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EXAMINING POLICIES TO IMPROVE SENIORS' ACCESS TO INNOVATIVE DRUGS, MEDICAL DEVICES, AND TECHNOLOGY

TUESDAY, SEPTEMBER 19, 2023

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 10:01 a.m., in Room 2322, Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Bucshon, Burgess, Latta, Griffith, Bilirakis, Johnson, Hudson, Carter, Dunn, Pence, Joyce, Harshbarger, Miller-Meeks, Obernolte, Rodgers (ex officio), Eshoo, Sarbanes, Cardenas, Ruiz, Dingell, Kuster, Kelly, Barragan, Craig, Schrier, Trahan, and Pallone (ex officio).

Staff Present: Alec Aramanda, Professional Staff Member, Health; Jolie Brochin, Clerk, Health; Grace Graham, Chief Counsel, Health; Sydney Greene, Director of Operations; Tara Hupman, Chief Counsel; Peter Kielty, General Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Dray Thorne, Director of

Information Technology; Caitlin Wilson, Counsel, Health; Lydia Abma, Minority Policy Analyst; Jacquelyn Bolen, Minority Health Counsel; Keegan Cardman, Minority Staff Assistant; Tiffany Guarascio, Minority Staff Director; Saha Khaterzai, Minority Professional Staff Member; Una Lee, Minority Chief Health Counsel; and Avni Patel, Minority Health Fellow.

Mr. Guthrie. The subcommittee will come to order. The chair recognizes himself for 5 minutes for an opening statement.

Today is our second hearing designed to examine solutions to help our seniors gain access to innovative medical drugs and technologies, to help lower drug costs as well as to ensure our regulatory policies are responsive to market innovation that will help seniors live longer and healthier lives. In July we heard from a panel of experts about the importance of update the Medicare program to meet the needs of a growing senior population. Now we are taking the next step to examine specific solutions which seek to turn the principles and ideas from members, previous expert witnesses and wide ranging stakeholder input into legislation to support millions of seniors across the country. For example, according to the National Cancer Institute, cancer cost the United States about $208 billion in 2020. Further analysis shows that late stage cancer cost the healthcare system $105,000 per patient in 2019 representing the highest cost among all cancer patients.

Today, patients and their families bear a significant financial burden despite the growing availability of less invasive and more successful treatments, along with cutting edge diagnostic tools that can personalize treatment plans and detect aggressive but treatable cancers sooner.

H.R. 2407, Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act attempts to address this policy imbalance by increasing access to these diagnostics and potentially lowering downstream costs in helping seniors live longer lives.

Additionally, I am proud to sponsor H.R. 1691, the strongly bipartisan Ensuring Patient Access to Critical Breakthrough Products Act, which would essentially codify the

Trump era Medicare coverage of innovative technology or MCIT rule and provide for a predictable Medicare coverage pathway for FDA approved breakthrough therapies for at least for years, while companies can collect data to make their case for more permanent coverage. These products, many of which are FDA approved, but have yet to receive CMS coverage could transform lives and make daily activities more manageable for seniors who may currently be bedridden or one device for technology away from being able to finally manage their cardiovascular disease.

On the top point coverage we have a number of solutions to make regulatory policies work better for innovators, for providers and more importantly for patients. My bill, H.R. 5389, the National Coverage Determination Transparency Act will hold CMS accountable to a more consistent process for making national coverage determinations, and specifically their communications with product sponsors ensuring patients can gain access to these products as quickly as possible.

We will also discuss policies that would help clarify the local coverage determination process so the medical items and services can expeditiously reach seniors.

For too long we have heard how broken the coverage process delays or in the case of Alzheimer's national coverage determination which will also discuss today significantly restrict access to lifesaving care for seniors.

We are finally looking at more effective ways to help address chronic disease management, as well as other policies to provide seniors access to generic drugs and biosimilars, particularly by allowing for biosimilar products to be added to Medicare drug formularies throughout the plan year if a biosimilar becomes available midyear, which would allow seniors to save more on lower costs clinically effective drug.

The Government Accountability Office recently finalized a report on the impact of

rebates in the Medicare part D program, specifically how rebates effect the prices senior pay at the pharmacy counter. The report also provided a detailed analysis on the impacts of rebates of senior's cost sharing an Medicare liabilities resulting from -- GAO indicated that for 79 of Medicare part D's top 100 highly rebated drugs, seniors our others on seniors' behalf spent $21 billion on their drugs versus the $5 billion the plan sponsors spend on these drugs after accounting for rebates. Seniors and taxpayers shouldn't be paying more for a drug than the actual value of the drug. That is why we are considering ideas today that are designed to help address these issues. Each proposal was drafted to ultimately achieve lower costs without the Federal Government directly negotiating the prices for these cases.

In closing, it is important to note that while these policies can help drive innovation, we also must consider the budgetary implications of each proposal. I look forward to working with my colleagues insuring these ideas are fully offset should -- as we continue our work.

I yield back.

The chair now recognizes the ranking member, the gentlelady from California for 5 minutes for her opening statement.

[The prepared statement of Mr. Guthrie follows:]

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Ms. Eshoo. Thank you, Mr. Chairman. And good morning colleagues and thank you witnesses and all of the advocates that are here today. I don't think there is a free seat in the audience. It is wonderful. Thank you.

I think we are entering a golden age of medicine thanks to breakthroughs in genomics, mRNA, multicancer blood tests and other new diagnostics. To bring these new cures from the benchtop to the bedside, patients need Medicare to cover new drugs and devices. With over 65 million Americans enrolled in Medicare, every coverage decision is fraught. Medicare beneficiaries deserve timely access to safe, effective and affordable treatments. But the Medicare coverage determination process can be lengthy and it is. According to the Stanford Byers Center for Biodesign nationwide Medicare coverage for breakthrough medical technologies can take on average 4 to 6 years following FDA authorization. Today, we are considering amongst 24 other bills, the Ensuring Patient Access to Critical Breakthrough Products Act, that attempts to shorten that wait.

I want to commend CMS for finally publishing the transitional coverage of emerging technologies proposed rule which takes a significant step forward in making sure seniors can access new medical devices.

One contributing factor to the delay is that CMS does not have the resources and expert staff to make nimble coverage decisions. Many of its local coverage decisions are outsourced to Medicare administrative contractors who wield significant power over more than a billion, that is with a B, more than a billion Medicare fee for service claims each year. These contractors can make a real impact on people's lives. For example, Representative Burgess and I sent a letter to CMS last month raising our concerns about

an ill considered March 2023 billing article from one of these contractors that withdrew Medicare coverage for very important blood tests that help transplant patients stay healthy and keep their new organs. This billing article was issued without, without allowing for public comment, including comments from the transplant patients who would be impacted. CMS should intervene as soon as possible.

We are hearing several bills impacting these administrative contractors and the local coverage decisions and I look forward to better understanding their impact.

While this hearing may be aimed at improving Medicare coverage for some drugs and devices, the House Republican budget does the direct opposite by cutting nearly $800 million from the centers that oversee Medicare. This massive cut will slow down coverage decisions, increase the reliance on contractors and most importantly hurt seniors and people with disabilities. I am also concerned that while this hearing is considering the huge slate of bills, as I said 25 in total, Republicans would not consider legislation to extend funding for State health insurance programs, the area agencies on aging, the Aging and Disability Resource Centers and the National Center for Benefits and Outreach Enrollment. These critical programs help Medicare beneficiaries everyday enroll in Medicare and access benefits that lower their out-of-pocket costs. But the funding will expire on September 30th. California's State health insurance program is called HICAP and it is outstanding. It provides stellar services every day for seniors in my district who have Medicare problems.

For Democrats, our North Star was and continues to be protecting and preserving the sacred promise of Medicare. While we consider these bills, I hope we will proceed carefully to make sure that the promise of affordable, quality coverage is kept without putting seniors or the Medicare trust fund at risk.

And with that, Mr. Chairman, I yield back.

[The prepared statement of Ms. Eshoo follows:]

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Mr. Guthrie. Thank you. The gentlelady yields back.

The chair will recognize the chair of the full committee, Chair Rodgers, for 5 minutes for an opening statement.

The Chair. Good morning, good morning colleagues. Good morning, advocates. Sadly, we have all heard from patients who are unable to assess medicines or devices that they need in their time of need. Many times it is because of bureaucratic red tape and a Medicare program that is struggling to keep up with innovation. Today our goal is to cut the red tape and roll out of red carpet for all.

In our July hearing we heard from Sue Wronsky, a patient advocate and caregiver who told her story about her mother, Lynn's battle with Alzheimer's. Millions of Alzheimer's patients today stand to benefit from newly approved treatments, treatments that Lynn never had the chance to receive. Today we are following up on that conversation with doctors, patients, innovators and caregivers. We will hear from Dr. Dora Hughes from CMS who will hopefully shed light on CMS's unprecedented coverage policies which are unfortunately limiting seniors' access to FDA approved drugs.

We are also interested in hearing from Dr. Hughes about CMS coverage policies, including the recent TCET approached notice. This has come more than 2-1/2 years after CMS delayed and ultimately repealed the MCIT policy which would have created a predictable transitional coverage policy for innovative technologies. We are all worried about seniors' access to innovative new technologies and we are going to discuss a lengthy list of bills. I would highlight 16 are bipartisan are lead by my Democrat colleagues. And I am hopeful that we can build more bipartisan support for many of the remaining bills in the weeks and months ahead. For example, we welcome Democrats

joining on legislation that would allow seniors to continue to assess the same technologies that they had access to in the commercial insurance, permitting seniors to upgrade their wheelchairs to increase their mobility and potentially improve their quality of life. Improve home infusion care safely in their homes and support a number of Medicare part D and PBM policies that have received bipartisan support in the Senate. These are policies that can help patients access innovative drugs and technologies and are distinct from major policies like the price setting scheme in the IRA, which we disagree on.

I am also glad that we have included several bills on the Medicare part D program, especially following the troubling report from GAO that found patients are paying more for drugs than insurance companies. And while I am glad that there are so many members on both side of the aisle it is true. Unbelievable. Members on both sides of the aisle have brought forward ideas that we will discuss today a lot more works needs to be done. A number of bills before us would increase what seniors pay as well as Medicare spending unless we are able to find reduction. There is a lot of big ideas and we need to think through steps to get these bills where they want to go. And today we are focused, though, on that first step.

What did they say? A journey begins with a single step. It will take stakeholders and Members rolling up their sleeves and working together to start making progress. You know nobody, nobody wants to see their family or their friends lose access to life saving and life improving care when they age into Medicare. Today's hearing and the number of bills being considered should be a warning about Medicare for all proposals. Imagine, imagine if it were up to the Federal Government to decide what treatment was covered for every American without other options fir coverage. And

being at the mercy of the healthcare bureaucracy you'd have to lobby your Congressman if you wanted to change coverage policy. Once again, Energy and Commence is leading the way on healthcare issues, top of mind for Americans from addressing the Fentanyl crisis working together on price transparency, we will get it to it the floor. And addressing consolidation in healthcare to making sure seniors have access to innovative of medicines and technologies. I am proud of the work this committee and I look forward to the hearing today.

I yield back, Mr. Chairman.

[The prepared statement of The Chair follows:]

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Mr. Guthrie. Thank you. The gentlelady yields back.

The chair recognizes the gentlewoman from New Jersey, the ranking member of the full committee Rep. Pallone for 5 minutes for an opening statement.

Mr. Pallone. Thank you, Mr. Chairman.

For almost 60 years Medicare has played a critical role in the laws of our Nation's seniors and disabled Americans. And today Medicare provides health coverage for over 65 million Americans. This committee has long been committed to sustaining the Medicare program, expanding coverage for seniors and insuring that the program delivers the highest quality care.

Over the last few decades we have seen an incredible acceleration in the number of scientific and medical breakthroughs and this has allowed for the creation of new treatments and technology to manage devastating diseases. The Centers for Medicare and Medicaid Services, CMS, plays an important role in assuring that Medicare beneficiaries can access these innovative technologies and treatments in a timely manner, a goal that we all share. CMS does all this while maintaining appropriate safeguards and rigorous evidence standards that prioritize the health and well-being of our Nation's seniors and the disabled. And there are reasonable discussions to be had about whether there are ways to improve the transparency and predictability of CMS' pathways to coverage.

And I look forward to or witnesses discussing those pathways today. However, I am concerned about some of the legislation before us that proposes to bypass these pathways to give handouts to Big Pharma and medical device companies.

My Republican colleagues have put forward a long list of extremely expensive bills

that cost hundreds of billions of dollars without any way of paying for them. The ironic thing is that this hearing comes at a time when their caucus is threatening a government shutdown over Federal spending levels. So my chief concern here is that these proposals would likely result in significant cuts to the Medicare program in order to offset spending of this magnitude. Enacting these proposals would also raise healthcare costs for seniors to increase premiums and this will place additional undue burdens on our Nation's senior and raise their out-of-pocket costs. Democrats have held firm in their commitment to oppose any efforts to cut Medicare benefits, raise the retirement age or increase beneficiary contributions. We will continue the fight to protect the Medicare program.

I am also disappointed that the committee Republicans refuse to include legislation that would directly expand access to care and reduce costs for seniors. We have a number of bills that will directly help Medicare beneficiaries. One bill would reduce cost sharing through the Medicare savings program and another would extend funding for outreach and enrollment programs for low-income beneficiaries and these bills were rejected by the majority.

Now also while I am disappointed that these bills were not included in today's hearing, I will continue to fight to lower costs and expand access to care for Medicare beneficiaries. I am pleased that H.R. 5386, the Cutting Copays Act was included in today's hearing. This bill would eliminate copays for generic drugs for low-income beneficiaries. And this would be a meaningful step to lowering costs for seniors around the country.

Lastly, I look forward to continuing to work on proposals that address and rein in unfair pharmacy benefit manager practices. There is clear bipartisan support for the

proposals we are discussing today which would address how PBMs use fees, rebates, DIR and specialty pharmacies in the Medicare part D program. And I look forward to many of these policies becoming laws, as well as our longstanding consensus policies to provide greater transparency into PBM practices in the commercial market.

And I look forward to continuing to work with my colleagues on both sides of the aisle to advance legislation that will meaningfully lower costs for patients and prioritize their health and well-being, rather than simply pad the pockets of Big Pharma and medical device companies.

And with that, I thank our witnesses. And I yield back, Mr. Chairman.

[The prepared statement of Mr. Pallone follows:]

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Mr. Guthrie. Thank you. The gentleman yields back. That concludes opening statements. We will have our witnesses opening statements today. I will introduce the witness.

First I think you testified before, you know the lighting system, you have 5 minutes. And 4 minutes into your opening statement the yellow light will appear. And once you see that begin knowing that you have 1 minute left to move forward.

So I will first introduce Dr. Dora Hughes acting director at the Center for Clinical Standards and Quality and acting chief medical officer at the U.S. Centers for Medicare and Medicaid Services. And we also have Mr. John Dicken, director of healthcare public health and private markets for the U.S. Government Accountability Office.

So Dr. Hughes, you are recognized 5 minutes for your opening statement.

STATEMENTS OF DR. DORA HUGHES, ACTING DIRECTOR, CENTER FOR CLINICAL STANDARDS AND QUALITY, ACTING CHIEF MEDICAL OFFICER, CENTERS FOR MEDICARE & MEDICAID SERVICES; AND JOHN DICKEN, DIRECTOR, HEALTH CARE, PUBLIC HEALTH AND PRIVATE MARKETS, U.S. GOVERNMENT ACCOUNTABILITY OFFICE

STATEMENT OF DR. DORA HUGHES

Dr. Hughes. Chairs McMorris Rodgers and Guthrie, Ranking Members Pallone and Eshoo, and members of the subcommittee, thank you for the opportunity to discuss the Centers for Medicare and Medicaid Services' work to ensure that Medicare beneficiaries have timely coverage for innovative treatments and medical technologies that treat life threatening or debilitating diseases and improve patient's quality of life.

CMS is committed to fostering innovation while insuring that Medicare has fast and consistent coverage processes for emerging treatments and technologies that will improve health outcomes. Our goal is to enhance coverage of new treatments and technologies while maintaining appropriate safeguards and rigorous evidence standards that are essential to the health of Medicare beneficiaries.

Medicare coverage and payment policies are provided in statute. They require that an item or service must be within the scope of a statutory Medicare benefit category and be reasonable and necessary for the diagnosis or treatment of an illness or injury in the Medicare population.

CMS makes coverage determinations using various pathways in order to facilitate timely beneficiary access to items and services that meet the statutory standard for

coverage. One Medicare coverage pathway is the national coverage determination process or NCD. NCDs are a transparent evidence-based process with opportunities for public participation. NCDs ensure that similar claims for items and services are covered in the same manner.

CMS is committed to a transparent NCD process. All of the potential NCDs that CMS is currently working on and the corresponding request letters are available publicly online. Additionally, CMS is developing a revised approach to NCDs that we believe will provide greater transparency, consistency and predictability to our decisions about which items and services should be considered for coverage at the national level. We look forward to the future release of that approach for public comment.

In some cases, CMS may provide Medicare coverage for items and services on the condition that they are furnished in the context of approved clinical studies or with the collection of additional clinical data to assess their appropriateness for use in the Medicare population. Coverage with evidence development or CED provides coverage for certainly improved treatments more quickly while collecting information about health outcomes needed to fulfill our statutory requirements.

CMS recognizes that new approaches are needed to compliment our existing coverage pathways in order to make decisions more quickly on certain new items and services and to provide expedited access to new and innovative medical technologies. To further this goal, CMS issued a proposed procedural notice outlining the new transitional coverage for emerging technologies pathway or TCET. The TCET pathway is voluntary for manufacturers. It supports innovation by providing an efficient, predictable and transparent coverage review process for certain eligible breakthrough devices that are FDA market authorized or cleared. The TCET pathway also includes

robust safeguards for the Medicare population. After transitional coverage, TCET devices may be covered at the national level as appropriate.

As we move forward, CMS will continue to engage with stakeholders, to ensure that Medicare promotes access to emerging treatments and medical technologies while maintaining the protections and the rigorous evidence standards essential to the health of Medicare beneficiaries.

Thank you for the opportunity to testify on this important topic. I am happy to address any questions you may have.

[The prepared statement of Dr. Hughes follows:]

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Mr. Guthrie. I thank you if for your testimony.

The chair now recognize Mr. Dicken for 5 minutes.

STATEMENT OF JOHN DICKEN

Mr. Dicken. Chairs Rodgers and Guthrie, Ranking Members Pallone and Eshoo, and members of the subcommittee I am pleased to be here today as you examine the role of Medicare in providing access to innovative drugs, devices and technology. Medicare part D provides about 50 million beneficiaries with access to drug treatments, including new innovative drugs. Part D also plays an important part in Medicare's physical sustainability with annual drug expenditures exceeding $20 billion.

Medicare part D drug plans vary in their premiums and in their list of covered drugs known as formularies. Plan sponsors place drugs into different formulary tiers with varying cost sharing amounts to encourage beneficiaries to use certain drugs. Plan sponsors or PBMs on their behalf may negotiate rebates from drug manufacturers in exchange for including a drug on a favorable formulary tier.

Policymakers and others have noted tradeoffs in how rebates effect Medicare spending, beneficiary access, and competition among prescription drugs. My statement today summarizes key findings and a recommendation from a recent GAO report on these issues.

First, it is important to recognize that rebates are concentrated among a small number of drugs. About 84 percent of the nearly $50 billion that manufacturers paid in rebates to part D plans in 2021 were for just 100 brand names drugs. These 100 most

highly rebated drugs represent about 1 percent of all part D covered drugs.

Further, 73 percent of these rebates were for drugs in three therapeutic classes, endocrine metabolic agent, anti-diabetic drugs such as insulins, blood modifiers including anti-stroke medications and respiratory agents including anti-asthma medication.

Our review of agreements between part D plan sponsors or their PBMs and drug manufacturers identified provisions intended to increase the use of certain drugs in exchange for rebates including these four, one placing a drug on a preferred formulary with lower cost sharing than competitor drugs.

Two, limiting the number of competitors by paying higher rebates if a drug was on a formulary tier with fewer drugs from other manufacturers.

Three, having competitor drugs be subject to restrictions to limit their use such as utilization management or formulary exclusion and four, bundling a manufacturers drugs with rebate amounts predicated on also having one or more of the manufacturers other drugs on the formulary.

We that found after counting for rebates plan sponsors generally paid less for the highly rebated drugs than for lower cost alternatives. In some cases, plan sponsors received more in rebates than they paid for the drug, resulting in a net profits the plan solely based on rebates received. Plans can use revenues from rebates to reduce premiums for all part D beneficiaries in Medicare.

Rebates however do not lower what beneficiaries pay for prescription drugs because their cost sharing is generally based on the cost before rebates. As a result, as in opening statements, beneficiary payments were four times as much to plan sponsor payments for 79 of the 100 highest rebate part D drugs in 2021.

Beneficiaries paid about $21 billion for these 79 drugs, plan sponsors paid about

$5 billion after receiving nearly $42 billion in manufacturer rebates.

In closing, we found instances where plan sponsors preferred highly rebated brand name drugs with higher beneficiary costs than lower cost alternatives. As a result, some beneficiaries, particularly those with certain chronic conditions such as diabetes or chronic obstructive pulmonary disease may not have access to lower cost medications.

Based on these findings, GAO recommended that CMS monitor the effective rebates on part D formularies and on Medicare and beneficiary spending. CMS disagreed, noting that already conducts clinical reviews of planned formularies. However, monitoring the effects rebates would provide important information on whether formulary and rebate practices may discourage enrollment of certain beneficiaries. And such monitoring could be particularly valuable as CMS begins implementing provisions of the Inflation Reduction Act.

This concludes my prepared statement. I would be pleased to answer any questions that you or subcommittees members may have.

[The prepared statement of Mr. Dicken follows:]

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Mr. Guthrie. Thank you. I thank the witnesses for their testimony.

The committee will now move to members questions. And I will recognize any self for 5 minutes for the purpose of asking questions. So Dr. Hughes, there is a recent report that shows that the average days of national coverage determinations in phase one and two have increased to 228 days between 2014 and 2020 that is up from an average of 52 days a decade prior. What are the causes of these increases?

Dr. Hughes. Thank you, and thank you for that question. CMS certainly agrees that we have to provide timely access to the items and services that meet our statutory standard. As you know, I have been in this position for about a month now so I can't speak to all of the historical issues with the NCD process. But I can say that in at least in the last 2 years for sure that we have met the majority of our statutory deadlines and we are committed to meeting these deadlines moving forward.

Mr. Guthrie. Okay. I have the bill. Thank you, with National Coverage Determination Transparency Act. It's aimed at reducing helping streamline the process to help address these backlogs. And I just went to ask you to commit to working with us and the committee on getting the bill right and getting it -- moving forward.

Dr. Hughes. We would absolutely work with you on this issue on how we can improve the transparency and timeliness less of NCD process.

Mr. Guthrie. Thanks. Appreciate that.

Dr. Hughes, you talked about TCET in your opening segment. The TCET proposal limits a submission to an expedited pathway to coverage for an FDA authorized or clear breakthrough device with just five devices in a cycle. CMS says it will prioritize devices to select based off those that have the potential benefits for the largest number of

beneficiaries. And so, my question is how can you ensure smaller manufacturers who are often as I found -- are often developing the most novel technologies? How can we ensure these smaller manufacturers of novel technology can gain access to the program because the greatest benefit of the program would accrue to these companies with less resources available to navigate the reimbursement process.

Dr. Hughes. And thank you for that question. Certainly we agree that we want to facilitate timely access to all items and services that meet our standard statutorily.

I want to emphasize that we have three pathways to coverage. We have at the national level through a national coverage determination. We have local coverage determinations or LCDs and then we have coverage on a claim-by-claim basis that are reduced by our Medicare Administration contractors or the MACs. So items and services even from small manufacturers that come to market they do have each of these three pathways available to them. And the vast majority of these decisions are actually made at the local level on a claim-by-claim basis or through an LCD. And we think that is helping to foster timely access to these tests.

Mr. Guthrie. Okay, thanks.

And also why do you think the impact on the greatest number is the right metric when technologies that produce lifesaving solutions for diseases such as cancer would apply to a smaller population but might provide a greater benefit?

Dr. Hughes. Thank you for that question.

Certainly CMS agrees that we have to think carefully about the items and services or in this case the breakthrough devices that we should focus on. We have stated publicly we are committed to releasing more information about how we will prioritize NCDs. We intend to release that in 2024. And we will take public comment, as noted

in the opening remarks, resource constraints certainly limit the number of devices that we will be able to review through the proposed TCET pathway.

Mr. Guthrie. Thank you.

And Mr. Dicken, in your report from this month you note that CMS doesn't use rebates as you talked about as they conduct annual formulary reviews. Why do you believe this would be beneficial for CMS? You further explain, I know you touched on it in your opening statement.

Mr. Dicken. Thank you. Certainly CMS is going through a process of reviewing formularies for a number of clinical standards and to make sure they meet statutory requirements. Given our findings that the formularies for certain areas or in conditions of individuals are highly concentrated and effect formulary decisions by the plans seem to be very valuable for CMS to also consider that information. It reviews formularies so it can consider if there are particular type of drugs or formularies that need to be reviewed to make sure that there is not having undue effect on individuals with those conditions or discouraging their enrollment.

Mr. Guthrie. So Dr. Hughes, do you have any comments on that.

Dr. Hughes. Thank you. We -- certainly CMS agrees with this committee and with GAO about the need to focus on transparency and accessibility of drugs for our Medicare beneficiaries. As alluded to, we review all the formularies before they are approved to make sure that all of the drugs across the classes that are needed by beneficiaries are there. We are confident that this process is effective.

Mr. Guthrie. Thank you. My time has expired.

And I recognize the gentlelady from California for 5 minutes for questions.

Ms. Eshoo. Thank you, Mr. Chairman. And thank you to our witnesses for your

testimony.

As I mentioned in my opening statement, one of Medicare's contractors decided to ignore precedent and restrict patient access to diagnostic tools that will harm transplant patients. There is an upending going on in the transplant patient community across the country on this.

So Dr. Hughes, what responsibility does CMS have when its contractors make decisions that are out of step with widely accepted evidence that a tool is effective?

Dr. Hughes. Thank you for that question.

We work with our local MACs in a number of different ways. First through the program integrity manual. It is fairly prescriptive in terms of the expectations for our contractors. The process they must follow, the public comment, the summary, the evidence, the --

Ms. Eshoo. If there wasn't any allowance for public input on this.

Dr. Hughes. So in those cases --

Ms. Eshoo. Something's gone awry.

Dr. Hughes. When we hear complaints such as that at CMS at our level we investigate. We look to make sure that the process was followed. And if it is not, we certainly do follow --

Ms. Eshoo. Well, I think I pointed out -- Dr. Burgess and I have pointed out what has not been followed. And so I want to ask you if CMS will commit to reviewing this decision. It deserves review.

Dr. Hughes. Yes, thank you and I will certainly follow-up and get more information about the specific situation to see how we can address it.

Ms. Eshoo. Okay. For years now I have worked to speed up the time between

FDA authorization of a new device and Medicare's decision to cover that device. CMS has finally published, as I said, a new proposed rule. I think it takes a very important step forward in making sure seniors can access new medical devices.

So Dr. Hughes, why did CMS limit the new coverage pathway to only five devices per year? It seems arbitrary to me. The new CMS rule excludes diagnostics from the new coverage pathway. So I would ask why on that one too.

Dr. Hughes. And thank you, thank you for your question.

At a high level, I most certainly must say FDA and CMS we do have a very collaborative partnership. And when we looked through their -- the number of devices that are in the pipeline, when you strip out the pediatric devices, cosmetics, software, those that don't have a benefit category the number does shrink considerably.

Ms. Eshoo. And what is the number?

Dr. Hughes. And we think that we are expecting to get about eight nominations for this TCET pathway every year. We think with our current resources that we will be able to undertake five, which I would note is a doubling of our current on average --

Ms. Eshoo. Yeah. It has taken years to finally get proposed rule for devices. What will happen if CMS has to start all over again in implementing the ensuring patient access to Critical Breakthrough Products Act, if it passes? How long do you think implementation of the new law will take?

Dr. Hughes. Certainly I can't comment on any specific bills that -- I am not familiar with that one. But I can say if we had -- if we were able to record --

Ms. Eshoo. I think you better read up on that one.

Ms. Hughes. I will do so.

Ms. Eshoo. My sensibilities are A, it is highly bipartisan. And I think it is a bill

that is moving so he better take a good look at it.

Let me just say something to Mr. Dicken. First of all, thank you for the work of the GAO. I have always found it to be superb.

I want to ask you, Dr. Hughes, CMS is unwilling to take up the recommendation that the GAO is making. It seems to me that in part D that the plans really have something going for them here. And the patient is not benefiting from that. And when I hear PBMs being involved, well then we know that for sure they don't do a damn thing for patients. Why aren't generics in this? And why won't CMS accept the recommendation that they are making? It seems to me that it is not menacing. Why are you rejecting that?

Dr. Hughes. Thank you for that question.

As I had mentioned, we do look at the formularies very carefully to make sure that the drugs are --

Ms. Eshoo. But I think that -- with all due respect, I think that the GAO is on to something here. You may be looking at them, but the most expensive drugs are the ones that the plans are giving the big boost too. Is that acceptable to CMS?

Dr. Hughes. Thank you for that question.

CMS is of course committed to providing accessible and affordable drugs for our beneficiaries.

Ms. Eshoo. I think you need to go back and reconsider, I really do. I don't think that this is menacing at all. It is documented. There is something wrong with that system.

Dr. Hughes. Certainly I will certainly take that back.

Ms. Eshoo. Okay.

I yield back, Mr. Chairman.

Mr. Bucshon. [Presiding.] The gentlelady yields back.

I now recognize Mr. Latta from Ohio, 5 minutes.

Mr. Latta. Well, thank you, Mr. Chair. And thanks for our witnesses for being with us today.

Today's hearing cannot come at a better time, as the title says it all. The government has long limited access to better drugs, devices and technologies due to overregulation bureaucratic red tape. There are also lingering questions about how government policies have exasperated the structural financial and demographic challenges facing the Medicare program. Because of the important role that our healthcare system plays in all Americans' lives, we must proceed in a responsible way to balance the importance of patient access to innovative treatments and cures of the structural, fiscal and demographic realities facing the Medicare program.

Dr. Hughes, I believe the investments are needed in new and innovative drugs, medical devices and technologies. Seniors access to better, earlier and more transformative care will help them see improvements in their daily lives and hopefully will limit the need for future, more costly services.

In addition to the legislation being considered here today, would you share any specific regulatory burdens that if lifted would improve seniors' lives and improve access to needed healthcare services? And before you answer, because again this is the Energy and Commerce Committee, one of the things that I am very proud of the fact that of all the different subcommittees that do have that we look over the horizon 5 to 10 years in a lot of cases, we look through the innovators. But things are changing so rapidly that there are new devices and medications that are coming out. So what can CMS do to

help on the innovation front to help on these healthcare services and to help our patients out there?

Dr. Hughes. Thank you for that question.

And certainly CMS shares your passion for the innovation and excitement about the new treatments and technologies that are already here, in many cases are coming down the pike. We have three coverage pathways. We provide coverage at the national level through the NCD. And that ensures that items and services are paid uniformly at the national level. The vast majority of coverage decisions are made at the local level on a claim-by-claim basis by our local Medicare Administration Contractors or MACs or by -- through a local coverage determination at LCD.

Mr. Latta. Well, thank you.

If I can go to Mr. Dicken, if I could ask, because this has come up from a couple of our members already, you know, when you are talking about what the costs are out there and what the recommendations that you have all made. One of the words I picked up on what you say is about monitor. Is there something stronger than the word monitor? What can you all be doing when you are getting back with CMS? Because again, we want to move things along here. But I just think the word monitor sometimes is just saying, like, well, there it is and just keep on going. So how do we change that existing thought process that is out there that we don't want to just keep doing the same things over and over again if they are not working right.

Mr. Dicken. No. Thank you for the question. And certainly monitoring is the starting point. It provides the information that can then be considered within the authorities and limits that CMS would have in how they could address that. But certainly in addition to assuring that formularies are meeting all statutory requirements

and are clinically appropriate. Also responsibilities that CMS has to assure that there is not discrimination against beneficiaries. And that is where we think at least having that information, given the findings of what is occurring now where a number of beneficiaries with certain conditions are perfectly affected and may not have access to lower costs alternatives, that that information could then lead to further steps that could be taken either by CMS or others in having that information more widely available.

Mr. Latta. Thank you.

Dr. Hughes, people living in rural areas of the Nation face unique challenges when it comes to assessing innovative medical innovation systems recently approved Alzheimer's drugs. It is my understanding that many doctors refer their patients to infusion centers to receive Alzheimer's drugs. This is especially true for small practices like many rural providers.

However, CMS recently imposed coverage with evidence development requirements on Alzheimer's drug for providers and to my knowledge has not provided specific guidance to the infusion centers about how reimbursement will work. As a result, few providers appear willing to take on financial risk of administering the medicines. That means additional access hurdles and further delays for people already taking short windows for treatment. What is the current status on Medicare reimbursement?

And how can both doctors and infusion centers be assured they will be reimbursed for those drugs.

Dr. Hughes. Thank you for that question.

As you may know, when FDA provided full coverage traditional approval for broader coverage was made that same day for Medicare beneficiaries, regardless of

where they live in the Nation.

Mr. Latta. Well, my time has expired. I will submit my other questions for the record.

Thank you, Mr. Chairman.

Mr. Guthrie. Yes. The gentleman yields back.

I now recognize Ms. Kelly from Illinois for 5 minutes.

Ms. Kelly. I didn't think I had be up this soon. I am so sorry. I didn't think I would be up this soon.

Thank you to the committee, Chairman Guthrie, and Ranking Member Eshoo for holding today's critically important hearing.

Life expectancy has been on the rise in the U.S. And by the year 2030 the number of Americans over the age of 565 is projected to be about 70 million. Innovations and medical science especially pharmaceuticals have shifted the focus of medicine from highly invasive treatments and surgeries with potentially serious risks to less invasive therapies focus on prevention and health maintenance. This shift has allowed many older Americans to remain healthy and independent, avoiding long hospital and nursing home stays.

One technology that proved beneficial during the COVID-19 pandemic was remote patient monitoring. Remote patient monitoring allows individuals to receive care from their providers while remaining in their home. This decreases many potential burdens such as prolonged hospitalizations, transportation hurdles and provider access.

Now I must say my late husband was a doctor and he used to make home visits which is very unusual with seniors. And then when COVID started, he did treat patients in their home from our home.

Dr. Hughes, the COVID-19 pandemic shed light on the need to reevaluate the minimum required duration of remote monitoring with CMS that a full 16 days of monitoring may not always be reasonable and necessary. However, the 16 day, 30 day period minimum duration for all patients was not updated. Can you speak as to what date CMS is seeking to support this crucial tool in healthcare accessibility?

Dr. Hughes. Thank you and I thank you for that question.

I would say that CMS agrees that we learned quite a bit through the pandemic and very generally about the importance of these newer technologies. I am not sure what information that we have been collecting internally, but I would certainly be happy to work with you after today's hearing on the proposals that you may be reviewing.

Ms. Kelly. That would be great.

What ways is CMS working to improve Medicare beneficiaries' access to early cancer diagnosis technologies?

Dr. Hughes. Thank you for that question.

And certainly at CMS we share your enthusiasm for some of these newer technologies that are coming through. For those technologies that meet our statutory standard of being medically reasonable and necessary for our Medicare beneficiaries, we are able to provide coverage. At the local level on a claims-by-claims basis on a more timely in many cases faster pathway we also have coverage pathways by way of the local coverage determination and nationally through national coverage determinations.

Ms. Kelly. Okay. I would like to close -- thank you for your response. I would like to close by saying that multicancer early detection technology was developed to address this deadly gap in screening. These tests provide opportunities to intervene early in cancer treatment. Yet access to these trolls is limited, especially for the most

vulnerable. Data from CDC shows that racial identity as well as geography have impact on surviving cancer. Disparities in respect to routine screening, such as for colon and prostate cancer exist among Black Americans.

Just as efforts such as mobile mammography can adjust such disparities access to multicancer early technology expands the benefits of screening to a wide range of cancer pathologies. Thus I yield my support for H.R. 2407, the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act to increase timely access to this potentially lifesaving technology by creating a direct pathway to Medicare coverage.

And with that, I yield back, unless you have a comment.

Dr. Hughes. Certainly we agree prevention is absolutely critical. And we would be happy to work with you on this bill.

Ms. Kelly. Thank you.

Mr. Guthrie. [Presiding.] Thank you. The gentlelady yields back.

The chair now recognizes Mr. Griffith for 5 minutes.

Mr. Griffith. Thank you, Mr. Chairman.

One of the bills we are discussing today, H.R. 5393, the Transparency and Fairness for Pharmacies Act is a bill that I crafted that would bring more transparency to pharmacies when dispensing a drug and require CMS to create a standardized quality metric system for plans in PBMs, pharmacy benefit managers, to use when determining payments to pharmacies. This is just one small step to bring more transparency and certainty to pharmacists when dispensing drugs.

This is a issue I hear about constantly from small and rural pharmacies in my district. I have lots of questions on that that I am not going to have time to get to because they only give me 5 minutes. So I am going to send you all questions after the

hearing if you all could respond to those.

Mr. Dicken, in your September 2023 highly rebated drug report you found that for almost 80 percent of the top 100 highly rebated drugs patients spent almost four times as much as the plan sponsors did. Do you think it is fair that patients are having to pay more at the pharmacy counter due to PBMs requiring higher rebates from drugs manufacturers for better formulary placement?

Mr. Dicken. Thank you, Representative Griffith. You captured well what we found for that small subset of brand name drugs with high rebates. Certainly, you know, that is different from the experience with most drugs and most insurance where plans are paying more than the beneficiaries for that group of drugs, so the situation reversed.

Mr. Griffith. Dr. Hughes, do you think that is fair for patients?

Dr. Hughes. Thank you for the question.

I would note that we have reviewed the GAO findings with great interest. We would also note that CMS does not contract with pharmacy benefit managers in the Medicare or Medicaid program. We are prohibited from interfering with private negotiations between plans, pharmacies and manuf --

Mr. Griffith. Yeah. But do you think it is fair. Yes or no?

Dr. Hughes. We share the concern that beneficiaries have full access to the drugs they need.

Mr. Griffith. And this is why I wanted to get to this because I practiced law for nearly 3 decades. And in that, I had a fiduciary duty to my clients. I believe that insurance companies working with their PBMs, sometimes they own them, sometimes they don't, have a fiduciary relationship with their subscriber, with the person who is paying them money to help them pay for their insurance -- to help them pay for their

medicines. And yet, what we have is a situation where in many cases, as Mr. Dicken pointed out in his opening statement, we have a number of cases where the patient is paying a higher amount in their co-pay than the insurance company has paid for the medicine. And to me it is a breach of their fiduciary duty and is unethical and immoral.

And that is why I didn't have time for the others questions, because I wanted to get that off my chest. And you all need to be aware that there are a number of us who feel this way on both sides of the aisle.

So Mr. Dicken, CMS disagreed with your recommendation requirement, oversight and analysis into the rebate structures that are in place with health plans. Would greater scrutiny over these rebates bring more fairness for patients?

Mr. Dicken. Certainly the hope is to make sure that there are not practices that could unduly effect or discriminate in the fact against individuals in certain conditions would help better align incentives, the beneficiaries plans in the Medicare program.

Mr. Griffith. Does your highly rebated report look to where these re-bate dollars went, that had the health insurance plans and PBMs received from the highly rebated drugs?

Mr. Dicken. We have looked at how the rebates are used. Those rebates are reported by the plans to CMS each year. They are included as CMS negotiates with the plans or works with plans to develop their premiums for future years. As well as we have found that in general win Medicare part D most of those rebates are passed through from the PBMs to the plans. That may be different from the experience outside of --

Mr. Griffith. To the plans and the plans are for-profit as they should be. But they are not necessarily benefiting the patient. Isn't that true? Particularly the patient who is buying one of those top 100 medicines.

Mr. Dicken. Yeah. They are not affecting what they are paying at the pharmacy for the drug. They may help reduce their premiums overall.

Mr. Griffith. All right.

Dr. Hughes, do you agree with me -- and I am going back to my original bill because I have 20 seconds left -- do you agree with me that having standardized quality metrics for plans and the new part D rule going into effect in January that will eliminate retroactive DIR fees will help pharmacies, especially small rural ones keep their doors open?

Dr. Hughes. CMS agrees with you that pharmacies just a trusted partners in critical space, that is why CMS is already taking steps to increase the transparency on the fees that pharmacies are being charged and to level the playing field for pharmacy providers.

Mr. Griffith. I appreciate that.

And I yield back.

Mr. Guthrie. Thank you. The gentleman yields back.

The chair recognizes Mr. Cardenas from California 5 minutes.

Mr. Cardenas. Thank you very much Chairman Guthrie and Ranking Member Eshoo for holding this hearing. And I appreciate the witnesses being here giving us their opinions and expertise.

I am glad to see several bills that I support notice in today's hearing. I will be focusing my remarks on just had a handful of those starting with the bill that I co-lead, the Ensuring Patient Access to Critical Breakthrough Products Act. We have previously discussed the importance of creating expedient access to devices, drugs and technologies. These innovations can be life altering and lifesaving, especially for our country's seniors.

The Ensuring Patient Access to Critical Breakthough Products Act would allow temporary Medicare coverage for designated medical breakthrough devices, putting the most innovative courses of treatment at patient's fingertips. This means more people living easier, longer, healthier lives. Expanding this type of access has been a priority for me.

And I am excited to see so much regulatory activity to broaden access to a full range of devices. This includes the new transitional coverage for emerging technologies, otherwise known as TCET rule which would establish a pathway for emerging technology to be covered.

Dr. Hughes, what kind of implementation timelines does CMS have for the TCET rule? And how will the agency ensure that it hits those dates?

Dr. Hughes. Thank you. And thank you for that question.

As you have eluded to, in the TCET pathway, we intend to start engaging with the manufacturers that are part of the pathway up to a year before their product is even authorized by FDA. We will commit to facilitating conversations with our colleagues in Medicare, on benefit category determinations payment and coding. We will review the evidence that exists even before the product is approved by FDA so we can identify any gaps in evidence earlier. All of these steps, in addition to committing to reviewing the evidence at specific times during the review processes. What we think that will help to address the needs for a manufacturer for a more timely decision, more consistency and more predictability.

Mr. Cardenas. Okay. Thank you.

What kind of recourse is in place for CMS if the deadline described in the TCET guidance are not met?

Dr. Hughes. We think that by being very transparent such as by our steps that

we took to update the NCD dashboard that we will be able to provide the transparency that manufacturers and other stakeholders need to make sure that we are meeting our timelines.

Mr. Cardenas. Thank you.

Meeting these deadlines is critical because time really is of the essence. It can even be the difference between life and death for many people, which why I should also take this moment to mention my concern that budget cuts and especially government shutdowns will have a tremendously detrimental impact on CMS's ability to implement this policy. I sincerely hope we all keep these impacts in mind in the coming weeks and months as Members of Congress.

Also, separately I want to call attention to the importance of covering a full range of treatment options for individuals with obesity, including medications. Racial disparities in obesity incidents are a serious health equity issue. In fact, the University of North Carolina study let by Dr. Claire Yang found Black and Hispanic women have higher BMI trajectories across their life in comparison to White women. This means they are at greater risk of obesity and the many comorbidities associated with it. By not covering anti obesity medications or AOMs, we are limiting the number of tools at our disposal to address these disparities. For this reason, I am glad that bill like the Treat and Reduce Obesity Act are being discussed today.

Dr. Hughes, in our opinion, what role could coverage for AOMs play in improving health and health equity for women, especially in Medicare?

RPTR MOLNAR

EDTR ROSEN

[11:00 a.m.]

Dr. Hughes. Thank you. Thank you for that question. CMS agrees that obesity remains a serious health condition for our Medicare beneficiaries, and certainly our Medicaid and marketplace beneficiaries as well.

As you know, the statute prohibits us from covering these medications through the Part D program. Although the Medicare Advantage plans are able to cover it as a supplemental benefit if they choose.

Mr. Cardenas. Okay. Thank you. Thank you for your response, and for all the work you are doing at CMS to ensure that we have access to care. Like I said, I hope that we can ensure a full spectrum of care options, whether it is access to innovative new devices or life-altering medications.

My time having expired, Mr. Chairman, I yield back.

Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes Chair Rodgers for 5 minutes for questions.

The Chair. Thank you, Mr. Chairman. Just picking up where my colleague, Mr. Cardenas, just left off, the importance of these decisions, life and death, medical technology. The ranking member, Ms. Eshoo, highlighted this, but the median time between FDA approval and some form of Medicare coverage for these technologies, unfortunately, on average, is 5.7 years. It is a startling gap in coverage, and I am concerned about the lack of accountability and predictability.

Dr. Hughes, you were just talking about in this new rule that you want to incor- -- you know, you want more consistency, more predictability. I just want to ask,

as you are in the process of incorporating the public comments, can you speak to the need for patients and innovators to have clear and accountable timelines for review on coverage decisions? I want the specific commitment to some timelines so that we don't continue this 5.7 years of people having to wait.

Dr. Hughes. Thank you, and thank you for that question.

Chair Rodgers, I do just want to note that when items and services are approved by FDA, they are able to get coverage at the local level on a claim-by-claim basis, or through local coverage determinations, without -- they do not have to wait on coverage through the NCD process, which, as you noted, can take more time.

We do agree, though, that we need to provide more transparency about the deadlines as part of why, to the TCET pathway, we have committed that we will establish deadlines, we will share these with manufacturers and the public so that they will know when they can expect the CD to be reviewed.

The Chair. Thank you.

The fact that we have so many bills before us today addressing new and emerging technologies, or well-known items like titanium wheelchairs, so that they are accessible for Medicare patients who may otherwise be able to access these technologies if they were in a private plan, is not a coincidence.

This is a feature, not a bug, of an antiquated Medicare fee-for-service program, a program which regularly requires Congress to intervene to clarify that CMS must cover certain products or services.

In a more rational, patient-driven system, patients would be able to access these products and services if they add value to patients' lives and the Medicare program.

So my question, Dr. Hughes, is, what is the logic behind a patient having access to

the latest continuous-glucose monitor or their cutting-edge cancer treatment at age 64, and then losing access to them merely because they aged into the Medicare program or develop ENRAGE renal disease?

And what specific steps has CMS taken to protect seniors against losing access to medical innovations that they already had by simply aging into the Medicare program?

Dr. Hughes. Thank you, and thank you for that important question. Certainly CMS agrees that our beneficiaries need full access to items and services that meet our statutory standard. And our statutory standard is that we are able to cover items and services for Medicare beneficiaries in compliance with our statute that can help to diagnose or treat illness or injury.

As part of that, our Medicare beneficiaries, they are older, they are frailer, they are sicker, and they are generally not represented in trials that the FDA reviews. And so, that is why, as part of our statutory requirement, we have to look at these items and services within the context of the needs of Medicare beneficiaries.

The Chair. Absolutely. I understand CMS previously considered technology assessments and coverage criteria among private health plans in its coverage policy for acupuncture for lower back pain.

CMS also proposed a policy similar to H.R. 5395. Would you commit to working with us on legislation that would require demonstration for commercial coverage parity for Medicare payments?

Dr. Hughes. Thank you for that. CMS would be happy to work with you on that proposal.

The Chair. Thank you.

Mr. Dicken, one of the major take-aways from your report is that seniors on fixed

incomes are paying more for their drugs than some of the Nation's largest, most consolidated, and most profitable insurance companies.

Mr. Dicken, your testimony report indicate that this unbalanced rebate dynamic is concentrated in certain types of drugs and certain types of patients. Would you just speak to the characteristics of the patients and the diseases they face, who are stuck paying more for drugs than the health insurance companies?

Mr. Dicken. Yeah. Thank you for the question, Chair Rodgers. You are right that we did see that these were very much concentrated among individuals who have certain types of conditions, noted that that could include those with respiratory conditions, diabetes, chronic obstructive pulmonary disease, and so, those are individuals where there are drug treatments that may be high cost, but are also highly rebated.

And so that is where the incentives that we saw can become misaligned, where the plans may be getting large rebates for those drugs that may lower their overall cost and the premiums that all beneficiaries are paying.

But for those individuals that rely on those high-cost drugs, they are not getting those savings when they are purchasing the drugs at the pharmacy.

The Chair. Thank you. Thank you for your insights. I yield back.

Mr. Guthrie. Thank you. The chair yields back.

The chair now recognizes the ranking member, Mr. Pallone, for 5 minutes.

Mr. Pallone. Thank you. In the U.S. we are lucky to benefit from one of the world's most innovative health systems with new drugs and medical devices coming to market every day, and these products vary drastically in their complexity as well as their usefulness to the diagnosis, treatment, and management of diseases.

And Congress gives CMS the authority to determine whether these new drugs and

medical devices are reasonable and necessary products for the population served by the Medicare program.

So I want to ask, Dr. Hughes, could you please elaborate on the factors CMS uses in its reasonable and necessary standard and explain why it is important for the agency to evaluate new medical products specifically in the context of the Medicare population?

Dr. Hughes. Thank you, and thank you for that question.

As you note, our statutory requirements, as directed by Congress, is that we cover items and services that are needed to diagnose, treat illness and injury for Medicare beneficiaries, and that is important because our Medicare beneficiaries, they tend to be older. They are definitely sicker, they have multiple chronic conditions, and they are also treated in certain settings that are not represented often in clinical trials where the individuals tend to be healthier and younger populations.

And so, that is why our statutory standard specifically mentions the Medicare beneficiary populations. Those are -- that is where our statutory charge focuses on.

Mr. Pallone. And clinical trials often have strict criteria that define who is allowed to participate. And I imagine this might exclude people with cormorbidities and potentially lead to a less diverse study population.

Can you speak to how CMS coverage determination process evaluates new products as they would be utilized in the more medically complex Medicare population?

Dr. Hughes. Thank you for that. Whether through the NCD, the national coverage determination process, or the same standards are applicable for those on the local level when local coverage determinations are being made, we specifically look to the evidence on whether a device or a drug, what is the effect on the health outcomes, what are the risks that may be posed, are there certain requirements that we should be put in

place in terms of who is able to administer the drug or device, what setting, what supports may be needed. All those factors we take into consideration when we decide to cover a drug or a device.

Mr. Pallone. And we have seen proposals that seem to circumvent CMS' process of determining what is reasonable and necessary, or impose arbitrary timelines. So, Dr. Hughes, given the unique characteristics of the Medicare population, why might it be dangerous to bypass CMS' coverage process?

Dr. Hughes. Thank you for that. We believe that a rigorous evidence review is necessary first to comply with our statutory requirement, to look at items and services needed for diagnosis or treatment, illness or injury.

But also in many cases, there may be unanticipated or unmitigated harms and risks that we should know about in advance so that we can appropriately work with our patients to make the best decision for their care.

Mr. Pallone. Well, thank you, Dr. Hughes. I think these decisions and determinations are complex, and it is certainly helpful to hear from an expert like yourself on the uniqueness of both the Medicare population and the coverage determination process, so thank you.

And with that, Mr. Chairman, I yield back.

Mr. Guthrie. Thank you. The ranking member yields back.

The chair recognizes Mr. Bilirakis for 5 minutes for questions.

Mr. Bilirakis. Thank you, Mr. Chairman. Appreciate it.

I was particularly glad to see the bill I co-led with Representative Wenstrup and Representative DelBene, and of course Representative Cardenas who sits on the committee. It is H.R. 1691, the Ensuring Patients Access to Critical Breakthrough

Products Act, noticed on today's hearing, and we really appreciate that. And I appreciate the testimony of the presenters.

I would like to ask for unanimous consent, Mr. Chairman, to insert into the record a statement of support from Dr. Wenstrup in support of this particular bill.

Mr. Guthrie. Thank you. I believe it is on our list, and we will take care of that at the end of the hearing.

Mr. Bilirakis. Thank you. I appreciate it.

It has been made very clear, from both sides of the aisle, Congress' intent for CMS to do more to provide a true coverage pathway for innovative breakthrough-designated medical devices.

These devices receive that designation when there are no approved alternatives for life-saving or debilitating diseases or offer significant advantages to patients compared to existing options.

For example, we have a fully implanted, active, middle ear hearing device that receives breakthrough designation by FDA and was approved as a class 2 medical device. Yet, it is not eligible for Medicare reimbursement due to the way it is categorized by CMS.

These types of decisions make or break smaller U.S. medical device companies, and again, it is withheld from the patients.

Dr. Hughes, I am glad to see, in your testimony, that you discuss a CMS transitional coverage for emerging technologies, or TCET, a guidance, and recognize the need for CMS to make quicker decisions.

Our bill would do just that by ensuring that devices have national coverage for new breakthrough devices through a statutory pathway, including a way to establish additional evidence or data during the transitional 4-year coverage period.

Unfortunately, the current CMS guidance goes through the existing NCD process, and may be limited to only five devices per year to receive coverage eligibility.

Will you commit to working with us to ensure this new pathway creates real certainty for Medicare patients and innovators as well as a pathway for new technologies, such as digital therapeutics.

Dr. Hughes. Thank you. Thank you for that question. CMS agrees with you about the need for more timely access to innovative products and therapies, including the breakthrough devices. I would note that for any device that is approved by FDA, they do have access on a claim-by-claim basis that can be made at a local level by our Medicare administrative contractors, or MACs, and also they can also receive coverage through an LCD, also at the local level. It is not required for device manufacturers to go through the national coverage determination process.

But that being said, as you noted with our new TCET pathway, we have committed to being very transparent about the deadlines that we will put in place for review, and other improvements to facilitate more timely access.

Mr. Bilirakis. Thank you very much.

Next question for Mr. Dicken. Your study noted MedPAC's previous work indicating patients receiving low-income subsidies have weaker incentives to choose cheaper alternatives since they have limited cost-sharing for their drugs.

It seems that if Congress were to significantly reduce generic copays for patients receiving LIS, and couple that with modest copays for nonpreferred drugs or all formulary drugs, patients would have an added incentive to choose the cheaper alternative drugs, saving themselves and the Medicare program money.

Question, would you be willing to work with me on my legislation, H.R. 5386, the

Cutting Copays Act, to encourage greater generic utilization and save money for low-income seniors.

Mr. Dicken. Thank you, Representative Bilirakis. I appreciate the interest. Certainly glad to talk to you and your office about those issues. You are right, the growing part of the Medicare population is receiving low-income subsidies, and certainly, that is the traditional role of formularies, is to encourage lower-cost therapeutic equivalents, including generics.

Mr. Bilirakis. Okay. Thank you very much.

I yield back, Mr. Chairman.

Mr. Guthrie. The gentleman yields back.

The chair will recognize Mrs. Dingell from Michigan for 5 minutes for questions.

Mrs. Dingell. Thank you, Chairman Guthrie and Ranking Member Eshoo for covering this important hearing.

Over the last several years, we have taken significant steps in Congress to expand access to healthcare beyond a traditional doctor's office or hospital setting.

So as we are having this conversation on how to modernize Medicare coverage, I think it is important to acknowledge that some existing coverage policies aren't reaching their full potential, and also deserve our attention.

One area where we still have significant room for improvement is Medicare's coverage for home infusion services for patients who need access to IV therapies, but don't otherwise need to be in a medical facility.

Mr. Dicken, as you may know, GAO concluded in a 2010 report that while private health insurers provide comprehensive coverage of home infusion therapy under all of their commercial plans -- which, by the way, I don't think is true anymore, and I will tell

you why in a minute -- coverage for these services and Medicare fee for services is often limited, requiring patients to obtain infusion therapy in a hospital, nursing home, or a physician's office, to have all therapy components covered.

And actually, I had to have a PICC and give myself antibiotics for, it was more than 3 months, and I gave myself the shot every day.

If I went to the infusion center, it cost $5,000 a day. All I had to do was pay for the medicine, but it didn't cover it, because, you know, save $5,000 or pay for the medicine. So I, myself, really learned about this because I thought that was absolute insanity, and I have private insurance and Medicare. Save money. Makes sense. Didn't need anyone to give it to me.

So, Mr. Dicken, given the demonstrated benefits of home infusion therapies, including potential cost-savings, enhanced patient comfort, and reduced exposure to hospital-associated infections, can you provide insights into the barriers preventing broader Medicare coverage of home infusion services?

Mr. Dicken. Thank you, and as you note, that is an issue that we have -- my colleagues have looked at in the past. Certainly glad to, you know, kind of look at the more recent experience that you are highlighting and work with your office in trying to look at some of those challenges that may be currently faced.

Mrs. Dingell. Well, you are not covering it right now, like, if somebody -- okay, I am a little older than 65, but not yet, but Medicare doesn't cover someone giving their own selves a shot. That is like a $5,000 savings every single day for 90 days. We should be looking at that.

So that is why I appreciate your response, and that is why I have introduced the Expanding Care in the Home Act, along with Representative Adrian Smith to modernize

Medicare reimbursement and increase patient access for home-based health services, including home infusion.

While I appreciate the goals of the home infusion proposal that was noticed today, this is a more comprehensive approach which would increase home infusion access to a much larger patient population. It would more closely resemble the model employed by nearly every commercial pair.

I have also introduced the Preserving Patient Access to Home Infusion Act with Representatives Buchanan, Sewell, and Harshbarger to provide technical clarifications to expand access to home infusion services for Medicare beneficiaries.

It is something I hear time and time again from my constituents. It is something they value. And as you can tell, I have had a very personal experience, and I think it was ludicrous, and everybody on the committee knew it at the time.

Now I want to run my attention to mobility-related equipment.

Dr. Hughes, in addition to new emerging technologies, timely Medicare coverage of mobile-related equipment is critical for individuals living with disabilities.

As co-chair of the Bipartisan Disabilities Caucus, I understand the importance of wheelchair coverage for Americans with disabilities, and appreciate the work CMS has done and continues to do to improve Medicare coverage policies of mobility equipment.

Last year, CMS opened a national coverage determination for seat elevation technology and announced this May that power seat elevation equipment would be covered for the first time.

It is a critical improvement, but it did not consider seat elevation technology, which is another element.

Dr. Hughes, can you elaborate on how CMS determines coverage for

mobility-related equipment, and can you share if CMS has planned to open an NCD for seat elevation technology?

Dr. Hughes. Thank you, and thank you that you mentioned a number of areas that are priorities for CMS, even with your earlier comments on how are we moving care into the home, and these are issues that I will make sure I run by my colleagues in Medicare to see if we can provide more information back to the committee.

As you note, we are starting to take more efforts to look at what assistive technologies may be eligible for Medicare reimbursement, and what additional information we may need. I will be happy to work with you on these issues moving forward.

Mrs. Dingell. Thank you.

Mr. Chairman, I have more, but I will yield back.

Mr. Guthrie. Thank you. The gentlelady yields back.

The chair recognizes Mr. Johnson from Ohio for 5 minutes.

Mr. Johnson. Well, thank you, Mr. Chairman, and good morning to our panelists. You know, innovation in healthcare is essential. It is a beacon of hope in our quest for a healthier and brighter future for all Americans.

No other industry in the world continues to evolve each and every day like the healthcare industry. Whether it be new-age Alzheimer's treatments or prescription digital therapeutics, or PDTs, there is a lot in the pipeline to be optimistic about.

Getting patients coverage for PDTs and a growing class of treatment everywhere, from mental and behavioral healthcare to Parkinson's disease and diabetes, will improve the quality of life and outcomes for millions of Americans.

That is why I was so proud to see included today, bipartisan legislation I am

co-leading alongside Reps Hern, Matsui, and Thompson. Our legislation, H.R. 1458, the Access to Prescription Digital Therapeutics Act of 2023 would provide a coverage pathway under CMS to get these innovative pieces of software into the hands of patients.

I believe this bill is a prudent step forward that will lead to greater preventative care, ultimately lessening the burden on the American taxpayer down the line. I urge all of my colleagues to support it.

My first question goes to Dr. Hughes. According to the National Alliance on Mental Illness, 22.8 percent of U.S. adults -- that is about 57.8 million people -- experienced some form of mental illness in 2021. Yet less than half received treatment.

There are several prescription digital therapies cleared by FDA, and still others in clinical trials, to treat major depressive disorder, PTSD, panic attack disorder, and other mental health illnesses.

These treatments could help us close this coverage gap, reach underserved communities, like the one I represent in rural Ohio, and improve health outcomes for millions of Americans.

So, Dr. Hughes, what is CMS doing to ensure that PDTs are being viewed as an important tool and are incorporated into those efforts?

And what is your approach to coverage and reimbursement for innovative health technologies like digital therapeutics?

Dr. Hughes. Thank you, and thank you for that important question. As you know, CMS has prioritized behavioral health as an issue that we have and will continue to focus on more intensively in the days ahead.

With respect to PDTs, as you note, they do have potential to really address some

of the access issues and provide our beneficiaries the care they need.

We have been exploring this issue. We ask questions. Through a recent proposed payment rule, we are looking to see the comments and the evidence that we receive back and hope that we can work with you on expanding access to PDTs --

Mr. Johnson. Okay.

Dr. Hughes. -- moving forward.

Mr. Johnson. Okay. Switching gears to some of the other legislation at issue in this hearing, Mr. Dicken, what are the policy tradeoffs of delinking payment from list price? What will the impact be on value-based contracting in Medicare and Medicaid and rebates in the Part D program?

Mr. Dicken. Thank you for the question. There are a number of important policy tradeoffs to consider with that. If prices that are paid are delinked, as you are suggesting, from the list price, and so that some of the savings that rebates have, can be passed on to the beneficiary, that would certainly change some of the incentives we saw for some of those really highly concentrated drugs where right now beneficiaries are, in some cases, paying more than the plans.

It also could provide the plans some more incentive to apply effective cost control. Cost effectiveness looks at that, that if they are receiving high rebates, that reduce their cost or even provide a net profit for using the drugs, that may discourage them from applying kind of reasonable cost effectiveness tools.

And so having the costs better aligned for the beneficiary of the plan could encourage that.

Mr. Johnson. So there is a balance?

Mr. Dicken. Yeah.

Mr. Johnson. Yeah.

Dr. Hughes, back to you quickly, could you explain the changes between direct and indirect remuneration, DIR, that is set to go into effect at the end of this year?

Dr. Hughes. Thank you for that question. I don't know that I can answer it quickly, but --

Mr. Johnson. Well, I tell you what, my time is already expired. Would you take that --

Dr. Hughes. Absolutely.

Mr. Johnson. -- and get us an answer back, please?

Dr. Hughes. Yes.

Mr. Johnson. All right. Thank you.

And, Mr. Chair, I yield back.

Mr. Guthrie. Thank you. The gentleman yields back.

The chair recognizes Dr. Schrier for 5 minutes for questions.

Ms. Schrier. Thank you, Mr. Chairman, and thank you, Madam Ranking Member. Thank you to our witnesses today.

I am so glad we are having this discussion. There is lots of improvements that we could make to Medicare to make reimbursement more streamlined for the provider and for our healthcare system to work better for seniors.

I especially appreciate the discussion we just had about digital technologies. These technologies are increasingly common tools for people and for providers to collaborate for better care.

First I would love to focus on the bill I have introduced with Representative Bilirakis, the Expanding Access to Diabetes Self-Management Training Act.

It is a mouthful, but I wanted to thank the chairman and the ranking member for including it in today's hearing.

This is an extremely bipartisan -- and I will mention, bicameral bill, that aims to make small but meaningful tweaks to diabetes self-management training and incentivize upstream care and teach good practices to patients to eventually prevent kidney disease and other potential complications of diabetes later.

I will speak as a physician and as a person with Type 1 diabetes since age 16. Both of these goals are really important to me. As you know, diabetes costs Medicare nearly $150 billion each year, as of 2017, which includes almost $6,000 per beneficiary spent on complications from Type 2 diabetes.

Diabetes self-management techniques are an evidence-based benefit that gives Medicare beneficiaries living with diabetes the tools and the skills to manage their condition and reduce the rates of these complications or the severity of the complications later.

Dr. Hughes, my understanding is that there are potential savings that could be generated for the Medicare program if Medicare beneficiaries had greater access to this benefit. And I was wondering if you could talk a little bit about how early intervention can prevent or mitigate future complications like kidney disease and eye disease and how that can impact the human cost and dollar cost to Medicare.

Dr. Hughes. Thank you, and thank you for that important question. Certainly CMS agrees with you on the evidence and the need for expanding access to self-management training programs.

As you may know, diabetes is an area of focus for CMS. It is one of the areas across center focus. We have, through our strategy, to think about where are the

opportunities, what are some of the areas that we can do more, and self-management training is on that list of areas that we think we could take additional actions. And so this is an area we would love to work with you more on to see how we can do more in this space.

Ms. Schrier. I think you are absolutely right, it would be a really, really good investment. And I would love to discuss utilization, because regardless of what you do, we need people to use these programs.

I remember, again, back from 1985 -- you can all do the math on that -- how much help I got from diabetes educators and nutritionists -- and by the way, I was able to have these appointments back-to-back, which is something that this bill addresses -- and those sessions put me on a really good path for better management, and hopefully a long and healthy life.

Yet, only 5 percent of Medicare beneficiaries who are newly diagnosed with diabetes even utilize this benefit, which I would argue might be even more important for Type 2 diabetes.

So in your opinion, Dr. Hughes, what are some of the reasons for the lack of utilization, and how can we expand access to this program?

Dr. Hughes. We have considered this a number of different ways -- and, again, I would love to work with you more on this -- we have looked at how well our beneficiaries are aware of the benefit. We are looking at the providers who are able to provide the training and the education, that we know that in certain areas access to these types of experts is even more limited.

And so -- and I have no doubt there is even more factors that are at play. But again, this is an area that is a priority for us, and we would love to work with you more on

your proposal.

Ms. Schrier. And I will add telemedicine to that as well which would increase --

Dr. Hughes. Yes.

Ms. Schrier. -- access.

I wanted to, before I close, just give a nod to Representative McMorris Rodgers about devices with diabetes. My understanding from my own endocrinologist is that it is a real headache to deal with some of the requirements.

Somebody on a CGM, a continuous glucose monitor, might have to present a certain number of finger sticks, and it just makes no sense. So reducing some of those barriers would be very helpful for the best technology and speedy approval.

And before I yield back, I just want to submit a letter of support on my bill. This is from several diabetes groups, and I will yield back. Thank you, Mr. Chairman.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Guthrie. Thank you. I believe it is on our list. We will take action at the end of the -- for that letter, but we accept it. We will take formal action. The gentlelady yields back.

The chair recognizes Dr. Burgess for 5 minutes.

Mr. Burgess. Thank you, Mr. Chairman.

Dr. Hughes, good to see you again. I think the last time we were together was at Johns Hopkins on a panel in the 2008 Presidential election, but it is a day I will never forget. It was an honor to be at grand rounds at Johns Hopkins.

So let me ask you a question. In March of this year, the CBO sent a letter to Sheldon Whitehouse over on the Senate Finance side, and it had to do with the estimation of Medicare spending, 2010 to 2019. And the actual estimate was off significantly.

And I will -- Mr. Chairman, I will ask unanimous consent after I finish to make this and one other article available for the record.

But there was a significant error in what was expected and what was observed.

Now, look, I know we were on different sides of the issue with the Affordable Care Act, and the Affordable Care Act people were quick to take credit, but I don't know that you can do that because really this reduction in spending in Medicare started in 2010.

The Fiscal Times -- the most important thing that happened with the Federal budget in the last 20 years was something strange is happening in Medicare.

The New York Times reports, instead of growing and growing and growing, as it always had before, spending curbed Medicare beneficiary has nearly leveled off for more

than a decade.

That obviously predated the Affordable Care Act, but if you widen the lens out a little bit and look at what happened, say, in the 4 or 5 years prior to that, Medicare Part D was passed by the Congress, signed by the President, and worked its way through the agency and became law.

Look, I am a firm believer in precision medicine, and I think that has got to be the wave of the future, but in other countries, they look at, I think they call it the poly pill. They kind of combine an anti-hypertensive, a baby aspirin, a statin, give it to large segments of the population, and reduce mortality for their populations in heart disease.

And you have to wonder if some of the same work was afoot in -- after passage of the Medicare Part D, which is what we all argued, who voted in favor of that, that more timely treatment of disease is going to result in a lower burden of disease, and therefore, a lower cost.

Now, the trick is, will that all persist through the coronavirus pandemic, and will it persist into this decade, and I don't know that anyone knows the answer to that.

But in the meantime, and one of the reasons I bring this up, is H.R. 4818, which is part of our discussion today, Dr. Wenstrup and Miller-Meeks and Mrs. McMorris' bill, that talks about the use of the newer Type 2 diabetes drugs which now have also become quite the fashion as anti-obesity drugs.

And it is not that this is a cosmetic concern, but some of these, like Wegovy and Mounjaro have demonstrated a 20, 25 percent reduction in heart disease. And this is just absolutely astounding when you think of the implications for the Medicare population.

So we have the model of Medicare Part D and the savings that was achieved then

in the next decade. Should we be looking at more of that long-term preventive health savings?

And that was a question.

Dr. Hughes. Oh, okay. Certainly, thank you, thank you for the question. We do agree that we have to focus more on prevention in order to reap the benefits long-term in terms of care and outcomes.

You raise a number of important issues. I am thoughtful all of which I think certainly helps to shape some of the work that we are doing at CMS, and I, no doubt -- you mentioned some of the proposals here. We would love to work with you more as you move forward with these proposals.

Mr. Burgess. So unfortunately, Representative DeGette is not here. She and I have had the Preventive Health Savings Act for a number of years.

The problem that we all face -- and I am on the Budget Committee too, and I apologize, I haven't been here for the whole hearing because I was at a budget hearing -- the problem we have on the budget side is the Congressional Budget Office always looks at a 10-year window, and what we all learned from our mothers years ago was, an ounce of prevention is worth a pound of cure.

So we are always paying for the ounce of prevention, thank you CBO -- it is important that we pay for it -- but we never get credit for the pound of cure which is in the next 10-year window and the next 10-year window.

So all I would ask, as we make these decisions about what perhaps are very fundamentally groundbreaking developments in the treatment of Type 2 diabetes and obesity, that it is not just a cost. There is a benefit to this as well.

Thank you, Mr. Chairman. I will make these two articles available, and I will yield

back.

Mr. Guthrie. Thank you. The two articles will be considered at the end of the hearing as on our list. We will make sure they have them on our list to be taken up for inclusion in the -- including in the record.

The chair now recognizes -- the gentleman yields back.

The chair now recognizes Mr. Sarbanes for 5 minutes.

Mr. Sarbanes. Thanks very much, Mr. Chairman. Thank you all for being here today.

Between 2011 and 2021, payments to Medicare Advantage plans nearly tripled, due, in part, to enrollment growth but also higher spending per beneficiary than in the traditional Medicare program.

While Medicare Advantage plans may offer coverage for additional service beyond those provided under traditional Medicare, it is difficult to fully understand the scope, the usage, and the cost of these benefits because frankly we just don't have the data to do it.

Dr. Hughes, what information does CMS currently collect on the supplemental benefits offered by Medicare Advantage plans and how much individuals are paying for the services provided?

Dr. Hughes. Thank you for that question. CMS shares your interest in increasing the transparency about how these benefits are being used, the rate of adoption. As you may be aware, earlier this year, we released the information collection request, the ICR, to signal to the plans that we would like more data on how these benefits are being used.

I would also note the CMS Innovation Center has started to collect data through the MA plans, participating in one of the models, with the same commitment in mind to

better understand and to increase transparency in how these benefits are being used.

Mr. Sarbanes. My understanding is that a recent GAO report showed that data collection on supplemental benefits in the Medicare Advantage plans is inconsistent across health plans, which makes it obviously hard to evaluate the impact of higher-per-beneficiary spending and ensure our investments are driving more comprehensive care and not higher premiums.

What effect does the lack of comprehensive data have on our ability to understand the quality of coverage these plans offer beneficiaries and the potential impact they have on individual and community health outcomes?

Dr. Hughes. Thank you for that. And, again, that is part of the reason CMS Innovation Center is collecting more data, not only just on the more clinically related benefits, but also some of the benefits relating to social determinates of health.

As we start to collect the data, to your point, we will be able to have a better understanding of the quality of care and the long-term outcomes for Medicare beneficiaries who are receiving these benefits.

Mr. Sarbanes. Well, I am glad of the interest, and I certainly think more data on the supplemental benefits provided by Medicare Advantage plans would not only inform better policy and put us in a better position, maybe, to make refinements and adjustments going forward but would also frankly help seniors evaluate.

I mean, seniors are trying to make a judgment a lot of times, should I stay in the traditional Medicare program, or does this Medicare Advantage plan that is being offered to me make more sense. It comes with some bells and whistles. It can be very appealing. But this kind of data would help seniors better evaluate the coverage options and find the best plan for them.

I do think maybe nudging, or putting some statutory expectations around the data could help with the collection that you are trying to do more on a voluntary basis.

And that is why I introduced legislation recently, H.R. 5380. It would increase transparency in the Medicare Advantage market. It wouldn't change any of the requirements relating to what the plans can offer. It just would require disclosure of beneficiary-level data, including data on the types of supplemental benefits offered, the plans' total overall spending for each benefit, the out-of-pocket costs that are paid by each utilizing beneficiary.

I know that neither of you can comment on specifics of any of the bills here today, but I imagine you would agree that increasing transparency in the Medicare Advantage program would help both policymakers and patients make more informed healthcare decisions.

Dr. Hughes. Thank you for that, and certainly we would agree that greater transparency would be helpful.

Mr. Dicken. Yeah, no, thank you, and you highlight the transparency and supplemental benefits. You know, GAO has made a number of recommendations over the years on improving data for Medicare Advantage plans, including supplemental benefits, as well as encounter data and other important things for monitoring quality and coverage.

Mr. Sarbanes. Thank you, and I look forward to continuing to work alongside my colleagues to pass H.R. 5380 and other policies that will ensure seniors have the tools to most effectively evaluate and navigate our healthcare system and access quality comprehensive and affordable care.

And I yield back. Thank you.

Mr. Guthrie. Thank you. The gentleman yields back. The chair recognizes the vice chair, Dr. Bucshon, for 5 minutes for questions.

Mr. Bucshon. Thank you very much, Mr. Chairman. I want to associate myself with Debbie Dingell on her comments about home infusion therapy. Medicare's policies on this have been wrong for decades and decades.

I was a cardiovascular surgeon. I could keep people in the hospital for 10 days and give them antibiotics, but I couldn't get it paid for if they went home.

And also with Dr. Burgess on the long-term savings issue in healthcare. Congressional Budget Office scores on healthcare, I think, stop a lot of good legislation that we all know would benefit patients.

And then I want to say that in my view, the PBM model being paid based on rebates needs to end. There needs to be a decoupling. This is putting upward pressure on list prices and limiting access to formularies, not in my opinion, but the opinion of the GAO.

This hearing is very important. Members of Congress have introduced dozens, if not hundreds of bills, attempting to increase patient access to important innovative therapies, and I know it wasn't easy to narrow today's list of bills for consideration for that reason.

But I am pleased we are considering bills like the Treat and Reduce Obesity Act, to provide patients with access to drugs proven to help fight obesity.

To Dr. Burgess' point, in the out years, this is going to decrease Type 2 diabetes, heart disease, and all kinds of other diseases related to poor health.

And the FIND Act to ensure access to diagnostic radiopharmaceuticals -- you may or may not know that that has been a problem -- by unbundling their payment from other

imaging services.

And I am grateful for the inclusion of my bill, the Coverage Determination Clarity Act, which will ensure that local coverage determinations from everything from nonopioid pain alternatives, to important items of durable medical equipment, are in line with national coverage decisions made by CMS.

My question is going to be related to coverage with evidence, CED, essentially conditions Medicare coverage for FDA-approved items on certain requirements such as clinical studies or trials or registries -- honestly, I thought that is what the FDA was for -- which means patients ineligible under CED protocols do not access the product until CED requirements are lifted, and the product achieves national -- traditional coverage.

Your testimony indicates that CMS has issued a total of 26 NCDs requiring CED, or coverage with evidence development, over the last couple of decades. So the question I have is, how many of the 26 NCDs requiring CED have been retired by the agency, meaning, CMS determined the evidence collection was ultimately sufficient to remove the CED requirements so patients could access the product?

Dr. Hughes. Thank you for your question. I certainly would say CMS shares your interest in increasing transparency and facilitating timely access to drugs and devices.

I am not sure how many --

Mr. Bucshon. I, of course, know the answer --

Dr. Hughes. Okay.

Mr. Bucshon. -- or I wouldn't have asked the question, right?

Dr. Hughes. All right.

Mr. Bucshon. Four of 26 that CMS has CEDs in place. That means 22 medical

items are still in limbo, i.e., patients can't get access to them because there is no coverage decision, several of which have been ongoing for more than 15 years.

So in your opinion, at what point -- is there a point at which evidence development should reasonably be expected to transition to a more predictable coverage policy?

Dr. Hughes. Yeah. Thank you for that. I have two thoughts. The first is, through our new TCET pathway that we have announced, we have committed to establishing deadlines and being very transparent, communicating the deadlines with manufacturers and stakeholders so that the CEDs do come to an end.

The second, for those patients who desire access to a drug or a device subject to a CED, they are able to receive coverage for those items and whether if they are part of the study required by the CED or if they are part of the registry that is required by CED, and that is, of course, as you know, how --

Mr. Bucshon. Okay. Sure.

Dr. Hughes. -- patients with Alzheimer's --

Mr. Bucshon. So let me just say this -- I was a medical doctor before -- one of the biggest problems we have right now in the United States, is we get FDA-approved products, whether that is a device or a drug, and CMS refuses to pay for them. And we fight for an average of 4 to 6 years for that to happen.

I had a medical device that treated glioblastoma -- we all know what that device was -- and it increased their life expectancy by 18 months. And if you know what that is, it is a brain tumor. Your life expectancy is short. Eighteen months is literally a lifetime for these people.

It took CMS 5 years to agree to cover it, even though every private insurance and

the VA paid for it. So the company gave it to Medicare patients for free in the meantime.

But we need to address this. And only four NCDs requiring a CED being retired, some of which are over 15 years old, is not acceptable. I know that is not your fault. That is for the broader CMS audience that is watching the hearing. We need to fix this.

So, Mr. Chairman, I yield back.

Mr. Guthrie. Thank you. The gentleman yields back.

The chair recognizes Ms. Kuster for 5 minutes for questions.

Ms. Kuster. Thank you, Chairman Guthrie. I appreciate it. I want to echo many of my colleagues' support for today's discussion about the important role that Medicare plays in improving access to innovative drugs, game-changing medical devices, and emerging health technology.

Innovation in Medicare is a defining feature of a healthcare system, and I am excited to co-lead and cosponsor several of the bills that we are considering, including the Kidney Patient Act, which I lead with Representative Carter, to preserve access to important medications for people on dialysis, and several bills today bringing Medicare coverage into the modern era, including the FIND Act, Access to Prescription Digital Therapeutics Act, and Ensuring Patient Access to Critical Breakthrough Products of 2023.

I am also proud to support the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act, to increase access to multi-cancer screening tests.

And I want to thank the witnesses for being here with us and for being part of the solution in modernizing Medicare.

One of the bills for consideration would eliminate copayments for low-income patients with Medicare Part D coverage for generic drugs.

By eliminating copayments for these lower cost alternatives, we can incentivize people with Medicare drug coverage to choose generic drugs over more expensive brand-name products.

Eliminating copayments for low-cost generics has two benefits: First, it saves patients money; and second, it saves Medicare money. This is a win-win.

Dr. Hughes, do you agree that increasing generic drug utilization will reduce overall drug spending?

Dr. Hughes. Thank you for that question. It has certainly been an area of focus for CMS in terms of increasing utilization of generic drugs. I would also note, we have recently increased assistance for patients who are receiving low-income subsidies to help them better afford their drug and necessary medications.

Ms. Kuster. Do you think eliminating copayments for generic drugs for low-income subsidy beneficiaries will help more people use generics?

Dr. Hughes. Thank you for that. I haven't seen the exact evidence on the exact question, but I would say, certainly, we know that even small copays can pose a challenge for patients who are lower income, and potentially reduce their filling their prescription or staying on their medicines.

Ms. Kuster. Great. Thank you.

The Inflation Reduction Act made many changes to the structure of the Part D benefit and expanded the low-income subsidy to reach more beneficiaries.

Dr. Hughes, can you briefly discuss these changes and specifically the impact on low-income Part D beneficiaries?

Dr. Hughes. Yeah. Thank you for that. Through the IRA, a number of changes have been made to the Part D sum that have been implemented, for example, the great

assistance of low-income beneficiaries. We have also eliminated copays for vaccinations. We are looking --

Ms. Kuster. That was our bill.

Dr. Hughes. Thank you for that.

We are certainly -- down the pike, there will be a cap at $2,000 of out-of-pocket cost-sharing for beneficiaries, in addition to, of course, reducing the price of drugs. And so, we are very much working very hard to implement the bills, to make sure that our Medicare beneficiaries have access to the drugs that they need and can afford these products.

Ms. Kuster. And do you have a timeframe for when the cap of $2,000 for prescription medication will go into effect and how that will impact Americans on Medicare across this country?

Dr. Hughes. Thank you for that question. I would note, I am not with the Center of Medicare, of course, and so they would be the better responders, but my understanding is, this cap will go into effect in 2025 if I am not mistaken. We can get back to you with more information on that.

Ms. Kuster. And it will cap the out-of-pocket expense for Medicare beneficiaries at $2,000 per year.

Dr. Hughes. That is my understanding.

Ms. Kuster. Great. Well, thank you for that. Democrats worked very, very hard last session, and we are committed to lowering prescription drug costs and delivering savings to seniors in every State, so thank you, and I yield back.

Mr. Guthrie. Thank you. The gentlelady yields back.

The chair recognizes Mr. Carter for 5 minutes.

Mr. Carter. Thank you, Mr. Chairman, and thank both of you for being here, and thank all of our advocates for being here. This is encouraging to see everyone here, and we appreciate it.

As many of you know, I am a pharmacist by profession, and I have witnessed firsthand the outrageous cost of medications.

I was the one at the front counter who had to tell the senior citizen how much their prescription was and watch them make a decision between buying their medicine and buying their groceries.

I was the one who had to tell the mother how much the antibiotic was for their child and watch her, in tears, as she tried to figure out how she was going to pay for that medication.

I made it my focus, when I became a Member of Congress 8-1/2 years ago to bring light to the problem that is in the drug pricing chain, and that is with the middlemen, with the pharmacy benefit managers, the PBMs, where we have three companies that control 80 percent of the market, with a company that is owned and with the situation that exists with the vertical integration, where the insurance company owns the PBM, that owns the group purchasing organization, it owns the pharmacy, that owns the doctor, and the problem that that causes.

And I just -- you know, I have been singing that and bringing this to attention for -- ever since I have been here, and even before then when I was a member of the Georgia State legislature.

But now it is just not me. Now we have got the GAO, the MedPAC, OIG, confirming these things, and it has been brought to the attention that PBMs bring no value whatsoever to the healthcare system. All they do is to raise prices.

That is why I have got a bipartisan bill. It is called Protecting Patients Against PBM Abuses Act. You know, PBMs get charged -- or get compensated by charging fees that are calculated as a part, a percentage of the cost of medicine, and this incentivizes the PBMs to increase the price of medicines and to blackmail the insurance companies for formulary access -- or blackmail the pharmaceutical manufacturers, I should say, for formulary access.

And what this bill does is to delink the administrative fees paid by PBMs from the price of medicines. It also prohibits PBMs from reimbursing nonaffiliated pharmacies more than they -- or less than they do for their own pharmacies.

These are things that Representative Lisa Blunt Rochester and I -- and she is on the other side of the aisle -- these are the things that we put in this bipartisan bill.

Dr. Hughes, will you commit to work with us on this critical piece of legislation so that we can protect patients and pharmacies from harmful PBM practices, and so that these advocates that are here with us today, that they can see some result in the lower drug prices?

Dr. Hughes. Thank you, and thank you for that question. And certainly we consider pharmacists to be trusted partners and just clinical leaders, particularly community-based pharmacists as you note. We would definitely work with you on these proposals.

Mr. Carter. Right. But what we are trying to do is to lower patient costs, to increase patient care. All of us want the same thing. Whether you are Republican or Democrat or independent, you want accessible, affordable, quality healthcare. It is not affordable right now because of what exists in the drug pricing chain.

Mr. Dicken, as you are aware, your recently released GAO report found that PBMs

are denying seniors savings on medicines by not passing on their savings directly to the beneficiary.

I understand that HHS didn't concur with your recommendation that CMS monitor the effect of rebates on insurance plans, formulary design, and on Medicare and beneficiary spending to assess whether rebate practices are likely to discourage enrollment for certain patients.

Can you elaborate on this? Why would they not go along with that?

Mr. Dicken. Yeah, well, thank you, and you are right that we did recommend the important first step is to monitor, to see, to make sure that there are not practices that may unduly affect or prevent enrollment by some groups of individuals.

Certainly appreciate that, you know, there are a number of changes, some that were talked about in this subcommittee today that are taking place. We think that as CMS is continuing to implement a number of provisions of, whether the Inflation Reduction Act or other things, it is important to really monitor --

Mr. Carter. Right.

Mr. Dicken. -- to make sure that rebates are being --

Mr. Carter. But in your report also, Mr. Dicken, you found that plans exclude or disadvantage lower cost drugs due to various factors that are related to branded manufacturer rebates. What is going on here?

Mr. Dicken. Yeah, that's right. For kind of a group of very highly rebated drugs, the plan may give them preference, as you note, on the formulary, even over other drugs that may be available at lower cost, either other brands or in cases -- some cases, even generic.

Mr. Carter. Look, I practiced pharmacy for almost 40 years. I am telling you,

these guys, the attorney general in Ohio is right. These are gangsters. They are ripping off the public. They are ripping off these people who are here today to advocate for lower drug prices.

They are not bringing any value to the healthcare system at all. This is something we have got to address, and I hope I can depend on both of you to help me in this quest that I have to bring about lower drug cost.

Thank you and I yield back.

Mr. Guthrie. Thank you. The gentleman yields back.

The chair recognizes the gentlelady from California, Ms. Barragan, for 5 minutes.

Ms. Barragan. Thank you. Dr. Hughes, one of the barriers patients currently face in accessing innovative FDA approved Alzheimer's treatments is imposed by CMS. Purely its own decisionmaking through the broad NCD, which applies to all monoclonal antibodies directed against amyloid for the treatment of Alzheimer's disease.

Through the use of coverage with evidence development, CMS requires patients to be enrolled in a registry in order to receive Medicare coverage for FDA-approved treatments for Alzheimer's disease.

I have continued to raise concerns around the possibility that this process will create unnecessary barriers for various underserved populations -- low-income seniors, seniors in rural areas, and seniors from historically underserved populations like Black and Hispanic Americans.

What is CMS doing to ensure that the registry requirement is not negatively impacting access?

Dr. Hughes. Thank you, and thank you for that question. We share your interest in making sure our beneficiaries have access to Leqembi and other treatments

that are in the pipeline that we expect will be available.

With respect to the registry, as you noted, that for patients who, working with their doctors, decide they want to take the drug, their providers have to sign up for the registry.

We have made this registry available on the CMS website. It is free. It takes an estimated 5 minutes to fill it out. We do not think that will pose a burden relative to the need to understand which of our beneficiaries may be at risk for the life-threatening side effects of Leqembi -- the brain edema, brain hemorrhage. We feel that we need additional information on that front, and we have heard that there are providers all across the country who have signed up and are working with this registry.

RPTR DEAN

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Ms. Barragan. So you don't think anything else needs to be done to make sure there is no -- you think it is so easy that there is going to be no barrier?

Dr. Hughes. Thank you for that.

The CMS -- in addition to the CMS registry, there are also a number of other organizations. And academic institutions have indicated interest in starting their own registries so providers will have a choice in which ones they use.

Ms. Barragan. Okay. Is there any way to track maybe concerns or complaints from people, especially in these rural areas, the underserved areas for people who call and say, hey, I don't have access or I am having a problem? Is there any number for people to call for registering their concerns?

Dr. Hughes. Thank you for that.

I agree. We share an interest in making sure our beneficiaries are able to access the drugs and that there is no undue barriers for the providers. And as we get more data we will be monitoring for any challenges that are unanticipated. And we will be also sharing this data with external partners who can support us with additional research studies.

Ms. Barragan. And has CMS heard from providers about challenges accessing the portal? And, you know, what is CMS doing to ensure it is capturing and addressing any of those concerns?

Dr. Hughes. To date, we have not heard from providers who have indicated that they are having difficulties accessing the portal. Buts this is something again we tend to

monitor. And I will certainly take this question back and follow up with you if we have received any more up to date information on that front.

Ms. Barragan. Okay. In the past, you know, when CMS issued NCDs that required coverage with evidence development it continued for an average of 11 years past the finalization of the coverage decision. Can you discuss why Medicare beneficiaries need more than an decade before they have full access to innovative treatments? And do you see this as being restrictive to patient access?

Dr. Hughes. Thank you for that.

And certainly we agree that having timely access to treatments and therapies must be a priority. It is part of our TCET pathway. As you may be aware, we have committed to including deadlines, being very public about these deadlines with manufacturers, other interested parties, having regular check ins. Our intention is that we will meet the deadline. So there is a defined TCET pathway and a defined length of time.

Ms. Barragan. Thank you, Dr. Hughes.

Medicare beneficiaries deserve to have timely Medicare care coverage of innovative treatments. And it is an important step in this direction that requires CMS to adhere to consistent and transparent timeline to change the coverage decision once CMS required trial or registry confirms a medicine's effectiveness.

I am proud that there has been bipartisan work in this Congress. I lead a bipartisan bill called the Access to Innovative Treatments Act with my colleague Representative Joyce that does just that. Our bill presents an opportunity to mitigate bureaucratic delays that prevent Medicare beneficiaries from accessing clearly proven treatments for Alzheimer's or for other chronic diseases. And so I urge this committee

to give this bill priority in advance of bipartisan solution that addresses this pressing need.

And with that, Mr. Chairman, I yield back.

Mr. Guthrie. Thank you. The gentlelady yields back.

The chair recognizes Dr. Dunn for 5 minutes.

Mr. Dunn. Thank you very much, Mr. Chairman.

I am excited to be continuing conversation about the unparalleled landscape of American innovation in the life sciences community and to have such an important array of bills before us today.

Our industry has delivered next generation therapeutics diagnostics and cures at a very impressive rate. But I hear frustrations every single day about the inefficiencies and inability of CMS, FDA and other governmental agencies to keep up with these innovations.

I want to thank my colleague, Scott Peters, for working with me on H.R. 1199, the FIND Act which seeks to address an insufficient payment policy related to precision diagnostic radio pharmaceuticals. I have firsthand experience with the utility and potential of advanced diagnostic radio pharmaceuticals. These tool are important not only for early diagnose, but also treatment planning and monitoring. Practice payments for these important tools currently limit access to them in Medicare population. And the FIND Act would improve payment for those diagnostic radio pharmaceuticals making their -- possible when appropriate. Adequate payment for these diagnostics who ultimately save the healthcare system time and money.

That brings me to another bill. We are running which is up for discussion, H.R. 5392, the Timely Access to Coverage Decisions Act. This bill will ensure the local coverage determinations are made in a timely manner. We have been talking about

that already. Preventing Medicare administrative contractors from sitting on coverage decisions for new products for years.

When seniors have access to innovative medical products soon after this come online, that is when we see improved outcomes and ultimately lower costs due to a decrease in complications, more personalized care and in short better health. Doctors, not Medicare contractors, should be driving these care decisions with the input of their patients. Let's get the bureaucrats out of the middle of the doctor-patient relationship.

When Congress passed the 21st Century Cures Act we took important steps to ensure the innovation reached the people in a more timely manner than ever before. And I look forward to building on those efforts.

Finally, I would like to thank my colleague on Ways and Means, Mr. Fitzpatrick, for working with me on a fix to the Medicare home infusion benefit. Our bill, the Joe Fiandra Access to Home Infusion Act would ensure that infused drugs delivered via durable medical equipment at home are covered by the home infusion benefits. The bill is named for one of his constituents who briefly benefited from home infusions but ran into access issues due to technicalities in the interpretation of statute.

This bill is a simple fix that allows future patients to benefit from innovation. This is 2023, I think we can do a lot more things at home than we used to do.

Dr. Hughes, can you define what is meant by the reasonable and necessary standard? And who specifically or which entity within CMS decides whether new technologies are in fact reasonable and necessary?

Dr. Hughes. Thank you. And thank you for that question.

Our statute that was provided in the statute provided by Congress we required to share any items that we cover, meet this reasonable and necessary standard. They have

to be reasonable and necessary for the diagnosis or treatment of illness and injury for Medicare beneficiaries. And as part of that Medicare beneficiaries, as you know, are very different than other populations, they are older, they are frailer, definitely sicker.

Mr. Dunn. If I may interject, you know, I have personally been in this position as a doctor with many, many patients, most of them on Medicare. I am a urologist, a lot of prostate cancer patients. And I find myself fighting tooth and nail to get treatments and diagnostics for people in their fifties, sixties, seventies. By the way -- seventies who have 15 and 20 years life expectancies. Are we going to write these people off? We are not using secret quality adjusted life years, are we?

Dr. Hughes. No, we are not.

Mr. Dunn. Okay. Because that would be really an anathema. I think all the members of this committee to try and place a dollar and set criteria on people's life. When was the last time your agency actually promulgated guidance related to the definition of reasonable and necessary?

Dr. Hughes. Thank you for that.

I would say in our program integrity manual for the local Medicare administration contractors we do have more prescriptive information to address some of the challenges that you were describing, some of our expectations for public comment for information they must provide the rationale. So that is -- if you are hearing specific issues --

Mr. Dunn. Unfortunately, I am running out of time. I hate this, but I will tell you, though, I have fought literally for people's lives with CMS to get them therapeutics that I know are far better than what they are getting.

With that, Mr. Chairman, I yield back.

Mr. Guthrie. Thank you. The gentleman yields back.

The chair recognizes Dr. Ruiz for 5 minutes for questioning.

Mr. Ruiz. Thank you, Mr. Chairman.

So we know that there is urgency to take immediate action to address disparities in healthcare and expand access to lifesaving medications and treatments for our Nation's seniors. Medicare is our Nation's promise to our seniors. But the current system leaves many seniors unable to receive or afford the care and treatments that they need.

After a lifetime of hard work, our seniors should not have to wait to receive necessary medical services or be forced to forgo the latest treatments or diagnostic modalities because Medicare irrelevant won't cover them. Today, we have before us a number of important legislative initiatives to consider that would make great strides towards supporting our seniors and making our healthcare system more accessible. I would like to highlight three of these bills that I believe would have the greatest impact to this effect, three bills I am an original cosponsor or that I helped introduce as one of the authors.

The first bill that I would like to highlight is H.R. 2407 the Nancy Gardner Sewell Medicare Multi-Cancer Early Detection Screening Coverage Act. I am an advocate for this bipartisan bill that would give Medicare the authority to cover blood based multicancer early detection tests as well as future test methods once they are approved by the FDA.

These diagnostic technologies are already out there. So let's not delay getting seniors access to these potentially lifesaving screenings over coverage disputes. Timing is of the essence. As a physician, I have witnessed firsthand the positive impact that early detection of cancer can have on patient outcomes and the fatal consequences that can arise when a diagnosis comes too late.

I would also like to bring up H.R. 4818 the Treat and Reduce Obesity Act or TROA, which would allow Medicare coverage of antiobesity medications. This is another bill I am an original cosponsor. I introduced it with a bipartisan group of colleagues. It would also allow more qualified healthcare providers to administer intensive behavioral therapy and this is an important step towards combating the obesity epidemic in getting readily available treatments into the hands of those who need them most.

Lastly, another bipartisan bill I helped introduce, H.R. 3842 the, Expanding Access to Diabetes Self-Management Training Act would improve access to diabetes self management training services under Medicare. With millions of Americans diagnosed with type I and type II diabetes, the importance of education and managing this condition cannot be overstated. When new medical technologies and treatments emerge, we need to ensure that our policies are up to date so that there are no gaps in coverage and no gaps in the people who get coverage and our seniors can benefit from the best possible care.

So Ms. Hughes, in your testimony you mentioned CMS's transitional coverage for emerging technologies pathway which includes a public comment period. How will CMS incorporate feedback to ensure the public's voice is reflected in the final coverage decisions?

Dr. Hughes. Thank you. And thank you for your work across all these different areas that you have mentioned.

As part of our issuing the procedure proposed for procedural notice we met with multiple stakeholder groups. We have received considerable comment on our proposal. And we seek to finalize that, hopefully by the end of this year. And as part of that, we have outlined how we intend to engage with the manufacturers and stakeholders

through this process.

Mr. Ruiz. Thank you.

You know, too often in the emergency department I see a patient that comes in -- I will tell you a story. This young woman came in during the holidays visiting her sister. And her sister forced her to come to the emergency department. And she came in with a mass in her breast. And she kind of knew that she should have gotten it checked out, but she didn't have a doctor. She was afraid of the diagnosis. She didn't have a way to get screened and all of these things. And they came in and it was pretty large. And it was something that looked very, very concerning. So, you know, we get worked to get her follow up with an oncologist and someone that can really follow up with a biopsy. And these are real stories of individuals who have to consider whether they are able to put money on for food, pay the gas, pay the groceries. This is very important for people who, you know, have -- are living check to check and can't access healthcare. And so being able to detect cancer earlier is not only to help save lives, it is to help improve their mental wellness and to help the entire family. And that is why we need to put people over politics and do the right thing to ensure people get the care when they need it.

Thank you.

Mr. Guthrie. I thank you. The gentleman yields back.

The chair recognizes Mr. Pence for 5 minutes.

Mr. Pence. Thank you, Chairman Guthrie and Ranking Member Eshoo. And thank you for the witnesses for being here today.

Mr. Dicken, your testimony was enlightening. I found that very interesting. But I digress. I would like to speak in support of the Ensuring Patient Access to Critical

Breakthrough Products Act. This bipartisan legislation would provide patients with faster access to FDA approved breakthrough medical devices, including diagnostics.

CMS however is contemplating excluding diagnostic lab tests granted FDA breakthrough designation under the transitional coverage for emerging technologies or TCET. Diagnostic tests should be included in the preposed coverage pathways since they are eligible for FDA breakthrough designation and should therefore be eligible for new coverage pathways. I urge CMS to carefully consider steakholder feedback and include diagnostic under the approached TCET pathway and the final CMS policy.

I would like also to speak in support of the Treat and Reduce Obesity Act. This bipartisan bill would increase patient's access to FDA approved obesity care medications. According to an August 2021 GAO report the government spending, including Medicare and Medicaid to treat cardiovascular disease, cancer and diabetes accounted for 54 percent of the $384 billion in healthcare spending to treat these three conditions.

While private plans, VA and the FEHB plans are already providing coverage for obesity medications, Medicare part D is falling behind and prohibits access to these in innovative treatments. It is important that Hoosier patients have access to obesity medications when appropriate so they can live their lives healthier.

I want to announce another issue that is strengthening to exasperate healthcare staffing issues across Indiana. And Dr. Hughes, I direct this towards you. Under the direction of the White House, CMS proposed minimum staffing ratio requirements for nursing homes earlier this month. On March 10th, I sent a letter to CMS with several of my colleagues on both sides of the aisle to oppose this perspective policy. Nursing homes, which I have talked to all across my district are already struggling to maintain current staff levels and fill vacancies. According to the Bureau ever Labor Statistics and

highlighted in CMS's proposed rule, there are roughly 236,000 fewer healthcare staff working in nursing homes and other long-term facilities compared to March 2020. Yet, they are increasing the number that are required.

Long-term care facilities in Indiana would need to hire nearly 3,000 new healthcare professionals to comply with the rule. Implementing higher mandatory ratios that these nursing homes can never meet is unrealistic and could put patient's in harm's way because they won't get the treatment.

Doctor, how do you think long-term care facilities will be able to recruit and retain enough nursing professionals to stay in compliance with the rule first? And what would be the penalties for non compliance?

Dr. Hughes. Thank you. Thank you for the question.

As you note and in the rule, the levels of staffing in nursing homes, long-term care facilities is correlative with the quality and the safety of the residents and that is why we have issued this proposal. But to your point, also it is approached. We think we have achieved a reasonable balance of robust proposal, but it is proposed and we would welcome comments if additional changes are made.

To your point, in your areas if there are areas that are rural or otherwise have workforce shortages, we have included staggered implementation and we have also included exceptions to the requirements for certain facilities that may need more time to comply.

Mr. Pence. Well, I hope you take a real closer look at that. You know, we have a shortage of employment all across the state of Indiana. And, you know, a lot of these healthcare providers in these facilities tell me I used to -- I can handle more. I have been in the business 25, 30 years and I just -- this is going to impose a reduction of patients

care or eligibility for patients to come into their facility. So if all of you would maybe bring a little common -- Hoosier commonsense to it.

With that, I yield back.

Mr. Guthrie. The gentleman yields back.

The gentlewoman, Ms. Trahan is recognized for 5 minutes.

Mrs. Trahan. Thank you, Mr. Chairman. I am grateful to you and Ranking Member Eshoo for holding this important hearing. And thank you to our witnesses for being here today.

For decades countless lives have been saved through medical innovation. And I appreciate the opportunity to be part of the conversation of how we can improve Medicare coverage pathways for innovative drugs, medical devices and technologies. And we are at a pivotal moment in the course of medical history. Many of the bills in today's hearing recognize this and are designed to ensure that Medicare beneficiaries can access innovative treatments in a timely manner.

When this subcommittee met in July to discuss access to healthcare innovations, I highlighted my home State of Massachusetts's role as a global leader in medical innovation, especially for diagnostic radio pharmaceuticals that provide incredible images to diagnose diseases such as prostate cancer and Alzheimer's. It is for that reason that I am working with 13 members of this subcommittee to advance the FIND Act, which I am pleased has been included in today's hearing.

In July, CMS requested comments on a number of options, including one similar to the FIND Act to revise its payment policy for diagnostic radio pharmaceuticals. And I commend CMS's openness to changing its package payment reimbursement system for diagnostic radio pharmaceuticals and urge them to adopt for a 2024 separate payment

such as what is proposed in the FIND Act.

Dr. Hughes, current payment policies restrict Medicare patient access to important diagnostic radio pharmaceuticals that work to identify dangerous conditions as early as possible. Is the agency thinking about fundamental changes to its payment policy to address this issue?

Dr. Hughes. Thank you. And thank you for that question.

As you know, I am not with the Center for Medicare and they certainly have taken the lead on considerations for how we make these payments. But I know that this is an area that they are discussing. And I would be happy to take your comments back and work with you on your proposals moving forward.

Mrs. Trahan. Thank you for that.

2 years after withdrawing the last administration's MCIT regulation I was pleased to see CMS finally release the proposed transitional coverage for emerging technologies or TCET guidance. TCET represents a first step toward establishing a more predictable and transparent coverage process for Medicare beneficiaries to assess new medical devices that can prolong their lives and improve their overall health and well-being. However, I am disappointed that TCET as proposed may expand patient access to only a very small number of innovative medical devices.

In July, our committee heard from witnesses concern that lifesaving technologies would be not be available to Medicare beneficiaries because under TCET only five innovative technologies would be approved for this pathway each year. CMS cited a lack of resources as the reason for the limitation. What resources was CMS need to increase the number of technologies approved under this new rule?

Dr. Hughes. Thank you. And thank you for the question.

I do just want to acknowledge that for breakthrough devices that are not complying and not on the TCET pathway, they still would be able to obtain coverage on a claims-by-claims basis by our MACs or through LCD at the local level. And that is where the vast majority of our products are actually covered. So the coverage -- those coverage pathways remain.

Through the TCET pathway, as you note, when we looked, worked with FDA to look at their pipeline, if we stripped out the devices that would not otherwise qualify, meaning they are for pediatrics or they are cosmetic or they don't have a benefit category, the number does shrink down considerably and we think that we expect to get eight nominations every year. And to your point with the resources we think that we would be able to review five.

Mrs. Trahan. Can you quantify resources?

Dr. Hughes. And that is -- certainly, as you mentioned, there is staffing, but there are other considerations as well. And so I would be happy to provide more detailed information and take that back.

Mrs. Trahan. Great.

Lastly, I recently sent a bipartisan letter to CMS urging the agency to address delays in a new benefit category for FDA approved exoskeleton technology that works to ensure wheelchair user suffering from a spinal cord injury can perform tasks in everyday life. The public comment period has now ended and CMS will release a final rule later this fall.

As CMS develops this final rule, how are you keeping in mind that proper coverage and payment for new technologies like exoskeleton will improve innovation and lead to more patient access to innovative treatments?

Dr. Hughes. Thank you. And certainly CMS agrees these new technologies we want to think about how can we provide access to our beneficiaries. We are reviewing comments that have come back in and we hope to release more information in the days ahead.

Mrs. Trahan. Great. Well, we look forward to that.

I yield back, Mr. Chairman.

Mr. Guthrie. Thank you. The gentlelady yields back.

The chair recognizes Ms. Harshbarger for 5 minutes for questions.

Mr. Harshbarger. Thank you, Mr. Chairman. Thank you for being here today.

First of all, I want to associate myself with my colleague, Buddy Carter's, comments about the misalignments sentence with, rebates in Medicare part D.

And Mr. Dicken, I think we need to take your GAO report and give that to the FTC as they do their investigative probe into pharmacy benefit managers. I think it would be eye opening for them as well, sir.

Dr. Hughes, I am going to talk about something that is not on the slate of bills today, but you know I introduced bipartisan legislation. It is called the Seniors' Access to Critical Medications Act. And unfortunately, post public health emergency CMS has ruled that physicians cannot deliver their patient's medicine via mail, nor can a family member pick up a sick cancer patient's medicine for example. And they say that they can't do that because it would violate the Medicare Stark self-referral law. And this does not make a lick of sense, especially as Medicare transitions from a fee for service to a value based model. And as we talk about Medicare modernization, we should especially be thinking about seniors who are too sick or don't have access to transportation to come pick their medication up.

I mean, we need to have mail order or we need to be able to have a family member come pick that up for them because the bottom line it is going to worsen their outcome. So my question to you, Dr. Hughes, is will CMS work with us to ensure Medicare patients have timely and appropriate access to their medications.

Dr. Hughes. Thank you for raising this. I certainly will take this back to my colleagues in Medicare and we certainly would love to work with you on this issue.

Mr. Harshbarger. Thank you, ma'am.

But I am going to talk about a bill that I know the subcommittee is considering as part of this legislation, it is the Coverage Parity for Medicare Patients Act. And as I said in our hearing in July, Americans should not have to rely solely on a health bureaucracy and politicians to determine the value of innovation and whether or not to cover a medical product. Yet in Medicare, that is exactly what happens. And we often hear that Medicare has to cover something before private insurers do.

As Mr. Carter, I have been a pharmacist for 36 years and I see how this coverage, how that is related to waiting 15 years or more for Medicare to pick up the slack. But it shouldn't have to be this way. Healthy insurance carriers in commercial markets should have incentives to cover their products that either number one reduces overall costs or make them more competitive by improving access to patients or number two, if a product meets this criteria for commercial payers, it makes sense that the same benefits should apply to Medicare.

This bill would establish a demonstration program for Medicare administrative contractors to test a new pathway for medical necessity exterminations under Medicare and it would maintain for Medicare coverage the requirements that an item e safe and effective and not experimental or investigational. But for the appropriateness criterion,

my bill would add a new pathway providing that appropriateness can also be satisfied if an item or service receives significant coverage in the commercial insurance market.

So the principle here is pretty simple, if an item is safe and effective and widely covered by the private market, seniors should be -- as a general matter have access to those innovations. And our family members shouldn't be treated any differently when they are put on Medicaid then when they have private insurance or Medicare when put on private insurance.

Dr. Hughes, I understand CMS has proposed a policy like this in the past to try to create coverage parity for Medicare patients. So would you commit to work with me on this, ma'am?

Dr. Hughes. Thank you for important question.

For us, our statutory standard also contemplates reasonable and necessary for Medicare beneficiaries. And there are important differences between our population and the commercial population, as you know. But that being said, we share your commitment to enhancing access and we would love to work with you on your proposal.

Mr. Harshbarger. Fantastic.

I have one other question for you, Dr. Hughes. On the issue of Medicare modernization, as you may be aware, Medicare has an inconsistent policy on how it reimburses compounded medications. For example, if a patient is hospitalized and needs something that is compounded from bulk ingredients, Medicare part A covers these products. However, part D plans are not allowed to reimburse for prescriptions that are compounded from bulk drug ingredients. Beneficiaries have to pay out-of-pocket for these prescriptions and it is a financial barrier to these patients. So would be willing to work with me to align Medicare part D's compounding from drug

substances reimbursement policy for seniors?

Dr. Hughes. Thank you for that.

We would work with you on this proposal.

Mr. Harshbarger. Thank you, ma'am.

And with that, I yield back.

Mr. Guthrie. Thank you. The gentlelady yields back.

Dr. Joyce is recognized 5 minutes.

Mr. Joyce. Thank you for yielding, Mr. Chairman, for convening this important hearing.

Included for consideration today are three commonsense bills that I have either lead or co-lead aimed at increasing access to care or decreasing costs for our Nation's seniors. Specifically, I would like to highlight H.R. 2408, the Access to Innovative Treatment Act. H.R. 4371, the Choices for Increased Mobility Act, and H.R. 5372, the Expanding Seniors' Access to Lower Cost Medicines Act. And thank the committee for including these pieces of legislation today.

Dr. Hughes, thank you for being here. I, like you, am a board certified internist. I understand the impact of what costly medicines patients have to make decisions each and every day. And this year we are seeing the first ever biosimilars for the popular drug Humira. We see that come online which could present substantial cost savings for our seniors. However, I have heard from companies who make these biosimilars that they have not seen a large amount of usage and volume in Medicare part D for these products.

Dr. Hughes, do you believe that allowing for real-time formulary adjustments in part D plans that CMS oversees has provided in my legislation H.R. 5372 can drive higher

utilization of these more affordable biosimilars so that the patients and that the government ultimately benefits from the savings that are offered by these lower cost products.

Dr. Hughes. Thank you. Thank you for the question. I certainly see, Mr. Joyce, that we have to enhance access to biosimilars for the reasons that you outlined, particularly to reduce drug spending for the government and for beneficiaries.

I would note the CMS Innovation Center and one of their -- the early oncology model, one of the encouraging findings that they found was the shift to greater use of biosimilars by providers and their patients. And so I certainly would love to continue to work with you on this proposal as you move it forward.

Mr. Joyce. Thank you. Would you commit to working with us to address the necessary formula adjustments so that these cost saving biosimilars are available to your point and mine saving both the government and saving patient's dollars?

Dr. Hughes. We would work with you on this.

Mr. Joyce. Thank you very much for that.

On another topic regarding breakthrough medical devices, in order for Medicare beneficiaries to have better access to innovative medical technologies, CMS must provide coverage pathways for these technologies. In the much awaited proposed notice on TCET, diagnostic tests unfortunately were not included. Diagnostic tests are a critical part of healthcare and yet they have been excluded.

Dr. Hughes, how can we work with you to ensure that the FDA approved innovative diagnostic technologies can obtain expedited Medicare coverage while the manufacturer develops evidence?

Dr. Hughes. Thank you for that question.

As you know, there are literally thousands ever these tests and many of them hold great potential for earlier diagnosis and helpful treatment for a number of conditions. Through our local Medicare administrative contractors, the MACs, a number of them help with review and local coverage decisions on these diagnostic tests. They have specialists, pathologists, geneticists others on staff that really are able to provide high level expertise that are needed to review these tests.

Mr. Joyce. As CMS continues its bipartisan supported focus on creating a coverage pathway for breakthrough products to Medicare and beneficiaries, I worry that the agency is ignoring the significant pediatric population that are covered by Medicaid. Nearly 35 million children under the age of 19 have health coverage under Medicaid. Today unfortunately there is no pathway for FDA approved devices with a breakthrough designation to get to pediatric patients in a reasonable period of time.

I am sure you can see how this could create an uneven playing field when kids with commercial insurance could get better and faster and more care, more available care to the latest technology before kids who unfortunately are on Medicaid. What steps can CMS take ownership of that challenge and help lead State Medicaid programs to providing the necessary coverage to breakthrough devices that are targeted at kids.

Dr. Hughes. Thank you for that.

As you know, the reasonable necessary standard does direct us to make these decisions for Medicare beneficiaries. But to your point, we are starting to work across the other centers at CMS, particularly of course their colleagues in Medicaid. Just think about how we could -- what additional steps that we can do to effect the quality and the care and access for pediatric populations.

And I think our work on the universal of measures is one good example of how we

are trying to prioritize the needs of our pediatric beneficiaries and Medicaid.

Mr. Joyce. Mr. Chairman, my time has expired. I thank the witness for being with us today. And I yield.

Mr. Guthrie. I thank you. The gentleman yields back Dr. Miller-Meeks is recognized for 5 minutes.

Mrs. Miller-Meeks. Thank you, Mr. Chair.

My bill, Treat and Reduce Obesity Act is designed to effectively treat and reduce obesity in older Americans by enhancing Medicare beneficiaries' access to providers who are trying to administer intensive behavioral therapy under part B and by allowing Medicare part D to cover FDA approved anti-obesity medications.

Dr. Hughes, CMS viewed is viewed as a leader in treatment coverage policy and programs for chronic disease management. It is undeniable that obesity is a serious chronic disease that effects 42 percent of Americans and approximately the same level in older Americans enrolled in Medicare. We know that on account of its antiquated structure and rigid coverage limitations traditional Medicare does not provide for flexible or customizable obesity treatment coverage policies in part B and part D.

The Medicare Modernization Act excluded coverage of anti-obesity medications in part D which made sense at the time given the paucity of available options. As a result of the remarkable scientific research and innovation since the MMA, obesity has become recognized as a serious chronic disease with highly effective medications to treat it. Moreover, the rapid growth in obesity and related health and economic consequences was corroborated by the University of southern California's Schaeffer Center dynamic analysis which suggested Medicare could save as much as $175 billion over 10 years if patients had access to obesity treatments.

Can you please detail any plan CMS has to update these coverage policies for obesity treatments and how your agency thinks about the tradeoff between increased utilization and obesity coverage on the front end with the prospective program and broader health system savings that may accrue over time?

Dr. Hughes. Thank you. Thank you for that important question. And CMS certainly shares your view that obesity remains a serious and significant public health problem, particularly for our Medicare beneficiaries, particularly for underserved beneficiaries.

As you note, we are prohibited by statute from covering drugs for weight loss under part D, we would be willing to work with you on your proposal as it moves forward.

Mrs. Miller-Meeks. Thank you very much for your comments. And I will enjoy working with you on this issue.

I am also proud to see the Share the Savings With Seniors Act included in this hearing. This bill is full rebate passthrough for medicines used to treat chronic conditions such as diabetes, asthma, chronic obstructive pulmonary disease, congestive heart failure and medicines used to prevent stroke. This ensures 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.

A recent GAO report authored by today's witness, Mr. Dicken, found that beneficiaries paid more than their plan's sponsor for nearly 80 percent of most rebated drugs. The report states that part D plans received $48.6 billion in rebates from drug manufacturers in 2021, but went on to say that rebates do not lower individual beneficiary payments for drugs as these are based on the gross cost of the drug before accounting for rebates.

Dr. Hughes, while I understand that HHS did not concur with the GAO's specific recommendation in the report, I hope you will agree with members of the committee that the status quo benefits industry actors at the expense of patients especially low-income patients with chronic conditions. As with your agency's recent actions to address some of these rebate policy accesses through your recent DIR policy, will you commit to working with me and others on addressing this PBM malfeasance in part D to lower patients' out-of-pocket costs?

Dr. Hughes. Thank you. And thank you for the question.

We certainly value transparency and want to make sure that our beneficiaries with afford medications. We would work with you on this proposal.

Mrs. Miller-Meeks. Thank you very much. I think the transparent part is important.

I now yield back the balance of my time.

Mr. Guthrie. Thank you. The gentlelady yields back. Seeing no other member of the subcommittee present for asking questions, the chair will now go to our waive ons and so the first will be Ms. Matsui from California. You are recognized for 5 minutes.

Ms. Matsui. Thank you very much, Mr. Chairman. I want to thank you, Mr. Chairman and Ranking Member Eshoo for having this hearing today. And I want to thank the witnesses for being here today.

I am excited to see my bill the Access to Prescription Digital Therapeutics Act noticed in today's hearing. This bill is critical to ensuring Medicare and Medicaid beneficiaries receive equitable access to innovative mental health treatments. I hope my colleagues will join me in pushing for this critical bipartisan bill in a markup soon.

Prescription digital therapies, also known as PDTs are software-based treatments designed to directly treat a disease. PDTs are tested and approved by the FDA, much like traditional prescription drugs. They are prescribed by healthcare providers to treat a wide range of mental health issues, including PTSD, insomnia, anxiety and depression. Patients deserve a timely access to the treatment that works best for them. Yet access to PDTs is hindered for the lack of Medicare coverage. That is why I am co-leading the The Access to Prescription Digital Therapeutics Act. They would expand Medicare and Medicaid coverage to include PDTs.

Dr. Hughes, how might digital therapeutics help raise the gap from mental health services among Medicare beneficiaries, especially among underserved populations?

Dr. Hughes. Thank you. And thank you for the question.

As you know, behavioral health is one of our key priorities at CMS and providing access in underserved populations especially within that. We recognize the potential for PDTs to address some of the accessing care needs of our beneficiaries. We are mindful the FDA has approved at least a couple of applications. We have asked questions in our recent payment -- proposed payment rule, we are reviewing those comments. And we hope to have more information shortly for you and the other interested parties on this issue.

Ms. Matsui. Yes. I realize that. What does CMS see as the next steps for incorporating digital therapeutics as an existing benefit.

Ms. Hughes. Yes and that is part of what we ask questions in our proposed rule. We also are looking in terms of thinking about the benefit categories, there is also coding and payment issues. I am -- not for the Center for Medicare but certainly I would be happy to take these questions back and provide more detailed information, if that would

be helpful.

Ms. Matsui. Yes, it would. Thank you very much.

I want to briefly turn to rare diseases. Dr. Hughes, your testimony focused on CMS's work to streamline coverage for innovative treatments and technologies. However, in the case of rare diseases, existing treatments may have promised a repurpose for additional indications beyond their approved use. Yet off label treatments remain out of reach from Medicare patients. Congress acted to address this issue for cancer patients who face the same issue. Dr. Hughes, how did the change to allow Medicare coverage for off label cancer drugs, if included in certain compendia impact cancer care?

Dr. Hughes. Thank you for that question.

As you know, we don't interfere or direct the decisionmaking by doctors. It is between doctors and their patients. We know that Congress developed the compendia proposal that is used in many settings. To the extent that it is an improved quality or access I haven't seen evidence on that, but I would love to get back to you with the information that we have likely within the Center for Medicare.

Ms. Matsui. Okay. Well, thank you very much. And I would like to work with you and this committee to explore a similar solution for rare disease also. So that is the end of my questions.

And I yield back, Mr. Chairman. Thank you.

Mr. Guthrie. Thank you. The gentlelady yields back.

The chair recognizes Mr. Balderson for 5 minutes for questions.

Mr. Balderson. Thank you, Mr. Chairman. It is an honor to be waived on to the team today. So thank you for allowing me to ask my questions, it includes two pieces of

legislation. Both of my bills included in this hearing expand seniors' access to care out of a hospital or a doctor's office to a provision of innovative technology like remote patient monitoring services. Expanding access to digital health can reduce provider workload while improving patient outcomes by catching problems early to help reduce avoidable hospitalizations. In communities like mine these services are particularly beneficial. In rural Appalachia Ohio and many communities like it providers are in shortage and patients often struggle with access to care.

The first bill I will discuss H.R. 5394 the Expanding Remote Monitoring Access Act that I reintroduces with Congresswoman Katie Porter as well as Dr. Dunn who is on this committee. During the COVID public health emergency, CMS lowered the monitoring requirement for billable remote monitoring services from 16 days to 2 days per month. This waiver demonstrated the clinical value of expanded monitoring. Our bill follows the model Congress started for our telehealth flexibilities and extends for 2 year's coverage of remote monitoring at the 2 days per month threshold while Congress and CMS work to develop a proper long-term billing threshold.

Dr. Hughes, my questions are directed at you today. As I have been here, you have received all of them. I have three questions today. And the first is -- and if you have been asked several times are you will to work to commit with me on expanding access to remote monitoring including by discussing the proper date threshold for billing?

Dr. Hughes. Yes, we will work with you on this proposal.

Mr. Balderson. Thank you very much.

My second bill, H.R. 5388, the Supporting Innovation for Seniors Act will expand flexibility for Medicare Advantage plans to cover innovative products that traditional Medicare does not offer. CMS offers value based insurance designed models that let

MA plans pass innovations to either lower overall costs of care or improve the quality of care for patients. One current model allows plans to cover an FDA approved medical device or technology either for the first time or for a new indication that is different from the Medicare coverage determination.

One MMA plan is for using this offer to coverage of continuous glucose monitoring devices for patients with diabetes or remote monitoring devices for patients with heart failure. My bill will permanently expand these flexibilities to allow all MA plans to offer these to qualified patients. The government should know be implementing the ability of MMA plans to lower cost and increased satisfaction for patients. That is why I wanted to open this flexibility up to all seniors. Dr. Hughes, can provide any further detail on the outcomes on the V bid model so far?

Dr. Hughes. Thank you for this question. I know through the CMS innovation center the V bid models there I know that they have started collecting more data on how these supplemental benefits are being used starting this summer actually. We should have more information early next year as I understand it.

Mr. Balderson. Thank you very much. And follow up with my office please. Thank you.

Many of the devices and technologies that provide remote monitoring services use artificial intelligence to analyze incoming patient data and alert providers to any concerns. Dr. Hughes, can you speak to how CMS is considering future coverage of artificial intelligence, particularly in FDA approved devices and software.

Dr. Hughes. Thank you. Across a number of different centers we are starting to explore the promise and potential for AI and technologies in thinking through what are the coverage implications for such technologies. And I think we as I understand it have

started to ask questions about it in certain -- in several of our proposed rules. So I would be happy to get back to you with more information and work with you on any proposals that you may have.

Mr. Balderson. Okay. Thank you very much. And I appreciate you both for being here. Thank you.

Mr. Guthrie. The gentleman yields back.

And the chair recognizes Mr. Obernolte for 5 minutes.

Mr. Obernolte. Thank you very much. Thank you, Mr. Chairman. Thank you to both of our witnesses on this really important topic.

Dr. Hughes, I would like to start with a question for you. I am a bag fan of the TCET program, I think it is, it has the potential to bring some really innovative treatments to Medicare and I am glad that CMS is implementing it, but it certainly has been criticized for its lack of breadth because with only the capacity to process five applications a year, you know, it really is not considered a viable pathway by a lot of different medical providers just because the competition for those slots is so intense.

We have got a bill that we are considering in the package today, H.R. 1691 which would provide some relief for that, but only in the case of medical devices, not treatments or medications. So can you give us some comfort that TCETS of Iowa program that maybe there is a viable pathway for these innovative treatments in the future?

Dr. Hughes. Thank you for that important question. Certainly we share your interest that we have to facilitate timely access to these devices. I would note that TCET pathway in addition to the other three coverage processes in the vast majority of decisions for breakthrough devices are made at the local level on a claim-by-claim basis or

through a local coverage determination. So those will stay in place.

With respect to the TCET pathway, as we work with FDA to look to see what is in the pike, once you would allow a number of devices that would not be appropriate whether it is for pediatric populations where they do have a benefit category or the cosmetics or the -- then the number does decrease significant and we expect about maybe eight nominations, this is voluntary -- self nominations by manufacturers and with our current resources we think that we could accommodate five reviews. Of course we have about four to five NCDs open at any one point in time generally so this adding additional five that is a significant expansion for us.

Mr. Obernolte. I think we would be interested in working with you to make sure that we have a viable pathway for the approval of these technologically advanced treatments, particularly in expanding the universe of services and products that we are offering those treatments in. For example, diagnostics is one that I think is underutilized right now. I think that over all the goal here is to not only improve the quality of healthcare for our beneficiaries but also to lower the cost. And these approvals that use the TCET pathway have the potential to do that in ways that few our treatment plans do. So we had be interested in working with you on that.

Dr. Hughes. Thank you. We would work with you.

Mr. Obernolte. Mr. Dicken, I really enjoyed your testimony. And I found some of it extremely eye opening, particularly with you talk about the impact that rebates have on the operation of the free market when it comes to the provisions of pharmaceuticals.

It is very clear that these rebates quite often are untransparent and that quite often they result in counterintuitive market behaviors that come with the disadvantage of the people ultimately paying the bills where the taxpayers and the patients. In

particular I was struck by the point that you made that you have identified cases where some companies use the rebate scheme to provide preferential treatment to brand name drugs, which actually resulted in a savings for them, but a higher cost to the people that ultimately paid the copays for those drugs which obviously is not something that we want to encourage.

And I know this is probably outside your purview at the GAO, but obviously you are an expert, can you tell me what should we in Congress be doing about that, because it really seems to be a really tenacious and pervasive problem.

Mr. Dicken. Yeah, no. Thank you for the question. And you have identified kind of -- where we found for these very highly rebated drugs that might mean 30, 40, 50 percent of the list price rebated, but not, which would lower the overall price for that drug, but not help the beneficiary when they are paying that drug cost share of the pharmacy.

That is why we recommended as the first step to at least have continued monitoring, certainly as new drugs come online as they are significant changes in the authority that CMS has under the Inflation Reduction Act, it is important to have that information that can help Congress, help CMS to make sure that these aren't unduly effecting certain types of beneficiaries that are knocking access to lower cost alternatives.

Mr. Obernolte. Well, I am sure I am not unique here on the dais when I say I am extremely skeptical that more monitoring is going to solve the problem. I mean, we have been monitoring. We are aware that this problem exists. When we have plans that are making more money on the rebates for a drug than costs them to buy the drug and that results in higher costs for the people who are taking drug, there is something wrong with the system.

And I think that we in Congress have a role in making sure that that does not continue.

But I thank you both for your testimony.

Mr. Chairman, I yield back.

Mr. Guthrie. Thank you. Thank you for your questions. The gentleman yields back.

That concludes member questions. And we have a list and some members mentioned unanimous consent, I believe they are encompassed on our list that I provided to the ranking member. I ask unanimous consent to inserting in the record the documents included on the staff hearing documents list, what I just gave you. It has everything mentioned that I just brought up today from both sides.

Without objection, that will be in order.

[The information follows:]

******** COMMITTEE INSERT ********

Mr. Guthrie. So thanks to everyone. I will remind the members they have 10 days to submit questions for the record. And I ask the witnesses to respond to the questions promptly. We appreciate that. Members should submit their questions by the close of business on October 3rd. And without objection, the subcommittee is adjourned.

[Whereupon, at 12:54 p.m., the subcommittee was adjourned.]