

March 7, 2022

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: RIN 0938-AU30, CMS-4192-P, Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs

Dear Administrator Chiquita Brooks-LaSure:

On behalf of the Council for Informed Drug Spending Analysis, I appreciate the opportunity to comment on RIN 0938-AU30, CMS-4192-P, Medicare Program; Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription Drug Benefit Programs (“the proposed rule”).¹ The Council for Informed Drug Spending Analysis (CIDSA) was established by the West Health Policy Center to provide a central, objective source of expert information on drug spending policy in light of the ongoing debates surround drug spending policies.² CIDSA is a group of drug spending experts without ties to the pharmaceutical industry which offers independent analysis of drug spending policy for policymakers and the media.

In the weeks following the release of the proposed rule, CIDSA asked its expert panel to review the proposed rule to determine its potential impact.³ In this letter, CIDSA summarizes the experts’ findings. CIDSA’s expert panel surveys use a simplified two-stage Delphi survey methodology. In the first stage, experts are presented with a description of the policy and asked to evaluate that policy on standardized metrics; the experts also suggest areas where more information is needed to evaluate the policy. In the second round, the experts once again evaluate the policy on the same metrics, but this time with an anonymous summary of how their peers evaluated the policy in the first round. The experts also score the areas where more information is needed that were suggested in the first round, highlighting questions for policymakers to address. After the second round, CIDSA staff create a visual representation of the second-round scores and summarize the policy in a standard format for publication. For their evaluation of this policy, the CIDSA experts were presented with the excerpts of the proposed rule that applied the new definition of ‘negotiated price’ to all phases of the benefit design, including the coverage gap.

Expert Panel Findings

The majority of the CIDSA experts agreed that the proposed rule would increase drug spending, the remaining experts felt it would not affect spending. The experts unanimously agreed that this policy would not affect list prices; while the majority also agreed that this rule would not affect net prices, one expert opined that it would moderately decrease net prices. While most patient

¹ 87 Fed. Reg. 1842-1960, January 12, 2022.

² <https://www.cidsa.org/>

³ <https://www.cidsa.org/survey/pharmacy-price-concessions>

groups' access would be unaffected by this policy, Medicare patients and large patient groups would see a moderate increase in their drug access.

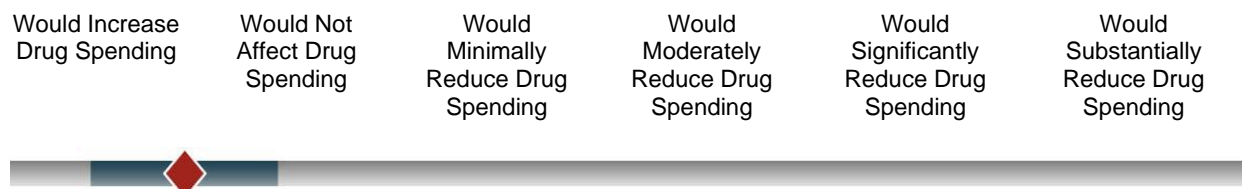
All of the experts opined that this policy would minimally advance drug spending policy. The experts also unanimously agreed that the size of the affected patient population would be a strength to this policy; the majority also believed that the ease of implementation would be a strength. Conversely, the experts unanimously agreed that the magnitude of the impact that the proposed rule would have on drug spending would be a policy weakness. Finally, the experts were split on the precedent setting value of this policy with three experts considering it a strength, three saying it remains unknown, and one considering it a weakness.

The expert panel highlighted several policy concerns for policymakers to consider. Most notably, the experts highlighted that pharmacies and health plans would be able to manipulate the lowest price they received for a given drug in order to reduce any penalties. Other significant information gaps that should be addressed include how Point-of-Sale (POS) transaction prices net of all concessions are actually recorded and verified by retail and mail order pharmacies, as well as the uncertainty of how beneficiaries will be directly impacted by this issue. The experts also called attention to whether manufacturer rebates for brand name drugs would be included in the calculations, how rebates would be passed through, which drugs would be subject to these fees, and whether these penalties will vary across pharmacies and drugs.

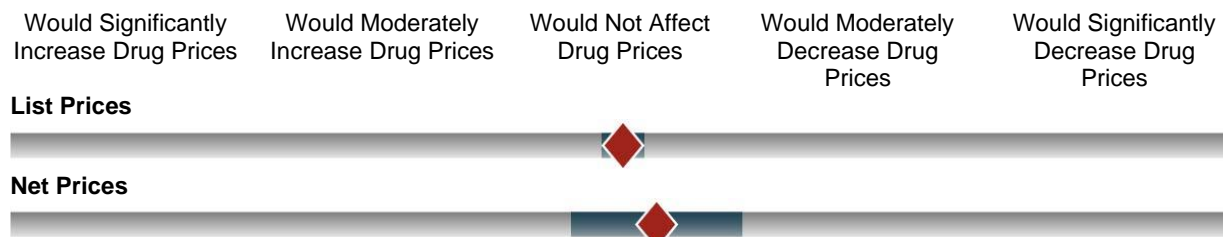
Visual Representation of Experts' Opinion

The below bars represent the experts' score on each question. The blue bars to the side of the red diamonds represent the standard deviation of experts' responses.

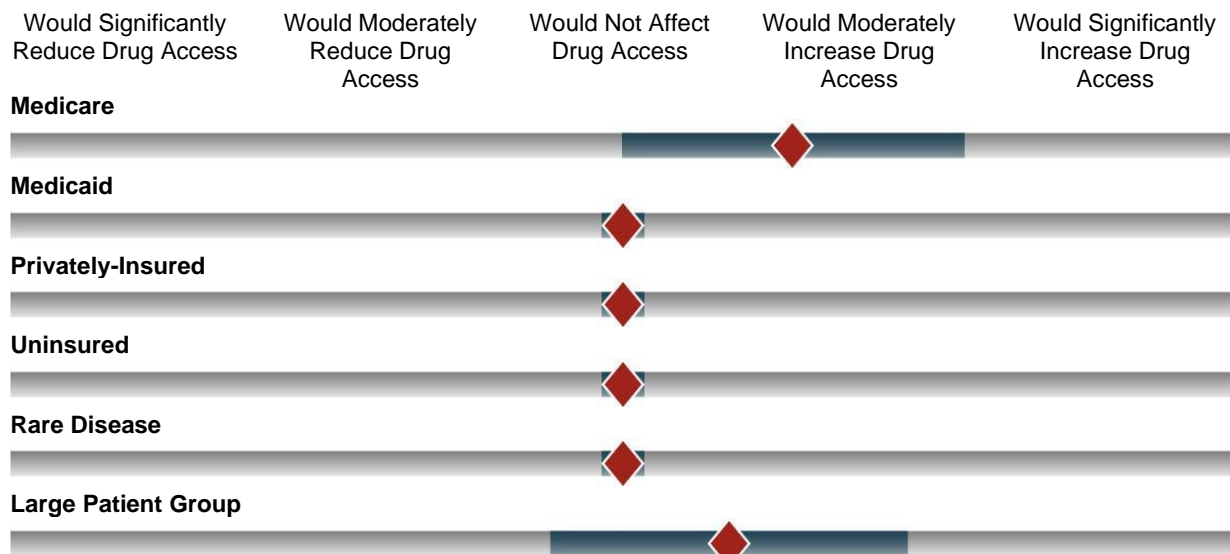
How likely would this policy be to reduce drug spending?



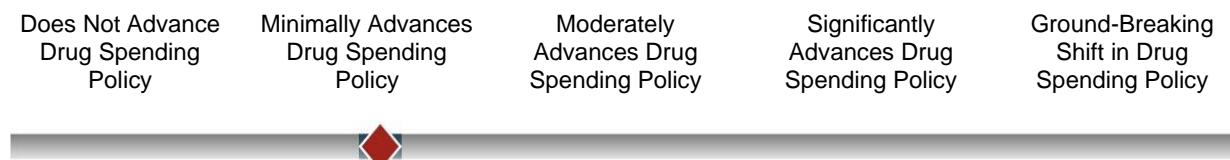
How likely would this policy be to reduce drug prices?



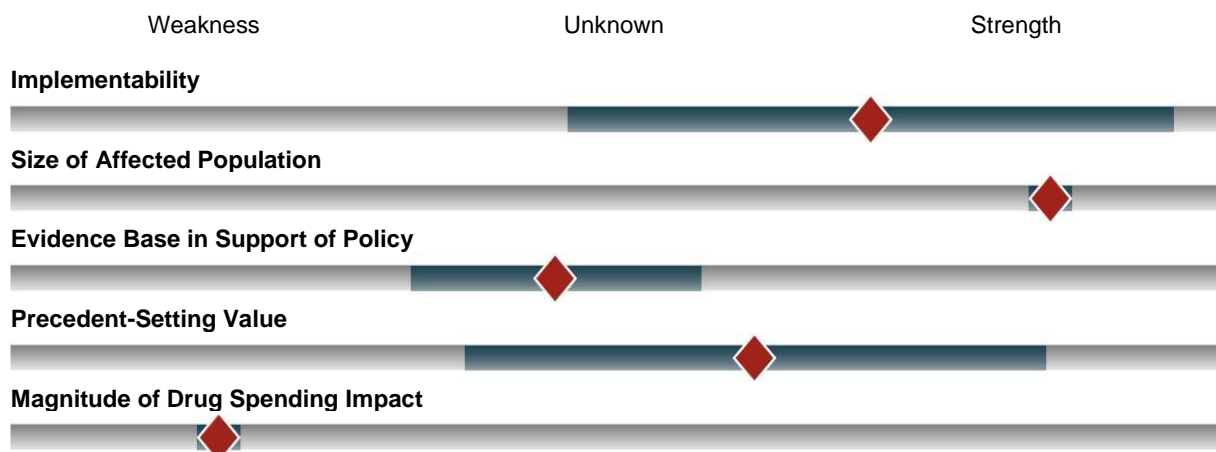
How likely would this policy be to increase patient drug access?



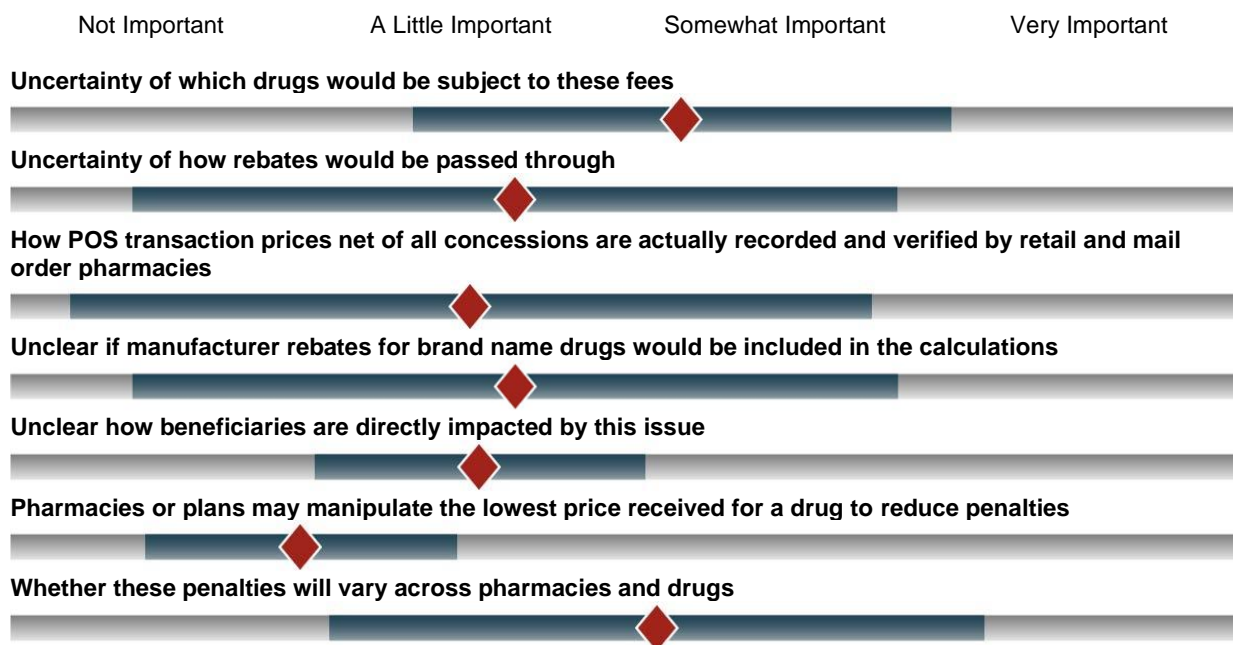
How significant is this policy in the evolution of US drug spending policy?



What are the strengths and weaknesses of this policy?



How important are the following in your analysis of the policy's impact?



* * *

On behalf of CIDSA, I appreciate the opportunity to offer comments on the proposed rule. We share CMS' goal of reducing drug spending and lowering costs for patients, and we hope our comments can assist CMS in its rulemaking.

Sincerely,

Sean Dickson
Chair, Council for Informed Drug Spending Analysis
Director of Health Policy, West Health Policy Center