Memorandum

March 8, 2022

POTENTIAL CMMI ACTION ON DRUG PRICING

I. Introduction

Following the collapse of the Build Back Better Act (BBBA), it remains unclear whether Congress will pass drug pricing legislation. While it is still possible for Congress to act on separate components of the BBBA (including drug pricing) via reconciliation, there is less insight into how exactly Democrats plan to move forward on these legislative priorities. It has remained WHG's perspective that, if Congress does not act on drug pricing, the Biden Administration may exercise waiver authority available through the Center for Medicare and Medicaid Innovation (CMMI) to advance demonstration models that address drug costs.

Due to the uncertainty around the BBBA and whether Congress will move forward on a drug pricing package, WHG has therefore prepared a brief memorandum that outlines the potential types of models CMMI could advance absent legislative action on drug pricing. The range of possible models are derived from comments that the Administration has offered in recent publications, notably including its Comprehensive Plan for Addressing High Drug Prices, as well as CMMI's Strategy Refresh White Paper.[1, 2] We break this possible range of models down into the following sub-categories for further consideration:

- Adjustments CMMI could make to existing models;
- New model concepts; and
- Models that employ concepts previously attempted but ultimately rescinded by CMMI.

In addition to overviewing what these models could include, we also offer brief commentary on the potential timing for when the Biden Administration could move forward on each of these models if it chooses to do so.

II. Adjustments to Existing Models

This first tier of potential actions includes revisions the Innovation Center may make to existing models as a means for lowering drug prices. Such options may be more feasible for the Administration to act on in the shorter term since they would involve changes to existing models rather than designing and implementing entirely new models. Possible actions along these lines are explored below.

Model	Description	Timing
Part D Senior Savings Model	CMMI has suggested it may test models that build on the Part D Senior Savings model, which tests the impact of offering beneficiaries Part D plan options that cap out-of-pocket (OOP) expenses	• CMMI could implement these changes for calendar year (CY) 2024, since it just released the

[1] https://aspe.hhs.gov/sites/default/files/2021-09/Competition%20EO%2045-Day%20Drug%20Pricing%20Report%209-8-2021.pdf

[2] https://innovation.cms.gov/strategic-direction-whitepaper

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Model	Description	Timing
	for an insulin prescription at $35 for a one-month supply.[3] Specifically, HHS noted in its Comprehensive Plan for Addressing High Drug Costs that it was considering the inclusion of additional drug classes associated with high OOP costs. The Medicare Payment Advisory Commission (MedPAC) also suggested CMMI could explore this option as well during their January 2022 session.	CY 2023 request for application (RFA) for the model.
Accountable Care Models	CMMI has stated it is considering whether to include drug spend in total cost of care models. These models typically do not include Part D spending in calculating spending targets on which shared savings calculations are based. While CMMI suggested it could consider developing a new model along these lines, CMMI could potentially modify existing models to test a total cost of care approach to controlling drug spending (e.g., by modifying the recently announced ACO REACH model).[4]	• CMMI could implement these changes as early as CY 2024.
Bundled Payments	CMMI has signaled it is considering whether to expand its current approach to episode-based bundled payments – which currently groups care under one payment amount for episodic services such as hip replacement surgery – to include payments for drugs and biologics as well. CMMI could adjust a range of ongoing models that employ a bundled payment approach, including: • Bundled Payments for Care Improvement Advanced (BPCI-Advanced);[5] • Comprehensive Care for Joint Replacement (CJR);[6] and • Radiation Oncology Model (RO).[7]	• Since BPCI Advanced is ending on Dec. 31, 2023, it is unlikely CMMI will include drugs in bundles for this program. • CMMI would have to implement these changes for CJR in CY 2023 since the model is ending on Dec. 31, 2024. • CMMI could propose to include drugs and biologics in the RO bundles as early as this year since the model is not slated to begin until Jan. 1, 2023. However, the model is already controversial and may be too difficult to amend in this way.

[3] https://innovation.cms.gov/innovation-models/part-d-savings-model
[4] https://innovation.cms.gov/innovation-models/aco-reach
[5] https://innovation.cms.gov/innovation-models/bpci-advanced
[6] https://innovation.cms.gov/innovation-models/cjr
[7] https://innovation.cms.gov/innovation-models/radiation-oncology-model

III. New Models

This second tier of potential actions overviews new models that CMMI could advance to act on its stated goals on reducing drug costs. Such models could take more time to implement given the extensive design process that model development teams must undergo before announcing new models. Moreover, CMMI is still in the process of implementing its new strategic vision for the next decade of model development, which will likely require additional time to fully operationalize and be accounted for in whatever new models it plans to advance. Notably, models will have to each include an explicit health equity component in terms of model participants selected, beneficiaries served, interventions and benefit flexibilities, quality measures, and evaluation criteria. As such, any drug pricing models will have to include such equity components, which could require additional time to develop prior to launch.

Model	Description	Timing
Small-scale Part B models that link payments to outcomes.	CMMI has stated it is considering small-scale mandatory models under Part B that link payment for prescription drugs and biologics to factor such as improved health outcomes, reductions in health disparities, patient affordability, and lower overall costs. The agency added such models could include incentives for use of high-value therapies such as biosimilars and generics and could include outcome-based arrangements with manufacturers. Last, CMMI said the model could include a multi-payer component and be made available to employer and Marketplace plans, and state Medicaid and CHIP agencies.	• CMS may be planning to propose a mandatory model along these lines in a proposed rule currently identified in the latest Unified Agenda that would advance a new mandatory alternative payment model.[8] No other detail is provided on what the model might include but it is possible it could be drug related. • The model is currently slated for release in August 2022, though that is subject to change.
Limited testing of congressional proposals	Though CMMI has not explicitly suggested it might do so, the Administration could direct CMMI to use its waiver authority to enact models that test – on a more limited basis – any or all of the components of the legislative drug pricing proposals included in the BBBA. As such, these models could include elements such as negotiations, inflation rebates, and Part D redesign. Such models could focus on the costliest drugs in Part B and Part D and eventually be expanded over time.	• If CMMI were to advance such a model, it would only do so if it was clear that Congress was unable to pass drug pricing legislation. • If Congress does not pass drug pricing legislation by the end of this year, the Administration could decide to move forward at that point on

[8] https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202110&RIN=0938-AU51

Model	Description	Timing
		designing a model to test these legislative proposals. • The earliest CMMI would do so is likely CY 2024.

IV. Revisiting Previous Proposals

As a final set of considerations, CMMI may also resurrect and iterate on previous ideas that were ultimately not advanced by the agency but that may impact drug costs. This set of models is less likely though could be advanced if the Biden Administration wants to take action on drug pricing beyond the types of models described above. However, the level of anticipated stakeholder pushback could thwart attempts at doing so. Such model concepts would also have to be updated to include explicit health equity considerations, as mentioned above as well.

Model	Description	Timing
Most Favored Nations (MFN)	While the Administration has rescinded the MFN model through rulemaking, it noted in multiple publications it is still reviewing the comments received on the MFN model for selected Medicare Part B drugs. While CMMI has not said so, it could consider advancing an MFN-like model that is either limited in size (i.e., affecting less of the Medicare population) or limited to certain drugs/drug types. Additionally, since there has been substantial concern with referencing international prices, CMMI could also consider a new model that ties drug prices to those commanded domestically across other federal payers (e.g., DOD and VA) in a "most favored prices"-type approach.	• CMMI could potentially advance this next year if it has been developing such a model. The forthcoming proposed rule on a mandatory alternative payment model could provide more insight as to whether CMMI is contemplating a mandatory Part B drug pricing model that is related to the MFN approach.
Six protected classes (6pc)	The Trump administration had proposed changes to the Part D Payment Modernization Model that would have allowed plans to not cover all antidepressants, immunosuppressants, antipsychotics, and anticonvulsant drugs, but the Administration walked back that change before it went into effect. However, given that the Obama Administration had also previously proposed changes to three of the protected classes and many current CMS officials are carry-overs from the Obama Administration, the Biden Administration could revisit this topic and put their own stamp on the policy. MedPAC has also	• CMMI could advance this model next year since it has already done substantial thinking around a model to loosen 6pc protections.

Model	Description	Timing
	been supportive of allowing plans greater flexibility to manage spending on protected class drugs.	

V. Conclusion

We hope this is a helpful overview of potential actions CMMI could take on drug pricing. Please let us know if you have any questions.