AMA
AMERICAN MEDICAL ASSOCIATION

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The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

Honorable David J. Kautter
Assistant Secretary for Tax Policy
U.S. Department of Treasury
1500 Pennsylvania Avenue, NW
Room 3120
Washington, DC 20220

Re: 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 and Assistant Secretary Kautter:

On behalf of the American Medical Association (AMA) and our physician and student members, I appreciate the opportunity to comment on the proposed Notice of Benefit & Payment Parameters (NBPP) for 2022. While the AMA acknowledges that the Administration's overall goal is to give states more flexibility and reduce burdens on stakeholders in order to stabilize the markets and improve health care affordability, **we believe that some of the proposals in the payment notice could undermine existing consumer protections under the Affordable Care Act (ACA) and harm patients.** Accordingly, the AMA's comments focus on several issues about which we have concerns, including changes to enrollment in health plans through exchanges, codification of certain changes under section 1332, and increases in premiums and cost-sharing. In addition, we comment on CMS' failure to address limits imposed by payers or pharmaceutical benefit manufacturers for high-cost pharmaceuticals.

Exchange Direct Enrollment Option

CMS proposes to allow states to transition away from a single, centralized marketplace (i.e., HealthCare.gov) to an Exchange Direct Enrollment (DE) option, where states could let people enroll in exchange plans using private sector entities (i.e., insurers, web-brokers, and agents and brokers) beginning in 2023. This proposal is similar to the section 1332 waiver CMS recently approved for Georgia, which will eliminate the use of HealthCare.gov and replace it with a decentralized enrollment system of web-brokers and insurers. In its proposed rule, however, CMS would allow states to use the Exchange DE option without having to apply for a waiver, although they would still need to ask for federal approval.

Over the last few years, CMS has encouraged alternative enrollment avenues, including through a federally created DE pathway where insurance companies and brokers (including web-based brokers) use their own websites to help people enroll in marketplace plans and access subsidies. And in late 2018, the federal government began approving entities to use the "enhanced direct enrollment" (EDE) pathway, which allows insurers and brokers to handle the entire application process, eliminating all direct contact

between the consumer and the marketplace. The EDE was implemented in 2018 and CMS has since approved nine entities for the pathway and another 30 that conduct direct enrollment. These entities combined facilitate about one-third of the enrollment through healthcare.gov, according to CMS. Any state could use one or more EDE or DE vendors instead of HealthCare.gov to enroll consumers into exchange plans. CMS now proposes to let state-based exchanges (SBEs) request permission to end their enrollment platforms starting in 2022 and the federally facilitated exchanges (FFEs) or state-based exchanges using the federal platform (SB-FFEs) can transition away from HealthCare.gov starting in 2023. CMS argues that the Exchange DE option has several advantages over states establishing their own exchanges, including that state-based exchanges confront challenges in innovating, are costly and burdensome to create, and result in "choke points" when too many consumers try to use the website at the same time. CMS also argues that the Exchange DE option results in savings to the federal government (through reduced use of the HealthCare.gov website and call center) and allows consumers to see a broader array of plan options, including on- and off -exchange plans as well as ancillary products.

The AMA believes that CMS' rationale for this proposal is outweighed by the likely confusion and disruption that could occur if it is implemented as proposed. The ACA established the exchanges to serve as consumer-facing, one-stop marketplaces where individuals could compare qualified health plans (QHPs) based on price and quality, choose the plan best suited to their needs, and learn about eligibility for and apply for financial assistance. Consumers can submit a single application at the exchange website to connect with the type of health coverage for which they are eligible, whether Medicaid, the Children's Health Insurance Program (CHIP), or a private plan. Thirty-two states rely on the federal insurance exchange, plus a few others that run their own state marketplaces under the law but depend on the federal online sign-up system. Now, CMS is continuing to create an alternative privatized exchange, with its own set of less stringent rules, that it is encouraging states to use. This seems to be a solution in search of a problem.

Direct enrollment raises several concerns, primarily because DE entities do not have all the benefits and protections that the ACA marketplaces provide. For example, many DE entities offer plans that do not comply with ACA standards, such as short-term limited duration insurance, and they may benefit financially if they enroll more people in them. One study has found that some DE sites use screening tools to shift consumers away from marketplace options. Since web-brokers can recommend specific products to clients, they can steer consumers away from more comprehensive plans.

In addition, under current rules, web-brokers are required to disclose and display all QHP information provided by the exchange or directly by QHP insurers. If not all QHP information is displayed, web-brokers must prominently display a standardized disclaimer that identifies those QHPs and refers consumers to the exchange. Now, CMS is proposing to provide web-brokers with more flexibility by allowing them not to list as much information about a QHP that they cannot sell. So, if a web-broker does not have an agreement with that insurer to enroll consumers in its products, under the proposed rule it could limit the display information for that QHP to the name of the insurer and the plan, the metal level, and premium and cost-sharing information. While the web-broker would still have to refer consumers to the exchange website, it would no longer have to display a summary of benefits and coverage, quality ratings, or other information. This means that consumers would no longer be able to comparison shop all QHPs based on price and quality on an apple-to-apples basis in one place.

The AMA is particularly concerned that individuals who are eligible for Medicaid or CHIP may face additional barriers to enrolling when they rely on a DE website. The marketplace has a "no

wrong door" policy, meaning that consumers who go to the exchanges can fill out one application and be routed to Medicaid, CHIP, or marketplace subsidies based on the information they provide. While it appears that exchanges would still be responsible for conducting Medicaid and CHIP eligibility assessments or determinations and referring individuals to state Medicaid agencies, if DE and EDE entities are the only enrollment mechanism, ensuring that eligible beneficiaries actually know they are eligible for Medicaid or CHIP and need to go to the exchange could be challenging.

The AMA is concerned that continuing on the path of privatizing the exchange with which millions of consumers are familiar and through which most consumers enroll could make it harder for people to find high-quality, ACA-compliant insurance with full benefits and could reduce overall enrollment. We also find it perplexing that CMS recently required the state of Georgia to apply for a waiver under section 1332 to do exactly what the agency is now proposing to allow all states to do without requiring such a waiver. It is not at all clear that CMS has the authority under the ACA to do so. For example, although CMS does not propose to formally revise the current definition of "exchanges," it suggests that "exchanges" in the proposed rule collectively refers to SBEs, FFEs, SBE-FPs, and the new DE options. This is in direct conflict, however, with the current statutory definition in section 1311(d)(1) of the ACA, which requires an exchange to be a governmental agency or non-profit entity that is established by a state, and the current regulatory definition, at § 155.20, which defines an exchange as a governmental agency or nonprofit entity that complies with federal ACA requirements and makes QHPs available to those who qualify. At the very least, this proposal would seem to violate the spirit and intent of the ACA's exchange provisions, and we urge CMS to withdraw it.

Codifying Certain Changes to Section 1332

The NBPP proposes to codify certain parts of the Administration's guidance interpreting section 1332 of the ACA, i.e., State Relief and Empowerment Waivers. CMS and the U.S. Department of Treasury adopted prior regulations on procedural requirements under section 1332 but interpreted the statute's substantive guardrails in guidance only. Guidance was initially issued by the Obama Administration in 2015 and then rescinded and replaced by the Trump Administration in 2018. Now, CMS and Treasury would incorporate the 2018 guidance into regulations to give states certainty about the future of section 1332 waivers. Specifically, the agencies propose to require states to submit analyses and data so federal officials could assess whether the proposal meets the substantive guardrails consistent with the 2018 guidance, and tie in the 2018 guidance to standards on monitoring and compliance and periodic evaluation. Federal officials would be required to evaluate waiver implementation consistent with the 2018 guidance and the approval's terms and conditions.

The AMA strongly opposes the agencies' attempt to codify the sub-regulatory guidance, especially their 2018 interpretation loosening the substantive guardrails in section 1332's guardrails, into regulations. As the AMA noted in our comment letter when the 2018 guidance was issued, we believe that the agencies' reinterpretation of the guardrails makes it easier for states to sidestep important ACA coverage requirements; will undercut crucial state and federal patient protections, especially for individuals with pre-existing conditions; will result in substandard, inadequate health insurance coverage; and will disrupt and destabilize the individual health insurance markets. Most significantly, under the Departments' guidance, states could use federal funds to subsidize non-ACA compliant plans, including short-term limited duration insurance (STLDI), which has skimpy benefits and fewer protections for individuals with pre-existing conditions. We believe that these changes are contrary to both the statutory text and congressional intent. **Accordingly, we urge the agencies to withdraw this proposal.**

Continuing Premium and Cost-Sharing Increases

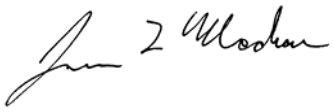
The NBPP proposes to continue the 2019 change in the formula used to calculate premium tax credits, which cut financial assistance for millions of people. **We opposed this change when it was proposed, and we continue to oppose it.** The formula change would have an even greater impact in 2022, raising premiums by 4.7 percent for most subsidized marketplace consumers after accounting for their tax credits (compared to about 2.7 percent this year). That amounts to a $360 annual premium increase for a family of four with $80,000 in income. The same formula change also increases the limit on consumers' total out-of-pocket expenses, which applies to both marketplace and employer plans. In 2022, that limit will be $400 higher for an individual, and $800 higher for families, than if the 2019 change were reversed. These proposed changes would disproportionately impact individuals with pre-existing conditions since they are more likely to hit their plans' out-of-pocket limits. **We urge CMS to reverse the change adopted in 2019.**

Manufacturers' Copay Assistance for High-Cost Pharmaceuticals

The AMA is disappointed that the NBPP does not address the issue of manufacturers' copay assistance for high-cost pharmaceuticals. CMS previously prohibited most so-called 'copay accumulator programs' and we urge the agency to adopt the copay accumulator language that was included in the proposed 2020 NBPP that prohibited payers from excluding copay assistance from counting towards patients' cost-sharing, with limited exceptions. The 2021 NBPP, finalized in May of this year, gives health plans the discretion not to count manufacturer copay assistance toward a beneficiary's annual cost sharing, regardless of generic availability. We are concerned this will result in increased costs to patients, or worse, result in some patients deciding not to take or continue taking their medications with severe adverse health consequences. **We urge CMS to address this critical issue, which is especially important to protect patients in the midst of a global pandemic.**

Thank you for considering the AMA's comments. If you have any questions, please feel free to contact Margaret Garikes, Vice President, Federal Affairs, at margaret.garikes@ama-assn.org or (202) 789-7409.

Sincerely,



James L. Madara, MD