September 6, 2016

Mr. Andy Slavitt, Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1633-FC
P.O. Box 8013
Baltimore, MD 21244-1850

Re: Medicare Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Short Inpatient Hospital Stays; Transition for Certain Medicare Dependent, Small Rural Hospitals under the Hospital Inpatient Prospective Payment System; Proposed Rule

Dear Mr. Slavitt:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the calendar year (CY) 2017 proposed rule: Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Procurement Organization Reporting and Communication; Transplant Outcome Measures and Documentation Requirements; Electronic Health Record (EHR) Incentive Programs; Payment to Certain Off-Campus Outpatient Departments of a Provider; Hospital Value-Based Purchasing (VBP) Program published in the Federal Register on July 14, 2016.

The ACS is a scientific and educational association of surgeons, founded in 1913, to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Our comments below are presented in the order in which they appear in the proposed rule.

OPPS General Provisions

Proposed OPPS APC-Specific Policies

CMS is proposing to make changes to APC clinical families to achieve better clinical and resource homogeneity.
**Imaging Services**

In CY 2016, most complete vascular ultrasound services, CPT codes 93930, 93970, 93978 and 93925, were grossly underpaid relative to their geometric mean cost. In addition, CMS had assigned limited vascular ultrasound services and complete vascular ultrasound services to the same APC, namely, Level 2 Ultrasound Services for CY 2016, even though the resources used to perform the services and the activities required to perform the procedures are different.

We support the Society for Vascular Surgery and commend CMS for recognizing these differences in their CY 2017 proposed APC assignments such that complete vascular ultrasound procedures, such as CPT code 93970 with a geometric mean cost of $217, are proposed to be reimbursed at $218 for CY 2017. However, limited vascular ultrasound procedures, with geometric mean costs ranging from $126 - $153, will be reimbursed at a lower proposed level of $117 for CY 2017. We continue to have concerns with some limited vascular ultrasound procedures being reimbursed below their geometric mean in CY 2017. We ask CMS to continue to evaluate and refine these payment categories as they are implemented over the next few years.

**HOSPITAL OUTPATIENT QUALITY REPORTING (OQR) PROGRAM UPDATES**

The Hospital OQR Program is a pay-for-reporting program for outpatient hospital services. The program requires hospital outpatient facilities to meet CMS administrative, data collection, submission, validation, and reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet these requirements.

**New Measures Beginning with the 2020 Payment Determination**

*OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687)*

CMS proposes to add the following quality measure to the Hospital OQR Program starting with the 2020 payment year: *OP-36: Hospital Visits after Hospital Outpatient Surgery (NQF #2687).* This is a new, claims-based measure that addresses hospital visits after same-day surgery in the outpatient department (OPD). The specific outcomes measured are inpatient admissions directly after the surgery and unplanned hospital visits defined as an emergency department (ED) visit, observation stay, or unplanned hospital admission within 7 days of the surgery. This proposed measure was endorsed by the NQF in September 2015; the MAP supported its inclusion in the OQR but noted that the NQF-endorsement occurred prior to the start of the
sociodemographic status (SDS) trial period and should be re-examined during measure maintenance to determine whether SDS adjustments are needed.

The ACS agrees with the MAP that this measure should be re-evaluated for the applicability of SDS risk adjustment during measure maintenance prior to inclusion in the OQR. The ACS supports SDS risk adjustment, when appropriate, for measures used in national quality measurement programs and think in this case it is necessary. Without the use of appropriate risk adjustment for this measure, clinical outcomes could be less reliable due to SDS confounding variables. Patients with low SDS may have fewer options for managing their care and therefore may require additional hospital visits compared to patients with more resources.


CMS is proposing to add five new measures to the OQR program which are based on the newly developed Outpatient and Ambulatory Surgery Consumer Assessment of Healthcare Providers and Systems (OAS CAHPS) survey. The measures proposed for OQR include three OAS CAHPS composite survey-based measures (OP-37a-c), each consist of six or more questions, and two global survey-based measures (OP-37d-e), which are comprised of a single question:

1. **OP-37a**: OAS CAHPS – About Facilities and Staff
2. **OP-37b**: OAS CAHPS – Communication About Procedure
3. **OP-37c**: OAS CAHPS – Preparation for Discharge and Recovery
4. **OP-37d**: OAS CAHPS – Overall Rating of Facility
5. **OP-37e**: OAS CAHPS – Recommendation of Facility

The ACS has several concerns regarding the lack of information on the development and testing of these measures. To start, there is very little publically available information detailing the survey development, including on the Agency for Healthcare Research and Quality (AHRQ) website. It is also unclear whether the measure was developed with multi-stakeholder input. After some searching we were able to find a slide deck discussing pilot studies with focus groups, a mode study, and a field test (18 HOPDs, 18 ASCs). However, many critical components (i.e. the sampling strategy, the number of patients studied, patient population, scoring, field testing details, psychometrics) remain unknown.

Additionally, the OAS CAHPS includes two questions addressing pain management. Given the nature of surgical pain, the timing of the survey, the
items included in the pain composite, coupled with lack of transparency of testing data, these measures are not ready for implementation on a national level. We commend CMS for initiating this important measurement of surgical care to improve quality. However, the ACS strongly believes that this process must be more transparent, and that these measures should be NQF-endorsed—especially if CMS is going to implement them nationally for public reporting and for reimbursement purposes.

In addition to the absence of NQF-endorsement, ACS is concerned about overlap between OAS CAHPS and the CAHPS Surgical Care Survey (S-CAHPS), which has been NQF-endorsed (NQF #1741) since 2012. Because the OAS CAHPS was not harmonized with the S-CAHPS and many items on the OAS CAHPS overlap with the S-CAHPS, there will be an unnecessary survey burden on the surgical patient. Also, ACS believes that it is imperative to use a provider-specific measure that provides surgeons with actionable information to improve the patient-centeredness of care. S-CAHPS questions were designed specifically to evaluate the surgeon and survey results are directly attributable to the surgeon to drive quality improvement.

In summary, the ACS believes the OAS CAHPS measures should be fully tested and specified before implementation as part of a national program, including consideration for harmonization with the S-CAHPS. The development and testing data should be publically available, and the measures should be NQF-endorsed. The ACS supports using the S-CAHPS, which was developed based on feedback from surgical patients and is NQF-endorsed, for the measurement of patient experience before, during, and after surgery.

Future Measure Topics

Measuring Across the Surgical Care Continuum

The ACS supports alignment between physician- and facility-level measurement. For physician-level measurement, we have worked to define a set of metrics to span across the various phases of surgical care that align with a patient’s clinical flow, including: preoperative preparation, perioperative final prep, intraoperative care, postoperative care and post discharge. Each of these phases involves key processes, critical care coordination to primary care physicians and anesthesia, as well as the technical side of surgical care that relates to safety, outcomes and avoidable harms. The phases of surgical care measurement framework broadly applies to surgical care for cross-cutting comparisons and was constructed to allow for more detailed, procedure-specific metrics to be added when necessary. We have spoken to various
stakeholders who have shared their support for this framework. The ACS has been working on a measurement framework that follows the phases of surgical care for the Merit-based Incentive Payment System (MIPS) program. We welcome collaboration with CMS to align this framework across facility-level measurement programs.

Possible Future eCQM: Safe Use of Opioids-Concurrent Prescribing

CMS is in early development of a new electronic clinical quality measure (eCQM) for the Hospital Inpatient Quality Reporting (IQR) and OQR programs that would capture the proportion of patients 18 years of age and older who have an active prescription for an opioid and have an additional opioid or benzodiazepine prescribed to them during the qualifying care encounter. CMS is seeking public comment on a future eCQM concept for OQR that addresses concerns associated with overlapping or concurrent prescribing of opioids or opioids and benzodiazepines.

The ACS understands and agrees that there is a strong need for a measure associated with overlapping or concurrent prescribing of opioids. Currently, state requirements for Prescription Drug Monitoring Programs (PDMPs) differ, which causes confusion for providers because the requirements are inconsistent, including which drugs are actually monitored and what information is collected.1,2 Therefore, before CMS creates and implements a measure to address the concurrent prescribing of opioids, the ACS believes there needs to be a drug monitoring infrastructure that exchanges data with EHRs, dispensing pharmacies, and other relevant sources and compiles the data into one mechanism. Until then, we believe any measure implementation would be premature, potentially confusing, and burdensome for facilities, and result in an inappropriate application of accountability.

Public Display of Quality Measures

Beginning with the CY 2018 payment determination, CMS proposes to publicly display data on the Hospital Compare Web site as soon as possible after measure data have been submitted to CMS. In addition, the Agency proposes that hospitals will generally have approximately 30 days to preview their data. The ACS has concerns with the 30 day preview period and seeks

further clarification on the preview and appeals process. Specifically, we request more information on the length of time it takes to appeal a misclassification and how CMS plans to address misclassification. Is 30 days enough time for a facility to identify an error, submit an appeal, and have CMS correct the misclassification before it is posted on Hospital Compare? If not, is the erroneous information posted on Hospital Compare, or will it be withheld until corrected? The ACS requests clarification on how the appeals process would take place within the 30 day window.

**ASC QUALITY REPORTING (ASCQR) REPORTING PROGRAM**

The ASCQR Program is a pay-for-reporting program that requires ambulatory surgical centers (ASCs) to meet administrative, data collection, and reporting requirements, or receive a reduction of 2.0 percentage points in their annual payment update for failure to meet the requirements.

**New Measures Beginning with the 2020 Payment Determination**


Similar to the OQR proposed measure, CMS is proposing to add five new measures to the ASC program which are based on the recently developed OAS CAHPS survey. The measures proposed for ASC include three OAS CAHPS composite survey-based measures (ASC-15-a-c), each consist of six or more questions, and two global survey-based measures (ASC-15d-e), which are comprised of a single question:

- ASC-15a: OAS CAHPS – About Facilities and Staff
- ASC-15b: OAS CAHPS – Communication About Procedure
- ASC-15c: OAS CAHPS – Preparation for Discharge and Recovery
- ASC-15d: OAS CAHPS – Overall Rating of Facility
- ASC-15e: OAS CAHPS – Recommendation of Facility

Similar to our comments regarding the inclusion of the OAS CAHPS measures in the OQR program, the ACS has several concerns regarding the lack of information on the development and testing of these measures. To start, there is very little publically available information detailing the survey development, including on the AHRQ website. It is also unclear whether the measure was developed with multi-stakeholder input. After some searching we were able to find a slide deck discussing pilot studies with focus groups, a mode study, and a field test (18 HOPDs, 18 ASCs). However, many critical components (i.e. the
sampling strategy, the number of patients studied, patient population, scoring, field testing details, psychometrics) remain unknown.

Additionally, the OAS CAHPS includes two questions addressing pain management. Given the nature of surgical pain, the timing of the survey, the items included in the pain composite, coupled with lack of transparency of testing data, these measures are not ready for implementation on a national level. We commend CMS for initiating this important measurement of surgical care to improve quality. However, the ACS strongly believes that this process must be more transparent, and that these measures should be NQF-endorsed—especially if CMS is going to implement them nationally for public reporting and for reimbursement purposes.

In addition to the absence of NQF-endorsement, ACS is concerned about overlap between OAS CAHPS and the CAHPS Surgical Care Survey (S-CAHPS), which has been NQF-endorsed (NQF #1741) since 2012. Because the OAS CAHPS was not harmonized with the S-CAHPS and many items on the OAS CAHPS overlap with the S-CAHPS there will be an unnecessary survey burden on the surgical patient. Also, ACS believes that it is imperative to use a provider-specific measure that provides surgeons with actionable information to improve the patient-centeredness of care. S-CAHPS questions were designed specifically to evaluate the surgeon and survey results are directly attributable to the surgeon to drive quality improvement.

In summary, the ACS believes the OAS CAHPS measures should be fully tested and specified before implementation as part of a national program, including consideration for harmonization with the S-CAHPS. The development and testing data should be publically available, and the measures should be NQF-endorsed. The ACS supports using the S-CAHPS, which was developed based on feedback from surgical patients and is NQF-endorsed, for the measurement of patient experience before, during, and after surgery.

**Public Display of Quality Measures**

Similar to the OQR program, beginning with the CY 2018 payment determination, CMS proposes to publically display data on the Hospital Compare Web site, or other CMS Web site, as soon as possible after measure data have been submitted to CMS. CMS proposes that hospitals will generally have approximately 30 days to preview their data. The ACS continues to have concerns with the 30 day preview period and seeks further clarification on the preview and appeals process. Specifically, we request more information
on the length of time it takes to appeal a misclassification and how CMS plans to address a misclassification within the 30 day window.

**TRANSPLANT OUTCOMES: RESTORING THE TOLERANCE RANGE FOR PATIENT AND GRAFT SURVIVAL**

**Proposed Revisions to Performance Thresholds**

CMS is proposing to modify the tolerance range for clinical outcomes set forth in the current transplant center (TC) certification regulations and to modify certain elements of the Organ Procurement Organization (OPO) certification regulations to be more consistent with Organ Procurement and Transplantation Network (OPTN) and Scientific Registry of Transplant Recipients (SRTR) standards. Along with the American Society of Transplant Surgeons (ASTS), we support increasing the tolerance range for all the reasons set forth in the preamble to the Proposed Rule. Furthermore, we believe that the issue of transplant center recipient outcomes requirements should be considered in the context of patient outcomes in the absence of transplantation. As Schold, et al, noted in their recent article, “Association Between Kidney Transplant Center Performance and the Survival Benefit of Transplantation, Versus Dialysis”, kidney transplant outcomes even in the “lowest performing” TCs are far superior to ESRD patient outcomes when a patient continues on dialysis. The greatest overall improvements in patient survival and cost reduction could be achieved by increasing access to transplantation.

The Proposed Rule would increase the Observed to Expected (O/E) threshold to 1.85 for all organ types which would essentially restore the absolute performance requirements in effect when the TC certification regulations were adopted in 2007. However, we do not believe that the 2007 threshold is necessarily the appropriate reference point. We believe there is now a pressing need for a more flexible tolerance standard than that established in 2007. As noted in the preamble to the Proposed Rule, the organ discard rate spiked when the regulations went into effect and have not returned to pre-2007 rates, even though other factors contributing to the spike (including modifications of the OPTN allocation methodology) have been addressed. This suggests that the O/E threshold adopted in 2007 has always been too stringent. It follows that it would be appropriate to establish the new tolerance threshold at a point that

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gives TCs more leeway than the 2007 standard allows, and we believe that a
tolerance threshold of at least 2.0 strikes a suitable balance.

**Changes to the Medicare and Medicaid Electronic Health Record**
**EHR** **Incentive Programs**

CMS seeks to reconcile potential differences in electronic reporting requirements for the EHR Incentive Program established in the Medicare and Medicaid Programs; Electronic Health Record Incentive Program—Stage 3 and Modifications to Meaningful Use in 2015 Through 2017 final rule from the proposals for the Advancing Care Information (ACI) program in the Medicare Program; Merit-Based Incentive Payment System (MIPS) and Alternative Payment Model (APM) Incentive under the Physician Fee Schedule, and Criteria for Physician-Focused Payment Models proposed rule. In order to help CMS align the program requirements with the Meaningful Use (MU) ASC and outpatient facilities program, below we share relevant comments we submitted on the ACI section of the MIPS proposed rule.

**General Comments on Meaningful Use/Additional Requests for Comments**

ACS believes the objective of MU should be the attainment of widespread health data interoperability—not only between meaningful users of certified EHR technology (CEHRT), but more broadly throughout the wider clinical data ecosystem, reaching all patients and providers across the country through a variety of technologies.

The long term goal of MU and the ACI category in MIPS should be the seamless exchange of data in patient care for quality improvement. The ACS strongly believes that CMS should set the groundwork for a system that promotes activities that demonstrate a provider’s use of digital clinical data to inform patient care and their commitment to bi-directional data interoperability. A good example of this is the CEHRT bonus introduced as a way to earn bonus points for the MIPS quality category. The CEHRT bonus encourages the use of qualified registries or QCDRs to obtain data from a CEHRT and use automated electronic systems to perform aggregation, calculation, filter, and report measures. Unfortunately, the MU proposals in this rule and those proposed in the MIPS ACI category maintain a strong focus on the reporting of numerator and denominator data through the EHR, which will unlikely improve patient care.

The ACS is working diligently to provide our members with the tools needed to succeed in an interoperable, digital health IT environment. As a testament to
our commitment to interoperability, we have invested in an ongoing project to recreate all of our registries on one data platform with a common data warehouse strategy. This will produce the ability to consume, map, and populate data from an EHR and other data sources (including financial data) into our registries or other applications. This will be a great benefit to patients and remove a large burden from physicians who are aiming to demonstrate achievement.

Below is a patient-centric data map that illustrates bi-directional data streaming across multiple sources including data from the lab, a skilled nursing facility, home health, a national cancer database, clinical data registry, EHR, public health registry, and so on.

**PATIENT-CENTRIC DATA MAP**

In response to the natural market incentive for health IT innovations, there are many other recent developments which support transitions of care use cases. For example, Apple has unveiled the CareKit apps for the iPhone that helps patients manage their medical conditions, share metrics and anonymized data, and communicate with their physicians.\(^4\) ONC has made it a priority to promote technology that allows providers to track patient-generated health data using patient portals and EHRs so they can learn how patients are doing between visits, view medication adherence, and monitor their health over

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time. Now that this degree of interoperability exists, the digital clinical information that is derived could be used to communicate with advanced surgical analytics.

Ultimately, the ACS envisions registry-based patient dashboards with metrics tracking the five phases of surgical care. We believe this would be meaningful and important to both surgeons and surgical patients. Defining measures along this continuum is an effective way to derive a single report for a single patient while encompassing impactful measures and patient-focused care. The ACS believes it is necessary to incorporate digital information in a surgeon’s workflow that is meaningful and actionable.

**EHR Reporting Period**

CMS proposes to change the EHR reporting periods in 2016 for returning participants from the full CY 2016 to any continuous 90-day period within CY 2016. This would mean that all eligible providers (EPs), eligible hospitals (EHs), and Critical Access Hospitals (CAHs) may attest to MU for a reporting period of any continuous 90-day period from January 1, 2016 through December 31, 2016. The ACS supports this proposal and thanks CMS for understanding the difficulty providers are facing while trying to incorporate updates from the 2015 EHR Incentive Program final rule and prepare for MACRA. However, the start of the final 90-day reporting period in calendar year 2016 is rapidly-approaching, and to ensure that EPs, EHs, and CAHs are able to take advantage of the flexibility associated with the shortened reporting period, the policy must be finalized as expeditiously as possible. The sooner CMS can provide certainty to providers and facilities about a 90-day reporting period, the more it will help participants successfully attest in 2016.

**Significant Hardship Exception for New Participants Transitioning to MIPS in 2017**

Due to the overlap between the new MIPS program performance period starting in 2017 and the previously adopted 90-day reporting for new users of MU in 2017 to avoid the 2018 penalty, CMS proposes to allow certain EPs to apply for a significant hardship exception from the 2018 payment adjustment. CMS is limiting this proposal to EPs who have not successfully demonstrated MU in a prior year and intend to attest to MU for an EHR reporting period in 2017 to avoid the 2018 payment adjustment and intend to transition to MIPS in

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2017. The ACS supports this proposal and thanks CMS for recognizing the overlap between MU and ACI could be very difficult for new participants to navigate. The competing demands of participating in both MIPS and MU in one reporting period is challenging for many providers and this hardship exception will assist new participants to focus on preparing for and successfully participating in MIPS.

**PROPOSED ADDITIONAL HOSPITAL VALUE-BASED PURCHASING (VBP) PROGRAM POLICIES**

Proposed Removal of the HCAHPS Pain Management Dimension from the Hospital VBP Program Beginning with the FY 2018 Program Year

One of the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) Survey dimensions that CMS has adopted for the Hospital Value-Based Purchasing (VBP) Program is Pain Management. Three survey questions that are used to construct this dimension are as follows:

1. During this hospital stay, did you need medicine for pain?
2. During this hospital stay, how often was your pain well controlled?
3. During this hospital stay, how often did the hospital staff do everything they could to help you with your pain?

CMS is developing alternative questions for the Pain Management dimension in the HCAHPS Survey due to its potential impact on providers prescribing habits. While CMS awaits the results of ongoing research and the modifications to the Pain Management dimension questions, CMS proposes to remove the Pain Management dimension of the HCAHPS Survey in the Patient- and Caregiver-Centered Experience of Care/Care Coordination domain beginning with the FY 2018 program year.

The ACS supports the removal of the Pain Management dimension from the HCAHPS survey and the VBP scoring. **The ACS does not believe pain scores should be used as a patient’s experience of care measure, especially in HCAHPS surveys.** We believe linking quality and pain, which is subjective, has led to an increase in opioid medication prescribing when acetaminophen and nonsteroidal anti-inflammatory drugs (NSAIDs) fail. Physicians are faced with the dilemma of having to treat patients who often have the unreasonable expectation that they are to be pain free. The requirement to treat pain, along with a number of other factors, has led to a major increase in overuse, misuse, abuse, and diversion of these highly addictive medications.
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 Jill Sage, Quality Affairs Manager, in our Division of Advocacy and Health Policy. She can be reached at jsage@facs.org or at (202) 672-1507.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director