 2019. With biosimilars for the blockbuster drugs Humira and Enbrel on the horizon, the scale of the potential savings from increased utilization of biosimilars stands to grow substantially.

Part D plans' limited coverage and promotion of biosimilars have prevented the program and its beneficiaries from maximizing potential savings. By not including biosimilars on formularies, many Part D plans effectively discouraged the use of these drugs. Even the most used and successful biosimilar—Zarxio—likely would have been used more frequently with wider formulary coverage. Most Part D plans also did not actively encourage use of biosimilars by placing them on lower formulary tiers or by requiring beneficiaries to try a biosimilar before the reference product.

Without further changes to the Part D program, the impact of these limitations will be magnified as biosimilars for blockbuster drugs become available. Unlike the drugs we examined in our study, Humira and Enbrel account for billions of dollars in Part D spending. As a result, plans may have even more incentives to limit formulary coverage or to employ utilization management tools to potentially discourage the use of biosimilars for these biologics. This is because drug manufacturers pay substantial rebates to Part D plans, potentially encouraging Part D plans to cover the manufacturers' reference products instead of the corresponding biosimilars, or to give the reference products preferential treatment. Left unexamined, this issue represents a serious vulnerability for future savings for Part D and especially for its beneficiaries, who—unlike Part D plans—typically do not realize any direct financial benefit from manufacturer rebates.

CMS could do more to ensure that beneficiaries have access to currently available lower-cost biosimilars under Part D and to prepare the program for the launch of future biosimilars. CMS has already taken some steps to increase utilization of lower-cost biosimilar drugs by allowing Part D plans to establish a second, "preferred" specialty tier with lower cost-sharing for beneficiaries. Part D plans have the flexibility to use this tier for either biosimilars or their reference products. To further promote the use of biosimilars now and help ensure that the program is poised to capitalize on potential future savings, CMS can encourage Part D plans to use formularies designed to increase the use of biosimilars and CMS can monitor Part D plans' treatment of biosimilars to identify future areas of concern.

We recommend that CMS:

Encourage Part D plans to increase access to and use of biosimilars

CMS should encourage Part D plans to increase access to and the use of biosimilars instead of their reference products within its authority. To do this, CMS could use a demonstration project to evaluate incentivizes for encouraging biosimilar use. For example, CMS could conduct a demonstration project to determine whether capped copayments increase the use of lower-cost biosimilars. CMS could also explore other methods to encourage biosimilar use, such as continuing its efforts to use the Star Ratings system, which helps beneficiaries compare the quality of prescription drug plans when they shop for Part D coverage. Although CMS—after receiving public feedback—did not pursue a previously proposed biosimilar utilization measure, it could explore additional options.[72] For example, CMS could consider developing a biosimilar access measure based on whether plans cover at least one biosimilar as an alternative to each reference product in instances when the biosimilar is less expensive or when there are two or more biosimilars on the market.

Monitor Part D plans' submitted formularies to determine whether they discourage beneficiaries from using biosimilars

CMS should monitor biosimilar coverage, cost-sharing, and utilization management requirements in Part D plan formularies on a regular basis to understand biosimilar coverage trends. Ideally, CMS would begin conducting such monitoring prior to any upcoming expected launches of biosimilars into the market—such as biosimilars for Humira and Enbrel, which would be the first biosimilars to be covered only under Part D. Such monitoring could be integrated into CMS's annual review of Part D formulary performance and content or could be conducted separately, to the extent that CMS's authority allows. To identify concerning trends in biosimilar coverage, CMS could monitor whether Part D plan formularies (1) exclude biosimilars, (2) place biosimilars on less preferential tiers than their reference products, or (3) employ stricter utilization management policies—such as prior authorization and step therapy—for biosimilars than for their reference products. The results of monitoring trends in biosimilar coverage could inform CMS's efforts to encourage biosimilar access and use within its authority.

[72] In its 2021 Rate Announcement, CMS stated that it would consider the public feedback it received "for any potential future development of generic utilization measures." CMS, "Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies," April 6, 2020. Accessed at https://www.cms.gov/files/document/2021-announcement.pdf on February 28, 2022.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with our first recommendation and neither concurred nor nonconcurred with our second recommendation.

In response to our first recommendation, CMS stated that it plans to examine how demonstration projects could be used to incentivize the use of biosimilars. CMS also indicated that it will continue to explore other options within its authority to increase access to and use of biosimilar drugs. CMS's commitment to supporting the increased use of biosimilars has the potential to protect the Part D program and beneficiaries from significant drug costs.

In response to our second recommendation, CMS stated that it has limited authority to review Part D plan formularies. Specifically, CMS said that its formulary review process is limited to ensuring that formularies provide access to medically necessary treatments and that formularies do not discriminate against particular types of beneficiaries. In response to CMS's comments, we clarified that the monitoring we recommend is intended to inform CMS's efforts to encourage the use of biosimilars within its authority. It is critical for HHS, Congress, and the public to have information about biosimilar coverage on Part D plans' formularies, particularly as biosimilars for Humira and Enbrel become available in the coming years.

DETAILED METHODOLOGY

Data Sources

Product information for biosimilars and reference products. We used FDA's Biosimilar Product Information, FDA's Purple Book, and First Databank to identify all biosimilars and reference products and their National Drug Codes (NDCs). FDA's Biosimilar Product Information lists all FDA-approved biosimilars. The Purple Book lists all biological products, including biosimilars. First Databank links drugs' proprietary names with their NDCs.

Prescription drug data. To analyze biosimilar utilization, Part D spending, and beneficiary spending, we used Medicare Part D PDE records. PDE records include the quantity of the drug dispensed, variables necessary to calculate Part D gross spending, and beneficiary spending. We considered each PDE record to be one prescription. We used detailed DIR data from CMS's Health Plan Management System (HPMS) to calculate rebates in order to calculate net Part D spending.

Formulary coverage and design data. To analyze biosimilar formulary coverage, we used Approved Formulary Submission data from HPMS. These data include information about the drugs covered on Part D plan formularies, such as tier placement and utilization management requirements.

Data Analysis

Identifying biosimilars and reference products. Using FDA's Biosimilar Product Information and Purple Book, we identified all biosimilars approved for use as of January 1, 2019 and their reference products. We used First Databank to identify all NDCs associated with these biosimilars and reference products. In total, we identified 81 NDCs for 4 reference products and 8 biosimilars covered by Part D plans.

Biosimilar drug group(s). We considered all biosimilars approved for the same reference product to belong to one biosimilar drug group. Biosimilar drug group(s) included biosimilars with different proprietary names and strengths. We analyzed average spending for each biosimilar drug group to avoid making assumptions about prescribing practices that are beyond the scope of this study (e.g., which biosimilar brand or strength would be prescribed).

Analysis of utilization and spending over time. We calculated Part D biosimilar utilization and spending over time by using PDE records for biosimilars and reference products from January 1, 2015 to December 31, 2019. For each year and quarter, we summed the number of prescriptions for each biosimilar drug group and reference product.

We calculated annual and quarterly utilization rates for all biosimilars and for each biosimilar drug group by dividing the number of biosimilar prescriptions by the total number of biosimilar and reference product prescriptions.

We calculated annual Part D and beneficiary spending for each biosimilar drug group and reference product. For Part D gross spending, we summed three PDE variables: ingredient cost, sales tax, and dispensing fee. This represents the total amount paid to a pharmacy at the point of sale for drugs covered by the Medicare benefit before rebates are taken into account. For beneficiary spending, we used the patient payment amount from PDE records. This amount represents the copayment or coinsurance paid by a beneficiary for a prescription.[73]

Lastly, we calculated 2019 Part D and beneficiary spending for the two reference products covered by Part D expected to face biosimilar competition in the coming years—Humira and Enbrel. Biosimilars for these drugs have been approved by FDA but are not yet available on the U.S. market.

Converting quantity to drug weight. To analyze biosimilars of different strengths as one biosimilar drug group, we converted the quantity dispensed to drug weight dispensed. To calculate the drug weight dispensed for each prescription, we multiplied the strength of the prescription (e.g., 480 mg/0.8 ml) by the quantity dispensed of the prescription (e.g., 1.6 ml). We summed the drug weight dispensed for each biosimilar drug group to calculate the total drug weight dispensed.

Average Part D and beneficiary spending by drug weight dispensed. We calculated average Part D and beneficiary spending amounts at the reference product and biosimilar drug group level by dividing Part D and beneficiary spending by the total drug weight dispensed.[74]

Part D and beneficiary spending for typical prescriptions. We used average Part D and beneficiary spending to illustrate differences in spending for typical biosimilar and reference product prescriptions. To calculate the amount dispensed for a typical prescription, we used the median drug weight dispensed for each biosimilar drug group and reference product. We then multiplied the average spending amounts for

[73] We excluded beneficiaries receiving other sources of support, such as State Pharmaceutical Assistance Plans, group health plans, or governmental programs, from the analyses of beneficiary spending and spending reductions. We also excluded beneficiaries enrolled with PACE (Program of All-Inclusive Care for the Elderly) organizations because these beneficiaries do not pay for their prescription drugs. For beneficiaries receiving the low-income subsidy (LIS), we analyzed only pre-catastrophic prescriptions because such beneficiaries often pay nothing in the catastrophic phase.

[74] LIS beneficiaries were analyzed separately. We calculated average spending for LIS beneficiaries by dividing total spending by the total number of prescriptions because LIS beneficiaries typically pay only a fixed copayment for biosimilars. To illustrate differences in LIS spending for typical biosimilar and reference product prescriptions, we compared the median LIS beneficiary payment for each biosimilar drug group and its reference product.

the biosimilar drug group and reference product by the drug weight dispensed for the typical prescription.

Part D and beneficiary spending reduction estimates with increased biosimilar utilization. We took two steps to estimate how any increase in biosimilar utilization could have changed Part D and beneficiary spending. We first estimated how much Part D and beneficiaries could have spent if all CY 2019 reference product prescriptions had been for biosimilars, using the average biosimilar spending amounts. We then used these figures—and actual biosimilar utilization and spending in 2019—to estimate how any increase in biosimilar utilization could have changed Part D and beneficiary spending.

We reported estimates of 2019 Part D and beneficiary spending at two specific utilization rates—if biosimilars had accounted for 60 percent and 90 percent of prescriptions. The first estimate assumed total biosimilar utilization matched the 60 percent utilization rate of the most used biosimilar group (i.e., filgrastim biosimilars). The second estimate assumed biosimilar utilization matched the 90 percent utilization rate for Part D generic drugs.[75] The total difference between the actual and estimated spending amounts represented the potential reductions in Part D and beneficiary spending had biosimilar use increased in CY 2019.

We used the same methodology to estimate how increased biosimilar utilization could have changed Part D net spending (i.e., when adjusting Part D spending for rebates). We calculated net spending by subtracting total rebates for each biosimilar drug group and reference product from its total Part D gross spending.[76] We did not adjust beneficiary spending for rebates because they do not typically affect beneficiary out-of-pocket costs.

Analysis of biosimilar formulary coverage and placement for CY 2019. We analyzed CMS's 2019 HPMS Approved Formulary Data to determine whether Part D plan formularies encouraged the use of biosimilars. We excluded Part D plan formularies without any enrolled beneficiaries from our analysis.

We analyzed formulary coverage and placement separately for each biosimilar drug group. We calculated the percentage of Part D plan formularies that included both biosimilars and their reference products, only biosimilars, and only biosimilars' reference products. For formularies that covered both biosimilars and their reference products, we calculated the percentage that (1) placed biosimilars on lower, higher, or the same formulary tiers as their reference products and (2) had different step therapy or prior authorization requirements for biosimilars and their reference products. We also checked Part D plans' cost-sharing requirements for the small number of formularies that placed biosimilars on lower formulary tiers than their reference

[75] CMS, "Increasing Access to Generics and Biosimilars in Medicare," February 5, 2020.

[76] Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

products. We did this to confirm that these plans, in fact, had lower cost-sharing for biosimilars on lower tiers than their reference products on higher tiers.

AGENCY COMMENTS

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: February 23, 2022

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicare Part D and Beneficiaries Would Realize Significant Spending Reductions with Increased Biosimilar Use*, OEI-05-20-00480

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report. CMS is committed to ensuring that Medicare beneficiaries have access to high quality and affordable health care while, at the same time, working to preserve the Medicare Trust Funds. Recognizing that Medicare payment policy can play a large role in promoting use of biosimilar and generic drugs, CMS is committed to continuing to use its authority to promote competition, support increased utilization of biosimilar and generic drugs, reduce the federal government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries.

Under the Medicare Part D system, Medicare contracts with private plan sponsors to provide a prescription drug benefit and entrusts plan sponsors with authority to negotiate drug prices with pharmaceutical companies. A provision in the law that established the Medicare Part D program specifically prohibits the Health and Human Services Secretary from interfering with the negotiations between drug manufacturers and pharmacies and plan sponsors, requiring a particular formulary, or instituting a price structure for the reimbursement of covered Part D drugs. However, CMS exercises its authority to review Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries.

It is important to note that factors outside of coverage and payment policy may affect provider and beneficiary preferences for a reference product versus the biosimilars, as well as inclusion on plan formularies. For example, prescribers or beneficiaries may prefer the more familiar reference product when a biosimilar first enters the market. In addition, after the biosimilar has been on the market for some time, the price of a biosimilar may fall below the cost of the reference product even when taking the reference product's rebate into consideration, which may drive uptake and increased market share for the biosimilar. As an example, the earliest biosimilar, Zarxio, which came onto the market in 2015 is now represented on over 80 percent of Medicare Part D plan formularies and has a significantly greater market share than its reference product.

CMS is committed to continuing to work within its authority to address both cost and access concerns. OIG's recommendations and CMS' responses are below.

OIG Recommendation
CMS should encourage Part D plans to increase access to and use of biosimilars.

CMS Response
CMS concurs with OIG's recommendation. Within our authority, CMS is committed to taking action, as appropriate, to increase access to and use of biosimilars. As discussed above, CMS' authority to review Part D plan formularies centers on ensuring that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries. In addition, while a multitude of policy and operational considerations influence whether CMS implements a demonstration project, CMS intends to examine how demonstration projects could be used to test methods to lower beneficiary and program spending on drugs and incentivize the use of biosimilar and generic drugs.[1] CMS will continue to explore options to address this issue.

OIG Recommendation
CMS should monitor Part D plans' submitted formularies to determine whether they discourage beneficiaries from using biosimilars.

CMS Response
As discussed above, CMS has the authority to review Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries. CMS uses that authority to review plan formularies for appropriate inclusion of all drug classes, including biosimilars.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

[1] https://innovation.cms.gov/strategic-direction-whitepaper

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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This report was prepared under the direction of Laura Kordish, Regional Inspector General for Evaluation and Inspections in the Chicago regional office, and Adam Freeman, Deputy Regional Inspector General.

Contact

To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

Office of Inspector General
U.S. Department of Health and Human Services
330 Independence Avenue, SW
Washington, DC 20201

ABOUT THE OFFICE OF INSPECTOR GENERAL

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CIVICA 2912 W Executive Pkwy, Ste 325, Lehi, UT 84043 | 1-888-304-0120 | civicarx.org | info@civicarx.org

07 November 2023

Senator Ron Wyden, Chair
Senator Mike Crapo, Ranking Member
Committee on Finance
United States Senate
BY ELECTRONIC TRANMISSION

Re: SFC discussion draft Title II, section 204, "Requirements for PDP sponsors of prescription drug plans and Medicare Advantage organizations offering MA–PD plans that use formularies under part D of the Medicare program"

Dear Chairman Wyden and Ranking Member Crapo,

Thank you for your focus on policies to support a functional marketplace and fair patient costs in the retail pharmacy setting.

Civica is a non-profit generic drug company established to reduce drug shortages and ensure a reliable supply of essential medicines to hospitals at fair prices. CivicaScript, a public benefit corporation, is the operating unit of Civica that was established in partnership with health plans to lower costs for consumers at the pharmacy counter. Civica is developing quality, affordable insulin that CivicaScript will make available to pharmacies, health plans and PBMs at a single, transparent low price, without the artificially inflated list prices and high rebates that have long characterized the brand insulin market to the detriment of consumers who may be charged based on list price.

We write in support of Title II, section 204 of the discussion draft released by the Senate Finance Committee on November 2nd.

Specifically, this section would require Medicare Part D (PDP) and Medicare Advantage prescription drug (MA-PD) plans to cover biosimilars that are available at a Wholesale

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Acquisition Cost (WAC) at least 45 percent below that of the reference product and to place them on a formulary tier with lower cost sharing than the higher WAC product.[1]

The proposed Section 204 allows exemptions for "high WAC" products when the net price after rebates is lower than that cost of the "low WAC" product. This wisely avoids the potential to mandate formulary coverage of a product with a higher net cost. The risk that beneficiaries would have to pay out-of-pocket based on a high list price is obviated by recent PDP and MA-PD reforms in the Inflation Reduction Act, which cap out-of-pocket costs.

Importantly, the draft legislation also ensures that utilization management tools will not be used to disadvantage the biosimilar drug compared to the higher-priced reference product.

Thank you for advancing a policy that will help to address the longstanding scenario where a highly-rebated reference biologic retains market share even when apparently lower-cost biosimilars are available – a dynamic that discourages competition and transparency in pricing.

Sincerely,

Allan Coukell
Senior Vice President for Public Policy
allan.coukell@civicarx.org

cc: Sen. James Lankford

[1] For insulins, which are already generally in tier 1, there would be no preferential tiering or cost-sharing.

Biosimilars FORUM

FOR IMMEDIATE RELEASE
November 3, 2023

Biosimilars Forum Supports Senate Finance Committee Legislative Discussion Draft Promoting Biosimilars

Juliana M. Reed, executive director the Biosimilars Forum, released the following statement announcing the Biosimilars Forum's support for the Senate Finance Committee's latest legislative discussion draft. The Committee's discussion draft contains provisions supporting high-discount biosimilars. The draft includes recommendations that starting in 2026, Medicare Part D plans must adhere to new rules covering "high-discount biosimilars," which are biosimilars priced at least 45% less than their reference biologics.

"The Biosimilars Forum is proud to support the biosimilars policies outlined in the Senate Finance Committee's latest legislative discussion draft. These policies promote uptake, access, and availability of lower-cost biosimilars within the Medicare Part D program. Increased access to biosimilars for Medicare patients is a win for everyone. Biosimilars are a commonsense bipartisan solution to skyrocketing prescription drug costs, and the Forum is looking forward to bringing the cost-savings promise of these treatments to reality.

"The Committee's discussion draft promotes the use of safe, effective, and lower-cost biosimilars through provisions requiring Part D plans to offer biosimilars to Medicare beneficiaries. This effort will directly lead to lower costs for patients.

"Eight Humira® adalimumab biosimilars have launched this year with virtually no uptake among Medicare Part D patients. These critical treatments should be readily available to seniors on Medicare when they have significantly lower prices than the reference product. However, the lack of Medicare formulary access means that patients cannot experience these cost savings. The discussion draft addresses this specifically by stating that "beginning with plan year 2026, Part D plans meet certain coverage and cost-sharing requirements with respect to "high-discount biosimilars..."

"The discussion draft also highlights that "On a biannual basis, CMS will release a list of biosimilars that qualify as high-discount biosimilars for particular reference products." This ongoing, midyear access for biosimilars will benefit patients by making lower-cost treatments more readily available.

"The ongoing lack of access to more affordable biosimilars has prevented free-market competition from working – limiting patient savings and harming the long-term sustainability of future biosimilar development. This discussion draft is an important first step in promoting access to these life-saving treatments for patients. The Forum strongly encourages the Committee to move forward with these crucial provisions.

"During a watershed year for biosimilars, this discussion draft is critical for the uptake and availability of biosimilars in the Medicare Part D program. In a year that saw eight lower-cost biosimilars launched referencing the world's best-selling drug, Humira®, pharmacy benefit managers (PBMs) have stifled uptake of these products despite their costs being up to 85% lower than Humira®. Humira® can cost upward of $84,000 annually and has risen in price 470% since first introduced. The adalimumab biosimilars for Humira® offer significant cost-savings, but access to these lower cost biosimilars is being blocked. Uptake for these treatments if virtually zero, which is a failure of the U.S. healthcare system.

"The dismal uptake and access for the Humira® adalimumab biosimilars are staggering. Out of 42,000 potential patients, less than 1,00 have received access to a biosimilar. In fact, Medicare Part D has the lowest utilization of the low-cost, Humira® biosimilars. Of the eight biosimilars that have been launched, six have pricing structures with a low-cost, low-rebate option. The discounts range from 5% to 86%. Patients deserve access to these lower-cost options.

"This current reality is unacceptable. Patients must be able to fully access FDA-approved, lower-cost biosimilars. When formularies, especially Medicare formularies, prioritize high cost, high rebate products, patients suffer. Lawmakers on the Hill must intervene to deliver on policies that provide more affordable biosimilars to those who need them so that we can continue to deliver on our commitment to bring competition and lower cost biosimilars to patients.

"Biosimilars save money. In fact, a competitive biosimilars market can save patients and the U.S. health care system $133 billion by 2025. The Medicare program alone could have saved millions and millions of dollars if all biosimilars had been used as frequently as the most-used biosimilars.

For more information on the Biosimilars Forum's work to increase access to lower-cost biosimilars, visit biosimilarsforum.org.

+++

MEDIA CONTACT:
Scott Lusk
Signal Group, Executive Vice President
202-288-3233; slusk@signaldc.com