Questions for the Record for
Deputy Administrator and Director of the Center for Medicare and Medicaid Innovation Elizabeth Fowler
Committee on Energy and Commerce, Subcommittee on Health Hearing:
"Checking In on CMMI: Assessing the Transition to Value-Based Care"
Thursday, June 13, 2024

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?

Answer:

We share your commitment to improving care coordination, quality, and outcomes for individuals with chronic conditions, including HIV. The Innovation Center has tested several models that improve primary care through advanced primary care payments and support patients' longitudinal care with their primary care provider which will likely support conversations around HIV prevention with sexually active adults and adolescents. These models include patient experience of care surveys that assess care received from their provider.

The Making Care Primary (MCP) Model seeks to improve care for patients by expanding and enhancing care management and care coordination, equipping primary care clinicians with tools to form partnerships with health care specialists, and leveraging community-based connections to address patients' health needs as well as their health-related social needs (HRSN).

Additionally, the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) Model builds on CMS' ten years of experience with accountable care initiatives, such as the Medicare Shared Savings Program, the Pioneer ACO Model, and the Next Generation ACO Model. The ACO REACH Model provides novel tools and resources for health care providers to work together more closely to improve the quality of care for people with Traditional Medicare. Under the ACO REACH Model, CMS uses an innovative payment approach to better support care delivery and coordination for people in underserved communities. REACH ACOs are responsible for helping all different types of health care providers — including primary and specialty care physicians — work together, so people get the care they need when they need it. In addition, people with Traditional Medicare who receive care through a REACH ACO may have greater access to enhanced benefits, such as telehealth visits, home care after leaving the hospital, and help with co-pays. They can expect the support of the REACH ACO to help them navigate an often complex health system.

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?

Answer:

CMS is testing new value-based principles such as outcomes-based agreements between drug manufacturers and states. In January 2024, the Biden-Harris Administration announced that sickle cell

disease (SCD) will be the first focus of the Cell and Gene Therapy (CGT) Access Model, which was initially announced in February 2023. The model is designed to improve health outcomes, increase access to cell and gene therapies, and lower health care costs for some of the nation's most vulnerable populations. Given the relatively small population impacted by SCD in some states, without CMS serving as a mediator and broker for these agreements across multiple states, states may not have the leverage on their own to negotiate these agreements with manufacturers of expensive cell and gene therapies. The model will test outcomes-based agreements (OBAs) for groundbreaking CGTs. Successful OBAs will increase affordable access to potentially lifesaving and life-changing treatment.

CMS will partner with participating states and manufacturers to build a framework that expands access to gene therapies for the treatment of SCD. Under the model, CMS will negotiate an OBA with participating manufacturers, which will tie pricing for SCD treatments to whether the therapy improves health outcomes for people with Medicaid. Negotiations will also include additional pricing rebates and a standardized access policy. Participating states will then decide whether to enter into an agreement with manufacturers based on the negotiated terms and offer the agreed-upon standard access policy in exchange for rebates as negotiated by CMS. As part of the CGT Access Model, CMS will negotiate financial and clinical outcome measures with drug manufacturers and then reconcile data, monitor results, and evaluate outcomes. The CGT Access Model will begin in January 2025, and states may choose to begin participation at a time of their choosing between January 2025 and January 2026.

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?

Answer:

The Center for Medicare and Medicaid Innovation's Kidney Care Choices (KCC) Model builds upon the Comprehensive End Stage Renal Disease (ESRD) Care (CEC) Model structure – in which dialysis facilities, nephrologists, and other health care providers form ESRD-focused accountable care organizations – by adding strong financial incentives for health care providers to manage the care for Medicare beneficiaries with chronic kidney disease (CKD) stages 4 and 5 and ESRD. Including Medicare beneficiaries with CKD stage 4 and 5 before they progress to ESRD promotes later and better starts on dialysis, or the avoidance of dialysis entirely. The model's goals include improved care, delay in the onset of dialysis, and increased rates of kidney transplantation.

The KCC Model is designed to incentivize better management of kidney disease. A group of kidney care providers is responsible for a patient's kidney care from the late stage of CKD through dialysis and post-transplant care. The patient is a key component of the Model's design. The tendency now is for patients with kidney disease to follow the most expensive treatment path, with little prevention of disease progression and an unplanned start to in-center hemodialysis treatment. By increasing education and understanding of the kidney disease process, aligned beneficiaries may be better prepared to actively participate in shared decision making for their care. The Model avoids the potential for care stinting

through risk adjustment and application of quality measures, as well as monitoring activities that will ensure beneficiaries receive needed services, while retaining freedom of choice of providers.

As of January 2024, the KCC model includes 123 Kidney Contracting Entities (KCEs) and CMS Kidney Care First (KCF) Practices, which are accountable for the quality and care of their aligned people with Medicare. The KCC Model has more than 9,227 participating health care providers and organizations, a 10% increase from 2023, serving 282,335 people with Medicare who have chronic kidney disease and end stage renal disease in 2024.

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?

Answer:
The CMS Innovation Center's vision for broad health system transformation is ambitious and requires collaboration with and actions by a wide range of stakeholders. In particular, alignment with private payers, purchasers, and states is needed to increase the number of providers participating in value-based payment models and to make their participation sustainable across payers. Achieving this vision requires working across CMS and beyond, taking a whole-of-government approach – and collaborating with employers, health plans, and states, as well as with patients, caregivers, providers, and community organizations. For example, the Health Care Payment Learning and Action Network (LAN), a public-private collaboration funded by HHS through the Innovation Center, is CMS's most public, structured, and significant mechanism for engagement and partnerships centered on shared value-based payment goals with external stakeholders. The LAN and its participants are critical partners in achieving the goals of multi-payer alignment by increasing the number of providers that are sustainably participating in value based payment models and to advance system transformation nationally. As future models are developed, such as the recently proposed IOTA model, the Innovation Center will continue to look for opportunities to drive multi-payer alignment, especially with Medicaid programs.

The Honorable Earl "Buddy" Carter
1. Can you tell me how many actively practicing pharmacists you have on staff?

   a. Actively practicing nurse practitioners?

Answer:
The CMS Innovation Center is fortunate to have a workforce made up of individuals with diverse skills and experiences, including practitioners who have participated in our models. The Innovation Center currently has multiple pharmacists and nurses on staff. Additionally, the CMS Innovation Center is committed to consulting clinical and analytical experts with expertise in medicine and health care management, beneficiaries, states, other Federal agencies, and Congress on the testing of models. CMS is

grateful to Congress and to the numerous stakeholders across the health care industry that have provided feedback on the model tests and potential future model tests. This feedback plays a critical role in our decisions about what models to test and we look forward to continuing this close collaboration as we build upon lessons learned to further the goals of value-based care.

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?

Answer:
CMS is exploring coverage pathways for digital services, including software as a medical device or prescription digital therapeutics. As technologies have evolved, we have sought public comment and expanded Medicare payment under Part B for use of technologies in remote monitoring of treatment and physical health. In 2018, CMS began paying for remote physiologic monitoring (RPM) services, and we have continued to improve and expand payment for remote treatment and monitoring in subsequent years. In 2022, we began paying for a new class of CPT codes for remote therapeutic monitoring (RTM) in addition to RPM, which enabled payment for monitoring of non-physiologic data, to help ensure Medicare beneficiaries have access to these services. In the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) final rule, we finalized a new remote therapeutic monitoring code for supply of a device for cognitive behavioral therapy monitoring, and in the CY 2024 PFS proposed rule, we requested information on digital therapeutics for behavioral health. Among many questions, we asked how practitioners determine which patients might be best served by digital therapeutics and how practitioners monitor the effectiveness of prescribed interventions on an ongoing basis once the intervention has begun.

In addition, as of October 2023, CMS has created billable procedural codes for "Prescription digital behavioral therapy, FDA-cleared, per course of treatment" and "Prescription digital visual therapy, software-only, FDA cleared, per course of treatment." CMS believes that establishing such codes may facilitate options for non-Medicare payers to provide access to these therapies in the home setting.

CMS also began making payment for algorithm-driven services that assist practitioners in making clinical assessments, and that providers pay for either on a subscription or per-use basis, referred to as Software as a Service (SaaS). Starting in 2018, we began making payment for the SaaS procedure Fractional Flow Reserve Derived from Computed Tomography, also known by the trade name HeartFlow, CMS has added payment for several additional SaaS codes since then, and we continue to be interested in any feedback from interested parties on this topic as we examine ways to improve our programs with the use of this emerging field.

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?

Answer:
As part of the Fiscal Year 2025 IPPS proposed rule, CMS proposed a mandatory model to test whether episode-based payments for five common, costly procedures would reduce Medicare expenditures while preserving or enhancing the quality of care. Building on lessons learned from previous models, the Transforming Episode Accountability (TEAM) Model would incentivize coordination between care providers during a surgery, as well as the services provided during the 30 days that follow, and require referral to primary care services to support continuity of care and drive positive long-term health outcomes. This model would complement other CMS value-based care initiatives by promoting collaboration with accountable care organizations. We considered making participation in TEAM voluntary. However, we would be concerned that a fully voluntary model would not lead to meaningful evaluation findings especially since the CMS Innovation Center has tested voluntary episode-based payment models for over a decade. CMS solicited comments on this proposed model. We are currently reviewing comments and will incorporate feedback as appropriate.

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?

Answer (4-6):
We share your commitment to improving care coordination, quality, and outcomes for individuals with chronic conditions, including COPD. While not solely focused on addressing COPD, the Making Care Primary (MCP) Model seeks to improve care for patients by expanding and enhancing care management and care coordination, equipping primary care clinicians with tools to form partnerships with health care specialists, and leveraging community-based connections to address patients' health needs as well as their health-related social needs (HRSN).

Additionally, the Accountable Care Organization Realizing Equity, Access, and Community Health (ACO REACH) Model builds on CMS' ten years of experience with accountable care initiatives, such as the Medicare Shared Savings Program, the Pioneer ACO Model, and the Next Generation ACO Model. The ACO REACH Model provides novel tools and resources for health care providers to work together more closely to improve the quality of care for people with Traditional Medicare. Under the ACO REACH Model, CMS uses an innovative payment approach to better support care delivery and coordination for people in underserved communities. REACH ACOs are responsible for helping all different types of health care providers — including primary and specialty care physicians — work together, so people get the care they need when they need it. In addition, people with Traditional Medicare who receive care through a REACH ACO may have greater access to enhanced benefits, such

as telehealth visits, home care after leaving the hospital, and help with co-pays. They can expect the support of the REACH ACO to help them navigate an often complex health system.

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?

Answer (7-8):
The Innovation Center's vision for broad health system transformation is ambitious and requires collaboration with and actions by a wide range of stakeholders. When designing new payment and service delivery models, the Innovation Center actively seeks input from a broad array of stakeholders across the country. For example, last year, we issued a Request for Information seeking public feedback regarding the design of a future episode-based payment model focused on accountability for quality and cost, health equity, and specialty integration (now known as the TEAM model). CMS is committed to taking under serious consideration all proposals submitted by the PTAC. We have incorporated components of PTAC proposals into a number of our models. We collaborate closely with PTAC and we've used what they've proposed in our models, including the Kidney Care Choices Model, the Enhancing Oncology Model, and the Bundled Payments for Care Improvement Advanced Model.

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?

Answer (9-10):
The End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model is an innovative payment model that aims to test whether greater use of home dialysis and kidney transplantation for Medicare

beneficiaries with ESRD will reduce Medicare expenditures, while preserving or enhancing the quality of care furnished to beneficiaries with ESRD. The ETC Model, which was finalized as part of a final rule[1] published in 2020, began on January 1, 2021 and has since been updated with improvements made through the standard comment and rulemaking process.

For example, in annual rulemaking to update the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2022, CMS finalized[2] a two-tiered approach to address disparities in home dialysis and transplant rates through the ETC Model's benchmarking and scoring methodology. This rule also finalized a process for sharing certain beneficiary attribution and performance data with ETC participating providers, and finalized an additional programmatic waiver and other flexibilities regarding kidney disease patient education services under the ETC Model. For calendar year 2023, CMS made further changes[3] to improve the scoring methodology and requirements related to flexibilities regarding kidney disease patient education services under the ETC Model. Most recently, for calendar year 2024 CMS finalized[4] modifications to the ETC Model administrative review policy.

CMS will continue to make improvements to the ETC Model through rulemaking, and the Innovation Center looks forward to upcoming evaluations of the ETC Model.

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?

Answer:
The GUIDE model aims to improve the quality of life for people living with dementia, reduce strain on unpaid caregivers and help people remain in their homes and communities through a package of care coordination and management, caregiver education and support, and respite services. Through the model, CMS will test an alternative payment for participants who deliver key supportive service to people with dementia, including comprehensive, person-centered assessments and care plans, care coordination, and 24/7 access to a support line. Under the model, people with dementia and their caregivers will have access to a care navigator who will help them access services and supports, including clinical services and non-clinical services such as meals and transportation through community-based organizations.

The model is also designed to enhance access to the assistance and resources caregivers need, a key priority of the National Plan. Evidence-based models of support for caregivers of people with dementia and dementia-capable community-based providers have been expanded over the last decade through investments in research and services by HHS and others. The model will provide a link between the clinical health care system and community-based providers to help people with dementia and their caregivers access education and support, such as training programs on best practices for caring for a loved one living with dementia. Model participants will also help caregivers access respite services, which enable them to take temporary breaks from their caregiving responsibilities. Respite has been

[1] Final Rule published in the Federal Register on September 29, 2020, titled "Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures"
[2] CY 2022 End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1749-F)
[3] CY 2023 End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1768-F)
[4] CY 2024 End Stage Renal Disease (ESRD) Prospective Payment System (PPS) Final Rule (CMS-1782-F)

found to help caregivers continue to care for their loved ones at home, preventing or delaying the need for facility care.

Through the GUIDE model, CMS aims to mitigate significant challenges of coordinating and managing health care and community-based supports and improve quality of life for patients and caregivers alike.

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?

Answer:
The Food and Drug Administration (FDA) approves certain drugs through a process called "accelerated approval" that allows for earlier approval of drugs that treat serious conditions, and fill an unmet medical need based on a surrogate endpoint. The Accelerating Clinical Evidence (ACE) Model would include Medicare Part B payment adjustments to providers for drugs approved via the accelerated approval program as a potential method to encourage the expeditious completion of manufacturer confirmatory trials. Incomplete and delayed data from confirmatory trials may result in ongoing utilization of drugs that subsequently fail to confirm effectiveness, which is concerning for patients and payers.

Feedback the Innovation Center has received, including from patient groups, providers, and manufacturers, has suggested that there is an opportunity for a model that would test ways to encourage completion of confirmatory trials. Additional review and consideration of existing authorities and the shifting mix of products entering the accelerated pathway is needed. The Innovation Center will continue to monitor these developments.

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?

Answer:
In January 2024, the Biden-Harris Administration announced that sickle cell disease (SCD) will be the first focus of the Cell and Gene Therapy (CGT) Access Model, which was initially announced in February 2023. The model is designed to improve health outcomes, increase access to cell and gene therapies, and lower health care costs for some of the nation's most vulnerable populations. The model

will test outcomes-based agreements (OBAs) for groundbreaking CGTs. Successful OBAs will increase affordable access to potentially lifesaving and life-changing treatment. CMS will partner with participating states and manufacturers to build a framework that expands access to gene therapies for the treatment of SCD. Under the model, CMS will negotiate an OBA with participating manufacturers, which will tie pricing for SCD treatments to whether the therapy improves health outcomes for people with Medicaid. Negotiations will also include additional pricing rebates and a standardized access policy. Participating states will then decide whether to enter into an agreement with manufacturers based on the negotiated terms and offer the agreed-upon standard access policy in exchange for rebates as negotiated by CMS. As part of the CGT Access Model, CMS will negotiate financial and clinical outcome measures with drug manufacturers and then reconcile data, monitor results, and evaluate outcomes. This model is different from price controls as the outcomes-based pricing will be based on health outcomes achieved from treatment received by patients, and will help make it easier for states to provide access to such therapies to people with Medicaid who are eligible for such treatments. The CGT Access Model will begin in January 2025, and states may choose to begin participation at a time of their choosing between January 2025 and January 2026.

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?

Answer:
The FDA approves certain drugs that treat serious conditions and fill an unmet medical need based on a surrogate endpoint through a process called "accelerated approval," but some drug manufacturers fail to complete confirmatory trials by the agreed upon date at the time of accelerated approval. CMS develops payment methods for drugs approved under accelerated approval, in consultation with the FDA, to encourage timely confirmatory trial completion and improve access to post-market safety and efficacy data. The Accelerating Clinical Evidence Model would test the efficacy of targeted adjustments in Part B fee-for-service payments to improve timely trial completion and reduce Medicare spending, while maintaining or improving quality of care. The model's start and end dates have not yet been announced as CMS is still in the process of compiling stakeholder input and consulting with the Food and Drug Administration on model development.

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?

Answer:
CMS Innovation Center model tests are designed to be time-limited, generally lasting five to ten years; the goal is to provide enough time to rigorously evaluate the impact of the test on care quality and program expenditures. With regard to the ACO REACH model, the CMS Innovation Center reviews all the evaluation results to determine if the model is enhancing or maintaining quality or reducing or maintaining expenditures. Every CMS Innovation Center model has resulted in important learnings and investments in the health care system that have helped clinicians move towards value-based care. Several models have informed successor generation models, and beneficial elements of models have been incorporated into permanent CMS programs, including the Medicare Shared Savings Program. We encourage providers participating in CMS Innovation Center models, including the ACO REACH model, to apply the lessons they learn during the model to continue to achieve equitable outcomes through high-quality, affordable, person-centered care. ACO REACH participants may participate in other programs, such as the Medicare Shared Savings Program or other value-based care models that may be announced.

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?

Answer:
The KCC Model is testing out a new payment model that includes accountability for cost and quality of care for aligned beneficiaries. Participating entities take on accountability for all Part A and B expenditures, with the dual goals of managing expenditures and improving care. Beneficiaries in the model are in fee-for-service Medicare and have access to all treatments covered by Medicare, including those from TDAPA. Though Innovation Center kidney models have not historically treated these separately from other expenditure categories, we appreciate the feedback and will consider a potential update to the policy.

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?

Answer (1-4):
Care innovations are part of the infrastructure needed to support the delivery of integrated, equitable, person-centered care. Measuring what matters to patients, data and tools to support care management and delivery, and learning supports are critical to the successful delivery of value-based care to more beneficiaries. In addition to model development, the Innovation Center can support system transformation through the provision of data to patients and providers on high-value care. For instance, models can include data and supports for primary care practices to make high-value specialty referrals, and ACOs can receive data to improve coordination and management of episodic care through virtual or shadow bundles. The ability to more seamlessly collect and share data that can be used to address disparities in care and outcomes is dependent on better data infrastructure. The Innovation Center will soon be posting demographic and social determinants of health (SDOH) FHIR questionnaires for public use and is exploring bulk FHIR APIs for use in health care data collection.

Agencywide, CMS is examining ways to use AI to improve health care administration and delivery. To guide our efforts, CMS released an updated Artificial Intelligence Playbook[5] in May 2024, outlining key considerations to be used when designing, developing, and deploying potential AI tools and models. The AI Playbook outlines practical frameworks and actionable insights to harness AI effectively within CMS's operations, aiming to enhance service delivery, optimize efficiency, and uphold the highest standards of care and ethical responsibility.

With regard to telehealth, CMS has posted the Medicare Telehealth Trends dataset to provide information about people with Medicare who used telehealth services.[6] CMS also posted a Medicare Telemedicine Snapshot about people with Medicare who utilized telemedicine services between March 1, 2020 and February 28, 2021. The data for the Snapshot comes from Medicare Fee-for-Service claims data,

[5] Available at: https://ai.cms.gov/assets/CMS_AI_Playbook.pdf
[6] https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-service-type-reports/medicare-telehealth-trends

Medicare Advantage encounter data, and Medicare enrollment information.[7] Many of the Innovation Center's models include waivers of the telehealth requirements.[8]

CMS is exploring coverage pathways for digital services, including software as a medical device or prescription digital therapeutics. As technologies have evolved, we have sought public comment and expanded Medicare payment under Part B for use of technologies in remote monitoring of treatment and physical health. In 2018, CMS began paying for remote physiologic monitoring (RPM) services, and we have continued to improve and expand payment for remote treatment and monitoring in subsequent years. In 2022, we began paying for a new class of CPT codes for remote therapeutic monitoring (RTM) in addition to RPM, which enabled payment for monitoring of non-physiologic data, to help ensure Medicare beneficiaries have access to these services. In the Calendar Year (CY) 2023 Physician Fee Schedule (PFS) final rule, we finalized a new remote therapeutic monitoring code for supply of a device for cognitive behavioral therapy monitoring, and in the CY 2024 PFS proposed rule, we requested information on digital therapeutics for behavioral health. Among many questions, we asked how practitioners determine which patients might be best served by digital therapeutics and how practitioners monitor the effectiveness of prescribed interventions on an ongoing basis once the intervention has begun.

In addition, as of October 2023, CMS has created billable procedural codes for "Prescription digital behavioral therapy, FDA-cleared, per course of treatment" and "Prescription digital visual therapy, software-only, FDA cleared, per course of treatment." CMS believes that establishing such codes may facilitate options for non-Medicare payers to provide access to these therapies in the home setting. CMS continues to be interested in any feedback from interested parties on this topic as we examine ways to improve our programs with the use of this emerging field.

With respect to the Medicare Advantage Value-Based Insurance Design (VBID) Model for calendar year 2025, CMS discontinued the flexibility to cover new and existing technologies and FDA-approved medical devices because there was limited participation by Medicare Advantage Organizations. Unfortunately, the limited participation did not allow for meaningful evaluation of the intervention.

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

[7] https://www.cms.gov/medicare-telemedicine-snapshot
[8] https://www.cms.gov/priorities/innovation/models

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.

Answer:
Under the Enhancing Oncology Care Model (EOM), novel therapy adjustments increase the benchmark prices for all episodes of a specific cancer type attributed to a specific EOM participant (or for all episodes of that cancer type attributed to the participants in a specific pool) for a given performance period when certain conditions are met. For each performance period, CMS identifies a set of new oncology drugs (which will be available on the EOM website) for the purposes of determining novel therapy adjustments. CMS also includes new combination therapies, as applicable, for the purposes of determining novel therapies adjustments. Only oncology drugs or combinations that received FDA approval after June 30, 2021 are considered for inclusion on the list of novel therapies. Oncology drugs or applicable combinations are considered "new" for 2 years from FDA approval for that specific indication.

We will consider additional items approved by the FDA for EOM cancer types as appropriate during the model's performance period.

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?

Answer (1-3):
The CMS Innovation Center is committed to sharing lessons learned from our models, and evaluations of our models are publicly available on the Innovation Center website. CMS is always looking for ways to securely improve data sharing that allows clinicians to review and make health care delivery decisions based on new data. Access to more actionable, close to real-time data are needed to support providers in value-based care arrangements. The CMS Innovation Center is committed to making practice-specific data on performance available and is considering options for a more interactive value-based care management system. Tools like actionable dashboards are key to giving providers access to more user-friendly information that also reduces their administrative burden of participation.

In addition, agencywide, CMS is examining ways to use AI to improve health care administration and delivery. To guide our efforts, CMS released an updated Artificial Intelligence Playbook[9] in May 2024, outlining key considerations to be used when designing, developing, and deploying potential AI tools and models. The AI Playbook outlines practical frameworks and actionable insights to harness AI effectively within CMS's operations, aiming to enhance service delivery, optimize efficiency, and uphold the highest standards of care and ethical responsibility.

This year, CMS announced increased participation in CMS' accountable care organization (ACO) initiatives in 2024, which will increase the quality of care for more people with Medicare. Of note, 19 newly formed accountable care organizations (ACOs) in the Medicare Shared Savings Program (Shared Savings Program) are participating in a new, permanent payment option beginning in 2024 that is enabling these ACOs to receive more than $20 million in advance investment payments for caring for underserved populations. An additional 50 ACOs are new to the program in 2024, and 71 ACOs renewed their participation, bringing the total to 480 ACOs now participating in the Shared Savings Program, the largest ACO program in the country. CMS also announced that 245 organizations are continuing their participation in two CMS Innovation Center models — ACO Realizing Equity, Access, and Community Health (ACO REACH) and the Kidney Care Choices (KCC) models. The Innovation Center is able to waive certain regulations that are necessary for the testing of a model and we look forward to feedback from stakeholders regarding needed waivers.

Additionally, as a part of the Innovation Center's recent strategy refresh, we plan to assess current participation requirements with an aim to reduce administrative burden. We believe that providers will also benefit from burden reduction as a result of alignment across payers on value-based care initiatives.

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?

[9] Available at: https://ai.cms.gov/assets/CMS_AI_Playbook.pdf

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.

Answer (4-6):
The KCC Model is testing out a new payment model that includes accountability for cost and quality of care for aligned beneficiaries. Participating entities, which voluntarily elect to participate in the model, take on accountability for all Part A and B expenditures, with the dual goals of managing expenditures and improving care. Beneficiaries in the model are in fee-for-service Medicare and have access to all treatments covered by Medicare, including those from TDAPA. Though CMMI kidney models have not historically treated these separately from other expenditure categories, we appreciate the feedback and will consider a potential update to the policy.

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?

Answer:
The End-Stage Renal Disease (ESRD) Treatment Choices (ETC) Model is an innovative payment model that is testing whether greater use of home dialysis and kidney transplantation for Medicare beneficiaries with ESRD will reduce Medicare expenditures, while preserving or enhancing the quality of care furnished to beneficiaries with ESRD. The ETC Model, which was finalized as part of a final rule[10] published in 2020, began on January 1, 2021 and has since been updated with improvements made through the standard comment and rulemaking process.

[10] Final Rule published in the Federal Register on September 29, 2020, titled "Medicare Program: Specialty Care Models to Improve Quality of Care and Reduce Expenditures"

For example, in annual rulemaking to update the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for calendar year 2022, CMS finalized[11] a two-tiered approach to address disparities in home dialysis and transplant rates through the ETC Model's benchmarking and scoring methodology. This rule also finalized a process for sharing certain beneficiary attribution and performance data with ETC participating providers, and finalized an additional programmatic waiver and other flexibilities regarding kidney disease patient education services under the ETC Model. For calendar year 2023, CMS made further changes[12] to improve the scoring methodology and requirements related to flexibilities regarding kidney disease patient education services under the ETC Model. Most recently, for calendar year 2024 CMS finalized[13] modifications to the ETC Model administrative review policy.

CMS will continue to make improvements to the ETC Model through rulemaking, and the Innovation Center looks forward to evaluations of the ETC Model.

[11]Final Rule published in the Federal Register on November 8, 2021, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model"

[12] Final Rule published in the Federal Register on November 7, 2022, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model"

[13] Final Rule published in the Federal Register on November 6, 2023, titled "Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, and End-Stage Renal Disease Treatment Choices Model"