March 20, 2023

Elizabeth Fowler
Deputy Administrator and Director
Center for Medicare & Medicaid Innovation
7500 Security Blvd.
Baltimore, MD 21244

VIA EMAIL (Elizabeth.Fowler@cms.hhs.gov)

RE: Anticipated Accelerating Clinical Evidence Model

Dear Deputy Administrator and Director Fowler:

On behalf of our more than 400 member hospitals and health systems, the California Hospital Association (CHA) is grateful for the opportunity to comment on the Center for Medicare & Medicaid Innovation's (CMMI) anticipated Accelerating Clinical Evidence (ACE) model, recently discussed in *A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans*[1]. CHA shares this administration's concerns about high drug costs — particularly for drugs whose clinical efficacy has not been fully proven. Our members have reported that their pharmaceutical costs have increased 41%.[2] since 2019. However, there are significant concerns that CMMI's anticipated payment model does not target the root cause of the problem and will create access issues for Medicare beneficiaries and other patients — particularly those most at risk for inequitable health outcomes.

The ACE model, as briefly described in the report, would target drugs provisionally approved under the Food and Drug Administration's Accelerated Approval Pathway (AAP) but where the manufacturer has not completed the required confirmatory trial(s) to verify that the drug provides a clinical benefit. To encourage manufacturers to complete confirmatory clinical trials in a timely manner, the ACE model will "adjust Medicare Part B payment amounts for Accelerated Approval Pathway drugs to give manufacturers an incentive to expedite and complete confirmatory clinical trials." FAQs released with the report indicate that the model "... could help ensure patients continue to have access to the drugs they need."

[1] https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report
[2] www.kaufmanhall.com/sites/default/files/2022-04/KH_CHA-2021-Financial-Analysis-Ebook.pdf

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The report does not provide specifics on how Part B payments will be "adjusted." However, given that it references Part B payments, a reasonable interpretation of the description is that CMS will reduce payments to providers. This approach appears conceptually like the Most Favored Nation (MFN) model put forward by CMMI under the prior administration to address high Part B drug costs. However, the MFN model was retracted by the Biden administration as the model was ill conceived and fundamentally did not address the root cause of high drug costs — manufacturers' high list prices and unreasonable annual price increases.

Targeting provider payments led to beneficiary[3] concerns about the risk posed to Part B drug access for Medicare beneficiaries and other patients. These concerns by beneficiaries were justified. An analysis by the Centers for Medicare & Medicaid Services in the MFN interim final rule found that beneficiaries would have lost access to 19% of the volume of separately payable Part B drugs covered in the MFN model. An additional 11% of beneficiaries would have been forced to seek those drugs from other providers. This would likely have increased the wait time for the next available appointment and the distances some Medicare beneficiaries — particularly those in rural areas — would need to travel to access these life-saving drugs.

If the AAP model targets Part B reimbursement to providers for qualifying separately payable drugs, it will interfere with providers' clinical decision-making and negatively affect access to the affected drugs. The impact of these unintended results will fall hardest on Medicare beneficiaries and other individuals most at risk for inequitable outcomes, such as those living in rural areas. However, CMS can easily avoid these undesirable outcomes.

The agency is already implementing an alternative model that will better achieve the desired effect without the unintended consequences. The rebate model incorporated into Section 1847(A)(i) of the Social Security Act by the Inflation Reduction Act of 2022 requires manufacturers to pay a rebate to CMS if prices for separately payable Part B drugs exceed a certain amount.[4] Under this approach, providers are still paid average sales price plus 6% with an increase in payment to reflect decreased beneficiary cost-sharing that resulted from the rebate CMS will require the manufacturer to pay. Instead of attempting to reduce demand — interfering with provider clinical decision-making for a targeted drug by decreasing Medicare payment to the provider — this model directly addresses the exorbitant annual manufacturer prices increases that CMS seeks to discourage.

CHA strongly supports this approach and encourages CMMI to explore how best to implement a similar one in the AAP model, which requires manufacturers to pay a rebate to CMS on drugs for which a timely confirmatory clinical trial has not been completed. The rebate amount that manufacturers would be required to pay for qualifying drugs could be calculated by comparing the amount paid to providers by Medicare for separately payable Part B drugs relative to the current standard of care. A similar rebate approach operationalizing a "payment cap" on qualifying separately payable Part B drugs was discussed at a recent Medicare Payment Advisory Commission meeting. Feedback from commissioners during the meeting was favorable[5] and it is anticipated that a similar recommendation will be included in the June report.

CHA appreciates the opportunity to comment on CMMI's ACE model. If you have any questions, please contact me at cmulvany@calhospital.org or (202) 270-2143.

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[3] https://canceradvocacy.org/wp-content/uploads/CLC-MFN-interim-final-rule-December-2020.pdf
[4] www.cms.gov/files/document/medicare-part-b-inflation-rebate-program-initial-guidance.pdf
[5] https://www.medpac.gov/meeting/march-2-3-2023/

Sincerely,

/s/
Chad Mulvany
Vice President, Federal Policy

cc: Xavier Becerra, Secretary, U.S. Department of Health and Human Services
Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services