

April 21, 2014

Marilyn B. Tavenner
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

Re: Proposed Rule on Exchange and Insurance Market Standards for 2015 and Beyond

Dear Administrator Tavenner:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to submit comments on the Proposed Rule on Exchange and Insurance Market Standards for 2015 and Beyond (Proposed Rule) issued by the Centers for Medicare & Medicaid Services (CMS) on March 14, 2014. Now that the first open enrollment period has ended and the nation's physicians have begun to provide care to the millions of Americans who are newly insured under the Affordable Care Act (ACA), we believe that it is imperative for CMS to modify some of its rules and guidance so that problems that have arisen with respect to coverage and access to care under qualified health plans (QHPs) purchased through the exchanges can be resolved. With this in mind, we hope our comments below—focused on prescription drug benefits, quality standards, and medical loss ratios—are helpful as CMS continues to examine lessons learned from this first open enrollment period.

Prescription Drug Benefits (Part 156)

The AMA appreciates that CMS is considering amending the formulary exceptions standards under § 156.122(c). We share CMS' concern that some enrollees, particularly those with certain complex medical conditions, may be having difficulty in timely accessing clinically appropriate prescription drugs, such as combination drugs, that are not covered by their plans' formularies. Section 156.122(c) requires issuers that provide essential health benefits to have procedures in place that allow an enrollee to request and gain access to clinically appropriate drugs not covered by the plan. We support CMS' proposal to amend the formulary exceptions standards to require that these processes can be expedited when necessary based on exigent circumstances, such as when an enrollee has a serious health condition, and that issuers make decisions within 24 hours following receipt of exceptions requests. However, as we indicated in our recent comments to CMS in response to the draft 2015 Letter to Issuers on the Federally-facilitated and State Partnership Exchanges, we believe issuers should be required to have transitional policies for enrollees who are already stable on a current course of treatment using a non-formulary drug.

Issuers should be required to temporarily cover non-formulary drugs, including drugs that are on the issuer's formulary but require prior authorization or step therapy, as if they were on the issuer's formulary during the first 90 days of coverage. This proposed transition policy would also allow those newly enrolled in a QHPs to receive temporary coverage for a non-formulary drug without using the exceptions process. A 90-day transition policy should provide enough time for patients to discuss medication options with their physicians and new health plan. Medicare Part D uses a 90-day transition, and we urge CMS to require this longer transition period for QHPs.

The AMA further recommends that during the formulary exceptions review process, QHPs should allow patients to have access to the drug in dispute during the entire process, and if the exception request is granted, the excepted drug should continue to be provided in subsequent years. With the increased use of step therapy and multiple drug tiers in the exchange QHPs, we believe these added protections are critical to ensuring continuity of care for patients. A recent study by Avalere Health found that most individuals in exchanges will face formularies with four or five cost-sharing tiers that commonly use coinsurance techniques for top-tier medications. According to the study, many issuers have added additional tiers compared to employer-sponsored plan formularies, including four or five tiers and tiers designated for specialty products. Drugs on Tier 4 of a formulary are more likely to have coinsurance rather than flat dollar copayments. Among exchange plans, Avalere found that 63 percent use coinsurance for fourth-tier drugs. The result is that consumers relying on specialty drugs used to treat complex and sometimes rare diseases, which often cost several thousand dollars, could face significant out-of-pocket costs, which many will not be able to afford.

We strongly urge CMS and state regulators to closely monitor formularies to ensure that patients with complex chronic conditions, such as patients with HIV/AIDS or cancer, or those who need specialized treatment, such as for mental health or substance use disorders, are not discriminated against. This is extremely important given the restrictive formularies and multiple tiers that many QHPs are using to keep costs down.

Given the use of restrictive formularies, formulary review must go beyond simply assessing whether a plan is covering a sufficient number of medicines in each class, as required under § 156.122(a)(1). Regulators need to examine what tiers drugs are placed on and whether prior authorization and step therapy are used appropriately. Cost should not be the sole criterion for imposing utilization restrictions. Formulary tiering should be closely monitored to ensure that patients have access to appropriate medicines on lower cost formulary tiers. Formularies should be reviewed to ensure that medicines are only placed on a higher cost tier when there is a therapeutically similar medicine on a lower cost tier.

Quality Standards (Part 156, Subpart L)

The AMA is seriously concerned with the handling of the design of the Quality Rating System (QRS) and lack of transparency around the selection of the QRS measures. As stated in the Proposed Rule, CMS intends to finalize the quality measures outlined in the QRS Notice and provide measure specifications in future technical guidance. CMS notes that its decision to finalize the QRS measures follow consideration of both public comment and recommendations by the National Quality Forum (NQF) Measure Application Partnership's (MAP) Health Insurance Exchange Taskforce. However, the QRS Notice published in November 2013 makes no reference to the MAP's review of the measures nor does it outline the measures that will be incorporated into the QRS. In addition, NQF released its recommendations for QRS measures on December 23, 2013, and provided less than 10 business days (over the holidays) in

which to comment. NQF specifically highlighted at the January 8, 2014 MAP meeting that they only received a total of seven comments, including only two comments from NQF member organizations. A stakeholder, who only reviews the QRS Notice and not the recommendations of the MAP, cannot receive a full understanding of the direction of the QRS. To address the lack of transparency and scant opportunity to comment, the AMA recommended in our QRS Notice comments that CMS should reopen the comment period regarding NQF's recommendations, and we once again urge CMS to do so.

The QRS is intended to be a tool to assist consumers with purchasing a QHP. However, the current set of measures scheduled for finalization does not adequately address network adequacy and measure attribution. QHPs should only have the ability to create narrow networks after full transparency on the QRS. A consumer needs to fully understand the type of plan he or she is purchasing and the adequacy of its network of providers. Otherwise, a consumer who does not understand the type of QHP plan, especially if it has a narrow network, will most likely provide poor scores under the Consumer Assessment of Healthcare Providers and Systems on questions related to physician care (Member Experience Domain). This in turn, will affect the Clinical Quality Management Domain, due to the possibility of a patient being unable to receive or follow prescribed treatment interventions by a physician. Therefore, the AMA recommends that CMS further drill down the measures to appropriately account for network adequacy on the QRS. Consumers deserve to understand the design of the network and whether it is based on cost or quality measurement and at what costs or level of measurement. Furthermore, they need an understanding of whether the narrowing of services occurs with inpatient, outpatient, pharmacy use, chronic care, and/or readmissions. Physicians also need this information because it will most likely influence referral patterns, hospital privileges, and/or seeking employed physician status.

The AMA believes that measurement adequacy (e.g., reliability, validity, and depth of measurement) does not currently exist to assure the rankability of delivery systems and physicians without significant risk of misclassification. Therefore, we are glad to see that CMS does not plan to publicly report information on physicians on QRS.

QRS Implementation and Reporting

Subsequent to the release of this Proposed Rule, CMS released the proposed QRS scoring methodology. We have concerns with the methodology proposed, which we will also address in a separate comment letter on the proposed QRS Scoring Specifications. Specifically, we are concerned with the composite score values. In order for a QHP to receive 5-stars on a composite, it must achieve a score of 90 percent or greater. While 90 percent or greater might appear ideal and work for measures related to *enrollee experience*, it is not appropriate for measures related specifically to *clinical quality management*. Nor is it appropriate for some of the measures related to *planning, efficiency, affordability, and management*, since a majority of those measures are based on claims data. Utilizing such a high cut-off point for claims-based measures when evaluating *clinical quality management* does not allow for any variation at the physician level and jeopardizes physician judgment.

Our concern is based on our experience with CMS' design of the Medicare Advantage (MA) 5-Star Rating System and CMS' proposal to use similar scoring specifications and the same measures for the QRS. Many MA plans are setting unrealistic targets for physicians due to the scoring specifications placed on health plans by CMS. Often, in order for a physician to qualify for a payment incentive or to be viewed as a high quality provider by a plan, compliance with a measure must be at 100 percent regardless

of whether the physician is providing appropriate and medically necessary care. There are instances when meeting the measure(s) is contrary to appropriate care and the plan does not incorporate exclusions for when the level of measurement is not applicable. Thus, in certain instances, the quality reporting requirements may drive inappropriate and harmful care. For example, an MA plan in Michigan is requiring a physician to hit a 100 percent threshold on the HEDIS Diabetes Care Management measures to be eligible for an incentive. As part of managing the patient's diabetes, the measure requires the physician to prescribe Angiotensin Converting Enzyme Inhibitors (ACE) and Angiotensin Receptor Blockers (ARBs). However, in this instance the patient is highly allergic to the recommended treatment regime, and the physician cannot comply. At a contract level, CMS might expect the frequency of ACE/ARB contraindications to be of no concern, but at the physician level, even a single patient with allergies is of concern. Therefore, there is once again the concern that QHPs will set the same unrealistic cut-off points on physicians so they will rate high on the QRS.

CMS also proposes to allow a QHP issuer to collect data for the QRS based on enrollees of QHPs offered through and outside of the exchange as long as they are considered the same plan. The AMA has concerns about this proposal as the QHP plans are still new, and we do not have enough information in regards to the types of consumers enrolled in the QHP plans. Due to the lack of information, by combining data on enrollees of QHPs offered through and outside of the exchange, the information reported on QRS may be skewed. Until we have more detailed demographic information as to why a consumer may enroll in a plan outside of the exchange, CMS should not combine data sources. In fact, a recent Express Scripts report highlights that early enrollees face more serious health problems and are older than those covered by employers.

Medical Loss Ratio and Temporary Risk Corridors Program (Parts 158 and 153)

The AMA believes that the medical loss ratio (MLR) requirements of the ACA have helped to ensure patients' premium dollars are spent on quality improvements and medical care instead of administrative costs. It is understandable, however, that CMS proposes to address the "challenges" and "special circumstances" faced by health care insurers due to the rocky rollout of health insurance exchanges. Without question, most health insurers have been forced to adapt, and in many cases, rely upon, paper-based applications and other time-consuming methods as part of exchange implementation and the 2014 enrollment process. The AMA, however, is concerned that CMS may have gone too far in relaxing MLR requirements.

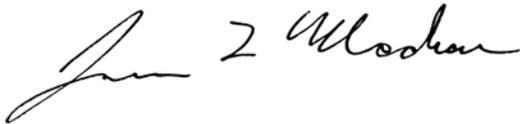
We recommend that CMS clarify that issuers who are allowed to increase the numerator portion of the MLR for any of the qualifying costs proposed by CMS be asked to demonstrate that those increased costs were specifically tied to the "special circumstances" during implementation of the exchanges and open enrollment. Furthermore, the AMA asks CMS to clarify that the increase to the numerator is limited to 2014.

CMS also proposes that the MLR formula not take into account any additional risk corridors payments resulting from an adjustment to the Temporary Risk Corridors Program (TRCP). The TRCP adjustment would increase the ceiling on allowable administrative costs from 20 percent to 22 percent to offset some of the unanticipated increased costs resulting from 2014 implementation. We are concerned that the proposed changes to the TRCP will result in weakening the MLR for patients. We encourage CMS to ensure that if an issuer faced increased costs due to the exchange rollout, the issuer should be asked to demonstrate those costs and take them into account as changes to the numerator portion of the MLR.

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In conclusion, the AMA appreciates your consideration of our comments and recommendations. We look forward to continuing to work with you as ACA implementation proceeds to ensure that our patients can access the care they need with the physicians of their choice. If you have any questions about this letter, please contact Margaret Garikes, Director of Federal Affairs, at margaret.garikes@ama-assn.org or (202) 789-7409.

Sincerely,

A handwritten signature in black ink, appearing to read "James L. Madara". The signature is written in a cursive style with a large, sweeping initial "J".

James L. Madara, MD