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May 7, 2012

Marilyn Tavenner
Acting Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

RE: CMS-0044-P, Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2, 77 FR 13698 (March 7, 2012)

Dear Ms. Tavenner:

The American Association of Orthopaedic Surgeons (AAOS) appreciates the opportunity to comment on the Centers for Medicare and Medicaid Services (CMS) proposed rule, entitled "Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 2," published in the March 7, 2012 Federal Register. The AAOS, which represents over 18,000 board-certified orthopaedic surgeons, has been a committed partner to CMS in patient safety, cultural competency, and the provision of high-quality, affordable healthcare. The AAOS supports the development of appropriate standards for meaningful use of electronic health records by Government agencies and private carriers which balance the needs of patients and their families, physicians and their staffs, and regulators. AAOS believes these standards should be collaboratively developed by physicians through their professional organizations in cooperation with government agencies. The process should emphasize the requirements for the highest level of quality patient care while recognizing the limits and clinical specialty focus of physicians who use the systems.

We commend CMS on its efforts to enhance usability of the electronic health record (EHR) system, and offer the following remarks regarding the proposed criteria that eligible professionals (EPs) must meet in order to qualify for an incentive payment during Stage 2.

Our comment letter focuses on proposed provisions that we believe will impact orthopaedic surgeons' practices as well as the patients we treat. We are committed to:

- **Ensuring access to care;**

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- **Adopting appropriate orthopaedic quality measures;**
- **Overcoming technology issues;**
- **Maintaining patient privacy and personal data security; and**
- **Limiting burdensome costs.**

Introduction

The AAOS applauds CMS' efforts to encourage physicians to become Meaningful Users of health information technology (HIT) specifically, electronic health records. Stage 2 criteria focus on improving care transitions and patient engagement including health information exchange and interoperability of electronic health records. As surgical specialists, the AAOS members have unique HIT needs and offer suggestions to improve Meaningful Use (MU) criteria and subsequent adoption of EHR technology to better reflect the needs of surgical specialists and their patients.

The most significant proposed changes to Stage 1 criteria include eliminating the core objective that providers must demonstrate the capability to exchange key clinical information among providers of care and replacing the requirement that providers provide patients with an electronic copy of their health information with the core objective that would instead require providers to provide patients with the ability to view online, download, and transmit their health information.

The AAOS is concerned about the negative impact that implementation of the Stage 2 proposed rules may have on indigent patients in both rural and urban settings. Many indigent patients rely on small or solo orthopaedic practices to obtain most or all of their care. Particularly in rural areas, a significant percentage of orthopaedic care is provided by small, independent practices and large practices are just not feasible in these areas.

At the same time, indigent patients are less likely to have Internet access, and they also may have low health literacy. People who cannot read, or have sixth-grade vocabularies, or no computer skills cannot successfully navigate the healthcare system. They are limited in their ability to fill out complex forms, to share personal information, such as health histories, with providers, and to engage in healthcare decisions. Provisions of the Stage 2 proposed rules discriminate against these patients as well as the physicians who care for them.

The cost of building out infrastructure to include patient portals, the time commitment of physicians and their staff necessary for implementation, as well as existing technological hurdles are typically too high for small or solo practices. Patient portal build-out includes up-front costs, training, which takes providers away from seeing patients, and maintenance and upkeep for the system.

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Moreover, the health information exchange requirement is onerous not only because exchanges are not up and running in all states nationwide, but they are expensive to use. The costs imposed by HIEs are increasing the expense of running a practice with no opportunity to generate offsetting revenue.

Gabriel Dassa, DO, is an orthopaedic surgeon in solo practice in Bronx, NY. His patient population is predominantly indigent and low-income Medicaid and Medicare beneficiaries, approximately 70 percent. Dr. Dassa has purchased an EHR system recently using his own funds and has begun to e-prescribe. He considered trying to meet the Stage 1 meaningful use requirements. However, as a solo practitioner Dr. Dassa's time, and that of his staff, to track data to meet Stage 1 would reduce time for patient care from his 65 – 70 hour work week. His time, he feels, is better spent caring for patients than seeking incentive payments.

Dr. Dassa recognizes many Stage 2 requirements are out of reach for him. His patient population does not own or use computers. His patients do not have access to the technology required to use patient portals and will not likely seek health information reports from him. It is highly unlikely that he can achieve the Stage 2 requirement for at least 10% of patients to access their protected health information and use secure messaging online. While he is able to electronically link to the hospital (Bronx-Lebanon), most other physicians in the Bronx are not purchasing an EHR, making electronic exchange of patient information for care transitions impossible. Dr. Dassa's major concerns are ensuring his patients have access to care and patient compliance with care instructions. Is it fair to penalize Dr. Dassa for circumstances that are beyond his control?

The AAOS is concerned that policies embraced by the proposed rules will push healthcare delivery into larger multi-specialty practices and threaten to put small and solo practitioners out of business, while simultaneously reducing access to care. The small and solo practices have no chance of meeting the proposed Stage 2 requirements, and will be financially penalized, further adding to their already strained financial resources.

The AAOS urges CMS to work to ensure that patients' access to care is not impeded. The AAOS advocates that the Meaningful Use program foster EHR adoption that reduces costs and boosts efficiency, but does not threaten to eliminate small or solo practices. In addition, we believe that it is important to make the Stage 2 requirements clear and balanced so health care providers will have a better chance of meeting them.

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Overall, we recommend providing physicians greater time to implement EHR technology in their practices. HIT implementation should not come at the cost of reducing access to care.

Delay in Implementation
The AAOS appreciates CMS' decision to delay implementation of Stage 2, which allows doctors and hospitals to adopt HIT in 2011 or later without meeting the new Stage 2 standards until 2014. Some AAOS members report they have completed the purchase of an EHR system, but are awaiting delivery from backlogged company representatives who are unable to install the system.

Alignment with Other Programs
The AAOS applauds CMS' efforts to better align clinical quality measures under the meaningful use program with other programs that involve quality reporting such as the Medicare Physician Quality Reporting System (PQRS) and the shared savings program for Accountable Care Organizations. The AAOS supports the goal of reporting clinical quality measures through a single mechanism for multiple CMS programs.

Patient Engagement
Proposed Stage 2 rules require healthcare providers to offer EHR access to more than half of their patients. Clinics and private practices must also prove at least 10 percent of their patients are actually accessing healthcare information on EHRs . This is a change from Stage 1 where a patient's action or inaction could not impact whether or not a provider is meeting Meaningful Use. Under this core objective of Stage 2, eligible healthcare professionals must prove that at least 10 percent of patients use secure electronic messaging platforms that are native to EHR systems to communicate with healthcare providers.

The AAOS believes that the infrastructure requirement to meet this core objective will be burdensome for many small practices. Patient portals are costly. Moreover, with certain patient populations, particularly indigent patients and those living in rural areas, the 10% threshold will be very difficult to achieve. The AAOS recommends that CMS offer more flexibility in how information can be transmitted to or obtained by patients.

Consider Dr. James Barber, an orthopaedic surgeon in solo practice in rural, Douglas, GA, a town of about 15,000 residents. One-in-four orthopaedic surgeons are in solo practice today. Dr. Barber sees about 40 – 45 patients in a typical day of practice. About 8 – 10% of his patients are indigent; 20 – 25% are supported by Medicaid, and another 25% by Medicare. Dr. Barber has not purchased an EHR. He has evaluated different systems and recognizes his

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investment might be as much as $100,000 for a complete system, a significant practice expense. Dr. Barber estimates there is little likelihood that he would be able to meet the Stage 2 meaningful use requirements.

Dr. Barber's patient population has limited access to a computer and limited computing skills. Internet service in rural Georgia is inadequate and there is a lack of IT support. Right now, Dr. Barber spends 2 – 3 hours each week, time he could be spending with patients, maintaining his office practice management computer system. Adding an EHR would increase his maintenance time at the expense of patient appointment time or increase his 65 hour work week.

Dr Barber estimates that at most 50% of his patient population has Internet access. To meet the 10% patient access requirement, 20% of Dr. Barber's patients with Internet access would need to access their medical record in order to meet the Stage 2 requirement. It would be difficult for Dr. Barber to meet the threshold. Typically, patients access their own medical record to review laboratory reports, access care instructions, and email the doctor. For orthopaedic surgery patients very few laboratory tests are ordered, and most patients participate in pre-operative classes (especially for total joint replacement) and receive protocol-based pamphlets detailing their post-operative instructions. As a result for Dr. Barber's orthopaedic patients there may be few, if any, reasons to access their records. If Dr. Barber were to install a secure patient portal, no one would use it!

Technology Issues

The AAOS believes that the Stage 2 proposed rules present providers with technological challenges. Executing the transitions of care requirements well will be a challenge and will require even more process and IT support in order to comply with both MU and state regulations.

Dr. Barber's colleagues in other medical specialties in this part of Georgia have limited resources and are not making an EHR purchase. If he did have an EHR system, it would be very difficult for Dr. Barber to share or receive patient medical information for care transitions with other eligible professionals.

Secure messaging is a requirement and there is a standard and certification requirement that direct project protocols are enabled in the EHR. In addition, the health information exchange requirement goes from merely performing one test to the ability to connect to at least three external providers in the primary referral network--but outside delivery system that uses the same EHR–or establish an ongoing bidirectional connection to at least one health information exchange organization. How will physicians meet this requirement if the state HIE is not ready to process data?

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Interoperability remains an obstacle. In many places, there is no interoperability available between hospital electronic medical record systems where the most value for patients could be found. In some cities for example, several hospitals may each have an Epic electronic medical systems, but those systems cannot speak to one another. While hospitals may foster this status to protect their "captured patients," it limits providers' ability to advance meaningful use goals. Moreover, proprietary electronic medical record companies also resist interoperability.

The AAOS believes that developing patient portals is not feasible for small practices at this point. The costs associated with portals are high, and accordingly, the AAOS urges CMS to add some flexibility. For example, a smaller practice that cannot invest in patient portal technology should be permitted to use some other transmission method, perhaps including the U.S. mail service to get personal health information to patients without computer access.

Another requirement that will prove challenging is the core objective calling for providers to incorporate clinical lab-test results into certified EHR technology as structured data for more than 55 % of all clinical lab test results. Many practices have interfaces to lab providers, but not all labs have the ability to interface with electronic health records.

The AAOS believes that the most pivotal measures presented in the proposed rules are also the most onerous because practices will have to invest in new technologies and work flows to achieve compliance. Specifically, the health information exchange, directing movement of information between disparate organizations, and the patient engagement requirements, establishing the ability of patients to view their own record, will present burdensome hurdles to overcome. While the percentage requirements on these items are fairly modest, both core criteria represent building out an infrastructure and approach that is still nascent in the industry, albeit important in achieving the long-term goals of the Meaningful Use program.

e-Prescribing

Under the proposed regulation, eligible healthcare professionals and hospitals must use electronic prescriptions 65% of the time and computerized physician order entry (CPOE) systems must be used for at least 60% of all orders including laboratory and radiology orders. CPOE under Stage I included only prescriptions. Under Stage 2, CPOE includes lab and radiology orders as well prescriptions.

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The AAOS believes that the 65% of prescriptions threshold is very high. The AAOS recommends that the threshold for e-prescribing should be kept fairly low, perhaps 25% - 30%, because patients can—and often do--opt out from prescriptions being sent to the pharmacy. For a prescription to count under the proposed rule, it has to be sent using qualified e-prescribing technology. Many people, however, get their prescriptions through mail order, a requirement of their insurance plan. In addition, frequently, a physician will tell the patient to fill the prescription only if the patient needs it.

In our previous comments, we asked CMS to consider the e-prescribing threshold and the conflicting rules for prescribing controlled substances like opioids for pain. A significant percentage of prescriptions ordered for orthopaedic patients fall into this category. Orthopaedic surgeons will not be able to meet the 65% e-prescribing threshold as most prescriptions for orthopaedic patients are not allowed for electronic transmittal. The e-Prescribing of controlled substances is further exacerbated by the White House Office of National Drug Control Strategy for reducing abuse of prescription drugs, specifically focusing on narcotic substances.

Quality Measures

The AAOS is concerned about the reporting of quality metrics. The AAOS believes that Stage 2 criteria would require eligible health care providers to collect data for too many measures. Moreover, we question whether the data will be accurate. To generate the measures from the electronic health record system, the provider or its IT vendor must map all relevant codes, and this may present an obstacle to getting accurate information.

The AAOS remains concerned about the lack of orthopaedic specialty specific criteria, which puts orthopaedic surgeons at a disadvantage in meeting the MU criteria. The clinical quality measures that directly link to orthopaedic practice focus on osteoporosis and back pain. As more and more orthopaedic surgeons specialize in adult reconstruction, sports medicine, pediatric orthopaedics or orthopaedic trauma, many would be unable to report on quality metrics for osteoporosis or back pain. AAOS would appreciate the opportunity to work with CMS to define quality measures for the broad orthopaedic specialty.

As in Stage 1, the Stage 2 criteria require orthopaedic surgeons to undertake tasks that are not typically required in the care of musculoskeletal patients. The impact of this will be to increase costs and reduce physician time to see other patients.

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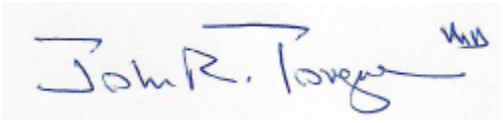
There will be reduction in patient access to care with no concomitant improvement in quality of care.

While we are encouraged by the direction of the Stage 2 proposed criteria, we have significant concerns about practicality. As specialty physicians, we face unique technology challenges ranging from certification issues to collection of appropriate data, as well as larger issues impacting all physicians such as interoperability and cost. The proposed Stage 2 criteria make it very difficult for orthopaedic surgeons to become Meaningful Users of HIT, despite our desire to adopt new technology. The amount of time orthopaedic surgeons would spend trying to meet proposed criteria would ultimately result in less time treating patients, thereby reducing patients' access to care. While we support the common goals of improving quality and providing appropriate documentation of patients' medical care, we are concerned the complete set of measures is onerous and more relevant to primary care physicians.

Conclusion

The AAOS appreciates this opportunity to provide comments on Meaningful Use Stage 2 criteria. We believe that health information technology is a fundamental component to improving our nation's health care system. We support the common goals of improving transitions, engaging patients, and enhancing interoperability of electronic health records, and we look forward to continuing to work with CMS to ensure that these goals are attained in a reasonable, pragmatic manner that does not impede patients' access to care. We are ready to work with CMS to create meaningful use requirements that are specialty specific and that lead to the successful implementation of EHR systems that support patient care. If you have any questions on the AAOS comments, please do not hesitate to contact our Medical Director, William R. Martin, III, MD, at (202) 546-4430 or martin@aaos.org

Sincerely,



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