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December 29, 2020

Seema Verma
Administrator
Centers for Medicare & Medicaid Services
200 Independence Avenue S.W.
Mail Stop 314G
Washington, DC 20201

**Re: Comments on Notice of Proposed Rulemaking, Patient Protection and Affordable Care Act; HHS Notice of Benefit and Payment Parameters for 2022 and Pharmacy Benefit Manager Standards; Updates to State Innovation Waiver (Section 1332 Waiver) Implementing Regulations, CMS-9914-P**

Dear Administrator Verma:

Thank you for the steps that the Centers for Medicare & Medicaid Services (CMS) has taken to increase states' ability to reform their individual and small group health insurance markets. We are pleased to offer the following comments to CMS on the Proposed Notice of Benefit and Payment Parameters (NBPP) for 2022 (hereinafter, "the proposed rule").

Section 1332 of the Affordable Care Act (ACA) permits the Secretary of Health and Human Services (HHS) and the Secretary of the Treasury (hereinafter referred to as "the Secretaries") to approve a state's proposal to waive specific provisions of the ACA, provided the proposal meets certain requirements. The "State Relief and Empowerment Waivers" guidance issued in the Federal Register (83 FR 53575) (hereinafter referred to as the "2018 Guidance") superseded previous guidance published on December 16, 2015, in the Federal Register (80 FR 78131). We strongly support CMS's proposal to codify the agency's 2018 Guidance into federal regulation.

John McDonough, a Harvard professor who served as a senior advisor to the U.S. Senate Committee on Health, Education, Labor, and Pensions from 2008 through 2010 when the ACA was debated and enacted, in 2014 wrote:

> Section 1332 of Title I of the Affordable Care Act offers to state governments the ability to waive significant portions of the ACA, including requirements related to qualified health plans, health benefit exchanges, cost sharing, and refundable tax credits. It permits state governments to obtain funding that otherwise would have gone to residents and

businesses through the ACA and to use those funds to establish, beginning in 2017, an alternative health reform framework within statutory limits.[1]

Unfortunately, the 2015 Guidance served to restrict states' ability to utilize 1332 waivers to improve their health insurance markets by tightening the statutory "guardrails" that must be satisfied for waiver approval. Three of these guardrails pertain to the number of people with coverage as well as the affordability of that coverage and nature of that coverage. The fourth guardrail requires that the waiver not increase the federal deficit. This 2015 guidance was far more restrictive than the statutory requirements and virtually nullified states' ability to innovate through section 1332.[2] As a result of the restrictive guidance and approach, only one state submitted and had a 1332 waiver approved prior to January 1, 2017.

Fortunately, the 2018 Guidance offers both an interpretation of the guardrails that makes 1332 waivers more useful for states as well as an interpretation that is more consistent with the statute. By codifying the 2018 Guidance, the Departments will further the intended aim of 1332 waivers to promote state policy innovation in designing programs that expand options, lower costs, and promote coverage without increasing the federal deficit.

The revised guidance was necessary to allow states to design programs that could expand options, lower costs, or increase coverage relative to baseline projections. Of course, these waiver applications would need to be approved by the Secretaries and can only be approved after both departments as well as the Office of Management and Budget are satisfied the proposal meets the four statutory guardrails.

Changing criteria at this point will increase regulatory uncertainty, make states less likely to submit 1332 waivers, and reduce the positive momentum around 1332 waivers with 12 states receiving 1332 waivers since 2017 in addition to the three states with waivers approved in 2017. States with approved 1332 waivers have generally experienced positive results. A June 2020 CMS analysis of the effect of 1332 waivers found that premiums were an average of 17.7 percent lower during the 2020 plan year in the 12 states that had approved 1332 waivers in place than they would have been without those waivers.[3] In 2020, another three states secured 1332 waivers. Consumers have thus benefited from 1332 waivers that are consistent with the existing guardrails. Changing those standards will likely discourage other states from applying for waivers that might similarly benefit their residents.

In this proposed rule, the Departments seek to provide certainty to states that the requirements and expectations of the Section 1332 waiver program will not change abruptly during a period in which states are doing the work to prepare a waiver proposal. We agree with the Departments that providing consistent application requirements will encourage more states to pursue the waivers since it will decrease uncertainty about sudden changes or changes that may be averse to

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[1] John E. McDonough, "Wyden's Waiver: State Innovation on Steroids," Journal of Health Politics, Policy, and Law (2014) 39(5): 1099-1111.
[2] Heather Howard and Dan Meuse, "New Section 1332 Guidance a Mixed Bag for States," Health Affairs Blog, February 29, 2016.
[3] CCIIO Data Brief Series, "State Relief and Empowerment Waivers: State-based Reinsurance Programs, June 2020. https://www.cms.gov/CCIIO/Programs-and-Initiatives/State-Innovation-Waivers/Downloads/1332-Data-Brief-June2020.pdf

states' goals. Codifying the Departments' 2018 Guidance would help states that are interested in undertaking the complicated and potentially expensive work to design a waiver program that meets the four guardrails, as defined in that Guidance. This is especially important because the process of developing a proposal and submitting it may take significant time and taxpayer resources, and states do not want to undertake these efforts if the probability of success is low and the probability of the Departments changing requirements is high. Federal equities would be protected because the 2018 Guidance reserves to the Secretaries the authority to suspend or terminate a waiver, in whole or in part, if the Secretaries determine that the state materially failed to comply with the waiver's terms and conditions.

Given the impressive results of 1332 waivers thus far, it is paramount that CMS not engage in regulatory whipsaw and that states are allowed to rely on existing regulatory direction across administrations, particularly if the existing framework demonstrates clear, positive results. Regulatory codification would also ensure that states have a seat at the table if a future administration wishes to modify the requirements. Such a proposed modification would need to go through the standard rule-making process, and this would provide states an opportunity to provide important feedback on any proposed modifications. Feedback from states is crucial to ensure that the criteria the Secretaries' use to evaluate 1332 waiver proposals permits states to actually make use of the waivers and to be innovative—the intended purpose of Section 1332 of the ACA—while satisfying the guardrails.

In closing, we thank you for the opportunity to comment on the proposed rule and for your continued work to promote state-based health reforms. We urge you to finalize this part of the rule—the codification of the 2018 Guidance regarding State Relief and Empowerment waivers—as proposed.

Sincerely,

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