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Centers for Medicare & Medicaid Services
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Baltimore, Maryland 21244-1850
Mail Stop-C5-15-02

Attn: Physician VBP Comments

The American Medical Association (AMA) appreciates the opportunity to provide our views to the Centers for Medicare and Medicaid Services (CMS) regarding development of a plan for the transition to a value-based purchasing (VBP) program for physicians and other professional services, as required by section 131(d) of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

In developing the plan, an internal CMS VBP Workgroup will address four major components: (1) measures; (2) data infrastructure and reporting; (3) incentive methodology; and (4) public reporting. The AMA addresses each of the components below.

MEASURES

Certain key tenets regarding measure development must guide CMS in developing a plan to transition to VBP. We urge CMS to adhere to these tenets, as discussed below.

Physicians Must Develop the Quality Measures Used in a VBP Program

Physicians must develop the quality measures used for reporting data. This ensures that the measures are accurate and clinically relevant to patients. Without this tenet, a VBP program cannot achieve its goal of quality improvement for patients.

In 2000, the AMA convened the Physician Consortium for Performance Improvement (PCPI) to develop clinical performance measures that are patient-focused and that can be implemented to improve patient outcomes. The PCPI actively engages all stakeholders

including payers, patient advocates and organizations that are committed to high quality care. The PCPI is comprised of over 100 national medical specialty and state medical societies; the Council of Medical Specialty Societies; American Board of Medical Specialties and its member-boards; experts in methodology and data collection; the Agency for Healthcare Research and Quality; and CMS. In addition, on May 30, 2008, the PCPI approved a position statement to expand the involvement of health care professional organizations, including the American Optometric Association, American Physical Therapy Association and American Dental Association, to name a few. This expansion will increase the ability of the PCPI to achieve consensus on its measures and their implementation across the healthcare continuum.

As the leading developer of physician-level measures, the AMA urges that the PCPI be recognized as such in CMS' plan to transition to VBP. The PCPI incorporates all critical factors in the measure development process. First, it operates through a transparent, consensus-based process for developing physician-level measures, and has worked aggressively in developing to date more than 250 physician performance measures and specifications covering 40 clinical topics and conditions. These measures are available for implementation and many have been adopted by CMS for use in CMS quality improvement demonstration projects and the Physician Quality Reporting Initiative (PQRI). **In addition, the PCPI ensures that measures: (i) are evidence-based and developed with cross-specialty representation and consensus; and (ii) include enhanced relevance to clinical practice. Any VBP program must use measures that meet these criteria.**

PCPI efforts are also underway to better communicate and document why a measure was developed and, if it is a process measure, what is the link to a patient outcome. As a part of the development process, a rationale behind a measure's construction and the reasons it may or may not be used at the individual or group level will be provided. In addition, whether a gap in care or variations in care exist will be explicitly discussed, and any efforts to harmonize with existing measurement sets will be outlined.

Because of the PCPI's aggressive measurement development efforts, numerous measures are available for use in reporting and other quality programs. Many subspecialties lack measures that address the scope of their practice, however, because there is a lack of evidence to support their development as well as challenges in capturing necessary information to develop a relevant measure. It is critical that any VBP program recognize this factor, and implement initiatives on a phased-in basis to ensure that certain initiatives are undertaken only when physicians have the opportunity to participate on a widespread basis.

While the PCPI should and will continue to identify and develop measures at the individual physician level, it recognizes that quality improvement programs can reach out to physicians in a variety of practice settings and that measures can be even more effective for patients and physicians when used to develop a more comprehensive picture of care provided through various provider settings. To achieve these goals, the PCPI is developing composite, care coordination, patient safety, overuse, and efficiency

measures, as well as episode of care-based measures regarding quality and cost. Each of these types of measures will provide a more comprehensive picture of all aspects of care, along with supporting evidence and the scope of clinicians who participate in the care delivery. This approach will also help identify where the greatest impact for quality improvement can occur.

PCPI development of episode of care measures is critical because some of the methods being used to develop episode of care measures are based on products developed without substantive clinical insight, *i.e.*, lack of clarity about the services and procedures involved in treating the condition. Further, physician development of and acceptance of these measures is essential. Physicians' past experiences with payers' use of black box software to develop measures that arbitrarily curtail payments underscores the need for CMS to ensure transparency of any software it uses.

We also caution that composite and care coordination and similar measures raise the issue of "to whom is the care attributable" since these measures would apply to groups of health care professionals, including physicians, that work as a team in delivering care to an individual patient. In this case, a VBP program should clearly address and resolve any attribution issues. In doing so, CMS should ensure flexibility for resolving attribution issues to allow for individual level and group level attribution.

Finally, we urge CMS to devote attention and support to the measure development pipeline. Without adequate resources significant measurement gaps will remain.

Use of Measures In Capturing Data

In developing a plan to transition to VBP, CMS must recognize that several options for reporting data on measures are necessary for physicians, including physician reporting through claims, registries or electronic health records (EHRs). Such flexibility allows physicians to participate in quality measure reporting, which in turn informs internal quality improvement efforts. Limiting options or creating mandates to comply with one reporting option will slow down the many ongoing quality improvement activities being realized by both small and large physician practices.

To best capture data from relevant measures and improve patient care, we urge that any VBP program include the following factors:

- Measures must be relevant to the patient and physician at the point of care, capture complexity of care decisions, provide support for appropriate variation due to a physician's clinical judgment, inform performance improvement efforts, and harmonized across care settings and payers.
- Physicians should have the opportunity to select measures relevant to their patients and practice. One of the shortcomings of the current PQRI is that physicians cannot choose their measures, and CMS arbitrarily determined that physicians should have reported on certain measures. In some cases, these

measures were not relevant to a physician's practices, yet CMS deemed that these physicians did not successfully report and thus did not receive a reporting bonus.

- CMS should identify a clear methodology for the retention and retirement of measures from the PQRI program. The data and the methodology utilized to make these decisions should be transparent to the providers using these measures. CMS should also track how physicians will be able to continue to participate when specific measures are retired. CMS should share data with measure developers so as to inform their processes and to ensure sufficient numbers of measures that have an impact on clinical care.
- Physicians should be able to participate in a VBP program through a variety of organizations, as individuals or in groups, since physicians frequently participate in multiple health care organizations.

DATA INFRASTRUCTURE AND REPORTING

In developing a plan to transition to VBP, CMS should ensure key concerns are addressed regarding data infrastructure and reporting, as discussed below.

Early Physician Education and Outreach

Key lessons from the PQRI are that quality reporting and VBP programs must allow physicians and CMS adequate lead time to implement changes, and CMS must aggressively educate and implement outreach activities for physicians and eligible professionals on how to successfully participate in a VBP program. These activities must also be conducted for Medicare contractors to ensure they understand their PQRI requirements as well. Educational programs must include detailed confidential, actionable interim and final feedback and compliance reports that inform physicians of reporting errors and how to correct them. These reports must also be issued on a timely basis. PQRI reports were issued far too late for physicians to address reporting problems and caused inaccurate reporting practices to continue far too late to be helpful even in the subsequent reporting year. Timely, detailed reports will assist in increasing the number of eligible professionals who successfully participate in VBP programs and, hopefully, result in quality improvements that will benefit both patients and the Medicare program.

Physician Verification of Quality Data

Physicians must be able to review the accuracy of the data that are the basis for determining successful participation or performance scores in a VBP program. If not, this calls into question how actionable and meaningful the program is for patients and physicians. Physicians must also have the opportunity for prior review and comment, along with the right to appeal and reconsideration.

The foregoing is underscored by the public-sector project, the Better Quality Information to Improve Care for Medicare Beneficiaries (BQI) Project, a CMS-funded quality improvement organization (QIO) special project. Under the BQI, the Delmarva Foundation for Medical Care subcontracted with 6 communities, or pilot sites, to test methods to aggregate Medicare claims data with data from commercial health plans and, in some cases, Medicaid, in order to calculate and report quality measures for physician groups and, in some cases, individual physicians.

All pilot sites have reported significant problems with aggregating Medicare data with other payer data. Specifically, shortcomings remain with the ability to analyze data to understand how to define the physician group being measured and how to verify and accurately assign the quality reporting scores generated from the data.

Much of the data generated from the six pilot-sites could not be reviewed for accuracy by participating physicians, as CMS would not provide patient identification information to physicians to assist with verification of the data behind their scores. Overall, quality reporting entities must be able to trust the data generated from quality reporting initiatives. **CMS must apply lessons learned from the BQI Pilots to the development of a plan to transition to a VBP program. Specifically, active physician input is required if efforts are to be viewed as credible. Further, physicians must be able to review and validate the data behind their scores, and request a reconsideration process if necessary.**

Registry-Based Reporting

The AMA supports the use of registries and EHRs as reporting mechanisms. Use of registries and EHRs will allow data capture and submission to move beyond the use of administrative claims data alone, and allows real time quality improvements. The AMA is working closely with the EHR vendor community and others to influence increased functionality in EHR systems that facilitate physician use of measures for quality improvement and reporting. The AMA, with the National Committee for Quality Assurance (NCQA), and the Health Information Management Systems Society's Electronic Health Record Association, continues to co-sponsor the Collaborative for Performance Measurement Integration with EHR systems (Collaborative). The Collaborative is focused on facilitating the integration of performance measures into EHR systems to enable accurate translation of measures and to promote quality improvement. The Collaborative also developed an XML format to provide consistent EHR measure specifications for EHR systems vendors to integrate PCPI and NCQA measures into their products. EHR systems vendors will further test the schema in 2009. Efforts are also underway to consider submitting the schema to a standards development organization. The AMA is exploring with registry vendors whether this schema will be useful for them or if additional specifications and tools are required.

In the 2009 PQRI, eligible professionals may report quality measures data through a qualified clinical registry by authorizing or instructing the registry to submit quality measures results and numerator and denominator data on quality measures to CMS on

their behalf. Further, CMS is preparing to test the submission of clinical quality data extracted from EHRs for five 2008 PQRI measures. This testing period will occur from July 1, 2008, through December 31, 2008. CMS proposes for 2009 to accept PQRI data from EHRs for a limited subset of the proposed 2009 PQRI quality measures, contingent upon successful completion of the 2008 EHR data submission testing process and a determination that accepting data from EHRs on quality measures for the 2009 PQRI is practical and feasible.

Procedural protections are needed, however, under a VBP program, to ensure the accountability of the registry or EHR product vendor for successful submission of data to CMS from physicians and eligible professionals. **CMS should specify procedures and requirements that registries (and EHR product vendors) must meet to minimize errors in the registry or EHR reporting process during the reporting period, including interim and final feedback reports, as well as procedures to be followed to correct errors that may occur when the registry or vendor submits the data to CMS.**

Other Recommendations for Data Infrastructure and Reporting

In addition to the above recommendations, the AMA urges consideration of the following in developing a transition plan for VBP:

- An interoperable health information technology (HIT) system is critical for the success for a VBP data infrastructure and reporting system. When implemented properly in a connected environment, widespread HIT adoption will transform the practice of medicine and provide physicians with a powerful tool that puts real-time medical information in physicians' hands at the point of care. To achieve this reality, a comprehensive HIT environment will need to be highly connected, secure, and affordable. To truly ensure success, HIT must be able to integrate into the typical workflow of medical practices as diverse as those where patients receive care, including large hospitals, community health centers, and small or solo physician practices.

We urge CMS to support legislation that would: (1) establish advisory committees comprised of public and private stakeholders to come up with effective policy and uniform, interoperable standards, (2) provide meaningful financial incentives, especially for smaller physician practices, and (3) ensure privacy and security of patients' confidential medical information. Meaningful grants, loans, and other financial incentives for acquiring, implementing, maintaining HIT systems and tools are essential for accelerating widespread adoption of HIT. Legislation that provides adequate financial incentives and that establishes the infrastructure for connected and secure systems and tools will further accelerate our nation's move toward a connected, nationwide HIT infrastructure that efficiently and reliably moves data smoothly among health care providers.

- Similar to hospitals, physicians should be able to send all-payer data to CMS (as recent attempts to merge data later presented difficulties.) For example, data from EHRs could be “all payer” and provided by physician practices.
- The data submission process under a quality program (whether data is submitted directly to a quality program, or through an intermediary) must be transparent, tested and reliable.

INCENTIVE METHODOLOGY

VBP programs must be structured carefully to promote program effectiveness and the quality and safety of patient care, and not penalize physicians. All physicians should be able to participate in the program voluntarily and should receive a positive base physician payment update, with an additional value-based payment for achieving quality goals. Performance measurement should be scored against both absolute values and relative improvements in those values.

Further, incentive payments should be based on a minimum performance threshold. Rewarding by percentile or highest improvement in performance removes individual physicians’ ability to gauge their performance throughout the year. If a physician provides high quality care and meets performance standards, these efforts should be rewarded. Arbitrary assignment to a certain percentile based on a curve would unfairly penalize high-performing physicians as well as physicians who make significant improvements in the quality of care they deliver.

Value-based payments should be funded with new money and should not be made on a budget neutral basis within the Medicare physician payment system. These payments should be offset through potential savings due to decreased hospital admissions, readmissions and emergency department visits due to up-front physician care. Further, VBP programs should not be funded through an overall percentage reduction of the physician payment update, such as a “withhold pool.” This is in contrast to other types of VBP programs, such as those using a “differential” payment structure, under which a base payment is made for services provided, with an additional value-based payment for meeting reporting and/or quality goals. VBP programs should also provide incentives in addition to annual positive increases in the Medicare physician payment update that accurately reflect increases in medical practice costs.

Payment incentives must be large enough to change behavior and incentives must be tied to actionable items. Studies, like that reported in the July/August 2008 *Health Affairs* comparing Massachusetts physician groups, have concluded that pay-for-performance programs had little to no impact on quality of care. The study suggested that to impact quality of care, incentives under these programs must be: (i) large enough to change behavior; and (ii) aligned with the quality measures and related processes of care that are actionable by a physician.

Physicians must also receive payments under a value-based (or quality reporting) program on a timely basis. Payments should be made as close as possible to the time that the service is rendered, without a substantial time lag in determining the amount of payment due to a physician. A physician practice, like any other enterprise must operate on a business plan based on predictable and reliable financial fundamentals. This is nearly impossible if a substantial amount of a practice's revenue stream is unknown and delayed for months or even years. Particularly in a credit-issue economy, small businesses, such as physician practices, cannot afford delayed payments as this creates significant cash flow problems. This, in turn, threatens the viability of physicians' practices, which impacts overall access to timely, quality health care.

Finally, VBP programs must recognize that physician practice arrangements vary by size, specialty mix, structure (*e.g.*, use of information technology systems). Thus, it will be difficult for a VBP program to meet the needs of all. A series of "pilots" or "demonstration projects," therefore, would help develop those aspects of a VBP program that help varying physician practice arrangements enhance the quality of care for all patients. These pilots will also help to develop a reporting infrastructure that supports accurate data collection, which is critical for increasing the rate of those who successfully participate in a program.

PUBLIC REPORTING

In developing a plan to transition to VBP, CMS must recognize that public reporting of quality data, if not approached thoughtfully, can have unintentional adverse consequences for patients. Significant barriers in the public reporting process must be addressed for effective reporting. If not, patient de-selection can occur for individuals at higher-risk for illness due to age, diagnosis, severity of illness, multiple co-morbidities, or economic and cultural characteristics that make them less adherent to established protocols. Further, health literacy may not be adequate to comprehend basic medical information. Programs must be designed so that appropriate information is available to patients to enable them to make educated decisions about their health care needs.

If done correctly, public reporting has the potential to help provide such appropriate information to patients. **There remain, however, several critical issues that CMS must ensure are resolved before public reporting provisions can be implemented.**

First, CMS should devote resources to develop improved risk adjustment methodologies. Without properly adjusting for risk, quality information will be skewed, and patients and physicians will be unfairly penalized and misinformed. **Further, CMS must ensure that any publicly reported information is correctly attributed to those involved in the care and accurate, user-friendly, meaningful and helpful to the consumer/patient.**

Thorough consideration must be given to the development of any cost of care, or "efficiency," measures. These measures must be evidence-based, like any other measure, and must seek quality improvement in patients care, not simply monetary savings as a

primary goal. "Efficiency" ratings attempt to measure the cost for specific episodes of care. There are three main organizations that provide systems to measure these episodes of care, but no study has been able to definitively determine which, if any, of the systems do it well. The number of incorrect physician ratings can exceed 30 percent, according to J. William Thomas, PhD, a leading scholar on efficiency measurement. Incorrect reporting of physician performance can mislead patients, disrupt patient/physician relationships and unfairly damage physician reputations. The importance of this is magnified when these incorrect ratings are used to assign physicians into tiers, and patients are incentivized to see physicians in the highest tier(s).

Because of the foregoing concerns, it is critical that physicians and other providers involved in the treatment of a patient have the opportunity for prior review and comment and the right to appeal with regard to any data that is part of the public review process. Any such comments should also be included with any publicly reported data. This is necessary to give an accurate and complete picture of what is otherwise only a snapshot, and possibly skewed, view of the patient care provided by physicians and other professionals or providers involved in the patient's care.

We thank you for the opportunity to provide our views on these critical matters and look forward to working with CMS to resolve issues related to quality reporting and VBP that could present barriers to a health care system in which physicians and other providers work together to deliver high quality, cost-effective care to our patients.

Sincerely,

A handwritten signature in black ink, appearing to read "Mike Maves". The signature is written in a cursive, flowing style.

Michael D. Maves, MD, MBA