November 19, 2018

Seema Verma  
Centers for Medicare & Medicaid Services  
Department of Health and Human Services  
Attention: CMS-3346-P, Mail Stop C4-26-05  
7500 Security Boulevard  
Baltimore, MD 21244-1850

Submitted electronically via http://www.regulations.gov

Subject: Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction

Dear Administrator Verma:

On behalf of over 34,000 orthopaedic surgeons and residents represented by the American Association of Orthopaedic Surgeons (AAOS), we are pleased to provide comments for the Centers for Medicare & Medicaid Services (CMS) Proposed Rule, “Medicare and Medicaid Programs: Regulatory Provisions to Promote Program Efficiency, Transparency, and Burden Reduction.”

Ambulatory Surgical Center (ASC): Transfer Agreements with Hospitals

AAOS appreciates CMS’ responsiveness to the ASC community’s concerns about hospital refusal to cooperate with local ASCs. However, AAOS believes that the transfer agreement and admitting privileges requirements serve an important patient safety function, and we continue to support them. Nevertheless, AAOS recognizes that these requirements have given hospitals too much bargaining power and contribute to unfair and uncompetitive practices.

The AAOS instead encourages CMS to revise the requirements to more closely align with those applicable to skilled nursing facilities (SNFs). As CMS knows, under the similar SNF transfer agreement requirements, “if an otherwise qualified SNF has attempted in good faith but without success to enter into a transfer agreement, this requirement may be waived[.]” We believe giving ASCs a similar “good faith” exception would strike the correct balance between protecting patients and counteracting bad actors in the hospital market.

ASC Requirements for Comprehensive Medical History and Physical Assessment

The AAOS appreciates CMS’ effort to reduce the regulatory burden through its proposal to remove and replace the existing history and physical requirements. The circumstances CMS
discusses in the Proposed Rule certainly demonstrate the need to reform this particular regulatory requirement. We recognize that rescheduling a surgery beyond the 30-day limit is incredibly common and that requiring a second evaluation for stable patients in these circumstances is unwarranted. Relatedly, requiring healthy patients to undergo a full history and physical workup, regardless of applicability to a particular procedure, is burdensome to patients and surgeons.

Nevertheless, we have concerns about the changes as proposed. The history and physical is a valuable tool to facilitate patient-doctor communication and continuity of care. As expressed above, we believe that quality patient safety protections should remain in place. The flexibility provided by the Proposed Rule is appreciated, but instead of complete removal-and-replacement, the AAOS would encourage CMS to retain some regulatory history and physical update attestation requirement. Commercial payers, state agencies, and the facility’s malpractice insurer may still require these evaluations to be performed. Rather than giving such deference to “the facility’s established policies” for history and physical, the AAOS encourages CMS to retain at the very least an annual history and physical requirement under the rules.

**Quality Assessment and Performance Improvement (QAPI) and Infection Control Programs**

The changes under the Proposed Rule would allow health systems to use a unified/central staff across multiple hospitals instead of having individual staff for each separately certified hospital. Similar to the proposal for the QAPI program, a governing body for a system of multiple separately certified hospitals could elect to have a unified and integrated infection control program. Under such a system, hospitals would have to demonstrate certain elements of such a program. This would need to be in line with applicable state and local laws. The AAOS supports these changes.

**Emergency Preparedness**

The emergency preparedness changes under the Proposed Rule would revise the requirements for annual reviews of emergency preparedness programs to allow facilities to instead review their plans at least every two years. The AAOS supports these changes.

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Thank you for your time and consideration of the American Association of Orthopaedic Surgeons’ suggestions. We commend CMS on its continued efforts to improve care quality, promote program efficiency, and relieve regulatory burdens. If you have any questions on our comments, please do not hesitate to contact William Shaffer, MD, AAOS Medical Director by email at shaffer@aaos.org.
Sincerely,

David A. Halsey, MD
President, AAOS

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