November 19, 2018

Seema Verma, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-3346-P
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Via online submission at www.regulations.gov

Re: Medicare and Medicaid Programs: Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction (CMS-3346-P, 83 FR 183, published September 20, 2018)

Dear Administrator Verma:

On behalf of the Ambulatory Surgery Center Association (ASCA), representing the interests of the nation's 5,700 CMS-certified Ambulatory Surgery Centers (ASCs), we appreciate the Agency's efforts to reduce regulatory burdens. ASCs are small businesses that strive to keep administrative costs low, allowing them to be efficient providers of high-quality outpatient care that reduce costs for the Medicare system by billions of dollars each year. We appreciate that CMS has proposed to modify some of the unnecessary and burdensome regulations that do not impact quality or patient safety but do hinder our efforts to keep costs down. Our comments on the three primary provisions of interest to the ASC community in the rule follow.

Governing Body and Management (§ 416.41(b)(3)(i) and (ii)): Hospitalization Requirements

ASCA supports CMS' proposal to remove the language found in 42 CFR § 416.41(b)(3), "Standard: Hospitalization." Under this requirement in the current Conditions for Coverage (CfCs), ASCs must either have a hospital transfer agreement with a local hospital or all physicians providing services in an ASC must have admitting privileges at a local hospital. While in many communities this does not pose a significant burden on facilities, both options do rely on the good faith of the hospital to work with ASCs, something that simply does not exist in some markets. Particularly in remote areas, hospitals often use this requirement to gain a competitive advantage against a local ASC, either by refusing to enter into a transfer agreement at all or requiring extremely burdensome "on-call" arrangements with the physicians before granting admitting privileges.

ASCA believes it is in the best interest of the patient, the ASC and the hospital if an agreement can be reached to allow for optimal coordination of patient care. However, ASCs should not have to close or be denied CMS certification simply because the local hospital refuses to act in good faith. As the rule indicates, the Emergency Medical Treatment and Labor Act (EMTALA) emergency response regulations would continue to address emergency transfer of a patient from an ASC to a nearby hospital, and ASCs would still be required to have in place an "effective

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procedure for the immediate transfer, to a hospital, of patients requiring emergency medical care beyond the capabilities of the ASC and that the hospital must be a local hospital that meets the requirements for payment for emergency services under § 482.2."[1]

If CMS determines that it is not prepared to remove the language found at 42 CFR § 416.41(b)(3) in its entirety, ASCA recommends that the Agency at least apply the transfer agreement language in the "Requirements for States and Long Term Care Facilities"[2] to our Conditions for Coverage. Under 42 CFR § 483.70(j)(2), it states that "the facility is considered to have a transfer agreement in effect if the facility has attempted in good faith to enter into an agreement with a hospital sufficiently close to the facility to make transfer feasible." While ASCA supports the proposal as written, we believe this alternative would also be acceptable.

Patient Admission, Assessment and Discharge (§ 416.52(a)(1), (2), (3) and (4))

ASCA supports the flexibility to physicians and facilities provided in the new medical history and physical assessment (H&P) proposed language, but respectfully requests that an H&P still be required for all patients, but the ASC be given the discretion to determine the timeframe for the H&P relative to the date of surgery. By simply changing § 416.52(a)(1) to state the "ASC must develop and maintain a policy that requires a medical history and physical examination prior to surgery," and keeping the rest of the new language, this would provide flexibility and burden reduction while ensuring the safest possible outcome.

Currently, the CfCs state that "not more than 30 days before the date of the scheduled surgery, each patient must have a comprehensive medical history and physical assessment completed by a physician (as defined in section 1861(r) of the Act) or other qualified practitioner in accordance with applicable State health and safety laws, standards of practice, and ASC policy."[3] The requirement that ASCs have an H&P that is current within 30 days of the surgery has long been a concern for our facilities. The proposed language found at § 416.52(a)(1)(ii) leaves it to the discretion of the facility to determine the timeframe the H&P should be required prior to surgery. This will alleviate a huge administrative burden for our facilities while still assuring patient safety.

As ASCs are providing elective surgery, there are many reasons that the surgery could end up being scheduled outside of the 30-day window. Regardless of when the H&P is completed, the CfCs still require "an updated medical record entry documenting an examination for any changes in the patient's condition since completion of the most recently documented medical history and physical assessment."[4] ASCA believes that it should be left to each facility to determine in its policies and procedures what timeframe should be used. For some, having an H&P current within 30 days may be ideal, and for others, having the results from that patient's most recent annual physical with their primary care physician might be sufficient. ASCA supports this revised language, but as stated above believes all patients should still have an H&P on record.

[1] § 416.41(b)(1) and (2)
[2] https://www.ecfr.gov/cgi-bin/text-idx?rgn=div5&node=42:5.0.1.1.2#se42.5.483_170
[3] § 416.52(a)
[4] §416.52(a)(2)

The second aspect of H&Ps on which ASCs find confusion is the word "comprehensive." The word "comprehensive" is vague and problematic. ASCA supports the proposed CfC language that directs the ASC and its physicians to consider "patient age, diagnosis, the type and number of procedures scheduled to be performed on the same surgery date, known comorbidities, and the planned anesthesia level" when developing the specific H&P requirements. In addition, ASCA supports that, instead of a one-size fits all standard, the proposed language directs physicians to "follow nationally recognized standards of practice and guidelines." The H&P could certainly look different for a cataract procedure as opposed to a total joint replacement.

Emergency Preparedness for Providers and Suppliers

ASCA strongly supports the proposed changes regarding emergency preparedness requirements for ASCs. As ASCA noted in our comments to the proposed rule regarding Emergency Preparedness Requirements for Medicare and Medicaid Participating Providers and Suppliers (78 Fed. Reg. 249, December 27, 2013), while ASCs serve an integral role in the health care delivery system, the role of ASCs in emergency situations is simply not the same as that of hospitals. ASCs provide outpatient surgery that in most cases is elective. As such, ASCs should not be subject to the same emergency preparedness standards as facilities that provide emergency and inpatient services. ASCA believes the flexibility and burden reduction that would result from these common-sense regulatory changes will allow our facilities to dedicate more resources to our primary objective – providing high-quality care to our patients.

We greatly appreciate the Administration's efforts to reduce regulatory burden for our facilities and thank you for the opportunity to comment on these proposals. For additional information or to set up a meeting to discuss our concerns, please contact Kara Newbury, ASCA Regulatory Counsel, at knewbury@ascassociation.org or 703.636.0705.

Sincerely,

William Prentice
Chief Executive Officer