AMA
AMERICAN MEDICAL ASSOCIATION

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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: CMS Quality Strategy: Request for Public Comment

Dear Administrator Tavenner:

The American Medical Association (AMA) appreciates the opportunity to provide our comments to the Centers for Medicare & Medicaid Services (CMS) regarding the agency's Quality Strategy. The AMA is committed to quality improvement and supports innovative efforts to provide high quality, cost-effective care to patients. We are committed to creating a cultural transformation that better supports delivery of the highest quality care for individual patients and communities and which, among other strategies, will allow for a more appropriate allocation of finite resources.

Alignment of Programs

We are disappointed that the CMS Quality Strategy does not place a greater emphasis on improvements in the alignment of the numerous federal quality programs under Medicare and Medicaid. Enhanced program alignment would greatly reduce the administrative burden on physicians and other providers. There are three individual quality reporting programs that apply to physicians today: the Physician Quality Reporting System (PQRS); Value-Based Payment Modifier (VBM); and Electronic Health Record (EHR) Incentive Program. Each of these programs was created under a separate statute and has its own unique set of detailed reporting requirements. Their corresponding incentives and penalties are established in law. However, there are areas where CMS has considerable discretion to align the requirements in a manner that ensures greater consistency among the various programs. For example, the quality reporting measures established under PQRS vary from those physicians must meet in order to be a "meaningful user" of a certified EHR within the EHR Incentive Program. **We strongly urge CMS to align the quality measure requirements for PQRS and the EHR Incentive Program**

to reduce the reporting burden on physicians. This burden is so substantial that many physicians find it impossible to comply with these requirements, and have elected instead to suffer the consequences, including penalties. The unfortunate result is a rather low level of physician participation, in both PQRS and the EHR Incentive Program.

Many of the PQRS quality measures are not available in the EHR Incentive Program. A physician may receive credit under both PQRS and the EHR Incentive Program's Meaningful Use (MU) quality reporting requirements by submitting electronically specified MU quality measures through certified EHR technology. However, the EHR Incentive Program has more restrictive and less flexible reporting requirements, and a more limited number of measures than PQRS. Furthermore, submission through certified EHR technology is not an option for the many physicians whose EHR systems do not meet certification standards. **Given the problematic nature of electronic specifications and vendors' inability to capture electronic specifications, it is even more crucial for submission of PQRS quality measures to count as the alignment threshold.** The burden is even greater for the many specialists who have few quality measures to select from in the EHR Incentive Program. These physicians have no choice but to dually (and separately) report under both programs in order to avoid penalties or receive incentives. In addition, there is less transparency with respect to the inclusion of new quality measures, and less frequent updating of measures, in the EHR Incentive Program. In contrast, PQRS has a clearly spelled out pathway and timeline for including new measures within its program and allows for regular updates of measures and measure specifications. PQRS measures are updated on a yearly basis, unlike those for MU. Furthermore, the timelines for reporting periods do not align. Currently, PQRS uses a 12-month reporting period. The EHR Incentive Program has an optional reporting period of 12 months + 90 days.

What are the top three quality topics that you think CMS should focus on?

There is much work that needs to be accomplished within existing CMS quality programs prior to the expansion of the CMS Quality Strategy. The AMA believes the proposed strategy is overly ambitious and expansive and CMS' finite resources would be better utilized by refining and simplifying its quality programs. That said, we offer the following specific feedback on the Quality Strategy.

Goal 1: Make Care Safer By Reducing Harm Caused in Delivery of Care

Electronic health records hold a lot of promise in reducing medical errors and making care safer, but the certified electronic health record technology (CEHRT) standards being adopted and certified for use under MU do not adequately address patient safety issues. Unfortunately, the vendors appear to be focusing their efforts entirely on designing the systems to ensure that providers are able to purchase systems that will meet the EHR Incentive Program MU requirements. Little consideration is given to how CEHRT can support patient safety and

enhance quality and efficiency of care. As a consequence, most physicians view CEHRT solely as a hindrance that provides little value to the day-to-day practice of medicine.

It is widely acknowledged that the electronic prescription of medications (eRx) is one of the most beneficial aspects of an EHR. The use of eRx provides valuable automatic assessment of drug interactions and patient allergies, reducing the likelihood of adverse medication events. Although limited in its scope, eRx embodies the most successful iteration of data exchange by contributing to a national database of electronic prescriptions—easily accessible by physicians while following patients from visit to visit. Data originating from eRx are already formatted for structured capture. This provides value to a patient's longitudinal record by contributing to his or her personal health record (PHR), and also facilitates secondary use in research and drug trials.

Clinical decision support (CDS), while not widely utilized in the ambulatory setting, has the potential to become the most important aspect of an EHR. Evidence-based medicine culled from journals, medical texts, and federal/educational institutions provides a plethora of knowledge available to the medical community. Searching, let alone digesting, this information poses a challenge to most frontline physicians who are already stretched thin by long work days and after-hour documentation. CDS has the power to parse through mounds of data and match relevant condition-specific information to physicians and their patients at the point of care. Newly developed treatments, current pharmaceutical information, and diagnostic testing data all can be presented to the clinician on-demand, organized by diagnosis or site of care. Sadly, EHR vendors have not devoted much effort to incorporating relevant CDS tools for specialty physicians. And CMS has neglected to make a serious effort to incorporate value from CDS requirements into MU. Stage 1 of the EHR Incentive Program also did very little to encourage EHR vendors to invest their efforts in usability, artificial intelligence, or natural language processing—all critical components of a successful and value-added EHR-CDS tool. **CMS and the Office of the National Coordinator for Health Information Technology (ONC) should focus more attention on certification and MU objectives that leverage the power of technology.** CMS' present approach of forcing paper-based processes into a digital framework interrupts patient care and well-established clinical workflows.

Goal 3: Promote Effective Communication and Coordination of Care

The integration of health care information exchange (HIE) and CDS has the potential to reduce admissions and readmissions, while improving patient safety and lowering costs. Limited examples of the successful marriage between these two technologies exist, primarily in large medical centers and the Veterans Health Administration (VHA). But the national framework for information exchange is almost nonexistent, and vastly limited to the exchange of secure emails. Physicians are largely limited by systems where data—even in electronic form—are housed in

"data silos." This makes care coordination across disparate health information technology (HIT) systems a remote reality.

The Direct Standard—the only industry-wide standard for exchange—leverages a 30 year-old email technology requiring users to manually push data between networks and is managed by little more than an Outlook inbox. For CMS to realize any of its desired outcomes outlined within the Quality Strategy, the groundwork needs to be laid through advanced, semantic interoperability standards. Some of this work is being carried out through the HL7 and S&I Framework, but little will be available in time for Stage 2 MU requirements. EHR usability with respect to information discovery, request, and transmission between two or more health care organizations must become simplified and streamlined to meet the needs of physicians at the point of care. **Therefore, we urge CMS to advise ONC to continue focusing on developing standards that support interoperability and enable data exchange.** The value of exchange and decision support could be greatly enhanced if CDS were made available to physicians as they diagnose patients, as easy as an Amazon recommendation, and if searching for a patient's record were as quick as a Google search.

In an effort to address care coordination loopholes, the AMA-convened Physician Consortium for Performance Improvement® (PCPI®) has embarked on its first performance improvement project to address physician-to-physician referrals in the ambulatory setting by establishing accountability standards and improving information transfer. This project, *Closing the Referral Loop* (CRL) aims to achieve higher satisfaction and understanding of the referral among patients and physicians. The objectives of the CRL project include:

- Test a model for quality improvement spread that includes "intermediate" organizational support for projects (e.g., state model);
- Build collaborative relationships with organizations that have complementary improvement expertise and infrastructure that complements PCPI's capability;
- Develop more "closing the referral loop" experts and build a learning community;
- If the pilot project is successful, expand the CRL project with external funding;
- Share learning through PCPI, AMA, and external partners' communication channels; and
- Assess the AMA-convened PCPI's role as a stimulator of quality improvement at the national level.

Goal 6: Make Care Affordable

The AMA has reservations about this goal, given the subjective nature of affordability and the weaknesses of current tools to measure and compare health outcomes and provider resource use. To borrow a phrase, affordability is in the eye of the beholder. Its definition and interpretation differ between physicians, patients, insurers, and purchasers. Even within cohorts, affordability can be measured and defined differently. Payment methodologies and site of service also

influence affordability in ways that may not be immediately apparent and that may be outside the control of the health care system. For example, a procedure performed in an ambulatory surgical center (ASC) may have a lower associated cost than a procedure performed in the hospital outpatient or inpatient setting. But state law may prohibit or discourage creating or operating ASCs in some regions. Medicare rules also determine which procedures may be safely performed and reimbursed in an ASC. Similarly, the cost of care for most services is lower in a physician's office than a hospital outpatient department. But a variety of Medicare payment policies are driving more and more physicians to sell their practices to hospitals, thereby raising costs to both Medicare and patients. Some physicians practice in areas or facilities where state or federal laws and regulations have led to higher costs. Should they be punished with a new set of federal policies that reduce their reimbursement or encourage the use of "lower cost" facilities? We do not think so.

Equitable measurement of "affordability" will also require CMS to consider who is incurring costs and over what period of time. Variations exist within health care due to patient mix, provider distribution, community characteristics, and a variety of other factors that drive the availability and use of health care resources. In addition, what appears to be more "affordable" in the short term may not be the most efficient or effective treatment over the long term. For instance, medical management versus surgery may seem more "affordable" in the short term, but the medical management may indeed end up more costly in the long term. In most cases, however, the answer is likely to be "it depends." This is because for any given patient, the calculus will be affected by the individual's projected life span and ability to withstand surgery, or tolerate a particular drug, as well as the availability of the appropriate surgical or medical specialist to provide the chosen course of care.

As demonstrated in the development of the VBM, however, the current efforts to calculate resource use, patient outcomes, and "value" of a service to an individual patient are rudimentary to say the least. Current measures are too crude to accurately reflect patient, provider, and community differences in any meaningful way. This is true even at the hospital or regional level, let alone at the level of an individual physician practice or an individual patient. **Much work is needed to refine the VBM calculations, and we urge CMS to complete this work before moving to the "affordability" issue**. Areas where additional effort is warranted include: improvement of Medicare's risk adjustment method; development of a more granular specialty list; refinement of the specialty mix adjustments; completion of a robust Medicare-specific episode grouper; and development and piloting of cost measures that are appropriate for use at the physician level to replace the current measures designed for use at the population or hospital level.

The AMA supports data transparency to encourage efforts to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The release of physician Medicare claims data, however, must be subject to safeguards to ensure that neither false nor

misleading conclusions are derived that could undermine the delivery of quality care or infringe on patient privacy. The AMA, therefore, supports efforts such as the Qualified Entity program that will ensure that the release of physician data is done thoughtfully and appropriately. Such information will allow providers to compare their performance with their peers, provide consumers access to price and quality information, and expand opportunities for researchers while maintaining key safeguards that protect patients and physicians.

Do you see your organization reflected in this strategy? If so, how will your organization help execute the CMS quality strategy?

As the nation's health care system continues to evolve, the AMA is dedicated to supporting sustainable physician practices that result in better health outcomes for patients. This work is captured in the AMA's five-year strategic plan, which aims to ensure that enhancements to health care in the U.S. are physician-led, advance the physician-patient relationship, and enhance the prudent management of health care costs. The AMA is in a unique position to reach physicians in all practice settings and specialties. Our work to improve the health of the nation positions us to bring physicians together with communities and public and private sector organizations to prevent—and to achieve measurable improvements in health outcomes for—cardiovascular disease and diabetes.

The AMA's plan emphasizes three core areas of focus:

- Improving health outcomes;
- Accelerating change in medical education; and
- Enhancing physician satisfaction and practice sustainability by shaping delivery and payment models.

The AMA is interested in collaborating with CMS and organizations whose efforts are aligned with our "Improving Health Outcomes" Initiative and our strategies around controlling high blood pressure and preventing diabetes.

The AMA is investing significant resources in evaluating a path to long-term sustainability of and satisfaction with the practice of medicine through effective care delivery and payment. Through research, data, and analytics, we are identifying effective delivery and payment models that lead to improvements in the quality of care for our patients, controlling health care costs for the nation, and increased professional satisfaction. The AMA is committed not only to establishing this evidence, but also to identifying, creating, and supporting physicians with the needed resources to thrive in the evolving health care environment.

We will build on the momentum for the adoption of appropriate delivery and payment models in both the public and private sector and encourage their implementation by organizations seeking

to attract physicians. This work builds on the AMA's ongoing federal and state legislative activities to shape better payment and delivery models for physicians and patients, which we believe strongly will bridge to a more stable environment that better serves physicians and the patients under our care.

Fundamentals for a better system include:

- Development of best practices for delivery that improve outcomes and health, increase productivity, and save lives and money;
- Adoption of payment policies that reflect the diversity of physician services, levels of clinical integration and risk; and
- Identification of options that allow physicians to choose models that fit their mode of practice.

The AMA is a national leader in creating tools to help physicians provide the highest quality of care to patients. In recognition of physicians' professional responsibility to provide quality health care, the AMA began developing physician performance measures in 1998, and in 2000 convened the PCPI. Therefore, we support the development of quality measures through a multi-stakeholder, public, and transparent process, which maintains certain processes to ensure measures are meaningful to users, uphold national standards, and harmonize with existing measures in widespread use. Standardized measures (using standardized specification) can be used to compare results nationally, which is especially important when there are financial penalties to consider. As the field of measure developers expands, there is an increased risk of un-harmonized measures and duplicative efforts. Providing incentives to coordinate efforts and co-produce Clinical Quality Measures (CQMs) are prudent considerations as well. It is imperative that measure developers have the necessary expertise with CQM standards currently in use (e.g., Quality Data Model, HL7 HQMF eMeasures) and are involved in national efforts focused on the future direction of health care standards.

The PCPI develops, tests, implements, and disseminates evidence-based measures that reflect the best practices and best interests of medicine. The PCPI also works with outside organizations to advance the science of performance measurement, utilize PCPI measures in public and private reporting programs, and define the appropriate use of data to evaluate and guide improvement in practice. Over the next year, the PCPI will create an outcomes toolkit for PCPI member organizations to support their ability to identify both leading outcomes relevant to their patient population(s) and a pathway to collect outcomes data. The PCPI also plans to promote broad access to outcomes information created by member organizations. However, **CMS must recognize that practice transformation, measure development, and implementation are costly endeavors. Therefore, CMS should allocate the necessary resources to guide medicine's transformation and for meaningful change to occur.** Without providing resources

to collaborative partners such as the PCPI, it will be difficult to move from the current to the future state and for the Quality Strategy to be properly implemented.

The AMA appreciates the opportunity to provide our views, and we look forward to continuing to work with CMS on these important issues.

Sincerely,

James L. Madara, MD