AMA
AMERICAN MEDICAL ASSOCIATION

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Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: U.S. Department of Health and Human Services (HHS) Notice of Benefit and Payment Parameters for 2017; Proposed Rule

Dear Acting Administrator Slavitt:

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 or the Agency) proposed Notice of Benefit and Payment Parameters for 2017 (NPRM or proposed rule). As millions of Americans have enrolled in coverage offered through health insurance exchanges under the Affordable Care Act (ACA), substantial progress has been made in fulfilling the AMA's long-time policy in support of expanding access to affordable, quality health insurance coverage. At the same time, however, implementation of the exchanges has certainly been complicated, and at times frustrating, for physicians and patients alike. This is especially true with respect to the provider networks offered in many of the exchanges' qualified health plans (QHPs). Accordingly, we appreciate that CMS, in the proposed rule, has acknowledged many of the concerns that the AMA and other physician and patient advocacy groups have raised about barriers to access experienced by enrollees in QHP coverage and has offered proposals to help address some of these barriers, including adequacy of provider networks. Our comments below focus on the following issues raised in the NPRM:

- Network Adequacy Standards
- Rate Review
- Navigators and Assisters
- Medicare Notices
- Standardized Options
- Drug Formulary Exceptions Process
- Availability of Medication-assisted treatment for opioid addiction as a mental health and substance use disorder Essential Health Benefit
- Premium Payment Threshold Policies and Grace Period
- Medical Loss Ratio

Network Adequacy Standards

The AMA is very pleased to see proposals to strengthen network adequacy standards for QHPs. The AMA was heavily engaged in the National Association of Insurance Commissioners' (NAIC) efforts to update its now final Health Benefit Plan Network Access and Adequacy Model Act (Model Act). While progress was made under the Model Act in terms of improving network adequacy for those states that may adopt it, the Model Act does not go as far as many stakeholders had hoped in terms of standardizing the measurement of adequacy in a state. As such, we strongly support proposals by CMS to establish quantitative network adequacy standards and make the following suggestions to help strengthen these proposals.

Quantitative standards

The use of quantitative measures allows state regulators to effectively evaluate, monitor, and enforce insurers' networks. Therefore, we are very pleased that CMS is proposing a shift toward requiring quantitative standards be used to measure network adequacy. We are also pleased to see that CMS is proposing a default standard for those states that do not create their own using CMS guidelines.

As CMS moves forward in determining the default standards, as well as standards from which states can choose to measure network adequacy, the AMA suggests the following:

- The use of multiple quantitative standards to measure network adequacy is critical. While time and distance standards alone can help provide a picture of the network, the addition of provider-patient ratios, provider availability, and capacity standards, etc., continue to create a complete story of the ability of the network plan to meet the needs of its members.

- Access to specialists and subspecialists should be part of any network evaluation so that patients have access to providers with the experience and expertise to meet their particular needs. This includes ensuring access to pediatric specialists and subspecialists.

- A network's ability to provide access to participating providers at participating hospitals is a critical component of adequacy. Regulators should actively evaluate and measure the coordination of hospital-based physicians and participating facilities.

- Quantitative standards should evaluate providers using a full time equivalency standard. If, in order to be adequate, the network needs four addiction medicine specialists in a particular region, certainly four part-time addiction medicine specialists is not going to be sufficient.

- All networks should be able to meet the needs of low-income or vulnerable covered patients, covered patients with serious, chronic or complex health conditions or physical or mental disabilities, and cover persons with limited English proficiency.

CMS requested comments on the use of Medicare Advantage (MA) network adequacy requirements. MA requirements utilize more than a single standard of measurement, focusing on both provider ratios and time and distance requirements, and in that respect, the AMA sees these standards as a good place from which to start building. However, the AMA has concerns about using these standards for QHPs without

modification. MA standards are designed for a specific population and one that likely differs quite significantly from the QHP populations. For example, access to pediatricians and pediatric specialists and subspecialists is an important component of adequacy for QHPs. Moreover, MA standards do not evaluate networks using a full-time equivalency standard, threatening access to care for many patients.

Expansion of requirements to all QHPs

The AMA urges CMS to apply requirements of a set of minimum quantitative standards or a default to federal standards beyond just QHPs in Federally-Facilitated Exchange (FFE) states, but also to all QHPs in State Based Exchange (SBE) states. The statute and section 156.230(a)(2) of the federal regulations require that all issuers offering QHPs maintain networks that are sufficient in number and types of providers to assure that all covered services are accessible without unreasonable delays. Therefore, we see no reason why this requirement could not be expanded, and see many reasons why it should be, including, most importantly to protect patient access to care, regardless of the state in which they purchase their QHP.

Prior approval of networks and reevaluation upon material changes

The AMA strongly urges CMS to require that all QHP network plans be reviewed and approved prior to being sold. In this changing health care environment, it is critical that regulators address network adequacy problems within a plan's network before the product is ever used by patients. This front-end evaluation will prevent consumers from purchasing an inadequate product and confronting access problems at the time care is needed.

Additionally, it is important that plans be continuously reviewed and reapproved, specifically when a material change is made to the network or the plan population. We suggest defining a material change to be "a change in the composition of a health carrier's provider network or a change in the size or demographic characteristics of the population enrolled with the health carrier that renders the health carrier's network non-compliant with one or more of the network adequacy standards."

Continuity of care

CMS is proposing that QHP insurers in FFEs be required to provide 30 days' notice to regular patients of providers who are being removed from the plan's network. The AMA supports such notice and, in fact, encourages CMS to require even earlier notice, such as 60 days' notice to ensure continuity of care.

Transparency of selection standards

CMS requests comments on transparency of issuers' criteria for selecting and tiering providers and whether issuers should be required to make their selecting and tiering criteria available for review and approval by CMS and the state. The AMA strongly supports this proposal.

Full transparency of issuers' provider selection standards is critical, given the shift toward narrow and tiered networks, many of which seem to be designed on the basis of cost, rather than quality. The tiering of certain specialty providers into higher cost tiers or the exclusion of those providers from a network is

problematic because it could place unanticipated costs onto patients enrolled in the plan or deter patients with serious medical needs from that plan or product.

Additionally, issuers may identify networks as "high-value" or "high-performing," thus implying that provider quality has been considered in the development of the network. In the event that quality is a factor that is used in the design of a network, consumers and providers should have information regarding the quality measures that were used. By the same token, if quality factors have not been used to create the network, it is critical that consumers, providers, and regulators are made aware of the basic methods that were used to create the network.

Out-of-network cost-sharing

CMS proposes new protections for patients receiving Essential Health Benefits (EHBs) from non-participating providers at participating facilities. The AMA strongly supports the proposal to allow cost sharing in such situations to apply to the plan's annual limitation on cost-sharing. To strengthen this provision, the AMA encourages CMS to clarify that such cost-sharing includes any amounts they are billed by a provider beyond the insurer's allowable amount or "balance bills." We also ask that CMS clarify that this provision applies to patients enrolled in plans without out-of-network coverage, as well as those with such coverage.

Additionally, while we strongly support issuer disclosure of the possibility of out-of-network care at participating facilities, the AMA does not think that such disclosure should provide an exception to counting cost-sharing toward the maximum out-of-pocket limits.

Moreover, the AMA believes this rule provides an opportunity for CMS to further address the issue of out-of-network care by placing additional requirements on issuers. As stated above, the AMA urges CMS to require network standards that evaluate patients' ability to access participating providers at participating hospitals. Unfortunately, too often a weak network will be able to meet network requirements without showing coordination of providers and hospitals. The AMA strongly recommends special attention be paid, and specific adequacy standards be applied, to hospital-based physicians and networks' ability to provide in-network access to hospital-based care.

The AMA also encourages CMS to require stronger transparency of out-of-network coverage. Often unanticipated bills result from the patient believing their out-of-network coverage was more comprehensive than it turns out to be. At the most basic level, insurers should be required to standardize the way in which they market and describe their out-of-network coverage, with comparisons to a realistic baseline derived from independent, out-of-network charge data.

Network breadth

As restrictive network designs quickly replace more robust networks, patients may not be aware that they have purchased a plan with very limited access or one that does not provide access to the type of care they need. Therefore, the AMA supports CMS' proposal to develop a classification system to assist patients in selecting a plan that best meets their needs, focusing on the breadth of the network compared to other plans in the region. The AMA encourages such a system to be conveyed to patients in a clear and concise manner, thereby making it easy for patients to understand. Additionally, such a system should evaluate

access to all providers, including primary care providers, specialists and subspecialists, as well as facilities.

Rate Review

The AMA supports several important proposed changes related to issuer rate review. Under the NPRM, non-grandfathered coverage in the individual and small group market beginning in 2017 would be subject to rate review if the average increase, including premium rating factors such as age or geography, for all enrollees weighted by premium volume for any plan within a product exceeds the threshold for unreasonableness. We agree with CMS that adding rating factors will help to avoid gaming by issuers of the premium increase threshold by changing the geographic rating area for a plan. We also support the following proposed changes, which we believe will strengthen rate transparency and help consumers better understand the rate setting process: requiring all issuers to submit rate filings to CMS using the Unified Rate Review Template not only when they seek an increase, but also for rate decreases or no change in rates; requiring issuers seeking rate increases to file an actuarial memorandum, as well as a written justification for increases above the threshold; making rate filing information publicly available if it is not a trade secret or confidential commercial or financial information; and requiring states, in order to be considered to have effective rate review programs, to make information publicly available on proposed rate increases subject to review and final rate increases.

Navigators and Assisters

CMS proposes to add several new requirements on navigators, non-navigator assistance personnel, and consumer assisters. Navigators would be required to provide targeted assistance to underserved and vulnerable populations. The AMA supports this proposal, which we agree is critical to improving access to health care for underserved and vulnerable populations who are at increased risk of poorer health outcomes. Focusing on these populations could help to narrow health disparities. We also support the proposal to require navigators to provide consumers with post-enrollment assistance, such as filing eligibility appeals, providing information about reconciling premium tax credits, filing for exemptions from the individual responsibility mandate, and understanding basic concepts related to using health coverage. Helping newly insured enrollees understand how to use their health insurance coverage is especially important in improving the health literacy level in this population, which could result in improved health outcomes. While navigators are required to assist consumers understand the availability of exemptions through the tax filing process and help them understand the tax reconciliation process, they are not allowed to offer tax assistance. To improve transparency, we support requiring navigators to disclose that they are not tax advisors, as well as requiring them to refer consumers to licensed tax advisors, tax preparers, and additional tax resources.

Medicare Notices

We appreciate CMS' acknowledgment of the importance of notifying enrollees who have exchange coverage of their potential eligibility for Medicare. In order to ensure a smooth transition to Medicare coverage, we recommend that all enrollees be notified that they may have become eligible for Medicare coverage through a special, highlighted message on the Healthcare.gov website that provides a link for further information. We think this would work better than using "pop-up" text because many computers use security filters to prevent pop-up notices from appearing. In addition, CMS should send a letter to

anyone aging into Medicare at least six months in advance, and at the time of enrollment if the enrollee will be turning 65 during the plan year.

Standardized Options

In order to reduce consumer confusion and simplify "the shopping experience," CMS proposes to create six standardized plan options for the FFEs, e.g., a bronze, a gold, a standard silver and three silver cost-sharing reduction plan options. The plans would have standard deductibles, four-tier drug formularies, only one in-network provider tier, certain deductible-free services, and a preference for copayments over coinsurance. Insurers would not be required to offer standardized plans and could offer non-standardized plans, as long as they meet meaningful difference standards, but standardized plans would be displayed on the Healthcare.gov website in a manner that makes it easier for consumers to find and identify them, including distinguishing them from non-standardized plans.

The AMA generally supports this approach. The intent of health insurance exchanges is to provide a patient-friendly market for patients to purchase health insurance, as well as increase the competition among plans based on quality and price. In general, patients have to navigate through many health plans to make the right choice that responds to their health care needs and budgetary realities. An HHS study that analyzed the exchange market in 35 states showed that patients had an average of 40 health plans to choose from for 2015 coverage, including catastrophic plans. The AMA agrees that navigating this wide range of health plan choices available on health insurance exchanges may be potentially difficult and confusing for patients, and therefore we support efforts to ensure clear and meaningful differences between plans offered on health insurance exchanges. Creating and highlighting for consumers standardized options with meaningful differences would be a step in this direction. At the same time, however, the AMA supports an "open market" approach to qualified health plan (QHP) certification and we would oppose CMS becoming more of an "active purchaser" by limiting the number of non-standardized options an issuer may offer in future years. In addition, the AMA recommends that there should be clear labeling of exchange plans that are eligible to be paired with a Health Savings Account (HSA) with information on how to set up an HSA.

While we generally support the approach of creating standardized options, we are concerned that the cost sharing options described in the proposed rule may not support access to the prescription medicines that patients need, particularly those with high levels of drug utilization. For example, the proposed coinsurance for the specialty tier for drugs in silver plans is 40 percent. This could be onerous, particularly for lower-income exchange enrollees who are receiving cost-sharing subsidies. According to an analysis by Avalere Health of 2015 QHP data, less than half of silver plans have specialty tier coinsurance of more than 30 percent. The 40 percent coinsurance level should be reduced or switched to a copayment; as CMS notes in the preamble, copayments are more transparent and make it easier for consumers to predict their out-of-pocket costs.

Drug Formulary Exceptions Process

Under current rules, non-grandfathered individual and small group plans are required to have an exceptions process for patients seeking access to an off-formulary medication, independent of the standard appeal processes. The exceptions process was finalized in the Notice of Benefit and Payment Parameters for 2016 and sets a 72-hour deadline for external review of a denied exception and 24 hours

for urgent situations. The costs of non-formulary drugs obtained through an exception apply to annual limitations on cost-sharing. Since some states have different processes for accessing non-formulary drugs, CMS is considering amending its exceptions process so that plans could comply with state requirements in states that have procedures that are more protective of consumers or that conflict with the federal process. The AMA would support allowing states with stricter protections to allow issuers in the state to defer to the state's process, as long as CMS retains its enforcement authority to ensure that the state's process is, in fact, more stringent and protective for consumers. We would not support, however, allowing CMS defer to states with less protective standards.

Medication-Assisted Treatment (MAT)

In recognition that opioid abuse has become a public health crisis in recent years, CMS is seeking comment on whether the substance use disorder requirement under essential health benefits EHBs needs additional clarification with regard to MAT for opioid addiction. The AMA strongly supports CMS taking steps to clarify the availability of MAT for opioid addiction as a mental health and substance use disorder EHB. Given the dramatic rise in opioid use disorders, there is a significant need for greater access to substance use treatment medications. According to a study published this year in the *Journal of the American Medical Association*, 80 percent of Americans with opioid addiction do not receive treatment.

Opioid use disorder is a chronic disease that can be effectively treated but it requires ongoing management, and MAT has been shown to be highly effective in the treatment of opioid addiction. MAT is the use of medications, commonly in combination with counseling, behavioral therapies, and other recovery support services to provide a comprehensive approach to the treatment of opioid use disorders. Food and Drug Administration (FDA) approved medications used to treat opioid addiction include methadone, buprenorphine (alone or in combination with naloxone), and naltrexone. Types of behavioral therapies include individual therapy, group counseling, family behavioral therapy, motivational incentives, and other modalities. Despite the expanded coverage for mental health and substance use disorder treatment under the ACA and mental health parity reforms, however, studies have shown that access to MAT remains limited. Less than 30 percent of treatment programs offer medications and less than half of eligible patients in those programs receive medications.

We are deeply concerned by the barriers faced by patients who need treatment and by physicians in finding and placing patients in addiction treatment and recovery programs. Many physicians regularly face this dilemma because there is inadequate capacity to refer patients for treatment and recovery programs. There are too few physicians and programs offering treatment and recovery services. Physicians who are on the frontlines of this crisis, particularly those in primary care and emergency departments, continue to report challenges in making referrals to meet patients' needs. As noted by the *Washington Post* in a front-page article focused specifically on the heroin epidemic, which was published on Sunday, October 4, 2015:

> Treatment centers are often prohibitively expensive, overcrowded, underfunded and subject to byzantine government rules. Health insurance coverage is stingy to nonexistent. And the social stigma of heroin addiction is still so potent that many users and their families are reluctant to seek help in the first place.

For example, many states do not offer a full range of MAT for patients in Medicaid programs, or subject Medicaid patients to various prior authorization requirements. Even if a state does cover MAT, some states impose limits on the length of time a patient may receive such treatment. And, despite parity rules for mental health and substance use disorders, some private insurance coverage also imposes limits on treatment, including duration of treatment, medication dosage, and level of care. The AMA strongly opposes such limits and believes that more specificity is required for issuers (as well as state Medicaid programs) to recognize that MAT works and that it must be covered under EHBs. This treatment should be made available to all patients with an opioid use disorder, including those insured by state Medicaid programs, those who are incarcerated and those who have failed a previous treatment plan. In addition, for long-term recovery, evidence-based behavioral therapies and other supportive services need to be covered and made available as an essential component of MAT.

Premium Payment Threshold Policies and Grace Period

The AMA supports CMS' proposal to allow issuers the option of adopting a premium payment threshold policy to avoid situations in which enrollees who are receiving advance payments of the premium tax credit (APTC) and owe only a *de minimis* amount of premium enter into a grace period or have their coverage terminated for non-payment of premiums. We believe this added flexibility will help enrollees who are having difficulty making full payments avoid the consequences of triggering the grace period or eventual coverage termination. CMS also proposes to make a corresponding change to the regulations governing the grace period so that an enrollee receiving APTCs who is in a grace period can reinstate coverage by making a payment that satisfies the issuer's payment threshold requirements.

The NPRM would also amend the grace period rules to clarify that if an individual loses premium tax credit assistance during the grace period, the entire three month grace period would still apply. We support these changes but urge CMS, as we have on previous occasions, to require insurers to communicate with physicians, in real-time, the status of enrollees during the grace period. Such communication is key to enabling physicians to educate their patients about the importance of keeping current with their premium payments in order to avoid termination of their health insurance coverage and maintain the continuity of their access to health care services. As we have previously commented in prior rulemakings, we reiterate our concern and opposition to the final grace period regulations which hold issuers responsible for claims only during the first 30 days of the grace period.

Medical Loss Ratio (MLR)

In the preamble to the proposed rule, CMS indicates that it is considering amending the MLR regulation to allow insurers' fraud prevention activities as incurred claims for calculating the MLR, and invites comments on whether the Agency should do so. The AMA strongly opposes such a change. This proposal was actively considered by the NAIC and CMS in 2010 and 2011 but it was rejected. Most recently, the insurance industry has been advocating that NAIC broaden the definition of what constitutes a "quality improvement activity" (QIA) to include various fraud detection and prevention activities among its other adjustments. The NAIC, however, in its deliberations and ultimately in its recommendations to HHS, emphasized that initiatives that would qualify as a QIA should meet clear criteria, including being capable of being objectively measured, of producing verifiable results and achievements, being evidence-based, nationally recognized by professional medical associations, directed

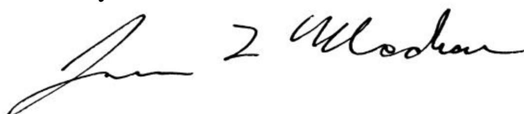
specifically at health improvements for individual enrollees, and other requirements. They would not qualify based on subjective, speculative or hypothetical benefits.

In creating the MLR, Congress looked to the NAIC, which held dozens of meetings, conference calls and hearings to ensure that all stakeholders had fair opportunity to present their views. The original intent of the MLR standard, as reflected in the regulations implementing the MLR, was to “provide value to policyholders, but also to create incentives for issuers to become more efficient in their operations.” Regulations to implement the MLR standard reflect the government’s interest in maintaining a strong MLR standard. Since the ACA was implemented, the MLR has worked as the NAIC and Congress intended. As currently implemented, the MLR standard provides greater transparency in the health insurance market for all parties. According to a 2015 Commonwealth Fund study, “total consumer benefits related to the MLR amount to more than $5 billion in the first three years due to savings of over $3 billion and almost $2 billion in rebates.” The AMA recognizes the MLR as an important component in ensuring value for patients’ health insurance premiums and costs. In fact, the hundreds of millions of dollars returned to consumers each year shows the MLR’s positive impact. Moreover, several reports, including a May 2015 report from the Robert Wood Johnson Foundation found that the MLR, in part, has contributed to reductions in insurers’ administrative costs and increased efficiencies in health insurance markets—both of which provide long-term benefits to consumers.

While the AMA recognizes that fraud detection and prevention activities are important, the AMA believes that such activities are a quintessential administrative and cost control expense and do not, and should not, qualify as an incurred claim. The MLR is a critical tool in addressing value in health insurance, but extreme care must be taken when considering changing any of the requirements. Therefore, the AMA would support CMS, through the NAIC, undertaking a thorough review of how insurers are claiming medical and quality expenses, and collect and thoroughly examine fraud prevention activity expense data. We believe that this detailed, deliberative process would benefit consumers and would help ensure that a strong MLR standard is maintained.

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

Sincerely,



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