STATEMENT OF

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CENTERS FOR MEDICARE & MEDICAID SERVICES

ON

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

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Chairs Rodgers and Guthrie, Ranking Members Pallone and Eshoo, and Members of the Subcommittee, thank you for the opportunity to discuss the Centers for Medicare & Medicaid Services (CMS) and the work that we do through the Center for Medicare and Medicaid Innovation (CMS Innovation Center) to test ways to improve the quality of care delivered to individuals and reduce federal spending in Medicare, Medicaid and the Children's Health Insurance Program (CHIP).

As the nation's largest payer for health care,[1] CMS plays a key role in driving the transition of the U.S. health system toward one that achieves equitable outcomes through high quality, affordable, person-centered care. Through the CMS Innovation Center, CMS tests new ways to deliver and pay for care that are expected to produce higher quality care and reduce spending, to accelerate the movement to value-based care and drive broader system transformation. We know that innovation in health care should be designed for the people it serves; its success should be measured by how well it improves health, experience, and affordability of care, and how well it supports partnerships between patients, health care providers, and other stakeholders across the system to drive transformation.

In conducting our work, 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.

[1] In 2022, the federal government accounted for 33 percent of national health spending, which totaled $4.5 trillion. *National Health Expenditures 2022 Highlights.* https://www.cms.gov/files/document/highlights.pdf

Establishment of the CMS Innovation Center

Congress created the CMS Innovation Center for the purpose of testing "innovative payment and service delivery models to reduce program expenditures while preserving or enhancing the quality of care" provided to individuals enrolled in Medicare, Medicaid, and CHIP.[2]

Since its creation, the CMS Innovation Center has implemented over 50 model tests; according to our most recent report to Congress, we estimate that these model tests impacted over 41 million patients and more than 314,000 health care providers and plans in all 50 states, territories, and the District of Columbia between October 1, 2020 and September 30, 2022.[3] Models selected for testing address populations for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures, which involve many facets of health care across the system and focus on a diverse array of care delivery approaches, payment policies, and quality improvement incentives. For example, model tests may be organized around certain specialties or procedures, like oncology or joint replacements, or a specific provider or plan type, like primary care practices or Medicare Advantage plans. In other cases, model tests may focus on addressing the holistic needs of a specific patient population, like people with dementia or substance use disorder, or on the populations of entire states or regions.

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. The CMS Innovation Center's authorizing statute[4] requires CMS to evaluate the impact of each of its model tests on care quality and program expenditures. Model test evaluations are conducted by independent external organizations and designed to be rigorous, timely, and actionable. They generally incorporate qualitative and quantitative analyses – a mixed-methods approach – and examine the impact of the model relative to a matched comparison group.

[2] Section 1115A of the Social Security Act (as added by section 3021 of the Affordable Care Act)
[3] CMS Innovation Center *2022 Report to Congress*, available at: https://www.cms.gov/priorities/innovation/data-and-reports/2022/rtc-2022.
[4] Section 1115A(b)(4) of the Social Security Act

The Secretary of the Department of Health & Human Services (HHS) has the authority to expand the scope and duration of a model test through rulemaking, which includes the authority to test a model nationwide. To exercise the authority to expand a model, the Secretary of HHS and the CMS Chief Actuary must review the CMS evaluations of the model test (as well as any other relevant information) and determine that expansion of the model test would reduce program spending without reducing the quality of care or improve the quality of care without increasing spending, and would not deny or limit the coverage or provision of benefits under Medicare, Medicaid, and CHIP.

Impact of the CMS Innovation Center

Every CMS Innovation Center model test – including those that have not met the statutory criteria for expansion – have resulted in important learnings and investments in the health care system that have helped clinicians move towards value-based care. CMS has expanded four models where the Secretary determined, and the CMS Chief Actuary certified, that the expansions were expected to result in spending reductions and preservation of the quality of care. CMS has incorporated learnings from CMS Innovation Center models across CMS programs, including testing successor models and incorporating relevant components in other programs.

CMS recently undertook a retrospective review of evidence generated by model tests[5] to understand the impact of select CMS Innovation Center model tests on enabling care delivery that better addresses patients' health and health-related social needs. The review found demonstrable evidence that the model tests were associated with enhanced care delivery by model participants, including increased use of strategies such as care coordination, team-based care, and using data to risk-stratify patients, which may lead to better patient outcomes at lower cost. In addition, the review found that care delivery trends and changes associated with the model tests extend beyond the CMS Innovation Center model tests themselves, with elements of model tests being incorporated into how clinicians furnish services even after the model test ends, because the clinicians have found the elements lead to improved quality and reduced costs.

[5] New England Journal of Medicine, "Accelerating Care Delivery Transformation — The CMS Innovation Center's Role in the Next Decade". Available at https://catalyst.nejm.org/doi/full/10.1056/CAT.23.0228.

Several model tests have informed successor generations of model tests, which are designed to incorporate the lessons learned from initial model tests with the goal of producing further improvements in care delivery and reductions in spending. For example, in June 2022, the CMS Innovation Center announced the Enhancing Oncology Model (EOM). This is a new model aimed at improving cancer care for Medicare patients and lowering health care costs by testing ways to improve health care providers' ability to deliver cancer care centered around patients, consider patients' unique needs, and in a way that will generate the best possible patient outcomes. The model focuses on supporting and learning from cancer patients, caregivers, and cancer survivors, while addressing inequities and providing patients with treatments that address their unique needs. This new model supports the President's Unity Agenda and Cancer Moonshot initiative to improve the experience of people and their families living with and surviving cancer. EOM incorporates lessons that were identified by the CMS Innovation Center in testing the Oncology Care Model (OCM) from July 2016 through June 2022. For example, OCM incentivized practitioners to improve the way in which they provide cancer care to focus on the patient, improve or maintain quality, and avoid unnecessary costs. Similar to OCM, EOM focuses on value-based, patient-centered care for certain cancer patients undergoing chemotherapy based on 6-month episodes of care, with a specific focus on health equity. EOM builds on lessons learned from OCM and feedback from the oncology community, including OCM participants, patient advocacy groups, oncology professional associations, and others, to further advance the journey in value-based care in oncology. EOM builds on lessons learned from OCM and feedback from the oncology community, including OCM participants, patient advocacy groups, oncology professional associations, and others, to further advance the journey in value-based care in oncology. For example, evaluations of OCM have shown that most reductions in spending in the model have been concentrated in a limited number of cancer types so EOM is focused on seven prevalent cancer types to allow EOM participants to focus their care management and coordination efforts more effectively.

In addition, beneficial elements of model tests have been incorporated into permanent CMS programs. For example, in 2015, after the Pioneer Accountable Care Organization (ACO) model was certified for expansion, CMS incorporated a new track in the Medicare Shared Saving Program. This new track was based on some of the successful features of the Pioneer ACO

Model, which included higher rates of shared savings, the prospective assignment of beneficiaries, and the opportunity to use new care coordination tools. In 2023, CMS also announced the incorporation of elements of the ACO Investment Model (AIM) tested by the CMS Innovation Center, into the Medicare Shared Savings Program. Called the Advance Investment Payment, this element offers eligible ACOs advance shared savings payments, including an upfront payment of $250,000 and two years of quarterly payments, to build the infrastructure needed to succeed in the Shared Savings Program and promote equity by holistically addressing beneficiary needs, including social needs. Also in 2023, after testing a screening tool in the Accountable Health Community model, CMS incorporated a screening for social drivers of health measure in the Hospital Inpatient Quality Reporting Program and the PPS-Exempt Cancer Hospital Quality Reporting Program to help identify patients with health-related social needs that can lead to poor health outcomes.

The CMS Innovation Center is also continuing our efforts to strengthen the primary care system. Access to primary care is associated with improved patient outcomes, increased equity, and lower mortality/higher life expectancy at similar or lower total costs.[6] Primary care clinicians are the first line of defense for prevention, screening, management of chronic conditions, and overall wellness. Previous Innovation Center models have demonstrated that primary care practices benefit from predictable, prospective, non-visit-based revenue and, in many cases, upfront investments to support the provision of whole-person, equitable, team-based care. Higher and more stable payments allow providers to develop advanced primary care capabilities that prevent provider burnout and meet the whole-person needs of patients, while assuming greater accountability for quality and costs over time.

The Innovation Center is creating multiple pathways to bring new primary care providers into value-based payment arrangements and to better support those already in value-based arrangements. For example, CMS recently announced the ACO Primary Care Flex Model, which will provide a one-time advanced shared savings payment and monthly prospective primary care payments to ACOs. New models will need to focus on different levels of the health care system

[6] CMS Blog, available at: https://www.cms.gov/blog/cms-innovation-centers-strategy-support-high-quality-primary-care

that can support primary care, including practices and primary care organizations, health systems, ACOs, and state-based or regional models. Additionally, the Making Care Primary Model will test prospective payments, targeting the large proportion of safety net providers and primary care providers that have not participated in previous value-based payment models. In addition, the voluntary States Advancing All-Payer Health Equity Approaches and Development (AHEAD) Model is a multi-payer total cost of care model that will test ways for states to increase access to and investments in primary care services, set health care expenditures on a more sustainable trajectory, and lower health care costs for patients.

The CMS Innovation Center is also working to improve the integration of specialty care and primary care, and is testing a range of options and approaches to meet primary care providers and their communities where they are and to offer value-based payment options that build infrastructure, support team-based care, and coordinate with specialty care. Accountable care requires access to and coordination of primary care and specialty care to meet the full range of patient needs, from primary and preventive care services to managing chronic conditions longitudinally and episodic care needs acutely. Much of that care is provided by specialty clinicians. Building on lessons learned from model tests of acute inpatient and hospital outpatient department episode payment models and condition-based episode payment models, the CMS Innovation Center developed a comprehensive specialty strategy[7] to test models and innovations that support access to high-quality, integrated specialty care across the patient journey.

For example, the recently proposed Transforming Episode Accountability Model (TEAM) incorporates beneficial elements and lessons learned from the Comprehensive Care for Joint Replacement (CJR) Model, the Bundled Payments for Care Improvement (BPCI) Model, and the BPCI Advanced Model. TEAM, if finalized, would test whether episode-based payments for five common, costly surgical procedures would reduce Medicare expenditures while preserving or enhancing the quality of care. TEAM 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

[7] https://www.cms.gov/blog/cms-innovation-centers-strategy-support-person-centered-value-based-specialty-care

outcomes. We know that before and after surgery, people on Medicare often experience fragmented care, especially following hospital discharge. By bundling all the costs of care for an episode and building on the experience of the predecessor models, this proposed model would incentivize care coordination, improve patient care transitions, and decrease the risk of an avoidable readmission.

Improving Model Test Development and Design

To chart its course for the next decade, in 2021, the CMS Innovation Center undertook a "Strategy Refresh" [8] – conducting an internal review of its portfolio of model tests and consultations with external research and experts, which culminated in a bold vision for the next ten years of achieving equitable outcomes through high quality, affordable, person-centered care. The Strategy Refresh established five objectives—to drive accountable care, advance health equity, support care innovations, address affordability, and partner to achieve system transformation. We continue to update and build on this comprehensive strategy[9], by incorporating lessons learned from model tests, while using the overarching goals to drive the strategic direction of the CMS Innovation Center.

In April 2024, the CMS Innovation Center announced a new Quality Pathway, a strategic initiative that will drive a heightened focus on improving quality of care and catalyze the ability to expand models on the basis of enhancing quality without increasing program expenditures by strengthening model design, elevating quality goals, and enhancing evaluation. The Quality Pathway is organized around the following principles: aligning quality goals throughout model design; advancing use of person-centered measures of outcomes and experience, particularly the use of patient-reported measures; and designing evaluations to better assess the impact of models on patient-centered quality goals. The Quality Pathway will benefit all Innovation Center model tests through rigorous assessment and dissemination of comparable findings that lead to better outcomes and experience for patients, thereby promoting broader health system transformation.

[8] CMS Innovation Center Strategy Refresh available at: https://www.cms.gov/priorities/innovation/strategic-direction-whitepaper

[9] 2022 Strategy Refresh update, available at: https://www.cms.gov/priorities/innovation/data-and-reports/2022/cmmi-strategy-refresh-imp-report

The CMS Innovation Center has also announced a new Transformation Initiative.[10] Through this Initiative, the Innovation Center will more systematically assess the impacts of models on health system transformation, for example by considering spillover effects of model tests on other providers or other patients who are not participating in the models. There will be a greater focus on understanding care delivery strategies and tactics that are associated with better quality, outcomes, and patient experience at lower costs. The Innovation Center is committed to developing a stronger evidence base through iterative learning and evaluation across models to accelerate health system transformation.

Driving Accountable Care

Beneficiaries in accountable care relationships experience longitudinal, accountable care with providers that are responsible for the quality and total cost of their care. To drive accountable care that promotes delivery of whole-person, integrated care, CMS has set a goal to have 100 percent of Original Medicare beneficiaries and the vast majority of Medicaid beneficiaries in accountable care relationships by 2030, and the CMS Innovation Center is critical to achieving this goal.

In 2023, CMS announced the incorporation of elements of the ACO Investment Model (AIM) tested by the CMS Innovation Center into the Medicare Shared Savings Program. Called the Advance Investment Payment, this payment option offers eligible ACOs advance shared savings payments, including an upfront payment of $250,000 and two years of quarterly payments, to build the infrastructure needed to succeed in the Shared Savings Program and promote equity by holistically addressing beneficiary needs, including social needs. As a result of these and other CMS efforts, 19 newly formed ACOs joined the Shared Savings Program in 2024 and are receiving advance investment payments of more than $20 million in total. These 19 new ACOs are hiring community health workers, utilizing health assessment and screening tools, and implementing quality improvement activities, such as case management systems, patient registries, and electronic quality reporting. In addition, 245 organizations are continuing their

[10] CMS Innovation Center's Transformation Initiative, available at: https://www.cms.gov/files/document/transformation-initiative-2pager-aag.pdf

participation in two CMS Innovation Center accountable care models — ACO Realizing Equity, Access, and Community Health (ACO REACH) and the Kidney Care Choices (KCC) models.

As we build on these efforts, the CMS Innovation Center will consider providing ACOs with tools to better engage specialists in accountable care, test ways to better link primary and specialty care upstream in the patient journey, and continue to incentivize better management of inpatient admissions and transitions back to the community for patients.

Advancing Health Equity

The CMS Innovation Center is committed to developing a health care system that advances health equity, a goal that is integral to our mission to improve health care quality. This includes developing models that promote and incentivize equitable care; increasing participation of safety net providers; increasing collection and analysis of equity data; and monitoring and evaluating models for health equity impact. The CMS Innovation Center's Key Concepts on Health Equity[11] describes CMS's overall approach to incorporating equity throughout our innovative model and demonstration design. The CMS Innovation Center has made meaningful progress in each of these areas. This includes all new models incorporating equity elements, as well as launching several condition-specific models aimed at reducing significant persistent health disparities in areas including Sickle Cell Disease, maternal health, behavioral health, and end-stage renal disease resulting in the need for kidney transplant. The CMS Innovation Center has also incorporated health equity into its model evaluations to understand and measure the impact of interventions on underserved populations.

Supporting Care Innovations

A critical part of improving care across the health care system requires ensuring that providers have the tools, data, and resources they need to improve health outcomes and achieve cost savings. That's why the CMS Innovation Center is testing tools that can support the delivery of integrated care, such as practice-specific data, technology, dissemination of best practices, peer-to-peer learning collaboratives, and payment flexibilities. Recognizing the critical importance of actionable, close to real-time data, the CMS Innovation Center is committed to making practice-

[11] Available at: https://www.cms.gov/priorities/innovation/key-concepts/health-equity

specific performance data available to model test participants and is considering options for a more interactive value-based care management system. Across these efforts, we work to ensure model tests are measuring matters that are most important to patients and are understanding how patients in model tests rate their experiences and outcomes.

The CMS Innovation Center has committed to including patient-reported outcome measures (PROMs) in its models[12] in order to measure what is meaningful to patients. This approach will be informed through engagement with and input from patient and beneficiary groups. The PROM strategy aims to include measures from the following domains: person-centeredness, seamless care coordination, wellness and prevention, chronic conditions, safety, and equity.

Improving Access by Addressing Affordability

Affordability can be a barrier to accessing health care for many individuals, especially as health care costs continue to rise. In addition to meeting our statutory obligation to test models that reduce federal program expenditures, the CMS Innovation Center is committed to pursuing strategies that lower out-of-pocket costs for Medicare and Medicaid beneficiaries in order to promote access to quality care. To measure its progress against this objective, CMS aims to have new models establish targets to reduce the percentage of beneficiaries that forego care due to cost by 2030. In addition, all model tests will consider and include opportunities to improve the affordability and reduce out-of-pocket costs of high value care for beneficiaries.

Partnering to Achieve System Transformation

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. The CMS Innovation Center will continue to work towards multi-payer alignment on key dimensions of value-based payment by developing models that engage more than one payer, aligning quality metrics across CMS programs and payers, and supporting data exchange to improve care.

[12] Available at: https://innovation.cms.gov/cmmi-person-centered-care

For the CMS Innovation Center to successfully build partnerships and transform the health care system, it must improve the transparency of its work and communication with key stakeholders. In particular, the CMS Innovation Center has committed to strengthening stakeholder outreach, making data on model tests more transparent, and understanding model impacts on broader factors of interest to stakeholders, such as patient experience, impact on provider administrative burden, and spread of model elements to other payers.

The CMS Innovation Center has strengthened its public communications, outreach, and engagement, particularly with beneficiary groups who are critical to informing the Center's work. For example, CMS has released data for numerous model tests to allow external researchers and organizations to generate insights on the impact of model tests on patients and the broader care delivery system. CMS also routinely releases publications and webinars to share new strategic direction and learnings and to solicit stakeholder input and feedback.[13]

Recent Models to Drive Improvements Across the Health Care System

The CMS Innovation Center is designing model tests aligned with its vision for a health system that achieves equitable outcomes through high quality, affordable, person-centered care. In 2023 and early 2024, the CMS Innovation Center announced a number of new model tests that aim to drive better care, improve outcomes, and lower costs, including Guiding an Improved Dementia Experience, Transforming Maternal Health, Innovation in Behavioral Health, Cell and Gene Therapy Access, and Increasing Organ Transplant Access. These model tests focus on a diverse array of health conditions and care episodes that have a meaningful impact on patients and providers across the health care system.

<u>Guiding an Improved Dementia Experience Model</u>

In July 2023, the CMS Innovation Center announced its Guiding an Improved Dementia Experience (GUIDE) Model, which 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

[13] Information on each model is available on the Innovation Center's website: https://www.cms.gov/priorities/innovation/overview

communities through a package of care coordination and management, caregiver education and support, and respite services.

Through the GUIDE Model, CMS will test an alternative payment for participants who deliver key supportive services 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. The GUIDE 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. When used over time, respite services have been found to help unpaid caregivers continue to care for their loved one at home, preventing or delaying the need for facility care. The model is also designed to reduce Medicare and Medicaid expenditures primarily by helping people with dementia to remain at home, and reducing hospitalization, emergency department use, the need for post-acute care as well as long-term nursing home care.

The GUIDE model delivers on President Biden's April 2023 Executive Order 14095[14] on Increasing Access to High-Quality Care and Supporting Caregivers and advances key goals of the National Plan to Address Alzheimer's Disease.[15]

Transforming Maternal Health Model

[14] https://www.whitehouse.gov/briefing-room/statements-releases/2023/04/18/fact-sheet-biden-harris-administration-announces-most-sweeping-set-of-executive-actions-to-improve-care-in-history/
[15] https://aspe.hhs.gov/collaborations-committees-advisory-groups/napa/napa-documents/napa-national-plan#:~:text=National%20Plan%20establishes%20six%20ambitious,Treat%20AD%2FADRD%20by%202025

Despite spending more per capita for maternity care than any other nation in the world, the U.S. has higher rates of adverse pregnancy outcomes than any other high-income country. Additionally, women enrolled in Medicaid and CHIP, including those in underserved communities and/or rural areas, often experience significant disparities in maternal health care and poor health outcomes for themselves and their newborns. To address these challenges, the CMS Innovation Center announced the voluntary Transforming Maternal Health (TMaH) Model in December 2023.

The goal of the TMaH Model is to ensure pregnant and postpartum mothers with Medicaid or CHIP health insurance receive personalized care that can improve their health outcomes, including fewer low-risk cesarean sections, and fewer instances of severe maternal morbidity. The TMaH Model also seeks to support or increase access to additional maternal care providers, such as midwives, birth centers, and doula services. Each participating state Medicaid agency will be eligible for up to $17 million during the model's 10-year period.

Additionally, states will foster connections to implement evidence-based practices and lessons, like monitoring pregnant women at home who are diagnosed with conditions that can lead to pregnancy-related complications, such as hypertension and gestational diabetes. Participating states will also have their maternity care providers screen for and address pregnant women's health-related social needs – including, but not limited to, challenges like inadequate access to nutritious food, housing insecurity, or SUD – by connecting mothers to community-based organizations. This model supports the White House Blueprint for Addressing the Maternal Health Crisis[16] and the CMS Maternity Care Action Plan.[17]

Innovation in Behavioral Health Model

In January 2024, CMS announced the Innovation in Behavioral Health (IBH) Model, a new model to test approaches for addressing the behavioral and physical health, as well as health-related social needs, of people with Medicaid and Medicare. The goal of the IBH Model is to reduce program expenditures and improve the overall quality of care and outcomes for adults

[16] https://www.whitehouse.gov/wp-content/uploads/2022/06/Maternal-Health-Blueprint.pdf
[17] https://www.cms.gov/files/document/cms-maternity-care-action-plan.pdf

with mental health conditions and/or SUD by connecting them with the physical, behavioral, and social supports needed to manage their care.

Medicare and Medicaid populations experience disproportionately high rates of mental health conditions and/or SUD, and as a result are more likely to experience poor health outcomes and experiences, like frequent visits to the emergency department and hospitalizations, or premature death.

The IBH Model seeks to bridge the gap between behavioral and physical health; practice participants under the IBH Model will screen and assess patients for select health conditions, as well as mental health conditions and/or SUD, in specialty behavioral health practices. IBH is a state-based model, led by state Medicaid Agencies, with a goal of aligning payment between Medicaid and Medicare for integrated services.

The IBH Model builds upon earlier Innovation Center efforts to include community-based behavioral health practices, including both mental health providers and substance use disorder providers, in value-based care. The IBH Model is based on the lessons learned from previous Innovation Center models, such as the Maternal Opioid Misuse Model, Integrated Care for Kids Model, and the Value in Opioid Use Disorder Treatment Demonstration. This model supports the President's mental health strategy and implements an action item in the HHS Roadmap for Behavioral Health Integration.[18]

Cell and Gene Therapy Access Model

In January 2024, CMS announced the Cell and Gene Therapy (CGT) Access Model, which aims to improve the lives of people with Medicaid living with rare and severe diseases by increasing access to potentially transformative treatments. Cell and gene therapies have high upfront costs but have the potential to reduce health care spending over time by addressing the underlying causes of disease, reducing the severity of illness, and reducing health care utilization. Initially, the model will focus on access to gene therapy treatments for people living with sickle cell disease, a genetic blood disorder that disproportionately affects Black Americans. By increasing

[18] https://www.hhs.gov/about/news/2022/12/02/hhs-roadmap-for-behavioral-health-integration-fact-sheet.html

access to transformative therapies, this model can potentially help address the historic disparities, poor health outcomes, and low life expectancy associated with sickle cell disease.

The CGT Access Model is a voluntary model for states and manufacturers that tests whether a CMS-led approach to developing and administering outcomes-based agreements for cell and gene therapies improves Medicaid beneficiaries' access to innovative treatment, improves their health outcomes, and reduces health care costs and burdens to state Medicaid programs. During the negotiation process, the CMS Innovation Center anticipates addressing care delivery gaps and other hurdles for people receiving cell and gene therapy, including requiring manufacturers to include a defined scope of fertility preservation services when individuals receive gene therapy for treatment of sickle cell disease.

Increasing Organ Transplant Access Model

In May 2024, the CMS Innovation Center announced the proposed mandatory model, Increasing Organ Transplant Access (IOTA) Model, which aims to increase access to kidney transplants for all people living with end-stage renal disease (ESRD), improve the quality of care for people seeking kidney transplants, reduce disparities among individuals undergoing the process to receive a kidney transplant, and increase the efficiency and capability of transplant hospitals selected to participate. In the proposed model, participating transplant hospitals would be measured by increases in the number of transplants, increased organ acceptance rates, and post-transplant outcomes. The Increasing Organ Transplant Access Model would hold kidney transplant hospitals accountable for the care they provide.

The proposed IOTA Model would build on the Biden-Harris Administration's priority of improving the kidney transplant system to increase organ donation and improve clinical outcomes, system improvement, quality measurement, transparency, and regulatory oversight. Further, this model would align with the strategy of the HHS Organ Transplant Affinity Group – a federal collaborative led by HRSA and CMS – to coordinate a series of initiatives to increase transplantation access through payment, quality, and regulatory efforts. Lastly, the IOTA Model would be complementary to existing and future regulatory efforts for Organ Procurement Organizations, nephrologists, and dialysis facilities to improve the overall transplant system for

people with ESRD. We are currently seeking public comment on the proposed IOTA Model and look forward to incorporating this feedback as we finalize the details of this model.

Moving Forward

This Administration is committed to driving innovative solutions that tackle the nation's health system challenges. Innovation in health care should be designed for the people it serves; its success should be measured by how well it improves health, experience, and affordability of care, and how well it supports partnerships between patients, health care providers, and other stakeholders across the system to drive transformation. The CMS Innovation Center, with its federal partners and external stakeholders, has started building the foundation toward a health system that achieves equitable outcomes through high-quality, affordable, person-centered care.

Since the CMS Innovation Center was established, value-based care has gone from a nascent concept to an important element of the nation's health care landscape. The first ten years of testing have laid a strong foundation. Each model test has yielded important policy and operational insights that can be applied in future models and inform overall efforts to improve quality of care and health equity and reduce costs.

In its second decade, the CMS Innovation Center is focused on using everything learned so far to test new models to drive higher-quality, more efficient care to improve outcomes for patients and reduce disparities. Leveraging the experience of the first ten years, the CMS Innovation Center continues to strategize and prioritize model tests that fulfill critical gaps, are feasible, are aligned with broader CMS efforts, and have the greatest impact on beneficiary quality, experience, and federal costs. We are committed to continuing to work with patients and families, providers, payers, states, and Congress to drive innovation that addresses the central challenges facing people in the health care system and transform patient care, outcomes, and experience.