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
200 Independence Avenue, SW
Washington, DC 20201

Re: Patient Protection and Affordable Care Act: Centers for Medicare & Medicaid Services (CMS) Notice of Benefit and Payment Parameters for 2020; Proposed Rule

Dear Administrator Verma:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments on the Centers for Medicare & Medicaid Services' (CMS) Proposed Rule on Notice of Benefit and Payment Parameters for 2020. The AMA provides comments below on the following significant issues: automatic re-enrollment; coverage for medication-assisted treatment (MAT); mid-year formulary changes; drug manufacturer coupons and accumulator adjustment programs; segregation of funds for abortion services; and changes to the premium adjustment percentage.

Automatic Re-enrollment

As CMS notes in the preamble to the proposed rule, enrollees in plans offered through a federally-facilitated Exchange or a State-based Exchange using the Federal platform have several options during open enrollment periods regarding their coverage. They can re-enroll in their current plan, select a new plan, or take no action and be re-enrolled in their current plan. While CMS does not propose any changes at this point to automatic re-enrollment, the agency does seek comment on re-enrollment policies with an eye to possible future rulemaking. CMS notes its concern that some consumers may be less aware of their options year-to-year and that "automatic re-enrollment eliminates an opportunity for consumers to update their coverage and premium tax credit eligibility as their personal circumstances change…." The agency also indicates concern with eligibility errors and potential government misspending as a result of automatic re-enrollment.

While we acknowledge that some consumers who are automatically re-enrolled may forego opportunities to review and update their coverage and tax credit eligibility, the AMA is more concerned that without automatic re-enrollment, many consumers might end up with no coverage at all. CMS itself acknowledges that automatic re-enrollment makes enrolling in health insurance more convenient for consumers, and notes that in the open enrollment period for 2019 coverage, 1.8 million people in states using the federal platform were automatically re-enrolled in coverage. CMS fails to acknowledge the impact that the drastic cuts to outreach and education resources made over the past two years have had on assisting

consumers in the enrollment process. Funding for the 2018 Open Enrollment consumer outreach and enrollment educational activities was reduced from $100 million to $10 million, a 90 percent cut from the previous year, and such activities continued to be funded at the same level during the 2019 Open Enrollment period. The AMA supports increased funding for outreach and educational activities in the future. We also note that automatic re-enrollment is even more important to ensure current enrollees maintain their coverage now that Congress has zeroed out the penalties for the individual mandate.

Discriminatory Benefit Design and MAT

We applaud the many initiatives that the Administration has undertaken to address the national opioid epidemic. We also appreciate that CMS, in the preamble to the proposed rule, is concerned about coverage for medication-assisted treatment (MAT) and recognizes that some insurers are excluding MAT coverage, even when MAT is included on a plan's formulary, when used for substance use disorder (SUD) treatment but covering MAT drugs for other medically necessary reasons, such as analgesia. We agree with CMS that such coverage decisions could violate the nondiscrimination requirements under essential health benefits (EHB) requirements, and appreciate that CMS reminds insurers that treating subsets of individuals differently in terms of their benefits must be justified, with evidence-based supporting documentation, to show that its benefit design is not discriminatory. Such coverage decisions could also violate the Mental Health Parity and Addiction Equity Act (MHPAEA) and federal civil rights laws, including the Americans with Disabilities Act, which prohibit discrimination against individuals who participate in or have completed SUD treatment, such as MAT.

With respect to the EHB benchmarking process, CMS should encourage states to adopt benchmarks that require health plans to provide access to comprehensive care options for all individuals with or at risk of opioid use disorders, including coverage of all medications used for MAT, and to comprehensive, multidisciplinary, multimodal pain care, including affordable access to non-opioid pain care alternatives. The AMA strongly supports removing prior authorization for FDA-approved medications used to treat opioid use disorder for all commercial, Medicaid, and self-insured plans.

The AMA believes it is long overdue to ensure that the MHPAEA fulfills its promise of ending discriminatory and illegal barriers to treatment. State and federal regulators must step up their enforcement of the MHPAEA. For example, state regulators should conduct market conduct examinations to determine whether the benefits as promised are actually the benefits as delivered, and when there are violations, regulators should both require swift corrective action plans, implement fines and other penalties as warranted by the violations, and then conduct re-examinations of the payers' efforts to ensure that the corrective action plans have been implemented.

Prescription Drug Coverage

Mid-year formulary changes

Existing federal rules on guaranteed renewability prohibit insurers from changing coverage except when the plan is renewed each year. This applies to mid-year formulary changes, except when necessary and appropriate, such as if new drugs become available in the market or if drugs have been withdrawn for safety reasons. CMS now proposes that beginning in 2020, insurers (i.e., in the individual, small group, and large group markets) would be allowed to make certain mid-year formulary changes that would not

result in the loss of a plan's grandfathered status. In order to incentivize the use of generic or other lower cost drugs, CMS would allow insurers to: 1) add a generic that becomes available on the market; and 2) remove the equivalent brand name drug from the formulary or move the equivalent brand name drug to a different cost-sharing tier. If a plan covers a brand drug where a generic exists, the brand drug would no longer be considered an essential health benefit.

The AMA strongly opposes the second part of this proposal—that is allowing issuers to remove the brand name drug from its formulary or moving the brand name drug to a different cost-sharing tier when a generic becomes available. The AMA frequently hears from physicians about the disruption and confusion that constantly changes to their patients' drug benefits cause. For physician prescribers and patients, it can be a moving target throughout the year as to what prescription medication will be covered under the patient's insurance plan and what restrictions around coverage will be in place. Changes to formulary restrictions can have negative effects on patients and can have a major impact on health care costs. If the brand name drug removed is no longer considered an EHB, plans would no longer be required to count co-pays of such drugs toward out-of-pocket maximums and ACA protections against annual or lifetime caps on benefits would no longer apply. Moreover, a patient with a chronic medical condition who has been stable on a particular medication may choose her health insurance plan largely because of its coverage of that medication. However, a move by her insurer or pharmacy benefit manager (PBM) to remove the medication from her formulary during the middle of her plan year and replace it with another medication that is not effective for her—or which the patient has previously tried and not done well on—could mean potential trips to the emergency department and/or hospitalizations, increased out-of-pocket costs if she has to pay for the drug herself, and potential physician and patient resources spent on appeals and alternative solutions. There is also no guarantee of access to the brand name drug through the exceptions or appeals process.

For the above reasons, the AMA urges CMS to withdraw its proposal to allow issuers to remove brand name drugs from formularies or move such drugs to a higher cost tier mid-year.

Drug manufacturer coupons

CMS expresses concern that the use of drug manufacturer coupons to patients to help lower their out-of-pocket costs incentivizes more expensive brand name drugs, thereby increasing overall drug costs and premiums. The AMA acknowledges this concern but does not agree with CMS' proposal to allow accumulator adjustment programs for the 2020 plan year. The AMA supports economic assistance, including coupons and other discounts, for patients, whether they are enrolled in government health insurance programs, enrolled in commercial insurance plans, or are uninsured. While co-pay cards and other forms of economic assistance are needed for patients given the current state of the prescription drug marketplace, we are very concerned that co-pay cards in particular further distort the market. The co-pay cards enable pharmaceutical manufacturers to keep prices high, offering no downward pressure on high list prices, nor providing any incentive for industry to lower the product list prices. PBMs' growing use of co-pay accumulator benefit designs also limits the success of co-pay coupons in improving overall medication affordability for patients. Under co-pay accumulator programs, PBMs do not apply the manufacturer's co-pay coupon to the patient's deductible or out-of-pocket maximum. When the co-pay coupon expires or runs out, or the patient exhausts all other forms of co-pay assistance, the patient is faced with a sudden—and often massive—increase in financial responsibility for the drug, as the coupons have not counted toward his/her deductible.

Segregation of Funds for Abortion Services

CMS proposes to require insurers that cover non-Hyde abortion services to also offer at least one "mirror" plan without the coverage of non-Hyde abortion services. A mirror plan would be required to provide identical benefit coverage other than excluding non-Hyde abortion services. The AMA is concerned that this proposal, in conjunction with several other recent regulatory initiatives, will impose barriers to women's access to abortion services, directly contravening the ACA's intent and language to allow insurers to choose to cover or not to cover non-Hyde abortions as part of their qualified health plans.

Premium Adjustment Percentage

CMS proposes technical changes to how the Administration would measure "premium growth," which is part of the formula for adjusting the ACA's "applicable percentages,"—i.e., the share of income that exchange enrollees are expected to pay toward silver plan health coverage—the maximum out-of-pocket limit, and the employer mandate penalty. The AMA is concerned that this proposal, which is not required by the ACA, would raise premiums for most marketplace consumers by cutting their premium tax credits and would increase limits on total out-of-pocket costs. According to the Administration's own estimates, the increased premiums would cause 100,000 people to drop marketplace coverage each year. These proposed changes would disproportionately impact individuals with pre-existing conditions since they are more likely to hit their plans' out-of-pocket limits. In addition, CMS acknowledges the proposed changes could negatively affect the marketplace risk pool, resulting in a decrease in marketplace enrollment among premium tax credit-eligible consumers, and could eventually result in net premium increases for enrollees that stay in the individual market. We urge CMS not to adopt this proposal in the final rule.

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