3300 Woodcreek Drive
Downers Grove, Illinois 60515
630-573-0600 / 630-963-8607 (fax)
Email: info@asge.org
Web site: www.asge.org

November 19, 2018

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3346-P
P.O. Box 8016
Baltimore, MD 21244-8013

Re: CMS-3346-P; Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction

Dear Administrator Verma:

The American Society for Gastrointestinal Endoscopy (ASGE) welcomes the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) proposed rule "Medicare and Medicaid Programs; Regulatory Provisions To Promote Program Efficiency, Transparency, and Burden Reduction" (CMS-3346-P), published in the *Federal Register* on September 20, 2018. Specifically, ASGE welcomes the opportunity to comment on Medicare regulations that CMS has identified as unnecessary, obsolete, or excessively burdensome for ambulatory surgical centers (ASCs).

The ASGE was founded in 1941 and since that time has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with more than 15,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

ASGE appreciates the Agency's emphasis of patients over paperwork and its continued efforts to reduce administrative burdens that do not correlate with care quality or better patient outcomes. For example, we appreciate the removal of duplicative and low-value measures from the Ambulatory Surgery Center Quality Reporting Program beginning with the 2019 performance year, as well as for a new scoring methodology for the Promoting Interoperability category of the Quality Payment Program (QPP), which should help to reduce burden for clinicians and enable them to focus more on patient care.

We encourage CMS to continue its focus on administrative burden reduction. ASGE members are particularly concerned with redundant and complex administrative systems that frustrate both patients in seeking, and physicians in delivering, high quality medical care. Prior authorization, step therapy requirements, and other care delivery impediments imposed as a condition of coverage or payment interfere with physician autonomy and unnecessarily delay access to the most appropriate and effective treatment or test and add layers and cost to the health care delivery system.

Step Therapy — Gastroenterologists treat disorders of the bowel that produce an inflammatory response and for which biologics, oftentimes administered in the physician's office and reimbursed under Part B, are the primary treatment. ASGE is disappointed that CMS has chosen to allow Medicare Advantage plans to use step therapy for Part B covered drugs effective starting 2019. ASGE members frequently run into the need to prove that a patient failed other therapies, including sometimes one or more drugs in the same category, before the requested therapy will be approved. Physicians are not given rules or indications of how these authorizations will be adjudicated. Frequently — an estimated 30-50 percent of the time — the way a gastroenterologist needs to use a biologic doesn't fit the Food and Drug Administration's initial indication and may be denied or held up for one or more levels of appeal, including appeal to outside peer review. For example, some individuals with Crohn's disease should have a higher dose infliximab — 10mg/kg, not 5mg/kg — even for initial therapy, or step up because of incomplete or failing responses. As another example, treatment of Crohn's disease may require weekly, instead of bi-weekly, administration of adulimumab; others need a repeat induction dose of medication to re-capture response. We urge CMS to reverse its decision to require step therapy for Part B drugs under Medicare Advantage.

Medicare Appropriate Use Criteria (AUC) Program — ASGE also asks CMS to not proceed with implementation of the Medicare AUC Program for advanced diagnostic imaging tests. It has become clear to ASGE members that the AUC Program will establish a complex and costly process of AUC consultation and documentation with questionable benefit. Consultation of AUC should be flexible and encouraged through mechanisms that now exist within the QPP. ASGE lacks confidence the program can be successfully implemented and seeks modification to deem clinicians who participate in the QPP as compliant with the AUC Program.

Colorectal Cancer Screening Cost Sharing — Lastly, we urge CMS to exercise its administrative authority to close the colorectal cancer screening colonoscopy beneficiary cost sharing loophole. It is illogical that national efforts to improve colorectal cancer screening rates are complicated by an unfair CMS policy that holds beneficiaries accountable for paying coinsurance for a screening colonoscopy that unexpectedly requires the removal of polyps for the prevention of cancer. The Department of Health and Human Services corrected this irrational policy for privately insured patients; it's time that the same be done for Medicare patients. Practice staff must spend considerable time chasing down payment and explaining Medicare's confusing cost-sharing policy to beneficiaries.

We thank the Agency for the regulatory relief proposals put forth in this rule and on which we offer the following comments. We urge CMS to place proposed changes into effect by January 1, 2019, or as soon as possible. Because many of the standards addressed in this rule are annual requirements, it is important the transition to new requirements not create confusion among providers and surveyors. Meaning, an effective date other than January 1 would complicate the transition to the new requirements, because compliance surveys are retrospective.

Ambulatory Surgical Center: Transfer Agreements with Hospitals

ASGE strongly supports CMS' proposal to remove the requirement for a written hospital transfer agreement or hospital physician admitting privileges. CMS is correct with its assessment that increasingly hospitals are declining to work with ASCs, either by declining to sign a transfer agreement or by declining to allow admitting privileges to the hospital by physicians who work in ASCs, due to competition between hospital outpatient surgery departments and ASCs. The result has been that ASCs, in some cases, are forced to sign transfer agreements with hospitals without regard of proximity to the ASC. Eliminating the requirement does not mean that ASCs will not have methods of seeking a higher level of care for their patients, it will just mean that hospitals cannot attempt to eliminate their lower-cost ASC competition.

ASC Requirements for Comprehensive Medical History and Physical Assessment

Current regulations require ASCs to ensure that a physician or other qualified practitioner provide a comprehensive medical history and physical assessment completed not more than 30 days before the date of the scheduled surgery. CMS proposes to remove the current requirements and replace them with requirements that defer to the facility's established policies for pre-surgical medical histories and physical examinations (including any associated testing) and the operating physician's clinical judgment, to ensure patients receive the appropriate pre-surgical assessments that are tailored for the patient and the type of surgery being performed. ASGE supports this proposal.

It is our experience that this requirement, as currently structured, can be confusing to physicians based on what constitutes "comprehensive." Gastroenterologists are focused on whether a patient can tolerate an endoscopic procedure. Substituting current requirements that give deference to a facility's established policies for pre-surgical medical histories and physical examinations and the operating physician's clinical judgment will remove any misunderstanding of what constitutes "comprehensive." At the same time, in the case a patient needs to be emergently transferred to higher-level care, these proposed changes preserve the documentation of information for the receiving physician.

Emergency Preparedness Requirements

Requirements for Emergency Plans —

ASGE supports CMS' proposal to eliminate part of the requirement for hospitals and other parallel provisions for other affected Medicare and Medicaid providers and suppliers, including ASCs, that facilities document efforts to contact local, tribal, regional, State, and Federal emergency preparedness officials, and that facilities document their participation in collaborative and cooperative planning efforts. When practical, ASCs can be integrated into the local disaster plan. Although, generally speaking, the nature of the endoscopy ASC makes it an impractical partner. Endoscopy centers do not stock supplies nor medications that would be useful in an emergency. In addition, a physician's contractual arrangement with a hospital may obligate the physician to staff the hospital in the event of a disaster or emergency, making ASCs an illogical partner in local disaster plans. It occurs to ASGE, however, that if facilities are still required to include a process for cooperation and collaboration with local, tribal, regional, State and Federal emergency preparedness officials' efforts, how will CMS verify that such a process is in place if documentation requirements are eliminated? Would it be expected that the process be documented, such as in the facility's emergency plan?

Requirements for Annual Review of Emergency Program —

ASGE supports CMS' proposal to require facilities to review their emergency preparedness program every two years rather than annually as currently required but, encourages CMS to consider further lessening the requirements by requiring review only if there are material changes to the surgical environment, facility, if new surgical procedures are added or if existing surgical procedures are eliminated.

Requirements for Training —

CMS proposes to require that a facility provide training every two years after it conducts initial training for its emergency programs. If the emergency plan is significantly updated in-between the two-year period, ASGE believes it is reasonable to expect that an ASC would document that its staff has been adequately trained consistent with changes. ASGE supports this proposal. Currently, ASCs must

complete an initial orientation within 30 days of a new hire, followed by an annual competency evaluation. Initial orientation, which includes verification the individual can perform his/her job duties as well as training on emergency plans is an absolute, making CMS' requirements simply a minimal standard. Additional training and documentation is unnecessary. Revising the training requirements to every two years would eliminate some cost without compromising preparedness or safety.

Requirements for Testing —

ASGE agrees with CMS that conducting two testing exercises of the emergency plan per year is overly burdensome. CMS proposes to require that providers of outpatient services, including ASCs, conduct only one testing exercise per year rather than two testing exercises. Furthermore, CMS propose to require that these providers participate in either a community-based full-scale exercise (if available) or conduct an individual facility-based functional exercise every other year. In the opposite years, CMS proposes to allow these providers to conduct the testing exercise of their choice, which may include either a community-based full-scale exercise (if available), an individual, facility-based functional exercise, a drill, or a tabletop exercise or workshop that includes a group discussion led by a facilitator — ASGE supports this flexible approach. However, we remind CMS that the National Fire Protection Association requires testing of the fire alarm with receipt by the local fire department, and evacuation drills quarterly. This means a Medicare certified ASC must, at a minimum, conduct five to six drills a year. Because the emergency plan constitutes a minimal standard, reducing the number of testing exercises to one annually when other testing requirements are considered.

Conclusion

The ASGE appreciates the opportunity to comment on CMS' proposals. Should you have any questions, please contact Lakitia Mayo, ASGE Senior Director of Health Policy and Education, at lmayo@asge.org or (630) 570-5641.

Sincerely,

Steven A. Edmundowicz, MD, FASGE
President