HOUSE COMMITTEE ON ENERGY AND COMMERCE
Subcommittee on Health

"Checking-In on CMMI: Assessing the Transition to Value-Based Care"

June 13, 2024 – 11:00 AM

OVERVIEW

On June 13, the House Energy and Commerce Health Subcommittee held a hearing titled, "Checking-In on CMMI: Assessing the Transition to Value-Based Care." During the hearing, Members and Center for Medicare and Medicaid Innovation (CMMI or CMS Innovation Center) Director Dr. Liz Fowler discussed the Accelerating Clinical Evidence (ACE) Model; Congressional Budget Office (CBO) estimates; measurements of success; accountable care organizations (ACOs); value-based care (VBC); stakeholder engagement; the Physician-Focused Payment Model Technical Advisory Committee (PTAC); Total Cost of Care (TCOC) models; the Transforming Maternal Health (TMaH) Model, artificial intelligence (AI) and data; healthcare consolidation; the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) Model; rural health; primary care models; safety net providers; specialty care; health equity; the Kidney Care Choices (KCC) Model; model expansion requirements; pediatric models; the Merit-Based Incentive Payment System (MIPS); CMMI staff; the physician fee schedule (PFS); and clinical significance.

OPENING STATEMENTS

- Full Committee Chair Cathy McMorris Rodgers (R-WA)
- Full Committee Ranking Member Frank Pallone (D-NJ)
- Subcommittee Chair Brett Guthrie (R-KY)
- Subcommittee Ranking Member Anna Eshoo (D-CA)*

**Opening statements not yet available*

WITNESS PANEL

- Dr. Liz Fowler, Ph.D, J.D. – Deputy Administrator and Director, Center for Medicare and Medicaid Innovation (CMMI), Centers for Medicare and Medicaid Services (CMS)

QUESTION AND ANSWER SUMMARY

Chair Brett Guthrie (R-KY) – I am excited about innovative medicines like cell and gene therapies, especially for sickle cell. I have friends who have that disease and I know how devastating it can be. CMS' proposal is to work directly with manufacturers to negotiate rates for these therapies on behalf of states and track outcomes; I am concerned that states are not working together and that it is instead all

coming out of CMS. How many letters of intent has CMMI received so far and did CMS contemplate permitting multistate compacts as opposed to this model?

Dr. Fowler – We are excited about this model and have received letters of interest from a majority of states that represent about 80 percent of patients with sickle cell disease. The letters are non-binding, and we understand that states reserve the right to negotiate directly with manufacturers. The model is voluntary for manufacturers as well. We have just started the process and look forward to having a successful model that drives better outcomes and access for patients.

Chair Guthrie – The Medicaid VBPs for Patients (MVP) Act (H.R. 2666) is not disease-specific. How does CMMI intend to address the fact that multiple diseases and conditions other than sickle cell would benefit from further exemptions to best price and average manufacturer price (AMP)? Does CMMI intend to "come back each time for a new disease?"

Dr. Fowler – We want to avoid "biting off more than we can chew," so we hope to be successful in the model that we outlined and are happy to explore other potential opportunities in that area if it is successful.

Chair Guthrie – During your tenure, CMMI has launched several programs that could be detrimental to life science innovation, specifically the Accelerating Clinical Evidence (ACE) Model to pay Part B providers less on accelerated approval drugs. It seems like the Administration views accelerated approval as an alternative path rather than approval, but "we think it's full approval." What kind of assessment did CMMI do related to patient outcomes and availability of other treatments as it decided to move forward with the model? Could it lead to increased costs on the healthcare system if patients lose access to these drugs?

Dr. Fowler – CMMI worked closely with the Food and Drug Administration (FDA), which indicated that new authority may suggest the need for further examination. "In a blog that we put out last fall, we indicated that we're continuing to talk about the model," but we're going to continue to work with FDA.

Chair Guthrie – Did FDA claim accelerated approval is not equivalent to traditional approval and therefore should be paid less?

Dr. Fowler – That is not something FDA said directly. We discussed the need for a model and FDA would like to see if its authority is sufficient. Discussions are ongoing.

Chair Guthrie – FDA does not think its existing authorities for accelerated approval are sufficient for use?

Dr. Fowler – The authority to require and elicit the confirmatory trials that they had agreed to with manufacturers. We were not talking about the approval and the pathway itself, just the need for potential authority to make sure those confirmatory trials are conducted.

Chair Guthrie – We are trying to get these medications to patients quicker because months matter. In the absence of alternative approval pathways, will it cost the system more for patients racing against diseases like Duchenne muscular dystrophy?

Dr. Fowler – As someone who spent part of her career working for the innovative industry, I believe in this pathway, and we do not want to disrupt it. The goal of the model is to see if we can drive confirmatory trials in the period that the manufacturers have agreed to. We are having further discussions with FDA on the need for the model.

Ranking Member Anna Eshoo (D-CA) – In 2021, CMMI completed a wholesale review of its activities and efforts to lower costs and improve care for patients, but the Congressional Budget Office (CBO) found last year that CMMI cost the government $5.4 billion more than it saved in its first decade and may be on track to cost $1.3 billion more than it saves over the next decade. Why is the Innovation Center not

generating savings? What metrics does CMMI use to determine whether a model is successful? An example would be helpful. What is CMMI's value outside of lowering costs for patients?

Dr. Fowler – We have learned something from every model we have tested, and the innovation process is sometimes unpredictable. Most models are voluntary, and this has affected CMMI's ability to generate savings, which CBO pointed out. Risk selection has undermined our ability.

Ranking Member Eshoo – Have there been more models that have been accepted than "providers pulling out?"

Dr. Fowler – We think all our models have been successful in that we are learning something regardless of the ultimate assessment. We have also thought about the impact on quality and have laid out a quality pathway. The statute gives authority to examine both quality of care and the impact on savings, and we are leaning into the quality improvement angle for patient reported outcomes and the patient care experience.

Ranking Member Eshoo – The accountable care organization (ACO) model has been successful in letting physicians and hospitals work together to coordinate care for patients to prevent complications or unnecessary hospitalizations, but my constituents distrust how ACOs might impact Medicare or cut corners to save money. How does CMMI ensure seniors can trust and rely on Medicare and communicate what being part of an ACO means for patients? Do patients know if they are in an ACO, and can they opt out?

Dr. Fowler – Beneficiaries are always informed if they are part of a model, and they are able to exempt their data. They may receive a letter and there is usually a notice provided by the physician at the office. We need to do a better job of explaining the value of value-based care (VBC), so we have started to highlight success stories on our website.

Rep. Michael Burgess (R-TX) – The Physician-Focused Payment Model Technical Advisory Committee (PTAC) has been vastly underutilized and provides an opportunity for doctors to "do this kind of work." I am working on legislation to ensure PTAC is fulfilling the role it was given by Congress and would like to know if you would be willing to work with me.

Dr. Fowler – We would be happy to work with you and provide technical assistance.

Rep. Burgess – Developing these models seems devoid "from any part of the practice of medicine," so it is not surprising that the number of successes is small. Would the people who wrote the Affordable Care Act (ACA) be surprised by how little it has saved patients? Without subsidies, the ACA has been unaffordable.

Dr. Fowler – The number of people who have received coverage –

Rep. Burgess – Coverage is not care. The advance premium tax credit has needed to be increased several times over what it was when the law passed. One argument in favor of the ACA is that increasing coverage would not increase the deficit but would instead return money to the Treasury, do you remember that?

Dr. Fowler – I can take back these questions to my colleague who is in charge of ACA marketplace coverage. The Innovation Center focuses on care delivery models, and we are excited about the potential for improving care and the care experience.

Rep. Burgess – A portion of the money that was supposed to be returned to the Treasury was supposed to come from CMMI. I thought the Administration would remove CMMI when it changed in 2017, but CBO prohibited it because of the savings that were built into the law. It turned out those savings were ephemeral and were not really savings at all, were they?

Dr. Fowler – I would go back to everything CMMI is learning from the models it is testing – it is yielding important results and innovations. We spend a lot of time talking to providers, including providers on the PTAC, and getting input on how to make models better and respond to pressures and challenges physicians have identified in the practice of medicine.

Rep. Burgess – Is it the agency's position that every physician will end up practicing in an ACO? Is the push to get every doctor and patient into an ACO that is controlled by the Department of Health and Human Services (HHS)?

Dr. Fowler – In addition to ACOs, we would like to see providers who would like to stay independent practicing in an advanced primary care approach. We have a number of models geared toward small, rural, and independent practices that may not want to join an ACO. The Making Care Primary (MCP) Model was geared toward giving them a path into VBC that allows them to be independent. It offers incentives and investments for infrastructure. We would like to see accountable care where there is a provider or clinician who is responsible and accountable for total cost of care and quality, but that does not have to be through an ACO, although we think that is a good path; advanced primary care is another pathway.

Rep. Burgess – I think I heard the answer to your question: you have to be in an ACO to make it work.

Rep. John Sarbanes (D-MD) – CMMI is doing important work to evaluate how the healthcare system can incentivize and reward care improvement and innovations. Maryland has been a leader in healthcare innovation and delivery through its hospital All-Payer system and its current Total Cost of Care (TCOC) Model, which has resulted in efficiencies that have saved taxpayer dollars, improved care coordination, promoted health equity, and advanced overall health outcomes. What does CMMI see as the biggest successes of TCOC?

Dr. Fowler – There has been a 2.1 percent reduction in Medicare fee-for-service (FFS) costs over the course of the last model and a 16 percent reduction in hospitalizations. There has also been a quality improvement for underserved populations in terms of lower hospital readmissions and other quality measures. The Maryland model informed CMMI's new States Advancing All-Payer Health Equity Approaches and Development (States Advancing AHEAD or AHEAD) Model, and we have been in discussions about what it might look like to transition the Maryland model into the AHEAD Model.

Rep. Sarbanes – Maryland is proud to have informed part of the AHEAD Model, which is also likely to be the next iteration of Maryland's own model. Maryland has worked with CMS and CMMI throughout the application process, and it will be critical to ensure the state can maintain and build on its innovation. AHEAD shares many goals of Maryland's TCOC model. What are some of the differences?

Dr. Fowler – The Maryland model inspired some components of AHEAD, but we are hoping to incorporate more primary care, population health goals, and health equity.

Rep. Sarbanes – The intent is to build in flexibility under the AHEAD Model to ensure each state in the first cohort can use the model to reflect its population's needs; Maryland looks forward to taking advantage of the flexibility and has experience it can leverage.

Rep. Bob Latta (R-OH) – The U.S. leads in healthcare due to innovation that attracts patients from around the world, but we are continuing to face a crisis of cost, quality of care, and how we reimburse the health system. CMMI promised to address these problems, but instead has increased direct federal spending with a 12 percent success rate in terms of models generating "statistically significant savings." What are the reasons for these shortcomings and how is CMMI addressing underlying issues to ensure future models generate cost savings? I know you already mentioned the voluntary nature of these models.

Dr. Fowler – I would like to reiterate that we have learned something from every model we have tested. The voluntary nature has impacted our ability to save. Every model we develop goes through a rigorous process and review with actuaries, the budget team, and payment experts and goes into the field with the expectation of savings.

Rep. Latta – You are using what you're learning from these models – is that helping reduce costs?

Dr. Fowler – Every model goes into the field with the expectation of potential savings, otherwise they would not be approved.

Rep. Latta – How will CMMI ensure its payment models are effectively improving patient outcomes and reducing costs going forward?

Dr. Fowler – We have committed to incorporating patient reported outcome measures as a measure of quality for all models. We are trying to understand the impact on the care experience and the potential to improve quality. We have not lost sight of the need to generate savings; the innovation process can be unpredictable, but we always start with the expectation of savings, and I am excited about the models we are going to test, including for dementia, maternal health, and behavioral health. We have high expectations for our ability to make progress in those areas.

Rep. Latta – Many stakeholders have expressed concern about the complexity, administrative burden, and perceived lack of transparency when participating in CMMI models. How does CMMI ensure providers, patients, and other stakeholders are involved in the development and implementation processes?

Dr. Fowler – I try to visit and hear from providers directly rather than waiting for them to come to CMMI. We are often able to make adjustments that reflect their input, and it informs the way we think about simplifying models going forward. Transparency is an important principle, so we are making all data from all models available to researchers.

Rep. Robin Kelly (D-IL) – I applaud the Transforming Maternal Health (TMaH) Model and the commitment to a holistic approach to pregnancy, childbirth, and postpartum care. The model addresses fragmentation that leaves mothers at risk and includes a health equity strategy to address outcome disparities in maternal health for minority groups and rural communities. I am worried that it will not reach the people who are most in need; how does CMMI plan to ensure the rollout of this model reaches the people who need it most?

Dr. Fowler – CMMI anticipates releasing the TMaH notice of funding opportunity (NOFO) for states in the coming months. The model envisions three years of pre-implementation that will be used to work closely with states to offer technical assistance on how to reach those communities and reflect the needs of populations we are trying to reach. We intend to use this time to build the workforce infrastructure to reach providers like midwives and doulas. This period will be crucial to reaching the underserved and rural populations we intend to reach.

Rep. Kelly – Can states expect to submit applications within this year?

Dr. Fowler – Yes, we will put the application period out and will accept up to 13 states in the model.

Rep. Kelly – As the co-chair of the Congressional Digital Health Caucus I am cautiously optimistic about the promise of artificial intelligence (AI) in health to address issues from provider shortages to precision medicine. CMMI launched a strategy refresh in 2021 requiring model participants to collect certain data on participants' social determinants of health. 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 – We are in the early stages of collecting this data. Addressing health related social needs (HRSNs) is an important part of the model, and we are using the screening tool developed in the Accountable Health Communities (AHC) Model, which is another example of how we are learning from previous models. How we use the data and ensuring we have the connections to refer patients for the needs that have been identified is the next step.

Full Committee Chair Cathy McMorris Rodgers (R-WA) – In my opening statement, I discussed how far off the projected impact of CMMI has been in terms of saving money. Dr. Fowler, do you agree that reducing cost is fundamental to CMMI's mission?

Dr. Fowler – It is a statutory mission of the Innovation Center.

Chair Rodgers – It seems CMMI has made a shift away from trying to reduce spending. Where does this priority rank?

Dr. Fowler – It is our statutory mission, and we remain committed to that goal. Every model we test undergoes a rigorous review process. We would not test anything that did not have the potential to save money.

Chair Rodgers – Many have suggested that most – if not all – new models CMMI has rolled out since 2021 are unlikely to save money based on their designs. Are you willing to shut down any model that is failing to show savings after its first two years to correct CMMI's "failing fiscal trajectory?"

Dr. Fowler – When we get information about a model's performance, we make adjustments accordingly. We have had to shut down models early on a couple of occasions, including the Emergency Triage, Transport, and Treat (ET3) Model and the Medicare Part D Modernization (PDM) Model. We do an annual evaluation of each model and extensive model review and make changes "or make a difficult decision" when the model is not performing.

Chair Rodgers – I was disappointed earlier this year when HHS Secretary Becerra said that a number of FDA drugs were safe and effective but "nothing happened" when people took them; it continues the rhetoric that the accelerated approval pathway does not have the FDA gold standard. Do you believe this pathway is full FDA gold standard approval?

Dr. Fowler – We have looked at accelerated approval in the context of one of the models we have put forward and are working with the FDA. In terms of our view on approval and coverage, I would defer this to the CMS Center for Clinical Standards and Quality (CCSQ), which leads Medicare coverage decisions and determinations.

Chair Rodgers – The Energy and Commerce Committee has spent a lot of time fighting consolidation in healthcare and lowering prices, but I am worried that many CMMI models designed around the largest healthcare systems will fuel consolidation and make it difficult for independent providers to participate in VBC. How is CMMI working to ensure it does not incentivize consolidation?

Dr. Fowler – We believe our role is partly providing a pathway for new entrants, and this is included in the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) Model. We also consider how to maintain small independent practices, many in rural areas, and MCP is geared toward keeping practices small and independent if that is their choice.

Rep. Morgan Griffith (R-VA) – Your 17-page written testimony only uses the word "rural" one time. Has CMMI done anything to increase the quality of healthcare in rural areas outside of trying to transition to VBC?

Dr. Fowler – Rural health is very important to me. Our models aim to provide opportunities to rural providers who want to come into VBC; MCP includes a track for rural providers to receive upfront investments.

Rep. Griffith – I don't think it's working. CMMI should look at other opportunities like physician-owned hospitals or greater use of pharmacists or other use of allied health providers, or even proposals related to Stark Law.

Rep. Burgess – I agree with the need to address physician owned hospitals. In terms of budget, what would be a reasonable savings target for CMMI over the next decade?

Dr. Fowler – I'm not sure I could come up with an estimate – it depends on the rollout of the models, who comes in, and the nature of innovation. We assume we will generate savings with the models we have announced.

Rep. Burgess – CMMI has mandatory funding. What is a reasonable return on the $10 billion investment over the next decade?

Dr. Fowler – I think this relates to CMMI entering the field with the expectation of savings. We expect positive results from the models we are testing.

Rep. Burgess – Can you share the spreadsheet with the Energy and Commerce Committee on your projected financial outlays for the next decade?

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

Rep. Burgess – Has CMMI implemented any PTAC models?

Dr. Fowler – We have incorporated recommendations from PTAC in our kidney models, our primary care model, and our oncology model.

Rep. Burgess – Is there enough evidence to determine whether models with PTAC input are more likely to deliver savings?

Dr. Fowler – Every model we test goes into the field with the expectation of delivering savings. PTAC has informed our work and its recommendations have served as important points of reference, especially for kidney care.

Rep. Burgess – How many times have you met with PTAC in your three years at CMMI?

Dr. Fowler – I meet with them every time they have a meeting. I speak as part of their meeting, including offering introductory remarks this Monday on a panel about chronically ill patients. We enjoy a mutually beneficial, positive relationship.

Full Committee Ranking Member Frank Pallone (D-NJ) – CMMI has shifted the healthcare system to reward high-value healthcare, particularly ACO models that incentivize efficiency and encourage providers to take on more risk while delivering high quality care. A recent report by CBO found that ACOs led by an independent physician and ACOs with large proportions of primary care providers are associated with greater savings. Could you elaborate on CMMI's efforts to move toward paying for value and its work to encourage participation in ACOs, especially for primary care?

Dr. Fowler – We have set a goal of having 100 percent of Medicare beneficiaries and a majority of Medicaid beneficiaries aligned to an ACO or an advanced primary care provider by 2030. Primary care is the cornerstone of the strategy. The ACO Investment Model (AIM) provides upfront funding and advanced payments to providers who want to come into the model, and the ACO Primary Care Flex (ACO PC Flex) Model will provide hybrid payments. There is "more in the hopper" and more to come. The innovations we are testing should have a permanent pathway in the Shared Savings Program (MSSP).

Ranking Member Pallone – Could you share more about investments in primary care and addressing barriers to care?

Dr. Fowler – Primary care is the cornerstone of the strategy, which is not to ignore specialists. There should be incentives to enter VBC either through an ACO or an advanced primary care practice or a model. Some of that is through upfront investment funding or new incentives. MCP does not require downside risk, only performance risk for small, independent, and rural practices that want to enter VBC.

Ranking Member Pallone – Initiatives that invest in primary care and chronic disease prevention may not generate immediate savings but are likely to pay dividends over the long term through improvements in

morbidity and mortality as populations age. How do CMMI's models impact health outcomes and quality and why should this be assessed over the long-term?

Dr. Fowler – It is hard to generate savings in short-term models in areas like primary care and rural health, which have been historically underfunded. MCP is a 10-year model and thinks about giving a longer period of time for providers to generate savings. We have seen positive outcomes in quality, the patient care experience, and outcomes, and we are excited to lean into quality through the new quality pathway we have outlined.

Rep. Gus Bilirakis (R-FL) – Community health centers (CHCs) in my district are eager to participate in VBC, but many alternative payment options do not consider their role as safety net providers. Which CMMI models enroll health center participants? What is preventing more of them from participating?

Dr. Fowler – ACO REACH provided a bonus payment to providers and organizations that enrolled higher proportions of underserved populations, resulting in a 150 percent increase in safety net provider enrollment between 2022 and 2024. MCP also has an explicit track to bring community health providers into the model.

Rep. Bilirakis – There is sometimes a divide between primary care and specialty care. How is CMMI working to ensure all types of physicians have opportunities to participate in value-based payment models that reflect diversity and variety of providers?

Dr. Fowler – We have engaged nephrologists, oncologists, and other specialists in specific models. We outlined a specialty care strategy two years ago to engage more specialists, including giving more data to ACOs. The Transforming Episode Accountability Model (TEAM) also intends to engage more specialists. We are looking for more ways to integrate specialty care and primary care.

Rep. Bilirakis – As co-chair of the Rare Disease Caucus, I share concerns that the ACE Model will harm accelerated approval incentives. Is CMMI considering that manufacturers in the rare disease space may have trouble conducting confirmatory trials?

Dr. Fowler – We have worked with FDA, which believes it has the authority ensure confirmatory trials are conducted. For rare diseases, we want to ensure that if there is a reason for noncompliance, such as small patient populations, those reasons are considered. We are continuing to engage in conversations with FDA about the model.

Rep. Raul Ruiz (D-CA) – Medicare alternative payment models (APMs) like ACO REACH are practical tools to improve patient care and reduce healthcare spending, especially in rural and underserved communities. Providers participating in ACO REACH are required to develop a plan to address health disparities. Has there been an impact on efforts to advance health equity since the implementation of this model?

Dr. Fowler – Yes, and we are excited about it. The direct result of the health equity benchmark adjustment has been a 150 percent increase in safety net enrollment between 2022 and 2024. These payments are helping to engage communities and providers.

Rep. Ruiz – How has ACO REACH made tangible changes to address health disparities in underserved areas?

Dr. Fowler – We are requiring all participants to submit a health equity plan that identifies specific health disparities within respective populations and plans to address them; we are currently reviewing these plans. We are also collecting data on HRSNs, meaning providers are asking beneficiaries about their needs such as food, housing, and transportation. We are ensuring health equity is part of the evaluation so we can determine by the end of the model that we have made a difference.

Rep. Ruiz – Healthcare spending in Medicare is highly concentrated, so to address high costs, it makes sense to focus on caring for the highest needs patients, many of whom come from underserved communities. This is why the high-needs component of ACO REACH is so important – it is specifically

tailored to the specialized needs of the highest needs patients and the providers that care for them, and the model is working. In 2022, high needs participants achieved 12.6 percent cost savings compared to 1.8 percent for participants in the standard track. This is like providing outpatient resources to repeat emergency room visitors. How will CMMI ensure that providers who care for the most vulnerable patients continue to have a way to participate in ACOs after ACO REACH?

Dr. Fowler – There have been positive results from the high needs track of ACO REACH and we are evaluating what makes sense in terms of the future of these innovations and whether it is sustainable to have a specific track for high needs beneficiaries. These organizations have made recommendations for adjustments, which we are considering.

Rep. Ruiz – I would like to work with you on those considerations. Does CMMI have plans to address the challenges faced by providers and patients in rural areas specifically?

Dr. Fowler – Rural health has been subject to underinvestment, which makes it hard to develop a model that generates savings. We have not given up and are exploring potential options.

Rep. Larry Bucshon (R-IN) – It sounds like we are talking about saving healthcare dollars by squeezing the money out of providers. I want to talk about solutions to the lack of competition: lifting the moratorium of physician-owned hospitals, the effects of state-based certificate of need lacks, reforming 340B, reimbursement cuts based on inflation, and site neutrality. CMMI is not going to save the kind of money the healthcare system needs to save. Members are quick to criticize CMMI because we do not have insight into the decisions it has made. CMMI solicits information from public health and payment provider experts but mostly ignores feedback in my opinion. Do you agree that clinicians are a good source and that their feedback should be prioritized?

Dr. Fowler – Yes, and we try to prioritize input both from providers who are impacted by our models and those who want to join but do not see a pathway. This feedback is a gift.

Rep. Bucshon – How many presentations has CMMI given at PTAC public meetings?

Dr. Fowler – I have spoken at every PTAC meeting that has happened since my time at CMMI.

Rep. Bucshon – How many PTAC models has CMMI adopted? I don't think a model has been approved through the PTAC pathway.

Dr. Fowler – It takes 18 to 24 months to generate an idea, announce a model, and then implement it. During that time, we have conversations with budget people, actuaries, and payment experts, and what comes out at the end is not what originally went into the process.

Rep. Bucshon – The answer is zero.

Dr. Fowler – PTAC's input has been helpful.

Rep. Bucshon – I know the Kidney Care Choices (KCC) Model precedes your tenure at CMMI. CMS recently decided to apply a Retrospective Trend Adjustment (RTA) to the Comprehensive Kidney Care Contracting (CKCC) option; I have heard from nephrologists and stakeholders that it could reduce participation and reverse progress from the model. Have any participants withdrawn since the announcement of changes for 2024 with no relief for 2022 and 2023?

Dr. Fowler – Kidney care is one area where we feel new entrants and innovation are "a direct result of the models we've been testing." We had 100 participants, and we now have approximately 80.

Rep. Tony Cardenas (D-CA) – Despite high costs of medical care, the U.S. has some of the worst healthcare access and poorest outcomes, especially among marginalized communities. FFS payment has incentivized providers to make money off more activity rather than encouraging them to generate

profits based on keeping people healthy and reducing disparities. How is CMMI working to move beyond FFS to improve outcomes?

Dr. Fowler – Moving toward VBC is a critical component of addressing health equity. We want to reach all communities, which is why we are working to enroll providers from all parts of our communities, including rural and underserved areas, and ensuring providers serve diverse patient populations. Data collection is important, especially for HRSNs like food insecurity, housing, and transportation. The Value-Based Insurance Design (VBID) Model includes a requirement starting in 2025 to address two out of three of those HRSNs as a condition of model participation. We hope to test innovative features to incorporate in Medicare and Medicaid in the future.

Rep. Cardenas – It sounds like you recognize that this is multi-dimensional and are trying to address it.

Dr. Fowler – Yes. We are trying to tackle it from multiple angles.

Rep. Cardenas – Do you believe CMMI has delivered cost savings and increased quality in ways that may not be measured in overall model evaluations with efforts such as advancements in incorporating health equity, screening for HRSNs, and navigation support?

Dr. Fowler – We believe there has been a greater impact than an evaluation of a single model may suggest and that there has been a spillover impact among providers who care for patients outside these models and providers who do not participate in these models but are adopting these best practices. We believe we have improved healthcare and are moving toward a more patient-centered system.

Rep. Cardenas – CMMI has reached more than 30 million patients through 50 models in its first 10 years and has been a leader in the VBC movement. I look forward to continued collaboration to develop models that reduce disparities and pave the way for health equity.

Rep. Buddy Carter (R-GA) – CMMI's authority is to test new models with the goal of saving money, but CMMI has failed to generate savings. The ACA included provisions making it difficult to review CMMI models from the outside. How does CMMI ensure its models' statutory requirements are met?

Dr. Fowler – We are a careful steward of public dollars and use funding as Congress intended.

Rep. Carter – It appears the program is not working, and Congress does not have input. Are you familiar with the Doctors Caucus?

Dr. Fowler – Yes, and we welcome input.

Rep. Carter – I would encourage you to work with the Health Subcommittee to establish a permanent mechanism for Congressional input and oversight.

Dr. Fowler – We value Congressional and stakeholder input on models.

Rep. Carter – Do you believe CMMI has been successful at improving patient outcomes and lowering costs?

Dr. Fowler – Yes.

Rep. Carter – At lowering costs?

Dr. Fowler – Some models have generated savings.

Rep. Carter – How many?

Dr. Fowler – Six models have generated statistically significant net savings; more models have generated savings on a gross basis but may not have a net impact when accounting for things like investments in primary care. We still think that for every model we have tested, we have learned something important.

Rep. Carter – We value learning, but we are "looking to stop the bleeding" of this country's debt. CMMI has launched more than 50 models, but only four have ever qualified to be expanded.

Dr. Fowler – We think the learnings and results have informed CMMI's work going forward and have been valuable to providers participating in the model.

Rep. Carter – CMMI did not use the entirety of its first $10 billion allocation and CBO projects it will also not exhaust its second tranche of funding. Do you believe $10 billion is appropriate?

Dr. Fowler – It takes 18 to 24 months to get a model into the field, which may account for the first decade. We have a plan for the second decade to spend the money that has been allocated to the Innovation Center.

Rep. Carter – I am disturbed that this program has escaped Congressional review and input. Please use this Subcommittee.

Dr. Fowler – We welcome input.

Rep. Kim Schrier (D-WA) – I echo the offer to work with you. I support innovation in general and want to thank you for the effort to transition the health system toward VBC models. Not every CMMI model is successful, but better health outcomes have been achieved through CMS innovation. As a physician, I have been a strong advocate for ACOs and the way patients are able to access more coordinated care and individualized treatment plans. In Washington state, ACOs saved $104.5 million for Medicare in 2021 and 2022. I am concerned that CMMI's current standards for program expansion might be too prohibitive – for example, the Medicare Care Choices Model (MCCM) showed substantial Medicare savings and care quality improvements but could not be expanded or certified due to low participation. What are the next steps for cases like this when there is a small sample size that performs well? Are there statutory barriers?

Dr. Fowler – MCCM reduced 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 it did not meet standards for generalizability. We have, however, built those innovations and regulatory flexibilities into future models like ACO REACH and AHEAD. This is one reason why it is hard to look at one number and determine overall success based on only six models.

Rep. Schrier – There is a lot to be learned here, and maybe a meeting with the Doctors Caucus could help us understand these standards and make improvements so we can get more of these authorized. Patients generally prefer this kind of care. On another note, what is the current state of pediatric VBC – are there specific CMMI models, and what are the results?

Dr. Fowler – When we look at our future portfolio, we consider gaps. Pediatrics is an area where we have not done a lot of tests. We have the Integrated Care for Kids (InCK) Model. We are starting to consider this gap. There may be challenges in this area, but we are interested in exploring this road if we can.

Rep. Schrier – I would love to work with you on this, particularly regarding mental health.

Rep. Mariannette Miller-Meeks (R-IA) – The healthcare system is subject to waste, poor health outcomes, and fragmented care. ACO models often fail to produce real savings to the Medicare program, and the value of physician investment in value-based arrangements is overburdensome or lagging. Physicians feel unheard by CMMI when it comes to creating new models, and the majority of models have not saved money. CMMI should engage the specialist community directly rather than working through consolidated entities. Are there enough approved APMs for all physician practices to participate, particularly specialty practices? Does the current environment allow all practices to move to VBC models?

Dr. Fowler – There is room for more engagement with specialists, which is why we outlined a specialty care strategy a couple years ago to identify ways to engage specialists in accountable care and in VBC more broadly. This is one of our goals for the future.

Rep. Miller-Meeks – Do you believe PTAC has a role in the creation of APMs?

Dr. Fowler – Yes, and we have had excellent engagement and consider PTAC an important partner that has informed a lot of our direction.

Rep. Miller-Meeks – Do you think there more opportunities to engage with physicians, especially specialists, for the APM model? Or their specialty organizations? I have heard from physicians that there is not engagement.

Dr. Fowler – I welcome the opportunity to talk with them.

Rep. Miller-Meeks – One of the focuses of the Center under this Administration has been on reducing challenges for various populations, including rural groups. Kidney disease disproportionately affects this population, and CMS has attempted to address this disparity through a number of actions, including the CKCC Model. Recent decisions by CMS to adjust the benchmark for 2022 and 2023 retroactively has put this successful model at risk financially. I applaud that CMS has recognized the issue and announced changes to limit the impact of the RTA for 2024, but nothing has been done for 2022 or 2023. Did any kidney model participants withdraw after the changes were announced?

Dr. Fowler – The RTA is part of models and is there both to protect the Trust Fund and participants if projections that go into benchmarks change in any direction. There was a lot of uncertainty coming out of the pandemic and the public health emergency (PHE), which affected projections. We have worked to address the RTA from 2024 on through corridors. We started the year with 100 participants, and we are at 80 participants currently.

Rep. Miller-Meeks – We should reconsider the RTA for 2022 and 2023.

Rep. John Joyce (R-PA) – The transition to VBC as envisioned under the Medicare Access and CHIP Reauthorization Act of 2015 (MACRA) "has left a lot to be desired." Based on the latest data, most physicians are still stuck in the Merit-Based Incentive Payment System (MIPS) instead of participating in an APM. Increases in APM participation seem to be driven by existing APM expansion rather than the creation of new options for those who are looking to participate. Is CMMI doing enough to get doctors into APMs?

Dr. Fowler – Thank you for extending the bonus payment for APMs – it is an important incentive to join. We aim to move as many providers as we can into APMs; this is one of our stated goals. There may not be enough models for everyone to join but we are continuing to think about how we can do more to incentivize this.

Rep. Joyce – Are you looking to create new models and more opportunities to engage physicians and practices to participate?

Dr. Fowler – Yes, and in forthcoming rules I hope we can give more signals about potential directions.

Rep. Joyce – What is a timeline for this?

Dr. Fowler – We would like to see all Medicare beneficiaries in ACOs or advanced primary care by 2030, which will necessarily involve engaging specialists in VBC. We are looking for additional pathways.

Rep. Joyce – Are there pathways to expedite that?

Dr. Fowler – We hope so.

Rep. Joyce – Many specialty physicians have invested significant time and resources to develop models and submit them through PTAC, but there is a gap between PTAC recommendations and CMMI's implementation. Why have CMMI and CMS largely ignored PTAC recommendations? How are these valuable insights being considered?

Dr. Fowler – PTAC is an important partner – I was just at its meeting and spoke publicly to its forum on Monday. There was a specific CMMI panel to discuss learnings from our specialty care models and models that target seriously ill and chronically ill populations. We have reviewed all PTAC recommendations which have informed many of our models, including in kidney care, oncology, and primary care.

Rep. Joyce – PTAC collaboration is important. In my home state, the Pennsylvania Rural Health Model (PARHM) is set to wind down at the end of the year and be replaced with a one-size-fits-all equity-focused model. Collaborating with state governments should be an important component. How does CMMI expect this change to help rural patients?

Dr. Fowler – We are currently in discussions with the state of Pennsylvania about what happens to the model.

Rep. Joyce – Were there benefits from the model?

Dr. Fowler – We think there were benefits.

Rep. Joyce – How will those benefits translate to a one-size-fits-all model?

Dr. Fowler – Unfortunately, PARHM did not generate savings on a net basis so it is not a model we can continue. We have offered to work with the state to figure out what comes next and ensure a smooth transition.

Rep. Joyce – What timeline should we expect to see for that model for rural districts?

Dr. Fowler – There is an automatic two-year transition.

Rep. Diana Harshbarger (R-TN) – CBO reports CMMI has spent $7.9 billion on operating models but it has a mandatory appropriation of $10 billion over 10 years. What happens to the unspent balance?

Dr. Fowler – Under the statute, the funding remains; we have a plan to use all spending that has been appropriated to the Innovation Center.

Rep. Harshbarger – Did CMMI spend $2.1 billion on staffing and administration?

Dr. Fowler – I do not have those figures in front of me but would be happy to get back to you.

Rep. Harshbarger – How many people work at CMMI?

Dr. Fowler – Approximately 500.

Rep. Harshbarger – What fraction of CMMI staff have experience operating health plans, hospitals, clinics, or pharmacies?

Dr. Fowler – Our aim is to bring in all sorts of experts to the Innovation Center. We have a great staff with a variety of expertise and experience, including having worked in plans and in practices. I am pleased with their ability to translate what they see in the world into the models and the work we do.

Rep. Harshbarger – It is important for the workforce to have real world experience with these operations and businesses so that CMMI gets results.

Dr. Fowler – We aim to have a diverse set of expertise and experience.

Rep. Harshbarger – We need people with real life experience in these positions. CBO estimates that CMMI costs money rather than producing net savings for the federal government. Should CMMI funds be directed toward improving the physician fee schedule (PFS)?

Dr. Fowler – We learn from every model we test, and we have a plan to use the funding that has been allocated.

Rep. Harshbarger – What is the timeframe for determining a model's success?

Dr. Fowler – Initially, probably three to five years, but what we have found is that it takes a while for providers that have joined the model to get up and running, make investments, and build the expertise and the platform to be successful. We are trying to consider longer models that give providers more of a runway.

Rep. Harshbarger – Maybe five to ten years?

Dr. Fowler – It depends on the model. We are starting a primary care model on July 1st that will run 10 years to provide more predictability.

Rep. Harshbarger – It is still voluntary, correct?

Dr. Fowler – Yes.

Rep. Harshbarger – That is something I struggle with. It is my understanding that the six successful models have miniscule improvements. Can you explain the difference between statistical and clinical significance when it comes to success?

Dr. Fowler – The Oncology Care Model (OCM), which did not generate the certification, has still made a tremendous difference in the care provided to Medicare patients undergoing chemotherapy through access to a hotline, keeping people out of the hospital, and more person-centered care, and yet it did not result in net savings because of these monthly investments. We used the learnings from that model to test the Enhancing Oncology Model (EOM) that starts in July.

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