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June 13, 2017

Ms. Seema Verma Administrator Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244-1850

RE: CMS-1677-P — Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Policy Changes and Fiscal Year 2018 Rates

Dear Administrator Verma:

The American Society for Gastrointestinal Endoscopy (ASGE), representing more than 15,000 members worldwide, welcomes the opportunity to comment on the Hospital Inpatient Prospective Payment System Proposed Rule as published in the *Federal Register* on May 3, 2017.

ASGE offers comments on the following areas of the proposed rule:

- Hospital Inpatient Quality Reporting (IQR) Program Measures
- Ambulatory Surgical Center (ASC)-based Eligible Professionals (EPs)
- Revisions to the Application and Re-Application Procedures for National Accrediting Organizations (AOs), Provider and Supplier Conditions, and Posting of Survey Reports and Acceptable Plans of Corrections (PoCs)
- Unintended Consequence from ICD-9 to ICD-10 Conversion Cap to Reductions in DRG Weights Needed

Hospital Inpatient Quality Reporting Program Measures

The ASGE was pleased to have had the opportunity to nominate members of our society to serve on the Clinical Committee convened in 2016 by Acumen. Acumen has been contracted to develop, with the input and direction of stakeholders, episode-based cost measures suitable for use in the Quality Payment Program. The result of that work was a draft list of episode groups and trigger codes on which ASGE provided comment. Subsequently, CMS issued a call for nominations for clinical subcommittees that are focusing on a set of procedural and acute inpatient medical episode groups, including episodes related to gastrointestinal (GI) disease management. ASGE is encouraged that all six of its nominees to the GI Clinical Subcommittee were accepted and that work has already begun to refine the episode triggers, as well as to identify what services should be included in episode costs. The GI subcommittee has 11 potential episode groups, and, based on a survey of subcommittee members, six of these episode groups were identified as most preferred, including GI hemorrhage (3rd) and disorders of the biliary tract (6th).

We understand the following clinical episode-based payment measures were previously finalized for the Hospital IQR Program for the Fiscal Year 2019 payment update: GI Hemorrhage and Cholecystectomy and Common Duct Exploration. The Acumen-led process, spearheaded and contracted by CMS, is an iterative, data-driven, evidence-based process that is multi-disciplinary, and driven by a tight timeline.

ASGE recommends that CMS reconsider the use of these two measures for the Hospital IQR Program for Fiscal Years 2019 and 2020 and instead allow the Acumen-led process with physician input to proceed and to utilize episodes of care that have been refined and validated.

Given the current engagement of physicians and specialty societies with Acumen, we question the wisdom of seemingly parallel, yet separate episode group development processes especially given that hospitals lack the clinician expertise and knowledge of how coding best fits into episodes of care.

There are several immediate concerns with the grouping rules as currently provided. For example, for Upper GI Hemorrhage, some ICD-9 trigger codes are listed that may be less relevant, including "Disorders of Function of stomach" (536). Such diagnoses are not directly related to Upper GI Bleeding and should not be listed as triggers. Grouping rules for post-discharge inpatient medical services (medical hospitalizations) by Base DRG include 811 with ICD-9 code 2800 "Iron Deficiency Anemia secondary to chronic blood loss," which seems inaccurate. Furthermore, as part of the Acumen process, we have recommended non-variceal upper GI bleeding as a subgroup, rather than any upper GI hemorrhage or GI hemorrhage in general. Variceal and non-variceal upper gastrointestinal bleeding are very different in terms of diagnosis due to underlying conditions.

We also wish to point out that quality of care parameters for these care episodes are lacking, imposing undue pressure on cost saving without providing for sufficient accountability for care quality is premature and dangerous. The Acumen-led process seeks to associate quality parameters with the episodes; however, this process is evolving.

For these reasons, we recommend that CMS not proceed with using the GI Hemorrhage and Cholecystectomy and Common Duct Exploration for the Hospital IQR Program at this time.

Ambulatory Surgical Center-based Eligible Professionals

The 21st Century Cures Act prohibits in 2017 and 2018 an Electronic Health Record (EHR) meaningful use payment penalty to an eligible professionals (EPs) who furnishes "substantially all" of his/her covered professional services in an Ambulatory Surgery Center (ASC).

Because the statute refers to an EP who furnishes "substantially all" of his or her covered professional services in an ASC, CMS must identify the minimum percentage of an EP's covered professional services that must be furnished in an ASC setting for the EP to be considered as furnishing "substantially all" of his or her covered professional services in an ASC.

As early as March 2010, in response to CMS' proposed rule for the EHR Incentive Programs, ASGE commented that because an ASC is not an entity eligible to receive an EHR incentive payment, procedures performed in the ASC should be exempt when determining whether an EP has met the 50 percent or more patient encounter threshold for determining whether the EP is a meaningful EHR user. To be a meaningful user an EP must have 50 percent or more of his/her patient encounters during the EHR reporting period at a location(s) equipped with certified EHR technology.

CMS is proposing two alternative definitions of an ASC-based EP: 1) an EP who furnishes 75 percent or more of his/her covered professional services in an ASC; or 2) an EP who furnishes 90 percent or more of his/her covered professional services in an ASC.

We believe CMS should neither arbitrarily define "substantially all" as 75 percent, which would conform with the definition of a hospital-based Merit-Based Incentive Payment System eligible clinician under the Quality Payment Program, nor as 90 percent, which would be the same as CMS' definition of a hospital-

based EP for the EHR Incentive Programs. Instead, CMS should define an ASC-based EP in a manner such that effectively responds to the problem which the legislation was meant to address, which is that physicians who deliver care in the ASC are having difficulty meeting the current 50 percent or more threshold.

In the proposed rule, CMS states that under a "substantially all" threshold of 75 percent, about 400 EPs would meet the ASC-based definition using a two-year look back of codes used in the HIPAA standard transaction. Under a threshold of 90 percent, the number of EPs meeting the ASC-based definition would fall to roughly 175-200.

EPs who provide the majority of their professional time and services in the ASC are disadvantaged under the current EHR Incentive Programs and a vast number of EPs will not be helped under the law should CMS finalize an encounter threshold of 90 or 75 percent.

The adequacy of arbitrarily setting the threshold at 75 or 90 percent would be better understood if CMS also shared how many EPs during 2015 and 2016 calendar years billed between 50 and 75 percent of their covered professional services in place of service (POS) 24. Specifically, having this information broken down in five percentage point increments would be informative and allow for more thoughtful public comment.

Revisions to the Application and Re-Application Procedures for National Accrediting Organizations, Provider and Supplier Conditions, and Posting of Survey Reports and Acceptable Plans of Corrections

A majority of ASGE members provide care in ASCs, and, according to CMS, about 27 percent are accredited by accrediting organizations, while the other 73 percent are surveyed by a state survey agency for compliance with the Medicare Conditions for Coverage (CfC) and Conditions of Participation (CoP).

ASGE believes that when meaningful information is provided to consumers in a clear, understandable, and consistent manner, consumer decision making can be improved. However, we reject the sharing of accrediting organization (AO) survey reports and Plans of Corrections (PoCs) that will be impossible for the lay person or patient to translate into meaningful information. In fact, we have serious concerns with the unintended consequences of CMS' proposal. Therefore, ASGE strongly urges CMS to withdraw its proposal to require AOs with CMS-approved accreditation programs to post final accreditation survey reports and acceptable PoCs on public-facing website designated by the AO.

In the proposed rule, CMS points to increasing concern of AO disparity rates based on the AO deficiency findings compared to serious, condition-level deficiencies found by the State Survey Agencies. The proposed rule highlights that in FY 2015, the disparity rates increased by 1 percent to 39 percent for hospitals and decreased by 6 percent to 69 percent for psychiatric hospitals, from FY 2014. CMS contends high disparity rates raise "serious concerns" regarding the AOs' ability to appropriately identify and cite health and safety deficiencies during the survey process.

We suggest the AO disparity rates do not necessarily reflect the ability of AOs to appropriately identify and cite health and safety deficiencies but rather it more likely reflects variability in the states' assessments. In California, for example, hospital- and ASC-based endoscopy suites have experienced substantial variability, and, in some cases, a flagrant misunderstanding by the state surveyors of CMS requirements; a misunderstanding arising out of failure to distinguish endoscopy procedure rooms from sterile operating rooms. Furthermore, CMS has assumed, without data to support, that state surveyor citations are accurate and the variability is due to AO surveyor inability to identify health and safety deficiencies during the survey process.

When there is a disagreement between a state surveyor's interpretation of findings and the surveyed organization, there is no mechanism for appeal unless the findings result in loss of accreditation. Publishing information that is inconsistently gathered and cannot be appealed will do nothing to further transparency to assist health care consumers in their decision-making. Instead, it is potentially damaging to institutions adversely affected with no due process.

We suggest that if CMS' priority is to address high disparity rates, the agency should focus on consistent application of Interpretative Guidelines rather than public disclosure of AO survey reports and PoCs. CMS needs to study where the variability is greatest and provide state and AO surveyor guidance through more specific guidance and surveyor training.

ASGE's additional concerns with CMS' proposal are as follows:

- The accreditation process is currently considered a confidential activity. To make it public changes the dynamic of the inspection.
- Peer review, a legally protected activity, is reviewed and discussed during the survey process. And, despite the confidential nature of peer review, associated comments may be included in the report.
- During the survey process, frank discussions are held related to current malpractice cases and the survey report may refer to those discussions.
- The health status of staff is reviewed and may be included in the report and should not be the subject of public disclosure.
- States are often slow to properly evaluate the quality of their surveyors and state employment regulations may make it difficult to remove a poor quality surveyor, thereby contributing to the disparity rates cited by CMS.

Lastly, AOs have a large pool of surveyors who are evaluated by the organization after every survey without fear of reprisal. Those surveyors are also typically not sent to the same organization. This is not true of state surveyors due to limited budgets and candidate pools. Surveyor evaluations by surveyed organizations should be a requirement and without the fear of reprisal by surveyors. Furthermore, if the survey report and the PoC are to be made public, the surveyor evaluations should also be made public and posted.

ASGE welcomes the opportunity to engage with CMS to evaluate how best to translate information about the safety and quality of facilities in which care is rendered and in a manner such that it is meaningful and understandable to the consumer.

<u>Unintended Consequence from ICD-9 to ICD-10 Conversion – Cap to Reductions in DRG Weights</u> Needed

For 2018, CMS is proposing some significant swings in DRG weighting for several DRG groups. Given there has been no change in the clinical practice, technology or resource use, ASGE cannot find any clinical explanation for the change in these DRG weights. The data appears to support that these significant changes are a result of the conversion from ICD-9 to ICD-10. Multiple GI-related DRGs are impacted with the highest being DRG 332- Rectal Resection w MCC with a 23.6% reduction in relative weights.

The proposed reductions to DRG weights resulting from the transition from ICD-9 to ICD-10 are counter to the goal of ICD-10 to accurately replicate ICD-9 assignments and to specifically avoid unintended payment redistribution. The proposed reduction in the relative weight for these reductions is not consistent with the goal.

While we appreciate IPPS is a prospective payment system and future claims data should result in an appropriate upward adjustment in 2019 for these DRGs negatively impacted by the transition from ICD-9 to ICD-10, hospitals should not be penalized so substantially while these proposed 2018 IPPS DRG rates will be in effect. To promote stability to hospitals and the healthcare system, for 2018, ASGE recommends CMS implement a cap of 10% as the maximum reduction to any DRG impacted by the transition from ICD-9 to ICD-10 experiences.

FY 2018 PROPOSED RULE, TABLE 5.—LIST OF MEDICARE SEVERITY DIAGNOSIS-RELATED GROUPS (MS-DRGS), RELATIVE WEIGHTING FACTORS, GEOMETRIC MEAN LENGTH OF STAY, AND ARITHMETIC MEAN LENGTH OF STAY; ALSO WITH NUMBER OF TRANSFER-ADJUSTED CASES		CHANGES IN RELATIVE WEIGHTS
MS- DRG	MS-DRG Title	FY 2018 Proposed Weights compared to FY 2017 Weights (% Change)
332	RECTAL RESECTION W MCC	-23.6%
333	RECTAL RESECTION W CC	-21.1%
334	RECTAL RESECTION W/O CC/MCC	-19.0%
334	RECIAL RESECTION W/O CC/MCC	-17.070
327	STOMACH, ESOPHAGEAL & DUODENAL PROC W CC	-18.2%
327	STOMACH, ESOPHAGEAL & DUODENAL PROC W CC	-18.2%

Conclusion

The ASGE appreciates CMS' consideration of its comments. For additional information, please contact Lakitia Mayo, ASGE's Senior Director, Health Policy, Quality, and Practice Operations, at lmayo@asge.org or 630-570-5641.

Sincerely,

Karen L. Woods, MD, FASGE

President

American Society for Gastrointestinal Endoscopy