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August 31, 2012

Ms. Marilyn B. Tavenner

Acting Administrator

Centers for Medicare & Medicaid Services

Department of Health and Human Services

Attention: CMS-1589-P

Room 445-G, Hubert H. Humphrey Building

200 Independence Avenue, SW

Washington, DC 20201

Re: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations

Dear Ms. Tavenner:

On behalf of the more than 78,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the calendar year (CY) 2013 proposed rule: *Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations*¹ published in the *Federal Register* on July 30, 2012. Our comments on issues of interest to the ACS will first address the outpatient prospective payment system (OPPS) proposals, followed by the ambulatory surgical center (ASC) proposals. We also provide comments on the Hospital Outpatient Quality Reporting (OQR) Program updates and the ASC Quality Reporting (ASCQR) Program.

A. UPDATES AFFECTING OPPS PAYMENTS

Calculation of Single Procedure APC Criteria-Based Costs

Endovascular Revascularization of the Lower Extremity (APC 0083, 0229, and 0319)

The ACS agrees with comments submitted by the Society for Vascular Surgery (SVS) regarding the endovascular revascularization codes in Ambulatory

¹ *Federal Register*. 77(146): 45061. July 30, 2012.



Payment Classifications (APCs) 0083, 0229, and 0319. We believe that the Centers for Medicare & Medicaid Services (CMS) has erred in assigning Current Procedural Terminology (CPT) codes 37223, 37234 and 37235 to APC 0083 (Coronary or Non-Coronary Angioplasty and Percutaneous Valvuloplasty) and recommends that CMS reassign these three codes to APC 0229 (Transcatheter Placement of Intravascular Shunt and Stents) for the same reason that 37221 (revascularization, endovascular, open or percutaneous, iliac artery, unilateral, initial vessel; with transluminal stent placement(s), includes angioplasty within the same vessel, when performed) was reassigned, namely that APC 0229 more accurately reflects the cost and clinical features of CPT codes 37223, 37234, and 37235.

Similar to 37221, these three codes (37223, 37234, and 37235) describe services that involve not only angioplasty, but also *stent placement*. Moreover, these three codes, represent procedures that were previously billed using separate component codes, which were individually paid under more than one APC. Although we appreciate the challenge CMS is facing in applying alternative rate setting approaches to translate the resources previously consumed by the various combinations of peripheral intervention codes to new bundled codes, the current APC class to which CMS has assigned these codes, APC 0083, does not reflect the resources used in the placement of a cardiovascular stent.

In contrast, APC 0229 currently contains 12 codes (including 37221), eight of which are stent procedure codes. The cost of the stent device typically constitutes a significant portion of the cost of the entire procedure. Also, codes 37223, 37234, and 37235 are most clinically similar to the services described in CPT code 37205 (peripheral stenting) and its add-on procedure code 37206 (peripheral stenting, each additional vessel). Both are currently assigned to APC 0229. In addition, we believe this reassignment would not violate the 2 times rule. Therefore, we urge CMS to consider our request to reassign CPT codes 37223, 37234 and 37235 to APC 0229.

Changes to Packaged Services

The proposed rule includes CMS' responses to recommendations on packaging policies made by the Hospital Outpatient Payment (HOP) Panel at its February 2012 meeting. The HOP Panel recommended that the status indicator for healthcare procedure coding system (HCPCS) code 19290 (Preoperative placement of needle localization wire, breast) be changed from "N" to "Q1," which would allow for either separate payment when this procedure is

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performed alone or for packaged payment when this procedure is performed with an associated surgical procedure.

We support CMS' acceptance of this HOP Panel recommendation. We agree with the HOP Panel that code 19290 may be appropriately billed, under certain circumstances, without a primary procedure furnished on the same day. Although placement of needle localization wires is almost always done on the same day as the surgical procedure itself for patient comfort and to avoid infection and bleeding, there could be situations where placement of a needle localization wire could occur specifically for subsequent surgery.

C. PROCEDURES THAT WOULD BE PAID ONLY AS INPATIENT PROCEDURES

CMS identifies procedures that are typically performed only in the inpatient setting due to the nature of the procedure, the underlying physical condition of the patient, or the need for at least 24 hours of postoperative recovery time or monitoring before the patient can be safely discharged. These procedures comprise the "inpatient list." CMS uses the following criteria to identify procedures that are being performed a significant amount of time on an outpatient basis, and appropriately may be removed from the inpatient list:

1. Most outpatient departments are equipped to provide the services to the Medicare population.
2. The simplest procedure described by the code may be performed in most outpatient departments.
3. The procedure is related to codes that CMS has already removed from the inpatient list.
4. A determination is made that the procedure is being performed in numerous hospitals on an outpatient basis.
5. A determination is made that the procedure can be appropriately and safely performed in an ASC, and is on the list of approved ASC procedures or has been proposed by CMS for addition to the ASC list.

The laparoscopic partial colectomy codes in the table below (44206, 44207, 44208, and 44213) are currently assigned status indicator "T," meaning that they can be paid under either the Inpatient Prospective Payment System or the OPPI. We urge CMS to add the codes below to the inpatient list because they should only be performed in an inpatient, not an outpatient setting. Most outpatient departments are not equipped to provide these services, and none of these

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laparoscopic colectomy procedures are simple. In addition, the place of service data, obtained from the American Medical Association/Specialty Society Relative Value Scale Update Committee database, show that these procedures are overwhelmingly performed in the inpatient setting. Finally, these procedures cannot be performed in an ASC. Therefore, in order to ensure that care is delivered in the appropriate setting for optimal outcomes and patient safety, we strongly recommend that CMS add codes 44206, 44207, 44208, and 44213 to the inpatient list.

Code	Descriptor	Place of Service
44206 (T)	Laparoscopy, surgical; colectomy, partial, with end colostomy and closure of distal segment (Hartmann type procedure)	Inpatient Hospital: 95.60% Outpatient Hospital: 4.12% Physician Office: 0.09% ASC: 0.09% ER: 0.09%
44207 (T)	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis)	Inpatient Hospital: 94.73% Outpatient Hospital: 4.98% Physician Office: 0.19% ASC: 0.10% ER: 0.00%
44208 (T)	Laparoscopy, surgical; colectomy, partial, with anastomosis, with coloproctostomy (low pelvic anastomosis) with colostomy	Inpatient Hospital 95.40% Outpatient Hospital 4.20% Physician Office 0.20% ASC 0.20%
44213 (T)	Laparoscopy, surgical, mobilization (take-down) of splenic flexure performed in conjunction with partial colectomy (List separately in addition to primary procedure)	Inpatient Hospital: 94.89% Outpatient Hospital: 4.91% Physician Office: 0.09% ASC: 0.08% ER: 0.03%

D. POLICIES FOR THE SUPERVISION OF OUTPATIENT SERVICES IN HOSPITALS AND CAHS

Conditions for Payment for Therapy Services in Hospitals and CAHS

In response to concerns expressed by ACS and other stakeholders, CMS clarifies that it does not intend to establish different requirements for critical access hospitals (CAHs) and OPSS hospitals for the same services, in this case, physical therapy, speech-language pathology, and occupational therapy, when furnished under a certified therapy plan of care. CMS states that if the services are billed by the CAH or OPSS hospital as therapy services, the supervision requirements do not apply, thereby applying the same requirements to both CAHs and OPSS hospitals by not applying the supervision requirements at all.

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We support CMS' clarification regarding not establishing different supervision requirements for CAHs and OPSS hospitals for the same services. As we stated in previous comment letters, the ACS shares concerns of the rural facilities and CAHs regarding the increasing shortage of general surgeons across the country. However, we support CMS' interpretation of the regulation to apply the supervision requirements based on the service type and applicable safety requirements rather than on the site of service.

Extension of Nonenforcement Instruction for the Supervision of Outpatient Therapeutic Services in CAHs and Small Rural Hospitals

CMS proposes to provide another year extension of its nonenforcement policy for direct supervision of outpatient therapeutic services in CAHs and small rural hospitals through 2013. CMS expects this will be the final year of this nonenforcement policy. While we understand the need to allow CAHs and small rural hospitals to become compliant with the recent clarifications regarding supervision requirements, as previously stated, the ACS believes supervision requirements must be applied uniformly across all care settings for reasons of patient safety.

E. OUTPATIENT STATUS: SOLICITATION OF PUBLIC COMMENTS

Although CMS is not making policy proposals in this proposed rule, the agency seeks comments on the impact on Medicare beneficiaries of the possible trend among hospitals to treat beneficiaries as outpatients receiving observation services for longer periods of time in lieu of admitting them. According to the rule, such beneficiaries face the likelihood that their aggregate copayments for all outpatient services received will exceed the inpatient hospital deductible, in addition to the fact that Part B does not usually cover self-administered drugs furnished in the outpatient setting. Moreover, the time spent as a hospital outpatient does not count toward the three-day qualifying inpatient stay for Part A coverage of post-acute care in a skilled nursing facility.

We agree with CMS that there should be more certainty regarding a patient's admission status. We also believe more transparency at the point of care regarding admission status is needed for both patients and physicians. From the patient perspective, we agree that it would be disadvantageous for beneficiaries to pay higher outpatient copayments, pay more for self-administered drugs, and not have time spent in a hospital outpatient count toward the three-day qualifying inpatient stay for Part A coverage of post-acute care in a skilled nursing facility. We urge CMS to require that patients be clearly notified if they

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are in observation status including a straightforward description of what that means compared to inpatient admission. We also encourage CMS to consider incorporating time spent in observation status into the three-day qualifying stay, per the SNF requirement.

From a surgeon's perspective, there can be lack of clarity regarding the decision between inpatient admission and outpatient status for a surgical patient kept overnight following a surgical procedure. According to the CMS Medicare Benefit Policy Manual,² an inpatient is a person who has been admitted to hospital bed occupancy for purposes of receiving inpatient hospital services. Generally, a patient is considered an inpatient if formally admitted as inpatient with the expectation that he or she will remain at least overnight and occupy a bed even if it later develops that the patient can be discharged or transferred to another hospital and not actually use a hospital bed overnight. The Manual also states that the physician or other practitioner responsible for a patient's care at the hospital is also responsible for deciding whether the patient should be admitted as an inpatient. Although physicians should use a 24-hour period as a benchmark, i.e., they should order admission for patients who are expected to need hospital care for 24 hours or more, and treat other patients on an outpatient basis, the Medicare Benefit Policy Manual acknowledges that the decision to admit is a complex medical decision affected by many factors. CMS and physician societies should further collaborate on bringing clarity to protocols for determining observations status.

In addition, some hospitals reverse a physician's order to "admit" a patient to outpatient status several days after the patient has been in a facility under the guise of a hospital's own assessment of severity of illness. This occurs not only for medical patients, but also for patients admitted for many outpatient surgical services. Patients who require extended care in a hospital, either overnight or for several days for valid patient-care issues, will receive physician care in the same way independent of the "status" that the hospital has assigned, either before or after the fact. This tendency of hospitals to assign or change the status of patients without providing a clear explanation to the physician compounds the site of service confusion noted above.

In summary, we believe that ultimately the physician, using his or her clinical judgment, should be allowed to make the decision whether to admit a patient, as

²Centers for Medicare & Medicaid Services, *Medicare Benefit Policy Manual*, chapter 1, available at

<http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c01.pdf>.

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stated in the Medicare Benefit Policy Manual. We urge CMS to increase the transparency of patient status for both patients and physicians and implement an appropriate payment policy for both outpatient and short inpatient hospital stays. We plan to develop a specific proposal on defining the distinction between inpatient admission and observation status and how the current instructions regarding inpatient admission can be improved. We will communicate with CMS regarding this proposal in the near future.

F. UPDATES TO THE AMBULATORY SURGICAL CENTER PAYMENT SYSTEM

We appreciate the work of CMS to review and update the ASC payment system; however, we are generally concerned about the growing difference in payment rates for the same services under the ASC and hospital outpatient department prospective payment systems. This divergence inappropriately creates an incentive to provide care in hospital outpatient departments when such care can safely be provided in either ASCs or hospital outpatient departments. This incentive is financially driven, rather than based on reasons related to patient care, safety, or choice. These incentives also result in patients losing the option of potential efficiencies from care delivered in ASCs. We urge CMS to work to equalize payment rates in ASCs and hospital outpatient departments. We provide additional comments related to specific ASC-related proposals below.

Update to the List of ASC Covered Surgical Procedures and Covered Ancillary Services

CMS proposes to add 16 procedures to the ASC list of covered surgical procedures after determining that they would not be found to pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in ASCs.

We agree with the addition of the 12 endovascular revascularization procedures. Because these procedures can be performed in the office setting, we agree that they would not pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in an ASC.

We have concerns regarding two codes proposed for addition to the ASC covered surgical procedures list: 0299T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and dressing care; initial wound) and 0300T (Extracorporeal shock wave for integumentary wound healing, high energy, including topical application and



dressing care). We do not believe these procedures should be added to the list for ASC payment.

Codes 0299T and 0300T are Category III CPT codes defined as temporary codes for emerging technology, services, and procedures. The purpose of Category III codes is for physicians, insurers, researchers, and policy experts to identify emerging technology and procedures for clinical efficacy, utilization, and outcomes. Category III designation does not imply clinical efficacy, safety, or applicability to clinical practice. Although we agree with CMS that these codes will not pose a significant safety risk to Medicare beneficiaries and would not be expected to require an overnight stay if performed in an ASC, we believe that current data on the clinical efficacy and outcomes of these procedures is limited. Therefore, we do not support CMS' proposal to include 0299T and 0300T on the ASC list of covered surgical procedures. We believe that additional information on the clinical efficacy and outcomes should be collected before these services are covered in the ASC setting.

Calculation of the Proposed ASC Conversion Factor and the Proposed ASC Payment Rates

CMS proposes to continue its policy of updating the ASC conversion factor by a measure of inflation in the Consumer Price Index for Urban Consumers (CPI-U). Recognizing the limits of the CPI-U, CMS has requested comments on the feasibility of collecting information to establish an ASC-specific market basket.

There is broad agreement that the CPI-U measures inflation in a basket of consumer goods that is atypical of what ASCs purchase and is therefore flawed for the purposes of the ASC payment system. In addition, we do not believe an ASC market basket will provide a more accurate reflection of ASC cost growth given the heterogeneity of ASCs. Development of an ASC-specific market basket would also not lend to better alignment between the ASC and hospital outpatient department payment systems. These parallel payment systems should be updated using the same inflation factor.

Giving the flaws in the CPI-U for the purposes of the ASC payment system and the lack of available ASC cost data, we encourage CMS to use the hospital market basket as the measure of ASC cost increases. The hospital market basket is an available proxy for ASC costs and is superior to the use of the CPI-U. The hospital market basket reflects producer price inputs, measures health care delivery-related costs, and is used by hospital outpatient departments. The CPI-U, on the other hand, measures costs of goods purchased by typical

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consumers, which reflects the types and weights of categories typical of an American household, rather than an outpatient surgical provider. In addition, aligning the ASC and hospital outpatient department update and productivity factors will help minimize the silos around settings of care. As such, we urge CMS to use the hospital market basket to update the ASC conversion factor because the hospital market basket more closely reflects the cost structure of ASCs compared to the CPI-U.

G. HOSPITAL OUTPATIENT QUALITY REPORTING PROGRAM UPDATES AND ASC QUALITY REPORTING PROGRAM

Safe Surgery Checklist Use (OP-25: 2014 Hospital OQR Measure; ASC-6: 2015 ASCQR Measure)

We support the use of a safe surgery checklist, but we stress the importance of hospitals' and surgeons' ability to adapt the checklist to fit different institutions and situations. Examples of common adaptations include omitting the operating teams' introductions and description of roles if all individuals already know each other or have been working together throughout the day and adding reminders about venous thromboembolism prophylaxis and beta blockers. As noted in previous ACS comments, we urge CMS to eventually move beyond measuring only the utilization of safe surgery checklists as a structural measure and begin to analyze whether the safe surgery checklists are being used appropriately and thoroughly. The value of checklists lies not simply in whether they are used, but rather in how they are used. For example, the use of a safe surgery checklist should not result in a rote task that does not improve the delivery of care for which checklists are intended. In summary, we are supportive of the inclusion of this structural measure in both the outpatient and ACS setting, but we believe that the way that safe surgery checklists are utilized is an important aspect of the value that they bring to surgery.

Outpatient Volume for Selected Outpatient Surgical Procedures (OP-26: 2014 OQR Measure; ASC-7: 2015 ASCQR Measure)

The ACS is committed to advancing the quality and safety of the surgical patient through quality measurement efforts designed from the perspective of the patients and the needs of the beneficiaries. We believe that this is best achieved through the use of meaningful outcomes measures. While we appreciate that CMS has had to take an incremental approach to move in the direction of outcomes measures and that there was need to begin collecting data via process measures, we believe that the crude measurement tool of monitoring

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surgical volume is moving the CMS quality reporting and value-based purchasing programs in a direction away from more refined and meaningful outcomes measures.

We believe that quality measurement science is evolving rapidly because of the value that organizations like the ACS are able to bring through audited and reliably validated clinical, risk-adjusted outcomes data available through registries like the National Surgical Quality Improvement Program (ACS NSQIP). With the continued proliferation of meaningful data and the creation of quality measures based on useful data, we believe the requirement of simply reporting a facility's volume without comment on outcomes or patient-reported assessments of care holds the potential to present misleading information to patients and even to Medicare about the care that providers deliver.

We appreciate the opportunity to provide comments regarding this proposed rule. The ACS looks forward to continuing dialogue with CMS on these important issues. If you have any questions about our comments, please contact Bob Jasak, Deputy Director for Regulatory and Quality Affairs in our Division of Advocacy and Health Policy. He can be reached at bjasak@facs.org or at (202) 672-1508.

Sincerely,

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