CATHY McMORRIS RODGERS, WASHINGTON
CHAIR

FRANK PALLONE, JR., NEW JERSEY
RANKING MEMBER

ONE HUNDRED EIGHTEENTH CONGRESS

Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
2125 RAYBURN HOUSE OFFICE BUILDING
WASHINGTON, DC 20515-6115
Majority (202) 225-3641
Minority (202) 225-2927

July 2, 2024

Dr. Elizabeth Fowler, Ph.D., J.D.
Deputy Administrator and Director
Center for Medicare and Medicaid Innovation
7500 Security Boulevard
Baltimore, MD 21244

Dear Dr. Fowler:

Thank you for appearing before the Subcommittee on Health on Thursday, June 13, 2024, to testify at the hearing entitled "Checking-In on CMMI: Assessing the Transition to Value-Based Care."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions with a transmittal letter by the close of business on Thursday, July 18, 2024. Your responses should be mailed to Emma Schultheis, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, DC 20515 and e-mailed in Word format to Emma.Schultheis@mail.house.gov.

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,

Brett Guthrie
Chair
Subcommittee on Health

cc: Anna Eshoo, Ranking Member, Subcommittee on Health

Attachment

Attachment — Additional Questions for the Record

The Honorable Robert Latta

1. Since it is estimated that 40% of people with HIV are insured through Medicaid, and given the new CDC recommendation that all sexually active adults and adolescents be informed about HIV prevention, how is CMMI incorporating HIV treatment and prevention in the new primary care models?

2. Can CMS provide specific examples of how this model tests value-based principles rather than simply implementing additional layers on innovative therapies?

    a. Please define the specific barriers to value based agreement adoption that states cannot do on their own.

    b. What exact gaps is CMMI filling for the states that they could not do on their own?

The Honorable Larry Bucshon, M.D.

1. Medicare and Medicaid spend significant sums treating patients with End-Stage Renal Disease (ESRD). While there have historically been few treatment options for patients with earlier stages of kidney disease before they crash into dialysis or need a kidney transplant, the FDA has recently approved a number of new such therapies, including for rare kidney disease. Meanwhile, providers and payors are increasingly exploring ways to better identify and treat patients with earlier stages of kidney disease. These developments present a significant opportunity to reduce Medicare and Medicaid costs, while simultaneously improving patient outcomes for the programs' beneficiaries. How does CMMI intend to leverage its authority to improve care for Medicare and Medicaid beneficiaries with earlier stages of kidney disease in order to prevent or delay the need for dialysis and transplant?

2. While ESRD provides an independent basis for Medicare eligibility, the same is not true for kidney disease generally. Therefore, many kidney disease patients under age 65 remain enrolled in non-Medicare plans. Improving the care for these patients has the potential to save Medicare money by delaying Medicare eligibility based on ESRD and ensuring patients are healthier (and less costly) when they do enroll. Notably, CMMI has tested some models that involve "multi-payer alignment," in which non-Medicare payors align their payment and coverage policies with those of the model. CMMI has not historically involved non-Medicare payors in its kidney models, however. Although CMMI has recently proposed to involve non-Medicare payors in the new Increasing Organ Transplant Access (IOTA) model, this does not address the needs of early-stage kidney disease patients. How does CMMI intend to align incentives across payors to improve care for beneficiaries with earlier stages of kidney disease before their kidneys fail and they need dialysis or a transplant?

The Honorable Earl "Buddy" Carter

1. Can you tell me how many actively practicing pharmacists you have on staff?

    a. Actively practicing nurse practitioners?

2. As a long-time supporter of telehealth and the lead sponsor of the Telehealth Modernization Act, I have been interested in the opportunities digital health can provide in increasing access and decreasing costs in the Medicare program. One area that I know CMS still struggles with is how to cover and reimburse for software as a medical device under existing benefit categories and statutory requirements. Software as a medical device, or SaMD, is "software intended to be used for one or more medical purposes that perform these purposes without being port of a hardware medical device," and the use of SaMD is greatly increasing, but CMS is not keeping pace. Given CMMI isn't subject to the same statutory restrictions as traditional Medicare, is CMMI exploring coverage pathways for SaMD or working to support these efforts throughout CMS?

3. While I support improving patient quality of care, I'm concerned that the proposed Transforming Episode Accountability Model (TEAM) would force hospitals in my district to participate regardless of their size or financial position to make a successful transition to a mandatory bundled payment model. Dr. Fowler, what steps will CMS take to evaluate suggestions to make participation voluntary and give organizations the autonomy to choose the episodes they believe will best improve the quality of care for their patients while achieving cost savings?

4. Given the disproportionate prevalence of COPD in the Medicare-aged population, which the CDC indicates is the sixth leading cause of death in the United States, can you tell us how CMMI is addressing COPD?

5. Data suggests that the prevalence of COPD in rural areas is almost twice that of in urban areas. Can you tell us how CMMI is addressing this rural health disparity?

    a. Are there any programs specific to making it easier for Americans in rural areas to get diagnosed and treated for COPD?

6. Data suggests that the vast majority of people living with COPD are under the care of a PCP. Can you tell us what CMMI is doing to support PCPs caring for COPD patients, especially PCPs in rural areas where access to pulmonologists may be more limited?

7. A central goal of MACRA was to move us away from a fee-for-service health care model to a system of value-based payment through the use of alternative payment models. Unfortunately, many specialty physicians wishing to move beyond fee-for-service will find that not a single physician-focused alternative payment model is available because none of the models approved by the Physician-Focused Payment Model Technical Advisory Committee (PTAC) have been tested as proposed. While numerous proposals have been recommended for testing or implementation by the PTAC, CMMI has not

moved forward with any of them. Dr. Fowler, how can Congress move the needle to make sure stakeholder-developed value-based care models for specialty medicine are put into practice?

8. Innovation requires the development of novel strategies to solve tricky problems as well as a willingness to iterate by testing multiple ideas and keeping and improving upon what works while discarding what is ineffective. Unfortunately, CMS has shown little willingness to test novel strategies, such as clinician-developed models recommended by the Physician-Focused Payment Model Technical Advisory Committee (PTAC). Dr. Fowler, isn't it possible that models developed by clinicians and specialty societies might have novel ways of improving care or increasing efficiency that current CMS models have not considered?

9. The ETC model is a mandatory model, one that is currently showing no evidence of improvement in home dialysis and transplant rates. Will CMMI make methodology improvements to the model such as focusing on improvement versus achievement or changing measures to be actionable and better aligned with current clinical practice?

10. The Administration's goals to increase both utilization of home dialysis and access to kidney transplantation are laudable, however, as currently designed, it appears the ETC Model will not realize those goals and will end up penalizing the providers (clinicians and dialysis facilities) included in the mandatory model. These ETC penalties will put further strain on physician reimbursement and continue to worsen the viability of some dialysis facilities, impacting providers' ability to expand home dialysis and increase transplant rates in more underserved areas. Given the model design flaws, what steps will CMMI take to mitigate these penalties to physicians and dialysis providers?

11. The GUIDE model highlights and advances key goals of the National Plan to Address Alzheimer's, including the goal to enhance care quality and efficiency. This plan, which was established by the National Alzheimer's Project ACT (NAPA), has increased action to maximize the quality of care for those living with Alzheimer's and other dementia, and their caregivers. Dr. Fowler, can you explain how the GUIDE model is expected to benefit the almost 7 million people living with Alzheimer's and their caregivers?

12. I am concerned that the Accelerating Clinical Evidence (ACE) Model would impede on FDA's authority, which itself has authority over clinical trials and the AAP and was glad that CMS announced last October that it was not moving forward with implementation and would continue to "monitor" data on trial completion There are a variety of reasons why a confirmatory trial may not be complete, such as the fact that the population cohorts in the study, such as rare disease patients, may be too small and it is difficult to enroll many people over time, or it could take years to see benefit in some diseases such as Alzheimer's. The FDA consistently monitors and receives updates on these trials from manufacturers. Can you confirm that CMS is not moving forward with this model?

    a. If CMS were to move forward, can you explain what expertise CMS has to make judgements based upon confirmatory trial completion?

The Honorable Dan Crenshaw

1. Most CMMI has implemented a Cell and Gene Therapy (CG&T) access demonstration project that would have CMS at the federal level negotiate innovative payment models with cell or gene therapy innovators on behalf of state Medicaid programs. I understand CMMI is currently talking to cell and gene therapy innovators and to states about participating in the model. Specifically, how many states have signed up to participate in the demonstration as of June 2024?

    a. The model seems to focus primarily on cost reduction through price negotiations via supplemental rebates. Is this model different from price controls?

2. Last year, CMMI proposed a model that would potentially decrease payments to Medicare Part B providers prescribing drugs approved through FDA's Accelerated Approval pathway until confirmatory studies are complete. As CMS appreciates, the purpose of the accelerated approval pathway is to allow for earlier approval of drugs that treat serious conditions and fill an unmet medical need based on a surrogate endpoint, with a post-marketing requirement to confirm clinical benefit. FDA applies the same gold standard of safety and efficacy to all drugs approved, including drugs approved through the accelerated approval pathway. CMMI's model appears to undermine FDA's authority and undervalues a drug approved through the accelerated approval pathway.

    FDA approves an Accelerated Approval drug as "safe and effective" based on studies that demonstrate that drug's effect on a surrogate or intermediate clinical endpoint, and studies must be "adequate and well controlled" as required by law. Do you believe FDA's clinical review teams aren't appropriately assessing whether these studies are adequate and well-controlled and therefore they lack the ability to judge whether the drugs are "safe and effective"?

    a. The FDA's mission is "safe and effective." CMS' mission is coverage that is "reasonable and necessary." Given that accelerated approval is an FDA approval, can you explain how you plan to not undercut the work of the FDA and prolong the Valley of Death for coverage with the proposed CMMI model for accelerated approval?

3. Constituent practices in my district participate in the ACO Reach Program. The program is set to terminate in 24 months—Can you give us any insight into the future of the model?

    a. Are you considering recommending that it become part of the MSSP program?

The Honorable John Joyce, M.D.

1. We have concerns that CMMI's Kidney Care Choices (KCC) Model presents obstacles to patient access for new and innovative drugs. While other models implemented by CMMI focused on hospital payments, including the recently proposed Transforming Episode

Accountability Model (TEAM), include mechanisms to ensure that patients have access to new and innovative treatments by allowing Medicare's approved transitional payments for them to bypass the benchmarks or target amounts, the KCC model does not do this for Transitional Drug Add-on Payment Adjustment (TDAPA) payments made under the End Stage Renal Disease (ESRD) benefit. The result has been that the vulnerable population of ESRD patients aligned with this model do not have access to these new and innovative treatments like regular (non-aligned) Medicare fee-for-service patients. Why does CMMI have policies to support access to new and innovative treatments for hospital focused models but not in the ESRD focused models, particularly given the need to support innovation in care for this vulnerable population?

a. Will CMMI consider a change in the payment structure of the KCC Model to ensure beneficiary access to new and innovative TDAPA drugs?

The Honorable Troy Balderson

1. What is CMMI doing to facilitate the adoption of digital health, such as innovative devices and technology or artificial intelligence?

2. Last year, within the V-BID model, CMMI continued offering Medicare Advantage (MA) plans the ability to cover innovative technology and FDA-approved devices to low-income patients with chronic diseases. One MA plan took advantage of this flexibility to offer access to continuous glucose monitoring devices for patients with diabetes, and remote patient monitoring devices for patients with congestive heart failure. Are you able to share any results from patient outcomes or plan savings from this model?

    a. Why did CMMI choose to discontinue this flexibility?

3. Is CMMI exploring the opportunities technologies like AI present in streamlining the administrative tasks of value-based care?

    a. Do you believe that reduced burden will help with uptake of value-based care?

4. Digital health is a key component of the transition to value-based care. However, we need more information on the use and efficacy of digital health tools in Medicare and Medicaid. What data, if any, do you currently collect on the use of telehealth by Medicare and Medicaid providers and patients?

    a. How does this data get reported to Congress?

    b. What data do you need to ensure digital health technologies are fully utilized by Medicare and Medicaid providers and patients?

The Honorable Dianna Harshbarger

1. Dr. Fowler, I really appreciate that CMMI is trying to improve the quality of care and experience of cancer treatment for patients and their families with the Enhancing Oncology Model, or EOM as you all call it. I have family members and friends who have survived, and some have passed away from the disease, and know how difficult it can be. It sounds like the additional services available to patients participating in the model can be very helpful, like having individual care plans for patients and 24/7 access to clinicians. While I appreciate your intentions, however, I am deeply concerned that the way the EOM is designed could prevent Medicare beneficiaries from having access to all of the new and innovative cancer treatments that will soon be coming available. Here, I am specifically speaking about this one technical element in the model's design known as the 'novel therapy adjustment."

   My understanding is that you included this technical adjustment so that clinicians participating in the EOM will not be penalized financially for giving patients these new and innovative anti-cancer treatments that we all know can be costly. Now, I would like to be clear that I like the intention you have here, but my concern is that not all new cancer therapies are eligible for it — you have limited it to only drugs and not included other types of innovative cancer therapies that prolong patients' lives. For example, there is an innovative technology under review at the FDA right now called Tumor Treating Fields, that clinical studies show extends patient survival in metastatic non-small cell lung cancer. But because Medicare covers this innovative treatment as durable medical equipment, or DME, and not as a drug, it is not eligible for this technical "novel therapy adjustment." Without it, I am very concerned that clinicians won't prescribe this life-extending therapy to Medicare beneficiaries.

   Can you assure me that you will make changes to the EOM so that patient access to this treatment will not be jeopardized once innovative new cancer treatment gets approved? The goal of the EOM is to improve the quality and experience of cancer care, and it just seems clear to me that ensuring patient access to life-extending treatment is a critical component of that overarching goal.

The Honorable Mariannette Miller-Meeks, M.D.

1. Director Fowler, the success of value-based care hinges on many things, including timely and accurate data sharing with clinicians participating in value-based care models. Is CMMI exploring the use of AI to better share quality program data with clinicians to allow them to succeed?

2. Director Fowler, how does CMMI plan to approach diminishing or unstable incentives to keep practice groups in value-based arrangements?

3. Director Fowler, regulations and reporting requirements vary widely across various models which increases the burden on practices. What are your thoughts on decreasing regulations or standardizing them to decrease administrative burden?

4. Dr. Fowler, in many models, CMMI has excluded from episode expenditures the add-on payments for innovative new technologies and therapies allowing the inpatient hospital new technology add-on payments (NTAPs) and outpatient hospital pass-through payments not to be subject to the model benchmarks or target prices. These models include:
    - Bundled Payments for Care Improvement (BPCI),
    - Bundled Payments for Care Improvement Advanced (BPCI-A),
    - Comprehensive Care for Joint Replacement (CJR),
    - The proposed Transforming Episode Accountability Model (TEAM).

    CMMI's stated rationale has been "it would not be appropriate for [the model] to potentially diminish beneficiaries' access to new technologies or to burden hospitals who choose to use these new drugs, technologies, or services with concern about these payments counting toward [the model] participants' actual episode spending" (See 80 FR 73308 for CJR (11/24/2015) and 89 FR 36417 for TEAM (May 2, 2024)). Similarly, CMMI's cancer models have included novel therapy adjusters to capture the full cost of newly approved therapies for model participants. However, in CMMI's Comprehensive Kidney Care Contracting model, which is also a total cost of care model, CMMI does not make adjustments for new and innovative therapies that have been determined by CMS to merit a similar add-on payment under the ESRD benefit. This model design choice is acting to diminish beneficiaries' access to new drugs, technologies or services. Please explain why CMMI takes steps to ensure beneficiary access to new and innovative therapies in many of its models, but has not done so in its kidney care models, an area where innovation in care is badly needed?

5. Dr. Fowler, the existing End Stage Renal Disease Payment System includes payments for innovative therapies and technologies under the Transitional Drug Payment Add-on Adjustment (TDAPA) and Transitional Add-on Payment Adjustment for New and Innovative Equipment and Supplies (TPNIES). In CMMI's Comprehensive Kidney Care Contracting (CKCC) Model, the expenditures of kidney contracting entities (KCEs) do include their spending on these new therapies. However, the KCE expenditures are compared to benchmarks that do not include projected spending for these add-on payments. In addition, since KCEs share in any savings and losses relative to the benchmark, there is a financial disincentive to provide these newest therapies since that spending will be considered an overage above their benchmark and lead to losses. What is the rationale for including spending on innovative therapies in KCE expenditures but not including projected expenditures on innovative therapies in benchmarks?

    a. Why did CMS not allow these payments to be made not subject to the benchmarks, similar to other models for hospitals, understanding that its approach under the CKCC model will disincentivize beneficiary access to these new and innovative treatments?

6. In order to assess whether this policy negatively affects access to innovative therapies, I request that CMMI track utilization of TDAPA and TPNIES therapies [and technologies] within and outside the model and include this information in model evaluations in order

to quantify the utilization difference occurring due to this disincentive in the model reimbursement structure. Please respond to the feasibility of this request.

The Honorable Tony Cárdenas

1. Will CMMI make methodology improvements to the End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model such as focusing on improvement versus achievement or changing measures to be actionable and better aligned with current clinical practice?