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CHECKING-IN ON CMMI:
ASSESSING THE TRANSITION TO VALUE-BASED CARE

THURSDAY, JUNE 13, 2024

House of Representatives,

Subcommittee on Health,

Committee on Energy and Commerce,

Washington, D.C.

The subcommittee met, pursuant to call, at 11:02 a.m., in Room 2123 Rayburn House Office Building, Hon. Brett Guthrie [chairman of the subcommittee] presiding.

Present: Representatives Guthrie, Burgess, Latta, Griffith, Bilirakis, Bucshon, Carter, Joyce, Harshbarger, Miller-Meeks, Rodgers (ex officio); Eshoo, Sarbanes, Cardenas, Ruiz, Kelly, Craig, Schrier, and Pallone (ex

officio).

Staff present: Sean Brebbia, Chief Counsel; Sarah Burke, Deputy Staff Director; Grace Graham, Chief Counsel; Jay Gulshen, Counsel; Nate Hodson, Staff Director; Calvin Huggins, Staff Assistant; Tara Hupman, Chief Counsel; Emily King, Member Services Director; Chris Krepich, Press Secretary; Emma Schultheis, Clerk; Caitlin Wilson, Counsel; Lydia Abma, Minority Policy Analyst; Keegan Cardman, Minority Staff Assistant; Waverly Gordon, Minority Deputy Staff Director and General Counsel; Tiffany Guarascio, Minority Staff Director; Saha Khaterzai, Minority Professional Staff Member; Una Lee, Minority Chief Counsel, Health; Sanjana Miryala, Minority Intern; and Caroline Oliver, Minority Intern.

*Mr. Guthrie. The subcommittee will come to order, and the chair recognizes my -- I recognize myself for five minutes for an opening statement.

Thanks to our witness, Dr. Liz Fowler, for being here with us today as we check in on the Centers for Medicare and Medicaid Innovation's progress in lowering costs and improving quality of care paid for by Medicare and Medicaid. Our healthcare system has undergone significant changes over the last decade, and Americans continue to cite healthcare costs as a top concern. More Americans are stuck paying more for healthcare now than they ever did in the past.

Taxpayers are also on the hook for our healthcare expenditures. In 2022, healthcare spending grew by four percent year over year, reaching four-and-a-half trillion, about 17 percent of the U.S. gross domestic product. During the same time, spending on hospital care reached 30 percent of total healthcare spending and physician and clinical service reached 20 percent of all healthcare spending.

Physicians are now being forced to spend more man hours on back office administrative tasks and efforts by taxpayers to keep costs low. Policymakers and stakeholders from

across the healthcare system have hope that by embracing value-based care, high cost and physician burnout will be addressed and patients would receive a higher quality of care. The Center for Medicare and Medicaid Innovation was supposed to be a key driver for this movement towards value-based care. However, Medicare and Medicaid's transition to value care has clearly stagnated.

CMMI was established as part of the Affordable Care Act with the dual goal of driving better patient outcomes and slowing the growth rate of Medicare and Medicaid programs -- cost of those programs. The Congressional Budget Office originally projected that CMMI would not just offset the cost of running pilot programs but drive significant long-term savings across our healthcare system. That, unfortunately, has not come close to materializing. A September 2023 CBO report founded (sic) that CMMI's activities increased spending by almost five-and-a-half billion.

Under the Biden administration, the Center has undertaken an internal reevaluation. Well, I hope the strategic refresh would generate renewed commitment to

better fulfilling CMMI's mission of reducing costs and improving quality in its second decade. However, I must admit that I am concerned the Center has instead further shifted focus from its congressionally anointed purpose.

I would be remise if I didn't mention a few specific actions CMMI has taken recently that would significantly harm the transition to value-based care. The first is the so-called Accelerating Clinical Evidence Model in which CMMI has proposed to slash payments to Part B providers who are prescribing therapies fully approved by the FDA through the accelerator approval pathway. This not only undermines the FDA gold standard but penalizes those attempting to drive transformative change for patients that otherwise lack treatment options.

I am further more concerned that CMMI's Cell and Gene Therapy Access Model, which may inhibit the states' ability to use value-based agreements to pay for curative cell and gene therapies approved by the FDA. We have 50 incubators across the country in the form of state Medicaid programs and waiver authorities that give states the ability to shape policies that make the most sense for their budgetary needs

and the needs of their beneficiaries by CMS directly negotiating drug rates for these therapies that weakens the ability for states to negotiate directly with manufacturers or to form state compacts that give states greater bargaining power in these situations.

I would instead urge CMMI and CMS to work with Congress to pass my MVP Act, which I have worked together with the ranking member, which would codify CMS's multiple best price rule and truly allow states to use value-based agreements to get life-changing treatments to patients as quickly and affordably as possible, which should be the goal of all of us.

In closing, I hope today's discussion helps us chart a path forward for CMMI that can ensure the Center is better delivering on its mission to facilitate innovation payment models that deliver for patients and taxpayers and re-energize the transition to value-based care.

[The prepared statement of Mr. Guthrie follows:]

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

*Mr. Guthrie. I thank you for being here today, and I will yield back. And the chair will now recognize the ranking member, Ranking Member Eshoo, for five minutes for her opening statement.

*Ms. Eshoo. Thank you, Mr. Chairman, and good morning, colleagues.

We begin today with good news. The Supreme Court has unanimously upheld women's access to the Mifepristone abortion pill and kept intact the FDA's authority to approve and regulate drugs based on science. This is a victory for women and families across our Nation.

Today we are going to discuss the Center for Medicare and Medicaid Innovation, also known as CMMI. Welcome to our distinguished witness, Dr. Liz Fowler, Deputy Administrator and Director of CMMI, who is testifying before our subcommittee for the first time. May it be a productive one. Thank you.

Medicare is the bedrock of our Nation's social safety net. It serves 65 million Americans, with approximately 10,000 Americans enrolling every day. It is our subcommittee's mission to strengthen and improve Medicare

without compromising the quality care patients rely on and deserve. I have seen firsthand what Medicare provided for my mother and father and the peace of mind they had with that card in their wallet. All Medicare patients deserve to have the same peace of mind that my parents did.

The Center for Medicare and Medicaid Innovation was created with that aim. The Affordable Care Act gave Medicare and Medicaid the ability to create new payment models focused on improving the quality of healthcare by paying for better patient outcomes rather than the volume of care. Before the ACA, Medicare and Medicaid paid for healthcare in a way that encouraged more services whether they improved health or not. CMS was also reliant on Congress to pass new laws each time it wanted to test a new payment model, constraining the Federal Government's ability to be nimble and find better ways to deliver care.

Today more than 41-and-a-half million patients with health coverage through Medicare, Medicaid, and private health insurance have received care from one of the 314,000 physicians and plans that participate in CMMI's programs. The Agency has also tested over 50 new ways to improve

healthcare and lower costs, many of which generated savings for taxpayers.

One successful model stemming from CMMI is accountable care organizations, or what we call ACOs. They allow physicians, hospitals, and other entities in the healthcare system to coordinate care for a patient to prevent complications or unnecessary hospitalizations. If they provide high-quality care to their patients at a lower cost, then they get to keep some of the savings. That is a real motivation.

Another example is the 35-dollar insulin cap that all Medicare patients now enjoy thanks to the Inflation Reduction Act. The insulin cap is rooted in successful, voluntary CMMI models established in 2020 that lowered insulin costs for patients with Medicare Part D. About half of Medicare Part D and Medicare Advantage plans participated in this model.

Much of today's hearing will focus on the recent CBO finding that CMMI cost the government 5.4 billion dollars more than it saved in its first 10 years. While these costs deserve critical discussion, and I think we are going to

have that today, it is also important to discuss what has worked for CMMI, including how it has been shielded from political wins in the annual budget process through its mandatory funding and statutory mandate to experiment.

I look forward to hearing from you, Dr. Fowler, today on how we can continue our bipartisan work to ensure that CMMI reaches its full potential because patients are counting on us.

[The prepared statement of Ms. Eshoo follows:]

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

*Ms. Eshoo. Thank you, Mr. Chairman, and I yield back.

*Mr. Guthrie. Thank you. The gentlelady yields back, and I now recognize the chair of the full committee, Chair Rodgers, for five minutes for an opening statement.

*The Chair. Here we go. Thank you, Chairman Guthrie. Good morning, everyone. Thank you to Dr. Fowler for being here today.

The Center for Medicare and Medicaid Innovation was created to help improve how Medicare and Medicaid pay for healthcare to be an engine in our drive towards value-based care. CMMI was given a 10-year, 10 billion dollar budget, and extremely wide-ranging authorities with limited built-in congressional oversight. The only directives Congress gave CMMI were to achieve two goals: lowering the cost of delivering care and improved patient outcomes.

Over the last decade-and-a-half, CMMI has tested over 50 models. Only two accomplished both those goals. When CMMI was created, the savings it was projected to generate were used -- were to be used to offset spending by the Affordable Care Act. Originally, CBO estimated that CMMI would save 1.3 billion dollars over its first decade of

operation. That same model also projected CMMI would save as much as 77-and-a-half billion dollars in its second decade from 2020 to 2023.

However, when CBO looked at the actual results in a September 2023 report, the disparity between those expectations and the reality proved to be staggering. Instead of reducing spending by 1.3 billion dollars in the first decade, CMMI increased spending by 5.4 billion dollars. For the second decade, instead of saving 77-and-a-half billion dollars, CBO is now projecting CMMI to increase spending by 1.3 billion. I have a hard time believing any objective observer could look at the results thus far and describe CMMI as a success.

So how do we move forward? Today we are joined by Dr. Elizabeth Fowler, the current director of CMMI, to discuss the Center's work and understand why it has failed to live up to the intended purpose thus far. I will note Dr. Fowler has not been with CMMI throughout its entire existence. In fact, CMMI has had multiple directors across multiple administrations. But you are at the helm now and responsible for correcting this program's trajectory, and

while there are still some reasons for optimism, a lot of what I have seen is concerning.

I have been disappointed to see CMMI devalue drugs approved through the FDA's accelerated approval pathway, which FDA leadership confirmed meet the Agency's gold standard just a few weeks ago in front of this committee. This pathway was designed to build on precision medicine, encourage innovation, and allow patients to access needed cures sooner. But CMMI's decision to cut reimbursements unilaterally for drugs approved via accelerated approval undercuts this mission.

In addition, when Congress passed MACRA, thanks in large part to the work of this committee, CMMI was given a central role in driving Medicare's transition to value-based care. While CMMI has developed and tested some new models, largely for primary care physicians, too many clinicians have been left without a pathway to participate in APMs. I am concerned that instead of focusing on fulfilling the role Congress gave CMMI in MACRA and working on developing new APMs, CMMI's focus has shifted to collecting information on patients' food insecurity and housing needs, and requiring

providers to waste time writing ridiculous health equity plans.

While I have concerns on the overall direction and lack of results with CMMI, there have been a few positive outcomes that deserve to be recognized. Looking at CMMI's most recent work, I am glad that you are continuing to build on Accountable Care Organization Model. While joining an ACO should not be the only pathway for providers to be able to participate in value-based care, these models are among the few that have actually managed to reduce overall spending and should not be abandoned. I was also encouraged to see CMMI work on trying to improve the care for Alzheimer's and dementia patients. Sadly, most people know someone who has suffered from this terrible disease, and I hope that this model is successful in improving community-based care for those patients.

Lowering the cost of healthcare in this country has been the primary mission of this committee this Congress, and we are on an unsustainable path and must continue to find ways to reverse the current trend. It makes it all the more important that CMMI carries out its intended mission

and advocates pursuing an alternative agenda and avoids -- I am sorry -- and avoids pursuing an alternative agenda.

I am grateful you are here today, Dr. Fowler, to share your expertise and eager to learn what lessons CMMI has learned and how we can get back on track with the mission and the directive that has come from Congress to CMMI.

[The prepared statement of The Chair follows:]

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

*The Chair. Thank you, and I yield back.

*Mr. Guthrie. Thank you. The chair yields back, and the chair will recognize the ranking member of the full committee, Ranking Member Pallone, for five minutes for an opening statement.

*Mr. Pallone. Thank you, Mr. Chairman. I am pleased to welcome Dr. Elizabeth Fowler to discuss the important work that the Center for Medicare and Medicaid Innovation is undertaking to lower healthcare costs and improve quality of care. There are so many things you are doing, it is hard for me to even mention them all.

But while more Americans have healthcare today than ever before, thanks in large part to the Affordable Care Act and the Inflation Reduction Act, we must continue to work to address high healthcare costs and the financial burden medical bills pose for American families, and our healthcare system is complex and challenging and there are many drivers of healthcare costs. So the ACA established CMMI to test innovative models that could improve quality of care and reduce costs for beneficiaries enrolled in Medicare, Medicaid, and CHIP, and the ACA gives CMMI broad authority

to develop models through demonstrations with the goal of improving patient care or lowering costs while improving the quality of care.

Now over the past decade, CMMI has developed more than 50 models and millions of Americans have benefitted from the Innovation Center's activities. In the last two years alone, more than 41 million beneficiaries were impacted or benefitted from the Innovation Center multi-payer models, and more than 314,00 healthcare providers participated in the payment and service delivery models.

So I am pleased that CMMI has developed and tested a broad range of models that reward healthcare providers for delivering high-quality care while reducing costs or improving patient outcomes. For instance, the Accountable Care Organization models have resulted in significant savings and it has incentivized efficiency while encouraging providers to deliver high-quality care.

The ACO Investment Model offered advanced payments to ACO and the results of the model demonstrated significant savings. Similarly, the ACO REA Model encourages providers to work together in ACOs to improve quality of care for

Medicare beneficiaries through better care coordination, including those beneficiaries who are underserved. And the ACO models have also continued to inform policies under the Medicare shared savings program which currently services more than 11 million beneficiaries across 483 Medicare ACOs and ensures that value-based healthcare is delivered to beneficiaries. To date, the MSPP has generated 1.6 billion in savings while producing high-quality performance results.

I am also pleased that CMMI has announced additional models that include opportunities for expanding access to primary care. Both the ACO Primary Care Flex and the Making Care Primary aim to improve quality of care for beneficiaries through increasing investments in primary care, and I believe these investments have the potential to improve access to high-quality primary care services.

And CMMI has also developed models to promote chronic disease prevention and improve care coordination for some of the leading causes of morbidity and mortality in the U.S. such as cancer, diabetes, dementia, and maternal mortality. It is important that evaluations of the Innovation Center's work capture the full benefits of these models and take into

account improvements in quality. Models that achieve significant quality improvements and address health equity without raising costs are also meaningful investments in high-value care and we must also consider improvements in quality in order to have a full and accurate understanding of the Innovation Center's full impact.

And lastly, I am glad that CMMI is taking steps to improve access and quality of care for Medicaid beneficiaries. For example, CMMI recently announced the Transforming Maternal Health Model to promote access to maternal health services and supports. Women enrolled in Medicaid often experience disparities in maternal healthcare and health outcomes for themselves and their newborns, and this model seeks to address these challenges by partnering with state Medicaid agencies to implement initiatives, such as patient safety bundles, and promote access to the service and supports of midwives, doulas, and perinatal community health workers.

And CMMI also announced the Cell and Gene Therapy Access Model which will test a CMS-led approach negotiating outcomes-based agreements with manufacturers of cell and

gene therapy starting with the Sickle Cell Disease. Sickle Cell Disease affects about 100,000 people in the U.S., the majority of whom are black Americans, and new cell and gene therapies hold incredible promise but have a high upfront cost. So I commend CMS's efforts to reduce program expenditures while ensuring that these treatments are accessible for all Americans who need them, and I look forward to hearing from Dr. Fowler on the lessons learned from the Innovation Center's first 10 years and about the ongoing work to improve the Nation's healthcare system.

I must say, though, that, you know, I do worry that so much of the system, American healthcare system, is monetized. You know, providers, whether doctors, hospitals, pharma, you know, they all come in and talk about how they are not making enough money, and I do worry that there is so much emphasis by the healthcare system on making money, and I know it is a capitalist system, but the problem is we don't have competition. I think the competition is not there for a market-based system, and that is one of the reasons why our committee, including our chair, has worked so hard for this price transparency bill because that is the

bill that I think creates competition, and we need more competition, otherwise a market-based healthcare system is just not going to work anymore.

[The prepared statement of Mr. Pallone follows:]

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

*Mr. Pallone. So thank you, and thank you, Mr. Chairman.

*Mr. Guthrie. Thank you. Thank you for your yielding back, and the chair will now introduce our witness today. The witness is Dr. Elizabeth Fowler, the Deputy Administrator and Director of the Center for Medicare and Medicaid Innovation. And, Dr. Fowler, you are recognized for five minutes for your opening statement.

STATEMENT OF ELIZABETH FOWLER, PH.D., J.D., DEPUTY ADMINISTRATOR AND DIRECTOR, CENTER FOR MEDICARE AND MEDICAID INNOVATION (CMMI)

*Dr. Fowler. Chairs Rodgers, Guthrie, Ranking Members Pallone and Eshoo, and members of the subcommittee, thank you so much for the opportunity to discuss the work of the CMS Innovation Center today.

As the Nation's largest payer for healthcare, CMS plays a key role in driving transformation of the U.S. health system toward one that achieves equitable outcomes through high-quality, high-value, affordable, person-centered care. The CMS Innovation Center was established in 2010 to test ways to improve the quality of care delivered to individuals and reduce federal spending in Medicare, Medicaid, and the Children's Health Insurance Program. Over the last decade, the Innovation Center has tested over 50 payment and care delivery models. These models have contributed to changing the landscape of how healthcare is paid for and delivered in the U.S.

When I joined the Innovation Center in 2021, we

undertook a strategy refresh to review the lessons learned from our first decade of model tests and chart a course for the next decade. The strategy refresh established five objectives: to drive accountable care, advance health equity, support care innovation, address affordability, and partner to achieve system transformation. Every Innovation Center model that we have tested has yielded important learnings and ultimately informed an approach to caring for patients that is more team-based, integrated, and person-centered.

Through our models, we know the basic building blocks that help clinicians move toward value include upfront investments for infrastructure and data that give providers the ability to identify the sickest patients and most likely to be hospitalized or readmitted, regulatory flexibilities that let providers care for patients in a home setting and provide more services through nurse practitioners, tools and data to better understand patients' needs and integrate primary care and specialty care, payment innovations that give providers more stable and predictable payments, and population-based payment incentives that reward better

outcomes, higher quality, and a better care experience.

In conducting our work, the Innovation Center consults regularly with clinical and analytical experts from across the health system as well as beneficiaries, frontline providers, and the Physician-Focused Payment Model Technical Advisory Committee, or PTAC, to understand the needs for innovation as we develop, implement, and evaluate and scale models tests. If the independent CMS actuary determines that a model meets a rigorous standard for certification, the HHS Secretary has the authority to expand the scope and duration of a model.

Most models come to their predetermined end, and through the extensive analyses and evaluation of the models that the Innovation Center undertakes, we can identify factors that led to improved quality or reduced spending, and then we can incorporate those factors into other model tests or CMS programs. One example is the ACO investment model, which was incorporated into the Medicare Shared Savings Program and renamed the Advanced Investment Payment Program. Through the ACO investment model, we learned that advanced payments allowed eligible ACOs to invest in the

infrastructure needed to be successful in the Shared Savings Program. These upfront investments are particularly critical for small, rural, and independent providers with fewer resources and is now a permanent pathway for them to participate in value-based care.

In 2023 and early 2024, the Innovation Center announced a number of new models that align with our strategy and help advance our person-centered care goals. I will highlight a few models that I am particularly excited about. First, the Guiding Improved Dementia Experience, or Guide, Model aims to improve the quality of life for people living with dementia and their caregivers and help people remain in their homes by offering access to 24/7 support and respite service for caregivers.

The Transforming Maternal Health, or TMaH, Model will test ways to improve maternal health and birth outcomes, including in rural and underserved areas where expecting parents often experience significant disparities in maternal health and poor health outcomes. And the Innovation and Behavioral Health, or IBH, Model is focused on improving the quality of care and behavioral and physical health outcomes

for Medicare and Medicaid populations with behavioral health conditions and substance use disorders.

Moving forward, the Innovation Center will continue to pursue our strategic direction as we work with stakeholders across the system to develop value-based care models that drive better care, improved outcomes, and lower costs.

Thank you so much for the opportunity to be here today and I look forward to answering your questions.

[The prepared statement of Dr. Fowler follows:]

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

*Mr. Guthrie. Thank you. Thank you for your opening statement. We will now move to begin questioning, and I will recognize myself for five minutes for the -- for questions.

So thank you for being here. I really apricate you being here today. And one of the things since I have been on this committee I have been most excited about is innovative medicines coming out, so cell and gene therapy, and particularly one area, drugs to treat Sickle Cell. I have had friends that have had Sickle Cell and I know how devastating that disease is and how it affects families.

And the proposal that you have is that CMS will work directly with manufacturers to negotiate rates for these therapies on behalf of states and help track outcomes and, you know, one of my concerns is that it is -- instead of having the states work together, it is all going to come out of CMS. And so my question is like how many letters of intent has CMMI received thus far and did CMS contemplate permitting multi-state compacts versus in this model which filters everything through CMS without much direct involvement from individual states?

*Dr. Fowler. Thank you for the question. This is a model we are really excited about. We have received letters of interest from a majority of states that represent about 80 percent of patients with Sickle Cell Disease. Of course, the letters of intent are non-binding and we understand states still reserve the right to see if they can negotiate directly with those manufacturers. It is a voluntary model on behalf of the manufacturers as well.

So we have just started this process and we look forward to hopefully having a successful model that really drives better outcomes and better access for patients.

*Mr. Guthrie. Thanks. So I have a bill -- we have a bill that a lot of us have been working on I think will help in this area, the MVP Act, and it is not disease-specific. And so the question I guess, how does CMMI intend to address the fact that multiple diseases and conditions would benefit from further exemptions to best price and average manufacture price beyond Sickle Cell Disease, and does CMMI intend to come back each time for a new disease?

*Dr. Fowler. Thanks for the question. I think we want to avoid biting off more than we can chew, so at this point

we are hoping that we are successful in the model that we have outlined, and if that approach proves successful, I think we are happy to explore other potential opportunities in that area.

*Mr. Guthrie. Thank you. So also during your tenure, CMMI has launched several programs that could be detrimental. I believe the life science innovation, specifically the Accelerated Clinical Evidence Model to pay Part B providers significantly less on accelerated approval drugs. It seems like the administration has a view that accelerated approval is not approval and it is just an alternative path for approval. We think it is full approval.

And so the question is, so you -- significantly less until they get the more traditional approval process, and my question is, what kind of assessment did CMMI do relating to patient outcomes and availability of other treatments as you decided to move forward with the model, and do you believe that patients losing access to these drugs could lead to increased costs for the overall healthcare system in the future?

*Dr. Fowler. Thanks for your question about the ACE Model. So that Accelerated Approval Model, we work very closely with the FDA. In discussions with them, they have indicated that new authority potentially may suggest the need for further examination, and so in a blog that we put out last fall we indicated that we are continuing to talk about the model, but we are going to continue to work with FDA to see --

*Mr. Guthrie. So did the FDA, when you discussed it with them, claim that accelerated approval wasn't equivalent to a traditional approval process? Were they saying this is a lesser approval process therefore we should pay less for it?

*Dr. Fowler. That wasn't something that they said directly. I think when we had discussions with them we talked specifically about the need for a model and I think they would like to see whether the authority that was given to them is sufficient, and so we are continuing to have discussions, but right now we are in discussion periods.

*Mr. Guthrie. So they didn't think that the authority they have now for accelerated approval is sufficient to give

approval for use?

*Dr. Fowler. In terms of the authority to require and elicit the confirmatory trials that they had agreed to with manufactures. So we weren't talking about the approval and the pathway itself, just the need for potential authority to make sure that those confirmatory trials are conducted.

*Mr. Guthrie. So we are trying to get these to marketplace quicker for people with patient -- that have -- that -- I mean, months matter in some of these cases. And so do you think it will cost the system more? Like if you were racing against muscular dystrophy or something like that it would cost the system more if we don't have alternative approval pathways like this?

*Dr. Fowler. So as someone who spent part of my career working for the innovative industry for one of the pharmaceutical companies, I believe very much in that pathway and I think we wouldn't want to disrupt it. I think the goal of the model was to see if we could drive those confirmatory trials in the period that the manufacturers had agreed to. And again, we have put that I wouldn't say on hold, but I think we are having further discussions with the

FDA on the need for the model.

*Mr. Guthrie. Thanks, appreciate that.

And I will yield back and recognize the ranking member of the subcommittee for her five minutes for questions.

*Ms. Eshoo. Thank you, Mr. Chairman.

Dr. Fowler, in 2021 CMMI completed a wholesale review of its activities and its efforts to lower costs and improve care for patients, but last year, and this is very much a part of this hearing, the CBO found that CMMI cost the government 5.4 billion dollars more than it saved in its first 10 years and may be on track to cost the government 1.3 billion more than it saves over the decade.

Why is CMMI not generating savings? And share with us what metrics CMMI uses to determine whether a model is successful and not just limited to savings, and if you can share an example with us, I think that would be helpful. And what is CMMI's value outside of lowering costs for patients? So we got three big questions in there.

*Dr. Fowler. Many questions in there. Thank you so much for your interest. So I would say first of all that we have learned something from every model that we have tested,

and I would also say that the innovation process itself is sometimes unpredictable. One factor that has affected our ability to generate savings is the fact that most of our models are voluntary, and this was an area that the Congressional Budget Office also pointed out, and when you have a voluntary model where providers can come in if they think the terms look favorable, if they can exit if they think the terms may turn against them or they weren't performing as well as they thought, they can drop out of the model. And so that has led to risk selection which has undermined our ability --

*Ms. Eshoo. So have there been more models that have been accepted than, you know, providers pulling out?

*Dr. Fowler. So we think that our models have all been successful in one sense or the other that we are learning something, regardless of the ultimate assessment. So we have also been spending a lot of time thinking about the impact on quality and we have laid out a whole quality pathway. The statute gives us authority to examine both the quality of care provided and the impact on savings and we are really leaning into the quality improvement angle,

particularly when it comes to patient-reported outcomes and the patient care experience, and we are trying to learn more from this approach to thinking more broadly about quality.

*Ms. Eshoo. Mm-hmm. One of the successful models has been the ACO, the Accountable Care Organizations. It lets physicians, and I mentioned this in my opening statement, physicians and hospitals to work together to coordinate care for a patient to prevent complications or unnecessary hospitalizations. But there is significant mistrust among constituents in my district about how ACOs may impact their Medicare or lead to cutting corners in the name of savings.

How is CMMI making sure that seniors can continue to trust and rely on Medicare and how are you communicating what being part of an ACO means for patients or how it impacts their care? Do patients know when they are in an ACO and, if they are, can they opt out?

*Dr. Fowler. Thanks for that question, I think it is a really important one. So in all of our models, we do let beneficiaries know if they are part of a model. There is a process if they decide they don't want to be part of that model that they can exempt their data from being considered.

*Ms. Eshoo. And how is that communicated --

*Dr. Fowler. Usually through a letter.

*Ms. Eshoo. -- I mean, do you write to them, does the doctor tell them, how do they know?

*Dr. Fowler. Both. So they may receive a letter and then there is usually a notice provided by their physician at the doctor's office. I think we also need to do a better job of explaining the value of value-based care, and so we have really started trying to do that with a new approach highlighting some of the success stories and the impact on patients. We have put a lot of that information on our website.

*Ms. Eshoo. Okay. I think -- I don't know if anybody wants my 40 seconds, and if not, I will yield back.

*Mr. Bucshon. [Presiding.] The gentlelady yields back. I recognize now Dr. Burgess for his five minutes.

*Mr. Burgess. Thank you. Just add that 40 seconds onto my time, that will be fine.

*Mr. Bucshon. Five minutes and 40 seconds.

*Mr. Burgess. Dr. Fowler, thank you for being here today. Thank you for talking with me offline several times.

I wasn't going to bring it up, but you did, PTAC, the Physicians Technical Advisory Commission (sic), federal law signed in 2015 by President Obama. It has been, in my opinion, vastly underutilized.

I actually see from looking at their website there is a current meeting going on right now, so that is good. We don't publicize these things very much, but this is an opportunity really for doctors to do the very type of work that you described as doing, and who better to do this work, and that is why it was included in MACRA, who better to do this work than doctors, but it really has been something significantly short of successful.

So I am currently working on legislation to ensure that PTAC is fulfilling the role that it was given by Congress, and I would just simply ask if you would be willing to work with me as we develop that.

*Dr. Fowler. We would be happy to work with you on that and provide technical assistance.

*Mr. Burgess. The -- you know, the difficulty always is when I look at what you do in developing these models, and it seems completely devoid from any part of the practice

of medicine, and I am not sure if patients feel the same way when they look at this, but just from a doc's perspective, this isn't the way the world works, so it is not surprising to me then that the number of successes that you can mark on the wall is small.

Look, the Affordable Care Act, and I don't know, the people that wrote the Affordable Care Act going back into the missives of time, do you think they would be surprised at how little the Affordable Care Act has actually saved patients?

*Dr. Fowler. Well, I think --

*Mr. Burgess. Without subsidies, the Affordable Care Act really has been anything but affordable.

*Dr. Fowler. So I think if you look at the number of people who have received coverage and who are newly covered under --

*Mr. Burgess. Yeah, I got to stop you there because coverage is not care, and I think any of us who spent any time in the delivery of care understand that. But here is the difficulty, the advanced premium tax credit has had to be increased several times over what it was back in 2009

when the law passed. Unfortunately, because the budget is so vast now on the advanced premium tax credit, that increase expires in just a couple of years and someone is going to have to deal with that down the road.

But for those of us who are old enough to remember the arguments in favor of the Affordable Care, and there were arguments in favor of the Affordable Care Act, but one of the arguments was you are going to get all of these people covered and it is not going to increase the deficit, in fact, there will be 142 billion dollars returned to the Treasury, it actually -- money will come back to the Treasury. Do you remember those arguments from back in 2009?

*Dr. Fowler. So I will just say that my colleague who is in charge of the ACA marketplace coverage, I am sure I will be -- I would be happy to take back some of these comments and questions. Our job at the Innovation Center is really to focus on care delivery models and I think we are really excited about the potential for improving care and the care experience for patients.

*Mr. Burgess. But here is part of the problem, that

142 billion dollars that was supposed to be returned to the Treasury, a good portion of that was coming from CMMI. In fact, when the administration changed in 2017, and I immediately thought here is our chance to remove CMMI, the Congressional Budget Office said you can't do that because of all these savings that are built into the law. But then it turns out those savings were ephemeral and they really weren't savings at all, were they?

*Dr. Fowler. Well, I would just go back to everything that we are learning from all of the models that we have been testing that have been yielding really important results and innovations. We spent a lot of time talking to providers, including the providers on the PTAC and getting their input on ways that we can make the models better and really respond to some of the pressures and some of the challenges that physicians have identified in the practice of medicine.

*Mr. Burgess. Is it the Agency's position that everyone will end up practicing in an ACO? I mean, is that where the push is to get every doctor and every patient into an ACO that is then controlled by the Department of Health

and Human Services?

*Dr. Fowler. We would like to also include accountable -- in addition to Accountable Care Organizations, we would also like to see providers, if they want to stay independent, practicing in an advanced primary care approach, and so we have a number of models that are really geared towards those small independent and rural practices who may not want to join an ACO, and so the Making Care Primary Model was really geared to giving them a path into value-based care that allows them to be independent so it provides those sort of incentives and investments for infrastructure.

So I think we would like to see accountable care where there is a provider, a clinician that is responsible and accountable for total cost of care and quality and -- but that doesn't have to be through an ACO, although we think that is a good path, but advanced primary care is another pathway.

*Mr. Burgess. I think I heard the answer to your question. You have got to be in an ACO to make it work.

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

*Mr. Bucshon. The gentleman yields back. I recognize Mr. Sarbanes, five minutes.

*Mr. Sarbanes. Thanks very much, Mr. Chairman.

Thank you, Dr. Fowler, for being here. Thank you for the important work that CMMI does to advance patient care, to valuate how our healthcare system can best incentivize, provide, and reward care improvements and innovations.

As you well know, my home state of Maryland has been a leader in healthcare innovation. We like to think we have been the leader but I will just say a leader in healthcare innovation and delivery for more than 50 years having had some form of a hospital all-payer system since the 1970s. So we have been at this for a long time and I think developed some very sophisticated approaches with the assistance of CMMI.

Right now our state operates the Total Cost of Care Model, as you know, which is the first CMMI model to hold a state fully at risk for the total cost of care for Medicare beneficiaries. This model has not only resulted in efficiencies that save taxpayer money but also improved care coordination, promoted health equity, and advanced overall

health outcomes for Marylanders. Could you briefly comment on what CMMI sees as some of the biggest successes of the Total Cost of Care Model?

*Dr. Fowler. Thanks for that question. And we have enjoyed a very close partnership and working relationship with the State of Maryland, and we have also been very pleased to see some of the results from that model which we recently shared with the administrator at CMS. We have seen a reduction in Medicare fee for service costs of 2.1 percent over the course of the last model and a reduction in hospitalizations of 16 percent. We have also seen an improvement in quality for underserved populations that we are really pleased about in terms of lower readmissions and other quality measures that really indicate that the model is making a difference.

The Maryland model informed our new model, the AHEAD Model, and we have been in discussions with the state about what it might look like to transition the Maryland Total Cost of Care Model into that AHEAD Model, and they have been great partners, and we look forward to what is coming next.

*Mr. Sarbanes. Thank you. And as you just noted, I

guess it was last September that CMS announced the creation of this new initiative, the State's Advancing All-Payer Health Equity Approaches and Development, or AHEAD Model, as you indicated, which is based in part on Maryland's current all-payer system. We have obviously informed that model, we are proud of that, and it is likely to be, assuming all things go well, the next iteration of Maryland's model as well.

We have worked, that is Maryland has worked extensively with CMS and CMMI throughout the application process. I want to thank you all for your important efforts in that regard. I think it has been a very constructive process and discussion. One of the things that is going to be critical is Maryland hopefully makes this transition into the AHEAD Model is ensuring the state can maintain and continue to meaningfully build upon its successful innovations.

While the AHEAD Model shares many of the components and goals of our existing Total Cost of Care Model, could you just briefly touch on some of the differences between them as you see it?

*Dr. Fowler. Sure. I think -- well again, and do

appreciate the Maryland model which has served as really an inspiration for some of the components of the AHEAD Model. We are really hoping to bring in more of the primary care side, so instead of being just a hospital model, and I know there was the -- there was a physician component in the Maryland model, but really hoping to build on that. And also thinking more about those population health goals and really leaning into the improvements that we can make in population health and also to advance health equity.

So I think those are some of the features that we have added to the AHEAD Model that build on what Maryland has done and some of those successes.

*Mr. Sarbanes. And I know the intent is to kind of build in some flexibility under the AHEAD Model to ensure that each state that is awarded a spot in this first cohort, seven or eight I think it is, ends up with a model that reflects the needs of its population and leverages the existing strengths of its current system. So obviously Maryland looks forward to taking full advantage of that flexibility and we really believe we have some experience that we can lift up, and I know others are now coming into

this space, but we are going to continue to try to be the absolute leader with respect to this and again look forward to continued engagement with CMS and CMMI on the future of Maryland's all-payer system and the very real impacts its success has had on patient care.

Thanks very much, and I yield back.

*Dr. Fowler. Thank you.

*Mr. Bucshon. The gentleman yields back. I recognize Mr. Latta, five minutes.

*Mr. Latta. Thank you, Mr. Chairman.

Dr. Fowler, the United States continues to lead in healthcare and we are fortunate for our innovators for developing lifesaving cures. Patients travel from around the globe because we have the best pharmaceuticals, therapies, and devices to offer. However, we continue to face an existential crisis of cost, quality of care, and how we reimburse our health system.

When the Center for Medicare and Medicaid Innovation was established under the Affordable Care Act, we were promised that CMMI would create solutions to address these problems. And again to reiterate what the ranking member

had brought up, according to the February 2024 CBO report, CMMI's initiatives have resulted in an increase of 5.4 billion in direct federal spending between 2011 and 2020, contrary to the initial projections of generating nearly three billion in savings. From 2011 to 2020, CMMI initiated 49 models with published evaluations with only six of those models generating statistically significant savings, a 12 percent success rate.

What are the primary reasons for the shortcomings and, more importantly, what steps are CMMI taking to address the underlying issues to ensure future models are generating most cost savings, and I know you have already mentioned about -- the question about the voluntary models and you are learning from it, but what shortcomings have you learned that you can correct and make sure we get these savings?

*Dr. Fowler. Well, I would like to reiterate that we have learned something from every model that we have tested and that the voluntary nature has impacted our ability to save. I would also like to say that every model that we develop goes through a rigorous process and review with our actuaries, with the budget team, with our payment experts,

and every model that is tested goes into the field -- goes into implementation with the expectation of savings, so --

*Mr. Latta. Well, let me ask, because as you said that you are using the -- what you are learning from these models, but has that -- is that helping reduce these costs that we have seen -- in these savings we are supposed to have seen, or is this something that has been added since then, or is this something that has happened before and we didn't see the significant savings?

*Dr. Fowler. So every model, the ones that predated my time here and the models that we have announced and are implementing all go into the field with an expectation of potential savings, otherwise they wouldn't be approved to go out the door, so --

*Mr. Latta. Let me continue. How will CMMI ensure that its innovative payment models are effectively improving patient outcomes and reducing costs going forward then?

*Dr. Fowler. Well, in terms of patient outcomes, we have committed to including patient-reported outcome measures as a measure of quality for all of our models going forward, and so we are really spending a lot of time trying

to understand the impact on the care experience and potential to improve quality, and I think that is a really important feature, really trying to emphasize that quality improvement angle. Again, we haven't lost sight of the need to generate savings.

As I mentioned earlier, the innovation process, and that is true with the Innovation Center as well as other aspects of innovation, can sometimes be unpredictable but we start out with the expectation of savings, which is why I am really excited about some of the models that we are going to be testing, including the one I mentioned earlier about dementia, in terms of maternal health, improving behavioral health. I think we have high expectations for our ability to make progress in those areas.

*Mr. Latta. Well, let me also continue. Many stakeholders, including healthcare providers and various industry stakeholders, have expressed concerns about the complexity, administrative burden, and perceived lack of transparency involved when participating in the CMMI models. Given reports of inadequate stakeholder engagement, how does CMMI ensure that healthcare providers, patients, and other

critical stakeholders are meaningfully involved in the development and implementation of the models?

*Dr. Fowler. Well, one of the things I have tried to do since taking over this role is really go out and visit the providers and hear from them directly rather than wait for them to come to us. And what they have told us is what is working, what is not, what they are learning, where we can make improvements, and a lot of times we are able to make adjustments to the models that reflect some of their input. When providers decide not to stay in a model, we have gone back and asked them what didn't work for you. I think all of that has informed the way that we think about models going forward and how to simplify models.

You mentioned transparency and that has been a really important principle as well. We are now making all of the data available from all of our models available to researchers so they can go and look at the impact of the results and see for themselves what has been happening in the models, what has worked and what hasn't. So I think we are really trying to be more transparent in the way that we conduct our business, trying to signal where we are going

next, which was the point of the strategy refresh that we put out in 2021, and really just generally trying to be good partners for the providers who are out there and make sure that we are reflecting their input in our work going forward.

*Mr. Latta. Mr. Chair, my time has expired. I will submit my last question to the witness.

*Mr. Bucshon. The gentleman yields back. I recognize Ms. Kelly for five minutes.

*Ms. Kelly. Thank you, Mr. Chair and Ranking Member Eshoo, for holding today's hearing.

Dr. Fowler, I applaud the Center's introduction of the Transforming Mental Health Model and its commitment to a holistic approach to pregnancy, childbirth, and postpartum care. This initiative is crucial as our healthcare system, despite being one of the highest spenders globally, has the poorest mental health outcomes, especially for black, brown, and indigenous moms. The model addresses the fragmented systems that leave so many mothers at risk for harm. The model also includes a health equity strategy to address disparities in maternal health outcomes in minority groups

and rural communities. However, despite how impressive this model is, I am concerned that it may not reach those in need -- the most need.

I questioned Secretary Bacerra a couple of months ago on this issue and will pose a similar question to you. How does CMMI plan to ensure that the rollout of this innovative model reaches states and communities most in need such as black communities and those in rural areas?

*Dr. Fowler. Thanks for that question, and the Transforming Maternal Health Model is one of the ones we are quite excited about. We anticipate releasing the notice of funding opportunity for states in the very near future. And the model envisions three years of what we call a pre-implementation period before the actual model starts and we intend to use that time to work very closely with the states that have applied and been accepted to provide that technical assistance on how to reach those communities, make sure that we are reflecting the needs and input from communities that we are trying to reach mutually and trying to improve the care for them.

So we also intend to use that time to build that sort

of workforce infrastructure to make sure that it is reaching providers that will be providing that care: midwives, doulas, and others. And so I think that period will be really important and the funding will be really important to those states that want to participate and hopefully we will be able to reach the populations that we intend to reach, those underserved and rural populations.

*Ms. Kelly. So are you saying states can expect to submit applications within this year?

*Dr. Fowler. That is right. We will put that application period out and we will accept up to 13 states in that model.

*Ms. Kelly. Also I am the co-chair of the Bipartisan Congressional Digital Health Caucus and I am cautiously optimistic about the promise of artificial intelligence in health to address issues from provider shortages to precision medicine. In 2021 CMMI launched a strategy refresh and now requires model participants to collect and report on certain social determinants of health data. Now that the data are being collected, do you have plans to use the data to power AI algorithms and dissipate bias that can

help provide additional care to Medicare beneficiaries?

*Dr. Fowler. Well, we are in the early stages of collecting that date, and thank you for the question, I think it is really important one, and addressing those health-related social needs are really an important part of the model, and we are using the screening tool that was developed in the Accountable Health Communities Model which is another example of how we are building on some of the lessons learned from our previous models. How we use that data I think and making sure that we have the connection, not just to screen but to refer patients for the needs that have been identified, is the next step and we are taking that into consideration very carefully as we plot our path forward.

*Ms. Kelly. Thank you so much for your answers, and I yield back.

*Mr. Bucshon. The gentlelady yields back. I now recognize the chairwoman of the full committee, Ms. Rodgers, for five minutes.

*The Chair. In my opening statement I discussed how far off the projected impact of CMMI has been compared to

reality in terms of saving our healthcare systems money. Dr. Fowler, do you agree that reducing cost is fundamental to CMMI's mission?

*Dr. Fowler. That is a statutory mission outlined in the statute that created our -- the Innovation Center.

*The Chair. Thank you. Despite having increased spending over five billion dollars across the first decade of existence, in CMMI's 2021 strategic refresh, and recent articles and Op-eds, and especially the recent launch of the so-called quality pathway, it seems there is an explicit shift and focus away from trying to reduce spending. Where does reducing spending rank in terms of your priority list?

*Dr. Fowler. Reducing spending is our statutory mission and we remain committed to that goal. Every model that we test goes through a rigorous review and evaluation and clearance process where our actuaries look very closely at what we are proposing the budget team. We wouldn't test anything that didn't have the potential to save money at the outset as we make those announcements and as we implement the model.

*The Chair. Okay. Many of the suggest -- many have

suggested that most if not all of the new models CMMI rolled out since 2021 are unlikely to save money based upon their designs. Are you willing to commit to shutting down any model that is failing to show signs of net savings after its first two years so we can correct CMMI's failing fiscal trajectory?

*Dr. Fowler. It is a great question, and when we do get information about a model's performance sort of mid-year, we make adjustments accordingly, and in a couple of occasions since I have taken on this role we have had to shut down models early. The Emergency Triage Transport and Treat Model is one where we didn't have enough participants and it didn't look like it would be generating those savings. Another model was the Medicare Part D Modernization Model which was also -- unfortunately we had to end that model early.

So we do an annual evaluation, we do an annual assessment of each model, we do a model review pretty extensively, and when it is not performing and doing what it is supposed to do, we make changes or make a difficult decision to reverse course and close it down early.

*The Chair. Well, I would -- I am encouraged to hear that because the congressional intent and the statute is pretty clear. On another note, I was disappointed to hear Secretary Bacerra state in our budget hearing earlier this year that a number of drugs that FDA approved, were safe and effective, but people took them and nothing happened. This continues a dangerous trend of rhetoric around drugs approved by FDA through the accelerated approval pathway being anything less than having the full FDA gold standard, which is untrue and leads to unnecessary delays in patient access to much needed innovation.

Dr. Fowler, is it your belief that drugs and biologics granted accelerated approval have full FDA gold standard approval?

*Dr. Fowler. So you are asking an important question. We have looked at accelerated approval in the context of one of the models that we had put forward and are continuing to talk with the FDA. In terms of our view, in terms of the approval and coverage, I would refer these questions and take this back to my colleague at the Center for Clinical Standards and Quality, which leads Medicare coverage

decisions and determinations.

*The Chair. Well, I am going to encourage you to talk to Dr. Marks and Dr. Cavazzoni at FDA because they testified that drugs and biologics approved via accelerated approval meet FDA's gold standard and we need to get on the same page.

This Congress, this committee has spent a lot of time and energy working to fight consolidation in the healthcare system and lower prices for patients. I am concerned, however, that many of the models CMMI has created in recent years only fuel consolidation across the healthcare marketplace as models designed primarily around the largest healthcare systems boost those providers while making it difficult for independent providers to participate in value-based care. What is CMMI doing to assess the potential marketplace impacts of your models and ensuring that they are not incentivizing consolidation?

*Dr. Fowler. That is a great question and we spend a lot of time thinking about that. In fact, we think that part of our role is providing a pathway for new entrants to come in, and so for the ACO REA Model we have a specific

track for new entrants who want to come into the program who may not have been ACOs and couldn't have met that standard for the number of beneficiaries before the model. So we also think very carefully about how to maintain those small independent practices who want to be -- continue to be independent and small and many of them in rural areas, and so our Making Care Primary Model is explicitly geared to keep them small and independent, if that is their choice.

We are not requiring downside risk. It is really about giving them incentives and implementation funding for them to be able to remain independent.

*The Chair. Thank you. There is bipartisan concern on this committee about the consolidation and it is not improving access or saving money, so stay focused.

Okay, I yield back.

*Mr. Bucshon. The gentlelady yields back. I now recognize Mr. Griffith for five minutes.

*Mr. Griffith. Thank you very much.

Dr. Fowler, in your 17-page testimony you mention the word rural one time. As the Centers for Medicare and Medicaid Innovation -- has the Centers for Medicare and

Medicaid Innovation done anything to analyze and increase the quality of healthcare in rural areas outside of trying to transition to value-based care?

*Dr. Fowler. Thank you for the question, and as someone who grew up in Kansas and worked for the Senator from Montana, rural health is very important to me and I think we all share the goal of making sure that rural --

*Mr. Griffith. Okay, it is important, but what are we doing about it?

*Dr. Fowler. So our models aim to provide opportunities for rural providers who want to come into value-based care. I just mentioned the Making Care Primary Model which includes an explicit track that is geared to allow rural providers to come into the model and receive that sort of --

*Mr. Griffith. All right.

*Dr. Fowler. -- upfront investment.

*Mr. Griffith. Let me just say I don't think it is working. You know, I would have loved it if you would have looked at other opportunities like physician-owned hospitals or greater use of pharmacists or other allied health

providers to provide rural care. Maybe even made proposals related to Stark. That would be helpful. I would love it if you could give me any data that you have on the 9th District of Virginia and where you have been successful because I think there are whole counties that have been left out.

That being said, I am now going to yield to Dr. Burgess the remainder of my time.

*Mr. Burgess. Thank you, Chairman Griffith. I will just echo what he said about physician-owned hospitals. I do think that is an area where we need to spend some time. But there has been some discussion on the dais this morning around CMMI falling short of the CBO projected savings. I am also on the budget committee and worked with CBO to understand how the mark was missed so dramatically.

From your perspective, what would be a reasonable savings target for CMMI over this next decade of CMMI's existence?

*Dr. Fowler. I am not sure I could come up with an estimate. I think it depends on the rollout of the models and who comes in, and as I mentioned earlier, I think the

nature of innovation can sometimes be unpredictable. So we go in with the optimistic assumption that we will generate savings and expect -- fully expect that the models that we have announced will do that.

*Mr. Burgess. So it is not a secret, everybody knows what your funding is going to be, it is mandatory funding. Even if we don't pass an appropriations bill, you still get your 10 billion dollars for the decade. What do you think is a reasonable return on CMMI's next 10 billion dollar investment?

*Dr. Fowler. You know, I think this goes back to everything that we are learning from the models and that we go into the field with the expectation of savings. We have a plan to spend the money that has been allocated to CMMI and we fully expect to see positive results from the models that we are testing.

*Mr. Burgess. And I don't recall seeing that during the budget hearing. Can you share that spreadsheet with the committee on how you -- your financial outlays are projected for the next -- for this next decade?

*Dr. Fowler. We would be happy to follow up with you.

*Mr. Burgess. I think that could be most instructive. Let me just ask you -- going back to PTAC for just a minute. Has CMMI implemented any PTAC model that has been brought to it?

*Dr. Fowler. So we have incorporated a number of recommendations from PTAC. PTAC recommendations have informed our kidney models, our primary care models, our oncology model. I think there is a number of areas where those recommendations have played an important role in the development of our models.

*Mr. Burgess. Has there been enough experience with that to develop an opinion as to whether or not models that are worked on at the PTAC level are more or less likely to deliver the savings that you are searching for?

*Dr. Fowler. So I think, as I said, every model we test goes into the field with the expectation of delivering savings and the PTAC has been very important in informing our work. You know, those recommendations have been important points of reference and really helped us build some of the models that we are testing, in particular, pointing to the kidney care model and that --

*Mr. Burgess. So you have been there for three years at CMMI. How many times have you met with PTAC?

*Dr. Fowler. I meet with them every time that they have a meeting. I speak as part of their meeting. I just spoke with them Monday offering some introductory remarks. CMMI had a panel of experts that talked about some of our models in the seriously ill and chronically ill work that we have done, as that was the topic of their meeting. We enjoy a very positive relationship and I think it has been mutually beneficial. I think we have benefitted from a lot of the work that they are doing in these theme-based meetings that they are having, and I hope to think that what we are providing to them is some of the experience from our models that has informed some of their future meetings.

*Mr. Burgess. It is not just a good idea, it is the law. PTAC was signed by President Obama in 2015.

I yield back.

*Mr. Griffith. I yield back.

*Mr. Bucshon. The gentleman yields back. I recognize the ranking member of the full committee, Mr. Pallone, five minutes.

*Mr. Pallone. Thank you, Mr. Chairman.

Thank you, Dr. Fowler, for being here. Since its inception, CMMI has played a critical role in beginning to shift the Nation's healthcare system toward a system that rewards high-value healthcare. In particular, ACO models have incentivized efficiency and encouraged providers to take on more risks while delivering high-quality care, and a recent report by the Congressional Budget Office found that ACOs led by independent physician and ACOs with large proportions of primary care providers were associated with greater savings.

So I wanted to ask you if you would briefly discuss CMMI's efforts to move health systems towards ones that pay for value and elaborate on CMMI's work to encourage provider participation in ACOs, particularly for the primary care providers, if you will.

*Dr. Fowler. Thanks for that question, I really appreciate it. We have set a goal of having a hundred percent of Medicare fee for service beneficiaries and the vast majority of Medicaid beneficiaries aligned to an Accountable Care Organization or an advanced primary care

provider by 2030. So primary care is the fundamental sort of cornerstone of our strategy.

We have outlined a number models where we think we are providing opportunities for both improving patient care through these organizations and also for providers to join if they so choose to join an ACO. We -- I pointed in my testimony, my opening remarks the ACO investment model which provides upfront funding and advanced payments to providers who want to come into the model. We also just announced the ACOPC flex model that provides -- will provide starting next year a hybrid payment, so looking at providing some more predictable payment for primary care providers participating in ACOs.

So I think, you know, we have got a lot more in the hopper and I think more to come. We spend a lot of time thinking about this and also thinking about how to make sure that the innovations that we are testing have a permanent pathway in the shared savings program, so been working closely with the Center for Medicare on that.

*Mr. Pallone. And I wanted to discuss a little more about investments in primary care. If you could just

discuss CMMI's work to increase investments in primary care and address barriers to care that the models are intended to address, if you would.

*Dr. Fowler. Thanks. Again, we see primary care, we really see that as the cornerstone of our strategy. It is not to ignore specialists. I think we are also thinking about how to engage more specialists, but primary care, we have spent a lot of time thinking about how to make sure there are incentives to come into the program and into value-based care, whether that be through an ACO, or an advanced primary care practice, or a model. Some of that is through upfront investment funding, some of that is through new incentives.

And the Making Care Primary Model, which I mentioned earlier, does not require downside risk, it only involves performance risk for those small independent and rural practices who want to come in to value-based care.

*Mr. Pallone. Well, let me ask you in particular initiatives that invest in primary care and chronic disease. You know, you heard me say it in my opening, I always worry that, you know, the system is monetized and, you know, even

though we have a market healthcare system, there is not competition, and I just think a lot of times the problem is that, you know, providers are only looking for -- you know, everybody is looking at short term rather than long term, and I think that initiatives that invest in primary care and chronic disease prevention may not generate immediate savings in the short-term but are likely to pay dividends over the long term, you know, improvements in morbidity and mortality as populations age.

So can you just discuss the impact of CMMI's models on improvements in health -- in quality and health outcomes and why it is important to look at this in a long term rather than just in a short term, if you would?

*Dr. Fowler. Thanks for that question. I think it is really important, and maybe it goes back to your questioning about primary care. When we look at some of our models, these short-term five-year models, it has been really hard to generate savings when you are talking about areas of the health system that have been historically underfunded like primary care, like rural health. And so the Making Care Primary Model, which is being tested in New Jersey, is a 10-

year model and really thinking about giving a longer period of time for those providers to come in, get settled, and start generating what we hope will be those savings that we want to see and I think we all want to see in the models that we are testing.

So we are looking at longer term models in some instances, and again, particularly those areas that are underfunded. We have seen positive outcomes in quality. I think a number of our models have really improved the patient care experience, improved quality, improved outcomes, and we are excited to lean into quality, as I mentioned earlier, through this new quality pathway that we have outlined.

*Mr. Pallone. All right, thank you so much.

Thank you, Mr. Chairman.

*Mr. Bucshon. The gentleman yields back. I recognize Mr. Bilirakis, five minutes.

*Mr. Bilirakis. Thank you. Thank you, Mr. Chairman, I appreciate it.

Thank you for your testimony today. Community health centers in my district are eager to embrace value-based

care, but many alternative payment options do not consider their role as safety net providers who serve patients with complex chronic conditions and socioeconomic burdens. Which CMMI payment models currently include health center participants and what is preventing more of them from participating?

*Dr. Fowler. Thanks for that question, it is a really important one. I have a couple of examples. One, I would point to the ACO REACH Model which provided a bonus payment or what we call a health equity benchmark payment to providers and organizations that enrolled a higher proportion of underserved populations. As a result, we saw an increase in safety net providers of 150 percent between 2022 and 2024 when we started using that additional bonus payment to engage some of those providers.

The Making Care Primary Model, which I also mentioned, has an explicit track that is intended to bring those small, independent, rural providers and including community health providers, into the model with no downside risk and enough investment to be able to be successful in the model.

*Mr. Bilirakis. Okay, next question. Sometimes when

we discuss physician payment policies there is a divide between primary care and specialty care, and while primary care can be relatively evenly applied across the board, specialty care has a wide variety of factions, as you know. For example, the CMS Clinical Labor policy negatively affected many office-based specialists, but some were hit significantly worse than others really.

What steps is CMMI taking to ensure all types of physicians have opportunity to participate in value-based payment models that reflect this diversity and variety of providers?

*Dr. Fowler. It is an important question. We have been engaging nephrologists, and oncologists, and other specialists in specific models. Two years ago we outlined a specialty care -- or a specialty care strategy to engage more specialists. Part of that has included giving more data to ACOs to engage specialists more fully.

We also have proposed the TEAM Model that we outlined in the inpatient prospective payment rule, the comment period just closed on Monday, intended to engage more specialists, and we are looking for additional alternatives

and new ways to engage with specialists and integrate specialty care and primary care. It has really been a focus for us, and I think there is more to come, and look forward to more conversations about what more we could be doing in that area.

*Mr. Bilirakis. Thank you. Next question. Dr. Fowler, I know others mentioned this issue, of course, and -- but I share the concerns about the CMMI's proposed Accelerated Clinic -- Clinical Evidence Model that would put treatments approved under the accelerated approval pathway under a different paradigm of adjusted payments. As co-chair of the Rare Disease Caucus, I know the accelerated approval pathway can serve as a critical incentive for manufacturers to work towards creating a safe and effective treatment -- treatments and cures despite the unique challenges in developing these products due to their small patient populations.

I fear that Accelerated Clinical Evidence Model, it -- will it harm those incentives. So I fear that it will harm those incentives and decrease investment in drug innovation. Are you considering these difficulties for many

manufacturers within the rare disease space who may not always have an easy ability to conduct confirmatory trials? If not, why not?

*Dr. Fowler. Thanks for that question. And as we looked at the ACE Model and considered whether to continue moving forward we have been engaged in a lot of conversations with the FDA who believe that they have the authority to make sure that those confirmatory trials are conducted. I think in the rare disease space we also want to make sure that if there is a reason for not complying with those confirmatory trial agreements that have been made with the FDA, when it comes to rare diseases, you know, they may not have the patient population to be able to complete those trials, so that is also a consideration for us.

So we have been continuing to engage in conversations with the FDA and I would say we are continuing to think about that model but maybe not as fast as initially proposed.

*Mr. Bilirakis. Well, thank you.

I yield back, Mr. Chairman.

*Mr. Bucshon. The gentleman yields back. I recognize

Dr. Ruiz, five minutes.

*Mr. Ruiz. Thank you. Thank you, Mr. Chairman. We spend a lot of time in this committee talking about the need to improve patient care while at the same time reducing healthcare spending. Nowhere are these efforts needed more than in our Nation's rural and underserved communities. Medicare alternative payment models like the ACO REACH Model are -- or ACO and REACH Model are practical tools to help achieve these goals.

The Accountable Care Organization Realizing Equity Access and Community Health Alternative Payment Model is an important step towards addressing the needs of underserved communities and coordinating care. For example, providers participating in the ACO REACH Model are required to develop a plan to address health disparities. Dr. Fowler, since the implementation of this model, have you seen an impact on efforts to advance health equity?

*Dr. Fowler. Thank you for that question. We have and we are really excited about it. We have seen the direct results of the health equity benchmark adjustment that we provided in the REACH Model where there are bonus payments

to ACOs that enroll a higher proportion of underserved populations, and as a result we have seen 150 percent increase in the number of safety net organizations in our models between 2022 and 2024. So we think that those payments are working in order to really engage those communities and those providers and make sure that those beneficiaries are receiving the benefits of the care innovations that we are testing.

*Mr. Ruiz. And in what ways have the REA model made tangible changes to address health disparities in underserved areas?

*Dr. Fowler. Well, in addition to this health equity benchmark adjustment, as you mentioned, we are requiring all participants to submit a health equity plan so they identify the disparities in their patient populations that they have identified and tell us how they are going to address them. We are in the process of looking through a lot of those health equity plans to make sure that they are robust and that those needs are being met. We are also collecting data on health-related social needs, and so providers in this model are asking beneficiaries in the model about their

potential health-related social needs like food insecurity, housing needs, transportation needs, and also making steps and taking steps to address them.

I will also say we have also started making sure that health equity is part of our evaluation, and so by the end of the model we can say, have we made a difference in addressing health disparities, yes or no. And we are hoping by the time we get to the end of the model that we will be able to affirmatively say that we have made a difference.

*Mr. Ruiz. Thank you. Healthcare spending in Medicare is highly concentrated. In order to address high cost of care in Medicare spending, it makes sense to focus on caring for our sickest, most high-need patients, many of whom come from underserved communities. That is why the high-needs component of the ACO REACH Model is so important. It is specifically tailored to the specialized needs of the highest need patients and the providers that care for them, and we have seen that the model is working.

In 2002, high-needs participants achieved cost savings of 12.6 percent compared to 1.8 percent for participants in the standard track. Dr. Bucshon, this is like those repeat

visitors in the emergency department with chronic illnesses where if you provide the outpatient resources and home care with nurses, they are healthier so they don't utilize the resources as much.

As CMMI thinks about the future and what comes after the ACO REACH, how will you ensure that providers who care for the most vulnerable high-need patients continue to have a way to participate in ACOs?

*Dr. Fowler. That is an important question and one we have given a lot of thought to, and I think we have seen very positive results from the high-needs track of the ACO REACH Model and we are currently evaluating what makes sense in terms of the future of those innovations and is it sustainable to have a specific track for beneficiaries with very high needs or should they be incorporated into other ACOs. I think those are questions we are grappling with.

We also know that those organizations have made recommendations for some adjustments and we are taking those under consideration as well.

*Mr. Ruiz. Well, I would like to work with you on those considerations. Does CMMI have any additional plans

to address the challenges faced by providers and patients in rural areas specifically?

*Dr. Fowler. We are looking very closely. I would say in the same way that primary care is a sort of underinvested area of our healthcare system, I would say the same about rural health. That makes it really hard to come up with a model that is generating savings in areas where there has really been a historical underinvestment. So we have had trouble I think identifying exactly what to do in rural areas, but we have not given up and I think we are still exploring potential alternatives.

*Mr. Ruiz. Great. Let's follow up after this committee. Thank you.

*Mr. Bucshon. The gentleman yields back. I now recognize myself for five minutes.

Thanks for being here. I was a provider before. Again, it seems we are talking around the fringes of saving healthcare dollars, mostly by squeezing the money out of providers.

But I want to follow up on what Ranking Member Pallone said about lack of competition and things that we actually

might do, big ticket things, like lifting the moratorium on physician-owned hospitals, the effective state-based certificate of need laws that limit competition, policies that we can address here like reforming 340B which has led to consolidation, policies that have facilitated massive consolidation and vertical integration in the healthcare system that has increased costs not decreased them.

I will mention two, one of which is the dramatic reimbursement cuts based on inflation to physicians that makes it impossible to stay independent; and number two, the huge disparity in reimbursement for the technical component of what is -- like if you do a cardiac echo at a hospital versus a practice, between hospitals and independent medical practices, the medical practice's reimbursement is dramatically lower. I mean, I think maybe we should just increase their reimbursement to what it is at the hospital level.

You know, there is a lot of things we can do. We are again talking around the fringes here. CMMI, I appreciate what you are doing, you are doing hard work, but it is not going to save the kind of money we need to save in the

healthcare system if we are going to get a handle on this.

I think one of the reasons members have -- are quick to criticize CMMI is because we don't understand a lot about the decisions CMMI has made when it comes to developing and running models. CMMI seems to solicit information from public health and payment provider experts but mostly ignores that feedback, it seems to me.

Do you agree that clinicians are a good source of improvements to clinical practice and policy and their feedback should be prioritized?

*Dr. Fowler. Absolutely, and we do try to prioritize impact and input from providers who are directly affected by our models as well as those who may want to join but don't see a pathway. We spend a lot of time talking to providers and other stakeholders and, you know, I would say that feedback and input is a gift, frankly, in thinking about --

*Mr. Bucshon. Okay.

*Dr. Fowler. -- how we do our work.

*Mr. Bucshon. I want to follow up on Dr. Burgess' line of questioning on PTAC. How many presentations has CMMI given at PTAC public meetings?

*Dr. Fowler. Since my time in this role, I have spoken at every PTAC meeting as a public speaker.

*Mr. Bucshon. And those are all public -- available to the public? Good.

*Dr. Fowler. Yes.

*Mr. Bucshon. And how many PTAC models, again, I know that you answered this somewhat, you tried -- you kind of did, have you actually adopted? Because I know you said you got input, but my understanding, there has not been a single model that has been approved through the PTAC pathway, so the answer is 12, or zero, or somewhere in between, or what?

*Dr. Fowler. As I have learned in this job, the time between an idea generation, announcement of a model, and implementation is about 18 months to 24 months, and during that time we go through a lot of conversations with the budget folks, with the actuaries, with our payment experts, and what goes into that process is not what comes out at the other end of that process.

*Mr. Bucshon. I understand. And in fairness, you have not been there very long and this has been a problem for a long time, so thanks for that. But the answer is zero.

*Dr. Fowler. Well, I would actually say their input has been very helpful.

*Mr. Bucshon. Their input has been a lot, but the following -- implementating (sic) a model that has gone through the PTAC process has been zero.

Similarly, I would like to ask about the role of nephrologist feedback in shaping the comprehensive Kidney Care Contracting Model launched in 2019. I know that precedes you. This came to my attention as I am co-chair of the House Kidney Caucus. As you know, CMS recently decided to apply a retrospective trend adjustment to this model and will retroactively reduce benchmarks for program years 2022 and 2023. I have heard from nephrologists and other stakeholders that this has the potential to drastically reduce participation in this model and reverse important progress that it has made.

So a couple questions. After it was announced, the changes for 2024 with no relief for 2022 and 2023, did any participants withdraw from the model?

*Dr. Fowler. So first, I just want to say that when we talk about competition, kidney care is one area where we

feel particularly proud that there are a lot of new entrants and a lot of innovation happening in the kidney care space that we think is a direct result of the models that we have been testing. With regard to your specific question, we had approximately a hundred participants in the model and we have now seen -- we have I think 80 participants in the model going forward.

*Mr. Bucshon. Okay, so you lost some --

*Dr. Fowler. That is correct.

*Mr. Bucshon. -- from the model. Okay. Well, thank you for answering my questions. I just want to reiterate again what I said at the beginning. We have a lot of big ticket items that need to be addressed by both political parties in Washington if we are going to get a handle on cost of healthcare, and this hearing, although very productive and important, is on the fringes of that.

I yield back.

I now recognize Mr. Cardenas, five minutes.

*Mr. Cardenas. Thank you, Chairman Guthrie and also Ranking Member Eshoo, for holding this hearing to discuss the work of the Center for Medicare and Medicaid Innovation.

Thank you, Dr. Fowler, for joining us in sharing your expertise with Congress and also the constituents today, and also I want to thank you for your public service.

America's families are facing healthcare affordability and quality crisis. Nearly half of all Americans have reported having to sacrifice medical care due to the cost. A third have indicated that the cost of Medicare -- medical care complicates their ability to secure basic needs like food and housing, and more than 100 million Americans struggle with medical debt. While Americans struggle between putting food on the table and affording their medical care, the United States experiences some of the lowest levels of access to care and the greatest inequities compared with other industrialized countries.

High cost and poor health outcomes disproportionately impact marginalized communities. Black, Hispanic, and American Indian, and Alaskan Natives communities face some of the highest rates of medical debts, preventable deaths, and maternity -- maternal mortality. Our current healthcare system has depended on fee for service payment which incentivizes providers to make money for doing more

activities rather than encouraging providers to generate a profit based on keeping people healthy and reducing disparities.

Dr. Fowler, how is CMMI working to move beyond fee for service to help deliver health and improve healthy outcomes?

*Dr. Fowler. Well, we agree with you that moving towards value-based care is an important goal and we also think that value-based care is one of the critical components of addressing health equity and some of these health disparities. So we share your interest in making sure that we are reaching all communities with these innovations and that is why we are devoting a significant amount of time to making sure that we are attracting and enrolling providers from all parts of our community, including rural and underserved areas, into our models and making sure that those providers are serving a diverse and -- - patient population.

So we are collecting data I think and making sure that data collection is on all factors, including health-related social needs is one area where we have spent time, and our providers in our models are now asking questions about food

insecurity, housing and transportation needs. And our Value-Based Insurance Design Model starting next year there will be a requirement to address -- or starting in 2025 there is a requirement to address two out of three of those health-related social needs as a condition of participating in the model.

So we think there is a lot of work to do here, but we think we can make good progress and test some really innovative features that we hope can be incorporated in Medicare and Medicaid in the future.

*Mr. Cardenas. So it sounds like you recognize that it is multidimensional, it is not monolithic, it is not simple, it is complicated, but nothing to fear, you are trying to figure out how to address this multidimensional community of the constituents that depend on your services.

*Dr. Fowler. Absolutely. I think we are trying to tackle it from a number of different angles. And thank you for your leadership on these issues.

*Mr. Cardenas. Thank you. Do you believe that CMMI has provided cost savings and increased quality in ways that may not have been accounted for in overall model evaluations

with efforts such as more intentional advancements in incorporating health equity, screening for health-related social needs, and navigating -- navigation support?

*Dr. Fowler. We do think that there has been a greater impact to CMMI models and the things that we have been testing than maybe an evaluation of a single model may suggest. We think there has been a spillover impact on providers who are caring for other patients in addition to Medicare and Medicaid patients and other providers who may not be part of the model but are adopting some of these best practices. So we think that we have made a difference in improving healthcare in the U.S. and moving towards a more value-based, patient-centered healthcare system.

*Mr. Cardenas. Thank you. In the first 10 years of CMMI, the Center launched over 50 models and has reached roughly 30 million patients. CMMI has played a critical role in beginning to shift healthcare payment and delivery away from fee for service economics and been a leader, an innovator in the value-based care movement. The work must continue to transform the healthcare sector aligning it with the health and financial security of the American people and

generating savings for Medicare, Medicaid, and all consumers.

I look forward to continued collaboration to develop models that reduce disparities and pave the way for health equity for all Americans and all the people in our country.

With that, Mr. Chairman, I yield back.

*Dr. Fowler. Thank you.

*Mr. Burgess. [Presiding.] The gentleman yields back. The chair thanks the gentleman and the chair recognizes the gentleman from Georgia, Mr. Carter, five minutes for questions, please.

*Mr. Carter. Thank you, Mr. Chairman.

Director Fowler, thank you for being here, appreciate your attendance. As has been pointed out here, and as you well know, the Affordable Care Act created the Centers for Medicare and Medicaid Innovation and gave it pretty broad authority. In fact, I would submit too broad of authority. But nevertheless, the authority was given to test new patient -- new payment models and the intent was with saving money, saving taxpayers money. And CMMI has failed to create a budgetary savings and instead has cost Americans

billions of dollars and even continues to increase federal spending day by day.

Unfortunately, the ACA also included a clause that attempted to block any administrative or judicial review of CMMI demonstration models and left the administrator as a key potentially unaccountable arbiter of whether or not the law's requirements are being followed. Dr. Fowler, how do you specifically ensure that the statutory requirements of the -- for CMI -- CMMI models are stringently adhered to?

*Dr. Fowler. Well, thank you for that question. And I -- as someone who spent most of my career in public service, I do see myself and our organization as a careful steward of public dollars. It is very important to us to make sure that funding is accounted for and used in -- for the purposes that they -- that Congress intended.

*Mr. Carter. And please understand, I am not accusing you of anything, I am just saying it appears that this program is not working and it appears that we don't have any input. Have you ever gone to Congress asking for any input on any of this? Are you familiar with the Doctor's Caucus here in Congress?

*Dr. Fowler. I am familiar with the Doctor's Caucus and we would be happy to engage and have any conversation and take any input --

*Mr. Carter. Well, please, please. We welcome you.

*Dr. Fowler. That would be fantastic, thanks.

*Mr. Carter. And I would ask you and encourage you also to consider working with the members of this committee, specifically of this subcommittee on health to establish some kind of permanent mechanism for congressional input and oversight.

*Dr. Fowler. Thank you. We value input from Congress as well as any other stakeholders that comes with new ideas and input on models, and how they are working, and how they are transforming care.

*Mr. Carter. Well, let me ask you a direct question. Yes or no. Do you believe CMMI has been successful at improving patient outcomes and lowering cost?

*Dr. Fowler. I do believe we have been successful.

*Mr. Carter. At lowering cost?

*Dr. Fowler. In some of our models we have generated a savings.

*Mr. Carter. How many of those models?

*Dr. Fowler. Six models have generated savings on a net basis that are statistically significant. More models than that have generated savings on a gross basis but may not -- once you account for some of the investments that we are making, for example, in primary care, the net impact has been -- has not been savings, but we still think that for every model we have tested we have learned something important.

*Mr. Carter. And that is important, it is important to learn, and I -- and we acknowledge that and value that. But at the same time, we have got 34-and-a-half trillion dollars in debt in this country, so we are looking to stop the bleeding, and this just appears to be an area. I mean, there -- so far as I understand it, and please correct me if I am wrong, CMMI has launched over 50 models and 30 of them are operational today but only four of those models ever qualified to be expanded.

*Dr. Fowler. We think the success of the models exceeds the four models that were expanded through certification. We think that some of the learnings and some

of the results and the evaluations have generated a lot of important learnings that have really informed our work going forward and hopefully been valuable to providers who have participated in the model.

*Mr. Carter. Well, let me ask you this. Given the fact that the CMMI did not use the entirety of its first allocation of 10 billion dollars and the CBO forecast that it will not exhaust its second tranche of funding prior to receiving its next tranche of 10 billion dollars in 2030, do you believe that 10 billion dollars is the appropriate amount of mandatory funding for Congress to provide to CMMI?

*Dr. Fowler. Well, I wasn't here for the first decade of our existence.

*Mr. Carter. Understood.

*Dr. Fowler. But I can say --

*Mr. Carter. Fair enough.

*Dr. Fowler. -- now that I am here that it does take about 18 to 24 months to get a model out and into the field, and so that may account for the first decade. I think for the second decade we have a plan to spend the money that has been allocated to the Innovation Center.

*Mr. Carter. So you base your plan on the money that has been allocated and not necessarily the money or just whatever you may need for your plan?

*Dr. Fowler. We have a plan to spend the money that has been allocated to --

*Mr. Carter. Like every agency in the Federal Government does. Whatever you are allocated, you spend that money.

Mr. Chairman, I thank you. And thank you, Dr. Fowler. And please again, we have a Doctor's Caucus in this Congress, we have a lot of institutional knowledge here, we want to help. And I am very disturbed that this program somehow has escaped congressional review and congressional input, and I would appeal to you to please utilize the congress -- particularly this subcommittee.

*Dr. Fowler. We would welcome that input. Thank you.

*Mr. Carter. Thank you, and I hope you will not only welcome it but solicit it, so thank you.

*Mr. Burgess. Is this --

*Mr. Carter. And I yield back.

*Mr. Burgess. Is -- okay, the gentleman yields back.

I appreciate the gentleman's comment. I do know people on the Doctor's Caucus and we will see if we can make that happen. We might even make one of those rare bipartisan meetings if there was sufficient interest.

I am now pleased to recognize the gentlelady from Washington, Dr. Schrier, five minutes for questions.

*Ms. Schrier. Thank you, Mr. Chairman. Thank you, Madam Ranking Member.

Thank you, Dr. Fowler for being here. I also consider myself a member of the Doctor's Caucus and we expect this caucus to hopefully grow and I will make that same offer. I look forward to working together with you and, yeah, I will simply echo that.

I want to start just by saying I am a big supporter of innovation in general and I want to thank you for your efforts in transitioning our health systems to value-based care models. And not every CMMI model deployed is successful, but a lot of good work and better health outcomes have been reaped by the work that your agency is doing to push innovation in CMS forward.

As a physician, I have been a strong advocate for

Accountable Care Organizations, the ACOs, and these models allow a group of providers to work together to provide their patients with high-quality care at lower costs, and this means the patients are able to get more coordinated care and individualized treatment plans. And in Washington State, ACOs have saved 104.5 million dollars for Medicare in 2021 and 2022, which translates to about $235 in savings per beneficiary.

In your testimony, you talk about beneficial elements from models being incorporated permanently into CMS programs. However, I am concerned about CMMI's current standards for program expansion and whether they might be too rigid and even prohibitive. For example, the Medicare Care Choices Model, MCCM, tested whether offering supportive and palliative care through Hospice providers without requiring beneficiaries to forgo treatment for their terminal conditions would reduce cost and increase quality of life, and the model showed substantial Medicare savings and quality of care improvements. In other words, it worked. But it wasn't able to expand or be certified due to low participation.

So my question is, when these models are successful and we are feeling optimistic, even if they have limited reach, what are the next steps? How can we in this case where we see a small sample size that does well expand it, and are there any barriers statutorily or otherwise that simply don't allow more of these models to be practiced permanently?

*Dr. Fowler. Thank you for that question, I think it is a really important one. And the model you mentioned, the Medicare Care Choices Model, did reduce net Medicare spending by 13 percent, decreased inpatient admissions by 26 percent, reduced outpatient emergency visits by 12 percent, and increased Hospice use by 18 percent. But, unfortunately, the model did not meet the standards under the evaluation for generalizability and so we were not able to expand it.

What we have done is used those innovations and those regulatory flexibilities and built them into future models, so those same flexibilities are part of the ACO REACH Model, we have considered them as part of the AHEAD Model, and other of our innovative models going forward. So even if it

doesn't reach that standard for certification, we still think that what we are learning can inform future models.

So it is a really important question and I think it is one of the reasons why it is so hard to just look at one number and say six models were certified and therefore it is not a success because there is a lot more to be learned from what we are doing.

*Ms. Schrier. A lot of learning there, and maybe a meeting with the Doctor's Caucus could help us understand those standards and make improvements so that we could get more of these authorized, improved. Generally patients prefer that kind of care.

I just want to touch on pediatric value-based care, and I will cut to the chase. I was just wondering what is the current state of pediatric value-based care, and are there some specific models that CMMI has implemented, and what were those results?

*Dr. Fowler. Thanks for that question, and I hope I am not going out on a limb here and my team, if they are watching, is not going to be too upset. But, you know, when we look at our future portfolio we look at gaps in the

portfolio and pediatrics is one of the areas where we haven't done a lot of tests, we have the Integrated Care of Kids Model, and we are starting to think about maybe that is a gap that we want to start looking more closely at, and so the team is starting to think about that. There may be some challenges in that area, but I think we are interested in looking down that road if we can. And I would be happy to talk to the caucus and follow up with what our thinking is and what the possibilities might be.

*Ms. Schrier. I would love to work with you on that particularly regarding mental health, for example. Thank you.

And I yield back.

*Mr. Burgess. The chair thanks the gentlelady. The gentlelady yields back. The chair now is pleased to recognize Dr. Miller-Meeks from Iowa, five minutes for questions.

*Mrs. Miller-Meeks. Thank you very much, Mr. Chairman, and thank you, Director Fowler, for testifying before the subcommittee today. I am grateful for the opportunity to have a discussion with you on barriers to increasing the

presence of value-based care in our healthcare system in the form of attractive payment models that benefit both patients and their physicians. Our healthcare system unfortunately is suspect to waste and poor health outcomes, and growing complexities in our system have invariably led to fragmented, uncoordinated, and costly care.

Rather than reimburse care based on quantity, that is the number of patients seen, tests, orders, or procedures done, value-based care shifts or is hoping to shift the focus to rewarding positive health outcomes that are based off quality. I don't doubt your commitment and your passion for this issue. However, one of the many challenges with existing Accountable Care Organizations, ASO, models is that they often fail to produce real savings to the Medicare program, and the value add for physicians to invest in value-based arrangements, and I don't mean invest only financially, I also mean invest their time and their effort, are overburdensome or lacking.

Additionally, I hear from specialists that they are often not heard by CMMI when it comes to creating new payment models. And the vast majority of CMMIs or the

Center's models have not saved money, with several on pace to lose billions of dollars.

You have mentioned several times about working with the hospitals in regards to specialists in a few of your responses, but I would hope, and I highly encourage you to engage the specialists community directly rather than work through consolidated entities. One of the things this committee has worked on is the consolidation that has occurred, so I would recommend reaching out to them.

Do you believe that there are enough alternative payment models, or APMs, approved by the Center for all physician practices to participate, particularly specialty practices, and in other words, is there currently an environment in which all practices are able to move to value-based care models?

*Dr. Fowler. Well, I think there is probably room for more engagement with specialists and that is why we outlined a specialty care strategy a couple of years ago to identify ways of engaging specialists more in not just accountable care but also in value-based care more broadly, so it is one of our goals and something we are focused on for the future.

*Mrs. Miller-Meeks. Do you think, and I think you mentioned this peripherally, Physician-Focused Payment Model Technical Advisory Committee, or PTAC, has an important role to play in the creation of APMs?

*Dr. Fowler. We agree with that and we have had excellent engagement with PTAC and consider them an important partner for our work that has informed a lot of our direction.

*Mrs. Miller-Meeks. So do you think that there are more opportunities to engage with physicians, especially specialists, to engage in the APM Model and/or their specialty organizations? Because I understand your comments, but the reality I have from physicians with whom I work with and engage is that there is not engagement with them.

*Dr. Fowler. I would welcome the opportunity to talk to them if you want to send them our way.

*Mrs. Miller-Meeks. Okay. One of the focuses of the Center under this administration has been to help reduce the challenges for various populations, including those in rural areas. One of the diseases which disproportionately hits

these populations is kidney disease, which I think Dr. Bucshon mentioned. CMS has attempted to address some of these disparity issues through a number of actions such as the Comprehensive Kidney Care Choices Model which has received bipartisan congressional support and has seen significant uptake and I think also success.

However, recent decisions made by CMS to retroactively adjust the benchmark for calendar years 2022 and 2023 has put this successful model at risk financially as financially providers will not be able to sustain the level of risk they are being asked to bear, despite being able to successfully manage care and lower spending for these patients. While I applaud the Center's recognition of the issue and recently announced changes to limit the impact of the retrospective trend adjustment to the benchmark beginning in 2024, still nothing's been done for 2022 or 2023.

After you announced the changes in April for 2024 with no relief, did any participants withdraw from the kidney model?

*Dr. Fowler. Thank you for that question. And if I might just step back a moment to talk about the

retrospective trend adjustment that is part of our models and the way that we design models, and it is there to protect both the trust fund and participants if it turns out that the projections that go into our benchmarks change in any one direction or another. There was a lot of uncertainty coming out of the pandemic and the public health emergency in making some of those projections. We have worked to address, as you mentioned, the RTA going forward from 2024 on through [indiscernible]. We, as a general rule, tend not to make retrospective --

*Mrs. Miller-Meeks. So if I may, and if you will indulge me, Dr. Burgess, as chair, my question was did any participants withdraw from the kidney model, and if yes, how many?

*Dr. Fowler. We started the year with a hundred participants and after the period to drop out at the end of April, we are at 80 participants currently.

*Mrs. Miller-Meeks. So 20 dropped out. So I think that means we need to reconsider the retroactive for 2022 and 2023. Thank you.

I yield back.

*Mr. Burgess. The gentlelady yields back. The chair thanks the gentlelady. The chair now is pleased to recognize Dr. Joyce from Pennsylvania, five minutes for questions.

*Mr. Joyce. Thank you for yielding and for holding this hearing on such an important topic. The transition to value-based care as envisioned under MACRA has left a lot to be desired, and I would like to thank Dr. Fowler for appearing today, as well as the committee for looking into ways to improve the value-based care pathway and how we can improve both quality of care and outcomes for American patients.

Dr. Fowler, looking at the latest data that we have from 2022 performance year, the vast majority of physicians are still stuck in the MIPS program versus participating in an APM. To the extent that we have seen increases in APM participation, it seems like that it is mostly driven by expansions of existing APM models instead of the creation of new options for those who are looking to participate. In your view, is CMMI doing enough to get doctors into advanced APMs?

*Dr. Fowler. Thanks for that question, and thank you also for extending the bonus payment for APMs, I think that is an important incentive to join those programs. We aim to move as many providers as we can into APMs and that is one of our stated goals. And are there enough models for everyone to join? Perhaps not, but I think we are continuing to think about how we can do more to incentivize.

*Mr. Joyce. Are you looking to create new models? Are you looking for more opportunities to engage physicians and practices to participate?

*Dr. Fowler. We are and I think in forthcoming rules hopefully will give more signals about some potential directions.

*Mr. Joyce. What is the timeline? What are we looking for to seeing those, please?

*Dr. Fowler. We have said we want to see all Medicare beneficiaries and Accountable Care Organizations or Advanced Primary Care by 2030. That will necessarily involve including specialists and engaging specialists in value-based care, and so we are looking for additional pathways to --

*Mr. Joyce. Is there additional pathways to expedite that closer to 2030?

*Dr. Fowler. We hope so. We are looking at that right now.

*Mr. Joyce. I think we need -- I think that is something that we need to. Moving on, the Physician-Focused Payment Model Technology Advisory Committee, PTAC, was established to review and evaluate physician-focused payment models that could be adopted to improve value-based care. Many specialty physicians have invested significant time and significant resources to develop these models and submit them through PTAC. However, there is a significant gap between the PTAC's recommendations and the implementation of these models by CMMI and CMS.

Can you explain why CMMI or CMS has largely ignored the PTAC recommendations, and what steps are being taken to ensure that these valuable insights and innovation models proposed by specialty physicians are given the consideration that they need?

*Dr. Fowler. Thanks for that question. We see PTAC as an important partner. I was just at their meeting and spoke

publicly at their forum on Monday and there was a specific panel that they had organized for CMMI to appear and share some of the learnings from our specialty care models and our models that target seriously ill and chronically ill populations.

We have reviewed, and some of this happened before my tenure here, we have reviewed all of the recommendations, and their recommendations have informed a number of our models, including in the kidney care space, the oncology model, and our primary care model, the Primary Care First Model. We look at all of those recommendations and have incorporated as factors that -- as many as we can into the work that we do.

*Mr. Joyce. And I want to acknowledge and congratulate you on that collaboration because I think that is incredibly important. In my home state of Pennsylvania, the Pennsylvania Rural Health Model is set to wind down at the end of this year. CMMI has made it clear that it would be sunsetting models like the Pennsylvania Rural Health Model instead of focusing on additional advancement to these. So instead of continuing to engage with providers in my state

to better address rural healthcare challenges, CMMI is replacing the Pennsylvania model with a one size fits all, equity-focused model. Collaborating with state governments should be an important part to be able to recognize what providers can provide into this situation and work better with the state models.

How do you expect this change to help rural patients in my state?

*Dr. Fowler. Thank you for that question. We are currently in discussions with the State of Pennsylvania about what happens to the Pennsylvania Rural Hospital Model. It has been --

*Mr. Joyce. Did you see benefits from that model?

*Dr. Fowler. We think that there were benefits to the model, in particular --

*Mr. Joyce. But then switching to a one size fits all, how do we take those benefits and move them into the next model that should be available?

*Dr. Fowler. So, unfortunately, the PAR Model did not generate savings on a net basis and so it is not a model that we can continue. We have offered to work with the

State of Pennsylvania and figure out what comes next and make sure that there is a smooth transition.

*Mr. Joyce. What timeline should we expect to see that model for rural states like -- rural districts like mine in the State of Pennsylvania?

*Dr. Fowler. The PAR Model includes a two-year transition automatically if the state and the providers in the state choose to take advantage of the transition, and we are in discussions whether that is a sufficient time or whether we need more time, and also thinking about what comes next.

*Mr. Joyce. My time in this questioning has expired. Again, I thank you for appearing here today.

Mr. Chair, I yield back.

*Mr. Burgess. The gentleman is correct, his time has expired. The chair --

*Mrs. Harshbarger. Yes, it has, Chair.

*Mr. Burgess. The chair thanks the gentleman. The chair is pleased to recognize the gentlelady from Tennessee, Mrs. Harshbarger, five minutes for your questions, please.

*Mrs. Harshbarger. Thank you, Mr. Chairman, and thank

you, Dr. Fowler, for being here.

We are going to talk about the CBO, of course. The Congressional Budget Office reports that the CMMI spent 7.9 billion on operating models, yet it has a mandatory appropriation of 10 billion over 10 years. And I was talking to Dr. Burgess about this earlier. What happens to the unspent monies on new health models?

*Dr. Fowler. Under the statute the funding remains, and we have a plan to utilize all of the spending that has been appropriated to the Innovation Center.

*Mrs. Harshbarger. Did CMMI spend 21 percent or 2.1 billion, which is equivalent to 200 million a year, on staffing and administration?

*Dr. Fowler. I don't have those figures in front of me and we would be happy to get back to you on that.

*Mrs. Harshbarger. That would be great. How many people work at CMMI?

*Dr. Fowler. Approximately 500.

*Mrs. Harshbarger. What fraction of CMMI staff have operating and business experience running health plans, hospitals, clinics, hospitals, pharmacies, do you know?

*Dr. Fowler. We aim to bring in all sorts of experts into the Innovation Center. I am blessed to work with some of the smartest people and have a great staff that have a variety of expertise and experience, including having worked in plans and in practices, so really pleased at the staff that we have and their ability to translate what they see out in the world into the models and the work that we do.

*Mrs. Harshbarger. Yeah. Well, you know, it makes sense to me as a former business owner in a pharmacy and running pharmacies for 38 years, you know, it is good to have operating and business experience if you put these people in positions of authority. And I guess my opinion of that is how do you expect to get different results when you have a workforce largely lacking real world care experience. That is what I am saying. And I can apply that to Congress, too.

*Dr. Fowler. Thanks for the question. We do aim to get a wide diverse set of expertise and experience when we hire.

*Mrs. Harshbarger. I think we need some -- you know, we need people in those positions that have real life

experience so that when we do have these things like the CBO budget and we have unspent monies, we just need to allocate that better.

CBO estimates that CMMI cost money rather than producing net savings for the Federal Government, instead of experimenting with the team that had scored only six successive of more than 50 models. Should we just direct those CMMI funds instead to improving the physician fee schedule? Because we always struggle with that.

*Dr. Fowler. Well, thanks for the question. I -- and not to sound like a broken record, but we do feel like we learn a lot from every model that we test and we do have a plan to utilize spending that has been -- or the funding that has been allocated to the Innovation Center.

*Mrs. Harshbarger. What timeframe -- tell me, and I think I know, but when you put these models into practice, what is the timeframe that you use to see if they are successful or not?

*Dr. Fowler. I think, you know, initially probably three to five years for the model, but what we have found is that it takes a while for providers that join the model to

really get up and running, and make those investments, and build the expertise and the platform to be able to be successful, and then the model ends. And so --

*Mrs. Harshbarger. Okay.

*Dr. Fowler. -- what we are trying to do is look at longer models that give them a little bit more of a runway to do that to make that --

*Mrs. Harshbarger. Maybe five to 10 years you think maybe?

*Dr. Fowler. It depends on the model. The Primary Care Model that we are starting on July 1st will be a 10-year model instead of a five-year model to give that more predictability.

*Mrs. Harshbarger. But it is still voluntary, correct?

*Dr. Fowler. It is still voluntary.

*Mrs. Harshbarger. And see I struggle with that part, too. Speaking of success, it is my understanding that most of the six models have miniscule improvements, and I guess my last question is, can you explain to us the difference between statistical and clinical significance?

*Dr. Fowler. You know, that is a really important

question because when I look at some of the models that may not have generated that certification like the Oncology Care Model, it has made a tremendous difference in the care that is provided to Medicare patients undergoing chemotherapy, the provision of 24/7 access to a hotline, keeping people out of the hospital, more person-centered care, and yet it didn't result in those net savings because the investments, the monthly payments to make some of those investments in some of those sort of patient-centered team-based approaches ended up not generating savings on a net basis but we still think it made a tremendous difference --

*Mrs. Harshbarger. Okay.

*Dr. Fowler. -- which is why we used the learnings from that model to then test a new oncology model, the Enhancing Oncology Model, that starts in July.

*Mrs. Harshbarger. Yeah, that is an important model.

I think my time is about to expire, Dr. Burgess, unless you want the last 10 seconds, sir.

*Mr. Burgess. You are very kind to donate those back to the cause, and the chair thanks the gentlelady. The gentlelady's time has expired.

Again, just to reiterate what I said earlier, and I think the last eight questioners have all been members of the Doctor's Caucus, so I do know people, and maybe we can see if we can continue this discussion at a Doctor's Caucus some morning.

I ask unanimous consent to insert in the record the documents included on the staff hearing documents list.

Without objection, that will be an order.

[The information follows:]

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

*Mr. Burgess. You don't want me to read those? I will remind members they have 10 business days to submit questions for the record. I ask the witnesses to respond to the questions promptly. Members should submit their questions by the close of business June 28.

Without objection, the subcommittee is adjourned.

Thank you, Dr. Fowler.

[Whereupon, at 1:04 p.m., the subcommittee was adjourned.]