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Center Insight Brief

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CMS Announces Model Concepts to Reduce Prescription Drug Costs

On February 14, 2023, the Centers for Medicare and Medicaid Services (CMS) announced that the Secretary of Health and Human Services (HHS) had selected three new payment model concepts for testing by the CMS Innovation Center (Innovation Center) "to help lower the high cost of drugs, promote accessibility to life-changing drug therapies, and improve quality of care."[i] The model concepts described in a report[ii] are in response to President Biden's Executive Order 14087, Lowering Prescription Drug Costs for Americans,[iii] which called for the HHS Secretary to select Innovation Center payment and delivery models "that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs." HHS Secretary Xavier Becerra selected three drug affordability and accessibility model concepts for testing, impacting Medicare Part D, Medicaid, and Medicare Part B,[iv] respectively:

1) **Medicare High-Value Drug List**, designed to improve access, address affordability, and advance health equity and outcomes for Medicare Part D beneficiaries through requiring the offering of a standardized list of high-value, low-cost generics;
2) **Cell & Gene Therapy Access**, designed to improve access to high-cost cell and gene therapies to Medicaid beneficiaries with rare and severe diseases, reduce administrative burden for state Medicaid agencies in implementing outcomes-based agreements, and ensure payment certainty for providers who may be hesitant to acquire and deliver the high-cost treatments; and,
3) **Accelerating Clinical Evidence**, designed to create payment incentives for manufacturers of accelerated approval drugs to complete confirmatory studies in a timelier fashion and ensure that patients are receiving treatments that are effective.

In this Center Insight Brief we summarize the model concepts, their stated objectives, their anticipated timelines, and next steps for implementation.

The Medicare High-Value Drug List Model

The Medicare High-Value Drug List Model would be a Medicare Part D model that would test Part D sponsors offering a Medicare-defined standard set of approximately 150 high-value generic drugs with a maximum copay of $2 for a one-month supply. The copay would apply across all phases of Part D coverage up to the out-of-pocket limit and include drugs for common chronic conditions (e.g., hyperlipidemia and hypertension). Additionally, included drugs would not be subject to step therapy, prior authorization, quantity limits, or pharmacy network restrictions. Once implemented, the model would test "the impact of standardizing the Part D benefit for high-value generic drugs on beneficiary affordability, access, health outcomes, and Medicare spending."

Rationale, Possible Impacts, and Implementation Timeline

HHS believes a standardized drug list with consistent cost-sharing would "allow providers to easily identify and prescribe appropriate medications without the worry of high prices for their patients" or unexpected utilization management restrictions. Meanwhile, the consistent, predictable co-payments for beneficiaries would help beneficiaries "access affordable, stable, predictably priced generic medications… [and] improve their adherence and, in

turn, their health outcomes." HHS notes that the model would complement Inflation Reduction Act (IRA) provisions, including a cap on out-of-pocket costs and the option of out-of-pocket "smoothing," and build upon the Part D Senior Savings Model, which allowed plans to set a $35 (or less) copay for select insulins. In contrast, the current Part D benefit structure would generally require plan sponsors to collect an additional premium to provide this sort of offering as enhanced benefits. In addition, depending upon the ultimate model design, CMMI could test whether modified incentives could change the tendency of standalone prescription drug plans (PDPs) to discourage adverse risk and prefer high drug costs over facilitating access to high-value drug therapies that offset medical costs.[v] Published materials suggest that participation in the model would be voluntary.

The HHS Secretary directs CMS to request input from stakeholders and announce model specifications "as soon as operationally feasible."

The Cell & Gene Therapy Access Model

The Cell & Gene Therapy (C&GT) Access Model would be a Medicaid-based model, designed as a partnership among CMS, drug manufacturers, and state Medicaid agencies to test a new approach for administering outcomes-based agreements (OBAs) to increase beneficiary access to high-cost cell and gene therapies. Rather than state Medicaid agencies pursuing manufacturer agreements individually, agencies would be permitted to assign CMS with the responsibility of structuring and coordinating multi-state OBAs with participating manufacturers. In addition, CMS would implement, monitor, reconcile, and evaluate the financial and clinical outcomes detailed in the OBAs. The model would target C&GTs for illnesses such as sickle cell disease and cancer. The model would be voluntary with participation from state Medicaid agencies and selected manufacturers. Ultimately, the model aims to determine whether a "CMS-led approach for administering OBAs for C&GTs improve beneficiary access and outcomes and reduce health care costs."

Rationale, Possible Impacts, and Implementation Timeline

The National Bureau of Economic Research predicts that over one million Americans will have a condition that may be treated through use of a C&GT over the next 10 years, with spending reaching $25 billion annually.[vi] However, the upfront costs for these therapies pose significant challenges for beneficiaries and payers, including state Medicaid agencies. As such, expanded use OBAs could be an effective way to manage the significant costs, while also ensuring that C&GT manufacturers are held responsible for ensuring that the therapy works. However, HHS notes that the complexity of data collection and evaluation and the need to negotiate for more meaningful outcomes are likely deterring increased use of OBAs, and that "additional federal support (e.g., administrative funding and monitoring/evaluation support) may be necessary to obtain better, timelier terms from manufacturers" and more efficient administration and evaluation of OBAs.

As a result, the model would be expected to reduce the burden and standardize the process for state Medicaid agencies to establish and maintain OBAs. Furthermore, the model would allow CMS to pool bargaining power across states for discounted pricing, condition the ultimate cost of G&CTs on outcomes, and shift the burden of administration from state Medicaid agencies to CMS. Meanwhile, G&CT drug manufacturers would have a simplified market access strategy through simplified, multi-state agreements, easier measurement of OBAs, and better revenue predictability. Multi-state OBAs may also incentivize G&CT manufacturers to offer larger discounts tied to clinical outcomes. HHS notes several precedents and drivers for such an OBA model, including state pooled purchasing arrangements, Louisiana's and Washington's "subscription" agreements for hepatitis C products, and state drug transparency requirements requiring rationale for setting prices.

HHS includes three different approaches that CMS could use to implement the model: (1) outcomes-based payments with an upfront payment, followed by remaining payment based on clinical milestones; (2) outcomes-based rebates with an upfront payment, followed by a rebate if specific clinical outcomes are not achieved; and, (3) outcomes-based annuities with fixed payments spread over time if beneficiaries continue to achieve specific clinical outcomes.

CMS is directed to "begin model development in 2023, consider announcing the model specifications in 2024-2025, and launch the model test as early as 2026." The model is expected to begin with a single therapeutic indication and expand to additional indications if improvements in beneficiary access, clinical outcomes, and cost are achieved.

The Accelerating Clinical Evidence Model

The Accelerating Clinical Evidence Model would adjust Medicare Part B payment amounts for drugs in the Accelerated Approval Program (AAP) to give drug manufacturers an incentive to expedite and complete required confirmatory trials. CMS, in consultation with FDA, is directed to consider various approaches that adjust provider payment for AAP drugs to help ensure improved access to post-market safety and efficacy data. The model would carefully consider the AAP goals of balancing the benefit of bringing novel treatments for patients with serious and life-threatening conditions to the market sooner with the risk of potential patient harms resulting from keeping an AAP drug on the market without confirmed clinical benefit. Incentives to expedite completion of confirmatory studies would provide earlier confirmation of clinical benefit for drugs that succeed in post-approval studies, while allowing faster withdrawal of AAP drugs that fail to demonstrate clear clinical benefit, resulting in improved clinical care for Medicare beneficiaries and reduced, unnecessary costs for CMS. HHS notes that any payment adjustments in the model must avoid penalizing physicians or beneficiaries for choosing, or avoiding, an AAP drug. Participation in the model would be mandatory for applicable Medicare Part B fee-for-service providers. Once launched, the model would help to assess whether "payments for AAP drugs accelerate confirmatory trial completion, provide timely information on the safety and effectiveness of AAP drugs on the market, facilitate earlier withdrawals of AAP drugs when appropriate, and reduce Medicare spending on drugs that do not have confirmed clinical benefit."

Rationale, Possible Impacts, and Implementation Timeline

As HHS notes in its report, the AAP has been increasingly criticized by lawmakers, patient advocates, and other stakeholders for the continued failure of drug manufacturers to complete confirmatory trials by the date to which they committed at the time of accelerated approval.[vii] As of May 2022, 104 out of 278 drug applications approved through AAP had incomplete confirmatory trials, with 34% having at least one trial past originally planned confirmatory trial date. This resulted in an estimated $18 billion in Medicare and Medicaid spending on AAP therapies past their scheduled confirmatory trial completion date.[viii] Given these AAP shortcomings, HHS believes that the model would help to address payer concerns about covering the therapies. In addition to consulting with FDA, HHS directs CMS to consider recommendations from the Medicare Payment and Advisory Commission (MedPAC), the Medicaid and CHIP Payment and Access Commission (MACPAC), and others who are studying the AAP process to "find the appropriate balance between the more rapid availability of new medications that show promise and the longer time needed for those medications to be evaluated through traditional pathways."

More importantly, the model would be expected to address misaligned drug manufacturer incentives to potentially seek a faster path to revenue through the AAP, with sometimes significantly delayed consequences for not meeting approval requirements. Although the FDA does have statutory authority to withdraw AAP products from the market, and those authorities have been enhanced in the recently enacted Consolidated Appropriations Act, 2023, the process is still time-consuming and may be challenging if there is no existing therapy on the market to which to compare AAP drug's efficacy. Ultimately, the model could increase pressure on manufacturers to quickly demonstrate the benefit of their product or remove it from the market. HHS notes that it may need to consider the need to treat certain AAP drugs differently if they have multiple indications, which may be subject to different confirmatory studies.

As a result of the recently enacted Consolidated Appropriations Act, HHS directed CMS to begin consultation with FDA to explore the model in 2023 and, if appropriate, "continue development thereafter with a targeted launch as soon as feasible."

Additional Areas for Research

In addition to the above model concepts, HHS directed the Innovation Center to evaluate potential models in three other areas:

1) Accelerating Biosimilar Adoption, including through "(1) aligning biosimilar cost-sharing and payment incentives for providers and beneficiaries; (2) creating shared savings arrangements and/or payment bundles for therapeutic classes; and, (3) adjusting payment methods to increase competition and promote investment in biosimilar development."
2) Data Access Changes to Support Price Transparency, including through models or other activities "that would allow beneficiaries and providers to use prescription drug data to consider alternatives, assess utilization management review requirements, compare price by fulfillment locations, and shop plan options."

3) Cell and Gene Therapy Access in Medicare Fee-for-Service, including "potential Medicare fee-for-service options [such as bundled payments] to support C&GT access and affordability, to complement the Medicaid-focused Cell and Gene Therapy Access Model."

Next Steps

Although CMS and the Innovation Center are directed to explore and launch the Medicare High-Value Drug List Model and Accelerating Clinical Evidence Model as soon as "operationally feasible," it will take time to solicit feedback from stakeholders and develop technical specifications for the models.

- The High-Value Drug List Model may be the least complex to develop and operationalize; however, if the Innovation Center were to target a launch in 2025, it would need to provide Part D sponsors with sufficient guidance in advance of bids being due in June 2024—an aggressive timeline for developing, clearing, and announcing a model that is still seeking public comment.
- Meanwhile, development of the Accelerating Clinical Evidence Model will require close consultation with the FDA, as well as consideration of MedPAC and MACPAC recommendations, to finalize the model details. At the same time, model development will inevitably be impacted by FDA implementation of AAP changes in the Consolidated Appropriations Act, and drug manufacturers and other stakeholders are likely to resist launch until those details are better understood.
- Finally, the Cell & Gene Therapy Access Model is not targeted to launch until 2026, as it will require significant coordination between state Medicaid agencies and CMS to determine the specific payment mechanism (e.g., milestone payments, rebates, fixed payments) and how to administer the OBAs across multiple states. Across all three models, we can expect CMS to solicit important feedback from patients and consumers groups to ensure that they meet the objectives of expanding access and lowering drug costs.

[i] Department of Health and Human Services. HHS Secretary Responds to the President's Executive Order on Drug Prices. February 14, 2023.
[ii] Department of Health and Human Services. Report to the Assistant to the President for Domestic Policy: A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans. February 2023.
[iii] Executive Order 14087: Lowering Prescription Drug Costs for Americans. FR 87(201): 63399-63400.
[iv] Department of Health and Human Services. Fact Sheet: Lowering Prescription Drug Costs for Americans, Response to President Biden's Executive Order. February 2023.
[v] K Lavetti and K Simon. Strategic Formulary Design in Medicare Part D Plans. National Bureau of Economic Research. June 2016.
[vi] CH Wong, D Li, N Wang, J Gruber, R Conti, A Lo. Estimating the Financial Impact of Gene Therapy in the U.S. National Bureau of Economic Research. 2021.
[vii] SL Kocot, T McCutcheon, and R White. FDA Accelerated Approval Program Reforms included in the 2023 Omnibus. Center for Healthcare Regulatory Insight. February 2023.
[viii] Department of Health and Human Services - Office of Inspector General. (2022). Delays in Confirmatory Trials for Drug Applications Granted FDA's Accelerated Approval Raise Concerns (OEI-01-21-00401).

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