OPEN EXECUTIVE SESSION TO CONSIDER THE MODERNIZING AND ENSURING PBM ACCOUNTABILITY (MEPA) ACT

WEDNESDAY, JULY 26, 2023

U.S. Senate,

Committee on Finance,

Washington, DC.

The meeting was convened, pursuant to notice, at 2:02 p.m., in Room SD-215, Dirksen Senate Office Building, Hon. Ron Wyden (chairman of the committee) presiding.

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

Also present: Democratic staff: Shawn Bishop, Chief Health Advisor; Nicole Brussel Faria, Investigator; Joshua Sheinkman, Staff Director; and Tiffany Smith, Deputy Staff Director and Chief Counsel. Republican staff: Becky Cole, Chief Economist; Kellie McConnell, Health Policy Director; and Stuart Portman, Senior Health Policy Advisor.

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

The Chairman. The Finance Committee will come to order. We are meeting today to consider the Modernizing and Ensuring PBM Accountability Act. This is going to be a busy day in the Senate, and for the information of Senators and staff, let me explain how I and Ranking Member Crapo would like to proceed.

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

After that, we will consider amendments to the mark. We will then vote on whether to report the mark. If a quorum for a vote is not present, we will vote when we have a quorum. With that, we are going to turn to opening statements, and I will give mine and then recognize Senator Crapo.

The Finance Committee is convened to vote on a set of proposals that finally are going to modernize federal prescription drug programs and put a stop to practices by pharmacy benefit managers that are driving up costs

for patients and for taxpayers.

Pharmacy benefit managers are the middle men between your health insurance and drugmakers that virtually seize every prescription handed from a doctor to a patient. Decades ago, the PBM served a role. That role was to assemble mountains of claims data and use bargaining power on behalf of insurance companies to negotiate with drugmakers for lower prices.

In recent years, these businesses have consolidated into mega-corporations that dominate the market. The consolidation has allowed PBMs to adopt tactics and play games with their data, that result in higher profits for themselves and higher costs for everybody else.

Each year, the United States spends more than $4 trillion on health care, and too much of that is frittered away on outdated middlemen practices. So the business before the Committee today is to begin to root out these outdated, inefficient middlemen practices.

These targeted changes to Medicare and Medicaid are going to stop the infuriating games and steer America's prescription drug market to a state of rationality, where the incentives are always about lowering costs for the patients and the taxpayers.

I would like to thank Ranking Member Crapo and

every Member of the Committee for their dedicated work on a bipartisan basis to get to this markup. I can look at the dais on both sides, and every single Member of this Committee has been working in a constructive way, and that is why we have a chance to do something very important today. I especially want to thank Ranking Member Crapo, every Member of the Committee for their dedicated work on a bipartisan basis to get to this mark-up.

A little less than four months ago the Finance Committee held a hearing to examine PBM industry practices that may be resulting in higher prices in a dysfunctional market. Since then, Members and our staff have been working around the clock to craft proposals to start a course correction.

I want to emphasize to Members that Ranking Member Crapo and I have agreed to work together, to continue to work together following today's Committee action to develop and include as many additional proposals as possible, as legislation reported out of the Finance Committee moves to the full Senate.

There is no shortage of bipartisan, thoughtful ideas, and I believe many of them can make it to the President's desk. Here are briefly some of the significant developments that the Finance Committee will

consider this afternoon.

This effort marks the first time in decades that Congress has taken on the power of middlemen that are keeping a big cut of the $4 trillion and sending health care costs skyrocketing for everybody else each year.

First up is putting a stop to PBM compensation being tied to the sticker price of the drug, that is causing these middlemen to often favor higher-priced drugs. The incentive of PBMs is just wrong. They win when prices are higher, not lower. Today's proposals will flip that on its head.

Another set of provisions will shine a light on PBMs that have been operating in the shadows for years. Our proposals make it clear when PBMs are giving taxpayers and patients a bad deal. So with this new sunshine, it is going to be complemented by independent audits and strong enforcement measures to ensure PBMs comply with the law.

The Committee's proposal also contains measures that we are including to set up new opportunities for small pharmacies in the days ahead. In many parts of the country, particularly rural areas and large cities, independent pharmacies are more familiar and most with the difficulty of dealing with this out of whack prescription drug market.

I have seen and heard firsthand in my home state of Oregon how precarious pharmacies are in small towns, like Grant's Pass and Pendleton and Redmond and so many communities across the state, and I will put my full statement into the record outlining those practices.

And these practices are essentially examples of big corporations using their market power to bully small businesses out of markets. What we are going to consider today is just the beginning of our effort to provide relief to small community pharmacies.

I would like to just note apropos of the bipartisan approach in this Committee, Senator Brown, Senator Grassley, Senator Casey, Senator Lankford, Senator Warner and Senator Thune all have teamed up to lead the charge to put in place a very different approach that would liberate these small pharmacies, so that they could be as competitive as possible.

Our proposals start by providing relief now and paving the way for more transformation in the role of small pharmacies in the coming months. As I have indicated, this bill did not happen by osmosis, colleagues. We had Senators on both sides of the dais coming together, and I think these are going to be important policies that begin to transform American health care because they are reducing the role of

middlemen for the first time in this $4 trillion annual economy.

Senator Crapo?

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

Senator Crapo. Thank you, Mr. Chairman, and thank you to both you and your staff for the tireless work and collaboration that have made this process so successful. In March when we held a hearing on access gaps and affordability challenges faced by many seniors in Medicare Part D, Members across this Committee spoke to the need for concrete and meaningful legislative solutions.

The following month, we crystallized these calls for action in our bipartisan framework, which created a comprehensive blueprint for modernizing federal prescription drug benefits to increase competition and drive down costs.

Today, we will take a critical step toward delivering on our commitment to patients and working families, by advancing this commonsense, market-driven and fiscally responsible legislation. For months, our staff have worked seven days a week to develop and refine the proposals included in this market, engaging with stakeholders from across the supply chain and Senators spanning the entire Committee, to build consensus and to address a broad range of challenges.

The resulting bill comprises a strong set of bipartisan, patient-focused proposals aimed at fueling competition, improving transparency and mitigating misaligned incentives in Medicare Part D and Medicaid.

Listing every provision would take more time than we have, but I will acknowledge some of the key contributions. Thanks to the leadership of Senators Blackburn and Menendez, the legislation would delink PBM fees from the drug prices under Medicare Part D. This will help curb preferences for higher-priced medications.

I look forward to working with the Chairman in the coming weeks to build on this foundation by preventing prescription drug plans from charging patients based on sticker prices for certain medications, even as these same plans take in deep discounts.

For chronic diseases, this distorted and hidden system of post-sale rebates deprives seniors of direct out-of-pocket savings. We may need to start small, but the Chairman's commitment to continuing this crucial work is deserving of recognition.

We reiterated this commitment in our recent letter to the Congressional Budget Office. From a patient perspective, we also need to do more to ensure pharmacy access, particularly for seniors living in rural areas.

When the Chairman and I voted to create Medicare Part D 20 years ago, we did so with an understanding, as codified, that the program would guarantee beneficiaries access to the pharmacy of their choice.

Oversight and enforcement, however, have fallen short of that promise, forcing far too many community pharmacies to close up shop, depriving Americans of critical frontline health care providers.

The legislation before us today will help to reverse these problematic trends, including through streamlined quality measures, increased transparency and key policies to discourage patient-steering. I thank Senators Thune, Barrasso, Lankford and Blackburn for their ongoing efforts on this front.

We have also included policies to give patients more control over the Part D regulatory process, thanks to the legislation spearheaded by Senators Scott and Warner. Senators Grassley and Carper for their part have taken vital steps towards addressing conflicts of interest on pharmacy and therapeutics committees.

Senators Tillis and Cortez Masto have proposed empowering plans with the tools and information needed to provide more and better choices for seniors. Our legislation takes a broad-based but targeted approach. Senators Lankford and Bennet, for instance, have drafted

a provision examining price-linked compensation arrangements across the entire supply chain, and Senators Tillis and Cortez Masto have advanced a robust set of PBM reporting requirements to increase competition.

These proposals represent a decisive first step towards reducing costs and enhancing access for American patients. As the Chairman and I stated in our recent letter to CBO, we intend to continue to work on a bipartisan basis to incorporate additional policies that will constitute a comprehensive suite of reforms.

We have requested CBO budgetary feedback by August 31st on proposals that would help to cut out-of-pockets costs, increase pharmacy access and ensure that seniors benefit from lower-cost biosimilars.

Senators Lankford, Cornyn, Carper, Blackburn, Menendez and others across the dais have shown strong leadership on these issues, and their continued partnership will prove essential as we attempt to address perverse incentives that drive costs higher for patients and taxpayers.

The Chairman and I have agreed that any savings from this mark-up will serve in the coming weeks to assist in reducing beneficiary costs and ensuring access to frontline pharmacy providers. Thank you to the

Congressional Budget Office staff for all of their hard work so far on this legislation, as well as their commitment to work on these additional proposals in August.

While not easy, there is no path to enacting these meaningful results for patients into law if we avoid problematic poison pills that divide Senators and work with our House colleagues on the next steps, so that the process continues to generate broad, bipartisan, bicameral support.

Again, I thank the Chairman and all of the Members on this Committee for their hard work and their support.

The Chairman. Thank you very much, Senator Crapo. And Senator Crapo has praised the Democratic staff, and I just want to praise the Republican staff, because they have spent months and months coming together on it. I think I know the answer to this question, but do any other Members wish to make opening statements? And we will go in order of appearance.

Senator Cantwell?

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

Senator Cantwell. Thank you, Mr. Chairman, and thank you to you and Senator Crapo for working on this important issue. Pharmacy benefit managers have been operating in the dark without oversight for too long, and since their inception in 1968, PBMs have grown from entities that help process claims to corporate giants who either control or have a stake in every step of the drug distribution process.

Relatively little is known about their activities, including how much in rebates they receive from manufacturers, how much of the rebates they keep or pass on, or the justifications for clawing back reimbursements from pharmacies.

That is why Senator Grassley and I introduced the Pharmacy Benefit Manager Transparency Act and directs the Federal Trade Commission to crack down on these unfair and deceptive practices, while shining a light on PBMs' bad practices to provide more transparency and accountability.

This legislation has moved through the Senate Commerce Committee and is now awaiting action on the floor. I cannot thank Senator Grassley enough for his

leadership on that important legislation.

We also must build existing efforts to hold PBMs accountable for their actions, which is why we also introduced the Cantwell-Grassley-Menendez-Daines amendment to this legislation we are considering today. This amendment I think has been accepted, would strengthen the existing reporting requirements to the HHS Secretary by adding group purchasing organizations and other PBM affiliates to the list of entities that actually have to comply with the reporting requirements.

It would also require PBMs to disclose any non-administrative fees that they receive from the manufacturers.

So I am pleased that this has been incorporated into the Chairman's mark, pleased that the two of you have been able to reach important decisions on this, just as Senator Grassley and I have for the Commerce Committee, and I hope that this transparency that is much needed in this market, that this is skyrocketing costs, that we will actually do something this Congress to help rein that in. Thank you, Mr. Chairman.

The Chairman. Thank you, Senator Cantwell. I just want to say colleagues, if I thank everybody for their contributions, we will all be here until breakfast time tomorrow. So I just want Members to know I am very

appreciative, and we will just do everything we can to move this along.

Senator Grassley is next.

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

Senator Grassley. Thanks to the Chairman and the Ranking Member for bringing us to this point of mark-up. PBMs play a central role in the high cost of prescription drugs. Five years ago, the only person who might know what a PBM does would be your local pharmacist. I am glad that we have been able to help educate the American people on what a PBM is and how they can negatively impact a patient's bottom line.

We have done this through efforts that we have started, the Chairman and I started in 2018 to get the FTC involved in studying PBMs, and secondly in our bipartisan two-year insulin investigation that showed price gouging by PBMs and drug companies.

In reviewing the Chairman's mark, three provisions are similar to policies we advanced in this Committee three years ago in the drug pricing mark-up that I chaired. I hope today's mark-up shows that we are taking aggressive action on PBM accountability.

If we are timid, we will be right back here in a few years from now, fixing the problem we thought we fixed at this point. One amendment that I filed that does not meet the Chairman's germaneness standard is to

allow pharmacy provider status under Part B. This bill would positively impact seniors' access to medications and local health care services.

I hope this Committee will consider the bill, Pharmacy in Medically Underserved Areas Enhancement in future Medicare conversations. I remain committed to my two PBM bills that I have worked with Senator Cantwell on, that have advanced out of the respective committees.

While not in this Committee's jurisdiction, they complement the efforts of Finance today. I hope the Senate does not miss this opportunity to hold the FTC accountable in requiring 6(b) study of drug middlemen to be produced within one year instead of three to five.

Also, the FTC can play an important role of holding PBMs accountable across all health insurance on spread pricing clawbacks. Finally, I appreciate the Chairman and Ranking Member for holding two of my amendments in the modified mark, the pharmacy and therapeutic Committee conflict of interest standards on PBMs, and secondly PBM administrative fee transparency enhancement under Section 1150(a). Thank you.

The Chairman. Thank you very much, Senator Grassley.

The next two will be Senator Menendez and then Senator Cornyn.

OPENING STATEMENT OF HON. ROBERT MENENDEZ, A U.S. SENATOR FROM NEW JERSEY

Senator Menendez. Mr. Chairman, Ranking Member Crapo, thank you for tackling this issue head on and bringing a strong bipartisan bill for consideration today. I appreciate your leadership and your partnership on these issues.

Just yesterday, I held an event at Sugarman's Pharmacy in my hometown of Union City, New Jersey. I spoke to New Jerseyans from all walks of life, listening to them as they shared their stories of struggling to afford medications at the pharmacy counter.

Each story was unique, yet all of them agreed that pharmacy benefit managers need to be held accountable for their role in rising costs. So yesterday I heard agreement today in this hearing room. I see broad-based consensus that the PBM industry is in desperate need of reform.

For too long, PBMs have held a vise grip over the prescription drug supply chain, price gouging hard-working families and seniors alike through the current perverse incentive structure. Whereby they turn a profit as a percentage of the list price of a prescription, PBMs wield their influence to have health

insurers cover more and more expensive drugs, even when cheaper options are available.

My Patients Before Middleman Act, which we have introduced alongside Senator Blackburn, the Chair, the Ranking Member, Senators Marshall and Tester among others, would replace the complicated scheme of opaque rebates and administrative charges with a flat fee, one that is negotiated before entering into a contract.

By delinking PBM compensation from drug prices, we help lower prescription drug costs for Medicare Part D beneficiaries, and better align incentives in the market. Our bipartisan Patients Before Middlemen Act would curb the biggest abuses in the PBM industry today.

For patients on Medicare, including those who rely on pharmacies like Sugarman's in Union City, it is a bill that has the power to make an enormous difference in their lives, and I want to thank the Chair and the Ranking Member for including it in today's mark-up.

The Chairman. Thank you very much, Senator Menendez.

Senator Cornyn?

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

Senator Cornyn. I too would like to thank you, Mr. Chairman and Ranking Member Crapo, for leading this bipartisan package. It is a difficult task coming up with good policies of low out-of-pocket costs for seniors, create cost savings in Medicare and Medicaid, and provide needed transparency to pharmaceutical drug supply chains.

Pharmacy benefit managers, as we have heard, play an important role in negotiating drug prices for patients. However, changes in the supply chain that have led to consolidation of stakeholders has made the system in which the PBMs operate increasingly complex and opaque. It has changed incentives away from prioritizing medicines that deliver the best results at the lowest price to encouraging higher rebates and higher list prices.

The Modernizing and Ensuring PBM Accountability Act addresses these misaligned incentives that drive up prices and costs by delinking PBM fees from the list price of prescription drugs. It provides much-needed transparency and prohibits anti-competitive behavior.

This is a great first step, but there is still

more work for us to do, especially to reduce out-of-pocket costs for seniors. I have been working with Senators Carper, Tillis and Brown on a proposal that would provide rebate pass-through for Part D beneficiaries with chronic conditions. These individuals, as we know, face high out-of-pocket costs and should directly benefit from the savings that plans and the PBMs negotiate on their behalf.

This proposal also addressed the misaligned incentives for plans to cover particular medicines based on their rebate, individual rebate levels. So I hope the Chairman and the Ranking Member can commit to continuing to work with all of us to include some of these priorities, particularly this one, before this package comes to the floor.

The Chairman. Thank you, Senator Cornyn. We are going to talk about those issues.

Senator Carper and Senator Cassidy are the next two.

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

Senator Carper. Thanks, Mr. Chairman. Good afternoon. To our colleagues and I also want to say to the members of our staff that are gathered here and those that are not, they have worked really hard, Democrats, Republicans, and we are grateful to each of you for your help.

I want to especially thank the Chairman and Ranking Member for their leadership for pulling this together, and several of the colleagues that are here today. Senator Grassley has worked these issues for a long time. I am delighted to be his colleague in some of these efforts today and also Senator Cornyn.

I tell people in Delaware, John Cornyn and I work on so many issues together. People in Delaware think my first name is Cornyn, as in Cornyn Carper, and I have tried to convince them that that is not true. I have been called worse, so as you all know, we are here to address the issues with the current practices of pharmacy benefit managers, also known as PBMs, and this is important to understand as a Member of Congress ensuring transparency in our health care system.

It is equally important for patients to understand

the role of PBMs because it directly affects costs that patients see at the pharmacy counter. Far too many Americans are forced to make the sometimes gut-wrenching decision of choosing between putting food on their tables and paying for the medications that they need.

As Members of this Committee, I think we are all honored to be a Member of this Committee. I wanted to be on this Committee even before I came to the Senate, and happy to be here with all of, all of you today.

We have a responsibility particularly to families and to seniors, and to take one of the worse practices by drug pricing middlemen and ensure that patients can afford their prescriptions. We all do our work together, Democrats and Republicans, to uncover how PBMs play a role in increasing the high cost of prescription medications, so that patients do not have to choose between dinner and a life-saving medication.

Today's legislative mark-up and in the hearing that we held recently on this topic, I strived to keep in mind four questions and I came up with these four questions when we were working on the IRA, and when we were working on pharmaceutical pricing.

But the four questions I ask is how would this affect or impact the work -- no, no. What would be the effect on patients? What would be the effect on

patients in terms of their pocketbooks? How does this increase transparency and understanding or diminish it? How does the particular act that we're thinking of taking make us better stewards of the federal government or worse stewards, and also what is going to be the impact that this work has on fostering innovation?

With these four guiding principles and the knowledge we have gained on the roles of PBMs, today we have an opportunity to put patients first and bring them back to the forefront of our medical system, and together we can hold PBMs accountable.

Again, my thanks to the Chairman and to the Ranking Member for including the modified mark the proposal that I authored along with Senator Grassley, to ensure that there are no conflicts of interest in getting prescription drugs from manufacturers to patients.

I appreciate everyone's commitment to working together to advance the entirety of the PBM Oversight Act as the legislative process continues. I look forward to taking bipartisan action on these important issues before today's mark-up, and I just close with some great testimony, some words we got, I think we heard in the EPW, in the Environment and Public Works Committee years ago at a confirmation hearing, one that

we got from John Barrasso, who has been nominated for a position at Interior.

He said these words. He said these words. He said "bipartisan solutions are lasting solutions." That is what he said. Bipartisan solutions are lasting solutions. I think we are going to prove that again here today. Thank you so much.

The Chairman. Thank you, Senator Carper.

Senator Cassidy is next.

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

Senator Cassidy. Thank you, Mr. Chair. First, I want to echo some of my colleagues. So I am going to echo Senator Menendez, who went to a pharmacy and the pharmacy spoke about PBMs. The pharmacists have done a wonderful job of educating Congress over the last several years about this issue. So a tip of a hat to our fellow Americans.

I want to also tip of the hat to Grassley and Cantwell. The HELP Committee has also worked on this, and I share what they said about how our work on HELP will complement that done by Judiciary, by Commerce and now by this Committee, and by the way, also by Ways and Means and also by Energy and Commerce. So there is a bipartisan, bicameral approach to this which is important.

Next, I want to speak to echo what Senator Carper said. This is about patients. There was just an article that came out this week in the Journal of the American Medical Association, in which it shows that since MA plans have voluntarily capped the price of insulin, and since it was otherwise capped by federal law, the number of refills on insulin prescription has

risen.

Whereas in the commercial market, which HELP is trying to address, as are my colleagues in their Committee, in the commercial market where it is uncapped, in which there continues to be a higher price for insulin, the number of refills has declined. The point being when you make drugs more affordable, people are more likely to refill their scripts.

And when people refill their scripts, they are more likely to be healthy, less likely to enter the hospital, more likely to just live life fully. So we are more than cost; we are more than PBMs. We are all about patients, about patients getting better and those patients include us and those patients are our fellow Americans. So let us get to work.

The Chairman. Well said, Senator Cassidy.

Senator Bennet then Senator Lankford.

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

Senator Bennet. Thank you, Mr. Chairman. Thank you so much for holding this mark-up and, Ranking Member Crapo, for your leadership as well on the Modernizing and Ensuring PBM Accountability Act. We need to do this, to help lower health care costs for patients and for taxpayers.

The last Congress, we finally overcame a series of very strong special interests to lower the costs of prescription drugs for seniors, as Senator Cassidy was just talking about the effect of -- the effect of that, and require Medicare to negotiate drug prices finally on behalf of the American people.

But we have more to do to bring down the cost of drugs in this country. We live in the wealthiest country in the world, and our seniors are resorting to cutting those meds. That is not just what a politician says; they are cutting those in half, and anybody who spends any time with seniors in this country knows it is true.

Coloradans tell me they are leaving their prescriptions at the counter because they simply cannot afford them. They are skipping doses, or worse they are

going without the prescriptions they need, as Senator Cassidy was just talking about.

I have worked on bringing down drug costs for over a decade, and I think most Americans would agree that this system that we have is needlessly opaque and confusing. With list and out-of-pocket prices, rebates and administrative fees, it is no surprise that any American can understand why they have to pay so much for their drugs or who is to blame.

So, I am glad that today's mark-up will include an amendment based on a bill Senator Lankford and I wrote together, to increase transparency across the entire drug supply chain, including pharmacy benefit managers and distributors. In addition to creating more transparency, we need to increase access to generics and biosimilars, the cheaper alternatives to brand name drugs.

To that end, I have offered an amendment with Senator Cornyn based on our increasing access to biosimilars. I have offered a similar amendment based on a bill I have worked on with Senator Smith, the American-Made Pharmaceuticals Act, which will increase American drug manufacturing.

There is more we can do to fix this broken system, and I look forward to our discussion today. Thank you,

Mr. Chairman.

The Chairman. Thank you, Senator Bennet.

Senator Lankford, you are next.

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

Senator Lankford. Mr. Chairman, thank you. I am so grateful we are having this hearing today. This has been an issue we have talked about for a long time. I am grateful to finally be at this day. I have been ringing the bell on PBMs for years.

We are almost four years to the day today from the last health care mark-up that this Committee actually held. At that mark-up, I brought a bill on PBMs dealing with greater access for seniors and lowering the costs for them. I am bringing that back up again today.

Unfortunately, from 2019 to now, CBO has not been able to do a score on it, and so we will have some opportunity to be able to talk about that as well. But this is an issue that I have been talking about for a very long time, and I am very grateful that we are all on board on this, as many of us have talked about this for a very long time as well.

This is a -- this is one of those issues that occasionally we get pressed on, to say are you opposed to free markets? I am not opposed to free markets. I am opposed to PBMs running my rural pharmacies out of business. That is what I am opposed to.

And over and over again when I talk to rural pharmacies, they tell me their frustration of a PBM changing the rules mid-month, charging them more for their DIR fees than the actual drug that they actually receive for a total. These are issues that we have got to be able to address.

So grateful that a number of the proposals that I am on with many of you on both sides of the aisle are also on, that deal with greater transparency, greater access to biosimilars, greater access to generics, greater opportunities for HHS to report to this Committee what is going on, greater opportunities to be able to get from GAO some additional information that is needed.

But also this is the front door toward dealing with additional items that need to be here, and quite frankly need to be strengthened even in this bill. I go back to something that Senator Grassley. We will get this shot to be able to do this. We need to make sure it is as strong as we can possibly make it.

And so we do not think we have actually solved the problem if the problem still yet to be solved. So I look forward to the conversation today.

The Chairman. Thank you, Senator Lankford.

Our next, our next two will be Senator Cortez

Masto and Senator Blackburn.

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

Senator Cortez Masto. Thank you. I too want to thank the Chairman and Ranking Member for this great bipartisan legislation that is before us today. I also appreciate the inclusion of the Medicare PBM Accountability Act in the Chairman's mark. It was a bill that Senator Tillis and I worked on. I appreciate both the Ranking Member and the Chairman joining us on this great bipartisan piece of legislation.

Seniors and working families in Nevada rely on health insurance coverage to help lower the cost of high-priced prescription drugs. But as we have all heard and are talking about today, there is a lot of deal-making happening behind the scenes here, and ultimately patients' access to affordable medicines can hinge on the efficacy of their plan, health plan's pharmacy benefit manager.

That is why Senator Tillis and I introduced the PBM Transparency legislation. It will ensure that PBMs are working to get the best deal for health plans and lower costs for the patients they serve. In order to select PBM services that work best for seniors, Medicare Part D plans need a line of sight into what is happening

when a PBM goes to negotiate those discounts with the drug companies.

Policies in the mark we are considering today will shine a light on the incentives in the system that work against affordable drug pricing. They will also make PBMs' conflicts of interest visible, so Medicare plans can negotiate against them. It really is time to hold PBMs accountable.

I also want to address the amendment that Senator Young and I also introduced that was accepted into the modified mark. This would require CMS to shine a light and post a public report related to preventing and addressing inappropriate pharmacy rejections and coverage denials.

I have been concerned. I am hearing this from Nevadans as well about the growing number of pharmacy rejections and claims denials in the Medicare Part D program. Far too often, seniors are showing up at the pharmacy counter to pick up their medications, medications that are prescribed by their doctors, only to learn that their insurer had denied their request.

So that is why Senator Young and I introduced this amendment. Part D plans cover nearly 50 million beneficiaries, to even lower rates of denied or delayed care could contribute to physical or financial harm for

many seniors and people with Medicare.

So, thank you again to the Chairman and Ranking Member, and really appreciate inclusion today.

The Chairman. Thank you, Senator Cortez Masto. We will also have Senator Warren's opening statement submitted into the record as well, I would say to the Clerk.

[The statement of Senator Warren appears at the end of the transcript.]

The Chairman. Senator Blackburn?

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

Senator Blackburn. Thank you, Mr. Chairman, and I thank you and Senator Crapo for your leadership and for moving us to the point that we do have a bill that is going to increase transparency in our federal prescription drug programs, and I am grateful that you all have included the PBM Act in your Chairman's mark and also for including my amendment regarding enforcement actions on the pharmacy access requirements in the modified mark.

And it has been a pleasure to work with Senator Menendez on the PBM Act, and that would delink the PBM compensation from the drug list price, a very important step, because that is part of correcting these misaligned incentives that exist in these programs. I understand that work is going to continue as we move forward today on this, and I do ask that you commit to building upon the bipartisan progress we have collectively made, and continue to advance policies that put patients and seniors first in the process.

This Committee should continue to work on policies that modernize Medicare's any willing provider pharmacy law; address exclusionary pharmacy networks in Part D;

and ensure cancer patients can get their oral chemotherapy and supportive care drugs from their treating providers.

So, I thank you for the ability to work together in a bipartisan basis. I look forward to a good, solid bill.

The Chairman. Thank you very much, Senator Blackburn.

Senator Cardin is next, followed by Senator Hassan.

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

Senator Cardin. Well, Mr. Chairman, I also want to thank you and Senator Crapo for bringing us together. As I am listening to everyone's opening statements, I have never seen so much harmony in a committee. So it is wonderful.

The Chairman. Keep it going.

Senator Cardin. I intend to do that. Last Congress, we made historic progress in addressing health care and prescription drug costs. Today marks another step forward in ensuring older Americans and those with disabilities have access to affordable prescription drugs.

Pharmaceutical benefit managers were initially established to act as intermediaries between insurance providers and pharmaceutical manufacturers and lower drug costs. However, the lack of transparency on pricing and profits, conflicts of interest and a lack of competition have allowed PBMs to profit without a clear benefit to patients.

The Modernizing and Ensuring PBM Accountability Act realigns the incentives of PBMs by delinking PBM income from prescription drug prices. It also promotes

transparency and oversight by requiring PBMs to report drug prices and costs, among other information, to the Department of Health and Human Services.

Mr. Chairman, I thank you very much for including an amendment that was offered by Senator Cassidy and I that deals with the drug shortage issues. To me, it is unacceptable, with out-sized profits being made, that low-cost, essential prescription drugs are not available, because they are just not making enough money off of it.

I hope that this study will lead us in the direction to take action to prevent these drug shortages in the future. I did offer a second amendment that would require point-of-sale rejection of prescriptions for coverable Part D drugs to be treated as prescription drug plan as coverage determinations subject to reconsideration and appeal.

Eliminating the need to formally request a coverage determination cuts unnecessary steps, reducing the burden on consumers and providers, and simplifies the Medicare Part D appeals process to improve access to needed medication.

I understand that is not within the scope of the bill, so it will not be considered. But I hope that we will have a chance to work on this issue as we move

forward.

The Chairman. I thank, I thank my colleague.

Next is Senator Hassan.

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

Senator Hassan. Well, thank you, Mr. Chair and Ranking Member Crapo, for not only the work we have all done, but for this mark-up, so that we can move forward on this very important issue. I just wanted to kind of reiterate what some of my colleagues have said, that this is life and death issues for a lot of our constituents.

I think about a constituent of mine who began cutting back on her medication. She was older, living alone, but because she was cutting back on her medication, she ended up having a stroke and is now in a nursing home and unable to care for herself.

So these are real-life consequences for our constituents. Everything we can do to bring transparency to PBMs and lower drug costs to make them more affordable and accessible for our constituents is what we should be focused on.

I am pleased that a provision that Senator Lankford and I have offered has been included in the bill, that really works to make sure generics and biosimilars are priced appropriately and not slotted in with brand name drugs and other medications. So with

that, thank you very much Mr. Chair, and I will be offering and withdrawing an amendment at the appropriate time.

The Chairman. Thank you very much, Senator Hassan.

The next two are Senator Johnson and Senator Stabenow.

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

Senator Johnson. Thank you, Mr. Chairman. I hate to break the harmony here, but I will try and do it as civilly as possible. I know I am new to this Committee, and I have not been steeped in this issue as so many of you have been. So, I certainly respect your viewpoints on this.

It should come as no surprise my comments, whether we are talking about tax reform or we have hearings on this, that I am always looking for simplicity. We have a horribly broken health care financing system in this country, and it is driven by the fact that the third party payment system, insurance and then government payment, has largely driven the benefit of free market competition out of health care.

I often describe the, you know, our government as the ship of state, with barnacles on that on the whole. The solution, the obvious solution would be to scrape the hull clean. What happens here in Washington is we just come up with another barnacle and stick it right on that hull on top of the other ones.

I am happy to be convinced and I will continue to work with everybody on our Committee to convince me that

this is not just another barnacle and this will actually scrape a couple of barnacles off that hull, which would be a good thing. But at this point, I am just not convinced. So I am going to have vote no on this, but I want to work with the Members of this Committee. I know you have got a lot more experience in this than I have.

But I really would urge my colleagues to always be looking how can we simplify these things, how can we scrape barnacles off as much as possible before we add a new one on. Thank you.

The Chairman. Okay. Let us go with Senator Stabenow, and then we will have an announcement of how we are going to proceed.

Senator Stabenow?

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

Senator Stabenow. Well, thank you so much. So back to harmony. [Laughter.]

No, you were very -- so it -- but let me just say that I think what we are trying to do is scrape off the problems of it being -- actually make this more transparent, lower prices and make the system work better.

So I want to thank the Chairman and Ranking Member Crapo for taking this bipartisan action. This is -- it is really terrific to see us coming together to work on addressing the high prices of prescription drugs. We know that Americans pay the highest drug prices in the world, three times as much as other countries.

That is why we move forward to have Medicare negotiate prices and cap $35 -- a cap on insulin last year for seniors. Hopefully we can do more with that as well. Nearly one in four people who take prescription medications struggle to afford them. We all know that.

We know the story even within our own family. We know it is not acceptable, and we have got to continue to do more, and that is why we are here today. So one way is to reform the pharmacy benefit manager system,

and I am really grateful for all of the hard work that has gone into this.

My Know the Lowest Price Act, which was actually signed back in 2018, banned PBMs from blocking our pharmacists, our local pharmacists, from telling people how they could pay less for a prescription. It was shocking to me when the pharmacists said they were not allowed to share that information.

But we know that gag clauses were only one of the many bad practices in the industry. So this legislation we are considering today will address many of those practices. It will ensure that PBMs are not paid more when a drug is more expensive.

It improves transparency for pharmacists, eliminates tactics in Medicaid that raise PBM profits while keeping drug costs high, and again I also want to thank the Chairman and Ranking Member for including important policies that I have worked on with my colleagues, and in the interest of time, rather than going through all of them, I would ask that it be -- the comments be submitted for the record.

But very much appreciate everything we have done, and I would finally just say that Senator Thune and I want to continue to work together, Mr. Chairman, with you to improve the use of real-time benefit tools, so

patients can understand pricing when they are prescribed a drug. And so this did not make it into the mark because of the germaneness, but we want to work with you and the Ranking Member.

Thank you.

The Chairman. Thank, thank you Senator Stabenow, and Senator Crapo and I have both indicated we want to work with Senator Thune and you on this.

Okay. Here is where we are procedurally.

After opening statements, Members are going to have the opportunity to ask questions of the staff. Then Members can offer amendments and have colloquies. Then we hope to be able to complete consideration of amendments and plan to vote on final passage around 3:30, and I encourage all Members to be in the hearing room for the vote at that time.

We have three Members still to give their opening statements. They are Senator Daines, Senator Thune and Senator Warner, so we recognize our colleague, Senator Daines.

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

Senator Daines. Mr. Chairman, thank you. I am glad we have come together here and have something to move forward on a bipartisan basis. The more that I dig into this issue of PBMs and so forth, in some ways the more complicated and opaque it becomes.

I think what we are doing here is trying to shine better light on it and provide greater transparency, and ultimately until the patient sees this information and the patient's in the middle of that pharmacy and prescription transaction, we are never going to make, I think, the progress we need to really lower the costs and drive the value back in the patient's pocket.

I am glad we have made this a priority to examine policies that can help Montanans, can help our fellow Americans across the country, applying appropriate scrutiny to PBMs, which have previously lacked transparency within the prescription drug supply chain.

I am glad we are going to be doing something there that is not going to stifle innovation. That has been a concern I think for many of us on actions from this Committee. It is like do something, even if it is wrong. We cannot do the wrong thing; we have got to do

the right thing, and this is something I think is heading in the right direction.

But I think we always want to keep our eye on the prize here in terms of ensuring that the innovation within, within new drugs and pharmaceuticals remains in the United States, and does not move to places like China. It is important we do maintain a holistic perspective as we look at this, as we deliberate about our nation's drug pricing challenges.

It is something all of us I know hear a lot about from our constituents back home. Chairman Wyden, Ranking Member Crapo, thank you. Thanks for getting us to this point in this process. As has been mentioned, I think this is a first step in the development of working towards meaningful reforms.

This legislation today is common sense. It is bipartisan and typically when something is common sense and bipartisan, it will have a better chance of getting passed versus getting a press release. Maybe in this case we get both.

I understand the Chairman and Ranking Member have agreed that any potential savings which result from the final package that we report out will be dedicated to this Committee's future work, and not used to offset additional or unrelated priorities.

I appreciate that. Whether they are partisan or otherwise, I appreciate your leadership from the two of for that assurance. With that being the case, I look forward to working with my colleagues on this legislation. Mr. Chairman, thank you.

The Chairman. Thank you very much, Senator Daines.

Our last two will be Senator Thune and Senator Warner.

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

Senator Thune. Thank you, Mr. Chairman, and I too -- I mean I think one of the reasons that we -- there are so many issues with drug pricing today is that it is not, it lacks the competitive aspects of a free market. I think that is partly a function of just government interference over the years.

Normally, you would have actors that would be -- the incentivizes would be to drive prices down. That would be the way a normal market would work if you had competition out there. Regrettably we do not, and so we are trying to build, you know, on what I think is a foundation that is now very distorted in terms of where the incentives are.

And one of the best things we do, can do, I think, is to bring transparency to that. I think the supply chain for prescription drugs is incredibly complicated and confusing to most people.

The analogy that I can think of is the dairy program in the Farm bill, again a policy that was put in place a long time ago that reflects a whole lot of government action, and if you did it today you would not do it this way. You would not build the model for

prescription drug supply chains today if you were starting over and in some ways, a lot of ways, that probably made sense.

But we are where we are, and so there are some very notable policies in this bill that I think will improve access to community pharmacies, ensure patients have access to lower prescription drugs and increased transparency in what is a very opaque drug supply chain.

There are a couple of bipartisan bills that are in the modified mark. I appreciate the Chairman and Senator Crapo for including those. Strengthening Seniors Access to Pharmacy Act would deter PBMs from steering patients to their own affiliated specialty pharmacies, and provide increased transparency of PBM practices.

And secondly, the PBM Reporting Transparency Act would ensure Congress has data on PBM practices and the effect on patients' out-of-pocket spending and pharmacy reimbursement. I wish we had not moved as quickly, I have shared that with you, because there are other policies that I think fit in this bill, but we just lack the technical assistance from the agency or CBO scores.

But I know I have talked with Senator Crapo and with the Chairman Wyden about that, and I hope that we can continue to work together to include some of these

policies that did not make it into today's mark, but which I think make sense in terms of the policy that this legislation is trying to achieve.

So I look forward to moving the process forward. Thank you.

The Chairman. Thank you, Senator Thune. We are going to continue our work. Senator Crapo and I have made that clear.

Senator Warner?

OPENING STATEMENT OF HON. MARK R. WARNER, A U.S. SENATOR FROM VIRGINIA

Senator Warner. Thank you, Mr. Chairman. I am going to try to get all of my statement in, so I can get over the AEI session and be back for the vote. I echo what everybody has said, thank both of you, thank also the staff for the amount of that they have done.

I want to echo what Senator Thune said. As a matter of fact, with PBMs and all the rebates, you could not create a more opaque system than we have got in this area, and I do think there has been a lot of good work.

There were three amendments, bipartisan amendments you included in the mark. I want to thank you for all three of those. The first would direct MedPAC to report to Congress and more importantly the public on contracts between Medicare plans and PBMs.

Another with Senator Lankford, as he sits back down, was to make sure that the quality of metrics PBMs require pharmacies to meet in order to get full payment are actually tailored for different types of pharmacies. Finally, one with Senator Scott, to ensure that CMS will hold at least one patient-focused listening session on how Medicare Part D is working or not, and what it takes to learn in terms of if we want to make improvements.

I was going to -- I will be very brief. We had an amendment with Senator Cassidy I was going to be offering later and withdrawing. It basically directs CMS, the voluntary retail surveys they have done since 2005 for most outpatient drugs and state Medicaid programs, really has not been fully getting the data we need.

The survey is voluntary and obviously there are some gaps, and one good thing that the mark does is it requires pharmacies now to participate in the survey. The amendment that Senator Cassidy and I had, which we offered and are withdrawing, would make sure that other types of pharmacies such as specialty pharmacies, long-term care pharmacies, home infusion pharmacies, mail order pharmacies and others. And I do hope that we will be able to continue work on that.

And again, I want to also give a quick thanks and an appeal to both you and the Ranking Member. We are continuing to work on the Long-Term Care Pharmacy Definition Act, and the Preserving Patient Access to Home Infusion Act. When I took up these issues, five or six years ago, I did not know they were going to be requiring my whole career to get them done.

But we do appreciate your staff's work on these. I think they are both bipartisan, common sense and

again, I hope at some point can be included in this overall package. Thank you for your work, and look forward to continuing working together.

The Chairman. Thank you, Senator Warner.

Senator Whitehouse?

OPENING STATEMENT OF HON. SHELDON WHITEHOUSE, A U.S. SENATOR FROM RHODE ISLAND

Senator Whitehouse. Thank you very much. I would very much like to be helpful as this process goes forward, but I would like to make a few points that help drive my understanding, anyway, of where we are.

The first is that we need to recognize that PBMs were created in the first place to bring drug prices down for patients. What PBMs do is they tangle with drug manufacturers to negotiate drug rebates that, if it is operating properly, ultimately get passed down to patients.

PBMs are perhaps are the most powerful institutional counterweight to the pharmaceutical industry. The pharmaceutical industry has done marvelous political jiu-jitsu to turn concern about its pricing into critiques of PBMs, who are perhaps their greatest institutional adversary and one of the most powerful forces for pushing their prices down.

In 2022, pharmaceutical and health product manufacturers and their trade associations spent $375 million on lobbying. PhRMA, the organization itself, spent alone over $29 million. In 2021, the American health care system spent $603 billion on prescription

drugs before accounting for rebates. $421 billion of that was on retail drugs.

Out of the $480 billion that the U.S. spent on drugs in 2019, 323 billion of that when to the pharmaceutical industry, and 23 billion went to PBMs. Which makes PBMs five percent of our total drug spend, and seven percent of what the pharmaceutical industry gets.

So, I will be the first to concede that there is work to be done to improve the behavior of pharmacy benefit managers, and that there is an occasion and an opportunity for self-dealing by them in this relationship, and that that self-dealing is probably best cured by transparency.

And so I look forward to working towards a successful passage of this bill. But I think it would be a shame if we took our eye off the ball and put all of the effort of this Committee into five percent of the total drug spend, and at the behest of the pharmaceutical industry, diverted ourselves from the central problem with pharmaceutical costs in this country, which is a pharmaceutical industry that insists on charging Americans higher prices for the same pill from the same factory that they charge foreign customers.

I just do not think that that is the best way to go at this problem, and I for one want to make darn sure that this Committee has not turned into a tool of the pharmaceutical industry, to turn us onto its most powerful institutional rival and check. Thank you very much.

The Chairman. I thank my colleague.

Now we have an ex-officio Member of this Committee, and in addition to his good work on health care, he was Chair of the Intelligence Committee, where I also served with him, and somehow being chair allowed him to figure out ways in which he can magically show up where he is least expected.

But I just would like everyone to note that we are always glad to have the ex-officio chair of this Committee, former Chairman of the Intelligence Committee in the House, our friend Senator Pat Roberts.

[Applause.]

The Chairman. Okay. Now I want to introduce our panel. We have got Ms. Polly Webster from the Senate Finance Committee Majority staff. We have got Mr. Conor Sheehey from the Senate Finance Committee Minority staff. Next, we have Dr. Phil Swagel, Director of the Congressional Budget Office, and also his colleague Dr. Paul Mase, Chief of the Medicare Cost Estimates Unit of

the Congressional Budget Office here.

I particularly want to thank Dr. Swagel and Mr. Mase. They are so accessible to Members. I keep hearing stories about people reaching out at virtually all hours of the day and night to folks at CBO. We are very appreciative of it, and know that you have not only spent long hours to get us to today, but as you have heard, Dr. Swagel, over the course of this afternoon, a lot of our Members are going to be working very closely with Senator Crapo and I and each of them to get their matters scored, so that we can have them in the fall and then it is our intention to give that to the bipartisan leadership of the Senate, so we can continue to keep moving. So we have got a lot of work to do.

Now Members have received the modification of the mark, so we will dispense with the description. At this point, Senators are welcome to ask any question they have of the staff. Hearing no --

Senator Lankford. I have one.

The Chairman. Oh, my colleague from Oklahoma, of course.

Senator Lankford. Sorry, thank you. Mr. Chairman, thank you very much for this. First of all, I do want to get clarification, because as I noted in my little tweak in my opening statement here, 2019 we

worked on a section of this bill, and then we have done some tweaks since then.

I have given it back to CBO. I am trying to be able to determine just the prioritization process. Some things have been scored, some things we are still waiting on scoring. Scoring is obviously exceptionally important to us in this Committee, especially as we work through the process. Help me understand a little bit how the prioritization works, for what ends up being scored and what ends up being set aside.

Dr. Swagel. Okay. No, thank you Senator. I can speak to that. So in the Committee, we look to the Chair and the Ranking Member to set our priorities and to help us understand what is coming forward, what will be in the mark, which amendments we should work on.

We never take direction of do not work on that. That is just -- that is never a thing. This bill, as you heard, has kept us pretty busy. It has sort of been a 24-7 activity for a couple of months for us.

We have a lot more work to do, and I heard loud and clear what the Chairman just said, that we are -- we are not finished, and I know we have work to do with you and your amendment. You have my commitment that we are going to keep working on it, and keep working for you.

Senator Lankford. That is great, thank you. I

appreciate that. You have had it for a couple of months, and I want to be able to make sure we get it right. We understand it is incredibly technical and a lot of these issues have never been addressed before.

So, we want to be able to be a participant at the table, to be able to walk through and help answer questions, be able to get the score right from the days ahead. So, we look forward to that partnership.

The Chairman. And let me also say, Dr. Swagel and Mr. Mase, it is the view of the Ranking Minority Member and myself that Senator Lankford has worked very hard to be thoughtful about these issues, and both the Ranking Member and I feel strongly about yours getting scored now, and that is the point of this period. Okay.

Senator Johnson. Mr. Chairman?

The Chairman. Yes, Senator Johnson. And just to bring everybody up to date, after Senator Johnson asks whatever question he may have or several questions, then we will go to the next stage of the procedural process. We are going to need a quorum for that.

Senator Johnson?

Senator Johnson. Again Mr. Chairman, I would like to be able to get to -- yes, because I would like to see improvement. So I would ask the CBO Director, in my analogy in terms of barnacles, as you have gone through

this in great detail and you have been scoring this, are we removing some barnacles here, or are we just adding new?

As Senator Whitehouse pointed out, I mean this was supposed to -- PBMs are supposed to be check in lowering health care, pharmaceutical costs. Did not work and now they are the problem. So, are we actually removing a few barnacles here and if so, what are they?

Dr. Swagel. Okay. You know, I can speak to that. That comes across in the estimate that we put out, the tables from the mark-up.

Senator Johnson. Okay.

Dr. Swagel. The impact of the legislation on federal cost is through transparency. So that -- so that is a key part of what is operating here is transparency, and I know many of the Members of the Committee talked about that is transparency, or plans to understand the financial flows that revolve around PBMs on the Medicare side.

It is also on the Medicaid side. There is transparency that helps states understand some of the discounts that are now off invoice and are hidden, and it provides them with tools. So I am not sure if it is a barnacle or not, but it is transparency that eventually lowers premiums and federal costs.

Senator Johnson. It is going to be another government regulation that people are going to have to comply with, right? I mean they are going to have to do something the government is telling them to do, that they otherwise would not necessarily do?

So, your -- it might be a useful barnacle I suppose, but we are adding two things. We are not scraping anything away; we are just adding. We are trying to fix a problem that caused a problem.

Dr. Swagel. Right. I mean there is a lot of transparency already that CMS enforces in Part D. This enhances that, and then it takes some of that transparency and moves it into Medicaid and provides transparency.

Senator Johnson. Okay. I will believe it when I see it. Thanks.

The Chairman. Senator Johnson, thank you, and we are going to continue to talk. I have gotten the message you want to continue that, and we will. A quorum for the purpose of conducting business under Committee Rule 4 is present. That being the case, the modification is hereby incorporated in the Chairman's mark, and the Chairman's mark is modified as open to amendment.

We are now going to go back and forth, Republican

and Democrat. We will start with a Republican amendment, and it is my understanding that our first amendment will be from our colleague, Senator Grassley.

Senator Grassley. Yes. Mr. Chairman, is it okay if I would discuss all three of them --

The Chairman. Yes, please, please.

Senator Grassley. --at once? Okay. You already included five provisions in the modified Chairman's mark that I have been suggesting for years and years, and you and I have worked together on those. I do have three more amendments that I would like the Committee to consider. I understand that the Chairman and Ranking Member are still vetting these three amendments.

So I will offer and withdraw these amendments. I hope that we can keep working on these priorities, so that we can advance them in the full Senate. So Grassley Amendment No. 1, co-sponsored by Menendez and Blackburn. I appreciate their approach to delinking provisions in the Chairman's mark.

I believe that delinking PBM compensation from drug price is a good way to hold PBMs accountable. It will save patients and taxpayer dollars. That said, I want to make sure that there is a robust oversight of this issue. I know that OIGs will be a watchdog, but there should be a hotline or email address for someone

in prescription drug supply chain like a pharmacist, to report non-compliance.

It will ensure the law is being followed. This is important given what at least one PBM executive said recently, they will adjust to changes that Congress enacts to maintain profit. In other words, it will be business as usual, even if this legislation passes.

That is his opinion, and he is probably realistic, found a way to do that. In my Sunshine Act, people can report to CMS via email if a physician is not complying with the law. This amendment does the same thing. Given we are still working on technical assistance and CBO score, I will withdraw that amendment, but I hope the Chairman and Ranking Member can commit to working with us on this, and include it in the package. Robust oversight is needed.

Now on Amendment No. 2, I have heard firsthand from rural and independent pharmacists in Iowa throughout my annual 99 county tour about the looming cash flow challenges created by the post-point of sale compensative changes that begin on January 1, 2024.

Pharmacies still face direct and indirect remuneration, clawbacks from PBMs for 2023, while at the same time accepting a lower point of sale reimbursement starting in 2024. This is all in response to CMS's

rulemaking. Now I support this clawbacks. They hurt patients and pharmacists.

CMS regulation was a step in the right direction, and the Chairman's mark takes another step in the right direction. Given these changes in drug reimbursement of pharmacists starting January 1, we need to be mindful how these powerful PBMs, some who are vertically integrated with chain pharmacies, could put rural and independent pharmacies out of business.

CMS said that they were quote-unquote "particularly attuned" to how pharmacy cash flow issues could hurt patients. They said that they are watching compliance to pharmacy access standards and prompt payment requirements. While CMS stated it is committed to oversight of this matter, this amendment is important to holding the agency accountable.

Now I have written to CMS about this, and I hope I can ask for unanimous consent to add my letter to this record.

The Chairman. Without objection, so ordered.

[The letter appears at the end of the transcript.]

Senator Grassley. I hope that I can have the support of you two leaders on this Committee to approve this matter following this mark-up.

My last amendment, co-sponsored by Senator Brown,

prescription drug prices need a dose of sunshine. Knowing what something costs before buying is common sense. For a long time, I have worked with Senator Durbin to require the disclosure of medication list prices in their advertisements. President Trump pursued this through regulation, and the Senate even passed the Durbin-Grassley measure in 2018. Obviously, it did not get through the House.

Each year, the pharmaceutical industry spends $6 billion in direct to consumer drug advertising, to fill the airwaves with ads resulting in the average American seeing nine direct to customer ads each day. Studies show that these activities steer patients to more expensive drugs, even when a lower cost generic is available.

GAO found that prescription drugs advertised directly to consumers account for 58 percent of Medicare spending on drugs. We ought to require the disclosure of the list price on the TV screen and the other advertisements, so that patients can make informed choices when inundated with drug commercials.

I want to note that drug companies can include a brief statement in their ad that a consumer might pay less than list price depending on their insurance coverage. It is a shame Big Pharma does not want the

consumer to know the price of a drug. I have been told this amendment does not meet the germaneness standard you have set up Mr. Chairman, so withdraw.

But I will note that we have gotten technical assistance from CMS and a confirmation from CBO that this does not impact direct spending. I hope the Chairman and Ranking Member can commit to working with me, Brown and Durbin on this issue. I thank you for your courtesy in listening to my proposals.

The Chairman. Thank you, and you are withdrawing the amendments at this time?

Senator Grassley. Yes.

The Chairman. We will work very closely with you, Senator Grassley. You have spent years toiling away on these issues, and your commitments to patients and taxpayers is noted. Senator Menendez would like to make a comment.

Senator Menendez. Very briefly, Mr. Chairman, on the amendment of Senator Grassley, I co-sponsored with him in terms of establishing mechanisms to report misconduct. You know, today the Committee I hope is going to take a major step forward. But we have to ensure that there are robust enforcement provisions over PBMs, who have proven time and time again their willingness to exploit the current lack of oversight.

We have to enable those who are working with PBMs to report non-compliance with the delinking provision. It is a common-sense solution to ensure PBMs adhere to this new structure, and that patients benefit from lower drug prices at the pharmacy counter, which is what I have been constantly all about, and we look forward to working with you and the Ranking Member to see if we can make that happen.

The Chairman. I thank my colleague, and he too has spent an enormous amount of time in this effort. Next will be Senator Cornyn to talk about his amendment, which I gather is Amendment 35.

Senator Cornyn. Thank you, Mr. Chairman. I call up Cornyn-Carper-Tillis-Brown Amendment No. 1. As you know, the Chairman's mark includes a study to seek out reforms to reduce out-of-pocket costs for seniors. I of course fully support that effort, and would like to highlight a policy that would do just that.

The Cornyn-Carper-Tillis-Brown amendment would require rebate passthrough to Medicare Part D beneficiaries for medicines used to treat certain chronic conditions. It helps ensure that patients who are most likely to face high out-of-pocket costs directly benefit from the savings that plans and PBMs negotiate on their behalf.

By targeting specific chronic conditions, this proposal is focused on medications with the best evidence to improve adherence, leading to offsetting savings from lower non-drug medical services, with fewer hospital stays or provider visits.

Additionally, it helps prevent misaligned incentives, which we have talked about before, for plans to cover particular medicines based upon their individual rebate levels. I want to thank Senators Carper, Tillis and Brown for joining me in this effort, and given the procedural posture we are in, Mr. Chairman, I intend to withdraw the amendment.

But I know Senator Carper has indicated he would like to say a few words about it.

The Chairman. Very good.

Senator Carper?

Senator Carper. Yes, thanks. My thanks to Senator Cornyn for allowing him, for allowing me along with Senators Tillis and Brown to join him in proposing this amendment, which he is going to be withdrawing. But for far too long, pharmacy benefit managers have been pocketing rebates from manufacturers rather than passing them on to people we represent in our states.

Patients, especially those with chronic conditions who take medications on a regular or permanent basis

should have access to affordable prescription drugs at the counter. This amendment, if enacted, will help lower out of pocket prescription drug costs for seniors with chronic health conditions.

I look forward to working with my colleagues, Senator Cornyn, Senator Tillis and Brown and the Chairman and the Ranking Member, toward advancing this important provision as the legislative process continues, and I yield back. Thank you.

The Chairman. I thank my colleague.

Senator Thune is next.

Senator Cornyn. Thank you. If I did not already, I withdraw the amendment.

The Chairman. Thank you. So noted. I thought that we had, but glad it is clear. Senator Thune.

Senator Thune. Thank you, Mr. Chairman, and I would do what some of my colleagues have done, as Senator Grassley. I have three amendments. I think you are familiar with all of them, and I might just speak briefly to them, then I will withdraw them because I do not think any of them fit within the very tight, restrictive germaneness rule that was adopted by the Committee.

But the first amendment, Amendment No. 2, was Stabenow, Grassley and Thune, would improve the ability

of patients and providers to access transparent drug pricing information. I co-authored the original requirement that Part D plans include real-time benefit tools and legislation that passed in 2020.

But there are hurdles that remain for patients and providers to fully utilize these tools. This amendment would pilot a program to test incentives to increase the provider uptake of real-time benefit tools, but also address issues of data interoperability and facilitate greater information-sharing at the point of prescribing.

I understand this amendment, as I said, is not in order so I withdraw it and I would ask the Chairman and Ranking Member's commitment to continue to work us on this legislation. That is Amendment No. 2, and thank you for your commitment to work with me.

The Chairman. I think the concept of real-time benefit tools is way too logical for government.

Senator Thune. Yes.

The Chairman. But I am with you, and Senator Crapo and I are going to work with you.

Senator Thune. Perfect, thank you. So, Amendment No. 3 is Thune-Warner. I do not think he is here, but in this pharmacy is obviously a critical part of the prescription drug supply chain. Especially in rural areas, I am pleased to see the underlying bill includes

policies that will improve access to community pharmacies.

However, I think we have to do more to ensure pharmacies are sustainable and can continue to serve patients. DIR fees remain a concern, and I appreciate my colleague, Senator Lankford's leadership on this issue.

Seniors often depend on their pharmacist to help manage their prescriptions and health conditions, and what my amendment would do was allow -- would allow pharmacists to continue to provide certain services to Medicare patients like giving flu shots and testing for strep throat, and they would only be able to provide services that are already allowed under state scope of practice laws.

So again, I understand this amendment is not in order and will withdraw it, but would ask again for the Chairman and Ranking Member's commitment to work with me and Senator Warner on this --

The Chairman. Senator Thune, this is particularly important. If we are going to have these pharmacies, particularly these little ones that are a lifeline for rural communities, we need to find a way to address what you are talking about, and we will work with you.

Senator Thune. I appreciate it, thank you. And

finally Thune-Brown is the Amendment No. 4, and that has to do with the 340B program, which is critical to hospitals and health centers in South Dakota. I also believe that the program would benefit from appropriate transparency, which is why I am currently leading the request for information on the 340B program, with five bipartisan colleagues.

I am concerned that the reporting measures included in the bill today do not provide appropriate context of how savings are used by entities in the program, and would only address one aspect of that program.

The goal of our RFI is to find consensus on transparency measures to improve the oversight of the program, as well as other solutions to issues like duplicate discounts and contract pharmacy.

I am going to again withdraw this amendment today, but hope my colleagues will continue to work with me through our RFI process to ensure that the 340B program serves its original intent. So I withdraw that.

The Chairman. Thank you, Senator Thune, and we will work very closely with you on this 340B issue. As you know, you and I have had a number of conversations with respect to this amendment on the floor. We made a change that the staff thought made some sense. Glad to

do it. We have got a lot of work to do, and let me just say while we have Dr. Swagel here, this is an area that there is great interest among Members.

It is a challenging one, and Senator Thune has asked. We are going to work closely over the summer months to get this right.

Senator Thune. Thank you, Mr. Chairman. Thank you.

The Chairman. Thank you.

Okay, our next -- let us see. Our next amendment will be Senator Casey's.

Senator Casey. Mr. Chairman, thanks very much. I am grateful for the work that you and the Ranking Member have done on this legislation. It is obviously bipartisan and speaks to some of the concerns that we all have. I will be speaking Casey-Cornyn 1, which I will be offering and withdrawing.

We must ensure, of course, that PBMs cannot continue to engage in business practices that unfairly raise the price of prescription drugs for our constituents. Senator Cornyn and I filed an amendment to address one of those, one of these practices.

Last week, we introduced the Protecting Seniors From High Drug Costs Act, Senate Bill 2456. This bill would prohibit PBMs from having cost-sharing that is

more than the negotiated net price of a covered Medicare Part D drug. A recent report by MedPAC found that for nearly eight percent of total spending in the Part D benefit, the cost-sharing amount set by plan sponsors exceeded net drug costs. This practice creates high prices for affected patients, many of whom are low income.

It is no benefit to patients and only increases the profits of PBMs. There is no reason why it should be allowed, and I want to thank my colleague from Texas, Senator Cornyn, for working with me on this important issue. While I will not be asking -- we will not be asking for a vote on the amendment, I ask that the Chairman and Ranking Member commit to working with us on this provision.

The Chairman. Senator Casey, we will commit. Everywhere I go in Oregon, these small pharmacies ask me about what you are talking about. So Senator Crapo and I will work closely with you.

Senator Casey. Thank you.

The Chairman. Okay. That is offered and withdrawn.

Next, I believe, will be Senator Lankford.

Senator Lankford. Mr. Chairman, thank you. I have two amendments. Mr. Chairman, are you okay if I go

ahead and give both of them to you?

The Chairman. Yes, please. Please.

Senator Lankford. Just a quick statement here. If all of us had a retail anything and I told you I was going to reimburse your shipping costs, go ahead and ship it and that I will pay you back for shipping later. And then two months later, after you have shipped it, I actually reimburse you half of the cost of shipping and said I have changed my mind. How would you respond to that?

The exact same way independent pharmacies do to DIR fees. That is the exact same thing. They are told one price. Then the rules change on them, where PBMs reach in and say no, we have changed the rules on how we are going to reimburse you, and they actually reimburse them less than they were paid at the counter for it.

These DIR fees are killing our rural pharmacies, and this is a primary issue. While I am very pleased to be able to see in this bill there is some work that is done on DIR fees, the language is vague and I do not think it is strong enough to actually be able to get at the root of the problem, and it still does not assure that independent pharmacies are actually reimbursed actually what it cost them to buy the drug.

And so there is something I think we do need to do

to be able to make this stronger. The largest independent pharmacy in my state lost $700,000 last year on DIR fees, and has let us know this is not survivable. So my war is not with PBMs; my war is with PBMs because they are killing my independent pharmacies, and I want to do what we can to be able to stop that.

So in this DIR bill that I have with Senator Brown, we are working to be able to bring transparency and clarity into the process for actually how they are evaluated, independent pharmacies, clarity in the reimbursement process on that, and I would like very much the Chairman and Ranking Member's help in trying to be able to get this bill done in the days ahead.

The Chairman. Senator Lankford, I will tell you. I think this is a particularly important effort that you are leading and as Dr. Swagel knows, I have talked to him about this several times, and have seen this problem in my state as well. So we are going to stay at this through the summer months and be ready to go in the fall.

Senator Lankford. That would be great.

The Chairman. Thank you.

Senator Lankford. Thank you very much for that, for both of you on that. The second one I had deals with the is the Ensuring Access to Lower Cost Medicines

for Seniors Act. This is a bill that I have with Senator Menendez, Senator Cornyn, Senator Hassan, Senator Tillis and Senator Bennet.

All of us are working together to be able to solve this one key issue, and that is where drugs end up on the distribution lists, what we know as tiering but what most folks would know as the branded tier or the generic tier on this.

Mr. Chairman, I also have -- I would ask unanimous consent. I have two letters of support for the record, one from the generics industry and one from a growing list of 21 patient advocacy groups that are very interested in this particular amendment.

The Chairman. Without objection, it will be so ordered.

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

Senator Lankford. Thank you. This amendment would ensure that Medicare Part D beneficiaries receive the full benefit of lower cost generic and biosimilar medicines. Right now as we know, very often that generic drugs and biosimilars, as they are coming out now, are not placed on the lower cost generic tier for actual sale to the consumer.

In fact over half, that is 57 percent of the covered generic products were placed on non-generic sale

tiers last year. 57 percent of those generics coming out are not actually being sold. What most folks would hear is they go to the pharmacy counter. They have a prescription. They ask their pharmacist is there a generic for this. Their pharmacist responds yes there is, but it the same price as the brand.

Every time you hear that, that is this game that is happening right here, where those generics are actually being placed on the higher cost tier. This is something that we need to be able to resolve, not only for the federal government in what we are paying, but what consumers are paying as well when lower cost generics are being placed on higher cost tiers to actually sell to the consumer.

A recent RAND Company study estimated that beneficiaries could save between one and three billion dollars by making this change. This is one of those areas that we need to get scored, and to be able to get it completed. But this would be a dramatic benefit for consumers and for the federal government in the days ahead, to be able to get this resolved.

The Chairman. Yes, and I think your concern, Senator Lankford, about making sure that the lower-cost drugs get on that lower tier, is a very important one, and we are going to make sure that Dr. Swagel gets this

to us in the fall.

Senator Lankford. Thank you.

The Chairman. Okay, if that is offered and withdrawn, next is Senator Hassan, and I think, colleagues, we will be pretty close to 3:30. We may not hit it right on the head.

Senator Menendez?

Senator Menendez. Can I just make a statement on the amendment?

The Chairman. Please. Senator Hassan, if you will hold for a moment, let us hear from Senator Menendez, and you will be next.

Senator Menendez. Just very briefly. I want to echo Senator Lankford's remarks. That is why I joined him in the amendment. You know, I think that New Jerseyans and people across the country rightly expect generic drugs to cost less.

But because of the complex and unfair pricing practices, sometimes a generic drug that should come with a lower price tag at the pharmacy counter actually costs as much or more than the brand name product, that is if the drug is even covered by insurance at all.

It is just simply not right. This is the type of amendment I hope we can work with you, Mr. Chairman and Ranking Member, to make happen. I think it would be an

enormous saver, and I thank my colleague for having me work with him on this.

The Chairman. Thank you, Senator Menendez.

Senator Hassan is next.

Senator Hassan. Thank you, Mr. Chair, and I too just want to comment briefly on Lankford-Menendez-Cornyn-Hassan 1, and then I will offer and withdraw Hassan 2. On the first amendment, I want to thank Senator Lankford and Senator Menendez for leading on this really important issue.

Like many of my colleagues, I often hear from seniors who are struggling to afford the medications they need. When low cost versions of drugs become available, seniors should be able to access these affordable options at a fair price. However, PBMs sometimes place these generic drugs on the same price tier as the relevant brand drugs.

This means that Medicare patients sometimes pay an inflated price at the pharmacy counter for what is a lost, a low-cost generic drug. Senator Lankford's amendment would require Medicare Part D plans to cover generic and biosimilar drugs at a fair price, ensuring that seniors benefit from innovative, low cost medications.

So, I look forward to working with Senator

Lankford and Menendez, and the Chair and Ranking Member, to advance this important legislation.

Now as to Hassan 2, I would like to offer and withdraw Hassan Amendment 2. This amendment would require a report to Congress on the out-of-pocket cost that seniors on Medicare pay to receive routine drugs in a doctor's office. Seniors on Medicaid -- Medicare are paying unfair fees to get routine services at their doctor's office, just because the doctor's office is owned by a hospital group.

For example, while a steroid injection might cost $90 at a community doctor's office, a senior could be forced to pay twice that amount if his or her doctor's office happens to be owned by a hospital. In these cases, seniors are paying unfair facility fees for drug administration services, even though they are receiving care in their community miles away from the hospital.

This is especially concerning, because seniors on traditional Medicare pay 20 percent out of pocket for these services, with no limit or cap on how much they might have to pay. There are ongoing bipartisan efforts to stop these unfair fees, and my amendment would take initial common-sense steps to determine how these fees are harming seniors on Medicare.

I understand that this amendment is considered

outside the scope of today's mark-up, given the focus on pharmacy benefit managers. Mr. Chair, I will withdraw this amendment given our focus today, but I urge all my colleagues on the Committee to examine the facts on a bipartisan basis regarding unfair facility fees that are being charged to seniors on Medicare.

The Chairman. Another good concept, and Senator Hassan, we will continue to work with you.

Senator Hassan. Thank you.

The Chairman. Okay. I think we are approaching the time for the vote.

Senator Cassidy, I think you will be next and last.

Senator Cassidy. Thank you, Mr. Chair. Mr. Chair, my amendment today would give small biotech companies additional incentive to research, develop and market life-saving drugs for patients.

Last year, the Congress passed the IRA by those who voted for it. It is a well-meaning bill, with the intention of reducing the cost of prescription drugs from Americans, a goal which both parties share. But both parties also share the -- recognize the importance of small biotech companies.

In the IRA, small biotech companies were exempt from drug negotiation for three years. However, even

with that three-year exemption, there is concern that the IRA risks closing off the innovation that has been at the forefront of many of the clinical breakthroughs in the pharmaceutical sector.

Small biotech companies continue to have an environment with less interest from outside capital for investment, longer and more complex clinical trials, and the potential for reduced revenues from Part D sales. And why is this important? Small biotech develops the new, most innovative drug.

According to a 2022 study, small biotech companies are developing nearly 4,000 drugs, approximately 65 percent of the total drug development pipeline, representing a growth of 165 percent since 2011. And it is not just that they are developing drugs; it is drugs in things like cancer, neurology, infectious disease vaccines that are the crying needs for our medical community for our patients.

In cancer alone, there are 608 small biotech companies focused solely on oncology, many with only a single molecule being developed. The risk of failure for these companies is high. Even those that are successful are seeing a higher cost to develop, as therapies are more complex.

Now for these, once a product is successfully

introduced, access to Medicare Part D is critical. A recent report suggests that over 22 percent of the revenue, the companies rely on Medicare for over 22 percent of their revenue compared to 14 percent for larger companies.

My amendment provides additional support to these companies working to develop cutting edge therapeutics. It allows a small biotech firm which has spent a certain average percentage of its revenue on R&D over a three-year period, the opportunity to delay entry into the Part D negotiation program for one year.

This amendment would continue to provide support for those small companies, as they bring these important therapeutics to market.

Now I recognize that this amendment is not germane to the underlying bill so withdraw, but I hope I am making the point that this is an issue, and hope that I can work with colleagues to move forward legislation like this, to help these small companies doing great things for Medicare beneficiaries. With that I yield.

The Chairman. Thank you, Senator Cassidy. We are going to wrap up with Senator Blackburn and go to the vote. I just want to assure you, Senator Cassidy, I am very interested in working with you on the biotech issues.

As you know, parts of the biotech debate are more controversial than others, and that was, I think, why you correctly said you would not insist on a vote. But we are going to continue to work on biotech issues, and I thank for it.

Senator Blackburn?

Senator Blackburn. Thank you, Mr. Chairman. I am offering Blackburn Amendment No. 1, which is based on the Neighborhood Options for Patients Buying Medicines Act or the No PBM Act. This is a bill that Senator Manchin and I recently introduced.

Loopholes in the law have allowed PBMs to circumvent Medicare's Any Willing Pharmacy requirement, which has resulted in restricted access to care, longer drives and higher cost of prescription drugs for Tennesseans. This amendment would modernize Medicare's Any Willing Pharmacy law to ensure PBMs are unable to discriminate against pharmacies that are willing to contract with them.

Independent pharmacies can represent one of the primary points of care in rural areas, and this common-sense proposal would allow seniors to fill their prescriptions at their local pharmacies.

I move to withdraw this amendment with the understanding that the Chair and Ranking Member will

continue working with me and my team, to receive technical assistance from relevant agencies and thoroughly examine the budgetary implications.

The Chairman. Thank you, Senator Blackburn, and Senator Crapo and I have discussed this proposal that you and Senator Manchin have. I think this is a priority issue, and we have made it clear to Dr. Swagel that we would like to have it scored as soon as possible.

All right, colleagues. Now that we have a sufficient number of Members present, I move that the Chairman's mark, as modified and amended, be reported favorably. Is there a second?

Senator Crapo. Second.

The Chairman. The Clerk will call the roll.

The Clerk. Ms. Stabenow?

Senator Stabenow. Aye.

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

Senator Cantwell. Aye.

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

Senator Menendez. Aye.

The Clerk. Mr. Menendez, aye. Mr. Carper?

The Chairman. Aye by proxy.

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

Senator Cardin. Aye.

The Clerk. Mr. Cardin, aye. Mr. Brown?
The Chairman. Aye by proxy.
The Clerk. Mr. Brown, aye by proxy. Mr. Bennet?
Senator Bennet. Aye.
The Clerk. Mr. Bennet, aye. Mr. Casey?
Senator Casey. Aye.
The Clerk. Mr. Casey, aye. Mr. Warner?
Senator Warner. Aye.
The Clerk. Mr. Warner, aye. Mr. Whitehouse?
Senator Whitehouse. Aye.
The Clerk. Mr. Whitehouse, aye. Ms. Hassan?
Senator Hassan. Aye.
The Clerk. Ms. Hassan, aye. Ms. Cortez Masto?
Senator Cortez Masto. Aye.
The Clerk. Ms. Cortez Masto, aye. Ms. Warren?
Senator Warren. Aye.
The Clerk. Ms. Warren, aye. Mr. Crapo?
Senator Crapo. Aye.
The Clerk. Mr. Crapo, aye. Mr. Grassley?
Senator Grassley. Aye.
The Clerk. Mr. Grassley, aye. Mr. Cornyn?
Senator Crapo. Aye by proxy.
The Clerk. Mr. Cornyn, aye by proxy. Mr. Thune?
Senator Thune. Aye.
The Clerk. Mr. Thune, aye. Mr. Scott?

Senator Crapo. Aye by proxy.

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

Senator Cassidy. Aye.

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

Senator Lankford. Aye.

The Clerk. Mr. Lankford, aye. Mr. Daines?

Senator Daines. Aye.

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

Senator Crapo. Aye by proxy.

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

Senator Barrasso. Aye.

The Clerk. Mr. Barrasso, aye. Mr. Johnson?

Senator Johnson. No.

The Clerk. Mr. Johnson, no. Mr. Tillis?

Senator Tillis. Aye.

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

Senator Blackburn. Aye.

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

The Chairman. Aye.

The Clerk. Mr. Chairman votes aye.

The Chairman. The Clerk will report.

The Clerk. Mr. Carper?

The Chairman. Excuse me, Senator Carper.

Senator Carper. Aye.

The Clerk. Mr. Carper, aye.

The Chairman. Okay. The Clerk will report.

The Clerk. Mr. Chairman, the final tally is 26 ayes, 1 nay.

The Chairman. The bill is reported favorably. I ask unanimous consent that the staff have the customary authority to make appropriate technical conforming and budgetary changes, and I hear no objection. I thank all Members and staff.

The Finance Committee meeting is adjourned.

[Whereupon, at 3:38 p.m., the meeting was concluded.]

SENATOR WARREN OPENING STATEMENT

Too many Americans are rationing their medication and getting sicker because they cannot afford the life-saving drugs they need. I'm grateful to Chair Wyden and Ranking Member Crapo for advancing proposals that will rein in the power of pharmacy benefit managers, or (PBMs), and lower drug prices for the American people.

I want to talk about two proposals. First, this legislation will shine a light on the anti-competitive games that drug manufacturers use to preference high-priced drugs. In one egregious example, drug manufacturers offer kickbacks to PBMs for agreeing to disfavor a competitor's drug. Let's be clear: these tactics should be outlawed, but this legislation takes step in the right direction by requiring PBMs to disclose these arrangements.

Second, the legislation will look at how vertical consolidation affects drug prices. Today, the top three PBMs – which manage 80% of drug claims – are each owned by a giant health insurance company, which in turn also owns its own pharmacies. These conglomerates want to keep as much money in-house as possible, so they steer patients to use these PBM-owned pharmacies, squeezing out local options. I'm glad the Committee will direct the HHS OIG to study these arrangements, but I've called on regulators to end this kind of vertical consolidation – because the companies paying for health care services shouldn't be the same entities providing those services.

I'm encouraged that the Committee will consider additional proposals on PBM steering and vertical integration, and I look forward to working with you on these policies to lower drug prices for Americans.

SUBMIITED BY SENATOR GRASSLEY

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

July 25, 2023

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

Dear Administrator Brooks-LaSure,

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

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

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

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

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

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

---

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

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

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

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

[9] *Id.*

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

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

[12] *Id.*

[13] *Id.*

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

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

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

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

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

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

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

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

Sincerely,

Chuck Grassley

Charles E. Grassley
Ranking Member

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

SUBMIITED BY SENATOR LANKFORD

July 26, 2023

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

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

Dear Chairman Wyden and Ranking Member Crapo:

As the Senate Finance Committee continues efforts to modernize the pharmaceutical supply chain and enact meaningful reforms to lower patient costs at the pharmacy counter, we urge you to prioritize policies that support beneficiary access to generic and biosimilar medicines. Specifically, we write to express our strong support for the inclusion of bipartisan legislation introduced by Senators Menendez (D-NJ) and Lankford (R-OK), the *Ensuring Access to Lower-Cost Medicines for Seniors Act* (S. 2129), which will reduce federal spending and out-of-pocket costs for Medicare beneficiaries and expand access to vitally important lower-cost generic and biosimilar medicines.

On behalf of the patients, consumers, and taxpayers we represent, we request the Committee address the pressing issue of delayed patient access to generic and biosimilar medicines in Medicare Part D -- a trend that has already cost seniors more than $22 billion in out-of-pocket costs since 2016. Failure to solve this problem will only increase beneficiary and health system costs and harm patients who desperately need greater access to affordable medicines.

Generics and biosimilars offer immense value to patients and the health care system. Over the last decade, they have saved America's patients and our system more than $2.6 trillion, including more than $119 billion in savings for Medicare in 2021 alone[1]. However, these future savings to both patients and Medicare are at risk due to misaligned incentives within Part D that incentivize prescription drug plans to cover higher-cost brand drugs, despite the availability of lower-cost generic and biosimilar medicines.

As a result of the misaligned incentives and discriminatory formulary practices, Medicare Part D prescription drug plans are increasingly not covering lower-cost generics and biosimilars or placing these medicines on higher cost-sharing tiers intended for brand drugs. A recent study[2] analyzed this practice over the last decade and found that this concerning trend is rapidly increasing. In 2011, 71 percent of generics were covered on the lowest cost-sharing tier in Medicare Part D plans. In 2022, only 10 percent of generics were covered on the lowest-cost sharing tier, and more than 50 percent of all generics covered by Part D plans were inappropriately placed on higher-cost sharing tiers intended for brand drugs.

Our organizations support the following simple, practical solutions to ensure patient access to lower-cost medicines: 1) automatic coverage under Part D of generic drugs and biosimilars costing less than their brand name reference product; 2) placement of generic drugs only on lower-cost sharing generic tiers; and, 3) creation of a new specialty tier reserved for biosimilars and specialty generics with lower cost-sharing for patients. These common-sense solutions have received bipartisan support in both the House and Senate and will meaningfully reduce federal spending and out-of-pocket costs for Medicare beneficiaries.

---

[1] Association for Accessible Medicines. U.S. Generic and Biosimilar Medicine Savings Report." September 2022.

[2] Avalere Health. "57% of Generic Drugs are not on 2022 Part D Generic Tiers." January 2022.

The Senate Finance Committee's work to address misaligned incentives that drive up costs within Medicare is critically important to lowering prescription drug costs for patients, increasing competition, and enhancing transparency. We urge the Committee to use this opportunity to finally address the concerning trend of discriminatory formulary design that impedes access to affordable medicines and unnecessarily increases costs for patients and taxpayers.

We stand ready to work with you and your colleagues to continue to tackle these issues and enact meaningful bipartisan policy reforms to lower out-of-pocket costs and strengthen the Medicare program.

Sincerely,

Allergy Asthma Network
American Diabetes Association
Asthma Allergy Foundation of America
Autoimmune Association
Black Women's Health Imperative
Bonnell Foundation
Boomer Esiason Foundation
Children With Diabetes
Color of Crohn's & Chronic Illness
Cystic Fibrosis Research Institute
Community Oncology Alliance (COA)
Diabetes Leadership Council
The Diabetes Link
Diabetes Patient Advocacy Coalition
Diabetes Sisters
HealthyWomen
Multiple Sclerosis Foundation
National Multiple Sclerosis Society
Patients Rising Now
Rock CF
ZERO Prostate Cancer

July 11, 2023

The Honorable James Lankford
316 Hart Senate Office Building
Washington, D.C., 20510

Senator Robert Menendez
528 Hart Senate Office Building
Washington, D.C., 20510

Dear Senator Lankford and Senator Menendez:

On behalf of the Association for Accessible Medicines and its Biosimilars Council, I am pleased to offer our strong support for your legislation, S. 2129 *The Ensuring Access to Lower-Cost Medicines for Senior Act*. This legislation enhances patient access to lower cost prescription drugs by ensuring the benefits of robust competition provided by lower cost generic and biosimilar medicines are passed on to consumers.

Patient access to safe and cost-effective therapies has never been more critical. Although generic and biosimilar medicines provide significant cost savings, patients and taxpayers are being denied access to these lower costs in the Medicare prescription drug program.

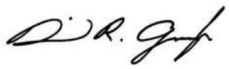
For instance, after six years of sustained deflation, generic prices are lower than ever, but patients are paying more for the same medicines because of plan and PBM decisions to shift generics to formulary tiers with higher costs. This can occur without warning and with no published clinical justification; and the result is higher spending by patients, forcing them to spend more than twice on generics even as the prices for those generics fell.

And the introduction of new generics and biosimilars bring savings and competition. Despite this, many Part D plans are slow to cover first generics and biosimilars. In fact, it takes as many as three years for new generics to be covered on half of all Part D formularies. Likewise, formularies are slow to cover lower cost biosimilars that bring noticeably lower prices.

S. 2129 *The Ensuring Access to Lower-Cost Medicines for Senior Act* addresses both of these problems. It protects patients from paying too much by requiring that formularies place generic medicines on generic formulary tiers. Not only does this lower patient costs by ensuring that copays are reflective of the low costs of generics, but it also will cause less patient confusion. It also ensures patients have access to new generics and biosimilars when these are priced lower than brand drugs. By requiring coverage of a generic or biosimilar at launch if it costs less than its brand competitor, this legislation encourages broad competition that benefits patients, taxpayers and plan sponsors alike.

We appreciate your work on behalf of seniors' access to generic and biosimilar medicines and look forward to working with you to advance this legislation into law.

Sincerely,



David Gaugh, R.Ph.
Interim President & CEO

601 New Jersey Ave NW, Suite 850 • Washington, DC 20001 • 202-249-7100 • info@accessiblemeds.org
accessiblemeds.org