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EXAMINING THE PROPOSED MEDICARE PART B DRUG DEMONSTRATION

HEARING

BEFORE THE

COMMITTEE ON FINANCE
UNITED STATES SENATE

ONE HUNDRED FOURTEENTH CONGRESS

SECOND SESSION

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EXAMINING THE PROPOSED MEDICARE PART B DRUG DEMONSTRATION

TUESDAY, JUNE 28, 2016

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

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

Present: Senators Grassley, Crapo, Roberts, Thune, Burr, Portman, Toomey, Coats, Heller, Scott, Wyden, Stabenow, Cantwell, Menendez, Carper, Cardin, Brown, Bennet, Casey, and Warner.

Also present: Republican Staff: Brett Baker, Health Policy Advisor; Chris Campbell, Staff Director; and Jay Khosla, Chief Health Counsel and Policy Director. Democratic Staff: Elizabeth Jurinka, Chief Health Advisor; Joshua Sheinkman, Staff Director; and Beth Vrable, Senior Health Counsel.

OPENING STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH, CHAIRMAN, COMMITTEE ON FINANCE

The CHAIRMAN. All right, the committee will come to order.

I would like to welcome everyone to this morning's hearing that will allow the committee to examine the Obama administration's proposed Medicare Part B demonstration. I would particularly like to thank Dr. Patrick Conway from the Centers for Medicare and Medicaid Services for testifying.

Today's topic is very important. The proposed CMS demonstration project would radically alter the ways in which Medicare pays for drugs and biologics, treatments that physicians prescribe and administer to patients in the outpatient settings that are covered under Part B.

Typically, these are drugs and treatments that are given in a physician's office or hospital. They are used to treat vulnerable beneficiaries who have serious medical conditions such as cancer, macular degeneration, rheumatoid arthritis, neurological disorders, primary immunodeficiency diseases, and a number of rare illnesses.

From the day CMS made their proposed demonstration public this past March, I have made my opinion very clear. I believe this experiment is ill-conceived and likely to harm beneficiaries. It is an overreach on the part of CMS that, in my opinion, goes beyond the agency's statutory authority, extends nationwide, and requires all Medicare Part B providers to participate.

And as we all know, the experiment would change the Part B payment system in two phases, both of which are very troubling, and that is putting it kindly.

Given these inherent concerns, I would like to hear an explanation from CMS as to why they believe their new payment changes will not harm Medicare beneficiaries. So far what they have given us lacks any such explanation or justification.

And that is not all that is missing from the elements of the demonstration that have been made public. Indeed, this proposal is troubling—and again, I am being kind with that description—not only for what is in it, but what has been left out.

For example, with its proposal, CMS has not indicated the conditions for which the agency believes a physician has the option to prescribe a high- or low-cost drug that has the same patient benefit. In addition, CMS has not provided an analysis of how many physicians, including those in small and rural practices, would lose money purchasing needed drugs. They have not provided an analysis of how often physicians would have to refer beneficiaries to the less-convenient, more costly hospital outpatient setting.

And CMS has not yet indicated how it will assess the impact on beneficiary access and quality, both during the course of the demonstration and the formal evaluation of it.

Not surprisingly, the proposed experiment has been widely condemned by experts and stakeholders. Almost immediately after the proposed demonstration was released, we received a letter from over 300 stakeholder organizations asking for our help in getting CMS to withdraw the proposal.

Now, these organizations included the Arthritis Foundation, the Caregiver Action Network, the Immune Deficiency Foundation, the Lung Cancer Alliance, and the National Alliance for Mental Illness.

The organizations that have reached out with concerns about this proposal represent patients who suffer from the diseases treated by these drugs, including cancer, arthritis, mental illness, and HIV. They represent the physicians who treat the patients with these devastating conditions, including oncologists, rheumatologists, and ophthalmologists.

I have also heard from my constituents in Utah. Many Utahans feel that the proposed demonstration would deprive them of the drugs that best treat their conditions and require them to have to travel great distances and incur significant additional expenses to receive the needed care.

Obviously, Utah is not alone here. Patients and providers from virtually every State have weighed in on this matter, which prompted all of the Republican members of the Finance Committee to send a letter to Acting CMS Administrator Slavitt urging the withdrawal of the proposal.

That is right. Fourteen Senators from the only Senate committee with oversight jurisdiction sent a detailed and thoughtful letter to CMS about their proposal. And how did the agency respond? We received what essentially amounts to a form letter thanking the committee members for sharing their views and noting that CMS will consider all public comments.

It could not have been more dismissive in its tone. That is the level of attention and seriousness CMS ascribes to oversight from

Congress. And sadly, this is not an isolated incident. For 7 years now, the entire Obama administration has patronized, stonewalled, or flat-out ignored oversight efforts on the part of Finance Committee Republicans.

Now, there are countless examples. Sometimes the agencies show disregard for the law, like when they refused to provide any meaningful response to numerous inquiries about illegal reinsurance payments issued under the so-called Affordable Care Act. And other times they discount our oversight role entirely, like when they denied Finance Committee staff access to last week's Medicare and Social Security Trustees reports until the press conference putting the administration's own misleading spin on the reports was well under way.

Now, I have on numerous occasions during hearings like this and elsewhere, expressed my hope that the administration as a whole will change its ways and become more transparent. I have asked countless nominees that have come before the committee to commit to being responsive to Senators' inquiries. Yet over 7 years, this unprecedented level of disregard has continued unabated.

Given the short time left with this administration, I will not renew these calls for more cooperation and responsiveness today. I feel quite certain that there are no new improvements on the immediate horizon.

However, given that we have a high-ranking administration official before us today, I hope that at the very least we can finally get some straight answers to the many questions raised by CMS's Part B drug proposal.

I note that our witness, Dr. Conway, stated in an early May interview on the proposed demonstration that CMS, quote, "will interact with Congress and take feedback and make adjustments as necessary."

And I do hope that our conversation today will be more consistent with that sentiment than the dismissive response letter shortly after that statement was made. The Senators on this committee and, more importantly, the constituents we represent, deserve at least that much.

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

The CHAIRMAN. With that, I will turn to Senator Wyden for his opening remarks.

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

Senator WYDEN. Thank you very much, Mr. Chairman.

Mr. Chairman and colleagues, what underlies this debate is, we are entering an era where there are going to be miracle treatments and there are going to be cures. There are drugs on the market and close on the horizon that were science fiction not very long ago.

The question for me, the foremost question, is whether or not the American people are going to be able to afford these medicines. With business as usual, too many of these treatments are going to clobber too many family budgets and threaten health programs across the country.

And that was one of the big takeaways, colleagues, from the 18-month investigation Senator Grassley and I conducted on a bipartisan basis into the rollout of one blockbuster drug. It was a drug that treats Hepatitis C and had a list price of $1,000 a pill. And I think that this is going to be the pattern, colleagues, for years and years to come, absent reform: lots of cures and a big, big question mark when it comes to access and affordability.

Now, the Hepatitis C drug that Senator Grassley and I did our bipartisan inquiry into is not the primary focus of today's hearing. Today the committee is going to examine a demonstration project set to begin in Medicare Part B, which, of course, is the Medicare program that covers outpatient care.

Part B pays for a small share of the drugs many seniors are prescribed, and the demonstration would affect the way those drugs are paid for. The demonstration has brought to the forefront additional major questions about how the country is going to address the trend of escalating pharmaceutical prices.

The fact is, too many seniors are getting pounded today by prescription drug bills. In my view, there is an enormous amount of work that has to be done to guarantee that seniors have affordable access to the medications they need.

In Medicare Part B, seniors are often hit especially hard because their share of drug costs is a co-insurance instead of a co-pay. That means rather than a flat, manageable fee, some older people face a huge burden, stuck paying a percentage of a drug's total cost.

I look at that burden the same way I look at the rising out-of-pocket costs for older people in Medicare Part D. So for Part D, I have proposed legislation that would establish an out-of-pocket cap to help protect older people. And in my view, this committee ought to take a close look at ways to make sure that seniors do not get pounded under Part B as well.

There are important questions to be addressed with respect to this particular demonstration project. That is why all of the Finance Committee Democrats and I sent a letter in April to Andy Slavitt, the Acting Administrator of the Centers for Medicare and Medicaid Services, outlining the key concerns we had about the impact the project is going to have on patients.

At their core, our concerns are about making sure that older people who are especially vulnerable have access to lifesaving medications. Protecting access is especially important in rural America, where seniors today so often face fewer choices and lower quality of care.

It is extremely important as well that the project not result in patients being told that they have to go get treatment at the hospital, where treatment is often more costly and less convenient.

Finally, our letter said that this demonstration project has to be in sync with the effort Medicare is making to move towards paying for treatment based on value, rather than volume. When you focus on the value and the efficiency of care, there is the potential to raise the quality of care for older people while saving money at the same time.

So, Mr. Chairman and colleagues, I hope the committee will examine these issues carefully as it looks at the Medicare Part B demonstration.

I also want to thank Dr. Conway for joining the committee here as well. We look forward to his testimony and members having the chance to ask questions.

Thank you.

The CHAIRMAN. Thank you, Senator.

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

The CHAIRMAN. Now I would like to take a few minutes to introduce today's witness.

Dr. Patrick Conway is here on behalf of the Centers for Medicare and Medicaid Services. Dr. Conway holds a number of high-ranking titles at CMS. In those positions, he has responsibility for overseeing health programs that provide services to over 100 million people.

Two of his roles, overseeing the CMS Innovation Center and serving as the Chief Medical Officer, make him well-suited to testify on the agency's proposed Part B drug demonstration.

Prior to coming to CMS, Dr. Conway was the director of hospital medicine and associate professor at Cincinnati Children's Hospital. Dr. Conway earned his medical degree from Baylor College of Medicine and completed his pediatric residency at Harvard Medical School's Children's Hospital, Boston.

I want to thank you, Dr. Conway, for taking the time to appear here today. And we will be glad to take your statement at this time.

STATEMENT OF PATRICK CONWAY, M.D., M.Sc., ACTING PRINCIPAL DEPUTY ADMINISTRATOR, DEPUTY ADMINISTRATOR FOR INNOVATION AND QUALITY, AND CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES, BALTIMORE, MD

Dr. CONWAY. Thank you, sir.

Chairman Hatch, Ranking Member Wyden, and members of the committee, thank you for the invitation to discuss the Centers for Medicare and Medicaid Services' initiative to improve how Medicare pays for Part B drugs to support physicians and other clinicians in delivering higher-quality care to beneficiaries in the Medicare program.

We very much value the input and feedback that we receive from Congress and members of this committee, and we are carefully reviewing the comments we have received from you and the public.

Part B drug spending has risen significantly over time, and CMS has heard from many stakeholders about concerns about access to and the cost and value of prescription drugs. To address these concerns, CMS issued a proposed rule to test a new model, with the aim of improving patient care and the value of Medicare drug spending.

This proposal aligns with the CMS Innovation Center's statutory goal to test innovative payment and service delivery models that reduce expenditures while preserving or enhancing the quality of care. The proposal is part of the administration's broader strategy to encourage better care, smarter spending, and healthier people by

paying for what works and finding new ways to coordinate and integrate care to improve quality.

CMS values public input and comments and looks forward to continuing to work with stakeholders through the rulemaking process in an ongoing manner to maximize the value and learning from the proposed model.

We have received feedback from a wide range of stakeholders on several issues, including the size of the model, patient access in small practices in rural areas, and the importance of patient input. We are reviewing all comments closely to determine whether adjustments are needed.

Our goal is to be responsive to the public comments and input from Congress. Under the current system, many Part B drugs, including drugs furnished in the hospital outpatient setting, are paid for based on the Average Sales Price, or ASP, plus a 6-percent add-on payment.

CMS's proposed rule outlines a new Part B drug payment model that would test whether alternative drug payment designs may improve how Medicare Part B pays for prescription drugs and support physicians and other clinicians in delivering higher-quality care.

Physicians can often choose among several drugs to treat a patient, and the current Part B drug payment methodology can create disincentives for doctors to select lower-cost drugs, even when these drugs are as good as or better for patients, based on the evidence.

Among the approaches to be tested are the elimination of certain incentives that work against the selection of high-performing drugs, as well as the creation of positive incentives for the selection of higher-performing drugs, including reducing or eliminating patient cost-sharing to improve patients' access and use of effective drugs.

In the first phase of the model, CMS would test whether changing the current 6-percent add-on payment to 2.5 percent plus a flat fee of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. The flat fee is calculated such that it is budget-neutral in the aggregate.

The second phase focuses directly on better outcomes and clinical indicators to improve the value of drug payments by utilizing value-based pricing tools currently employed by private health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization successfully.

Ensuring beneficiary access to high-quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and would retain complete freedom of choice of doctors, hospitals, and other providers or suppliers.

The proposed model would not affect drug coverage or any other Medicare benefits. It also includes a number of beneficiary protections. For example, the proposed model would include a new pre-appeals exceptions process, in addition to the standard appeals processes, that would allow the beneficiary, provider, or supplier to explain why Medicare's value-based pricing policy is not appropriate for a given beneficiary and to seek an exception from the model's value-based pricing approach under phase II.

In addition, CMS would closely monitor beneficiary access and health outcomes during the model. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

Millions of Americans rely on medications to manage chronic illnesses and to treat acute conditions. CMS is committed to ensuring that its beneficiaries have and maintain access to the high-quality treatments they need while pursuing better drug value.

Moving forward, HHS and CMS are committed to listening to and working together with Congress and other stakeholders to advance ideas that improve access, affordability, and innovations so all Americans have access to the breakthroughs ahead.

There are no easy answers to these multi-faceted challenges, but there is a significant benefit to all of us working together to find a solution.

I appreciate the committee's interest and look forward to answering your questions. Thank you for having me.

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

The CHAIRMAN. Well, thank you, Doctor. I appreciate you appearing before the committee. And perhaps you can be of great help to us here today to understand some of these things.

You know, some people feel that CMS intends to use the Innovation Center to undermine the successful Part D prescription drug program, perhaps by unilaterally waiving the provision that prevents the Federal Government from negotiating drug prices. Now clearly, such an undertaking would be a massive overreach beyond CMS's statutory authority. However, as we have seen on a number of occasions, the Obama administration does not always feel bound by the clear limits that are provided in the statute.

That being the case, I take the specific speculation about Part D very seriously. Therefore, I feel compelled to ask, is the Innovation Center working on any project or initiative that would allow the government to negotiate prices or on any other Part D change related to drug prices? And, as you are the head of the Innovation Center, I would like to have a direct answer on that, if I could.

Dr. CONWAY. We have no Part D proposals at this time. We are constantly listening to and engaging with stakeholders across the health-care system. So we have payers, manufacturers, providers, others that bring ideas to us across health care, including in the drug space.

We view it as our role to engage with those stakeholders, to listen to ideas, whether they come from Congress or providers or payers or others, so we engage deeply on our statutory mission, which is to engage in testing payment and service delivery models with a high likelihood of improving quality and maintaining or lessening expenditures.

The CHAIRMAN. Well, Dr. Conway, my stated position, that CMS needs to withdraw this proposed Part B rule, is shared by many. Once again, over 300 stakeholder groups weighed in and called for the proposal to be withdrawn almost immediately upon its release.

And without objection, the letter I referenced, signed by over 300 patient provider organizations, will be included in this record.

[The letter appears in the appendix on p. 71.]

The CHAIRMAN. In addition to these stakeholders, nearly 300 members of Congress, Republicans and Democrats alike, have urged CMS to withdraw the proposal.

Many of the 1,300 public comments that CMS received pointed out serious flaws. Considering all this backlash, I would say it is pretty obvious that if CMS moves forward with this experiment, it would be doing so against the interests and judgment of the vast majority of experts and policymakers in this field.

Now, are you willing to acknowledge that there is widespread opposition and commit to withdraw this proposed rule?

Dr. CONWAY. So we take the input from Congress and from stakeholders across the health system very seriously. That is why we proceeded through the rulemaking process, which is the most public and transparent of processes that we can engage in.

We are reviewing the comments now and plan to make adjustments in the final rule. Currently we have over 1,300 public comments. We want to review those closely, carefully, and thoroughly so that we can be as responsive and thoughtful as possible to the public input and the input from Congress.

The CHAIRMAN. Well, it seems that with this rule, CMS is operating under a premise that physicians are knowingly and purposefully prescribing higher-cost drugs when a lower-cost equivalent drug is available.

Now, the agency's view is apparently that most physicians' clinical decisions are driven by maximizing profit instead of patient welfare. It seems to me that this is overly simplistic.

Now, given that you are a doctor, can you tell us the specific type of prescribing changes that physicians are expected to make under the phase I payment scheme? And please, if you will, provide specific conditions and drugs, if you could do that for us.

Dr. CONWAY. Yes. So I am a practicing physician. I think the vast majority of physicians make prescribing decisions based on patient interest. And I want to say clearly I would want every physician and clinician to prescribe the medicine needed for their patient.

We believe this proposal allows that to happen, and we are looking closely at whether adjustments are needed, because access to medications, as you alluded to, is the first priority for CMS and for myself personally.

In terms of the reason we proposed this test, the current system can have disincentives for physicians who may use lower-cost medication. So, for example, if a physician prescribes a $10 medication, the current 6-percent add-on is only 60 cents, and that may not fully cover the cost of acquiring and administering that medication.

And so we are proposing this test to test a proposal that we think would remove some of the current disincentives in the system to allow physicians, clinicians, to make prescribing decisions without regard to financial incentives. And we clearly want physicians and clinicians to prescribe the medicines that their patients need and for patients to receive those medicines.

The CHAIRMAN. Senator Wyden?

Senator WYDEN. Thank you, Mr. Chairman.

Dr. Conway, let us go right to the question of prescription drug prices, because for so many older people, they just feel like they are getting hit by a wrecking ball.

Medicare Part B drug spending more than doubled between 2005 and 2015, increasing from $9.4 billion in 2005 to $22 billion in 2015. Now Medicare has, as you know, begun to move toward paying for quality and value, rather than the volume of services. That has been something that has been recommended for ages, and finally it is under way. But so far, prescription drugs have largely been left out of that equation, that move towards paying for value rather than volume.

I have been working on these issues since the days when I was co-director of the Oregon Gray Panthers, and I think it is appropriate to ask now, if the issue of prescription drug prices is not addressed, aren't the costs going to become increasingly unaffordable for older people, and really put at risk the Medicare guarantee? Because that is what Medicare is: it is a guarantee.

Will these costs not put at risk the Medicare guarantee for future generations?

Dr. CONWAY. Thank you, Senator Wyden. You correctly note the growth in Part B drug spending, and it has been over 8-percent growth, year on year, since 2007.

I share your concern on access to medications. The current environment, as you noted, with co-insurance and the potential for 20-percent co-insurance, as you can imagine, for seniors on a fixed income—20 percent of a $10,000 drug or whatever the cost might be—can be a substantial financial hardship and can limit access to medications.

We also did propose this test because we had not to date had a proposal directly in the drug space—paying for value. We do think paying for value is important, as you said, across the health system, including in the drug space. And so hence, we made this proposal.

We have other proposals that include drugs as a part of the proposal, but we do think paying for value in drugs is important, similar to how it is important across our health system, whether it is hospitals, physicians, et cetera.

Senator WYDEN. Does this threaten the sustainability of the program for future generations, absent some reforms?

Dr. CONWAY. So the costs of the Medicare program have the potential to threaten the program, and drugs are a substantial part of that cost.

And the reason I do this job, quite frankly, is I care deeply about the 55-plus million Americans in Medicare, including my own mother, and I want Medicare to be around for my four children. And I think we have to make major positive changes in delivery system reform for that to be the case.

Senator WYDEN. Now, I appreciate the agency's interest in looking at strategies to improve quality and value in all aspects of the health system, including prescription drugs. But one of the concerns that has been brought to members—certainly members on our side—is, especially in a rural area, a small rural area with not exactly a large practice, physicians can be put in a position where the cost of the drugs is higher than the Medicare payment.

So what we are getting told on our side is that it would not be possible to afford to provide the medications to the patients.

I would be interested in your response to this, and also if, in responding, you could tell us what happens if that is the case, where the provider sends their patient to a hospital outpatient program, which means you have then higher overall costs for both the older people and for Medicare. Tell me your response to that.

Because I know members on our side have heard that and have brought it up; we have all talked about it. I assume colleagues on the other side have as well. Your reaction to that?

Dr. CONWAY. Thank you for the question.

So we propose to include rural providers and small practices. However, we noted in the proposal concern about some of these issues about making sure that we have access both to medications and treatment while we propose these changes.

We will look closely at the public comments and determine whether any adjustments are needed for rural practices or small practices. We are doing that review now, and the type of things we would look at include maintaining access to medications.

In addition, we proposed a monitoring plan similar to what we have used in other programs, which can include real-time claims data monitoring. But we are monitoring for access, patient outcomes, and shifts in site of service.

So we would monitor that, to see if we needed to make adjustments, both at the macro level in the policy, if you will, but also with an exceptions process where we could make adjustments down to the individual patient or practice level, if needed.

Senator WYDEN. Thank you, Mr. Chairman.

The CHAIRMAN. Senator Grassley?

Senator GRASSLEY. I only have two questions, but before I ask those, Dr. Conway, I want to thank you for coming today. And as you have heard, there are many people concerned about this ill-conceived experiment. Additionally, the administration has not been responsive to congressional inquiries.

In addition to the letter signed by every Republican on the committee, I sent my own letter to Secretary Burwell April 29th. I have not yet received an adequate response.

In my letter, I asked for clarification on whether the proposal constitutes human subject research. I hope that you would expedite an answer to that.

One question among the many concerns I have over this proposal is the result it will have on practices that are small, particularly in rural areas like most of my State of Iowa, or for those patients with rare diseases.

First question: what safeguards does CMS have with regard to treating patients served by smaller practices, those in rural areas, and those with rare diseases?

Dr. CONWAY. Yes, Senator, I share your commitment to small and rural practices. I grew up in a small town in Texas with a two-person family practice caring for our family.

We did propose to include rural and small practices, but we also noted in the proposed rule that we were concerned and focused on the access issues and that we would address access issues, if needed. So we sought comment about whether any adjustments or ex-

clusions or other changes were needed either for small or rural practices. So we will assess the comments and determine whether any adjustments are needed.

Senator GRASSLEY. Number two, we have heard from a number of groups that many patients' and providers' concerns in the proposal could have been avoided if patients had been included in the design of the demo at the front end.

What plans have you put in place to involve small practices and rural and rare disease stakeholders in the future?

Dr. CONWAY. Yes. So we proposed a process for phase II that would include input at multiple points, including patient input. We are looking at the comments now to determine if any adjustments or enhancements are needed for that process.

To give you a tangible example, I personally met with 20-plus patient and consumer groups, and I do that routinely. That was about 2 weeks ago. They gave input on this proposal and things across the Innovation Center.

So that patient-consumer input is probably the most critical input we get into these models, because our focus needs to be on the beneficiary, on the patient, on the consumer, at all times.

Senator GRASSLEY. Mr. Chairman, I will yield back my time.

Thank you, Dr. Conway.

The CHAIRMAN. Senator Stabenow?

Senator STABENOW. Well, thank you very much, Mr. Chairman and Ranking Member. And, Dr. Conway, we appreciate your time, and we appreciate your leadership on so many issues that affect all of us and our constituents. I just want to underscore what has been talked about first and our ranking member talking about our letter that a number of us sent to you.

I am concerned that the scope of the current proposal seems broader than is typical of a demonstration project, and just to underscore the concerns that have been raised about rural communities, I also share those.

And I understand the proposal is intended to drive providers toward prescribing more generic drugs in order to produce cost savings, and I fully support that objective.

But I think, as we look at those savings, there are other questions that I have about things that we should be focused on more in order to be able to do that. And so that leads me basically to questions in a broader sense.

First of all, the Medicare trustees report released last week—I just want to underscore, I think for all of us—shows that once again Part B premiums could be impacted by new enrollees and those who are dual-eligibles, as we call them, those who both qualify for Medicare and Medicaid, a situation we will learn more about this fall as it relates to the Social Security cost-of-living adjustments' impact on Part B.

And so, the chairman and our ranking member, I know, will follow this closely. I am very concerned about what could happen in terms of seniors and unintended increases in premiums related to them. And so I just want to get that out there now, that this is something we need to be very involved in.

And then another issue raised by the trustees report is really the big issue, which is Part D, which has been talked about. But as you

noted in your testimony, in 2015 CMS and seniors, through cost-sharing, paid $22 billion in Part B drugs and, according to the trustees report, nearly $89.5 billion in Part D.

So if we are talking about the elephant in the room, the area where we should be most focused is on Part D in terms of the costs for seniors. Part D spending increased last year 8.3 percent, the year before, 8.6 percent. Part B, which we are talking about today, increased 2.4 percent.

So when we are talking about 3½ times more growth, this is, I think, the area we need to be focused on.

So, Dr. Conway, if the goal is to drive down the prescription drug costs for seniors, for beneficiaries on the Medicare program in general, are we focusing on the right part when we say Part B, or should we not be paying more attention to Part D costs?

Dr. CONWAY. Yes. So in terms of Part D, in the President's budget there are a number of proposals for Congress to consider in the Part D space. We are open to ideas, including in Part D, at all times.

We have had manufacturers come to us with ideas around Part D and value-based arrangements in Part D. Similarly, we have had providers—for example, in our next-generation ACO program—talk about how they want to bring in arrangements that are voluntary between the provider and Part D plans for a new payment model.

So we are open to ideas from Congress, from you, Senator, from stakeholders across the health system, on ideas of what we should be doing in the Part D space as well.

Senator STABENOW. Thank you. And just to underscore what our ranking member said—and he has been such a champion on these issues—I have heard from three constituents in the last few months that have had Hepatitis C. They were not sick enough to get their insurance company to pay for the expensive drug treatment, but they had insurance, so they did not qualify for charity care.

Now, in one case we were able to help someone be able to get the medication that he needed, frankly, to cure his disease. But in the other two instances, that has not happened yet, and it is not a very good system when somebody has to call their U.S. Senator to intervene for them to get the medicine that they need to be able to save their life.

And so this is a huge, huge issue, whether it is Medicare, Medicaid, private insurance. We have to do much better. And I hope we will be doing actually a hearing on Part D where the focus is on the costs and the areas with which I think seniors are most concerned.

So thank you, Mr. Chairman.

The CHAIRMAN. Thank you, Senator.

Senator Roberts?

Senator ROBERTS. Yes, thank you, Mr. Chairman.

I would like to ask unanimous consent that a letter here from over 20 patient groups—including the National Alliance on Mental Illness, the Arthritis Foundation, the Lupus Foundation of America, Veterans Health Council, and the AIDS Institute—to the Finance Committee, highlighting concerns in opposition to the demonstration project, be included in the record.

The CHAIRMAN. All right. Without objection.

[The letter appears in the appendix on p. 77.]

Senator ROBERTS. When this committee was debating the Affordable Care Act, I was concerned about several provisions that I believed would decrease individual choice and open the door to government rationing.

There were four rationing bodies created by the Affordable Care Act. CMMI is one of those creations. And we have before us a proposed demonstration project or test, as the agency's press release called it, which could disrupt care from some of Medicare's most vulnerable patients.

By the way, Dr. Conway, thank you for being here today.

I want to first share with you some comments and questions from a couple of constituents in Kansas. Eileen of Overland Park suffers from hypogammaglobulinemia and lupus. She wrote to me asking, "Is anyone at CMS looking at the possible effect of such a demonstration on the people it will impact? Do any of them care that good, honest Americans will die without access to these treatments, or are they merely trying to save money by cutting costs? Their proposed actions will at least cause a degraded overall health outlook for many rheumatology, arthritis, and other patients and will certainly sign the death warrant for many patients like me."

Another constituent, Bradley from Wichita, wrote, "The CMS experiment is an intrusion on the close relationship our doctors have with patients and their clinical decision-making. This experiment will backfire, costing patients and taxpayers even more for cancer care."

Now, according to the statute, CMMI is to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care. That is where I think we are running smack into trouble.

How are you going to ensure that beneficiaries do not have trouble accessing appropriate and timely treatments in the setting they prefer? I give the example of a patient going to a rural oncology doctor in a rural area, sent to a hospital about 100 miles away.

Is there any data indicating these proposed payment changes will improve quality of care or patient outcomes?

Dr. CONWAY. Yes. So first, the goal of the Innovation Center is to improve quality, as you said, or maintain quality. And I will say—and this is what I have been doing for 20-plus years, both in the public and private sector—the paramount importance is improving quality and better patient outcomes. It also, as you said, is to maintain or reduce expenditures.

In this specific proposal, we are proposing a value-based framework in phase II which, from the private sector, from private payers, from pharmacy benefit managers, from providers, has been demonstrated to focus on paying for value in medications.

We are proposing to test that in Medicare Part B, and we believe it can maintain or improve quality. And that is our focus on the quality side of the equation.

Senator ROBERTS. Well, on that issue—and pardon me for interrupting, but I have very limited time. Under the ACA, the Secretary is prohibited from using comparative effectiveness research findings in determining Medicare coverage.

However, in phase II, CMS plans to test paying for a drug based on how effectively it treats different conditions. Does CMMI believe it has the authority to waive this prohibition, or are you doing what you should not be doing?

Dr. CONWAY. So in terms of the CMMI, or the Innovation Center, we are proposing to pay for value, which can be things like risk-based sharing arrangements based on outcomes. So it is consistent with the statutory authority to test new payment and service delivery models.

I would highlight on CMMI broadly, we have thousands of providers in every State in the Nation engaged in delivery system reform. We have millions of patients who have received, in many instances demonstrated by independent evaluation reports, improved outcomes, improved care experience. And we can certainly talk about that more; I know we are tight on time.

Senator ROBERTS. Thank you, Doctor. I appreciate that. Let me just say that you have said the public comment period for the proposed rule concluded on May 9th, and CMS is carefully considering all the public comments on this proposal that were received by the end of the comment period. You said, "We value public input; we look forward to continuing to work with stakeholders to maximize the value and learning from this model."

That is in direct conflict with the letter that we have here from 32 patient groups that say there was a lack of stakeholder input from the beginning of this process and many of the problems with the demonstration could have been mitigated had patient groups been involved on the front end.

I think what we have here is a failure to communicate. I remain gravely concerned about how this demonstration, or test, as the administration calls it, will impact patient access to care.

I would like to reaffirm my request, as all on this side of the aisle have requested, that CMS simply withdraw this proposal.

Thank you, Mr. Chairman.

The CHAIRMAN. Well, thank you.

Senator Menendez is not here. Senator Portman, you are next.

Senator PORTMAN. Mr. Chairman, thanks very much. And I appreciate you being here, Dr. Conway, and your service at Cincinnati Children's where, as you know, my wife is very involved: vice chair and incoming chair of one of our great children's hospitals.

I wish I could say the same things about this proposal that I can about Children's Hospital. I am concerned about it, and I am concerned about it for some of the reasons that have been stated already.

And I want to ask you about one specific, deep concern I have about the specific proposal. First, it is called a demonstration, and yet my understanding is it is going to cover about 75 percent of Part B medications, which is hardly an experiment. The control group is 25 percent.

And I was just looking through some of the correspondence that I have gotten, and letters and e-mails from some of my constituents. Tom Clark, his wife is a cancer patient. He is very worried about her ability to get her cancer treatments.

Barb E. writes me a long letter about her immunodeficiency disease and what is going to happen to her. She is applying for disability now. She is already having a tough enough time. She wanted to do her infusions at home; she fainted at home. She has to go to her doctor. She has told her if she goes to the hospital, it will be much more expensive and/or they will not be able to afford to provide it. So just a lot of deep concerns about it.

The specific concern that I am hearing from Ohio is more about these community health centers and rural health centers. We have lost over 50 practices, physicians' practices, as you know, because you have been in Ohio, going to the big hospitals. This will continue that and accelerate it.

So I think this proposal, which is, again, not a demonstration—hardly, if it is 75-percent coverage—but is a wholesale change, is going to really dislocate a lot of the people I represent and cause a huge concern among some of these smaller practices that are already having a tough time making it in the current health-care environment with the Affordable Care Act.

But let me ask you about something that concerns me about your specific proposal that perhaps you are not aware of. I assume if you were aware of it, you would not be doing it.

But this is a revenue-neutral proposal, and so you cut reimbursement for some of these outpatient clinics we are talking about, some of these rural providers and so on, who are going to have a tough time making it. And you increase reimbursement in other areas in order to make it revenue-neutral.

One of the places where you increase reimbursement, as you know, is with regard to prescription drugs that are used for pain management. And specifically, you have a dramatic increase in reimbursement incentives for the kinds of pain medication that are addictive and that are causing much of the problem we have now with this opioid epidemic that we have in Ohio and around the country.

And let me give you some numbers on that, just in case you are not aware of it. But on the expected impact on interventional pain management medication, you are seeing an increase of 46.9 percent and 33.7 percent versus a cut on hematology/oncology drugs by minus .6 percent.

So it is a dramatic increase, and I think the whole basis of your proposal is that, if the reimbursement is cut, there is going to be less utilization, right? That is part of how you are trying to save money.

And on the other hand, you are increasing reimbursement at a time when I think there is a general sense in the administration, certainly at HHS—because we have worked with them very closely—that there is too much overprescribing of certain kinds of pain medication that are addictive, that are causing so much of the opiate crisis.

The Comprehensive Addiction Recovery Act, which has passed the Senate by 94 to 1, deals with that overprescribing issue, including enhanced drug monitoring. I think there is generally a view at HHS that this is a problem. We work closely with them. Senator Whitehouse and I are the coauthors of that legislation. This seems to run counter to that.

So all the concerns you will hear from other colleagues, as you did from Senator Stabenow, Senator Roberts, and others about these providers, are of course concerns of mine in the fact that this is not a demonstration.

But I have this bigger concern about the fact that under this proposed rule, which you say is to drive the prescribing of the most effective drugs, the reimbursement for these particular kind of opioids, this increase, could have a very negative impact and increase the problem with this opioid epidemic.

For those who do not follow it closely, it is believed that four out of the five heroin addicts who are overdosing today—and 129 will lose their lives today, on average—four out of five of them started on prescription drugs. And often it was for pain medication; it was a prescription that they got because of a procedure.

So could you briefly respond to that, Dr. Conway?

Dr. CONWAY. Yes. Three quick responses. One, on the scope, we are evaluating the comments. We will determine whether adjustments are needed. Two, on the practice issue, overall it is budget-neutral, as you described. Overall, there is a slight shift in the impact tables towards the physician/clinician space.

A specific thank-you for your focus on the opioid epidemic. As you know, for the first time in U.S. history we have ZIP codes in the U.S. where life expectancy is going down, and a large portion is driven by opioid issues. We will evaluate comments, including in specific classes of drugs.

What you have named here is the fixed fee. Because the fixed fee is $16.80 as proposed, there are some very low-cost drugs, as you named, where the percentage increase looks large. So we will have to look at that specifically and determine across classes of drugs—and you named one—are any adjustments needed in the proposals?

Senator PORTMAN. Just briefly—and I am sorry, Mr. Chairman—just one comment, if I could have an answer to this maybe in writing.

Fentanyl is an example; it is a big problem right now around the country. It is believed that it is causing more overdoses in Ohio, by the way, than heroin is right now. It is a synthetic form of heroin. As I look at this, it receives a 2,000-percent increase in reimbursement under this model, Fentanyl alone.

So again, I am very concerned that we are going to incentivize increased utilization, rather than the opposite.

Dr. CONWAY. And that is from the fixed fee, but we can give you a formal answer to that. But it is from the $16 fixed fee.

Senator PORTMAN. Thank you, Dr. Conway.

The CHAIRMAN. Senator Thune?

Senator THUNE. Thank you, Mr. Chairman, and thank you, Dr. Conway, for being here.

As many of my colleagues have pointed out, the lack of consultation with stakeholders is striking, and it further indicates not only the flawed nature of this demonstration, but of CMMI as an entity.

But I want to draw attention to one section of CMMI's authorizing statute which states that CMMI shall consult representatives of relevant Federal agencies.

Now, we know at the Federal level there is HHS's Rural Health Task Force, the HHS National Advisory Committee on Rural

Health and Human Services, and the newly created Rural Health Council, all dedicated to rural health policy.

And I have also been told that CMS coordinates with HRSA's Office of Rural Health Policy to, and I quote, "ensure that health care providers in rural America can function to the best of their ability within the boundaries of our statutory and regulatory frameworks."

So the question I have is, can you inform us as to whether CMMI, as it is statutorily required to do, consulted with these various Federal entities dedicated to rural health policy to ensure that what many of us believe is a flawed demonstration program would not adversely impact care delivery in rural areas?

Dr. CONWAY. Yes. CMMI works closely across the Federal Government. This proposal went through the standard clearance interaction processes. And you mentioned the CMS Rural Health Policy Task Force that Mr. Slavitt and I established. We think that that is critical for rural issues.

And as I noted earlier, we made a proposal in rural areas, but we also noted that we were focused on access in rural areas and access to medications. And so we are going to review the public comments now and determine whether any adjustments are needed in rural areas.

Senator THUNE. Dr. Conway, could you detail the feedback that you received from these entities that I mentioned after this hearing, or provide the committee with any documents you might have regarding that input?

Dr. CONWAY. Yes, we can provide input on the process.

Senator THUNE. Good. Well, it would be nice to know if in fact those entities that I mentioned were in fact consulted and what their feedback consisted of.

Dr. CONWAY. I understand.

Senator THUNE. All right. It is well-known that not all drugs utilized for the treatment of cancer have cheaper alternatives. So the question is, how will beneficiaries who need these lifesaving treatments have better access to care when their best treatment option may force their provider into a situation where he or she can no longer afford to provide it?

Dr. CONWAY. So we would want, and I would want personally, every doctor, including any cancer doctor, to prescribe the medicine that their patient needs. We believe this proposal maintains access through paying the Average Sales Price plus a 2.5-percent add-on fee plus a fixed fee.

However, these are the type of comments that we would look closely at. If a physician or clinician could show that this is an access concern, in the comment period where we consider whether adjustments are needed, we would consider that. We also proposed an exceptions process where we proposed practices for patients where the proposal created an access issue, so we could make adjustments.

Sorry to give a long answer on this one, but it is—I was asked earlier. I personally get e-mails all the time today from Medicare beneficiaries who cannot access their medications.

As a practicing physician, I care about that deeply, and I want patients to have access to the right medicine. I want every patient

to get the medicine they need, and I want every doctor to be able to prescribe the medicine they need for their patients.

And so those are the type of comments that we will look very closely at.

Senator THUNE. Well, and I would just add too, if you have a provider who no longer is able to afford the drug and you have a senior who must receive treatment at a hospital's outpatient department as a consequence of that, then how is that increased cost-sharing going to impact that patient's ability to continue to receive the treatment? I mean, that is——

Dr. CONWAY. So we will review first of all what comments came in, but also if you think about a practice, I hope there are people in the practices looking at it across the board, as opposed to one individual drug. If reimbursement goes up for some oncology products in terms of the ASP formula that was proposed, that is obviously revenue to a practice.

So we are going to look at overall access to medications in the aggregate from the policy and whether adjustments are needed.

And then also in the specifics, MedPAC has also put out information on this and what different ideas they had and access numbers that they think are covered by different ASP plus 2.5, 3.5 permutations. So we will look at information from the public comments, most importantly, and also the public domain.

Senator THUNE. Mr. Chairman, my time has expired. Thank you.

The CHAIRMAN. Well, thank you.

Senator Carper?

Senator CARPER. Thanks, Mr. Chairman. Dr. Conway, very nice to see you. Thank you for joining us today. Thanks for your hard work and that of your staff.

You have a tough job. You have a tough job, but we acknowledge that and admire the energy and intellect you bring to a very tough challenge.

Dr. CONWAY. Thank you.

Senator CARPER. Among the comments I have heard about the demonstration is, why is it so big? You normally think of demonstrations—we work with demonstrations across the Federal Government. I am an old Governor, and we always think of the States as laboratories of democracy. We try something out in a State, see how it works before we try to do it in an entire country.

Why such a large, expansive demonstration, please?

Dr. CONWAY. Yes. So first, it is a proposal, so we will seek comments on the scope, and many people have noted that.

What we think about in terms of proposals is, first and primarily, the statutory mission, which is to propose models we think have a high likelihood of improving quality and lowering cost.

Then on the geographic scope, we need to think about three issues primarily. One, that areas are big enough that most practices are going to be within an area, sort of the geographic size.

Two, that it is evaluatable. So the goal is to evaluate models and determine whether they meet criteria in improving quality and lowering cost. So you have to have a sufficiently large sample so you can evaluate the model.

And three, that you are able to have comparison groups so geography allows you to compare to other comparable geographies. But

we will look at the public comments and determine, based on those criteria and the public input, whether adjustments are needed.

Senator CARPER. Thank you.

My staff gave me a briefing. I am sure all of our staffs gave us briefings. They said—I just want to read you a short paragraph from a briefing memo my staff gave me.

CMS expects—this is phase I, all right?—CMS expects this phase of the proposed demonstration project to incentivize physicians and health-care providers to select drugs of better value and lower cost for patients, leading to savings—something we are all interested in. Certain doctors, such as oncologists and rheumatologists, who often prescribe higher-cost drugs, will receive somewhat lower payments under this demonstration, while primary-care physicians who may prescribe lower-cost drugs will likely receive higher payments.

Is that a correct assessment? Would you just talk about that? Is that correct? Do you want to modify that? What would you have to say about that paragraph?

Dr. CONWAY. Yes, that is from the impact table, so it is correct. There are relatively modest—it was actually quoted earlier—adjustments for oncology and rheumatology. There are also adjustments up in the primary-care arenas.

But we publish an impact table because we want to be transparent about the current proposal's effects, and if adjustments are made, we would then publish a final impact table with the effects across practice types also: urban, rural, et cetera. These are the types of issues we care deeply about, and we want to be transparent.

Senator CARPER. Last year the Medicaid Part B program spent, I believe, about $22 billion on prescription drugs. Does that sound about right?

Dr. CONWAY. Yes.

Senator CARPER. A cost shared by seniors, as you know—disabled individuals, taxpayers, and our government. Several drug companies have proposed value-based payment models to ensure that patients and Medicare are getting the best value and outcomes in return for a fair reimbursement.

My question is, in the proposed Part B demonstration project, how is CMS to effectively evaluate value-based payment models for prescription drugs? And the second half of that is, is the first phase of the demonstration program necessary for advancing these alternative payment models for prescription drugs?

Dr. CONWAY. Yes, so we proposed the two-phase approach. They are proposed as separate arms, if you will, of intervention. And yes, the second phase directly builds on what we have seen in the private sector, or are hearing from the private sector, about the desire to test value-based arrangements such as outcomes-based pricing and other methodologies that incentivize higher value and outcomes. Hence, our proposal.

Senator CARPER. You have answered a lot of questions here today that you anticipated. Is there a question that you wish had been asked that has not been asked? What would be a good question, say, why did he not ask me that one?

I see your staff writing feverishly behind you.

Dr. CONWAY. Yes, they probably will give a better answer later, and then I will feel bad.

You know, I think, one, we have not noted that Congress wrote in the Innovation Center statute—and I will not get the statutory language exactly right—that we cannot limit any benefit to Medicare beneficiaries. And we are not limiting benefits to Medicare beneficiaries.

I have said this, but to reiterate it, we care deeply about access to medications, innovation, and better health outcomes. The question we collectively have to work on is, how do we propose tests and models that help us achieve those outcomes?

Sorry for the long answer, but about the current system today, I literally get contacted daily from beneficiaries who do not have access to a given medication or do not have access to care in a given area.

So if we think the status quo is optimal, we are mistaken, and we need to test new payment and service delivery models to improve care for millions of Americans. And I think we are on a learning path today that is much better than it was 3 years ago.

Senator CARPER. All right. Thanks so much.

Senator WYDEN [presiding]. Senator Toomey?

Senator TOOMEY. Thank you, Senator Wyden.

Dr. Conway, thanks for joining us. Just a couple of questions. We are running well into the vote here, so I want to move quickly.

I do want to go back to the scope issue, because it is something that is a concern raised by many of my constituents. And by my reading of the statute, the Affordable Care Act States that CMMI has the authority to test a model addressing, and I quote, "a defined population for which there are deficits in care."

But this rule would change the terms of reimbursement for 75 percent of all docs who administer Part B drugs under the ASP-plus-6 approach, and every single drug that is subject to the ASP-plus-6 reimbursement, as I understand it.

How could that be consistent with the congressional intent of a defined population? It just seems almost universal, which is not the same.

How is it a defined population?

Dr. CONWAY. So as you noted, the Innovation Center authority is to propose tests of new payment and service delivery models. You know, here we defined a population based on geography. We are looking at the comments now.

The scope of that geography is a key issue that we will evaluate.

Senator TOOMEY. But just so that I understand, it is true that, as I understand it, there are these different subsets that will undergo different experiments. But almost everybody is involved in this broader experiment to some degree.

Dr. CONWAY. So the current proposal has three arms and therefore does have, as you noted, 75 percent approximately of the country in Innovation arms. We will evaluate the comments and take a look at key issues around the number of arms or interventions in the study and the geographic scope and whether adjustments are needed.

Senator TOOMEY. Well, yes, I would just strongly urge you to focus on that particular issue. I was not here when the Affordable

Care Act was written, but I think a layman's reading of a defined population suggests something much narrower than what is contemplated here.

A second question I have for you goes to the purpose, as I understand it. At least one of the stated purposes is to make sure there is no incentive to drive a physician toward a more expensive alternative than some other alternative, which the current system seems to suggest.

In its June report, MedPAC listed the 10 drugs with the highest Part B expenditures. Do you know how many of them had FDA-approved alternatives?

Dr. CONWAY. I do not want to quote a number and be wrong.

Senator TOOMEY. That is fine. The answer is zero among the top 10. So it strikes me that clearly it is not the payment model that drives the docs to prescribe the 10 highest-expenditure drugs; it is the fact that there is no alternative.

So if we were to make this change, is there a concern that it could create an incentive for physicians to experiment with off-label use for some purposes? Was that a consideration?

Dr. CONWAY. So, a few comments. One, the proposal does not just focus on drugs where there are interchangeables, if you will; so for example, as you noted, interchangeable to generic.

We are proposing to pay the Average Sales Price, which is the average cost of the drug, plus 2.5 percent, plus a fixed fee. We are going to look at the public comments to determine if there are adjustments that are needed in that formula, either overall or in certain settings.

So the goal is, for both high-cost drugs and low-cost drugs, that we are paying appropriately for those drugs. The current system does have a disincentive that we have heard about from MedPAC and others on the low-cost drugs, where if it is a $10 drug and it is 60 cents, the real question is about whether it covers the cost of the physician or the clinician prescribing said medication.

So we are trying to remove the financial incentive but still pay appropriately for the provision of drugs that you named or of other drugs. And we would want the oncologist or rheumatologist, physicians, clinicians, to prescribe the medicine that they need us to pay for and the physician—or the patient—to receive the medicine that they need.

Senator TOOMEY. Thanks, Mr. Chairman.

Senator WYDEN. I thank my colleague.

Dr. Conway, we are at the point in the hearing where the choice is really for me to either filibuster until my colleagues get back or to offer a couple of additional questions.

So I am going to opt for the second route and ask you about how this proposal interacts with other payment reform proposals. It is obvious that there has been progress made overall toward moving the health-care system to one that moves away from volume, that incentivizes quality and value.

You all reached the target of making 30 percent of Medicare payments through alternative payment models. That is a plus—9 months earlier than expected. And obviously, what is called the MACRA legislation—the Medicare access bill and the bill that had the critical program for kids—was passed last year to replace this

hugely flawed, what is called the SGR program, with a payment system that rewards doctors for providing high-quality, cost-effective care to patients.

Now, I have heard from some providers that the proposed Part B drug demonstration could unintentionally discourage participation in the new payment delivery and reform models, such as the Oncology Care Model and the alternative payment models incentivized by the major Medicare legislation.

What would be your response to those concerns? And how do you envision making sure that this demonstration does not in any way discourage participation in these other model programs you all are looking at?

Dr. CONWAY. Thank you, Senator Wyden. We think this proposal aligns with those programs. So, specifically to give you an example, the basic construct of MACRA—and we want to thank Congress for that—was to pay physicians and clinicians based on value, so quality resource use, clinical practice improvement, and use of technology.

This proposal also aligns with paying physicians and clinicians based on value, so we think they would actually work well together. We also, through different methods of evaluating one model to a comparison group in another area where it is not, can estimate the effects of various models.

But we think this Part B model will actually align with MACRA and encourage participation in these alternative payment models.

I will not filibuster, but I do want to take the opportunity——

Senator WYDEN. Go ahead.

Dr. CONWAY. You know, your leadership and this committee's leadership on delivery system reform has been hugely important. The Care Choices model, where I was with the hospice and palliative care community on concurrent hospice and palliative care just a couple of weeks ago, was due to your leadership, and I want to thank you for that.

Senator WYDEN. I thank you, Doctor. I think it would be very helpful if you could explain in something resembling English exactly how Medicare Care Choices works. Because this was something that I had really been dreaming would be done almost since those Gray Panther days.

And as I understand it, what you all are doing with Medicare Care Choices is trying to make sure that eventually—because this is a big pilot now—every senior in America could have the opportunity to get hospice without giving up the prospect of curative care.

And you are a physician, and a very skilled one. I gather that this also would make it easier for patients and families to time the kinds of choices they make so it is best for them.

Could you explain how that works?

Dr. CONWAY. You are correct. We are pilot-testing the ability for patients and families to choose concurrent hospice and palliative care with so-called curative care. It is actually in almost 40 States. And it allows for much more patient-centered choices.

I will actually, if it is all right, use not my own words, but in that panel I had the pleasure of sitting beside Atul Gawande, who talked eloquently about the importance of this model and how it

was one of the biggest positive changes in palliative and hospice care in U.S. history.

We will continue to modify and learn and refine, based on input from Congress and others, but it is a huge positive step. As a son and a physician, I have been through that with family members and patients, and it enables much more patient-centered choice.

And probably the most powerful thing was, on the other side of me sat a gentleman whose wife passed away, and he said if this had been available for her, they would have been able to make better choices that would have more aligned with their goals of care.

And at the end of the day, that is what it is about. It is about patients and families, as you know well. You have been a leader in making choices for them.

Senator WYDEN. Well, keep me apprised on this.

I want to recognize Senator Cardin. I just want it understood that that program, that program to provide more choices for older people, that was really born in this room.

Because during the Affordable Care Act debate—my colleagues remember this discussion—we constantly heard this nonsense about how there were death panels. Well, there were no death panels.

And now with Medicare Care Choices, it is very clear that older people are going to have a wide array of choices that allow them to choose what is best for them in line with their views about health and religion and morals and all of the other factors. I appreciate your taking us through it.

Senator Cardin?

Senator CARDIN. Thank you, Senator Wyden. And, Dr. Conway, thank you very much.

I really want to drill down a little bit as to what your objectives are, particularly as you move towards the second phase of the demonstration.

As I understand the first phase—and I was listening to Senator Portman's questioning—it is revenue-neutral, which means you are going to have winners and losers. You have those challenges; I understand that. I understand what you are trying to achieve, and you are trying to do it in a way that uses current resources more effectively in dealing with the reasonable costs associated with administering these drugs.

With the second phase, I am not quite as clear as to your objectives. Is it your anticipation that it will save projected costs? And if it is going to save projected costs, do you know the range that you are trying to get to in that second phase?

Dr. CONWAY. Yes. We believe both phases have the potential to maintain or generate savings and improve quality for patients.

And in the second phase, as we put in the proposal, we would come forward with, in the future, the specifics around drug classes and the various arrangements. We had different tools, so outcomes-based pricing, risk-sharing arrangements, indication-based payment. We would come forward with the classes and the proposals, would get patient input, consumer input, and input from Congress and others on those proposals.

A tangible example that has actually come to us from outside CMS is entities that want to do risk-sharing arrangements, where

if a given drug may lower costs in the Part A and B space, we think about how that could have benefits across the health-care sector to improve quality and lower costs.

To give you an example, we have lower cost-sharing for beneficiaries who are selecting certain medications as one of the proposed tools.

So the goal here is to test an array of tools that have been used in the private sector to improve quality and lower costs, to test them in the Medicare Part B program.

Senator CARDIN. We have seen in previous efforts to impose delivery system changes that are more cost-effective, give you better value, that the budget can prevent it from being implemented the way it was intended, because you need to produce a certain amount of cost savings, since everyone has to share in the realities of the budget.

Do you build into this demonstration the confidence and credibility that you really are looking for value and not just to cut the cost issues here?

Dr. CONWAY. Our statutory authority calls out both quality and expenditures, but we actually focus on quality and patient outcomes first. So when we think about new payment model tests, we lead with quality and patient outcome.

So I think we would take that approach here as well, where our goal is to maintain access, to improve outcomes for patients, and then to either maintain or lessen expenditures. And the statute includes the provision, if a program improves quality and maintains its expenditures, that that can meet criteria for expansion.

Senator CARDIN. And how do you intend to engage the stakeholders as you go through into the two phases here?

Dr. CONWAY. So we are reviewing the comments now. But I would say the principles that we will try to put in place, which are true across the Innovation Center, are robust patient and consumer input into the models, input from providers and stakeholders across the health system, certainly input from Congress. At the end of the day, broad input and transparent processes are critical to shaping this work.

I mentioned this earlier, but we now have innovations in our models in all 50 States, thousands of providers, millions of beneficiaries, and it is deep, deep engagement with the various participants.

In our bundled payment model, our voluntary BPCI, Bundled Payment for Care Improvement model, 48 States and over 1,500 hospitals, physician groups, and others, are redesigning care for patients and improving care and care coordination. So that is the kind of engagement we want.

Senator CARDIN. Thank you.

Thank you, Mr. Chairman.

Senator WYDEN. Does my colleague have any additional questions?

Senator CARDIN. Well, I have a lot of comments, but I think, related to this subject, Maryland is in a somewhat unique position. And one of the issues that we will need to talk about is the impact it has on each State, including my own State. But it is different for Maryland.

Dr. CONWAY. Yes.

Senator CARDIN. But I assure you, my principal objective is getting better value, better outcomes. I think the more you can coordinate, the better off you are.

But I always am concerned about the pressures on the budget that are used, at times, to use well-intended programs just to produce savings rather than to produce better outcomes.

And, Dr. Conway, I take you at your word when you say that that is not the objective here. And we obviously will be watching this pretty closely.

Dr. CONWAY. Thank you.

Senator WYDEN. I thank my colleague. And just one last question from me, Dr. Conway.

So phase II of the demonstration seeks to move into this value-based arena which you have heard that I and certainly others—this has been something that has had support on both sides of the aisle for some time—believe is constructive, moving away from clunky, volume-driven, fee-for-service medicine. That is what phase II builds on.

How does it coordinate with the other laudable goal of precision medicine? In other words, you all seek, in the days ahead, to really make sure that drugs and treatments—and what is striking about this is, this means what it sounds like—really are tailored exactly to the needs of a particular individual, recognizing that one particular drug or therapy does not affect George and Harry in the same way, and certainly does not affect George and Sally in the same way.

Tell us, if you would, so we have a sense of where you are going, how does phase II, in particular, in effect build on the Precision Medicine Initiative in the administration?

Dr. CONWAY. Thank you for the question. We think it very much aligns with Precision Medicine, and let me explain how.

For example, if you had a new therapy that generated significantly better outcomes for patients and you are paying based on outcomes and value, that actually supports paying for that therapy and the innovation and better patient outcomes it delivered.

Similarly, for indications of base pricing, you could imagine if you can really tease apart for which patients this therapy is maximally effective and then pay appropriately for that, it really incentivizes innovation and precision medicine, better outcomes for the specific patients who will benefit from specific therapies.

And we think it is a very exciting place to work across the health-care system: manufacturers, payers, providers, patient groups in support of both precision medicine and paying for value and better patient outcomes.

Senator WYDEN. Senator Burr?

Senator BURR. Thank you, Mr. Chairman.

Dr. Conway, I have great admiration for the role that you play. And it has to be extremely tough for a doc to defend an agency that says we can determine treatment better than the attending physician, because I think that is what this Part B rule in fact does.

You stated that you met regularly with patient and provider groups. Have any of those groups that you met with been supportive of this rule?

Dr. CONWAY. Yes, we continually meet with patient groups, consumer groups, provider groups.

Senator BURR. The question is very simple. Have any of them been supportive of the Part B rule, yes or no?

Dr. CONWAY. Yes. We received——

Senator BURR. Would you provide for this committee the list of those groups that have come out and said, we are supportive of this Part B rule?

Dr. CONWAY. Yes, and I believe we may have even received another letter recently. But yes, we can provide that information.

Senator BURR. Is CMS considering withdrawing this rule, yes or no?

Dr. CONWAY. We are evaluating the public comments now and intend to take those comments into account in finalizing the rule.

Senator BURR. Is CMS considering withdrawing the rule?

Dr. CONWAY. We intend to take the public comments into account in finalizing the rule.

Senator BURR. Are you doing this to save money or to reach a better health outcome?

Dr. CONWAY. We are doing it because we believe it can both reach a better health outcome and maintain or lessen expenditures.

Senator BURR. Does CMS believe they can design a better treatment pathway than a physician can?

Dr. CONWAY. As you noted, I am a practicing physician. I believe physicians care about their patients, and I want physicians and clinicians to make treatment decisions based on what is best for their patients.

I would like to maintain, and the agency has focused on maintaining, that a patient, a beneficiary, should receive the medicine they need, and that a physician or clinician should prescribe in all instances the medicine that is best for their patient.

Senator BURR. And would you also agree that the location they get that at is important? Transportation is the number one issue with health care in this country. It is in the Veterans Administration, it is in Medicaid, and I believe it is in Medicare.

So when you limit the rural access to these lifesaving treatments, have you in fact bettered the outcome?

Dr. CONWAY. We do not want to limit access, including in rural areas. Many of my family members are private practice physicians in independent practice. We support independent physician-clinician practice.

We are proposing a model that we think can support independent physician-clinician practice, including rural and small practices. But we will review the public comments to determine whether adjustments are needed.

Senator BURR. Well, you talked earlier—and I apologize for being out; I had to go vote—about disincentives that exist in the current system. You do not consider it a disincentive for a local-based delivery point when you are saying, but if you go to the hospital, we are going to pay you more money?

Dr. CONWAY. This proposal proposed to pay the same ASP plus 2.5 percent plus a fixed fee, both in the hospital outpatient and physician setting.

Senator BURR. Dr. Conway, 4 years ago I authored the Advancing Breakthrough Therapies for Patients Act with the chairman and my good friend from Colorado, Senator Bennet. And our objective was to bring forward promising breakthrough therapies as fast as possible, including those that would be impacted by what CMS is proposing.

This bipartisan law saw remarkable success, particularly in bringing forward cancer treatments even faster. As a result of the law, in its first 4 years, over 130 drugs have been designated as breakthrough and more than 45 drugs have been approved by FDA so far.

I fear that this demonstration project will jeopardize access to these breakthrough drugs just as they are becoming available.

Can you assure the committee today that your proposal will not negatively impact the success of the breakthrough therapy legislation?

Dr. CONWAY. We believe the proposal aligns with innovative breakthrough therapies that improve patient outcomes, because the proposal is about focusing on paying for drugs and therapies that generate better outcomes for patients.

Senator BURR. My constituents have also written me expressing concerns about this CMS proposal. The CEO of an oncology clinic in Hickory, NC said this: "Physicians and caregivers are not prescribing medications to profit themselves. This team in Hickory, NC is prescribing medications and therapies because they work."

Do you fear that providers are profiting themselves, versus providing the therapies because they work?

Dr. CONWAY. I would want those physicians to continue providing those therapies that work for their patients.

Senator BURR. So if they feel like this in some way, shape, or form takes that ability away from them, then you would see a need to change this legislation?

Dr. CONWAY. We want to review theirs and any other public comments, because we want the proposal to support access to medications for beneficiaries.

Senator BURR. Last thing, Mr. Chairman.

Senator WYDEN. The time of the gentleman has expired. Why don't you have one last question so we can go to Senator Scott?

Senator BURR. Thank you, Mr. Chairman.

A North Carolinian suffering from primary immune deficiency who relies on infusion treatments writes: "Members of my community on Medicare and the providers who care for them already face complexities accessing medical care and treatments. They should not have to face the consequences of an initiative that eliminates their treatment options. This cost-cutting measure would become a life-cutting measure, and I urge you to intervene to stop this proposed reimbursement model."

That is a patient. I think a patient probably heard from a provider that if this goes through, here is the impact on you. What do you say, as a doc, to that patient with immune deficiency disorder?

Dr. CONWAY. I would say as a doctor to that patient, I want them to receive the medicine they need for their immune deficiency. I would say to their physician, I want them to prescribe the right medicine to their patient at all times, like all physicians should.

Senator BURR. Then I urge you to really look at this proposed rule.

Thank you, Mr. Chairman.

Senator WYDEN. Senator Scott?

Senator SCOTT. Thank you, Mr. Chairman.

Thank you, Dr. Conway, for being here today. And certainly you are from a rural part of Texas. I am from a very rural State, South Carolina. So I think we both have the appreciation and affinity for the health-care costs and challenges for people living in rural areas that are absolutely severe.

The thing I have heard from my constituents consistently as it relates to this demonstration project is fear. They are scared.

Picture, if you will—and I know your mother is on Medicare, as you stated, and mine is as well—picture if you will senior citizens living in rural South Carolina scared.

They are on fixed incomes, and we now have a demonstration project that covers the entire Nation. And what they see as the result of this experiment is higher prices, less access, and perhaps, in order to receive the lifesaving treatment that they need desperately to stay alive to see their grandkids one more time, a 2- or 3-hour drive from Manning, SC to Charleston. And so with great uncertainty, feeling confused and afraid, they write into our offices.

And one of the more difficult things to do in Congress today is to find a way to unite Republicans and Democrats on a topic. And this demonstration project has done a very good job of creating and getting concerns from Republicans and Democrats that all sound fairly similar, save one component of the discussion.

And my questions are not that different from the questions you have heard so far, Dr. Conway. They are around rural access; they are around rare diseases, the impact on the folks who are socially and economically challenged and folks who are concerned that now we are seeing the government practicing medicine and determining value, as opposed to working together to figure out what truly is the value proposition of their visit to the doctor.

And I think, Dr. Conway, you and I both can agree at least that these concerns are at least valid concerns, given the scope, the magnitude, the impact on citizens. And I believe that your desires, your intentions are good.

Frankly, you are looking for a way, as you said earlier, to help Medicare be there not only for your mother, who is currently receiving the benefits, but for your four kids. I think we share the same concern, perhaps with a different outcome.

And I hope, I would even plead with you on behalf of the citizens of South Carolina who are so concerned about this project, to take a second look, a step back from a nationwide implementation that could have dire effect on folks depending on their very certain paychecks, on their certain benefit from Social Security.

And so just to highlight a couple of areas, one question being in the rare disease arena where, for patients in my State, sickle cell anemia is a very powerful weapon against so many folks in my State.

For patients with sickle cell and other rare diseases, blood transfusions are one of the only methods of treatment. While it is clear that blood products are excluded from phase I of the demonstra-

tion, it is unclear if they will be excluded during phase II of the demonstration.

Can you clarify for my folks at home?

Dr. CONWAY. So, you are right on blood products. They were proposed to be excluded from phase I. We have put out a proposal for phase II that we would come forward with the specific drug classes or areas for phase II that we plan to address and receive comment on those areas, both public input and patient consumer input.

So our goal is to engage with Congress and with the public and specifically patients, consumers. And we did note in the proposed rule that if there were specific classes or other issues that needed to be addressed, and rare diseases was an example we named, that we would look to those public comments and consider how best to address those issues.

Senator SCOTT. Mr. Chairman, do you have time for me to ask another question?

Senator WYDEN. Everyone else has gotten an extra one or two, so please feel free, Senator Scott.

Senator SCOTT. Well, thank you, sir. I appreciate the extra 10 minutes. I really appreciate that, sir. [Laughter.] I did not think that was that funny, but we will go on anyway.

I certainly have appreciated the concern of my constituents about the amount of time that they could spend on the road trying to find the right practitioner, perhaps the right hospital to go to. If you are living in Manning, Sumter, or in a rural area of South Carolina, driving to Columbia or Charleston is not just a hop, skip, and a jump. It is a more serious proposition.

I also note that Obamacare is going to provide a partnership or ride-sharing service for young folks to sign up for the health-care law. How can we justify the department going out of its way to transport the young adults to sign up for Obamacare when the program you are proposing will limit access for some of our most vulnerable, like the elderly and disabled?

Have we figured out a transportation-sharing program that will help with the impact of transportation in rural areas?

Dr. CONWAY. So for the proposal, we would want the proposal to maintain access, including in rural areas, smaller practices, et cetera. For patients and physicians who want to deliver medicines, we want them to receive the medicines when and where and how they want to receive said medicines.

We put forward the proposal because we thought the proposal maintained access and improved quality and could maintain or lower expenditures. But we will be looking closely at the public comments, including on smaller physician practice issues and rural issues, in determining whether adjustments are needed.

Senator SCOTT. Well, Mr. Chairman, I will stop where I started.

I do not doubt the sincerity or the intentions of Dr. Conway or anyone within his employ. I do want to echo my concerns for my citizens, particularly those in rural areas, those with rare diseases—sickle cell being among them—those folks who are just financially strapped. A life that is socially, economically challenged, that sounds cool, but the fact of the matter is it means that you have too much month for the money that you have.

And so we are talking about people who are seriously challenged, and now are very concerned. And, as you have heard echo throughout the hearing today, the concerns are real, because, while the intentions are good, the access issues are still real concerns.

And frankly, the pricing, though you may have a static number, $16.80, the impact of those numbers on the actual costs can be quite high.

Thank you, Dr. Conway. Thank you, Mr. Chairman.

Senator WYDEN. Thank you, Senator Scott.

Dr. Conway, I just want to make sure. You are a pediatrician. You are a career employee in the department. You are not a political appointee. I know you have been published in some of the country's leading medical journals, and you are a career employee. Is that correct?

Dr. CONWAY. Yes, sir. I am a career employee.

Senator WYDEN. All right. On behalf of Chairman Hatch, I would ask for colleagues and staff who are here that any written questions for the record be submitted by Tuesday, July 12, 2016.

With that, the Finance Committee is adjourned.

[Whereupon, at 11:50 a.m., the hearing was concluded.]

APPENDIX

ADDITIONAL MATERIAL SUBMITTED FOR THE RECORD

PREPARED STATEMENT OF PATRICK CONWAY, M.D., M.SC., ACTING PRINCIPAL DEPUTY ADMINISTRATOR, DEPUTY ADMINISTRATOR FOR INNOVATION AND QUALITY, AND CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE AND MEDICAID SERVICES, DEPARTMENT OF HEALTH AND HUMAN SERVICES

Chairman Hatch, Ranking Member Wyden, and members of the committee, thank you for the invitation to discuss the Centers for Medicare and Medicaid Services' (CMS) initiative to improve how Medicare pays for Part B drugs and to support physicians and other clinicians in delivering higher quality care in the Medicare program.

Part B drug spending has risen significantly over time. Total Part B payments for separately paid drugs in 2015 were estimated at $22 billion (this includes cost sharing). In 2007, the total payments were $11 billion; the average annual increase since 2007 has been 8.6 percent. This significant growth has largely been driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from $3 billion to $8 billion respectively.[1]

CMS has heard from many stakeholders about concerns about the cost, value, and access to prescription drugs. As part of an initiative to address rising drug costs, the Department of Health and Human Services (HHS), convened a forum that brought together consumers, physicians, clinicians, employers, manufacturers, health insurance companies, representatives from State and Federal Government, and other stakeholders to discuss ideas on how the health care system can meet the dual imperatives of encouraging drug development and innovation, while ensuring access and affordability for patients. To help further this mission, CMS issued a proposed rule to test a new model to help improve patient care and the value of Medicare drug spending.

This proposal is part of the administration's broader strategy to encourage better care, smarter spending, and healthier people by paying for what works, unlocking health care data, and finding new ways to coordinate and integrate care to improve quality. CMS values public input and comments as part of the rulemaking process, and looks forward to continuing to work with stakeholders through the rulemaking process to maximize the value and learning from the proposed tests. We have received feedback from a wide range of stakeholders on several issues, including the size of the model, patient access in small practices and rural areas, and the importance of patient input. We are reviewing all comments closely to determine whether adjustments are needed. Our goal is to be responsive to the public comments and input from Congress while preserving the integrity and effectiveness of the model.

PROPOSED NEW MEDICARE PART B DRUG PAYMENT MODEL

Medicare Part B includes a limited drug benefit that encompasses certain drugs and biologicals. Currently covered Part B drugs fall into three general categories: drugs furnished incident to a physician's services, drugs administered via a covered item of durable medical equipment (DME), and other drugs specified by statute. These types of drugs include intravenous infusions (IVs) like cancer treatment

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[1] CMS Proposed Rule, "Medicare Program; Part B Drug Payment Model," *https://www.federalregister.gov/articles/2016/03/11/2016-05459/medicare-program-part-b-drug-payment-model.*

drugs, injectables like antibiotics or eye care treatments, and other drugs that require a medical professional to administer.

Many Part B drugs, including drugs furnished in the hospital outpatient setting, are paid based on the Average Sales Price (ASP) plus a statutorily mandated 6 percent add-on. The ASP is calculated quarterly using the manufacturer-submitted data on sales to all purchasers (with limited exceptions specified in statute, such as sales at nominal charge and sales exempt from best price) with manufacturers' rebates, discounts, and price concessions included in the ASP calculation. The ASP payment amount does not take into account the effectiveness of a particular drug nor the cost of clinically comparable drugs. The Medicare Payment Advisory Commission (MedPAC) has noted that ASP methodology may encourage the use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.

The proposed rule that CMS issued describes a new Part B Drug Payment Model that would test whether alternative drug payment designs may improve how Medicare Part B pays for prescription drugs and supports physicians and other clinicians in delivering higher quality care. More specifically, this proposed rule is designed to test different provider and patient incentives to do two things: drive the prescribing of the most effective drugs and test new payment approaches that reward positive patient outcomes. Physicians often can choose among several drugs to treat a patient, and the current Medicare Part B drug payment methodology can penalize doctors for selecting lower-cost drugs, even when these drugs are as good or better for patients based on the evidence. Among the approaches to be tested are the elimination of certain incentives that work against the selection of high performing drugs, as well as the creation of positive incentives for the selection of high performing drugs, including reducing or eliminating patient cost sharing to improve patients' access and appropriate use of effective drugs.

Phase 1: Adjustments to the ASP+6 Percent Add-on Methodology

The proposed model would test whether changing the current 6 percent add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. CMS would update the flat fee at the beginning of each year by the percentage increase in the consumer price index for medical care for the most recent 12-month period.

CMS expects that the add-on payment of 2.5 percent plus a flat $16.80 fee will cover the cost (the ASP) of any drug paid under Medicare Part B. The flat fee is calculated such that it is budget neutral in aggregate. CMS intends for the test to result in savings through changes in prescribers' behavior, as we hope that the revised pricing removes any excess financial incentive to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available. In other words, we believe that removing the financial incentive that may be associated with higher add-on payments may lead to some savings during phase I of the proposed model.

Phase 2: Value-Based Purchasing (VBP) Tools

Commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization successfully employ an array of tools including value-based pricing and feedback on prescribing patterns to improve the value of drug payments. To produce a menu of value-based purchasing options, CMS reviewed the numerous tools used by entities that manage drug and health benefits and identified those that may be applicable to payment for Part B drugs with the same positive results.

The proposed rule sought comments on testing different alternative approaches for Part B drugs to improve outcomes and align incentives to improve quality of care and spend dollars wisely; these include:

- *Discounting or eliminating patient cost-sharing.* Patients are often required to pay for a portion of their care through cost-sharing. This proposed test would decrease or eliminate cost sharing to improve beneficiaries' access and appropriate use of effective drugs.
- *Feedback on prescribing patterns and online decision support tools.* This proposed test would create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications. Examples could include best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends.

- *Indications-based pricing.* This proposed test would vary the payment for a drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time. The goal is to pay for what works for patients.
- *Reference pricing.* This proposed test would analyze the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products.
- *Risk-sharing agreements based on outcomes.* This proposed test would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

Scope of the Model

The proposed model would run for 5 years with the goal of having the incentive and value-based purchasing tests fully operational during the last 3 years to evaluate changes and collect sufficient data. All providers and suppliers furnishing and billing for Part B drugs would be required to participate in the model. This would help ensure that observed outcomes do not suffer from selection bias inherent in a voluntary participation model and would help test whether the model can ultimately be generalized to providers and suppliers billing for Part B drugs with various characteristics, such as different geographies, patient populations, and specialty mix. With limited exception, CMS proposed to include all Part B drugs and biologicals in this model.

Under the proposal, providers and suppliers would be placed in a control or study groups based on Primary Care Service Areas, which are clusters of zip codes based upon patterns of Medicare Part B primary care services (excluding the State of Maryland where hospital outpatient departments operate under an all-payer model). The exact geographic locations the model would be operational in would be posted once the model is finalized, as we have done with other models.

Maintaining Beneficiary Access to Quality Care

Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. In Medicare Part B, most beneficiaries pay a monthly premium for coverage of certain services including prescription drugs administered by infusion or injection in physician offices and hospital outpatient departments, doctors' services, outpatient care, and durable medical equipment (DME). Beneficiaries must also meet a deductible of $166 in 2016; once that is met, the beneficiary typically pays 20 percent of the Medicare-approved amount for the services they receive. Under this structure, beneficiaries utilizing Part B drugs, especially those using higher cost drugs, may face significant out-of-pocket expenses. To the extent that prescribing patterns do shift toward lower cost drugs, in aggregate, beneficiaries would benefit along with the Medicare program.

Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits. The proposed model also includes a number of beneficiary protections. All standard Medicare appeals processes would stay the same. The proposed model would include a new pre-appeals exceptions review process under Phase II, in addition to the standard Medicare appeals processes, that would allow the beneficiary, provider, or supplier to explain why Medicare's value pricing policy is not appropriate for the beneficiary and to seek an exception from the model's pricing approach. Exceptions decisions would be issued within five business days. In addition, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

The public comment period for the Proposed Rule concluded on May 9, 2016, and CMS is carefully considering all the public comments on this proposal that were received by the close of the comment period. HHS and CMS value public input, and we look forward to continuing to work with stakeholders to maximize the value and learning from this model.

CONCLUSION

Millions of Americans rely on medications to manage chronic illnesses and treat acute conditions. CMS is dedicated to ensuring that its beneficiaries have and maintain access to the high quality treatments they need while pursuing better drug value. Moving forward, HHS and CMS are committed to continuing to listen and work together with stakeholders to advance ideas that improve access, affordability, and innovation so all Americans have access to the breakthroughs ahead. There are no easy answers to these multifaceted challenges, but there is a significant benefit—to all of us—of working together to find a solution. I appreciate the committee's interest and look forward to answering your questions.

QUESTIONS SUBMITTED FOR THE RECORD TO PATRICK CONWAY, M.D., M.SC.

QUESTIONS SUBMITTED BY HON. ORRIN G. HATCH

ANALYSIS BEHIND PROPOSED DEMONSTRATION

Question. Does CMS have data indicating that the payment changes in the phases of the proposed model, or demonstration will improve quality of care, patient outcomes, or result in savings? If so, why were they not included in the proposed rule?

Answer. The Medicare Part B Drug Payment Model proposed rule proposed to test a new model under the authority of the Center for Medicare and Medicaid Innovation (the Innovation Center). Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries.

Testing the proposed Part B Drug Payment model would allow us to learn more about how value-based purchasing tools and changes to Average Sales Price (ASP)-based reimbursement could reduce Medicare spending on drugs, while preserving or enhancing the quality of care furnished to Medicare Part B beneficiaries. The current ASP methodology for Part B drugs may encourage use of more expensive drugs because the 6 percent add-on generates more revenue for more expensive drugs.

The proposed rule discusses the specific approach for the use of an add-on percentage with a flat fee described in MedPAC's June 2015 Report to Congress. Specifically, as described in the proposed rule, MedPAC evaluated changing the add-on to 2.5 percent of ASP plus a budget neutral flat fee per dose of $14. The result redistributed add-on payments by decreasing payments for expensive drugs in favor of drugs that are paid at lower amounts. Redistribution under this approach favors the provider specialties and suppliers that utilize relatively inexpensive drugs. The June 2015 MedPAC report determined that under this approach physician specialties that heavily utilize drug therapy would see a decrease in drug revenues while specialties that utilize fewer drugs like primary care would see an increase in drug revenue. CMS has proposed the same basic approach under phase I of the model that was described in the June 2015 MedPAC report: A fixed percentage with a flat fee, specifically, a fixed percentage of 2.5 percent and a flat fee of $16.80 per drug per day administered.

Question. The proposed rule presupposes there are lower cost Part B drug alternatives available for all Medicare patients. How many treatment situations exist where there are true clinical substitutes, with one costing significantly less than the other? What evidence did the agency use in making that determination? Did the agency account for patients' perspectives and experiences in making the determination?

Answer. CMS proposed two phases for the Part B Drug Payment Model. In phase I of the model, CMS proposed implementing a variation to the add-on component of Part B drug payment methodology in different geographic areas of the country. Phase I would establish payment at Average Sales Price (ASP) plus a 2.5 percent add-on percentage and a flat fee per administration day as a budget neutral test.

In phase II of this proposed model, CMS proposed to implement value-based purchasing (VBP) tools in conjunction with the phase I variation of the ASP add-on payment amount for drugs paid under Part B. Phase II would use tools currently employed by commercial health plans, pharmacy benefit managers (PBMs), hospitals, and other entities that manage health benefits and drug utilization. Specifi-

cally, CMS proposed to apply one or more VBP tools, such as indications-based pricing, reference pricing, and clinical decision support tools to Part B drugs.

Neither phase of the Part B model presupposes there are lower cost Part B drug alternatives available for all Medicare patients. Rather, the proposed model would test, in specific geographic areas, whether the proposed alternative approach for the ASP add-on payment and proposed VBP tools would strengthen the financial incentives for physicians to choose higher value drugs.

Under the proposed Part B drug payment model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits. In the proposed rule, CMS noted that the current Part B drug payment policy at ASP+6 percent could have incentives for prescribing higher cost drugs when comparable lower cost drugs are available, increasing expenditures. CMS also proposed a pre-appeals exceptions review process for phase II of the model, which would create a mechanism for beneficiaries, providers, and suppliers to request an exception to Medicare's value-based pricing policy, if warranted in the beneficiary's circumstances. CMS is carefully considering the comments received from stakeholders during the comment period on the proposed model to determine whether adjustments are needed.

EFFECT OF REDUCED AVERAGE SALES PRICE ADD-ON

Question. The reality is that the Part B drug payment rate is not Average Sales Prices (ASP) plus 6 percent but ASP plus 4.3 percent after the mandatory sequester is applied. This effective rate does not even take into account prompt pay discounts, which are widely estimated at 1–2 percent of ASP. Does CMS agree with this assessment?

Answer. CMS is required to reduce Medicare payments for Part B drugs under the Balanced Budget and Emergency Deficit Control Act of 1985 (BBEDCA), as amended by the Budget Control Act of 2011. The application of the sequestration requires the reduction of Medicare payments by 2 percent for Medicare FFS claims with dates-of-service or dates of discharge on or after April 1, 2013. The manufacturer's ASP is calculated based on sales to all purchasers other than sales exempt from best price (such as prices charged to 340B covered entities) and sales at nominal charge, and is net of volume discounts, prompt pay discounts, cash discounts, free goods that are contingent on any purchase requirement, chargebacks and rebates (other than rebates under the Medicaid drug rebate program). The model does not address the underlying ASP calculation, including the inclusion of prompt discounts in accordance with the ASP statute. The model also does not consider reductions applied to Medicare payment under sequestration, which is independent of Medicare payment policy.

Question. Considering that ASP is an average, with some providers inherently paying above it and some below it, won't some providers be paying more to acquire some drugs that they are reimbursed for them considering that the payment rate amounts to ASP plus less than 1 percent?

Answer. Under phase I of the Part B Drug Payment Model, CMS proposed to modify the ASP add-on amount in a budget neutral manner. Overall, Part B drug payment to practitioners, pharmacies, and hospitals by specialty in phase I of this proposed model would not change, as the ASP add-on revision is proposed to be budget neutral. We do not expect a sizable overall reduction in Part B drug spending associated with phase I of this model, but we do anticipate an incentive to use higher value drugs. We believe that phase I of this model will not change how Part B drugs are acquired by providers or suppliers, or how drug manufacturers sell their products to providers, suppliers, or intermediaries such as wholesalers. CMS is carefully considering the comments received from stakeholders during the comment period on the proposed model to determine whether any adjustments to the model are needed.

Question. The Medicare Payment Advisory Commission (MedPAC) looked at invoice prices for 34 high expenditure drugs, many of them likely cancer drugs, and found that one-third were being sold at more than 102 percent of ASP. How does CMS expect oncologists (or other physician specialists) in small, rural and community-based practices to acquire necessary cancer drugs if they will be paid less than their acquisition cost?

Answer. CMS is aware of the unique challenges that patients and providers in rural areas and providers in small practices may face. The proposed rule set forth

our belief that the proposed payment rate of 102.5 percent of ASP plus $16.80 should be sufficient to cover the provider's or supplier's purchase price. Additionally, in the proposed rule, we estimated that overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. As part of the proposed rule, we specifically solicited comments on the potential effect that this proposed model may have on rural practices, how rural practices may differ from non-rural practices, and whether rural practices should be considered separately from other practice locations. We also solicited comments on any potential effects this proposed model may have on small practices, how small practices may differ from large practices, and whether small practices should be considered separately from other practices. These are important issues, and CMS is closely reviewing the comments received during the comment period to determine whether adjustments are needed.

Question. Has CMS conducted any analysis as to whether certain practices, especially those that are small and/or rural, would close or sell to a hospital?

Answer. There have been longstanding trends in site of service driven by market forces unrelated to what the proposed Part B Drug Payment Model would be testing.[1] This proposed Part B Drug Payment Model is intended to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. In the proposed rule, we estimated that, in the aggregate, rural practitioners would be estimated to experience a net benefit under phase I of the model. And overall, spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

Question. If practices are unable to provide drugs for which their acquisition cost exceeds the payment—and close or sell to a hospital as a result—it is possible that beneficiaries would forgo or delay receiving needed drug treatments? If so, what is the impact on beneficiary health and program expenditures on account of the likely increase in other services, including expensive preventable hospital admissions and readmissions?

Answer. The proposed Part B Drug Payment Model is intended to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. The proposed rule set forth our belief that the proposed payment rate of 102.5 percent of ASP plus $16.80 should be sufficient to cover the provider's or supplier's purchase price.

CMS's evaluation of the Part B Drug Payment Model would test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

Additionally, as discussed in CMS's testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

In addition to the current Medicare claims appeals processes, which would remain available, CMS is proposing to establish a pre-appeals payment exceptions review process for phase II of the model which would allow the provider, supplier, or beneficiary to explain why an exception to the model's value-based payment policy is warranted in the beneficiary's circumstance. This process would be in addition to, not in lieu of, the current appeals process. Payment exceptions decisions would be issued within 5 business days of receipt of the request for a payment exception. CMS sought comment on these proposed beneficiary protections and values public input. We are carefully reviewing all the comments we received during the comment

[1] MedPAC March 2016 report, *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0.*

period, and CMS looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

SHIFT IN SITE OF SERVICE; POTENTIAL FOR CONSOLIDATION

Question. Has CMS evaluated how this demonstration could impact the ability of a physician practice in the community, including those in oncology, rheumatology, ophthalmology, and others, to remain independent and keep patients out of more costly care settings?

Answer. The proposed Part B Drug Payment Model is intended to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. The proposed rule includes estimated impacts of the proposed rule on physician specialties, including oncologists, rheumatologists and ophthalmologists. In the proposed rule, we estimated that overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

Question. The cost of treating patients in community-based clinics treating cancer (and other conditions) as opposed to the outpatient hospital setting results in significantly lower costs to both patients and the Medicare program. What steps is CMS taking to ensure this demonstration will not push patients out of community care settings into the more costly hospital based setting?

Answer. Under the proposed Part B drug payment model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits. We know that under the current Part B cost structure, beneficiaries utilizing Part B drugs, especially those using higher cost drugs, may face significant out-of-pocket expenses. To the extent that prescribing patterns do shift towards lower cost drugs, in aggregate, beneficiaries would benefit along with the Medicare program.

As discussed in CMS testimony, CMS would also be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstance. CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care for Medicare beneficiaries.

Question. What impact will this proposal have on consolidation in the health-care system and the continued shift of care from the physician office to the hospital?

Answer. The proposed Part B Drug Payment Model was intended to lead to better value for Part B by encouraging providers and suppliers to choose drugs that are higher value, while preserving or enhancing the quality of care provided to Medicare beneficiaries. There have been longstanding trends driving changes in site of service driven by market forces unrelated to what the proposed Part B Drug Payment Model would test.[2]

While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. In the proposed rule, overall, we estimated spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

[2] MedPAC March 2016 report, *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0.*

Question. How will CMS track, and respond to, shifts in the site of care that may result from the proposed demonstration? What protections will CMS take to ensure that the demonstration does not further exacerbate the existing trend of hospital-physician consolidation?

Answer. As discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns, as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

BENEFICIARY IMPACT AND ENGAGEMENT

Question. As the proposed rule does not contain detail on how CMS will assess beneficiary access to needed drugs and the quality of care they receive for their conditions during the course of the demonstration nor the evaluation of it, please indicate: the mechanisms the agency has in place, or plans to develop, to track patient access to Part B drugs; and the plan to monitor patient outcomes in real time to ensure patients are accessing appropriate courses of treatment.

Answer. CMS's evaluation of the Part B Drug Payment Model would test the proposed innovative health-care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

Additionally, as discussed in CMS's testimony, CMS would also be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

Question. What quality measures will the agency use to determine if patients are receiving not just appropriate but high quality care?

Answer. CMS's proposal to evaluate the Part B Drug Payment Model would focus upon whether the intervention reduces costs while maintaining or improving quality of care. We proposed to examine the model impact at the provider and supplier level and at the beneficiary level. The evaluation would address questions such as: what is the impact on quality of care, access to care, timeliness of care, and the patient experience of care? It also could include assessments of prescribing and utilization patterns, health outcomes, Medicare expenditures, provider and supplier costs, and other potential impacts of interest to stakeholders.

Question. How will the agency act fast enough to address any access, quality, or outcome problems identified so as to ensure that beneficiary care is not jeopardized or beneficiaries are otherwise put at risk?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. In accordance with the statute, CMS will modify or terminate the model if, after testing has begun, the Part B Drug Payment Model is not expected to improve or maintain the quality of care for beneficiaries.[3]

Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to

[3] *https://www.ssa.gov/OP_Home/ssact/title11/1115A.htm.*

explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstance.

Additionally, as discussed in CMS's testimony, CMS would also be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

Question. Does CMS plan to track the impact of this demonstration on long-term biopharmaceutical innovation?

Answer. In phase I of the model, CMS proposed to implement a variation to the add-on component of Part B drug payment methodology in different geographic areas of the country. We would test whether an alternative approach for the ASP add-on payment would strengthen the financial incentive for physicians to choose higher value drugs. While this proposed approach would address the add-on to the manufacturer's ASP, it does not directly address the manufacturer's ASP, which is a more significant driver of drug expenditures than the add-on payment for Part B drugs.

As required by statute, CMS's evaluation of the Part B Drug Payment model would focus upon whether the intervention reduces costs while maintaining or improving quality of care. As proposed, the evaluation would focus on key policy questions such as: payment, prescribing patterns, prescriber acquisition prices, outcomes/quality, unintended consequences and variable model effects. In addition, in the Part B Drug Payment Model proposed rule, CMS sought comments on other potential questions for inclusion in the evaluation of the Part B Drug Payment Model. We are assessing the comments received during the public comment period.

Question. Given that there is a concern about randomizing patients to treatment arms that may have fewer treatment options and diminished quality of care, does CMS plan to require patients to provide informed consent prior to participating in this demonstration?

Answer. Ensuring beneficiary access to high-quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers regardless of model arm. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted under the beneficiary's circumstances. In addition, CMS would be evaluating beneficiary access, quality of care, timeliness of care, and the patient experience of care during the model. For example, there would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model. CMS has released a fact sheet for beneficiaries that includes key information they need to know about the proposed model.[4] CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

OVERLAPPING MODELS AND INTERACTION WITH OTHER PAYMENT CHANGES

Question. The Oncology Care Model (OCM) officially launched on July 1st. Has CMS thoroughly evaluated how this proposed demonstration will impact those practices participating in the OCM? If both demonstrations run concurrently, how does CMS plan to track outcomes and attribute savings achieved to either model?

Answer. We acknowledged in the proposed rule that there is potentially greater overlap between the Part B Drug Payment Model presented in the proposed rule and the Oncology Care Model (OCM) in that both models would affect providers' and suppliers' incentives for the use of oncology drugs, but in different ways. The pro-

[4] *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08-02.html.*

posed rule set forth our belief that including OCM practices in the Part B Drug Payment Model would not compromise our ability to evaluate effectively the effects of either model. In the proposed rule, we solicited comment on our approach to include OCM practices. We also solicited comment on our proposal to include OCM practices, including the best mechanism to account for the overlap between these two models in our sample design and whether we should consider excluding OCM practices entirely. We are carefully reviewing all of the comments received during the comment period to determine whether adjustments are needed.

Question. Some have speculated that CMS will exempt oncologists participating in the OCM from this demonstration. While this would be a step in the right direction, it would not spare beneficiaries with cancer from potential adverse impact. How many oncologists are participating in the OCM and how many oncologists who treat Medicare patients are not participating?

Answer. The goal of OCM is to utilize appropriately aligned financial incentives to enable improved care coordination, appropriateness of care, and access to care for beneficiaries undergoing chemotherapy. OCM encourages participating practices to improve care and lower costs through an episode-based payment model that financially incentivizes high-quality, coordinated care. The Innovation Center expects that these improvements will result in better care, smarter spending, and healthier people. In June 2016, CMS announced that 195 practices and 17 non-Medicare payers are participating in the Oncology Care Model. More than 3,200 oncologists are participating in OCM from these physician practices, and these practices treat nearly a quarter of all Medicare Fee-for-Service beneficiaries with cancer who receive chemotherapy.[5]

Question. In 2015, Congress enacted physician payment reforms through the bipartisan Medicare Access and CHIP Reauthorization Act (MACRA) that encourage physicians to participate in alternative payment models (APMs). This Part B drug proposed demonstration significantly effects oncologists, rheumatologists, ophthalmologists, gastroenterologists, and physicians in other specialties that are interested in developing or participating in APMs. Doesn't this demonstration, especially with its reduced ASP based payment for many drugs, make it significantly harder for physicians to invest the time and resources to successfully participate in APMs as envisioned by MACRA and as the administration has made a priority?

Answer. The proposed Part B Drug Payment Model is intended to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. The proposed rule includes estimated impacts of the proposed rule on physician specialties, including oncologists, rheumatologists, and ophthalmologists. The proposed rule set forth our belief that the proposed payment rate of 102.5 percent of ASP plus $16.80 should be sufficient to cover the provider's or supplier's purchase price.

In the proposed rule, we estimated that overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

We know that physicians and other clinicians may need assistance in transitioning to the Merit-based Incentive Payment System (MIPS) created by the Medicare Access and CHIP Reauthorization Act (MACRA), and we want to make sure that they have the tools they need to succeed in a redesigned system. MACRA provided funding for technical assistance to small practices, rural practices, and practices in medically underserved health professional shortage areas (HPSAs).

CMS announced the availability of $20 million of this funding for on-the-ground training and education for Medicare clinicians in individual or small group practices of 15 clinicians or fewer. These funds will help provide hands-on training tailored to small practices, especially those that practice in historically under-resourced areas including rural areas, HPSAs, and medically underserved areas. As required by MACRA, HHS will award $20 million each year for 5 years, providing $100 million in total to help these practices successfully participate in the Quality Payment Program.

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[5] *http://www.hhs.gov/about/news/2016/06/29/hhs-announces-phvsician-groups-selected-initiative-promoting-better-cancer-care.html.*

In addition to MACRA implementation efforts, last month, CMS launched the second round of the Support and Alignment Networks under the Transforming Clinical Practice Initiative. TCPI is leveraging primary and specialist care transformation work and learning that will catalyze the adoption of APMs on a large scale. CMS is carefully considering the comments received from stakeholders on the Part B Drug Payment Model proposed rule and the proposed MACRA rule.

PHASE II POLICY IDEAS

Question. The proposed rule provides little detail on the numerous phase II policy ideas, while leaving it open that providers will have to participate in up to all five of the ideas as early as January 1, 2017. CMS has made comments subsequent to the release of the proposed rule seeming to acknowledge that, at a minimum, a multi-step process is needed to develop any of the ideas before they are even possibly workable. Does CMS plan to engage stakeholders in an iterative process before implementing any of these ideas?

CMS proposes that phase II include reference pricing, which would effectively limit payment for Part B drugs based on a CMS assessment of whether there is a "therapeutically similar" medicine available at a lower cost.

How will CMS identify "therapeutically similar" therapies considering the highly individualized reactions that patients can have to different treatments, especially biologicals that interact directly with a patient's own immune system.

Answer. Phase II of the proposed Part B Drug Payment Model would use tools currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. The proposed rule set forth our belief that some of these approaches, when appropriately structured, may be adaptable to Part B.

In the proposed rule, we proposed several value-based pricing tools: reference pricing, indications-based pricing, outcomes-based risk sharing agreements, and discounting or eliminating patient coinsurance amount. This group of tools would serve as a framework for interventions for selected Part B drugs. We would not apply all these tools to all Part B drugs but implement these tools in a limited manner for certain HCPCS drug codes after considering these tools' appropriateness to specific Part B drugs within these codes.

As we noted in the proposed rule, we would gather additional information on the proposed tools, including which specific Part B drugs would be suitable candidates for the application of specific tools within the group. CMS also proposed to finalize the implementation of specific tools for specific HCPCS codes after soliciting public input on each proposal by posting on the CMS website, and we would allow 30 days for public comment. CMS will also notify the public by posting on the CMS website of application of any VBP tools 45 days before implementation.

Question. Does CMS have a plan in place to address situations in which not every product in a therapeutic class is approved for the exact same set of clinical indications?

Answer. Under phase II of the proposed Part B Drug Payment Model, CMS would gather additional information on the proposed tools, including which specific Part B drugs are suitable candidates for the application of specific tools within the group. We would not apply all these tools to all Part B drugs but implement these tools in a limited manner for certain HCPCS drug codes after considering these tools' appropriateness to specific Part B drugs within these codes. CMS also proposed to finalize the implementation of specific tools for specific HCPCS codes after soliciting public input on each proposal by posting on the CMS website, and we would allow 30 days for public comment. CMS will also notify the public by posting on the CMS website of application of any VBP tools 45 days before implementation.

Furthermore, CMS has proposed a new pre-appeals payment exceptions review process under phase II of the model, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value based pricing policy is warranted in the beneficiary's circumstances.

Question. CMS proposes that phase II include indications-based pricing, which seeks to pay for treatment of different indications for a drug at different rates. Does CMS have the ability to track the specific indication for which a drug is provided through the current coding and claims processes?

Answer. CMS proposed to use indications-based pricing, which would pay varying prices for a given drug based on its varying clinical effectiveness for different indications that are covered under existing Medicare authority, specifically section 1861(t) of the Act, and existing national and local coverage determinations. Tracking a specific indication for which a drug is furnished is part of ensuring that items and services furnished are reasonable and necessary for Medicare coverage and payment.[6]

Question. What evidence would CMS use to determine a drug's effectiveness for each of the different indications?

Answer. In the proposed rule, CMS proposed to use indications-based pricing where appropriately supported by published studies and reviews or evidenced-based clinical practice guidelines to more closely align drug payment with outcomes for a particular clinical indication. Indications-based pricing decisions would reflect the clinical evidence available and strive to rely on competent and reliable scientific evidence from neutral and/or independent sources. As defined in the proposed rule, high quality evidence is comprehensive, relies on randomized trial designs where possible, and measures outcomes. Research findings should be valid, competent, reliable and generalizable to the Medicare population.

Question. Would the determination of effectiveness reflect the standard of care for individual patients?

Answer. As noted above, CMS proposed to use indications-based pricing where appropriately supported by published studies and reviews or evidence-based clinical practice guidelines to more closely align drug payment with outcomes for a particular clinical indication. As we stated in the proposed rule, research findings should be valid, competent, reliable and generalizable to the Medicare population.

Furthermore, CMS has proposed a new pre-appeals payment exceptions review process under phase II of the model, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value based pricing policy is warranted in the beneficiary's circumstances.

Question. CMS proposes that phase II include value-based contracting, which would determine the payment for a drug based on the outcome achieved by the patients taking it. How would the agency determine the desired outcome for a drug; *e.g.,* would it be done by agency officials, contractor personnel?

Answer. Under phase II of the Part B Drug Payment model, we proposed to test approaches for transitioning from a volume-based payment system into one that encourages or even rewards providers and suppliers who maintain or achieve better patient outcomes while lowering Part B drug expenditures. As we noted in the proposed rule, the market today uses the term "value based" to encompass a wide variety of different options designed to improve clinical results, quality of care provided, and reduce costs. The following example highlights one of the value based pricing tools currently in use, which was described in the proposed rule. We proposed to test one or more of these tools during phase II of the model.

We proposed to use indications-based pricing where appropriately supported by published studies and reviews or evidenced-based clinical practice guidelines to more closely align drug payment with outcomes for a particular clinical indication.

Indications-based pricing decisions would reflect the clinical evidence available and strive to rely on competent and reliable scientific evidence from neutral and/or independent sources. We understand that the quality of available evidence can vary for any given drug or indication. As defined in the proposed rule, high quality evidence is comprehensive, relies on randomized trial designs where possible, and measures outcomes. Research findings should be valid, competent, reliable, and generalizable to the Medicare population.

To protect beneficiaries and to allow for the consideration of special circumstances that may warrant the use of non-model payments in certain situations, we proposed a pre-appeals payment exceptions process for phase II of the model. CMS also sought comment on potential safeguards that could be implemented with each of the value-based pricing tools to make certain that the intent of the policy is not undermined. We are carefully reviewing the comments received during the comment period.

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[6] *https://innovation.cms.gov/initiatives/part-b-drugs.*

Question. Does CMS believe that the existing data infrastructure is equipped to measure patient outcomes in real time and determine, in an evidence-based manner, that the outcomes are the direct result of treatment decisions? Has the agency assessed the impact of these phase II ideas on the ability to realize the promise of personalized medicine, which is a priority of the administration?

Answer. We proposed the Part B Drug Payment Model to test whether alternative drug payment designs would lead to a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. This proposed model's goals are consistent with the administration's broader strategy to encourage better care, smarter spending, and healthier people by paying providers and suppliers for what works, unlocking health-care data, and finding new ways to coordinate and integrate care to improve quality.

Ensuring beneficiary access to high-quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits. As we noted in the proposed rule, we would gather additional information on the proposed value based pricing tools, including specific Part B drugs suitable for the application of these group of tools.

As stated above, CMS's proposed evaluation of the Part B Drug Payment Model would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care. In the context of our proposal regarding outcomes-based risk-sharing agreements, we also sought comment on methods to collect and measure outcomes, including parameters around standardizing value metrics based on differences in drug treatments and their targeted patient subpopulations.

In addition, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

IMMUNE DISORDER IMPACT

Question. The Part B drug demonstration as proposed will have an adverse impact on patients with auto-immune diseases such as rheumatic diseases, Crohn's Disease, and Lupus, among others. These patients face debilitating pain and suffering, often eased only by the use of targeted medications provided by or under the close supervision of a rheumatologist. Further, these diseases often precipitate or are associated with collateral chronic conditions and are often associated with heightened sensitivity to changes in medication.

Did CMS conduct any analyses on the impact of this proposed demonstration on patients with immune disorders?

Answer. Under the proposed Part B Drug Payment Model, beneficiaries, including those with immune disorders, would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstances. In addition, CMS would be evaluating beneficiary access and health outcomes during the model.

For example, there would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model. CMS values public input and looks forward

to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

Question. Which, if any, specialty societies and/or patient groups were consulted to assure that any reimbursement-driven change in medications would not negatively impact the health of patients with immune disorders?

Answer. We solicited comments on many different aspects of the proposed Part B Drug Payment Model such as scope of the model and the effects on small practices and practices in rural areas. In all, we received more than 1,350 comments from a wide range of stakeholders, including specialty societies and patient groups. The Department of Health and Human Services (HHS) also convened the HHS Pharmaceutical Forum where we heard from a broad range of stakeholders on opportunities to improve patient access to affordable prescription drugs, develop innovative purchasing strategies and incorporate value-based and outcomes-based models into purchasing programs in both the public and private sectors. Stakeholder input is very important to us, and is one key reason why we utilized the notice and comment rulemaking process in developing this model. We are carefully considering the comments received during the comment period to determine whether adjustments are needed. Our goal is to be responsive to public comments received during the comment period and input from the Congress.

Question. The proposed demonstration will have a significant impact on physicians that treat immune disorders. The vast majority of rheumatologists practice with at most 1 or 2 fellow physicians, and those practicing in rural areas often have solo practices. In fact, many smaller communities have access to few or no rheumatologists. Further, while the demand for rheumatology services is projected to grow significantly in the next decade, the number of practicing rheumatologists will only increase by just over 1 percent.

Did CMS examine the relative impact on rheumatologists by urban and rural location, or by size of practice?

Answer. We are aware of the unique challenges that rheumatologists and other types of practitioners in small practices or in rural areas may face. The Part B Drug Payment Model proposed rule includes estimated impacts of the proposed rule on physician specialties, including rheumatologists. In the proposed rule, we estimated that, in the aggregate, rural practitioners would be estimated to experience a net benefit under phase I of the model. And overall, spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model.

As part of the proposed rule, we specifically solicited comments on the potential effect that this proposed model may have on rural practices, how rural practices may differ from non-rural practices, and whether rural practices should be considered separately from other practice locations. We are carefully considering the comments received during the comment period to determine whether adjustments are needed.

Question. Did CMS undertake any distributional analyses of the affected specialty physicians, in particular whether its use of Primary Care Service Areas as an organizing principle was appropriate for a project affecting shortage specialties such as rheumatology?

Answer. CMS proposed Primary Care Service Areas (PCSAs) as a unit of analysis to meet the needs of the Part B Drug Payment proposed model. The PCSAs were developed with funding from the Health Resources and Services Administration (HRSA) to address health workforce planning and policy, and the PCSA datasets available from HRSA include measures of specialty physician capacity that can be used to examine their distributions.[7] CMS also solicited comment in the proposed rule for many topics that could affect the way the model test would have to address shortage specialties, including the scope of the model and the effect of the model on small practices and rural areas. We are reviewing all comments received during the comment period to determine whether adjustments are needed.

Question. Did CMS assess the impact of the demonstration on the health-care workforce, especially with respect to the number of rheumatology internship positions?

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[7] *http://bhpr.hrsa.gov/healthworkforce/data/primarycareserviceareas/index.html.*

Answer. We are aware of the unique challenges that rheumatologists in small practices or in rural areas may face. The Part B Drug Payment Model proposed rule included estimated impacts of the proposed model on physician specialties, including rheumatologists. However, CMS did not assess the impact of the model on the number of rheumatology internship positions for purposes of the proposed rule.

Question. My understanding is that Medicare Part B covers seven drugs to treat rheumatoid arthritis. It is also my understanding that it is very common for rheumatoid arthritis patients to try multiple treatments before they find the one that works well for them. Even once a patient is stable, they can stop responding to a treatment and may need to switch medications to continue to effectively manage their condition. For these patients the availability of multiple treatment options is the key to optimizing their health. Realizing that the proposed payment changes are may effectively limit the number of treatment options, doesn't this amount to CMS making decisions regarding the best treatment option as opposed to the physician and the patient?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted under the beneficiary's circumstances. In addition, CMS would be evaluating beneficiary access, quality of care, timeliness of care, and the patient experience of care during the model. For example, there would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model. CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

SELF-ADMINISTERED DRUGS

Question. What is the CMS rationale for including the self-administered drugs covered under Part B in the demonstration when the prescriber is not financially connected to the prescription? This scenario seems to be outside of the agency's primary stated purpose for the demonstration.

Answer. The Part B drug benefit includes many categories of drugs, and encompasses a variety of care settings. With limited exceptions, CMS proposed to include all Part B drugs in this model so that alternative payment approaches could be examined across the entire range of Part B drugs. CMS solicited comments on the drugs that were proposed for inclusion in the model. We are carefully reviewing the comments received during the comment period to determine whether adjustments are needed.

QUESTIONS SUBMITTED BY HON. PAT ROBERTS

Question. How does, or will, CMMI account for whether this test is putting the next generation of treatment advances at risk by stifling innovation, and subsequently new medicines, for Medicare patients due to the level of uncertainty in Medicare payment that this proposal creates?

Answer. In phase I of the Part B Drug Payment Model, CMS proposed to implement a variation to the add-on component of Part B drug payment methodology in different geographic areas of the country. We proposed to test whether an alternative approach for the ASP add-on payment would strengthen the financial incentive for physicians to choose higher value drugs. While this approach would address the add-on to the manufacturer's ASP, it would not directly address the manufacturer's ASP, which is a more significant driver of drug expenditures than the add-on payment for Part B drugs.

CMS's evaluation of the Part B Drug Payment Model would test the proposed innovative health care payment model in this proposed rule to examine its potential

to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care. In addition, in the Part B Drug Payment Model proposed rule, CMS sought comments on other potential questions for inclusion in the evaluation of the Part B Drug Payment Model.

Additionally, as discussed in CMS's testimony, CMS would also be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

Question. Does CMMI believe it has the authority to waive the Affordable Care Act's prohibition from using comparative effectiveness research findings in determining Medicare coverage? And if so, please provide the statutory citation from where this is derived.

Answer. Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. The statute gives the Secretary the authority to design and test payment and service delivery models that meet certain requirements as to spending and quality. For the Part B Drug Payment Model, we proposed to exercise this authority to test whether alternative drug payment designs discussed in the proposed rule would lead to spending our dollars more wisely for drugs paid under Part B, that is, a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Question. How does CMS plan to monitor and respond to site of care changes that may occur as a result of the proposal?

Answer. There have been longstanding trends driving changes in site of service driven by market forces unrelated to what the proposed Part B Drug Payment Model would be testing.[8] This proposed Part B Drug Payment Model is intended to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. In the proposed rule, we estimated that, in the aggregate, rural practitioners would be estimated to experience a net benefit under phase I of the model. And overall, spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

Question. How does CMS plan to monitor that patients' access to medications remains the same as prior to the model? If issues arise, how would the agency address the issue in a timely manner?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare

[8] MedPAC March 2016 report, *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0.*

claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted under the beneficiary's circumstances. In addition, CMS would be evaluating beneficiary access, quality of care, timeliness of care, and the patient experience of care during the model. For example, there would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

In addition, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures.

Question. CMMI is in the process of implementing the Enhanced MTM Management Model. How many applications did CMS receive, were they even across the 5 regions, how many Part D beneficiaries are expected to be affected by the demo? In addition, please provide a description of the types of models that you are working to implement with detail on the manner in which MTM is delivered—either in person or remotely.

Answer. The Part D Enhanced Medication Therapy Management (Enhanced MTM) model is an opportunity for stand-alone basic Prescription Drug Plans (PDPs) in selected regions to offer innovative MTM programs, aimed at improving the quality of care while also reducing costs. As part of the "better care, smarter spending, healthier people" approach to improving health delivery, CMS will test changes to the Part D program that would achieve better alignment of PDP sponsor and government financial interests, while also creating incentives for robust investment and innovation in better MTM targeting and interventions. The objectives for this model are for stand-alone basic PDP sponsors to learn how to "right-size" their investment in MTM services and identify and implement innovative strategies to optimize medication use, improve care coordination, and strengthen system linkages.

The Enhanced MTM model test will begin January 1, 2017 with a five-year performance period. CMS will test the model in 5 Part D regions: Region 7 (Virginia), Region 11 (Florida), Region 21 (Louisiana), Region 25 (Iowa, Minnesota, Montana, Nebraska, North Dakota, South Dakota, Wyoming), and Region 28 (Arizona). Eligible basic stand-alone PDPs in these regions, upon approval from CMS, can vary the intensity and types of MTM items and services based on beneficiary risk level and seek out a range of strategies to individualize beneficiary and prescriber outreach and engagement. Given that the model participants and their model strategies are still in the provisional acceptance phase, it would be premature to release any information on the model applicants, number of Part D beneficiaries impacted by the model, plans provisionally selected for the model and their proposed MTM model strategies before participants are finalized.

QUESTIONS SUBMITTED BY HON. JOHNNY ISAKSON

Question. I believe that health-care providers and patients should make treatment decisions based on individual patients' needs. If health-care providers are subject to CMS's proposed policies that place them under increased financial pressure, is it possible that CMS reimbursement policy changes will drive decision making rather than the individual needs of a patient?

Answer. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

CMS proposed in phase I of this model to test whether an alternative approach for the ASP add on would strengthen the financial incentives for physicians to choose higher value drugs.

As described in the proposed rule, the 6 percent add-on may create incentives for use of higher cost drugs when lower priced alternatives exist. To remove the financial incentive that may be associated with higher add-on payments, CMS proposed

in phase I to test whether an alternative approach for the ASP add-on would strengthen the financial incentives for physicians to choose higher value drugs.

Phase II of the proposed Part B Drug Payment Model would use tools currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. The proposed rule set forth our belief that some of these approaches, when appropriately structured, may be adaptable to Part B. CMS also proposed a pre-appeals exceptions review process for phase II of the model, which would create a mechanism for beneficiaries, providers, and suppliers to request an exception to Medicare's value-based pricing policy, if warranted in the beneficiary's circumstances. CMS is carefully considering the comments received from stakeholders during the comment period on the proposed model to determine whether adjustments are needed.

Question. How is CMS factoring in individual needs of patients with complex illnesses such as Parkinson's, Multiple Sclerosis, and others into its reimbursement proposals?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed Part B Drug Payment Model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits. We know that under the current Part B cost structure, beneficiaries utilizing Part B drugs, especially those using higher cost drugs, may face significant out-of-pocket expenses. To the extent that prescribing patterns do shift towards lower cost drugs, in aggregate, beneficiaries would benefit along with the Medicare program.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstances. In addition, CMS would be evaluating beneficiary access and health outcomes during the model. As discussed in CMS testimony, CMS would also be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model. CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

Question. If community providers—who will be hit hardest by these proposals—cannot afford to furnish these therapies to patients, patients will either have to forgo care or seek care in hospital outpatient departments. Won't this increase costs for the Medicare program given that treating patients in the hospital outpatient department is more expensive than treating them in the community setting?

Answer. There have been longstanding trends driving changes in site of service driven by market forces unrelated to what the proposed Part B Drug Payment Model would be testing. The Part B Drug Payment Model was proposed to lead to better value for Part B by encouraging providers to choose higher value drugs.

The proposed rule set forth our belief that the proposed payment rate of 102.5 percent of ASP plus $16.80 should be sufficient to cover the provider's or supplier's purchase price. The proposed rule presented information that, overall, spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model.

Under the proposed Part B drug payment model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

CMS's evaluation of the Part B Drug Payment Model would test the proposed innovative health-care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

In addition to the current Medicare claims appeals processes, which would remain available, CMS is proposing to establish a pre-appeals payment exceptions review process for phase II of the model which would allow the provider, supplier, or beneficiary to explain why an exception to the model's value-based payment policy is warranted in the beneficiary's circumstance. This process would be in addition to, not in lieu of, the current appeals process. Payment exceptions decisions would be issued within 5 business days of receipt of the request for a payment exception.

CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. Additionally, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

CMS sought comment on these proposed beneficiary protections and values public input. We are carefully reviewing all the comments we received during the comment period, and CMS looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

Question. Won't this also result in higher out-of-pocket costs for patients due to higher copays/coinsurance?

Answer. CMS's proposal to evaluate the Part B Drug Payment Model would focus upon whether the intervention reduces costs while maintaining or improving quality of care. We proposed to examine the model impact at the provider and supplier level and at the beneficiary level. The evaluation would address questions such as: what is the impact on quality of care, access to care, timeliness of care, and the patient experience of care. It also could include assessments of prescribing and utilization patterns, health outcomes, Medicare expenditures, provider and supplier costs, and other potential impacts of interest to stakeholders.

Question. If patients have to forgo care, won't this negatively impact their health, and increase Medicare expenditures due to otherwise preventable hospitalizations, surgical interventions, and physician offices visits as well as other expensive services?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed Part B Drug Payment Model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. CMS's proposed evaluation of the Part B Drug Payment Model would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

Additionally, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

Question. Did CMS account for these higher costs to Medicare when developing the proposed rule?

Answer. The Medicare Part B Drug Payment Model proposed rule presented information indicating that the model design would not favor hospitals over physician practices. Specifically, CMS estimated that overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. However, we received feedback from stakeholders on this issue. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

Question. I am concerned about the impact the proposed demonstration will have on "small" practices. However, I think it is important that we carefully consider what constitutes "small" in the context of the proposed demonstration. In this case, "small" isn't just necessarily the number of providers in a practice. "Small" could also be determined by the number of doses of a drug that a practice orders. Practices that do not order large quantities are less likely to be able to secure rebates or other discounts that high volume practitioners receive when purchasing medications. For example, in ophthalmology, a "small practice" might be one that orders 1,000 or fewer injections per year for the treatment of age-related macular degeneration.

How is CMS looking at what is considered a "small" practice to ensure that the demonstration does not negatively impact patient access to their needed treatment options?

Answer. In the proposed rule on the Part B Drug Payment Model, CMS estimated that overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. In addition, CMS solicited comments on any potential effects this proposed model may have on small practices, how small practices may differ from large practices, and whether small practices should be considered separately from other practices. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

QUESTIONS SUBMITTED BY HON. ROB PORTMAN

Question. Medicare Advantage plans must cover the same benefits as FFS, but their reimbursement is partially tied to fee for service costs. The Part B demo will change reimbursement for drugs covered under Part B covered drugs for the majority of the country if implemented as proposed. How does the demo interact with MA bids and benchmarks particularly after year one of the demo?

Answer. Under phase I of the proposed Part B Drug Payment Model, CMS proposed to modify the ASP add-on amount in a budget neutral manner. Overall, as proposed, Part B drug payment to practitioners, pharmacies, and hospitals by specialty in phase I of this proposed model would not change, as the ASP add-on revision was proposed to be budget neutral. We do not expect a sizable overall reduction in Part B drug spending associated with phase I of this model, but we do anticipate an incentive to use higher value drugs. The proposed rule set forth our belief that phase I of this model would not change how Part B drugs are acquired by providers or suppliers, or how drug manufacturers sell their products to providers, suppliers, or intermediaries such as wholesalers. The model only applies to payment for Part B drugs for beneficiaries with Medicare fee-for-service; Part D drugs and drug payment under Medicare Advantage plans are not included. However, any changes to Medicare FFS spending, whether or not they are attributable to this model, would be reflected in Medicare Advantage benchmarks in future years. As noted in the proposed rule, Medicare Part B currently covers and pays for a limited number of prescription drugs.

Question. CMS is currently testing a number of demonstration programs in the oncology space, including the oncology care model. How does the ASP demo relate to the OCM demo? If a provider is in the OCM demo, will they be forced to also participate in the ASP demo? What about for other wide-scale demos, particularly mandatory ones like the Comprehensive Care for Joint Replacement model? Similarly, can you explain in detail how the demo will interact with the push to move to alternative payment models for reimbursement for both Phase I and Phase II of the model?

Answer. As noted in the Part B Drug Payment Model proposed rule, there are possibilities of overlap between the proposed Part B Drug Payment Model and the Medicare Shared Savings Program, the Medicare Intravenous Immune Globulin (IVIG) Demonstration, and other Innovation Center payment models, such as the Oncology Care Model (OCM) and the Bundled Payments for Care Improvement (BPCI) initiative. In general, CMS proposed not to exclude beneficiaries, suppliers, physicians or providers in the Part B Drug Payment Model from other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program. For other models tested by the Innovation Center, we have worked to prevent duplication and to monitor arrangements that minimize duplication of effort. We expect limited overlap between this model and bundled payment models such as BPCI and

CJR, given that the incentives to reduce spending in those bundled payment models are not generally targeted at Part B drugs. As we also noted in the proposed rule, we anticipate undertaking similar efforts for the Part B Drug Payment Model.

We acknowledged in the proposed rule that there is potentially greater overlap between the proposed Part B Drug Payment Model and the OCM in that both models will affect providers' and suppliers' incentives for the use of oncology drugs, but in different ways. CMS proposed to include OCM practices in all arms of the Part B Drug Payment Model.

In the proposed rule, we solicited comment on our approach to include OCM practices, including the best mechanism to account for the overlap between these two models in our sample design and whether we should consider excluding OCM practices entirely. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

Question. The administration has promoted many initiatives and requested $1.1 billion from Congress to combat the prescription opioid and heroin abuse epidemic. The Surgeon General has also recently laid out a goal to reduce opioid prescriptions. In contrast, the Part B demo seeks to increase reimbursement for pain management providers in order to make the cuts to Part B drugs for most providers appear budget neutral. In fact, these providers will receive larger increases than any other provider category under the proposal. Given that the premise of the model stands on the notion that reimbursement for drugs incentivizes prescribing behavior, what is CMS' estimate for the impact this will have on prescribing of opioids and how will this impact other initiatives to decrease prescriptions for opioids and the opioid and heroin abuse epidemic overall.

Answer. Addressing the opioid crisis is a top priority for the administration, and the Secretary is committed to bipartisan solutions and evidence-informed interventions to turn the tide against opioid drug-related overdose and misuse. As a part of this effort, the Department of Health and Human Services (HHS) and CMS are committed to working with providers to encourage appropriate prescribing of opioids.[9]

While we share the concern regarding unnecessary opiate use, we believe it is important to distinguish between the types of opiate analgesics covered under Medicare Part B and those opiate analgesics covered under other parts of the Medicare program. With the exception of implanted pain pumps and palliative care, opiates furnished under the Medicare Part B drug benefit are generally not used for long-term analgesia. Instead, these short-acting injectable agents are typically used in incident to settings (*e.g.,* in the physician's office) for acute pain relief and procedure-related analgesia/sedation. Opiates furnished under the Medicare Part B drug benefit are not self-administered and must be administered by a physician in an office or hospital outpatient department. Also, these drugs generally would not be provided to patients to be used in the home, unlike oral and other self-administered opiate analgesics that are covered under Medicare Part D and dispensed at retail pharmacies. We also note that overall utilization for opiate analgesics under Medicare Part B is limited, although we are aware that a large portion of injectable morphine and hydromorphone use is associated with the care and treatment of terminally ill beneficiaries with cancer.

In the Part B Drug Payment Model proposed rule, we noted that the proposed flat fee of $16.80 would increase the payment for some low cost drugs. While we expect that contractors will continue to examine claims (as well as patterns of claims) for potentially unnecessary use (that is use that is not reasonable and/or necessary), we also sought comment on whether additional measures should be taken to limit add-on amounts, especially for very low cost drugs. As discussed, opioids covered under Medicare Part B are used in the physician practice setting are primarily used in a limited number of circumstances and are not typically administered to patients outside of the outpatient setting. CMS is carefully reviewing comments received on the proposed model during the comment period to determine if adjustments are needed.

Question. Can CMS align national provider identifiers to claims information and the ASP pricing file to determine if prescribing increases when prices and ASPs increase? Why or why not? If not, can CMS detail and provide the exact data that

[9] HHS Announces New Actions to Combat Opioid Epidemic, *https://www.hhs.gov/about/news/2016/07/06/hhs-announces-new-actions-combat-opioid-epidemic.html.*

indicates that the current ASP structure is contributing to increased prescribing of more expensive drugs when a cheaper alternative is available?

Answer. As a result of the design of the average sales price (ASP) payment methodology established in 1847A of the Act, CMS only has information on manufacturers' reported ASP, which is an average. Providers and suppliers do not report their drug acquisition costs to CMS and are not required to do so when submitting a claim.

CMS is able to determine from the claims data when utilization has increased. A relatively small number of drugs account for a significant share of Part B spending. The top 20 drugs in terms of Medicare payment account for 57 percent of total Part B spending while the top 10 account for 38 percent of total payments.[10]

Phase I of the proposed model would test a change in the percent add-on portion of the payment methodology, but would not alter the ASP reporting structure. The add-on provides a larger payment to a provider or supplier when that provider or supplier prescribes a more expensive drug than a cheaper drug. We proposed to change the add-on from a percentage to a flat fee plus smaller percentage to strengthen the financial incentive for physicians to choose higher value drugs.

Question. Did CMS explore smaller demonstration areas, such as CMS regions? Is it necessary to "test" the changes in payment methodology to the entire country in order to obtain valid results? How does CMS plan on differentiating the effects of this demo when layered on top of other demos and payment changes that are taking place in the Medicare program simultaneously?

Answer. In the Part B Drug Payment Model proposed rule, CMS solicited feedback from stakeholders on the geographic unit of the proposed model. In order to fully test the model, the proposed rule set forth three criteria for selecting the geographic unit. First, the areas would need to be sufficiently large so that most providers and suppliers do not have practice locations in multiple areas. Second, the areas would need to be sufficient in number to ensure adequate statistical power for evaluation of the model. And third the areas would need to have characteristics that are relatively similar when compared to one another so that observed changes can be more clearly attributed to the intervention and not to other factors.

As noted in the Part B Drug Payment Model proposed rule, there are possibilities of overlap between the proposed Part B Drug Payment Model and the Medicare Shared Savings Program, the Medicare Intravenous Immune Globulin (IVIG) Demonstration, and other Innovation Center payment models, such as the oncology care model (OCM) and the Bundled Payments for Care Improvement (BPCI) initiative. In general, CMS proposed not to exclude beneficiaries, suppliers, physicians or providers in the Part B Drug Payment Model from other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program. For other models tested by the Innovation Center, we have worked to prevent duplication and to monitor arrangements that minimize duplication of effort. We expect limited overlap between this model and bundled payment models such as BPCI and CJR, given that the incentives to reduce spending in those bundled payment models are not generally targeted at Part B drugs. As we also noted in the proposed rule, we anticipate undertaking similar efforts for the Part B Drug Payment Model.

CMS sought comment on our proposed approach and the potential interactions with existing models and payment provisions. We are currently reviewing comments we received during the comment period.

Question. Will CMS have an exceptions process if beneficiaries are negatively impacted by the demo? For example, if a rural provider decides to no longer treat patients, and the patient must travel a distance (say more than 50 miles) to a hospital to receive chemotherapy, will CMMI exempt the provider from the demo's payment reductions?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS' work. Under the proposed Part B Drug Payment Model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare

[10] ASPE Issue Briefing: Medicare Part B Drugs, Pricing, and Incentives, *https://aspe.hhs.gov/pdf-report/medicare-part-b-drugs-pricing-and-incentives.*

claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted under the beneficiary's circumstances. In addition, CMS proposed to evaluate beneficiary access and health outcomes during the model. CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

Additionally, while the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. In the proposed rule, we estimated that, in the aggregate, rural practitioners would be estimated to experience a net benefit under phase I of the model. And overall, spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. We are carefully considering the comments received during the comment period to determine whether adjustments are needed.

Question. Please detail the manner in which CMS will monitor patient access and quality outcomes compared to the control group under the current system. If either patient access or quality of care is determined to be harmed, what are CMS's plans for altering the model or making exceptions for patients who cannot access medications in a timely and affordable manner?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed Part B Drug Payment Model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. CMS's proposed evaluation of the Part B Drug Payment Model would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

As discussed in CMS testimony, CMS also would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

In addition to the current Medicare claims appeals processes, which would remain available, CMS is proposing for phase II to establish a new pre-appeals payment exceptions process which would allow the provider, supplier, or beneficiary to explain why an exception to the model's value-based pricing policy is warranted in the beneficiary's circumstances.

Question. Can CMS detail the metrics and methods it will use to determine success or failure of the demo for both phase I and phase II? In particular, what quality metrics are included and how will they be analyzed? If no quality metrics are included in the analysis, why not?

Answer. As required by statute, CMS's evaluation of the Part B Drug Payment model would focus upon whether the intervention reduces costs while maintaining or improving quality of care. We proposed to examine the model impact at the provider and supplier level and at the beneficiary level. As proposed, the evaluation would examine the impact on quality of care, access to care, timeliness of care, and the patient experience of care. It also could include assessments of patient experience of care, prescribing and utilization patterns, health outcomes, Medicare expenditures, provider and supplier costs, and other potential impacts of interest to stakeholders.

Question. CMS intends the demonstration to be budget neutral. In cases where there is only one targeted therapy and cheaper alternatives do not exist, which is often the case with diseases treated by Part B covered drugs, and the drugs will receive a lower reimbursement under the proposal, how is it possible to maintain budget neutrality under the proposal? In fact, Avalere estimated that any drug that costs more than $480 is the point at which a drug will be cut. Can CMMI detail

the number and percentage of drug administered under Part B that are both over and under the $480 threshold? How many of these drugs over $480 do not have a clinically equivalent or comparable alternative?

Answer. Under phase I of the Part B Drug Payment Model, we proposed to modify the ASP add-on amount to be 2.5 percent plus a flat fee of $16.80. We proposed to establish the amount of the flat fee to ensure total estimated payments under this model would be budget neutral to aggregate Part B spending, using the most recent year of available claims data. Said differently, while payments for expensive drugs would be lower, payments for less expensive drugs would be higher—resulting in a budget neutral impact.

Neither part of the Part B Drug Payment Model presupposes there are lower cost Part B drug alternatives available for all Medicare patients. Rather, phase I of the proposed model would test, in specific geographic areas, whether the alternative approach for the ASP add-on payment strengthens the incentives for physicians to choose higher value drugs, where appropriate and available.

Question. Since CMMI will be increasing payment rates for lower cost drugs, how will this impact beneficiary cost sharing? Beneficiaries are subject to 20 percent cost sharing for these drugs. Similarly, beneficiary costs have been proven to increase when outpatient provider offices are required by hospitals or if a patient must move to an inpatient to access services. If a provider office sells its practice because it cannot cover the cost of procuring more expensive drugs due to the cuts in reimbursement or if a provider office closes and patients must revert to an inpatient setting, how will patient cost sharing be impacted? Similarly, how will the Medicare trust fund and general treasury funds be impacted?

Answer. The Part B Drug Payment Model was proposed to lead to better value for Part B by encouraging providers to choose higher value drugs. The proposed rule set forth our belief that the proposed payment rate of 102.5 percent of ASP plus $16.80 should be sufficient to cover the provider's or supplier's purchase price. The proposed rule presented information that, overall, spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model.

Under the proposed Part B drug payment model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

CMS's evaluation of the Part B Drug Payment Model would test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

In addition to the current Medicare claims appeals processes, which would remain available, CMS is proposing to establish a pre-appeals payment exceptions review process for phase II of the model which would allow the provider, supplier, or beneficiary to explain why an exception to the model's value-based payment policy is warranted in the beneficiary's circumstance. This process would be in addition to, not in lieu of, the current appeals process. Payment exceptions decisions would be issued within 5 business days of receipt of the request for a payment exception.

CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. Additionally, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

CMS sought comment on these proposed beneficiary protections and values public input. We are carefully reviewing all the comments we received during the comment period, and CMS looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

Question. The President's budget includes a proposal to lower the ASP add on from 6 percent to 3 percent, which produces savings of $6.8 billion, according to CBO. The Part B demo proposes to lower ASP to 2.5 percent plus a dispensing fee

of $16.83 minus sequestration, yet CMS maintains the demo will be budget neutral. Please explain in detail how the proposal is budget neutral and how the demo wouldn't save money in Phase I, particularly after year one of the demo is completed.

Answer. Phase I would establish payment at ASP plus 2.5 percent and a flat fee per administration day as a budget neutral test. CMS proposed to derive the flat fee, which is not included in the President's budget proposal, from the difference in total payment between total payments with a 6 percent add-on percentage across Part B drugs in the most recently available calendar year claims and total estimated payment for Part B drugs in the same set of claims with a 2.5 percent add-on percentage to the flat fee. We stated in the proposed rule that we do not expect a sizable overall reduction in Part B spending associated with phase I of the model, but we do anticipate an incentive to use higher value drugs.

In the proposed rule, we articulated that we believe that removing the financial incentive that may be associated with higher add-on payments will lead to some reduction in expenditures during phase I of the proposed model. We also noted that an exact estimate of the amount of savings that might be achieved through behavioral responses is not readily available, and that prior research on behavioral changes following modifications to drug margins suggests that the modifications we propose to the 6 percent add-on are likely to change prescribing behavior.

Question. There are a number of payment changes taking place currently and in the near future for both outpatient providers and hospitals. Please provide a table detailing the changes that are scheduled to take place that the demo will impact or interact with over the next 3 years and estimate the accumulative total impact on payments for Part B drugs for various provider types in both urban and rural settings. These changes should include other demos taking place at CMMI, alternative payment models that will increase under MACRA, as well as the effects of sequestration, prompt pay, and others.

Answer. As noted in the Part B Drug Payment Model proposed rule, there are possibilities of overlap between the proposed Part B Drug Payment Model and the Medicare Shared Savings Program, the Medicare Intravenous Immune Globulin (IVIG) Demonstration, and other Innovation Center payment models, such as the oncology care model (OCM) and the Bundled Payments for Care Improvement (BPCI) initiative. In general, CMS proposed not to exclude beneficiaries, suppliers, physicians or providers in the Part B Drug Payment Model from other Innovation Center models or CMS programs, such as the Medicare Shared Savings Program. For other models tested by the Innovation Center, we have worked to prevent duplication and to monitor arrangements that minimize duplication of effort. We expect limited overlap between this model and bundled payment models such as BPCI and CJR, given that the incentives to reduce spending in those bundled payment models are not generally targeted at Part B drugs. As we also noted in the proposed rule, we anticipate undertaking similar efforts for the Part B Drug Payment Model.

We stated in the proposed rule that, overall, we believe that phase I of this model will not change how Part B drugs are acquired by providers or suppliers, or how drug manufacturers sell their products to providers, suppliers, or intermediaries such as wholesalers. Because total payments under this phase are not expected to change considerably, we anticipate that providers or suppliers will continue to buy and bill for Part B drugs that they furnish to their patients. In general, we estimated that phase I has an overall effect of modestly shifting money from hospitals and specialties that use higher cost drugs to specialties that use lower cost drugs.

CMS sought comment on our proposed approach and the potential interactions with existing models and payment provisions. We are currently reviewing comments we received during the comment period.

QUESTIONS SUBMITTED BY HON. DANIEL COATS

Question. While CMS's proposed mandatory demonstration project on Medicare Part B seeks to reduce cost, the unintended effect is likely to limit access to care for vulnerable populations. This projected impact is deeply concerning. I have heard from many Hoosiers who are concerned that their access to lifesaving medications will be compromised. Given the input from Congress and other interest groups, do you have any recommendations for how CMS could modify this proposal so all high-cost Part B medications are not adversely impacted?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed Part B Drug Payment Model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. CMS's proposed evaluation, the Part B Drug Payment Model, would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

As discussed in CMS testimony, CMS also would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

In addition to the current Medicare claims appeals processes, which would remain available, CMS is proposing for phase II to establish a new pre-appeals payment exceptions process which would allow the provider, supplier, or beneficiary to explain why an exception to the model's value-based pricing policy is warranted in the beneficiary's circumstances.

Question. Dr. Conway's testimony references that overall Medicare Part B payments have consistently risen over time. However, reimbursement based on ASP for Medicare Part B drugs is roughly around 3 percent of total Medicare spending. To break this down further, in Medicare Part B, medicines accounted for 10 percent of overall Part B spending in 2005. In 2013, medicines under Part B represented just over 9 percent of total Part B spending. Trends suggest that this proportion will remain stable over the next decade. Is there any concern that this demonstration project will create instability?

Answer. As we stated in the Part B Drug Payment Model proposed rule, based on our claims data, we estimate total Part B payments for separately paid drugs in 2015 were $22 billion. In 2007, the total payments were $1 1 billion; the average annual increase since 2007 has been 8.6 percent.[11] This significant growth has been largely driven by spending on separately paid drugs in the hospital outpatient setting, which more than doubled between 2007 and 2015, from $3 billion to $8 billion respectively.With the proposed model, CMS intended to remove any excess financial incentive for physicians to prescribe high cost drugs over lower cost ones when comparable low cost drugs are available. We stated in the proposed rule that, overall, we believe that phase I of this model will not change how Part B drugs are acquired by providers or suppliers, or how drug manufacturers sell their products to providers, suppliers, or intermediaries such as wholesalers. Because total payments under this phase are not expected to change considerably, we anticipate that providers or suppliers will continue to buy and bill for Part B drugs that they furnish to their patients.

We are carefully considering all the comments received from stakeholders during the comment period to determine whether adjustments are needed.

Question. In phase I of this proposal, these payment changes would disproportionately impact the most innovative drugs that treat smaller patient population—specifically cancer patients. With substantial advancements in Part B medicines in the near future, what is the rationale for creating uncertainty at a time when we need increased innovations that bring new medicines to Medicare patients?

Answer. In phase I of the Part B Drug Payment Model, CMS proposed to implement a variation to the add-on component of Part B drug payment methodology in different geographic areas of the country. We proposed to test whether an alternative approach for the ASP add-on payment would strengthen financial incentive for physicians to choose higher value drugs. While this approach would address the add-on to the manufacturer's ASP, it would not directly address the manufacturer's

[11] GAO report, "Medicare Part B Expenditures for New Drugs Concentrated Among a Few Drugs, and Most Were Costly for Beneficiaries" (GAO–16–12), October 2015, *http://www.gao.gov/products/GAO-16-12.*

ASP, which is a more significant driver of drug expenditures than the add-on payment for Part B drugs.

CMS's evaluation of the Part B Drug Payment Model would test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care. In addition, in the Part B Drug Payment Model proposed rule, CMS sought comments on other potential questions for inclusion in the evaluation of the Part B Drug Payment Model.

Additionally, as discussed in CMS's testimony, CMS would also be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

QUESTIONS SUBMITTED BY HON. DEAN HELLER

Question. The proposed demonstration is very broad in scope—it is a nationwide demonstration, covering virtually all Part B drugs for all Medicare beneficiaries across all settings of care. At full implementation, it appears that this demonstration will impact 75 percent of Part B providers nationally. This is larger than any previous CMMI demonstration. How did CMS arrive at the decision to test the Part B payment changes on this scale? Did CMS consider smaller sample sizes for the program? Why was a smaller test size rejected?

Answer. CMS solicited feedback from stakeholders on the geographic unit of the proposed model. In order to fully test this model, the proposed rule set forth three criteria for selecting the geographic unit. First, the areas would need to be sufficiently large so that most providers and suppliers do not have practice locations in multiple areas. Second, the areas would need to be sufficient in number to ensure adequate statistical power for evaluation of the model. And third the areas would need to have characteristics that are relatively more similar when comparing one another so that observed changes can be more clearly attributed to the intervention and not to other factors. We are carefully considering all of the comments received during the comment period.

Question. Other than the 5-year time limit for the proposed demonstration, what are the other limits on the demonstration's scope?

Answer. CMS is proposing a two phase model to test whether alternative payment approaches for Part B drugs improve value (relative to current drug payment approaches under Part B), and improve outcomes, while reducing expenditures for Part B drugs. CMS proposed two phases for the Part B Drug Payment Model. In phase I of the model, CMS proposed implementing a variation to the add-on component of Part B drug payment methodology in different geographic areas of the country. Phase I would establish payment at Average Sales Price (ASP) plus a 2.5 percent add-on percentage and a flat fee per administration day as a budget neutral test.

In phase II of this proposed model, CMS proposed to implement value-based purchasing (VBP) tools in conjunction with the phase I variation of the ASP add-on payment amount for drugs paid under Part B. Phase II would use tools currently employed by commercial health plans, pharmacy benefit managers (PBMs), hospitals, and other entities that manage health benefits and drug utilization. Specifically, CMS proposed to apply one or more VBP tools, such as indications-based pricing, reference pricing, and clinical decision support tools to Part B drugs.

We proposed that the model would run for 5 years; phase I would begin in late 2016 (no earlier than 60 days after the rule is finalized) and phase II would begin no sooner than January 1, 2017. We expected initiation of the VBP tools could take several years to fully implement. Our goal was to have both phases of the model in full operation during the last 3 years to collect sufficient data and to estimate

the effect of the alternative payment designs on beneficiary outcomes and Medicare expenditures.

We also proposed to exclude certain categories of Part B drugs from the model because we did not believe that all Part B drugs are appropriate candidates for including of the model. These include, but are not limited to, the following categories: contractor-priced drugs; influenza, pneumococcal and hepatitis B vaccines; drugs infused with a covered item of durable medical equipment for phase I; certain end-stage renal disease drugs; blood and blood products; and drugs in short supply. We are carefully considering stakeholder comments received during the comment period.

Question. Given the broad scope of the proposed demonstration, does CMS consider the demonstration to be a "test" versus a new Part B payment policy? If CMS does consider the proposed demonstration to be a true "test," please explain your conclusions in detail and the basis for your conclusions. If not, please explain why the proposed model does not conform to statutory requirement to test models.

Answer. Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries.

Models to be tested under section 1115A of the Act must address a defined population for which there are either deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. Section 1115A(b) of the Act describes a number of payment and service delivery models that the Secretary may choose to test, but the Secretary is not limited to those models. In addition, the statute directs the Secretary to focus on models expected to reduce program costs while preserving or enhancing the quality of care received by beneficiaries. We proposed to exercise this authority to test whether the alternative drug payment designs discussed in this proposed rule would lead to spending our dollars more wisely for drugs paid under Part B, that is, a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries. While we proposed to establish drug pricing under phase I of the proposed model to be budget neutral to total expenditures in the CY 2014 claims, we expected changes in prescribing behavior that would result in program savings.

Stakeholder input is very important to us, and is one key reason why we utilized the notice and comment rulemaking process in developing this model.

As permitted by section 1115A of the Act, we proposed testing the Part B Drug Payment Model within specified geographic areas. In phase I of the model, we proposed implementing a variation to the add-on component of Part B drug payment methodology in different geographic areas of the country. We would test whether the proposed alternative approach for the ASP add on payment, which is discussed in this proposed rule, would strengthen the financial incentive for physicians to choose higher value drugs. To eliminate selection bias, we proposed that all providers and suppliers furnishing any Part B drugs included in the Part B Drug Payment Model who are located in the geographic areas that are selected for inclusion in the model would participate.

We also proposed to use a control group to compare those regions where there is a change in Part B drug payment under the proposed model to regions where there is no change in Part B drug payment. We proposed to exercise this authority to test whether the alternative drug payment designs proposed in the proposed rule would lead to spending our dollars more wisely for drugs paid under Part B, that is, a reduction in Medicare expenditures, while preserving or enhancing the quality of care provided to Medicare beneficiaries.

In phase II of this proposed model, CMS proposed to implement value-based purchasing (VBP) tools in conjunction with the phase I variation of the ASP add-on payment amount for drugs paid under Part B. Phase II would use tools currently employed by commercial health plans, pharmacy benefit managers (PBMs), hospitals, and other entities that manage health benefits and drug utilization. Specifically, CMS proposed to apply one or more VBP tools, such as indications-based pricing, reference pricing, and clinical decision support tools to Part B drugs.

Question. Most models that have been tested by CMMI have been voluntary for participants, and the few mandatory models that CMMI has tested have been based on evidence from an initial, voluntary test. Why in this case has CMMI chosen to move forward with a demonstration that is mandatory at its initiation?

Answer. Section 1115A of the Social Security Act (the Act) authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. As stated in the proposed rule, we believe a model in which all providers and suppliers furnishing included Part B drugs in the selected geographic areas participate in the model would be appropriate to ensure that observed outcomes in each arm of the model would not suffer from selection bias inherent in a voluntary participation model and that observed outcomes could be generalized to all providers and suppliers billing Part B drugs. In addition, this would allow us to observe the experiences of an entire class of providers and suppliers with various characteristics, such as different geographies, patient populations, and specialty mixes, and to examine whether these characteristics would impact the effect of the model on prescribing patterns and Medicare Part B drug expenditures.

Question. In testing previous demonstrations, CMS has conducted extensive modeling to assess the potential unintended consequences of its design on providers and patients prior to initiating a model test. These model simulations have been released publicly. Has CMS conducted such modeling for this Part B demonstration? If CMS has not conducted simulations, please explain why. If it has conducted simulations, what do the results of this modeling show about the potential for unintended consequences or provider behavior changes? Why hasn't CMS released its findings?

Answer. The distributional impacts are presented in the proposed rule and are the projected effects of phase I of the proposed Part B Drug Payment Model. Phase I would establish payment at ASP plus 2.5 percent and a flat fee per administration day as a budget neutral test. CMS proposed to derive the flat fee from the difference in total payment between total payments with a 6 percent add-on percentage across Part B drugs in the most recently available calendar year claims and total estimated payment for Part B drugs in the same set of claims with a 2.5 percent add-on percentage to the flat fee. We stated in the proposed rule that we do not expect a sizable overall reduction in Part B spending associated with phase I of the model, but we do anticipate an incentive to use higher value drugs.

In the proposed rule, we articulated that we believe that removing the financial incentive that may be associated with higher add-on payments will lead to some reduction in expenditures during phase I of the proposed model. We also noted that an exact estimate of the amount of savings that might be achieved through behavioral responses is not readily available, and that prior research on behavioral changes following modifications to drug margins suggests that the modifications we propose to the 6 percent add-on are likely to change prescribing behavior.

We estimated the effects of the proposed change in payment policy by examining the estimated change in payment on various categories of providers and suppliers. In general, phase I would have the overall effect of modestly shifting money from hospitals and specialties that use higher cost drugs to specialties that use lower cost drugs. In aggregate, rural practitioners were estimated to experience a net benefit and rural hospitals were estimated to experience smaller reductions than urban hospitals.

We did not model the impact of phase II because the proposed rule invited extensive comment on which VBP tools would be appropriately applied to the Part B and hospital outpatient drug benefit and we cannot yet quantify the overall impact of VBP.

Question. How feasible will it be for CMS to prepare and build the systems, processes, and other infrastructure necessary to test the model within existing time and resource constraints? Will CMS be able to appropriately monitor the model and the activities of its participants to ensure program integrity?

Answer. CMS's proposed evaluation of the Part B Drug Payment Model would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care. In addition, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mor-

tality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

Question. The primary care service areas that CMS will use to randomize Part B providers into the demonstration are fairly small. As a result, practices with multiple locations could have sites that fall into different arms of the demonstration. How many practices will be experiencing multiple arms of the model?

Answer. CMS proposed Primary Care Service Areas (PCSAs) as a unit of analysis to meet the needs of the Part B Drug Payment proposed model. The PCSAs were developed with funding from the Health Resources and Services Administration (HRSA) to address health workforce planning and policy, and the PCSA datasets available from HRSA include measures of specialty physician capacity that can be used to examine their distributions.[12] PCSAs are areas defined by aggregating clusters of ZIP codes with the goal of representing service areas for office based primary health care services. As we outlined in our proposed rule, CMS considered a number of options before proposing to define regions by PCSAs. Based on our analysis, PCSAs were most appropriate when compared to defining the regions by ZIP codes or other options. We are reviewing all comments received during the comment period to determine whether adjustments are needed.

Question. Given the significant changes under Medicare Part B already passed by Congress, why did CMS decide to propose these changes before any formal guidance regarding the implementation of MACRA?

With passage of MACRA, many Medicare providers are engaged or will soon begin to engage in alternative payment models (APMs). Will this model hinder the ability of physicians, particularly oncologists, rheumatologists, ophthalmologists, and other specialists who provide Part B medicines as part of their practice to participate and succeed in APMs? How will changes under the demo impact physician practices' ability to capture bonus payments earned under MACRA?

Answer. The proposed Part B Drug Payment Model is intended to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. The proposed rule includes estimated impacts of the proposed rule on physician specialties, including oncologists, rheumatologists and ophthalmologists. The proposed rule set forth our belief that the proposed payment rate of 102.5 percent of ASP plus $16.80 should be sufficient to cover the provider's or supplier's purchase price. In the proposed rule, we estimated that overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. We are carefully considering the comments received during the comment period to determine whether adjustments are needed.

We know that physicians and other clinicians may need assistance in transitioning to the MIPS created in MACRA, and we want to make sure that they have the tools they need to succeed in a redesigned system. The Congress provided funding in MACRA for technical assistance to small practices, rural practices, and practices in medically underserved HPSAs.

CMS announced the availability of $20 million of this funding for on-the-ground training and education for Medicare clinicians in individual or small group practices of 15 clinicians or fewer. These funds will help provide hands-on training tailored to small practices, especially those that practice in historically under-resourced areas including rural areas, HPSAs, and medically underserved areas. As required by MACRA, HHS will award $20 million each year for 5 years, providing $100 million in total to help these practices successfully participate in the Quality Payment Program.

In addition to MACRA implementation efforts, CMS launched the second round of the Support and Alignment Networks under the Transforming Clinical Practice Initiative. TCPI is leveraging primary and specialist care transformation work and learning that will catalyze the adoption of APMs on a large scale. CMS is carefully considering the comments received from stakeholders on the Part B Drug Payment Model proposed rule and the proposed MACRA rule.

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[12] *http://bhpr.hrsa.gov/healthworkforce/data/primarycareserviceareas/index.html.*

Question. With the ongoing demands of a changing health-care system, has CMS considered the feasibility of physician practices being able to successfully implement changes of this magnitude in such a short period of time?

Answer. CMS is cognizant of challenges physicians face; we have heard from numerous clinicians who tell us that they want to focus on delivering the care that is best for their patients, not on reporting or paperwork. Many of CMS's payment systems require annual updates. For each of these updates CMS provides outreach to physicians to help them better understand the changes.

We proposed that the model would run for 5 years; phase I would begin in late 2016 (no earlier than 60 days after the rule is finalized) and phase II would begin no sooner than January 1, 2017. CMS will also notify the public by posting on the CMS website of application of any VBP tools 45 days before implementation. We expected initiation of the VBP tools could take several years to fully implement. We received numerous comments from stakeholders regarding the proposal and are working to review the comments received during the comment period.

Question. Numerous studies have found that the cost of cancer care is more expensive for beneficiaries and the Medicare program when it is delivered in the hospital setting. To what extent do the changes proposed by CMS create the risk of shifting more care into higher cost settings, like hospital outpatient departments? What effect will this have on beneficiary access to care in their communities and beneficiary cost sharing for Part B services? Has CMS considered the potential for site-of-service shifts in its analysis of the model's impact? If not, why wasn't this considered?

Answer. The Part B Drug Payment Model was proposed to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. There have been longstanding trends driving changes in site of service driven by market forces unrelated to what the Part B drug payment model is testing.[13]

While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. In the proposed rule, we estimated overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. We are carefully considering the comments received during the comment period to determine whether adjustments to the model are needed.

Question. Will CMS need to issue an amendment to the contracts with Medicare Administrative Contractors (MACs) to implement this model for either phase I or phase II or will all of the changes required under the model be covered under their current scope of work?

Has CMS considered whether additional payments will be required under revised MAC contracts?

Answer. Many of CMS's payment systems require annual updates, which are implemented by the MACs. The Medicare Administrative Contractors (MACs) would process claims under phase I of the model and would update their systems to reflect the model pricing. For phase II, CMS proposed that there would be a VBP contractor that CMS would contract with to assist in implementation of the VBP tools included in this phase of the model.

Question. With so many different parts of the country being subject to different Part B reimbursement methodologies (particularly in phase II), how will CMS monitor MAC implementation to ensure the model is being conducted properly and without fraud or error?

Answer. CMS conducts vigorous oversight of its MACs. CMS routinely collects various types of data from MACs, has regular calls with MACs, makes MAC performance information publicly available, and meets with providers and the industry as requested to discuss policy and operational concerns. CMS also oversees MAC reviewer training and conducts accuracy reviews.

Question. In phase II, does CMS envision a role for MACs in using the tools proposed in the rule (*e.g.,* reference based pricing, indications based pricing, clinical decision tools)? Or will CMS be making only national determinations? If the latter,

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[13] MedPAC, March 2016 report, *http://www.medpac.gov/docs/default-source/reports/chapter-3-hospital-inpatient-and-outpatient-services-march-2016-report-.pdf?sfvrsn=0.*

will CMS continue to follow local coverage determinations and policies or will CMS waive these requirements?

Answer. Phase II of the Part B Drug Payment Model would use tools currently employed by commercial health plans, pharmacy benefit managers (PBMs), hospitals, and other entities that manage health benefits and drug utilization. In the proposed rule, we articulated our belief that some of these approaches, when appropriately structured, may be adaptable to Part B.

In the proposed rule, we proposed several value-based pricing tools: reference pricing, indications-based pricing, outcomes-based risk sharing agreements, and discounting or eliminating patient coinsurance amount. This group of tools would serve as a framework for interventions for selected Part B drugs. We would not apply all these tools to all Part B drugs but implement these tools in a limited manner for certain HCPCS drug codes after considering these tools' appropriateness to specific Part B drugs within these codes.

We proposed using indications-based pricing to vary prices for a given drug based on its varying clinical effectiveness for different indications that are covered under existing Medicare authority, specifically section 1861(t) of the Act, and existing national and local coverage determinations.

In the proposed rule, we solicited comments regarding the proposed tools, including specific Part B drugs suitable for the application of this group of tools.

QUESTIONS SUBMITTED BY HON. SHERROD BROWN

CLARIFYING THE INTENT OF THE PART B DEMO

Question. The growth in the cost of Part B prescription drugs is unsustainable. The rapidly increasing costs have created a status quo where many seniors—who are often on fixed incomes—cannot afford these lifesaving medicines. Every day I get a call or a letter from an Ohioan who has trouble affording their prescription drugs. This is unacceptable, and it must be addressed. We cannot continue to ignore the rapidly rising cost of prescription drugs or prematurely halt any proposal designed to address the problem.

As you wrote in your testimony, Dr. Conway, Part B drug payments were estimated at $22 billion in 2015 alone. That is why CMS must act to find this solutions to this problem. As your testimony makes clear, the status quo—where increased Part B cost increases exceed inflation year after year after year—is unsustainable for taxpayers and for seniors.

The following three questions are clarifying questions to ensure my colleagues and I understand the intent and the scope of the demo.

First, does this proposed model make any changes to a Medicare beneficiary's benefit?

Second, does this proposed model make any changes to a beneficiary's drug coverage?

Third, under this proposed model, would a Medicare beneficiary lose access to any Part B drug?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstances. In addition, CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. CMS's proposed evaluation of the Part B Drug Payment Model would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS

proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

As discussed in CMS testimony, CMS also would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

THE ADDITION OF BENEFICIARY PROTECTIONS

Question. Although the demonstration is designed to make prescription drugs covered by Medicare Part B more affordable, there are some improvements that could be made to the model to ensure its success. For example, a series of suggestions submitted to the committee in a letter by organizations focused providing consumers with a voice, including AARP and the Medicare Rights Center, would help protect consumers and ensure constant monitoring of the demo.

One of the policy proposals they have is to create a dedicated ombudsman program for this model. An ombudsman could help monitor beneficiary and provider experiences throughout implementation of the model, publicly report on the findings, and act as a resource to help quickly resolve any potential beneficiary issues.

Will you please describe some of the additional beneficiary protections included in the demo, and if possible, share what additional consumer protections—such as an ombudsman program—may be incorporated in the final version?

Will CMS be monitoring claims data related to this demonstration real-time?

Can you describe the pre-appeals process for the demo? How will CMS educate providers and consumers on this process?

Answer. CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries. Ensuring beneficiary access to high-quality care and treatment is always at the forefront of CMS's work. We solicited comment regarding beneficiary protections in the proposed rule and are closely reviewing the comments we received during the comment period.

Coverage of drugs and all other Medicare benefits would be unaffected by the proposed model. CMS's proposed evaluation of the Part B Drug Payment Model would test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care. CMS proposed to evaluate the quality and costs associated with the proposal throughout the life of the model, including to evaluate ensure patient experience of care.

Additionally, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

In addition to current Medicare claims appeals processes, which would remain available, CMS proposed to establish a new pre-appeals payment exceptions process which would allow the provider, supplier, or beneficiary to explain why the model's VBP-tool based payment amount is not appropriate for the beneficiary. This exceptions process would be in addition to, not in lieu of, the current appeals process. Payment exceptions decisions would be issued within 5 business days of receipt of the request for a payment exception.

OUR GROWING MEDICARE POPULATION

Question. Medicare currently covers more than 55 million seniors and individuals with disabilities. That number is expected to grow exponentially over the next several years as more and more baby boomers age into the program.

Do you have a plan to address the fact that tens of thousands of individuals will age into Medicare during this demo? How do you plan to manage the influx of new patients? How will this compare to existing Medicare beneficiaries?

Answer. Medicare enrollment has increased from 19 million in 1966 to 58 million beneficiaries expected in FY 2017. In the future, CMS expects that the average monthly enrollment will expand from 57 million beneficiaries in FY 2016 to 75 million by FY 2026.

Coverage of drugs and all other Medicare benefits would be unaffected by the proposed model, including coverage of drugs and all other Medicare benefits for beneficiaries newly eligible for Medicare. Additionally, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. CMS's proposed evaluation of the Part B Drug Payment Model would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

QUESTIONS SUBMITTED BY HON. MICHAEL F. BENNET

Question. Dr. Conway, we have heard concerns that the acquisition costs for rural practices exceed the Medicare payment amount for certain cancer drugs, this could lead to patients needing to use hospital-based outpatient departments. Some physicians have stated that under the demo, they believe that they will not be reimbursed adequately and would no longer be able to administer infusions to patients, particularly in rural areas where patients already have to travel significant distances to see their specialists including oncologists and rheumatologists. As these specialists could stop providing services, we hear concerns that care will shift to costlier settings. Have you heard this concern, and is this potential access and health care spending issue something you are taking into account as you are going through comments?

Answer. The proposed Part B Drug Payment Model is intended to lead to better value for Part B by encouraging providers and suppliers to choose higher value drugs. The proposed rule includes estimated impacts of the proposed rule on physician specialties, including oncologists, rheumatologists and ophthalmologists. The proposed rule set forth our belief that the proposed payment rate of 102.5 percent of ASP plus $16.80 should be sufficient to cover the provider's or supplier's purchase price. In the proposed rule, we estimated that overall spending on drugs furnished in the office setting would increase while spending on drugs furnished in the hospital setting would decrease under phase I of the model. While the proposed rule presented information indicating that the model design would not favor hospitals over physician practices, we have received feedback from stakeholders on this issue. We are carefully considering the comments received during the comment period to determine whether adjustments are needed.

Question. Obviously, we here in Congress and you all at CMS have gotten a great deal of feedback from many that want to move forward and pay for value and quality but are concerned about access to both their provider and the right course of treatment. Can you talk about CMS's current engagement with the patient and provider community on this demonstration?

Answer. We solicited and received comments on many different aspects of the proposed model such as scope of the model and the effects on small practices and practices in rural areas. Stakeholder input is very important to us, and is one reason why we utilized the notice and comment rulemaking process in developing this model. We are carefully considering the comments we received during the comment period. Our goal is to be responsive to the public comments received during the comment period and input from the Congress.

In addition to the notice provided through the rulemaking process, CMS has proposed to engage in certain educational activities. Specifically, we proposed to develop an evidence-based clinical decision support tool and make prescribing pattern reports available to practitioners.

Question. As you are working on the final rule, are you considering any specialized protocols for treatments that are used in oncology or other specialty areas that do not have a lower cost therapeutic alternative? Along the same lines, are there considerations for patients with rare diseases that are limited to specific treatments?

Since most rare diseases do not have established treatment guidelines and quality measures, will CMS have alternative safeguards in place to ensure beneficiary access for those with a rare disease? How do you plan to engage with the rare disease patient stakeholder community as you work to address their concerns?

Answer. Ensuring beneficiary access to high-quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstance.

In addition, CMS has proposed to closely evaluate beneficiary access and health outcomes during the model. CMS's proposed evaluation of the Part B Drug Payment Model would also test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact on quality of care, access to care, timeliness of care, and the patient experience of care.

As discussed in CMS testimony, CMS also would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

CMS values public input and looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

Question. In your testimony you discussed maintaining the standard Medicare appeals process throughout the demonstration and including a new pre-appeals exceptions review process under phase II. Can you describe how the appeals process will operate in real time so that patients maintain access to needed medications? What can other Medicare appeals processes tell us in terms of how long it might take for patients to receive a response?

Answer. Under the Part B Drug Payment Model proposed rule, CMS proposed to establish a pre-appeals payment exceptions review process for pricing established under the value-based pricing section of phase II. This process would allow the provider, supplier, or beneficiary an opportunity to dispute payments made under phase II. This process would be in addition to, not in lieu of, the current appeals process, and would be available to any providers, suppliers, or beneficiaries receiving services in PCSAs assigned to one of the VBP arms. Providers, suppliers, and beneficiaries would have the opportunity to appeal any payment determination via the appeals mechanisms that currently exist outside of this model.

CMS has proposed that the payment exceptions decisions would be issued, in writing, within 5 business days of receipt of the request for a payment exception. Throughout this process, providers and suppliers would be prohibited from charging a beneficiary more than the applicable cost sharing, even if a payment exceptions request is not approved by the contractor or the payment amount determined by the contractor remains unchanged as a result of the appeals process.

QUESTIONS SUBMITTED BY HON. ROBERT P. CASEY, JR.

Question. People with disabilities have opposed the use of a measure called "quality-adjusted-life-years" or QALYs as a determinant of the value of health care. Currently, there is a statutory safeguard that prevents the agency from using this kind of cost effectiveness or QALY measure as the basis for Medicare policy in an effort to prevent discrimination against people with disabilities and other vulnerable populations.

What assurance can you give people with disabilities that CMS will not waive this safeguard?

The statute referenced is:

Sec. 1182 (42 U.S.C. 1320e–1).

(e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.

Answer. CMMI did not propose to waive 1182(e), and this Model will abide by the laws and regulations governing the Medicare program. Section 1115A of the Act authorizes the Innovation Center to test innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care furnished to Medicare, Medicaid, and Children's Health Insurance Program beneficiaries. Under the proposed Part B Drug Payment model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protection in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the current Medicare claims appeals processes, that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstance. CMS sought comment on this protection and values public input. In addition, CMS proposed to evaluate quality of care, access to care, timeliness of care, and patient experience of care during the model.

We are carefully reviewing all the comments we received during the comment period. CMS looks forward to continuing to work with stakeholders to ensure quality care and high value for Medicare beneficiaries.

Question. When it comes to pharmaceuticals, we have long recognized the important role played by drugs that are the only available therapies for their indications, which can include many drugs for rare diseases. For example, during drug development, the FDA grants promising therapies for rare diseases the "orphan drug designation," which can confer extra exclusivity if the drug is ultimately approved, and entitles the manufacturer to qualify for the Orphan Drug Tax Credit to help offset development costs.

Similarly, we must consider how changes to drug payment policy will impact patient access to drugs when there is no alternative therapy. One of the main concepts this demonstration is looking to test is the incentive to prescribe a more expensive drug to achieve higher reimbursement, but what precautions has CMS taken to ensure access when there is only one drug available for a rare condition? If a physician is no longer able to afford to prescribe the drug, what is the beneficiary supposed to do?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed model, beneficiaries would still have access to the same drugs and will retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed Part B Drug Payment Model would not affect drug coverage or any other Medicare benefits. We are carefully reviewing the comments we received during the comment period.

CMS's proposed evaluation of the Part B Drug Payment Model would test the proposed innovative health care payment model in this proposed rule to examine its potential to lower program expenditures while maintaining or improving the quality of care furnished to Medicare Program beneficiaries. One of the key evaluation questions that CMS proposed for this purpose pertained to the proposed model's impact

on quality of care, access to care, timeliness of care, and the patient experience of care.

Additionally, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

Question. Mental health advocates including the National Association for Mental Illness, the National Council for Behavioral Health, Mental Health America, and the American Foundation for Suicide Prevention have raised concerns about what these proposals mean for patients with mental illness. Many of these patients use Part B medications to treat their mental illness, but for others their mental illness is a comorbidity that impacts their adherence and response to treatments for cancer or other complex conditions.

How will CMS account for the role of mental illness, or other comorbidities, in determining treatment value in phase II of the demonstration?

Answer. Ensuring beneficiary access to high quality care and treatment is always at the forefront of CMS's work. Under the proposed Part B Drug Payment model, beneficiaries would still have access to the same drugs and would retain the complete freedom of choice of doctors, hospitals, and other providers or suppliers. The proposed model would not affect drug coverage or any other Medicare benefits.

Additional beneficiary protections in phase II of the proposal included a proposed pre-appeals payment exceptions review process, in addition to the standard current Medicare claims appeals processes that would allow the beneficiary, provider, or supplier to explain why an exception to Medicare's value-based pricing policy is warranted in the beneficiary's circumstance. In addition, CMS proposed to evaluate quality of care, access to care, timeliness of care, and patient experience of care during the model.

Additionally, as discussed in CMS testimony, CMS would be closely monitoring beneficiary access and health outcomes during the model. There would be a real-time claims monitoring program to track utilization, spending, and prescribing patterns as well as changes in site of service delivery, mortality, hospital admissions, and several other high-level claims-based measures. This would help ensure that Medicare beneficiaries will continue to have access to Part B drugs under the model.

QUESTIONS SUBMITTED BY HON. MARK R. WARNER

Question. On June 22, 2016, the Board of Trustees of the Federal Hospital Insurance and Federal Supplementary Medical Insurance Trust Funds released its annual report, showing that growth in the costs of prescription drugs paid by Medicare continue to exceed growth in other Medicare costs and overall health expenditures. As we move to a system that pays for value, not volume, this growth threatens the gains our country has made in helping to drive down health-care costs, after an unprecedented run of 5 years of slow growth. There are numerous reasons why patients and heath care payers are experiencing rising prescription drug costs, and the solutions are not simple.

The Department has the intended goal of linking 80 percent of Medicare payments to value by 2018, including 50 percent to alternative payment models such as bundled payments. While there has been substantial innovation in how health plans and government reimburse for hospital and physician services, payment for prescription drugs is often based on more traditional outcomes; for example, volume of product purchased.

In light of these circumstances, please consider the following questions:

Do risk-sharing agreements, in which payments are linked to agreed-upon patient outcomes, hold promise in improving how government reimburses for prescription drugs?

In the proposed demonstration, phase II will look at various models to "pay for value." What tools and resources do we have, whether from CMMI or in the private market, that can help generate the evidence we need to ensure that we pay for value?

Answer. CMS proposed and sought comment on a set of value based pricing tools to be used in phase II of the model that are currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. In the proposed rule, we stated our belief that some of these approaches, when appropriately structured, may be adaptable to Part B.

There are a number of innovative tools being used in the private sector. One example is risk-sharing arrangements that link the payment for drugs to patient health outcomes. As we highlighted in the proposed rule, the University of Washington's School of Pharmacy maintains the Performance Based Risk Sharing Database,[14] which currently lists detailed information on the 311 risk-sharing arrangements subject to participation fees and licensing agreements.

The private market also capitalizes on reference pricing, which refers to setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products. Like all other models, CMS analyzed practices from the private sector and sought public input regarding the proposed tools. CMS is currently reviewing the public comments we received during the comment period.

The Part B Drug Payment Model proposal is part of the administration's broader strategy to encourage better care, smarter spending, and healthier people by paying providers for what works, unlocking health care data, and finding new ways to coordinate and integrate care to improve quality.

Question. In your view, do we have enough objective data on clinical effectiveness to move towards value purchasing agreements on a large scale? If not, what investments are necessary to move in that direction? Do you believe that there are other entities, public or private, that should be conducting this research?

Answer. Phase II of the proposed Part B Drug Payment Model would use tools currently employed by commercial health plans, pharmacy benefit managers, hospitals, and other entities that manage health benefits and drug utilization. These tools have been used for years with positive results, and we believe that some of these successful approaches may be adaptable to Part B. We will test whether the implementation of the tools affects expenditures and outcomes.

In the proposed rule, we proposed several value-based pricing tools: reference pricing, indications-based pricing, outcomes-based risk sharing agreements, and discounting or eliminating patient coinsurance amount. This group of tools would serve as a framework for interventions for selected Part B drugs. We would not apply all these tools to all Part B drugs but implement these tools in a limited manner for certain HCPCS drug codes after considering these tools' appropriateness to specific Part B drugs within these codes. In the proposed rule, we solicited comment on the proposed tools, including specific Part B drugs suitable for the application of this group of tools.

Question. Phase II of the proposed demonstration will also include clinical decision support tools for providers and suppliers. How does HHS propose to ensure that patients and others are aware of this information, as well as the results of value-based evaluations?

Answer. The proposed two component clinical decision support (CDS) tool would be offered through a web-based format. This tool would allow participating physicians in the VBP arm of the model to conveniently access up-to-date literature and consensus guidelines, as well as feedback reports.

Physicians who voluntarily accessed the proposed educational CDS tool would be free to decide if and how they would apply information from the tool to their practice. This educational component would provide information on prescribing for specific indications that reflects up-to-date literature and consensus guidelines focusing on effective treatments as well as safe and appropriate drug use for specific diagnoses. For example, we anticipated that information would be listed and indexed to correspond to drugs and disease states or conditions that are commonly treated in Part B. This tool is not intended to act as or replace, in any way, the physician's medical judgment for the treatment of patient-specific clinical conditions nor is the tool intended to replace a practitioner's ability to order reasonable and necessary Part B drugs as appropriate.

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[14] *https://sop.washington.edu/department-of-pharmacy/performance-based-risk-sharing-database/*.

The proposed feedback report component of the CDS tool would provide information on Part B claims payment patterns for specific drugs and/or indications either nationally or within specific geographic areas. These reports would provide feedback on how an individual physician's drug claims patterns compare with local or national data or even recommended guidelines. This information would be intended for use solely to support a physician's interest in mindful prescribing.

Question. To what extent has CMS considered addressing statutory or regulatory impediments to the adoption of value-based contracts outside of this demonstration model?

Answer. The Part B Drug Payment Model proposed rule is part of the administration's broader strategy to encourage better care, smarter spending, and healthier people by paying providers for what works, unlocking health-care data, and finding new ways to coordinate and integrate care to improve quality.

The Affordable Care Act established tools such as the Medicare Shared Savings Program and the Center for Medicare and Medicaid Innovation to use alternative payment models to achieve better care, smarter spending, and healthier people. Alternative payment models are ways for Medicare to reimburse providers based on the quality of care rather than the number of services provided. Examples include accountable care organizations, advanced primary care medical homes, and models that bundle payments for episodes of care.

Before the Affordable Care Act, very few Medicare payments flowed through alternative payment models. By 2014, approximately 20 percent of payments were made through alternative payment models, and today more than 30 percent of payments are made through alternative payment models.[15] In addition to Medicare, dozens of insurance companies, health systems, employers, and organizations have joined CMS in setting their own goals to move to alternative payment models. As part of this effort, in 2015, HHS established the Health Care Payment Learning and Action Network to align efforts between government, private sector payers, employers, providers, and consumers to broadly scale these gains in better care, smarter spending, and healthier people.

PREPARED STATEMENT OF HON. ORRIN G. HATCH, A U.S. SENATOR FROM UTAH

WASHINGTON—Senate Finance Committee Chairman Orrin Hatch (R–Utah) today delivered the following opening statement at a hearing to examine the Centers for Medicare and Medicaid Services' (CMS) proposed drug rule for Medicare Part B:

I'd like to welcome everyone to this morning's hearing that will allow the committee to examine the Obama administration's proposed Medicare Part B drug demonstration. I would like to thank Dr. Patrick Conway from the Center for Medicare and Medicaid Services for testifying.

Today's topic is very important. The proposed CMS demonstration project would radically alter the ways in which Medicare pays for drugs and biologics treatments that physicians prescribe and administer to patients in the outpatient settings that are covered under Part B.

Typically, these are drugs and treatments that are used in a physician's office or hospital. They are used to treat vulnerable beneficiaries with serious medical conditions, such as cancer, macular degeneration, rheumatoid arthritis, neurological disorders, primary immunodeficiency diseases, and a number of rare illnesses.

From the day CMS made their proposed demonstration public this past March, I have made my opinion very clear: I believe this experiment is ill-conceived and likely to harm beneficiaries. It is an overreach on the part of CMS that, in my opinion, goes beyond the agency's statutory authority, extends nationwide, and requires all Medicare Part B providers to participate.

As we all know, the experiment would change the Part B payment system in two phases, both of which are very troubling—and that's putting it kindly.

Given these inherent concerns, I'd like to hear an explanation from CMS as to why they believe their new payment changes will not harm Medicare beneficiaries.

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[15] "HHS Reaches Goal of Tying 30 Percent of Medicare Payments to Quality Ahead of Schedule," *http://www.hhs.gov/about/news/2016/03/03/hhs-reaches-goal-tying-30-percent-medicare-payments-guality-ahead-schedule.html.*

So far, what they've given us lacks any such explanation or justification. And, that's not all that's missing from the elements of the demonstration that have been made public.

Indeed, this proposal is troubling—and, again, I'm being kind with that description—not only for what is in it, but what has been left out.

For example, with its proposal, CMS has not indicated the conditions in which a physician has the option to prescribe a high or low cost drug that have the same patient benefit.

In addition, CMS has not provided an analysis of how many physicians, including those in small and rural practices, would lose money purchasing needed drugs.

They have not provided an analysis of how often physicians would have to refer beneficiaries to the less-convenient, more costly hospital outpatient setting.

And, CMS has not yet indicated how it will assess the impact on beneficiary access and quality both during the course of the demonstration and the formal evaluation of it.

Not surprisingly, the proposed experiment has been widely condemned by experts and stakeholders.

Almost immediately after the proposed demonstration was released, we received a letter from over 300 stakeholder organizations asking for our help in getting CMS to withdraw the proposal. These organizations included: the Arthritis Foundation, the Caregiver Action Network, the Immune Deficiency Foundation, the Lung Cancer Alliance, and the National Alliance for Mental Illness.

The organizations that have reached out with concerns about how this proposal represents patients who suffer from the diseases treated by these drugs, including cancer, arthritis, mental illness, and HIV. They represent the physicians who treat the patients with these devastating conditions, including oncologists, rheumatologists, and ophthalmologists.

I have also heard many of these same concerns from my constituents. Many Utahns feel that the proposed demonstration would deprive them of the drugs that best treat their conditions and require them to have to travel great distances and incur significant additional expenses to receive needed care.

Obviously, Utah is not alone here. Patients and providers from virtually every State have weighed in on this matter, which prompted all of the Republican members of the Finance Committee to send a letter to Acting CMS Administrator Slavitt urging the withdrawal of the proposal.

That's right, 14 Senators from the only Senate committee with oversight jurisdiction sent a detailed and thoughtful letter to CMS about this proposal.

And, how did the agency respond? We received what essentially amounts to a form letter, thanking the committee members for sharing their views and noting that CMS will consider all public comments. It could not have been more dismissive in its tone.

That is the level of attention and seriousness CMS ascribes oversight from Congress. And, sadly, this is not an isolated incident. For 7 years now, the entire Obama administration has patronized, stonewalled, or flat-out ignored oversight efforts on the part of Finance Committee Republicans. There are countless examples.

Sometimes the agencies show disregard for the law—like when they refused to provide any meaningful response to numerous inquiries about illegal reinsurance payments issued under the so-called Affordable Care Act.

Other times, they discount our oversight role entirely—like when they denied Finance Committee staff access to last week's Medicare and Social Security Trustees Reports until the press conference putting the administration's own misleading spin on the reports was well underway.

I have, on numerous occasions, in writing, during hearings like this, and elsewhere, expressed my hope that the administration, as a whole, would change its ways and become more cooperative and transparent. I have asked countless nominees that have come before the committee to commit to being responsive to senators' inquiries. Yet, over 7 years, this unprecedented level of disregard has continued, unabated.

Given the short time left with this administration, I won't renew these calls for more cooperation and responsiveness today. I feel quite certain that there are no new improvements on the immediate horizon.

However, given that we have a high-ranking administration official before us today, I hope that, at the very least, we can finally get some straight answers to the many questions raised by CMS's Part B proposal.

I note that our witness, Dr. Conway, stated in an early May interview on the proposed demonstration that CMS "will interact with Congress and take feedback and make adjustments as necessary."

I do hope that our conversation today will be more consistent with that sentiment than the dismissive response letter shortly after that statement was made. The Senators on this committee—and more importantly, the constituents we represent—deserve at least that much.

LETTER SUBMITTED BY HON. ORRIN G. HATCH

March 17, 2016

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, DC 20510

The Honorable Paul Ryan
Speaker of the House of Representatives
U.S. House of Representatives
Washington, DC 20515

The Honorable Harry Reid
Minority Leader
U.S. Senate
Washington, DC 20510

The Honorable Nancy Pelosi
Minority Leader
U.S. House of Representatives
Washington, DC 20515

Dear Leader McConnell, Leader Reid, Speaker Ryan, and Leader Pelosi:

We, the 316 organizations listed below, are writing to express our strong concern with the Centers for Medicare and Medicaid Services' (CMS) March 8, 2016 proposed rule that would implement a new "Medicare Part B Payment Model." We believe that this type of initiative, implemented without sufficient stakeholder input, will adversely affect the care and treatment of Medicare patients with complex conditions, such as cancer, macular degeneration, hypertension, rheumatoid arthritis, Crohn's disease and ulcerative colitis, and primary immunodeficiency diseases. We previously sent a letter to Department of Health and Human Services (HHS) Secretary Sylvia Burwell asking her not to move forward with this type of initiative, and we now respectfully request that you ask CMS to withdraw the proposed rule.

Medicare beneficiaries—representing some of the nation's oldest and sickest patients—must often try multiple prescription drugs and/or biologics before finding the appropriate treatment for their complex conditions. These patients need immediate access to the right medication, which is already complicated by the fact that treatment decisions may change on a frequent basis. These vulnerable Medicare patients and the providers who care for them already face significant complexities in their care and treatment options, and they should not face mandatory participation in an initiative that may force them to switch from their most appropriate treatment.

A Center for Medicare and Medicaid Innovation (CMMI) initiative that focuses on costs rather than patients and health-care quality, implemented based on primary care service areas, rather than the unique challenges of patients, is misguided and ill-considered. Medicare beneficiaries with life-threatening and/or disabling conditions would be forced to navigate a CMS initiative that could potentially lead to an abrupt halt in their treatment. This is not the right way to manage the Medicare program for its beneficiaries.

As CMS contemplates payment and delivery system reforms, there is a critical need for transparent, comprehensive communications with stakeholders throughout the process. We were deeply disappointed that CMS only provided a limited opportunity for stakeholder input before announcing sweeping proposed changes to Medicare Part B drug payments. In doing so, the agency largely failed to consider stakeholder concerns that the initiative could adversely impact patients' access to life-saving and life-changing Medicare Part B covered drugs.

We believe these types of initiatives should be initially implemented in a targeted, patient-centered and transparent way that accounts for the unique needs of Medicare beneficiaries. In fact, CMMI is statutorily required to ensure that its initiatives target "deficits in care," and can only expand the scope and duration of a model after careful assessment of the model's impact on quality of care, patient access, and spending. We are very deeply concerned, therefore, that CMS' proposed Part B Model would be applied on a nationwide basis—to all states except Maryland, due to its all-payer model—and would include the "majority" of Part B drugs. Furthermore, given the success of the current Part B reimbursement methodology in ensuring patient access to the most appropriate treatments, it is unclear what "deficits in care" CMS is attempting to address in this incredibly wide-ranging initiative.

In the proposed rule, CMS expresses concern that the 6-percent ASP add-on payment "may encourage the use of more expensive drugs because the 6-percent add-on generates more revenue for more expensive drugs." This assumption fails to take into account the fact that providers' prescribing decisions depend on a variety of factors, including clinical characteristics and the complex needs of the Medicare population. Most importantly, there is no evidence indicating that the payment changes contemplated by the model will improve quality of care, and may adversely impact those patients that lose access to their most appropriate treatments. In fact, data suggests that the current Part B drug payment system has been *both* cost effective and successful in ensuring patient access to their most appropriate treatment, as Part B expenditures remain relatively stable [1] and Part B drugs account for just 3% of total program costs.[2]

Finally, it is important to understand that with the Budget Control Act, CMS has already cut Medicare reimbursement for physician-administered drugs by 2 percent, further impacting some providers' ability to administer essential drugs *at the current reimbursement rate.* It is imperative CMS acknowledges and evaluates the impact of the current, real payment rate and engages multiple stakeholders, starting with patients and providers, *before implementing a new, severe reimbursement cut* that is effectively ASP + 0.86 percent (plus a small flat fee). In closing, we urge you to ensure that our nation's oldest and sickest patients continue to be able to access their most appropriate drugs and services. We therefore request that you ask CMS to permanently withdraw the Part B Drug Payment Model from consideration.

Sincerely,

1 in 9: The Long Island Breast Cancer Action Coalition	Action CF
ADAP Advocacy Association (aaa+)	Advocates for Responsible Care (ARxC)
Aimed Alliance	Alabama Academy of Ophthalmology
Alabama Cancer Congress	Alabama Gastroenterological Society
Alaska Society of Eye Physicians and Surgeons	Alliance for Patient Access (AfPA)
Alliance of Specialty Medicine	Alzheimer's and Dementia Alliance of Wisconsin
American Academy of Allergy Asthma and Immunology (AAAAI)	American Academy of Ophthalmology
American Association of Diabetes Educators	American Bechet's Disease Association
American College of Mohs Surgery	American College of Rheumatology
American Gastroenterological Association	American Liver Foundation, Upper Midwest Division
American Society of Clinical Oncology (ASCO)	American Urological Association
AmerisourceBergen	Anticoagulation Forum
Arizona BioIndustry Association (AZBio)	Arizona United Rheumatology Alliance

[1] 2015 Medicare Trustees Report.
[2] Medicare Payment Advisory Commission, "Medicare Drug Spending;" presentation at September 2015 public meeting; available at: *http://www.medpac.gov/documents/september-2015-meeting-presentation-medicare-drug-spending.pdf?sfvrsn=0.*

Arkansas State Rheumatology Association	Arthritis Foundation
Asian Americans for Community Involvement	Association of Black Cardiologists
Association of Community Cancer Centers (ACCC)	Association of Idaho Rheumatologists
Association of Indian Physicians of Ohio	Association of Northern California Oncologists (ANCO)
Association of Women in Rheumatology (AWIR)	Asthma and Allergy Foundation of America, New England Chapter
Axis Advocacy	Biocom
BioFlorida, Inc.	BioForward
BioHouston	BioKansas
BioNJ	Bionorth TX
Bioscience Association of West Virginia	Biotechnology Innovation Organization (FKA Biotechnology Industry Organization)
BioUtah	Brain Injury Association of Georgia
California Academy of Eye Physicians and Surgeons	California Hepatitis C Task Force
California Life Sciences Association (CLSA)	California Rheumatology Alliance (CRA)
Cancer Support Community	Cancer Support Community Central Ohio
Cancer Support Community North Texas	CancerCare
Cardinal Health	Caregiver Action Network
Caring Ambassadors	Cascade AIDS Project
Center for Healthcare Innovation	Central Texas Rheumatology Society
Chicago Life Sciences Consortium (CLSC)	COA Patient Advocacy Network (CPAN)
Coalition of Hematology Oncology Practices (CHOP)	Coalition of State Rheumatology Organizations (CSRO)
Coalition of Texans with Disabilities (CTD)	Colon Cancer Alliance
Colorado BioScience Association	Colorado Gerontological Society
Colorado Rheumatology Association	Colorado Society of Eye Physicians and Surgeons (CSEPS)
Colorado State Grange	Community Access National Network (CANN)
Community Liver Alliance	Community Oncology Alliance (COA)
Connecticut Oncology Association (CtOA)	Connecticut Rheumatology Association
Cutaneous Lymphoma Foundation	Delaware Academy of Ophthalmology
Delaware BioScience Association	Dia de la Mujer Latina
Digestive Disease National Coalition (DDNC)	Digestive Health Physicians Association (DHPA)
Easter Seals Massachusetts	Eastern Pennsylvania Chapter, National Hemophilia Foundation
EDSers United Foundation	Elder Care Advocacy of Florida
Epilepsy Foundation of Greater Chicago	Epilepsy Foundation of Western Wisconsin
Fabry Support and Information Group	Florida Allergy, Asthma and Immunology Society (FAAIS)
Florida Gastroenterologic Society	Florida Psychiatric Society

Florida Society of Clinical Oncology (FLASCO)
Florida Society of Neurology
Florida Society of Ophthalmology
Florida Society of Rheumatology
Florida State Hispanic Chamber of Commerce
GBS/CIDP Foundation International
Georgia Bio
Georgia Chapter of the American College of Cardiology
Georgia Mental Health Consumer Network
Georgia Society of Clinical Oncology (GASCO)
Georgia Society of Rheumatology
Global Colon Cancer Association
Global Healthy Living Foundation
H.E.A.L.S of the South
Hawaii Society of Clinical Oncology
Health Coalition, Inc.
Healthcare Distribution Management Association
Healthcare Institute of New Jersey (HINJ)
Healthcare Leadership Council
HealthHIV
Hematology-Oncology Managers of New York (HOMNY)
Hepatitis Foundation International
iBio—Illinois Biotechnology Industry Organization
Idaho Society of Clinical Oncology
Idaho Society of Ophthalmology
Illinois Medical Oncology Society
Illinois Society of Eye Physicians and Surgeons (ISEPS)
Immune Deficiency Foundation (IDF)
Indiana Academy of Ophthalmology (IAO)
Indiana Health Industry Forum (IHIF)
Indiana Oncology Society
INDUNIV Research Consortium
International Cancer Advocacy Network (ICAN)
International Foundation for Autoimmune Arthritis (IFAA)
International Institute for Human Empowerment, Inc.
ION Solutions
Iowa Academy of Ophthalmology (IAO)
Iowa Biotechnology Association
Iowa Oncology Society
Iowa State Grange
Kansas City Area Life Sciences Institute, Inc.
Kansas Rheumatology Alliance
Kansas Society of Clinical Oncology
Kansas Society of Eye Physicians and Surgeons (KSEPS)
Kentuckiana Rheumatology Alliance
Kentucky Association of Medical Oncology (KAMO)
Kentucky Life Sciences Council
Large Urology Group Practice Association (LUGPA)
Life Science Washington
Louisiana Oncology Society
Lung Cancer Alliance
LUNGevity
Lupus Foundation of America (LFA), Indiana Chapter
Lupus Foundation of Colorado
Maryland DC Society of Clinical Oncology
Maryland Society for the Rheumatic Diseases (MSRD)
Massachusetts Association for Mental Health
Massachusetts Society of Eye Physicians and Surgeons (MSEPS)
Massachusetts, Maine and New Hampshire Rheumatology Association
MassBio
Mayors Committee on Life Sciences
McKesson
Medical Oncology Association of Southern California (MOASC)
Medical Partnership 4 MS
Medical Society of the State of New York
Men's Health Network

Mental Health Systems, Inc.
Metropolitan Atlanta Rheumatology Society (MARS)
MichBio—Michigan Biosciences Industry Association
Michigan Lupus Foundation
Michigan Osteopathic Association
Michigan Rheumatism Society
Michigan Society of Eye Physicians and Surgeons (MiSEPS)
Michigan Society of Hematology and Oncology (MSHO)
Midwest Oncology Practice Society (MOPS)
Minnesota Academy of Ophthalmology
Minnesota Society of Clinical Oncology
Mississippi Academy of Eye Physicians and Surgeons
Mississippi Arthritis and Rheumatology Society
Mississippi Oncology Society
Missouri Biotechnology Association (MOBIO)
Missouri Oncology Society
Missouri Society of Eye Physicians and Surgeons (MoSEPS)
Montana BioScience Alliance
Montana State Oncology Society
NASW–NC (National Association of Social Workers)
National Alliance on Mental Illness (NAMI)
National Alliance on Mental Illness Greater Des Moines (NAMI)
National Alliance on Mental Illness Iowa (NAMI)
National Alliance on Mental Illness Kentucky (NAMI)
National Alliance on Mental Illness Texas (NAMI)
National Association for Rural Mental Health
National Association of County Behavioral Health and Developmental Disability Directors (NACBHDD)
National Association of Hepatitis Task Forces
National Blood Clot Alliance (NBCA)
National Cancer Care Alliance
National Hispanic Medical Association
National Infusion Center Association (NICA)
National Medical Association (NMA)
National Minority Quality Forum
National MPS Society
National Patient Advocate Foundation
Nebraska Academy of Eye Physicians and Surgeons
Nebraska Medical Association (NMA)
Nebraska Oncology Society
Neurofibromatosis Mid-Atlantic
Nevada Oncology Society
New England Biotech Association (NEBA)
New Jersey Academy of Ophthalmology
New Jersey Association of Mental Health and Addiction Agencies, Inc. (NJAMHAA)
New Jersey Rheumatology Association
New Jersey Society for Oncology Managers (NJSOM)
New York State Ophthalmological Society
New York State Rheumatology Society
NewYorkBIO
NMBio
NORM—National Organization of Rheumatology Managers
North American Thrombosis Forum
North Carolina Biosciences Organization (NCBIO)
North Carolina Oncology Association
North Carolina Psychiatric Association
North Carolina Psychological Association
North Carolina Rheumatology Association (NCRA)
North Carolina Society of Eye Physicians and Surgeons (NCSEPS)

Northern New England Clinical Oncology Society
Ohio Association of Rheumatology
Ohio Foot and Ankle Medical Association
Ohio Gastroenterology Society
Ohio Hematology Oncology Society
Ohio Ophthalmological Society (OOS)
Oklahoma Academy of Ophthalmology
Oklahoma Society of Clinical Oncology
Oncology Managers of Florida
Oncology Nursing Society
Oregon Bioscience Association
Oregon Rheumatology Alliance
Oregon Society of Medical Oncology (OSMO)
Oregon State Grange
Oregon Urological Society
Patients Rising
PCa Blue Inc.
Pennsylvania Academy of Ophthalmology
Pennsylvania Bio
Pennsylvania Rheumatology Society
Pennsylvania State Grange
Pharmaceutical Research and Manufacturers of America (PhRMA)
Philadelphia Rheumatism Society
Phoenix Rheumatology Association
Physicians Advocacy Institute (PAI)
Premier Oncology Hematology Management Society (POHMS)
Prevent Blindness
Prevent Blindness, Ohio Affiliate
Prevent Cancer Foundation
Prostate Conditions Education Council (PCEC)
Puerto Rico Society of Ophthalmology
Pulmonary Hypertension Association
Quality Cancer Care Alliance (QCCA)
RetireSafe
Rheumatism Society of the District of Columbia
Rheumatology Alliance of Louisiana
Rheumatology Association of Iowa (RAI)
Rocky Mountain Oncology Society
Rush To Live
Salud USA
SCBIO
Society for Women's Health Research
Society of Utah Medical Oncologists
South Carolina Gastroenterology Association
South Carolina Oncology Society
South Carolina Rheumatism Society
South Carolina Society of Ophthalmology
South Dakota Biotech
South Florida Cancer Association
Southern California Rheumatology Society (SCRS)
Spina Bifida Association of Kentucky
State of Texas Association of Rheumatologists (STAR)
State of Texas Kidney Foundation
StopAfib.org
Taking Control of Your Diabetes (TCOYD)
Tech Council of Maryland
Tennessee Oncology Practice Society (TOPS)
Tennessee Rheumatology Society
Texas Association of Business
Texas Association of Manufacturers
Texas BioAlliance
Texas Healthcare and Bioscience Institute (THBI)
Texas Life Sciences Collaboration Center
Texas Nurse Practitioners
Texas Ophthalmological Association
Texas Society of Clinical Oncology
Texas State Grange
The American College of Surgeons/ Commission on Cancer
The Arizona Clinical Oncology Society
The Crohn's Colitis Effect
The Medical Alley Association
The Mended Hearts, Inc.
The Retina Society
The U.S. Oncology Network
The Vasculitis Foundation
U.S. Hereditary Angioedema Association

United States Cutaneous Lymphoma Consortium	Utah Ophthalmology Society
Veterans Health Council	Vietnam Veterans of America
Virginia Association of Hematologists and Oncologists	Virginia Biotechnology Association
Virginia Hematology Oncology Association (VAHO)	Virginia Society of Eye Physicians and Surgeons
Washington Academy of Eye Physicians and Surgeons	Washington Rheumatology Alliance
Washington State Medical Oncology Society	Washington State Prostate Cancer Coalition
Washington State Urology Society	Wellness and Education Community Action Health Network
West Virginia Oncology Society	West Virginia Rheumatology State Society
Wisconsin Academy of Ophthalmology	Wisconsin Association of Hematology and Oncology
Wisconsin Association of Osteopathic Physicians and Surgeons	Wisconsin Rheumatology Association
Wyoming Epilepsy Association	Wyoming Ophthalmological Society

cc: The Honorable Orrin Hatch
Chairman
Committee on Finance
U.S. Senate

The Honorable Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate

The Honorable Fred Upton
Chairman
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Frank Pallone
Ranking Member
Committee on Energy and Commerce
U.S. House of Representatives

The Honorable Kevin Brady
Chairman
Committee on Ways and Means
U.S. House of Representatives

The Honorable Sander Levin
Ranking Member
Committee on Ways and Means
U.S. House of Representatives

LETTER SUBMITTED BY HON. PAT ROBERTS,
A U.S. SENATOR FROM KANSAS

June 28, 2016

Hon. Orrin G. Hatch
Chairman
Committee on Finance
U.S. Senate
Washington, DC 20510

Hon. Ron Wyden
Ranking Member
Committee on Finance
U.S. Senate
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

The undersigned patient and disease advocacy organizations representing a diverse array of Medicare beneficiaries are writing to thank you for convening today's hearing on the proposed Medicare Part B Drug Payment Demonstration. As organizations that represent Medicare beneficiaries living with a broad range of chronic and disabling health conditions, we have a number of concerns with the proposed Demonstration put forward by the Centers for Medicare and Medicaid Innovation (CMMI) and appreciate that the Finance Committee is willing to engage in oversight regarding the design and potential impact of program on beneficiaries.

Many of our organizations have submitted comments to CMMI on this proposed Demonstration expressing concerns on a range of issues, including:

- While this has been deemed a "demonstration" by CMMI, participation will be mandatory for many physicians and their patients and will affect 75% of the

Medicare population, making it much larger than a typical demonstration project.
- The payment methodology outlined in Phase 1 of the Demonstration has significant potential to limit access to the full range of available treatments under Part B to treat serious illnesses and conditions such as cancer, arthritis, multiple sclerosis, primary immune deficiency, macular degeneration and schizophrenia.
- Patients often have to try several different treatment options before finding one that works for them. Under the Demonstration, patients could be forced to switch from the most appropriate treatment or discontinue treatment because of transportation hurdles.
- CMMI's Phase 2 proposals to engage value assessments of treatments based on the "average" patient fail to capture the complexity of medical co-morbidities and the diverse complex needs of individual patients. Many of the patients who will be affected have rare and/or chronic diseases and are not the average patient.
- There was a lack of stakeholder input from the beginning of this process, and many of the problems with the Demonstration could have been mitigated had patient groups been involved on the front end.
- There is concern that this Demonstration could have an impact beyond Part B, and ultimately affect patient access to Part D drugs.

While there are several consumer groups that have come out in support of this Demonstration, it is important to note that consumers and patients are two very different constituencies. Patients are the ones utilizing the health care system on a regular, on-going basis, and should be protected and considered most thoroughly throughout this process.

We are grateful for the Committee's willingness to carefully examine the proposed CMMI Demonstration with a particular focus on how it will impact access to treatment for Medicare beneficiaries that live every day with life threatening and chronic illnesses. We urge you to demand answers form CMMI and would encourage your efforts to block full implementation of this Demonstration until these questions are answered.

Thank you for your leadership in ensuring that the concerns of patients are addressed. Please contact Sandie Preiss, Vice President of Advocacy and Access at the Arthritis Foundation with any questions at spreiss@arthritis.org, 202–887–2910.

Sincerely,

AIDS Institute
Alliance for the Adoption of Innovations in Medicine (Aimed Alliance)
Alliance for Patient Access
American Autoimmune Related Diseases Association
Arthritis Foundation
Asthma and Allergy Foundation of America
Caregiver Action Network
COPD Foundation
Epilepsy Foundation
GBS/CIDP Foundation International
Global Healthy Living Foundation
Health HIV
Hemophilia Federation of America
Hepatitis Foundation International
Immune Deficiency Foundation
International Foundation for Autoimmune Arthritis
Lupus and Allied Diseases Association
Lupus Foundation of America
MLD Foundation
National Alliance on Mental Illness
National Psoriasis Foundation
NeedyMeds
Partnership to Improve Patient Care
Prevent Blindness
Pulmonary Hypertension Association
RetireSafe
Scleroderma Foundation
Sjogren's Syndrome Foundation
U.S. Hereditary Angioedema Association
Veterans Health Council
Vietnam Veterans of America

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

What underlies this debate, in my view, is the fact that the United States is in an era of miracle treatments and cures. There are drugs on the market today and close on the horizon that were science fiction not too long ago. The question now is whether Americans will be able to afford them. These treatments threaten to become a major strain on our health care programs, on insurers, and on family budgets across the country.

That was one of the big takeaways from the 18-month investigation Senator Grassley and I conducted on a bipartisan basis into the rollout of one blockbuster drug. You could see in that one case, a drug that treats Hepatitis C, the balancing act this country faces between miracle cures and limited resources to pour into prescribing them. And I believe this will be the pattern for years to come. Absent reforms, this is going to continue—lots of cures, and a big question mark when it comes to access and affordability.

Now, those Hepatitis C drugs are not the focus of this hearing. Today the committee will examine a demonstration project set to begin in Medicare Part B, which is the part of the program that covers outpatient care. Part B pays for a small share of the drugs many seniors are prescribed, and the demonstration would affect the way those drugs are paid for. The demonstration has brought to the forefront some big questions about how the United States is going to address the trend of climbing drug prices.

The fact is, seniors are getting pounded by drug costs. And in my view, there is an enormous amount of work that has to be done to guarantee that seniors have affordable access to the medications they need. In Medicare Part B, seniors' pocketbooks are often hit especially hard because their share of drug costs is a co-insurance instead of a co-pay. That means rather than a flat, manageable fee, some seniors are facing a huge burden, stuck paying a percentage of a drug's total cost. I look at that burden the same way I look at the rising out-of-pocket cost for seniors in Medicare Part D. For part D I've proposed an out-of-pocket cap to help protect seniors. And in my view, this committee ought to take a close look at ways to make sure seniors aren't getting clobbered in Part B as well.

There are also important questions to be addressed with respect to this demonstration project. That's why all the Finance Committee Democrats and I sent a letter in April to Andy Slavitt, the Acting Administrator of the Centers for Medicare and Medicaid Services, outlining key concerns we had about the impact this project would have on patients.

At their core, our concerns are about making sure that vulnerable seniors have access to life-saving medications. Protecting access is a big issue in rural areas where seniors today are often facing fewer choices and lower quality of care. And it's extremely important that the project not result in patients being told that they have to go get treatment at the hospital, where treatment is typically more costly and less convenient.

Finally, our letter said that this demonstration project has to sync up with the effort Medicare is making to move toward paying for treatment based on its value, rather than its volume. When you're focusing on the value and the efficiency of care, there's the potential to raise the quality of care for seniors while saving money at the same time.

I hope the committee is able to examine these issues carefully today as it looks at the Medicare Part B demonstration. I want to thank Dr. Conway for joining the committee here today, and I look forward to hearing his testimony.

COMMUNICATIONS

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Hon. Orrin G. Hatch
Chairman
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

Hon. Ron Wyden
Ranking Member
Senate Finance Committee
219 Dirksen Senate Office Building
Washington, DC 20510

Dear Chairman Hatch and Ranking Member Wyden:

The Academy of Managed Care Pharmacy (AMCP) appreciates the opportunity to submit comments for the record on the hearing titled "Examining the Proposed Medicare Part B Drug Demonstration" held on June 28, 2016. AMCP submitted detailed comments [1] to the Centers for Medicare and Medicaid Services (CMS) in response to the proposed rule titled "Medicare Program; Part B Drug Payment Model (CMS–1670–P)" published in the Federal Register on March 11, 2016.

AMCP is a professional association of pharmacists and other practitioners who serve society by the application of sound medication management principles and strategies to improve health care for all. The Academy's 8,000 members develop and provide a diversified range of clinical, educational, medication and business management services and strategies on behalf of the more than 200 million Americans covered by a managed care pharmacy benefit.

While AMCP was pleased to see a commitment by CMS to evaluate methods to move from quantity and process-orientated payments for drugs under Medicare Part B to payment policies focused on rewarding higher quality and improved patient outcomes, AMCP expressed concern that the proposal, as written, did not fully consider the unintended consequences to beneficiaries that may result from the scope and design of the model. AMCP offered comments on several elements that we believe were either missing from the proposed rule, could be improved upon, or required clarification. AMCP urged CMS to carefully consider comments received and release a revised proposed rule with an opportunity for additional stakeholder feedback prior to finalization and adoption to ensure that the perspectives of managed care pharmacy and other stakeholders are considered. AMCP recommended that after consideration of comments, CMS reissue the proposal focused on areas that could successfully achieve the objectives of improving outcomes and quality and lowering costs without jeopardizing beneficiary access to medications.

Specifically, AMCP commented that:

- **The Scope and Breadth of the Model Should be Narrowed**—The proposed rule would require significant and complex changes and could ultimately result in a mandatory nationwide pilot that would impact up to 75 percent of providers. CMS should narrow the scope in consultation with providers and health plans and pharmacy benefit management companies (PBMs) that have implemented value-based purchasing initiatives in the commercial market to determine the potential for success under Medicare Part B.

[1] AMCP comments to CMS Re "Medicare Program; Part B Drug Payment Model (CMS–1670–P)." Available at *http://bit.ly/27biTT5.* Accessed June 28, 2016.

- **The Model Should Include Pharmacists as Key Members of the Health Care Team**—Pharmacists play a critical role as members of the health care team by serving as the medication management experts to help patients achieve clinical goals, reduce overall health care costs, and improve patient satisfaction. CMS should include pharmacists as key members of the health care team for phase II of the model to achieve enhanced benefits to Medicare beneficiaries through a collaborative approach to medication management.
- **The Model Should Create an Allowance for Formularies and Utilization Management Tools**—The proposed rule does not accommodate the use of pharmacy and therapeutics (P&T) committees established by health plans and PBMs to develop formularies for Medicare Part B or allow for the use of utilization management tools, which are elements that have been key to the success in decreasing costs, improving quality, and increasing value in Medicare Part D and the commercial market. CMS should consider the inclusion of a requirement to establish a Part B formulary with appropriate utilization management tools facilitated by health care providers, health plans, and PBMs under phase II of the model.
- **The Model Should Detail How VBP Tools Will Be Monitored and Evaluated**—CMS should release detailed plans for how it will evaluate the model's success, including specific clinical end points (such as quality of life, patient-reported outcomes, and survival rates).
- **The Model Should Focus on Targeted Disease States**—AMCP is concerned that the proposed rule is overly ambitious in including Part B drugs for all disease states in the model. CMS should reevaluate the scope of the model and focus on specific disease states that are prevalent in the Medicare population that have multiple therapies available with non-significant differences in clinical benefit but significant differences in cost of therapy, such as the treatment of age-related macular degeneration. In addition, CMS should also consider disease states and drug categories where biosimilars are entering the marketplace such as psoriasis, rheumatoid arthritis, and white blood stimulants.
- **The Model Should Require Documentation of Part B Drug Claims Using NDC Numbers**—A barrier to evaluating the success of VBP tools in Part B is the current method of documenting drugs under Part B using Healthcare Common Procedure Coding System (HCPCS) codes and not National Drug Code (NDC) numbers. The ability to track the drug administered to the specific NDC number is critical to truly implement VBP tools as they are used today in Medicare Part D and in the commercial market. CMS should require documentation of NDCs on all Medicare Part B claims.
- **The Model Should Evaluate the Impact on Specialty Care Providers**—Primary Care Service Areas (PCSAs) may not be the most appropriate geographic unit for specialty care providers, as specialty care providers are typically located in very different geographical areas and practice settings than a traditional primary care provider, and often entail networks that may span across multiple PCSAs. CMS should evaluate the impact of using PCSAs on specialty care providers and whether there is sufficient correlation between the two or whether consideration of an alternate geographic unit for specialty care providers is warranted.
- **The Model Should Use a Comprehensive Approach to Develop Evidence-Based Clinical Practice Guidelines**—CMS should support medication product selection by P&T Committees and providers using the totality of the evidence. Therefore, CMS should be comprehensive in the type of information that is used to develop VBP frameworks, and to avoid relying on a single source.
- **The Model Should Monitor for Unintended Consequences to Beneficiaries**—CMS should amend the proposed rule to include a mechanism for monitoring unintended consequences to beneficiaries and a strategy for suspending the model, in part or in its entirety, if beneficiary harms are identified.
- **The Model Should Evaluate the Impact of Competing CMMI Initiatives**—AMCP is concerned about the impact and potential overlap of the proposed Part B payment model with other CMMI initiatives, such as the Oncology Care Model, and alternative payment models under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA). CMS should consider the potential overlap in test models and ensure a mechanism is in place to encourage active

participation in ongoing and future test models to allow for meaningful assessment for improving value in the U.S. health care system.

- **The Model Should Evaluate the Impact on Medicare Advantage Benchmarks**—The proposed rule does not reference Medicare Advantage, which covers approximately one-third of Medicare beneficiaries. CMS should clarify how Medicare Advantage plans are accounted for in the proposed rule and whether Medicare Advantage plans will have access to the same VBP tools to help offset reductions in benchmarks.
- **The Model Should Evaluate Potential Market Shifts**—CMS should consider how the proposed rule may result in a market shift of costs from Medicare Part B to other payment areas and care settings with greater costs.

AMCP appreciates your concern with the proposed rule and the opportunity for stakeholders to be heard. If you have any questions regarding AMCP's comments or would like further information, please contact me at 703–683–8416 or scantrell@amcp.org.

Sincerely,

Susan A. Cantrell, RPh, CAE

Chief Executive Officer

AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS (ASHP)
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Phone: 301–664–8710

ASHP (the American Society of Health-System Pharmacists) respectfully submits the following statement for the record to the Senate Finance Committee hearing on examining "Examining the Proposed Medicare Part B Drug Demonstration."

ASHP represents pharmacists who serve as patient care providers in acute and ambulatory settings. The organization's more than 43,000 members include pharmacists, student pharmacists, and pharmacy technicians. For over 70 years, ASHP has been at the forefront of efforts to improve medication use and enhance patient safety.

ASHP appreciates CMS's ongoing efforts to enhance healthcare quality and value, and we support the Model's goal of reducing Medicare spending, while improving care and maintaining patient access. After careful review and analysis of the Model, we remain concerned that the Model's scope, timeline, and methodology could negatively impact patient access and quality of care. The Model's extremely aggressive timeline alone raises red flags, and CMS's decision to not solicit any input from key stakeholders—including physicians, pharmacists, and patients—prior to proposing a mandatory demonstration program magnifies the issue. Given the Model's potential to disrupt care, coupled with what will surely be costly implementation and oversight, ASHP in its comment letter to the agency urged CMS to rethink and restructure the Model with input from stakeholders and patients. A considered, collaborative approach has worked for other demonstration programs; in departing from best practices in this case, CMS will miss an opportunity to engage experts in crafting a demonstration project that can meet our shared goals without undermining care or destabilizing patient access. To better convey our concerns to the Committee, we highlight the following risk areas in the Model and propose alternative approaches.

I. The Model's timeline and scope threaten patient access.

As noted above, while we support the Model's goals, its proposed timeline and scope could disrupt patient access and reduce quality of care. Generally, we question the imposition of a large-scale mandatory demonstration program without first testing its methodology in smaller, more targeted pilot programs.

A. *Timeline of Model*

Although we appreciate the importance of data, the Model presents clear risks for patients, including provider disruption and care delays, which outweigh the value of comprehensive data on pricing of all Part B medications. Further, due to the randomized nature of Phase I and a rapidly approaching target start date, providers will have minimal time to prepare for changes that can significantly impact their budgets as well as their ability to continue certain patient care services. This issue

seems likely to intensify for Phase II, which includes only vague descriptions of potential models, but which is slated to be rolled out only a year after Phase I begins. With no previous opportunity to engage with CMS on the Model, and without adequate time to plan for these changes, it will be extremely difficult for providers to implement programs in a way that protects patients from unintended negative consequences. Therefore, as noted above, we advocate for collaborative revision of the Model's scope and timeline.

B. *Scope of Model*

Broad Inclusion of Part B Drugs: ASHP suggests that the Model's broadly inclusive approach fails to target medications appropriately and may create negative consequences for patients. While we understand that CMS is seeking to gather data on prescribing practices, the Model is premised on two erroneous assumptions: (1) that prescribing decisions are intrinsically linked to profit margins; and (2) that there are always lower-cost alternatives to higher-cost medications. Regarding the first assumption, due to medication purchasing practices, prescribers are often unaware of the purchase price of medications, which would also make them unaware of any prescribing incentives. Prescribers choose the best therapeutic option for their patients—and the best option may be a higher-cost medication. Further, for some drugs, such as rituximab and CMV immune globulin, the best option is also the only option. Given the time constraints of the comment period, we could not fully survey our members regarding drugs with no lower-cost alternatives, which raises concerns that there are similarly situated medications that have not yet been identified. To safeguard patients, we recommend limiting a demonstration of this type only to medications that have known lower-cost equivalents.

Additionally, while we were pleased that CMS excluded drugs in "short supply," we are concerned that CMS defines this term too narrowly. Relying solely on the FDA shortage list would offer only a piece of the shortage picture.[1] Coupled with the agency's proposal to require that a drug appear on the FDA shortage list at the time the Model's quarterly price report is produced, a narrow definition of shortage could exacerbate access problems. Thus, the FDA list should be supplemented with other recognized lists, including, but not limited to, the ASHP shortage list.[2]

Impact on Existing Models and Demonstrations: ASHP supports expansion of alternative payment models (APMs) linked to quality and value. Although some of the proposed Phase II value-based payment models sound promising, we question how CMS will overlay multiple models on systems with ongoing APMs and demonstrations without interfering with them. ASHP requests that the Committee ask CMS to clarify how both phases of the Model will interact with new and existing APMs. Specifically, how will CMS treat the Model under the new MIPS and MACRA proposals? Will the Model be treated as an APM? Will CMS be able to control for Model participation when evaluating providers through other APMs and demonstrations—particularly after Phase II is rolled out? Based on feedback from our members, if the Model is implemented as proposed, it could create a chilling effect on provider participation in other APMs. ASHP members indicated that logistical and administrative burdens created by the Model, particularly for providers with practice sites in different model arms, would make them less likely to participate in other CMMI demonstrations or APMs simultaneously. Absent clear evidence that CMS has considered the Model's impact on, and interaction with, current APMs and demonstrations, we are concerned that it may distort program results and undermine participation in value-based programs/models.

II. The Model may disrupt patient access and care quality, while failing to provide patients with immediate, measurable benefits.

Patient Costs: Optimal, safe, and effective medication use is impossible without actual patient access to medications, and medication costs can hinder patient access to vital medications. ASHP is committed to finding workable solutions to this problem, but CMS provides no evidence that Phase I of the Model will result in concrete patient savings. CMS notes that it "doesn't expect a sizable overall reduction in Part

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[1] *See, e.g.,* Sheri Fink, "Drug Shortages Forcing Hard Decisions on Rationing Treatments," *NY Times* (January 29, 2016), available at *http://www.nytimes.com/2016/01/29/us/drug-shortages-forcing-hard-decisions-on-rationing-treatments.html?_r=O;* and ASHP, "Understanding and Managing Drug Shortages" (2002), available at *http://www.ashp.org/Doclibrary/Policy/DrugShortages/DShort-abbott-drug.aspx.*

[2] *See* ASHP Drug Shortages Resource Center, available at *http://www.ashp.org/shortages;* and ASHP, "Contrasting the FDA (CDER) and ASHP Drug Shortage Websites: What Are the Differences?" available at *http://www.ashp.org/Doclibrary/Policy/DrugShortages/FDA-versus-ASHP.pdf.*

B drug spending associated with Phase I of this model, but we do anticipate an incentive to use higher-value drugs."[3] CMS makes no claim that any cost savings in the system will be passed on to beneficiaries in the tangible form of reduced out-of-pocket costs. Further, as discussed below, the Model carries serious unintended negative consequences for patient access—yet these risks are not balanced by reward in the form of unambiguous gains for patient access and outcomes.

Patient Access: Based on discussions with our members and other clinician stakeholders, ASHP anticipates that payment changes in Phase I will likely result in a significant shift of patients from community settings to hospital outpatient departments. The proposed Model test payment (2.5% of ASP + $16.80) does not cover the overhead and handling costs for many medications in the hospital and health-system setting[4]—and it seems likely that this would also be true in community settings. Given the limited comment period, we were unable to survey members regarding drugs that are "under water," but anecdotally our members indicate that there are examples at all price points, including infliximab, a higher-cost biologic. Additionally, ASHP members indicate that the reduced payment (particularly when the cost of sequestration is factored in) may result in losses on a number of other drugs, including ipilimumab and melphalan. Reimbursement reduction may limit the ability of providers to offer certain services (*e.g.,* infusions), leaving hospital outpatient departments as the only alternative. The resulting disruption of provider-patient relationships would fragment care, complicate beneficiary access, and increase pressure on hospital outpatient departments.

We appreciate CMS's attempt to address patient safety by offering a prior approval process for Model drugs and proposing to implement a "real-time claims monitoring" system to monitor beneficiary access. However, as proposed, neither fully safeguards patient access. Prior approvals come at the cost of increased administrative burden and delays for patients. We believe prior approvals should be a last resort, not a solution for the larger medication-access issues that the Model may generate. As noted above, not all medications have acceptable lower-cost equivalents—for providers who prescribe those drugs, prior approvals will be the rule rather than the exception. Similarly, CMS's proposal to implement a "real-time claims monitoring process" to protect patient access lacks sufficient detail. Our understanding is that developing this system would require, at minimum, extensive technology upgrades plus personnel support and oversight. Further, it is unclear how access problems would be identified and resolved. Given how essential effective monitoring is to ensuring patient access, we ask that the Committee request CMS clarify how the monitoring process will work in practice.

Conclusion

ASHP greatly appreciates the opportunity to provide a statement for the record and commends the Senate Finance Committee for holding this hearing on the CMS's Part B Model Demonstration project. Again, we reiterate our support for the Model's underlying goals; however, based on the concerns highlighted above, ASHP is advocating for significant revisions to the Model's scope and timeline after comprehensive, meaningful consultation with stakeholders, including physicians, pharmacists, and patients. We have already signaled our eagerness to assist CMS in any way possible as it revises the Model, and we offer the same assistance to the Committee as you collaborate with other industry stakeholders.

AMERICAN SOCIETY OF RETINA SPECIALISTS (ASRS)
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Phone 312–578–8760
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May 9, 2016

Andrew Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services

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[3] 81 Fed. Reg. 13239 (March 11, 2016).

[4] ASHP has consistently advocated for a reimbursement rate of ASP + 6% in its comments on CMS's annual Hospital Outpatient Prospective Payment System rules. As noted in these comments, the 6% rate allows hospitals to cover their costs. Factoring in sequestration's impact, hospitals already face reimbursement rates lower than the minimum required to cover the costs of core pharmacy services, and the Model would further reduce those reimbursement rates.

Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Re: Medicare Program Part B Drug Payment Model [CMS–1670–P]

Dear Acting Administrator Slavitt:

On behalf of the American Society of Retina Specialists (ASRS), its members and their patients, we submit the following comments on the Centers for Medicare and Medicaid Services (CMS) Medicare Program Part B Drug Payment Model [CMS–1670–P]. The ASRS is the largest retinal organization in the world, representing over 2,700 fellowship-trained members. Retina specialists are board-certified ophthalmologists who have completed fellowship training in the medical and surgical treatment of retinal diseases.

ASRS SUPPORTS CMS'S GOALS BUT NOT THE CURRENT PROPOSAL

The ASRS supports CMS's stated goals of "improving incentives for the best clinical care" and desire to "drive the prescribing of the most effective drugs."[1] We also wholeheartedly support the alternative payment model framework offered by the Medicare Payment Advisory Commission (MedPAC) Commissioners at its December 2014 meeting and agree a successful alternative payment system must:

- Provide sufficient incentive for providers to maximize health outcomes and value while reducing costs;
- Ensure that payment policies do not compromise quality of care or limit patients' treatment options;
- Assess the impact of such payment policies on low-income patients; and
- Implement a sufficiently transparent and adequate exceptions process to allow providers to prescribe more-expensive products when medically necessary.

Unfortunately, the current proposal falls short in not meeting: (1) the stated goals of the proposal itself, and (2) the standards set forth for MedPAC. As a result, the payment proposal has the potential to negatively impact patient care and outcomes when Medicare beneficiaries are treated with injectable drugs in the office setting.

IMPLICATIONS OF PAYMENT POLICY ON TREATMENT PATTERNS AND PRACTICE FINANCIALS

The proposal has several limitations due to the following:

- The existing ASP-based fee schedule payment methodology of 106% (104.3% after sequestration) does not yield profit for physicians and thereby does not provide an inappropriate incentive for them to choose high-cost treatment;
- Interchangeable treatment options are not necessarily available; therefore, less costly alternatives may not be an option to treat patients; and
- Across retinal diseases, we have no data demonstrating that changes in current treatment patterns would improve the quality of patient care.

What Do We Know About Physician Practice Expenses for Drug Acquisition and Other Overhead?

The House Ways and Means Committee has requested from the GAO a cost study to examine how Medicare's payment for drugs covered under Medicare Part B compares to actual acquisition and overhead costs. We feel that any proposal from CMS should be formulated after the GAO results are available.

ASRS membership, in response to the CMS proposal and to reply to requests from Deputy Administrator Conway, commissioned a study of 8 practices that were able to pull detailed cost accounting data for calendar year 2015 in the short time allotted in the comment period. The study found that drug acquisition and overhead expenses for injectable drugs that have their own unique HCPCS J codes was, on average, 98.9% (range 96.5% to 103.2%) of total payments across the 8 practices. (For more information, see appendix A.)

It is worth noting that given the limited time available to collect these data, only high volume practices with capable financial staffs were able to respond to the sur-

[1] *https://www.cms.gov/Newsroom/MediaReleaseDatabase/Fact-sheets/2016-Fact-sheets-items/2016-03-08.html.*

vey in this short period of time. Even under these circumstances, not all high volume practices generated net revenue from office administered drugs. In fact, our belief is that lower volume practices, which provide the majority of patient care in retina around the country, would have less purchasing power and higher overhead costs compared to the practices in the study from which we were able to collect data.

Based on the analysis of real retina practice data, we believe the ASP + 2.5% and a flat fee even without sequestration do not recognize the true costs of purchasing and handling the more complex biologics, and will limit the ability of some providers to administer essential sight-saving drugs. For physicians to be able to continue to purchase Part B drugs on behalf of their patients, the payment rate must at least cover all overhead costs. If not, patients will be forced to travel to the more expensive hospital outpatient departments to receive monthly treatments. Driving more care to an often less convenient, more costly setting will make it more challenging for beneficiaries to access needed care and will increase overall Medicare costs. This will lead to further consolidation and less choice for seniors.

Therefore, before proposing any payment policy that is not based on ASP + 6% it would be helpful if CMS would explain why it has changed its position that "ASP + 6% payment is an appropriate payment rate for separately payable drugs and biologicals."[2]

Financial Incentives Do Not Influence Drug Choice

The ASRS takes issue with the assumption that physicians may choose their patients' drug therapy based on which drug provides them the highest reimbursement. MedPAC considered this issue and concluded that there is little evidence to support such a claim. Moreover, our research also suggests this is not the case. In the ASRS 2015 Preferences and Trends survey, 64% of respondents indicated that they currently use the least-costly alternative, Avastin®, as the first-line treatment for new patients with wet AMO. However, when asked which anti-VEGF agent they would choose if Avastin®, Lucentis® and Eylea® were the same price, respondents dropped Avastin® to the last choice. Avastin® was also the last choice of our members when asked "which anti-VEGF do you believe most effectively treats the broadest range of wet AMO patients." For those familiar with the results of recent clinical trials, these survey results are not surprising.

Treatment Options Are Not Interchangeable

In its June 2015 report, MedPAC recognized that a number of clinical factors, including variations in effectiveness of drugs in treating patients with specific conditions and comorbidities, potential side effects, on or off label use of a drug, as well as whether or not a drug is compounded, may influence a provider's choice among therapeutic alternatives. For retina specialists, all of these factors are in fact considered.

Currently, of the 3 utilized anti-VEGF agents, only Lucentis® and Eylea® have specific FDA approval for treatment of age-related macular degeneration, diabetic macular edema, and retinal vein occlusion. Avastin not only does not have FDA approval for the treatment of these retinal diseases, but it must also be used in a compounded form. Many patients are reluctant to choose a compounded drug being used off-label and should not be forced to do so when several FDA-approved options exist.

Clinical response varies among the 3 anti-VEGF agents in individual patients. While all 3 anti-VEGF agents have similar efficacy in many patients, various trials have demonstrated differences in subsets of patients. Retina specialists must evaluate each patient individually, and select the appropriate agent accordingly. Ultimately, the retina specialist utilizes clinical judgment and the patient's response to a particular drug to select the best course of therapy. As the recently released results of the National Eye Institute funded study Comparison of Age-related Macular Degeneration Treatments Trials (CATT) 5-year follow up found, patients often switch anti-VEGF agents and dosages. This ability of a physician to individualize treatment and select the most efficacious agent for each patient is critical to safely maximizing recovery and maintaining visual function in patients with blinding diseases of the retina.

Since anti-VEGF agents are not interchangeable, ASRS is seriously concerned that for many retina specialists the phase I new payment methodology will no longer cover the costs to deliver FDA-approved drugs to their patients. If retina specialists are unable to cover the costs of the medically necessary Part B drug, patients will

[2] 77 Fed. Reg. at 8,387.

be forced to go elsewhere (likely farther away and/or to a more costly care setting) to receive their injections.

THE RETINA COMMUNITY IS AND WILL CONTINUE TO BE VESTED IN IMPROVING PATIENT OUTCOMES AND BEING FINANCIALLY RESPONSIBLE

The ASRS is concerned that the CMS has not provided guidance on how it defines "most effective drugs." It is a physician's duty to base clinical decisions on clinical evidence, not just cost. Retina specialists work in a specialty that requires the administration of expensive Medicare Part B drugs—Lucentis® and Eylea®—to save vision, and the ASRS and its members have devoted tremendous resources to supporting efficacy, comparative effectiveness clinical research, and the dissemination of clinical trial results.

Through this research, cost savings have already been achieved. For example, the treat-and-extend protocol, now widely used in the treatment of macular degeneration and diabetic retinopathy, allows retina specialists to treat less often than done in pivotal phase III clinical trials, yielding significant savings in terms of treatment burden and cost while maintaining excellent vision outcomes. In other cases, comparative effectiveness studies have found statistical differences in treatment options that support use of the more expensive treatment option.

Protocol T, for example, found that the relative benefit of Eylea® was clinically and statistically significant for the subset of eyes that had 20/50 or worse vision at baseline. If phase I moves forward unchanged, this subset of diabetic retinopathy patients may not be able to receive the most effective treatment. Given this, and the fact that more than 300 clinical trials are currently underway to explore additional ways to treat AMO and diabetic retinopathy with fewer injections and achieve even better outcomes, we believe CMS needs to establish a mechanism for defining "most effective drugs." Since the National Institutes of Health (NIH) fund many of the comparative effectiveness studies, we believe CMS should consider collaborating with NIH to develop this mechanism. Moreover, since some patients simply respond better to one treatment over another, ASRS recommends that CMS create a sufficiently transparent and adequate exceptions process to allow providers to prescribe medically necessary drugs irrespective of cost.

CONCLUSION AND RECOMMENDATIONS

Given the concerns expressed above, the ASRS recommends that CMS not continue with phase I of the demonstration project as written, and reevaluate the development of alternative payment models that can achieve the same goal without increasing risks for patient outcomes after real-world practice data is available to guide this process.

ASRS appreciates the opportunity to provide comments on the proposed Medicare Program Part B Drug Payment Model. If we may provide any additional information, please contact Jill Blim, ASRS Executive Vice President, at jill.blim@asrs.org.

Sincerely,

Tarek S. Hassan, M.D.
President

Mark S. Humayun, M.D., Ph.D.
President-Elect

John S. Pollack, M.D.
Vice President Governance

Timothy G. Murray, M.D., M.B.A.
Treasurer

Carl C. Awh, M.D.
Secretary

Philip J. Ferrone, M.D.
Vice President Education

Geoffrey G. Emerson, M.D., Ph.D.
Chair, Federal Affairs Committee

Jill F. Blim, M.S.
Executive Vice-President

APPENDIX A

ANALYSIS OF PRACTICE REVENUES AND EXPENSES FOR DRUGS ADMINISTERED IN RETINA PHYSICIAN OFFICES

BACKGROUND

On March 8, 2016, the Centers for Medicare and Medicaid Services (CMS) announced a proposed rule to test new models to improve how Medicare Part B pays

for prescription drugs and supports physicians and other clinicians in delivering higher quality care.

Currently, Medicare Part B covers prescription drugs that are administered in a physician's office or hospital outpatient department, such as cancer medications, injectables like antibiotics, or eye care treatments. Drugs paid under Medicare Part B generally fall into three categories:

(1) Drugs furnished incident to a physician's service in the office or hospital outpatient settings,

(2) Drugs administered via a covered item of durable medical equipment, and

(3) Other categories of drugs explicitly identified in the law.

PROPOSED RULE AND CHANGES IN PAYMENT THAT WOULD APPLY TO OPHTHALMIC DRUGS ADMINISTERED BY RETINA PHYSICIANS

Medicare Part B generally pays physicians and hospital outpatient departments the average sales price of a drug, plus a 6 percent add-on. The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. CMS goes on to say that:

> "CMS expects that the add-on payment of 2.5 percent plus a flat $16.80 fee will cover the cost of any drug paid under Medicare Part B. The flat fee is calculated such that it is budget neutral in aggregate."

While the proposal may be budget neutral in aggregate, the fact is that CMS does not know the impact of specific subspecialties based on provider financials, treatment mix, and so forth.

Therefore, the American Society of Retina Specialists (ASRS) commissioned an independent study by an economics and accounting firm, Quorum Consulting, Inc. (San Francisco, CA) to gather data from retina practices to: (1) determine revenue for injectable drugs; (2) account for direct and indirect costs associated with injectable drugs; in order to: (3) report profit or loss for physician administered drugs that may be affected by the proposed rule.

ABSTRACT OF STUDY METHODS AND RESULTS

Methods

We solicited members of the ASRS to provide detailed financial and cost accounting data. We requested data on revenues (total collections) and costs (expenses) for calendar year 2015. We obtained data on all injectable drugs administered retina physician practices offices (hospital and ASC facilities were not included). The scope of the analysis was specific to FDA approved drugs with product specific HCPCS "J" codes, which are addressed within the scope of the CMS proposal.

Cost Accounting Data Collection

For direct and indirect expenses, we obtained site-specific data on:

Drug Acquisition Costs (by HCPCS code)

A. Acquisition price per unit
B. Added costs
   a. Shipping and handling
   b. Sales tax
   c. Other cost increases
C. Cost offsets
   a. Discounts
   b. Chargebacks
   c. Rebates
   d. Other cost offsets

Other Practice Expenses

A. Practice Expenses
B. Staff Time
   - Salaries and benefits for staff time responsible for acquiring, storing, preparing, transporting, and disposing of drugs and drug revenue collections (this differs from GAO allocated based on time spent on these activities).
C. Other indirect expenses
   - Space—Physical space used for storing and preparing drugs.

- Equipment—Equipment used for storing, preparing, transporting, disposing of drugs and claims management (office equipment, PODIS, EHR, other IT, etc.).
- Supplies—Supplies used for storing, preparing, transporting, and disposing of drugs.
- Support Contracts—Contracts for other organizations to provide services supporting acquiring, storing, preparing, transporting, and disposing of drugs (*e.g.,* waste disposal).
- State provider taxes.

Results and Discussion

We obtained detailed revenue (collections) and expenses (direct and indirect costs) for calendar year 2015 from 8 retina practices from around the country. While sites were from regions throughout the country, participating sites all tended to be high volume practices. This is likely due to the fact that sites had to provide data in a short amount of time (to accommodate the CMS comment period), and only high volume sites had accounting and other administrative staff available to provide the requested information. Participating sites also varied in their payer mix and utilization of different types of drugs.

We found that drug acquisition and overhead expenses for injectable drugs included in the analysis were on average 98.9% (range 96.5% to 103.2%) of total collections across the 8 practices. In some cases, practices made a profit on injectable drugs while in other cases had a net loss. There was variation in drug profit or loss by drug and by practice.

It is worth noting that given the limited time available to collect these data, only high volume practices with capable financial staff were able to respond to the survey in this short period of time. Even under these circumstances, not all high volume practices generated profits on office administered drugs. In fact, our belief is that lower volume practices, which provide the majority of patient care in retina around the country would have less purchasing power and higher overhead compared to the study for which we were able to collect data.

BIORX, LLC

Senate Committee on Finance
Dirksen Senate Office Bldg.
Washington, DC 20510–6200

Dear Honorable Chairman Orrin Hatch:

BioRx, LLC, a Diplomat company ("BioRx"), is a specialty and home infusion pharmacy which provides pharmacy services to patients dealing with chronic and/or rare diseases, such as cancer, autoimmune disorders, and hemophilia. The patients we treat are often prescribed expensive medications which have complex therapy requirements. At BioRx, we strive to provide quality pharmacy services to our patients, and to ease patients' burdens and worries while they manage their conditions.

BioRx appreciates the opportunity to comment on the proposed Part B drug payment model. While BioRx understands the Centers for Medicare and Medicaid's (CMS) desire to lower the cost of Part B medications, BioRx is concerned that the proposed revisions will limit the ability of specialty and home infusion pharmacies to provide services to Medicare patients and will ultimately block patient access to life-saving medications. BioRx has the following concerns regarding the proposed rule:

1. The proposed rule should exclude IVIG, hemophilia products, orphan drugs, and drugs that are in short supply from the proposed payment model.

When implementing the final rule, CMS should take into consideration the fact that there are not always comparable lower priced drug alternatives. The main rationale for the proposed rule, besides reducing Medicare expenditures, is to discourage providers from prescribing expensive medications when there are lower priced alternatives available. IVIG, hemophilia products, and new or short supply drugs often do not have comparable lower priced drugs available, and the proposed pricing methodology may hinder a pharmacy's or doctor's ability to prescribe or provide to patients those medications.

IVIG, orphan and short supply drugs tend to have very little price variation between the different medications, meaning prescribers have little to no incentive to prescribe one product versus the other. Most hemophilia products are in a similar position to IVIG, orphan and short supply drugs, even though there are four categories of hemophilia products, (in order from least expensive to most: plasma derived, recombinants, recombinants with a longer half-life, and inhibitors), which do have different prices. While plasma derived products are the least expensive, they are not the same as inhibitors. Hemophilia patients who develop inhibitors, have an allergic reaction, or need a quicker clotting response time to stop a serious bleed (such as one in the brain) will need to use the higher priced inhibitor medication, and trying to force clinicians to use the lowest cost hemophilia products, which, while comparable, do not provide the same medical benefit or fast acting solution, could seriously harm the patients. Trying to discourage caregivers from prescribing or providing needed high cost medications could have a negative impact on patient health outcomes.

Because IVIG, hemophilia, and orphan and short supply drugs do not provide "any excessive financial incentive to prescribe high cost drugs over lower cost drugs,"[1] as lower priced comparable alternatives are typically unavailable, these products should be excluded from the proposed Part B payment model.

2. Specialty pharmacies should also be excluded from the proposed rule, as specialty pharmacies do not prescribe the medication, nor do they have access to the service fees paid to physicians and hospitals for infusion services and can provide significant cost savings to CMS.

The proposed rule does not address the role of pharmacies in providing care to patients, nor does it consider the affect the rule will have on pharmacies that provide home infusion services to patients. Specialty pharmacies do not prescribe or select the medication; therefore, the proposed rule's rationale for needing to discourage providers from prescribing the more expensive medications would not apply to pharmacies. Additionally, pharmacies provide high quality, cost effective care to beneficiaries, and the proposed payment model could limit their ability to participate in the Medicare programs.

When a pharmacy provides home infusion services to the patient, the pharmacy bills CMS under Part B, and the pharmacy does not receive payment from CMS for the injection or infusion. The current price of ASP + 6% helps specialty pharmacies cover the cost of the medication, and the cost of services performed. If specialty pharmacies are only able to receive ASP + 2.5% and a flat fee of $16.80 for the medication, then the specialty pharmacies will not be able to cover their operating or infusion costs.[2] Attached in Exhibit A is an example of how the payment change reduces the pharmacies ability to pay overhead costs. A healthcare provider cannot provide services under an arrangement which causes them to consistently lose money.

Beyond filing the prescriptions and performing back-end benefits investigations and adherence monitoring, most specialty pharmacies also arrange for the home administration of IVIG and other infusion products. Home infusion is not only easily accessible to the patients; it also saves plans at least $20,000 per year per patient. However, specialty pharmacies cannot provide those cost savings under the proposed rule, as they would be unable to cover their medication and operation costs with the new fee.

If specialty pharmacies are unable to provide the medication and home infusion services, then more and more patients will have to go to emergency or out-patient settings to receive their medication. This arrangement would increase the costs of care, and make it more burdensome for patients to receive their medications. Therefore, specialty pharmacies should be excluded from the proposed rule.

3. The demonstration for the proposed rule is overly broad, and a small scale pilot version of the proposed rule should be conducted first, before the proposed rule, if effective, is expanded to cover all providers.

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[1] CMS Medicare Part B Proposed Rule, pg. 16.

[2] *See,* "Pharmacy Dispensing Cost Analysis for the State of Maryland," December 7, 2011 (the survey concluded that the average dispensing cost for specialty pharmacies was $185.24 per prescription). *See also,* Exhibit B, which provides a list of common specialty pharmacy services, which create the high overhead cost, *https://mmcp.dhmh.maryland.gov/pap/docs/md_2011_pdca_report.pdf.*

The demonstration is overly broad, and it seems ill-advised to implement such a wide reaching rule when CMS has failed to conduct a small scale test pilot of the proposed rule to determine possible affect. The potential impact on providers and beneficiaries is too great to roll out on such a large scale when there is little to no concrete knowledge or data on how the rule will affect all interested parties. Traditionally, CMS uses smaller scales to test new payment models, and BioRx respectfully requests CMS to test the proposed payment model out on a small population before implementing the method on a larger scale.

4. The proposed rule needs greater clarification on the methodology of assigning PCSAs and the variation add-on methodology for different geographic locations.

The stratified randomized selection methodology of assigned PCSAs requires further clarification; the verbiage is very technical and we need the methodology defined so it makes more sense to the participating entities. Additionally, because the proposed model is a 5 year demonstration, CMS needs to provide clarity on whether or not providers experiencing financial hardship may opt out of the experiment or not.

5. Competing CMS proposals and demonstrations should not be overlapped with the Part B proposed model.

CMS acknowledges the potential for overlap with other CMS proposed pricing models, such as the Oncology Care Model or the alternative payment models incentivized by the Medicare Access and CHIP Reauthorization Act of 2015, but offers no way to handle the matter. CMS needs to provide some controls to its proposed model to ensure that providers are not participating in more than one proposed rule demonstration. Furthermore, CMS ignores the potential for skewed data they may receive from providers who are operating under more than one of the proposed Part B payment models. It is crucial that CMS finds some way to control the demonstration so that providers are only affected by one demonstration.

6. CMS needs to provide greater detail and narrow the scope on Phase II of the proposed payment model before it can be used.

CMS stated on page 14 that in Phase II, it proposes to "test the application of a group of value-based purchasing ("VBP") tools that commercial and Medicare Part D plans use to improve patient outcomes and manage drug costs." While BioRx is fully supportive of implementing new systems that will provide cost effective quality care, CMS should carefully consider which tools to utilize before testing, and should considering excluding DME infusion drugs and specialty pharmacies from Phase II.

DME infusion drugs should be excluded, because Medicare already limits the use of infusion drugs through Local Coverage Determinations (LCDs). These LCDs already narrowly define which infusion drug can be used for each indication, and ensures the appropriate use of infusion medications. Additionally, some patients require multiple medications which may need to be carefully vetted to prevent complications or negative drug interactions, and the VBP tools may not adequately take those circumstances into consideration.

Specialty pharmacies should either be excluded from Phase II or the VBP tools should be narrowly tailored to apply to the applicable organization. VBP tools used for a clinician or hospital setting is often inappropriate for a specialty pharmacy, as specialty pharmacies do not prescribe or order the medications and can provide valuable cost savings to plans that may not be accessible in other healthcare settings.

For example, specialty pharmacies play a crucial role in providing home infusion services, which saves plans an estimate of $20,000 per patient a year.[3] Specialty pharmacies also offer patients access to pharmacists and/or nurses 24/7, which can reduce the amount of emergency room trips a patient takes in a year. Savings can also be found through increased medication adherence rates in patients and partial fill programs, which allows patients to fill half of a prescription in order to determine medication tolerance prior to purchasing the full amount.

7. Several lawmakers have expressed great concerns or even direct opposition to the CMS proposal.

Both Republican and Democrat representatives have written and signed letters to CMS regarding the proposed rule, and the response has been negative. The bipar-

[3] ESI/Accredo, *Specialty Pharmacy Times,* February 2014.

tisan reaction to the proposed rule shows that there are clear flaws in the proposed rule.

In a letter signed by about 65 representatives sent to CMS on May 16, 2016 regarding the proposed rule, the representatives expressed concerns regarding the potential effects the rule may have on beneficiaries and physicians.[4] The representatives in this letter even urged CMS to work with stakeholders while revising the rule "to ensure that this model does not undermine the quality of and access to care that Medicare beneficiaries expect and deserve."[5] In another letter sent on May 2, 2016 to CMS, the representatives asked CMS to withdraw the proposed rule, as they believed the proposed rule would limit senior citizens access to care.[6] Around 250 representatives signed this letter.

While the two letters differ in their level of opposition to the proposed rule, both letters express the same concern that the proposed rule will limit patient access to medication. There is also concern among representatives that the proposed rule will force patients to receive care in emergency rooms or at hospitals, where the cost of treatment is much higher and less convenient.[7] BioRx, as previously mentioned, has the same concern that this proposed rule will limit seniors access and ability to receive home health services or be able to infusion their medications at home.

For the above reasons, BioRx respectfully requests that the Senate Committee on Finance continues to ask CMS to withdraw the Medicare Part B Drug Demonstration, or exclude DME infusion drugs and specialty pharmacies from VBP tools, or to narrowly tailor the tools to fit the appropriate health care provider.

BioRx appreciates the opportunity to comment on this proposal and hopes that the Senate Committee on Finances passes these comments onto CMS, for serious consideration.

Sincerely,

Scott Sorenson
Director, Medicaid and Government Services
BioRx, LLC—A Diplomat Company

Exhibit A

Price Effect Example

Product	J-CODE	BioRx Cost as of January 2016	CMS Allowable Effective January 2016	GM% today	CMS Proposed Allowable	GM% with new proposal	Reduction %
A	J7192	$1.0200	$1.1770	12.74%	$1.1378	10.35%	18% GM loss

GM = Gross Margin

Exhibit B

Specialty pharmacies often provide the following services:

Clinical Pharmacist and Pharmacy Tech

- ➢ Consulting with prescribers
- ➢ Monitoring for potential drug interactions
- ➢ Dispensing
- ➢ Assay management
- ➢ Pharmacist time in validating an individual's coverage prior to dispensing
- ➢ Preferred drug list review activities
- ➢ Monthly/quarterly reporting to state Medicaid agency
- ➢ Medication profile set up and drug utilization review
- ➢ Emergency telephone support
- ➢ On call (24/7 nurse and pharmacist) clinical and delivery support for patients

[4] *http://www.citizen.org/documents/66-ds-may-16-2016-cms-demo-letter.pdf.*
[5] *http://www.citizen.org/documents/66-ds-may-16-2016-cms-demo-letter.pdf.*
[6] *http://www.citizen.org/documents/240-rs-4-ds-may-2-2016-cms-demo-letter.pdf.*
[7] Pear, Robert, "Plan to Cut Medicare Drug Payments Leaves Senators Skeptical," *The New York Times,* June 28, 2016 (*http://www.nytimes.c/2016/06/29/us/plan-to-cut-medicare-drug-payments-leaves-senators-skeptical.html?_r=O*).

Warehouse, Shipping and Delivery Personnel

- ➢ Couriers
- ➢ Emergency deliveries
- ➢ Tracking of deliveries
- ➢ Packaging
- ➢ Manufacturer communication
- ➢ Ensuring stock rotation

Reimbursement Personnel

- ➢ Prior authorizations/receipt of approval
- ➢ Billing per insurer's guidelines and providing required documentation

Nursing

- ➢ Initial patient assessment/education
- ➢ Home infusion training
- ➢ Ongoing patient assessment/education
- ➢ Consumer/patient counseling
- ➢ Staff education and training
- ➢ Disease management
- ➢ Developing and coordinating emergency plans with schools, caregivers, work, etc.

Materials (Supplies) and Dispensing

- ➢ Needles
- ➢ Syringes
- ➢ Alcohol wipes/sanitizer
- ➢ Bandages
- ➢ Medical tape
- ➢ Sterile gloves
- ➢ Tourniquets
- ➢ Needle disposing containers
- ➢ Temperature controlled boxes
- ➢ Heat/cold packs
- ➢ Masks/coolers/IV supplies, swab sticks
- ➢ Sterile drapes
- ➢ Coolants
- ➢ Shipping insurance
- ➢ Prescription dispensing materials (packages, labels)
- ➢ Postage

Advocate

- ➢ Home inventory check of factor and supplies
- ➢ Factor utilization and infusion log
- ➢ Patient communication and therapy monitoring

THE CENTER FOR FISCAL EQUITY
14448 Parkvale Road
Rockville, Maryland 20853

Statement by Michael Bindner

Chairman Hatch and Ranking Member Wyden, thank you for the opportunity to submit our comments on this topic. We will leave the description of the experiment to the Administration witnesses and concentrate on why the experiment may or may not be necessary. As usual, our comments are based on our four-part tax reform plan, which is as follows:

- A Value Added Tax (VAT) to fund domestic military spending and domestic discretionary spending with a rate between 10% and 13%, which makes sure every American pays something.
- Personal income surtaxes on joint and widowed filers with net annual incomes of $100,000 and single filers earning $50,000 per year to fund net interest payments, debt retirement and overseas and strategic military spending and other international spending, with graduated rates between 5% and 25% in either 5% or 10% increments. Heirs would also pay taxes on distributions from estates, but not the assets themselves, with distributions from sales to a qualified ESOP continuing to be exempt.

- Employee contributions to Old-Age and Survivors Insurance (OASI) with a lower income cap, which allows for lower payment levels to wealthier retirees without making bend points more progressive.
- A VAT-like Net Business Receipts Tax (NBRT), essentially a subtraction VAT with additional tax expenditures for family support, health care and the private delivery of governmental services, to fund entitlement spending and replace income tax filing for most people (including people who file without paying), the corporate income tax, business tax filing through individual income taxes and the employer contribution to OASI, all payroll taxes for hospital insurance, disability insurance, unemployment insurance and survivors under age 60.

While the Administration may be correct in siting this experiment as a way to both improve cost and care, the underlying reason has to be cost minimization. As we saw with Medicare Part C in the mid-90s, minimization on its own leads to decreased care and providers who exit the system and need premium pay to return.

Aside from throwing up our hands and agreeing to deficit spending, as Congress did in establishing such incentives for Part C when it established Part D, some form of revenue increase is required.

Both the Simpson-Bowles Commission and the Rivlin-Domenici Commission recommended an increase in Part B and D premiums. That is all well and good, but seniors and the disabled don't simply have spare cash to throw around without decreasing other spending, like housing or food. For most people, that European vacation only comes as a gift from grateful children or merciful siblings. Therefore, the only way to increase premiums is to also increase the basic Social Security and Disability benefit (which will need to happen anyway if the drive to a $15 minimum wage keeps gaining success).

Increasing the benefit is usually seen as a matter of raising the income cap and making the bend points in benefit calculation more severe so that the contribution increase does not simply lead to higher benefits for wealthier retirees. There is, however, another option.

Our proposal is to lower the employee income cap on contributions to decrease the entitlement for richer retirees while the employer income cap is eliminated, the employer and employee payroll taxes are decoupled and the employer contribution credited equally to each employee at some average which takes in all income. If a payroll tax is abandoned in favor of some kind of consumption tax, all income, both wage and non-wage, would be taxed and the tax rate may actually be lowered.

Ultimately, fixing health care reform will require more funding, probably some kind of employer payroll or net business receipts tax—which would also fund the shortfall in Medicare and Medicaid (and take over most of their public revenue funding), regardless of whether Part B and D premiums are adjusted.

Our Net Business Receipts Tax/Subtraction VAT proposal above is the recommended consumption tax. It would not show up on the receipt because it can be offset by employer provided substitutes.

The NBRT can provide an incentive for cost savings if we allow employers to offer services privately to both employees and retirees in exchange for a substantial tax benefit, either by providing insurance or hiring health care workers directly and building their own facilities. Employers who fund catastrophic care or operate nursing care facilities would get an even higher benefit, with the proviso that any care so provided be superior to the care available through Medicaid. Making employers responsible for most costs and for all cost savings allows them to use some market power to get lower rates, but no so much that the free market is destroyed.

This proposal is probably the most promising way to arrest health care costs from their current upward spiral—as employers who would be financially responsible for this care through taxes would have a real incentive to limit spending in a way that individual taxpayers simply do not have the means or incentive to exercise. While not all employers would participate, those who do would dramatically alter the market.

A kind of beneficiary exchange could be established so that participating employers might trade credits for the funding of former employees who retired elsewhere, so that no one must pay unduly for the medical costs of workers who spent the majority of their careers in the service of other employers.

Thank you for this opportunity to share these ideas with the committee. As always, we are available to meet with members and staff or to provide direct testimony on any topic you wish.

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Introduction

The National Association of Chain Drug Stores (NACDS) thanks Chairman Hatch, Ranking Member Wyden, and members of the Committee on Finance for the opportunity to submit a statement for the hearing on "Examining the Proposed Medicare Part B Drug Demonstration."

NACDS and the chain pharmacy industry are committed to partnering with the Department of Health and Human Services, policymakers, and others to work on finding ways to lower prescription drug costs in the Medicare Part B program. NACDS supports sensible efforts to control spending while preserving patient health and access to the services they need. As the face of neighborhood healthcare, chain pharmacies and pharmacists work on a daily basis to provide the best possible care and the greatest value to their patients with respect to access to critical medications and pharmacy services. We help to assure that patients both are able to access their medications and take them properly.

Pharmacists work with patients to find ways to lower prescriptions costs through the use of generic drugs, helping to navigate insurance plans, and encouraging participation in pharmacy drug discount programs. We encourage patients to empower themselves by building and maintaining relationships with their physician, specialists, and pharmacist to help improve the quality, accessibility, and affordability of their care.

As this committee examines the Part B Drug Payment Demonstration, we offer the following for its consideration.

Value of Pharmacy

In Phase II of the model, the agency plans on incorporating new and innovative approaches to reducing prescription drug costs through the use of Value-Based Purchasing tools. Today, pharmacists play an increasingly important role in the delivery of services, including key roles in new models of care beyond the traditional fee-for service structure. Pharmacists are engaging with other professionals and participating in models of care based on quality of services and outcomes, such as accountable care organizations. Pharmacies, in their role as leaders in medication management services such as medication therapy management (MTM) and promotion of generic utilizations, could play an important role in Phase II of the model by improving and ensuring medication adherence and reducing prescription drug costs for the Medicare program.

Poor medication adherence costs the U.S. healthcare system $290 billion annually. Pharmacist-provided services such as MTM are important tools in the effort to improve medication adherence, patient health, and healthcare affordability. Improved medication adherence and MTM not only reduce costs, but improve patient care, enhance communication between providers and patients, improve collaboration among providers, optimize medication use for improved patient outcomes, contribute to medication error prevention, improve hospital and readmission cost avoidance, and enable patients to be more actively involved in medication self-management.

Pharmacies have also long promoted generic drugs as safe, cost-effective alternatives for many patients. Increasing the use of generic drugs in a public program is one of the most effective ways to reduce prescription drug costs. For every 1 percent increase in generic utilization, the Medicaid program could save $558 million. For example, if all other states could match the generic utilization rate of Hawaii (82.7%), the Medicaid program could save $6.56 billion annually. Because community pharmacies have a higher generic dispensing rate—71%—than any other practice setting, it is important to recognize the role of community pharmacies in promoting generic drug utilization.

We believe options should be explored to better utilize pharmacists in the Medicare program. One option we urge you to consider is recognizing pharmacists as providers in the Medicare program. Pharmacists provide access to health tests, help to

manage chronic conditions such as diabetes and heart disease, and provide expanded immunization services. However, the lack of pharmacist recognition as a provider by third-party payors, including Medicare and Medicaid, limits the number and types of services pharmacists can provide, even though fully qualified to do so. Retail pharmacies are often the most readily accessible healthcare provider. Research shows that nearly all Americans (86%) live within 5 miles of a retail pharmacy. Such access is vital in reaching the medically underserved.

We urge you to increase access to much-needed services for underserved Medicare beneficiaries by supporting H.R. 592/S. 314, the Pharmacy and Medically Underserved Areas Enhancement Act, which will allow Medicare Part B to utilize pharmacists to their full capability by providing those underserved beneficiaries with services (subject to state scope of practice laws) not currently reaching them. This important legislation would lead not only to reduced overall healthcare costs, but also to increased access to healthcare services and improved healthcare quality.

Misplaced Incentives for the Part B Drug Payment Model

The goal of the model is to incentivize the use of lower costs prescription drugs in Phase I through the use of a reduced average sales price (ASP) plus add-on fee of $16.80 may lead to unintended consequences and hardships for providers and suppliers who merely dispense medications. Under the model, the dispensing of higher cost medications will result in a significant reduction in reimbursement. While this is the goal of the new payment methodology, it unfairly penalizes pharmacies that are only able to dispense medications as prescribed by the physician. Pharmacies have little control over the medications prescribed to beneficiaries under Medicare Part B, forcing them to dispense the prescription for a reduced payment amount.

Because the pharmacy would be the one dispensing and getting reimbursed for the medications, there would be no impact on the prescribing practices of providers for those medications dispensed outside of the office setting. Prescribers would have no incentive to change their prescribing practices. In the alternative, policies should focus on testing payment methodologies that impact the incentives and the buying and billing practices of prescribers. This includes payment policies that incent the dispensing of generic drugs and biosimilars that would increase the uptake of generic drugs and biosimilars as a means of providing lower cost medications and reducing beneficiary cost sharing, which contribute to overall Medicare drug spending. This includes examining an enhanced reimbursement for these medications, such as an ASP + 8% or ASP + 6% and a flat fee each time a generic drug or biosimilar is prescribed. Unfortunately, the proposed Part B Drug Payment Model misses the opportunity to encourage the use of these lower cost medications that could ultimately lower drug spending for the Medicare program.

Waiver of Statutory Requirements for Infusion Drugs

Payment for drugs infused with a covered item of durable medical equipment (DME), such as insulin used with a covered insulin pump, are statutorily reimbursed based on the average wholesale price (AWP) in effect on October 1, 2003. As the Office of Inspector General noted in a 2013 report:

> These payment-related issues could significantly affect drug utilization and acquisition. For example, excessive payments could present incentives for providers to overutilize a particular product, *while payments that are below cost could contribute to an inability or unwillingness to provide a particular drug.*

While the goal of the proposed payment model is to reduce incentives for overutilization of higher cost products, NACDS is pleased that CMS recognized the issues related to underpayment for certain medications by proposing to waive the statutory requirement and include infusion drugs that are furnished through covered DME items in the model. However, in doing so, CMS is proposing to:

> . . . exclude this category of drugs from phase I of the model so that DME policy can focus on issues related to DME and so that the model does not interfere with decisions related to the inclusion or exclusion of these drugs in DME competitive bidding.

NACDS believes infusion drugs that are furnished through covered DME should be included in Phase I of the payment model. The lack of updates to reimbursement amounts for more than a decade has serious implications for Medicare beneficiaries. This is particularly true in the case of insulin.

Insulin that is self-administered by a beneficiary with an injection is covered under Part D, whereas the same insulin administered through an insulin pump is covered

under Part B. However, reimbursement to a pharmacy for dispensing insulin under Part D is almost twice as much as Medicare reimbursement for the same insulin under Part B. The disparity has increased to the point that a pharmacy dispensing insulin under Part B is doing so below their acquisition cost.

As a result, this may mean that beneficiaries with an insulin pump find it harder and harder to find locations able to fill their Part B insulin. This likely would lead to poorer beneficiary health through decreased adherence and increased Medicare costs through increased hospitalizations and utilization of other more expensive services.

CMS's proposal to exclude infusion drugs, such as insulin administered via an insulin pump, from Phase I of the model may contribute to access issues for Part B beneficiaries. For this reason, NACDS recommends the inclusion of these drugs in both phases of the model.

Administration, Supplying, and Dispensing Fees in Phase II

NACDS is concerned with CMS's proposal that Phase II of the model may incorporate changes to the furnishing, supplying, and dispensing fees that are associated with dispensing drugs under the payment model. These include inhalation drug dispensing fees and supplying fees to pharmacies for certain immunosuppressive, oral anticancer, and oral antiemetic drugs.

It appears the proposal for Phase II of the model envisions decreasing or eliminating dispensing and supplying fees for drugs included in the model. NACDS believes such a step would be very troubling. NACDS believes steps should be taken to ensure dispensing and supplying fees are fair and adequate, and providers and suppliers are paid at rates that are sufficient to cover the cost of dispensing prescriptions drugs to Medicare beneficiaries. This is particularly true in the Part B program where increasing supplying or dispensing fees for Part B drugs would help offset burdensome administrative costs incurred in Medicare Part B claims submission.

CMS has not updated supplying and dispensing fees since 2005, even though the cost of providing services to Medicare patients continues to increase. CMS's failure to increase supplying and dispensing fees results in community pharmacies' reimbursement falling below the actual cost to dispense Part B prescriptions. Fair and adequate Medicare dispensing fees help to ensure that pharmacy providers are paid at rates that are sufficient to cover the cost of dispensing prescriptions drugs to Medicare beneficiaries. Such rates could allow for a reasonable return above the pharmacies' costs of acquiring and dispensing prescription drugs, encouraging pharmacies to agree to participate in the Medicare program and thereby promoting patient access to their Part B medications.

In fact, CMS has recently acknowledged the important role fair and adequate dispensing fees play in maintaining patient access. In releasing the Final Medicaid Program Covered Outpatient Drugs Rule earlier this year, CMS stated that:

> We agree that pharmacy providers should be reimbursed adequately for their professional services. . . .

Furthermore, CMS stated that the proposal to revise the term from "dispensing fee" to "professional dispensing fee" was:

> . . . designed to reinforce our position that the dispensing fee should reflect the pharmacist's professional services and costs to dispense the drug product to a Medicaid beneficiary.

In recognizing the negative impact inadequate dispensing fees can have on beneficiary access, CMS required that:

> . . . states must provide information supporting any proposed change to either the ingredient cost or dispensing fee reimbursement which demonstrates that the change reflects actual costs and does not negatively impact access.

NACDS believes the importance of supplying and dispensing fees in the Medicare Part B payment model should be recognized and increased to properly reflect the costs to providers and suppliers in dispensing and administering Part B drugs.

Conclusion

NACDS thanks the committee for consideration of our comments. We look forward to working with policymakers and stakeholders on these important issues.

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May 9, 2016

Andy Slavitt
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RIN 0938–ASSS: Medicare Program; Part B Drug Payment Model Proposed Rule

Dear Administrator Slavitt,

The National Rural Health Association (NRHA) is pleased to offer comments on the Medicare Part B Drug Payment Model Proposed Rule. We appreciate your continued commitment to the needs of the 62 million Americans residing in rural and underserved areas, and look forward to our continued collaboration to improve health care access and quality. While we support the inclusion of rural providers in the proposed part B drug payment model, rural hospitals must be excluded to avoid exacerbating the existing rural hospital closure crisis.

NRHA is a non-profit membership organization with more than 21,000 members nationwide that provides leadership on rural health issues. Our membership includes nearly every component of rural America's health care infrastructure, including rural community hospitals, critical access hospitals, doctors, nurses and patients. We work to improve rural America's health needs through government advocacy, communications, education and research.

Access to quality, affordable health care is essential for the 62 million Americans living in rural and remote communities. Rural Americans are more likely to be older, sicker and poorer then their urban counterparts. Specifically, they are more likely to suffer with a chronic disease that requires monitoring and follow up care, making convenient, local access to care necessary to ensuring patient compliance with the services that are necessary to reduce the overall cost of care and improve the patients' outcomes and quality of life. Yet, many rural Americans live in areas with limited health care resources, restricting their available options for care, including primary care.

Rural hospitals provide beneficiaries a local access point for health care close to home. Though rural seniors are often forced to travel significant distances for care, especially specialty services, rural hospitals are able to accommodate a variety of patient needs through the use of telemedicine and local follow up care for specialty care received elsewhere. Rural physicians and hospitals work around a plethora of challenges to provide high quality personalized care to their patients. Services such as providing local infusions of medications ordered by distant specialists to ensure patients are able to adhere to medication schedules that would be prohibitive if the patient was required to travel, often hours in each direction, to a distant specialist.

Rural hospitals are closing. Seventy-one rural hospitals have closed since 2010. Right now, 673 additional facilities are vulnerable and could close—this represents over ⅓ of rural hospitals in the U.S. In fact, the rate of closure has steadily increased since sequester and bad debt cuts began to hit rural hospitals; resulting in a closure rate six times higher in 2015 compared to 2010. Continued cuts in hospital payments have taken their toll, forcing far too many closures. Medical deserts are appearing across rural America, leaving many of our nation's most vulnerable populations without timely access to care.

While the Sole Community Hospitals (SCH), Low Volume Hospital (LVH) and Medicare Dependent Hospital (MDH) programs have helped stabilize some rural hospitals, rural hospitals paid at a Prospective Payment System (PPS) rate are more

vulnerable to closure. Sixty-five percent of the closures have been of PPS hospitals, though these hospitals are less than one-third of all rural hospitals. A recent study out of the Sheps Center at University of North Carolina found that overall "profitability of rural hospitals decreased while the profitability of urban hospitals has increased since FY 2012."[1] Specifically of concern is that "R[ural] PPS hospitals with 26–50 beds and MDHs had the lowest profitability compared to other hospitals," both had negative median operating margins. MDHs had median operating margins less than negative 2 percent. This result is unsurprising considering the MedPAC March 2016 report indicating that "average Medicare margins are negative, and under current law they are expected to decline in 2016." For rural hospitals that on average serve an older, sicker, and poorer population, negative Medicare margins often mean negative overall margins. These vulnerable hospitals are unable to absorb further cuts without exacerbating the closure crisis.

Rural hospitals must be excluded from the proposed Part B Drug Payment model to avoid additional rural hospital closures and maintain continued access by vulnerable populations. The proposed rule estimates a net negative impact for rural hospitals (−0.3% overall, 2.2% of drug payments for a total loss of $322 million). While this cut may appear small on its own, it must be taken in context of other Medicare cuts already leading to the closure crisis, including sequester, bad debt reductions, and Disproportionate Share Hospital (DSH) cuts. At a time where extensive Medicare cuts are already causing far too many rural hospitals to close, this additional cut would be one additional cut causing more hospital closures. These rural hospitals often provide safety-net services for vulnerable populations that have little or no capacity to travel great distances for care.

NRHA appreciates that the proposed rule specifically requested comment on "the potential effect that this model may have on rural practices, how rural practices may differ from non-rural practices and whether rural practices should be considered separately from other practice locations," as well as the recognition that "this proposed rule may have a significant impact on small rural hospitals [located outside of a metropolitan statistical area and has 100 or fewer beds] selected for the model." The regulatory impact analysis on the effects on small rural hospitals provided in the proposed rule coupled with the uncontroverted evidence of the hospital closure crisis caused by the already enacted Medicare cuts which disproportionately impact rural PPS hospitals supports the exclusion of these vulnerable hospitals from this proposed model.

Thank you for the chance to offer comments on this proposed rule, and for your consideration on our comments. We very much look forward to continuing our work together to ensure our mutual goal of improving quality of and access to care. If you would like additional information, please contact Diane Calmus at dcalmus@nrharural.org, or 202–639–0550.

Sincerely,

Alan Morgan
Chief Executive Officer
National Rural Health Association

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[1] Thomas, Sharita R.; Holmes, G. Mark; and Pink, George H. (March 2016). 2012–14 Profitability of Urban and Rural Hospitals by Medicare Payment Classification. Available at *https://www.ruralhealthresearch.org/alerts/113.*