AMA
AMERICAN MEDICAL ASSOCIATION

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Marilyn 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: 2015 Letter to Issuers in the Federally-facilitated Marketplace (FFM)

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 draft 2015 Letter to Issuers in the Federally-facilitated Marketplace (Letter) issued by the Centers for Medicare & Medicaid Services (CMS) on February 4, 2014. As millions of Americans enroll in marketplace Qualified Health Plans (QHPs), the Affordable Care Act's (ACA) goal—and a long-time AMA priority—of expanding access to affordable, quality, health insurance coverage has become a step closer. However, having an insurance card does not necessarily ensure access to medical care or to physicians of the patient's choice. The AMA is concerned about the narrow provider networks that many QHPs are offering in 2014 and with continuity of care issues that have resulted from these narrow networks. We also are concerned about limitations in formularies and inaccurate provider directories. Our comments below focus on these areas.

Network Adequacy/Network Development and Continuity of Care (Chapter 2, Section 3)

A number of reports over the past six months indicate that many insurers offering QHPs on the exchanges are limiting access to care in some areas by significantly narrowing or tiering provider networks. Several states have intervened to stop insurers from selling narrow network plans, some providers have brought legal challenges against insurers for being excluded from plan networks, and a recent study by McKinsey & Company found that about two-thirds of exchange-based plans included narrow or ultra narrow hospital networks. With the promise of increased patient volume, insurers have negotiated lower reimbursement rates with some providers. They also have excluded many providers from their plans, claiming that they have done so due to these providers' higher costs. Some health plans have explicitly stated that new provider networks were determined based solely on cost.

As a result of these insurers' decisions, some patients may have lower premiums, but they also may have greatly reduced access to care, e.g., to the primary care physicians with whom they have established relationships, to the specialized physicians they need, and to their preferred hospitals. Patients may also

incur higher out-of-pocket costs if they need to seek services outside the narrow networks. Such costs can impose a significant financial burden on patients, particularly since the ACA's out-of-pocket cost limit only applies to in-network services. The AMA is very concerned about potential adverse effects on patients and physicians as a consequence of these narrow networks.

With respect to network adequacy, ACA regulations require health insurer networks to include: essential community providers; a network that is sufficient in number and types of providers, including providers that specialize in mental health and substance use disorder services, to assure that all services will be accessible without unreasonable delay; and an accurate provider directory that identifies providers that are not accepting new patients (45 C.F.R. 156.230). The AMA believes that these requirements are too vague, leave too much discretion to insurers to determine network adequacy, and need to be strengthened in future rulemaking. It is also unclear whether, how, or to what extent these general requirements are being monitored or evaluated by federal and state regulators. We believe that there is a need for improved oversight by federal and state regulators.

In 2014, CMS largely relied on plan accreditation and state review to ensure adequate provider networks. While we understand that CMS did so largely due to the constraints of time and resources and the need for exchange plans to be certified to be ready for open enrollment, we do not believe this constituted adequate review of plan networks. We are pleased to see that in the 2015 Letter, CMS has proposed strengthening network adequacy requirements. For 2015, CMS indicates that it intends to review provider lists to evaluate provider networks using a "reasonable access" review standard, and will identify networks that fail to provide access without unreasonable delay as required under the network adequacy rules. CMS also indicates that in order to determine whether an issuer meets the reasonable access standard, it will focus most closely on those areas which have historically raised network adequacy concerns, such as hospital systems, mental health providers, oncology providers, and primary care providers. CMS states that it intends to use its review to develop time, distance, and other standards for future network review and rulemaking.

We support the proposed strengthened network adequacy review standards, and urge CMS to maintain these enhanced standards in its Final 2015 Letter to Issuers. However, we recommend that CMS—and state regulators, who are primarily responsible for reviewing exchange QHPs—strengthen these standards and existing regulations as follows:

- Certification shall only be awarded to health plans that demonstrate their enrollees will have access to timely medical care, including all essential health benefits and emergency services. This will, necessarily, vary by state due to differences in geography, demographics and other factors.
- Health insurers must set forth the geographic and population capacity of their proposed provider networks. This includes an evaluation by county of the number of enrollees by age and gender. The health insurer's attestation of adequacy must be accompanied by a report from a certified actuary who calculated the insurer's premium for the specific network offered. The attestation and actuarial report must be made publicly available at the time of its filing.
- The actuarial report must include a breakdown by type and number of primary care physicians, pediatricians, women's health physicians, geriatric medicine physicians—by specialty and subspecialty (if applicable)—who are in the specific plan network.
- The report must identify whether each physician is accepting new patients.

- The report must cross-reference each physician with each network in which the physician has contracted.
- The network development process must be transparent, and each insurer must provide to CMS, the applicable state(s), and providers the criteria and methodology used to evaluate a physician for network inclusion. Physician profiling programs used to create narrow or tiered networks must use accurate, meaningful, and statistically valid measures, methodologies, and data. If the methodology includes cost considerations, it must also incorporate quality data, and must include proper safeguards (e.g., risk adjustment, adequate sample size, etc.) to ensure the integrity of the data.
- No physician or physician group should be profiled based on cost alone. Cost-efficiency cannot be measured without consideration of patient-specific characteristics and health care outcomes. In compliance with the non-discrimination rules, QHPs should be prohibited from excluding physicians because their practices have a large number of patients with expensive medical conditions.
- Insurers must develop, and make publically available, the quality assurance standards used to monitor whether its network(s) is adequate.
- Insurers must develop, and make publically available, the appeals and complaint resolution processes used to help patients and physicians with network issues.
- Physicians and their patients should be given advance notice that network changes are being considered so that they can provide input on and challenge such changes. All decisions about network selection and de-selection should be on record and made public.

Utilization data used by state departments of insurance and CMS to analyze adequacy must include:

- Prior year comparisons against regional and national benchmarks;
- Number of hospital admissions for chronic conditions;
- Emergency department visits;
- Preventive services provided;
- Out-of-pocket costs incurred by enrollees;
- Out-of-network costs incurred by enrollees;
- Number of out-of-network visits made by enrollees;
- Percent of services received from in-network providers;
- An evaluation of the quality assurance standards used by the insurer;
- Regular provider surveys to help determine network capacity and accessibility of health care services as well as to solicit providers' perspectives and concerns;
- Percentage of total costs for in-network and out-of-network services; and
- Specific corrective actions made against insurers determined to have inadequate networks shall be posted publicly online.

To help with further **monitoring of networks**, the AMA recommends that:

- Regular patient surveys be made for each network plan offered by a QHP, and these surveys should be compared against other network survey results;
- Insurers report at least bi-annually whether their proposed networks are fulfilling the attestations made in their certification proposals;

- Plans submit monthly totals of physicians accepting new patients for each network, and the total number of physicians in each network;
- Complaints against insurers relating to network adequacy be publicly posted online, and include what steps and other measures the insurer made to resolve the issue; and
- CMS should work with state regulators to address network adequacy concerns relevant to each state and continuously monitor network adequacy.

One of the AMA's biggest concerns about narrow networks is the need for enrollees in exchange QHPs to have adequate protections when they are transitioning to new providers. CMS indicates that it is considering policies to help with transitions for certain new enrollees (page 33 of Letter). We strongly urge CMS to establish a hardship exception for patients enrolled in new exchange QHPs, especially those with narrow provider networks, so that when patients are in the middle of a treatment, such as for cancer therapy, obstetrical care, or a sequence of surgical procedures, they can complete the course of treatment without incurring higher out-of-network costs. Likewise, we recommend that CMS require QHPs to create a stronger in-network exception process. Plans should be required to create an appeals process to authorize in-network cost-sharing if a medically necessary service is not available within the network but is available out-of-network. Any additional costs related to the service should not be imposed on the patient but should be assumed by the plan. Such an exception is allowed for preventive services and it should be expanded to include other essential health benefits.

Provider Directories (Chapter 6, Section 1)

Accurate provider directories are essential to patients when choosing plans and in helping regulators monitor network adequacy. Many exchange enrollees have not had the benefit of accurate directories during open enrollment for 2014. We were pleased that in the December 17, 2013, Interim Final Rule CMS urged QHPs to provide the most current online directory to potential enrollees and during the beginning months of coverage, to treat out-of-network physicians as in-network if they were listed in the in-network provider directory when the patient enrolled. However, we recommend that CMS mandate, rather than encourage, plans to do so. We also urge CMS to require QHPs to update their provider directories in real-time and to expeditiously correct errors.

Provider directories need to be easy to access and user-friendly for potential enrollees, patients, and providers. CMS states in the Letter it expects that the issuer's URL link to their provider directories will directly link to the directory, so that consumers do not have to log on, enter a policy number, or otherwise navigate the issuer's website in order to find the directory. In addition, CMS indicates that it expects the directory to include location, contact information, specialty, and medical group, any institutional affiliations for each provider, and whether the provider is accepting new patients. We strongly support these directives, but urge that they be included in the regulations governing provider directories in future rulemaking. CMS also indicates that the agency is considering creating an online search tool that would allow consumers to search provider directories by clinician and hospital name in order to better choose an appropriate plan. We strongly support the creation of such a tool.

Prescription Drugs (Chapter 3, Section 2)

As part of the QHP Application, issuers must provide a URL to their formularies and provide information regarding formularies to consumers (45 C.F.R. 147.200). According to reports, however, it has been very difficult for consumers to access QHP formularies during open enrollment for 2014. For patients with

chronic medical conditions, such lack of access makes it very difficult to choose an appropriate plan since they do not know whether their current prescription drugs will be covered. In its Letter, CMS indicates that it expects the URL link to direct consumers to an updated formulary where they can view the covered drugs, including tiering and cost-sharing, that are specific to a given QHP. As with online access to provider directories, CMS expects that the URL will link directly to the formulary. We believe this requirement is a good first step in providing patients with the information they need to choose the right plan. However, formulary lists alone will not allow patients to easily compare plans. Similar to the online provider directories, there should be a searchable formulary tool, such as the one used by Nevada's state-based exchange, which should include a comprehensive out-of-pocket cost calculator that estimates total costs.

The AMA appreciates that CMS states that it intends to propose through rulemaking that exchanges may require that issuers 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 30 days of coverage, starting with the 2015 plan year. This proposed transition policy would also allow those newly enrolled in a QHP to receive coverage for a non-formulary drug without using the exceptions process. CMS also "encourages" issuers to accommodate the needs of new enrollees by covering a transitional fill of non-formulary drugs.

The proposed policies outlined by CMS are a good first step towards providing meaningful protections for new QHP enrollees. However, the AMA recommends that the proposed policies be strengthened. The final version of the Letter and the forthcoming regulation should require that exchanges include transition protections instead of leaving it to the discretion of the exchanges. The transition policy should be extended from 30 to 90 days. The proposed 30-day transition policy will not 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. We also recommend that additional protections be provided to patients who can demonstrate that they are already stable on a prescribed medication regimen.

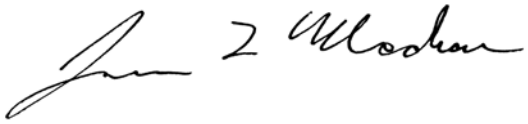
The AMA recommends that during the formulary exception review process, QHPs should allow patients to have access to the drug in dispute during the entire process, and if the exception request is granted, the excepted drug should continue to be provided in subsequent years. With the increased use of step therapy and drug tiers in the exchange QHPs, we believe these added protections are critical to ensuring continuity of care for patients.

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. 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.

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. 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.

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,



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