AMA
AMERICAN MEDICAL ASSOCIATION

James L. Madara, MD
Executive Vice President, CEO

American Medical Association
515 N. State Street
Chicago, Illinois 60654

ama-assn.org

(p) 312.464.5000
(f) 312.464.4184

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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: Medicare Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Systems; Proposed Rule for CY 2014. 78 Fed. Reg. 43,533 (July 19, 2013); CMS-1601-P; RIN 0938-AR54

Dear Administrator Tavenner:

The American Medical Association (AMA) writes in response to the Centers for Medicare & Medicaid Services (CMS) request for comments on proposals included within the proposed rule for the Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment System for Calendar Year (CY) 2014.

The AMA's comments focus on several main issues presented in the proposed rule. Our principal recommendations are set forth below, followed by more detailed comments.

- CMS proposes to bundle many separately payable services into packages of services. CMS believes this would reduce incentives for providing unnecessary services in the hospital outpatient setting. The AMA has concerns about this proposal and recommends that it not be finalized or implemented at this time.

- CMS proposes to replace 20 CPT codes within the four current five-code families of Evaluation and Management (E/M) services, with three Healthcare Common Procedure Coding System (HCPCS) G-codes, and to align the Extended Assessment and Management (EAM) Composite Ambulatory Payment Classification (APC) with the new G-codes. The AMA believes that this proposal has not been adequately vetted and has potentially serious negative consequences for many patients, physicians, and facilities.

- CMS proposes to change the nature and structure of Quality Improvement Organizations (QIOs). The AMA continues to have serious concerns, which were first expressed in a sign-on letter that responded to a May 2013 Medicare Request for Information (RFI), with

proposals that would make QIOs less representative of, and less responsive to, the needs of local physicians and their patients.

- CMS proposes to continue a number of policies—including its policy of updating the ASC conversion factor by a measure of inflation in the Consumer Price Index for Urban Consumers (CPI-U)—that will further widen the gap between hospital outpatient department (HOPD) and ASC payment rates. The AMA believes that the current gap is indefensible and urges CMS to take immediate steps to reduce it.

Packaging Proposals for Hospital Outpatient Services

Embedded throughout the notice of proposed rulemaking (NPRM) are proposals by CMS to bundle OPPS services into larger packages and APCs for payment purposes. **These bundling initiatives represent a radical departure from longstanding Medicare policy and practice, lacking in proper analysis of the impact on patient care. We urge CMS to withdraw its proposals to bundle services and delay such significant changes until the agency can provide stakeholder groups with accurate data files and more detailed impact analysis.** The proposed policies have serious implications for physicians, hospitals, and patients.

As an example, CMS proposes to package supporting items and services, the prices of which vary significantly from product to product, into the APC payment for the primary service as a means to make the total payment more reflective of the average resource costs. One possible unintended consequence of this proposal is that it could afford outpatient providers less flexibility to select the supporting items and services that are medically appropriate for a given patient. Instead, such providers will be pressured to limit these items and services as a means to reduce costs to align with the APC payment level. Some patients might see lower costs, but others would be faced with higher costs and/or the loss of the array of services most appropriate for their particular conditions and circumstances.

After numerous questions about this proposal were raised by various hospital and physician organizations, CMS published a corrected file on its web site and extended the comment period related only to those errors for an additional 10 days. Unfortunately, the corrected data was not available until August 28, 2013, and was not summarized and generally noticed until September 5, 2013. The information that has been provided, and the interaction of various policies, make it extremely difficult to trace the impacts of the significant APC modifications as well as the technical errors upon underlying policy changes and particular services. For example, additional information in the addenda to the proposed rule was difficult to follow, and the repeated entreaties to visit http://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/HospitalOutpatientPPS/index resulted in less clarity.

The changes that CMS is proposing are substantial and further review is warranted before they are implemented. CMS should delay a final decision on the OPPS bundling proposals until CY 2015, thereby giving the agency another year to review its calculations, address concerns, and seek further input from stakeholders in order to gain a better understanding of the implications of this proposal.

On a related issue, many physicians are interested in the concept of bundled payments and other new models that are currently being tested by the Center for Medicare and Medicaid Innovation (CMMI).

The AMA believes that CMS should encourage physician involvement in the design of new models by enhancing CMMI's capabilities to rapidly review the backlog of proposals and respond to applicants with timely and meaningful feedback.

Proposed Calculation and Use of Cost-to-Charge Ratios (CCRs) for Imaging Services

Beginning in CY 2014, CMS proposes to calculate the OPPS relative payment weights for cardiac catheterization, computed tomography (CT) scan, and magnetic resonance imaging (MRI) using distinct cost-to-charge ratios (CCRs) and to continue using a distinct CCR for implantable medical devices. Some stakeholders have pointed out that the proposed cost centers would not appropriately reflect the cost of performing these imaging services, which have different equipment costs and employ different technologies. We are also concerned that CMS does not appear to have performed a thorough analysis of the likely effects of this policy upon sites of service outside of the inpatient or outpatient facility setting. **Therefore, the AMA urges CMS to conduct a thorough evaluation of this policy, including an in-depth study to produce verifiable data regarding the effects that this change could have upon patient access to care for CT and MRI outside of the hospital setting.**

Extended Assessment and Management (EAM) Payment for Observation Care

CMS proposes to allow any visit furnished in a hospital, in conjunction with observation services of substantial duration, to qualify for payment through the EAM Composite APC. The AMA supports efforts to appropriately compensate physicians and other providers for patient care. Medicare recently issued guidance in the CY 2014 Inpatient Prospective Payment System (IPPS) final rule that was intended to clarify how and when to bill observation care services in the inpatient setting. This guidance was issued due to significant confusion on the part of providers that resulted in miscoding and admitting policies aimed at avoiding payment denials and audits. The lack of clarity also had serious consequences for patients as the difference between observation and inpatient status has a major impact on Medicare coverage of post-acute care services. **Before finalizing the rule, CMS should carefully consider the potential for this proposal to cause further confusion in a policy that is already incomprehensible to many physicians and most beneficiaries.**

Also, CMS proposes to replace two levels of EAM Composite APCs with a single composite APC (APC 8009). As justification, CMS cites alignment with a related proposal (discussed below) to collapse the five-level Evaluation and Management coding structure into three new G-codes. Proposals to collapse code levels are likely to penalize certain outpatient facilities, such as those that are attached to safety-net or teaching hospitals, which treat more complex patients and populations. This could lead to a decision by some facilities to admit borderline cases or deny treatment to beneficiaries who require complex care rather than absorbing losses in their outpatient departments due to the inability to bill a higher level EAM Composite. **The AMA does not support proposals that do not accurately account for the cost of providing a service. CMS should carefully assess the potential impact of this proposal upon different types of facilities and patients before moving forward.**

Replacement of E/M Codes for Clinic and Emergency Department Visits with New HCPCS Single Level Visit Codes

CMS is proposing an entirely new coding structure for patient visits in hospital outpatient clinics and emergency departments to replace the current codes for such visits. Three separate Level II HCPCS

G-codes are proposed—one for visits in outpatient clinics, and one for each type of emergency department visit (24 hour and non-24 hour). These would be paid at the same level, and align with newly created APCs. The new codes would completely replace the use of the CPT E/M codes in these settings. There are currently 20 separate E/M codes for office visits which are grouped into four families with five codes in each (9920X, 9921X, 9928X, and G038X). These have very detailed code descriptions and criteria for billing, to reflect the five different levels of complexity of medical decision making and patient complexity.

The AMA is strongly opposed to such a fundamental change in coding and payment policies for hospital clinic and emergency department visits. Under this policy, hospitals would be paid the same rate regardless of the complexity of medical decision making and the duration of the patient visit. If the distribution of Medicare's sickest and most complex patients were the same in all hospitals, this might average out over time. However, patient mix does vary significantly between different hospitals. This policy seems destined to benefit hospitals whose patients are generally well-educated and relatively healthy while penalizing the major teaching hospitals, safety net facilities, trauma centers, and other institutions that routinely treat patients requiring the most intensive use of services.

The AMA understands CMS' objective to eliminate opportunities for unjustified increases in coding intensity. But this should not be accomplished through a complete replacement of E/M codes in hospital outpatient clinics and emergency departments. The CPT Editorial Panel, the AMA Resource-Based Relative Value Scale/RBRVS Update Committee (RUC), and specialty societies have devoted years of effort and considerable resources to develop and fine-tune the E/M codes and their reimbursement. The E/M codes are designed to encompass patient visits across all types of facilities and settings. While hospitals have called for clear CMS billing and documentation guidelines when they use the current E/M codes for billing of facility services, the AMA does not believe that the answer to their questions is to simply ignore variation in the intensity of E/M services by eliminating any choice between levels of service. **Instead, the AMA urges CMS to work with hospitals, physicians, and the coding community to develop modifications or guidelines that address the hospitals' needs.**

Another concern with this proposal has to do with the tendency of some Medicare payment policies that were designed for one setting to find their way into the rulemaking for other settings. For example, in the CY 2014 Physician Fee Schedule (PFS) proposed rule, CMS proposed to pay 200+ physician services at OPPS or ASC rates. As detailed in the AMA comments on the CY 2014 PFS proposed rule, the application of an OPPS rate to physicians is inappropriate because the OPPS rate is based on average costs for a diverse group of procedures, whereas physicians are paid at the individual service level. The proposed consolidation of E/M codes in hospitals is misconceived and potentially inequitable, even within the hospital system. These problems would be further magnified in the physician setting where patient mix can vary even more significantly.

The AMA urges CMS not to finalize the OPPS proposal to replace 20 E/M service codes with 3 HCPCS G-codes. The AMA also would adamantly oppose extension of this policy to the Physician Fee Schedule.

Services in Off-Campus Hospital Provider-Based Departments

CMS notes that the growing acquisition of physician practices by hospitals has led to a rise in physician services furnished in a hospital outpatient setting, and billed under the OPPS. Services provided in a hospital setting generally receive a higher total Medicare payment than when performed in a freestanding clinic or physician office; beneficiaries also incur increased coinsurance for hospital outpatient services. CMS wants to collect information on the frequency, type and payment for services furnished in "off-campus provider-based hospital departments," which are frequently billed under the OPPS. CMS is considering creating a new place of service code (for item 24B of the CMS-1500 claim form) or a new HCPCS modifier to be reported with every code; and requiring more consistent break-out of hospital costs and charges for these departments, as outpatient cost centers (on the Medicare hospital cost form, 2552-10).

If this proposed collection of information is finalized, the AMA would not support the addition of a new HCPCS tracking modifier. There are currently numerous modifiers, in addition to other reporting requirements, which must be considered when billing current Part B services. Adding another modifier, which would have to be appended to every physician service delivered in the hospital outpatient setting, would increase both the administrative burden and the likelihood of future billing errors. As a simpler and more reasonable alternative, **the AMA would support adding a new site of service code that specifically identified Medicare claims for services delivered in off-campus provider-based hospital departments. We agree with those who have urged CMS to share any resulting data with stakeholders before drawing conclusions about what it means. We further urge that physician organizations be included in any such efforts.**

Quality Improvement Organizations (QIOs)

The OPPS proposed rule reflects several planned changes to the structure and mission of QIOs that would make them less focused on quality improvement at the community level and less able to forge partnerships with providers and patients to address challenges. Many of the proposed changes represent a more detailed version of the CMS May 2013 Request for Information (RFI) on options to change the QIO contracting process. The AMA and 47 state medical societies responded to the RFI in a July 2013 sign-on letter (see: www.ama-assn.org/resources/doc/washington/quality-improvement-organizations-sign-on-letter-11july2013.pdf.) urging CMS to postpone such changes until the pace of healthcare reform is less frenetic, physician practices are more stable, and we have a clearer sense of how the proposed changes would impact the quality and costs of patient care.

Of significant concern, CMS proposes to greatly expand the definition of "physician" under the regulations for QIOs (in 42 CFR sections 475.1 and 476.1) so that a doctor of medicine or osteopathy may no longer be required to perform case review of activities by his or her peers. The proposal states that "A physician is (1) A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor as described in section 1861(r) of the Act; (2) An intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor as described in paragraph (1) above; and (3) An individual licensed to practice as a doctor as described in paragraph (1) above in any Territory or Commonwealth of the United States of America." The NPRM indicates that CMS intends "to interpret our proposed regulation so as not to prohibit the use of professionals in the health care industry that are not licensed physicians or certified practitioners. We recognize/anticipate that these other professionals

may offer valuable insight to QIOs on ways to enhance the performance of their QIO functions, as well as to provide services designed to help QIOs maximize their impact." (78 Fed. Reg. 43,673.) CMS also proposes to replace the term "peer review" with "quality improvement."

CMS' proposals are extremely vague, and their impact is far from clear. **We are extremely concerned that the proposed removal of "peer review" and expansion of the term "physician" could lead to review of the actions of doctors of medicine and osteopathy (MDs and DOs) by other limited licensed practitioners.** This would be fundamentally inappropriate. The actions of MDs and DOs should only be subject to review by other physicians—preferably practicing physicians in the same specialty. **CMS should clarify that these changes are not intended to replace peer review by QIOs with reviews of physicians' decisions by non-physician providers.** Physicians devote many years in education and training in order to become licensed to practice medicine and legally authorized to perform the wide array of services and procedures for all types of patients. It would be completely inappropriate to allow other types of clinicians to assess the quality of care provided by physicians. We urge CMS to clarify that this will not be permissible.

CMS also proposes to redefine the term "QIO area" to allow for more flexibility in selecting an appropriately sized geographic area; no longer require QIOs in every state; and promote the establishment of function-specific QIOs. Many practicing physicians have spent years, even decades, building relationships with their local QIOs. State-based QIOs have ties to their local communities and a degree of credibility with local patients and providers. They are better able to identify problems in their communities, design appropriate solutions, and identify local physician leaders to initiate projects which have credibility with their peers. Maintaining the local perspective of QIOs would be difficult in a regionalized structure.

The establishment of function-specific QIOs is an interesting concept that has already been tested in some states. For example, the AMA understands that some state-based QIOs have expanded their focus to include additional resources for specific care settings, while others address the needs of specific patient populations. While some function-specific QIOs may address unmet needs, these should not be established at the expense of state-based QIOs. A cost effective alternative would be for Medicare to give high-performing existing QIOs the option to expand their portfolio of quality improvement activities during contract renegotiations. This would enable a modest amount of QIO specialization without sacrificing their core mission, to serve the local patients and providers of a particular state.

In total, the AMA believes that the proposed changes to the structure and mission of QIOs would undermine the positive relations that most physicians have with their QIOs, thereby making them less credible partners in the significant efforts of the medical profession to improve quality of care. We urge CMS to work with physicians and other stakeholders to enact positive reforms that would not disrupt the historical mission of QIOs.

Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rate

When CMS implemented the revised ASC payment system in 2008, the agency estimated significant growth in volume and diversification of services within the ASC due largely to a shift into the ASC of

services previously performed in the HOPD. Over the last five years, however, very little market share has migrated to the ASC and hospitals are actually increasing their share of many services commonly performed in the ASC setting. Moreover, in the last 12 months (June 2012 to June 2013), the number of operating ASCs has grown by just 57 centers—the fourth consecutive year of growth less than two percent and the second year with growth less than one percent. And new capacity that is coming online is primarily the result of newly created or expanded hospital outpatient departments. A key reason for the slower-than-anticipated ASC growth can be found in Medicare policies that lead to ASC payment rates that are just 58 percent of the HOPD payment rate.

Because of this difference, both Medicare and its beneficiaries pay significantly less when services are provided in an ASC than when they are delivered in an HOPD. We believe that this rule continues the policies that have produced this gap and discouraged shifting services to ASCs, while also potentially increasing the gap through some of its new bundling proposals. As we have previously noted, **there is no good reason for using different wage indexes in the calculation of rates for the two sites.** Nor is there any justification for subjecting the ASCs to lower annual payment updates year after year. With regard to the annual update, CMS proposes to continue its policy of updating the ASC conversion factor by a measure of inflation in the Consumer Price Index for Urban Consumers (CPI-U). There is broad agreement that the CPI-U measures inflation in a basket of consumer goods that is atypical of what ASCs purchase and is therefore flawed for the purposes of the ASC payment system. The hospital market basket, on the other hand, is an available proxy for ASC costs and is superior to the use of the CPI-U. The hospital market basket is also used to update the OPPS payment rates. Because the OPPS cost structure looks much like the cost structure of ASCs, if the hospital market basket is appropriate for updating OPPS payment rates, it is also appropriate for updating ASC payments. **We therefore urge CMS to adopt the hospital market basket instead of the CPI-U to update ASC payment rates for inflation.**

We are also concerned that the APC modifications that CMS is proposing for 2014 will exacerbate the existing gap between HOPD and ASC payments. In some instances, this occurs because the policies proposed for the HOPDs would not be mirrored in the ASC. In other cases, the proposed modifications will trigger redistributions in the APCs that have negative ramifications in the ASC system, although it is difficult to trace and analyze this impact given the problems in tracing the proposals' effect on hospitals. This heightens our previously stated concerns with CMS' proposals to increase APC packaging and consolidate visit and emergency department codes and strengthens the case for withdrawing these proposals until the impact on both hospitals and ASCs is further studied.

Finally, we wish to echo the repeated pleas from the ASC industry and various physician specialties for more transparency in the designation of services that Medicare will pay for in an ASC. Experience with private sector patients clearly indicates that many of the 492 CPT codes for which Medicare reimburses HOPDs but not ASCs could safely be performed in the ASC. CMS's exclusion of these codes from coverage in an ASC is therefore inexplicable. We urge the agency's careful consideration of comments from individual specialties regarding additional procedures they believe should be covered in ASCs. Such additions would not only cut Medicare costs per service, but would also afford beneficiaries greater access, convenience, and options for care. We also endorse the ASC industry's call for a process by which CMS would indicate on a code-by-code basis why some services are excluded from payment in an ASC.

Use of Clinical Quality Measures Across Settings

In this NPRM as well as the PFS CY 2014 proposed rule, CMS is proposing importing and applying clinical quality measures developed specifically for one setting or program, and employing them in other quality programs in other settings, without detailed analysis or testing as to whether these are actually appropriate for the new purpose and setting. While it may be possible, and appropriate, to "retool" certain measures for use in new settings, this should not be done willy-nilly without careful consideration and input from the clinical quality community, as well as the intended users of such measures.

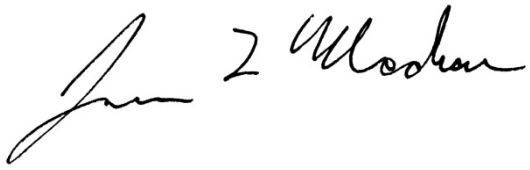
It is important to note that retooling a measure for capture in a different setting and at a different level of measurement (i.e., facility/hospital as compared to individual physician level) is not an insignificant task. **We encourage CMS to work with the affected specialties as well as measure developers like the AMA-convened Physician Consortium for Performance Improvement® (PCPI®) to ensure careful selection of measures and a smooth process for their retooling.**

The AMA defers to the individual specialties on the question of whether the agency should allow attribution of reporting periods and performance results from quality reporting programs for facilities to individual eligible professionals or group practices employed by such facilities, who elect to do so. **In evaluating this approach, the AMA urges CMS to consider how performance in an HOPD, ASC, etc. on a measure would be attributed to a physician who practices in multiple hospitals or ASCs for treating the same condition.**

Conclusion

The AMA appreciates the opportunity to offer its perspective on the 2014 OPPS/ASC proposed rule and looks forward to working with CMS to achieve resolution of each of the foregoing matters. Please feel free to contact Margaret Garikes, Director, Federal Affairs at 202-789-7409 or margaret.garikes@ama-assn.org with any questions or concerns related to the foregoing comments.

Sincerely,



James L. Madara, MD