June 13, 2017

Seema Verma, Administrator
Centers for Medicare & Medicaid Services
Attention: CMS-1677-P
P.O. Box 8011
Baltimore, MD 21244-1850

RE: 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; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices

Dear Ms. Verma:

On behalf of the over 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to submit comments to the proposed rule: 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; Quality Reporting Requirements for Specific Providers; Medicare and Medicaid Electronic Health Record (EHR) Incentive Program Requirements for Eligible Hospitals, Critical Access Hospitals, and Eligible Professionals; Provider-Based Status of Indian Health Service and Tribal Facilities and Organizations; Costs Reporting and Provider Requirements; Agreement Termination Notices (Proposed Rule) published in the Federal Register on April 28, 2017.

The ACS was founded in 1913 to improve the quality of care for the surgical patient by setting high standards for surgical education and practice. Since a large proportion of surgical care is provided in the inpatient hospital setting, we have a strong interest in the Centers for Medicare & Medicaid Services’ (CMS) Inpatient Prospective Payment System (IPPS) and related hospital quality improvement efforts and can offer insight to CMS’ proposed modifications to these programs.
QUALITY METHODOLOGY: ACCOUNTING FOR SOCIAL RISK FACTORS

CMS solicits feedback on the issue of accounting for social risk factors across its quality reporting and value-based purchasing programs. CMS highlights the Assistant Secretary for Planning and Evaluation (ASPE) report to Congress in December 2016 analyzing the effects of social risk factors on quality and resource use measures in the Hospital Readmissions Reduction Program (HRRP) and other CMS programs,1 as well as a second report issued in January 2017 by the National Academy of Sciences, Engineering and Medicine which addresses accounting for social risk factors in Medicare payment.2 CMS also notes that the National Quality Forum (NQF) will likely issue recommendations after the conclusion of the two-year trial period during which social risk factors are included in the risk adjustment methodology of certain measures. CMS continues to note its concern that adjusting for social risk factors may mask disparities or minimize incentives to improve the outcomes of disadvantaged patients.

The ACS applauds CMS on its responsiveness to recent findings examining the adjustment of social risk factors, including the concern regarding the potential impact the lack of social risk factor adjustment may have on hospitals with low socioeconomic status (SES) patient populations. ACS has long advocated for further study in this area. ACS believes that we have just begun to understand the impact of SES factors on health, and there is a critical need for even further study in this area. We must specifically identify which factors have an impact on vulnerable populations. For example, CMS solicits a response on whether measures should be adjusted for dual eligible status in Medicare. We would argue that this adjustment may be too blunt, and we may be misinforming the public and incorrectly measuring hospitals—we need more information regarding which specific factors result in higher spending and/or poorer health care outcomes. In fact, research has demonstrated that racial and economic disparities fail to explain the poor health outcomes across the U.S., and when comparing our health system to other industrialized nations, U.S falls short in our investment in social services to support the broader social determinants of health.3 ACS strongly encourages CMS to look at how social determinants of health

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affect Medicare beneficiaries and how SES can be incorporated into measurement. ACS also recommends the Secretary encourage CMS to work with other Department of Health and Human Services (HHS) agencies to prioritize research efforts to examine the broader social determinants of health.

In general, ACS supports SES risk adjustment for measures used in accountability applications (e.g., public reporting and pay-for-performance) on a case-by-case basis. It is well established that without the use of appropriate risk adjustment for certain measures, clinical outcomes will be less reliable due to SES confounding variables. Closely evaluating the appropriate factors for SES confounding variables will lead to a deeper understanding of the relationship between these variables and clinical outcomes. Until there are further findings on the appropriate application of risk adjustment, including further study on social support services, the ACS supports the following methodology, when appropriate:

- For purposes of accountability (e.g., public reporting, pay-for-performance), SES factors should be included in risk adjustment of the performance score unless there are conceptual reasons or empirical evidence indicating that adjustment is unnecessary or inappropriate; and
- For purposes of identifying and reducing disparities, performance measures should be stratified on the basis of relevant SES factors when used in analysis by individual providers, policymakers, researchers, and the public working to reduce disparities.⁴

By providing both the risk adjusted and the stratified results, CMS can avoid unfairly penalizing hospitals with a more vulnerable patient population, while also allowing hospitals to drill down on relevant SES factors to improve the outcomes of disadvantaged patients.

OTHER DECISIONS AND CHANGES TO THE IPPS FOR OPERATING COSTS AND INDIRECT MEDICAL EDUCATION COSTS

Hospital Readmissions Reduction Program

Hospitals whose Medicare risk-adjusted readmission rates are greater than the national average rates will have their IPPS payments reduced under the HRRP. The list of conditions for 2017 is: acute myocardial infarction, heart failure, heart failure with reduced or preserved ejection fraction, heart valve replacement, stroke, and hip or knee replacement.

pneumonia, total hip arthroplasty, total knee arthroplasty, chronic obstructive pulmonary disease and coronary artery bypass surgery.

As discussed above, CMS is seeking feedback on the application of SES factors across its quality reporting and value-based purchasing programs. ACS would like to highlight a recent example of the need for further research in the SES factors. In a recent study, Hong et al. concluded that vulnerable hospitals, including hospitals having a higher proportion of Medicaid patients (HMH), and safety net hospitals (SNH), or hospital which are both, have higher readmissions (all payer) after major cancer surgery, despite the application of the current risk adjustment factors used in the HRRP. This study included the following covariates: HRRP factors: age, sex, Charlson Index, type and year of procedure; other covariates: race and ethnicity, ZIP code-level median income, primary insurance and emergency status of index operation, and hospital factors: number of hospital beds, residency training program, Commission of Cancer-approved program, and the procedural volume to compare vulnerable to non-vulnerable hospitals. Similar to past studies,5,6,7 Hong et al found that SNHs were more likely to be penalized under the value-based purchasing and HRRP than non-vulnerable hospitals. The primary contributors to high readmissions at the HMHs were patient-related factors, and the primary drivers for readmission at SNH were hospital-related factors. We encourage CMS to carefully consider the impact of the HRRP program on disadvantaged hospitals and patients. Based on the literature, it appears that the risk adjustment methodology is not sophisticated enough to account for factors that may be putting these hospitals at an even greater disadvantage by reducing their payments. As discussed above, ACS encourages CMS to look at how social determinants of health affect Medicare beneficiaries and how SES can be incorporated into measurement. ACS also recommends the Secretary encourage CMS to work with other HHS agencies to prioritize research efforts to examine the broader social determinants of health.

CMS also explains that the 21st Century Cures Act outlines considerations the Secretary may take into account with respect to the risk adjustment

methodology. The Secretary may consider the removal as a readmission of an admission that is classified within one or more of the following: transplant; end-stage renal disease; burns, trauma; psychosis; or substance abuse. ACS supports the removal of these cases from the readmission measures, as the complex comorbidities or sequelae of these diseases and conditions will make risk adjustment difficult without further study while potentially penalizing hospitals unfairly. The 21st Century Cures Act also requires the Secretary to stratify hospitals into peer groups for purposes of assessing HRRP payment adjustments beginning in fiscal year (FY) 2019. As discussed in the section above titled Quality Methodology: Accounting for Social Risk Factors, ACS supports the concept of stratification of hospitals with similar peer groups for purposes of identifying and reducing disparities.

Hospital Value-Based Purchasing (VBP) Program

Under the Hospital Value-Based Purchasing (VBP) Program, CMS calculates a VBP incentive payment percentage for a hospital based on its Total Performance Score for a specified performance period. The total amount available for value-based incentive payments for a fiscal year is equal to the total amount of the payment reductions for all participating hospitals for such fiscal year, as established by the Secretary. Beginning FY 2017, the available funding pool for value-based incentive payments is 2.0 percent. For each payment year, CMS specifies through rulemaking a VBP measure set, and a baseline and performance period for each measure. Measures available for inclusion in the VBP Program are those that are included in the Inpatient Quality Reporting (IQR) Program and have been included on the Hospital Compare website for at least one year prior to the start of the relevant VBP Program performance period.

Patient Safety and Adverse Events Composite

Beginning with FY 2019 payment, CMS proposes to remove the Patient Safety Indicator (PSI) 90 composite patient safety measure from the VBP Program. The reason for the removal of PSI 90 is that an ICD-10 version of the current PSI 90 measure is not being developed and ICD-10 AHRQ QI software will not be available in time to calculate performance scores for the FY 2019. In its place, CMS proposes to adopt a modified version of this measure, the Patient Safety and Adverse Event Composite, measure beginning with FY 2023 payment. The revised measure is a composite of 10 AHRQ PSIs:

- PSI 03 Pressure Ulcer Rate
- PSI 06 Iatrogenic Pneumothorax Rate
- PSI 08 In-Hospital Fall with Hip Fracture Rate
- PSI 09 Perioperative Hemorrhage or Hematoma Rate
- PSI 10 Postoperative Acute Kidney Injury Rate
• PSI 11 Postoperative Respiratory Failure Rate
• PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate
• PSI 13 Postoperative Sepsis Rate
• PSI 14 Postoperative Wound Dehiscence Rate
• PSI 15 Unrecognized Abdominopelvic Accidental Puncture/Laceration Rate

ACS appreciates the updates to the PSI-15 which were refined so that the indicator focuses on the most serious intraoperative injuries due to an accidental puncture or laceration. The updated measure better captures clinical outcomes for which a surgeon has some control. However, ACS continues to have concerns with the PSI 12 measure.

**AHRQ PSI-12 (Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate)**

The ACS appreciates the two changes made to PSI-12: removal of isolated calf vein DVTs from the numerator specification, and removal of patients with any diagnosis of acute brain and/or spinal injury from the denominator specification. The ACS also appreciates that under the modified weighting methodology that accounts for patient harm, the weight of PSI-12 within the composite measure drops from 34 percent to 18 percent. However, we continue to have concerns about the vulnerability of PSI-12 to surveillance bias. Studies have shown that hospitals with increasing numbers of structural quality characteristics (i.e. larger hospitals with more accreditations, more complex patients, and engagement in quality initiatives that typically suggest high quality care) have better venous thromboembolism (VTE) prophylaxis, but actually have higher VTE rates, or an increase in PSI-12 event rates. In other words, hospitals with more sophisticated tools and technology used to track VTE show higher rates of VTE and are being penalized for doing a better job at detection. To this end, performance on PSI-12 may reflect differences in VTE imaging use rather than differences in quality of care, and the inclusion of PSI-12 could unfairly penalize hospitals with increased vigilance in VTE detection. For example, trauma surgeons test nearly all of their patients for VTE. Therefore, they find and treat more cases yet are being penalized under

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this measure—this is an unintended consequence which could incentivize surgeons to screen less, rather than more, when surgeons should be incentivized to screen all high risk patients. For these reasons, we strongly recommend that CMS and AHRQ consider replacing this measure with a process measure that focuses on the screening and testing of DVT in patients at high risk for DVT—not the identification of DVT cases.

**Surgical Site Infection: Colon and Abdominal Hysterectomy**

The VBP Program previously finalized the Surgical Site Infection (SSI): Colon and Abdominal Hysterectomy measure as part of the Safety domain. This SSI measure is an ACS National Surgical Quality Improvement Program (NSQIP) measure which was harmonized with The Centers for Disease Control and Prevention (CDC) National Healthcare Safety Network (NHSN) SSI measure. In theory, measures harmonized for use in the public domain seem ideal for making cross-cutting comparisons across providers, however, harmonizing quality measures across registries alone does not ensure accurate benchmarking due to inconsistencies in program implementation and data interpretation, including the lack of standardized data definitions, lack of standardized risk adjustment/data analytics, inconsistency of data ascertainment methods, and lack of common normalization methods.

A recent paper by Mila et al, studied the implementation of this measure across hospitals. After harmonization, results showed that NSQIP participants had higher SSI rates compared to the CDC NHSN registry participants. Through further study, it was determined that this discrepancy was not because NSQIP participants had poorer surgical outcomes, instead, the discrepancy was due to the lack of rigor used to track patients and collect data for use in the NHSN registry when compared to NSQIP.12 “Colon SSI rates from the NHSN and the ACS NSQIP cannot be used interchangeably to evaluate hospital performance and determine reimbursement. Hospitals should not use the ACS NSQIP colon SSI rates for the NHSN reports because that would likely result in the hospital being an outlier for performance. It is imperative to reconcile SSI monitoring, develop consistent definitions, and establish one reliable method. The current state hinders hospital improvement efforts by adding unnecessary confusion to the already complex arena of perioperative improvement.”13 (Mila et al 2015, 51) To this end, ACS strongly asserts the recommendations of this study calling for the need to reconcile SSI monitoring, develop consistent

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definitions, and establish one reliable method. ACS welcomes collaboration with CMS and the CDC to resolve these issues.

Risk Adjustment for Social Risk Factors
For further comment on the inclusion of SES risk adjustment factors, please refer to the above section, Quality Methodology: Accounting for Social Risk Factors.

Hospital-Acquired Condition Reduction Program
Section 3008 of the Affordable Care Act required CMS to implement a hospital-acquired conditions (HAC) payment adjustment beginning in FY 2015. This requires CMS to reduce hospital payments by one percent for hospitals that rank among the lowest performing 25 percent with regard to HACs specified under this program. The payment adjustment will result in the applicable hospitals receiving 99 percent of the payment that would otherwise apply.

CMS requests stakeholder feedback on risk-adjusting the CDC NHSN measures for disability or medical complexity. Based on the findings in the ASPE report, ACS agrees that disability and medical complexity should be accounted for in the HAC Domain 2 outcome measures.

For further comment on the inclusion of SES risk adjustment factors, please refer to the above section, Quality Methodology: Accounting for Social Risk Factors.

CRITICAL ACCESS HOSPITALS

Notice Regarding Changes to Instructions for the Review of the CAH 96-Hour Certification Requirement
Section 1814(a)(8) of the Social Security Act required CMS to enact a provision under which physicians must certify that patients may reasonably be expected to be discharged or transferred to another hospital within 96 hours after admission to a critical access hospital (CAH). For inpatient services rendered in CAHs to be payable under Medicare Part A, CMS requires that all physician certification requirements be completed and documented in the medical record no later than one day before the date on which the claim is submitted for payment.

To minimize the burden of physician certification requirements on CAHs, CMS proposes to make the 96-hour certification requirement a low priority for medical record reviews occurring on or after October 1, 2017. Under this proposal, CMS
will not require Quality Improvement Organizations (QIOs), Medicare Administrative Contractors (MACs), Supplemental Medical Review Contractors (SMRCs), and Recovery Audit Contractors (RACs) to conduct medical record reviews of the 96-hour certification requirement in the absence of evidence of potential fraud, waste, or abuse.

The 96-hour certification requirement has imposed significant burdens on the surgical community, whose members extend essential surgical care to Medicare’s rural beneficiaries. The ACS remains concerned that strict compliance with the 96-hour certification requirement may violate the Emergency Medical Treatment and Labor Act (EMTALA) as well as a CAH’s Medicare Conditions of Participation, and we therefore continue to advocate for definitive legislative resolution of this issue. However, the ACS strongly supports CMS’ proposal to make the 96-hour certification requirement a low priority for medical record reviews. This proposal indicates that CMS is aware of the problems inherent in the 96-hour certification requirement, and we urge the Agency to provide a remedy for these problems in future rulemaking that goes beyond instructing audit entities to forgo reviews of medical records for this requirement unless there are specific concerns related to program integrity.

QUALITY DATA REPORTING REQUIREMENTS FOR SPECIFIC PROVIDERS AND SUPPLIERS

Hospital Inpatient Quality Reporting Program

Under the Hospital IQR program, hospitals must meet the requirements for reporting specific quality information to receive the full market basket update for that year, and hospitals that do not will receive a two percentage point reduction in that year’s inpatient hospital payment update factor.

Refinements to Existing Measures for the FY 2020 Payment Determination and Subsequent Years

HCAHPS Pain Management Domains

In response to the opioid epidemic, CMS and other stakeholders have raised concerns that the existing HCAHPS pain questions have the unintended consequence of incentivizing hospital staff to prescribe more opioids to receive higher scores. In response, CMS has proposed a new set of questions and renamed the pain domain “Communication About Pain” instead of the current “Pain Management.” The proposed questions focus on effective communication with patients about pain management issues, discussion of treatment options and patient understanding of pain management options.
ACS agrees that it is critical to immediately address any possible unintended consequence of overprescribing opioids and agrees that the proposed questions in the pain domain could address the overprescribing concerns. However, we strongly recommend that CMS also consider the measurement of an overall analgesia strategy as part of an enhanced recovery pathway (ERP). Surgical science has advanced around enhanced recovery protocols, commonly referred to as ERAS. The ERP analgesia strategy process begins in the preoperative period, continues through the intraoperative period, and moves well into the postoperative recovery. The multidisciplinary nature of successful enhanced anesthesia recovery strategies is well-documented and widely-supported throughout the medical literature. The American Society for Enhanced Recovery (ASER) and Perioperative Quality Initiative (POQI) recently published a Joint Consensus Statement on Optimal Analgesia for colorectal surgery. POQI asserts that the ERP approach to treating pain should be multifaceted and the goal should be to deliver “optimal analgesia”, defined as a technique that optimizes patient comfort and facilitates functional recovery with the fewest medication side effects.\textsuperscript{14,15} While the need for patient reported experiences in the management and communication of pain will continue to be critical, the ERP analgesia approach through ERAS is a more comprehensive patient-centered approach to optimize patient pain relief.

Possible New Quality Measures and Measure Topics for Future years

Quality of Informed Consent Documents for Hospital-performed Elective Procedures

In the proposed rule, CMS describes a list of measures it is considering for future addition to the IQR Program and invites comments. ACS commends CMS on the goal of the Quality of Informed Consent Documents for Hospital-performed Elective Procedures measure and notes that obtaining informed consent is sometimes viewed as a document signing event, in particular when the signature form is either highly generic or simple fill-in-the-blank forms that either lack specific details or are at a level beyond the understanding of the average patient and their family. However, we do not support the current version of the Informed Consent measure. Upon careful review of the


measure under consideration, we and have the following recommendations and comments:

1. **Inclusion of a Patient-Specific Decision-Support Tool**
   
   To facilitate the informed consent discussion and to enable patient-centered decision making for surgery, we strongly encourage the use of a patient-specific decision-support tool as part of the informed consent process. ACS developed the ACS NSQIP Surgical Risk Calculator which is one example of a patient-specific decision-support tool based on reliable multi-institutional clinical data, which can be used to estimate the patient’s risk for a specific operation (the calculator includes data on most operations). For more information on the ACS Risk Calculator, please visit [http://riskcalculator.facs.org/RiskCalculator/](http://riskcalculator.facs.org/RiskCalculator/).

2. **Alignment with the ACS Statement on Principles on the Topic of Informed Consent**
   
   Because the surgeon is responsible for obtaining informed consent, we strongly encourage CMS to consider these principles in the development of the informed consent document quality measure to ensure that the measure aligns with the ACS principles:

   Informed consent is more than a legal requirement. It is a standard of ethical surgical practice that enhances the surgeon/patient relationship and that may improve the patient's care and the treatment outcome. Surgeons must fully inform every patient about his or her illness and the proposed treatment. The information must be presented fairly, clearly, accurately, and compassionately. The surgeon should listen carefully to understand the patient's feelings and wishes and should answer all questions as accurately as possible. The informed consent discussion conducted by the surgeon should include:

   1. The nature of the illness and the natural consequences of no treatment.
   2. The nature of the proposed operation, including the estimated risks of mortality and morbidity.
   3. The more common known complications, which should be described and discussed. The patient should understand the risks as well as the benefits of the proposed operation. The discussion should include a description of what to expect during the hospitalization and post hospital convalescence.
   4. Alternative forms of treatment, including nonoperative techniques.
5. A discussion of the different types of qualified medical providers who will participate in their operation and their respective roles.

The surgeon should not exaggerate the potential benefits of the proposed operation nor make promises or guarantees. For minors and incompetent adults, parents or legal guardians must participate in the informed consent discussion and provide the signature for elective operations. Any adequately informed, mentally competent adult patient can refuse any treatment including operation. When mentally incompetent patients or the parents (guardians) of minors refuse treatments jeopardizing the patient's best interest, the surgeon can request legal assistance. When patients agree to an operation conditionally or make demands that are unacceptable to the surgeon, the surgeon may elect to withdraw from the case.

3. Measure at the Level of the Surgeon, Not the Hospital
Informed consent is a critical aspect of a surgeon’s relationship with the patient and the surgeon is responsible for obtaining informed consent. Yet, the proposed methodology measures informed consent at level of the hospital. ACS believes that this is a missed opportunity to enhance the surgeon/patient relationship and promote patient-centered decision-making. The responsibility for informed consent should be measured by the party responsible for working with the patient to ensure comprehensive informed consent.

4. The Measure Should Capture the Informed Consent Discussion, Not Simply the Timing of Signing the Legal Document
The Draft Measure Methodology Report for this measure acknowledges that clinicians and patients have come to view the informed consent document as a transaction necessary for obtaining a signature of consent, rather than for information sharing or prompts for discussion. The report notes that these quality gaps are “conflicting with the ethical and legal principles of informed consent. They do not support patient autonomy and often undermine the decisional process of informed consent.”

To address these gaps in quality, ACS believes that the measure should be inclusive of the discussion of informed consent—when the decision to operate is being made—not simply when the legal documents are signed. The proposed measure assumes that there is only one workflow for obtaining informed consent, when there are multiple workflows and scenarios. For example, the informed consent discussion often takes place during moments after the decision to operate, when the procedure is scheduled. Or, the surgeon and patient may have had the informed consent discussion a week prior to the
procedure, and the office staff may have had the informed consent signature on file in the office. In conclusion, the proposed measure assumes incorrect timing for informed consent and does not recognize the diverse ways informed consent occurs.

5. Streamline the Informed Consent with Process Interoperability
ACS strongly encourages CMS to realize the need for the creation of standards for informed consent to streamline the flow of data with electronic health records (EHRs) and other data sources. Much of the work outlined in the methodology document includes the abstraction of data by trained abstractors which introduces the possibility of bias and creates additional burden on the provider or the hospital/office staff. Instead of a specific tool for informed consent, ACS sees many opportunities to streamline this process with digital workflows using an application program interface (APIs) in an open platform around EHRs. For example, this process could be included in the toolkits identified as part of the Office of the National Coordinator for Health Information Technology (ONC) Patient Engagement Playbook and joined with the ACS NSQIP Surgical Risk Calculator as a tool for a more comprehensive and complete informed consent discussion. For more information on the Patient Engagement Playbook visit https://www.healthit.gov/playbook/pe/.

6. Simplify the Number of Elements in the Measure
The final taxonomy of the measure has far too many elements. We strongly encourage further testing with patients in an effort to capture only the elements that are most important and understandable to the patient. We also note that if standards for informed consent document process are created to allow for interoperable exchange of data, as suggested above, this will be less of an issue.

7. Require Random Sampling to Reduce Bias
The proposed measure methodology allows for hospitals to select which procedures they would like to report. Allowing hospitals to select the sample to be reported will introduce bias, thereby compromising the validity and reliability of the measure.

Additional Comments on Current IQR Measures

PSI 12 Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate
As discussed in the VBP section, ACS has comments regarding the AHRQ PSI-12 (Perioperative Pulmonary Embolism (PE) or Deep Vein Thrombosis (DVT) Rate and Surgical Site Infection: Colon and Abdominal Hysterectomy Comments which is component of the Patient Safety and Adverse Events
Composite (modified PSI 90). Please refer to pages 5-8 for comments to those measures.

**Cholecystectomy/Common Duct Exploration Episode Payment**

In the FY 2017 IPPS proposed rule, CMS proposed to include the clinical episode-based payment measure Cholecystectomy and Common Duct Exploration (Chole/CDE) in the Hospital IQR Program for FY 2019 and subsequent years. ACS did not support the inclusion of this measure, but CMS finalized the proposal in the FY 2017 IPPS final rule. Accurate cost measurement is an important component of measuring value in hospital care. The measure specifications for the Chole/CDE measure include a three-step process for grouping related pre-admission and post-discharge services to the episode: (1) organize the claims into clinically-meaningful services; (2) exclude services constituting insignificant payment; and (3) perform clinical review to determining grouping rules. For the reasons described below, we support the CMS Episode Grouper for Medicare (EGM) model instead of the episode grouper methodology set forth in the Chole/CDE measure. As CMS moves forward with episode-based cost measure development for both hospitals and physicians, we urge the Agency to consider the advantages of the CMS EGM over other methodologies.

First, the Chole/CDE measure does not take into account the heterogeneity of patients’ confounding risk factors in the pre-admission and post-discharge periods. The Chole/CDE episode window begins three days prior to the episode trigger, which is the relevant inpatient admission. The CMS EGM, however, typically begins 30 days prior to the inpatient admission and does a "look back" for several years to establish the patient factors important to risk adjusting cost. A patient’s history prior to the three-day pre-admission window is crucial to determining the cost of the episode. For example, the cost associated with a patient admitted for cholecystectomy with diabetes, versus a patient admitted for cholecystectomy with heart disease, versus a patient admitted for cholecystectomy with no comorbidities are all different. Whereas the Chole/CDE methodology attempts to account for severity of illness by using MS-DRGs to divide episodes into clinical types and subtypes, the CMS EGM model uses CPT codes and provides for a more granular assessment in handling patient heterogeneity. This added granularity is critical in a model that prevents physicians from being driven to cherry-pick patients in order to avoid costs.

The Chole/CDR measure specifications also do not explain how this episode would interact with other episodes. The specifications do state that the

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16 Acumen. Measure Specifications: Hospital Clinical Episode-Based Payment Measures; April 2016.
Chole/CDR episode would allow inpatient admissions occurring in the 30 days following the trigger inpatient stay to start a new episode if the readmission meets an episode’s trigger specifications. The CMS EGM model, however, goes further and is able to function with multiple nested episodes running concurrently, while only attributing service costs once. The current proposal will end up confounding matters and double counting costs or avoiding costs that should be included for true costs and optimal risk adjustment.

In addition, the Chole/CDR measure does not take all claims into account when determining relevant services to be grouped into the episode. The measure specifications list six categories of services to be assessed for the post-discharge period (Inpatient; Outpatient ER; Major Outpatient Non-ER; Physician/Supplier Part B and Remaining Outpatient; Durable Medical Equipment, Prosthetics, Orthotics, and Supplies; and Home Health), but only services from physician/supplier Part B claims were assessed for the pre-admission period. This model also excludes services considered “insignificant,” because they represent 0.5 percent of the total physician/supplier Part B payments for the pre-admission period and 1.0 percent of total payments for the post-discharge period. Finally, the Chole/CDR model is intended to only include services whose likelihood of occurrence and/or intensity are under the control of the hospital where the trigger inpatient stay occurred and are related to the named episode.

The CMS EGM model, on the other hand, considers all Medicare Part A and Part B claims, for the entire episode. This EGM is patient-centric and requires the grouping of claims in a manner that considers all costs that make up a patient profile and are associated with a patient’s episode of care and attributing a portion of those costs based upon a provider’s role in the specific episode for the specific patient. The EGM episodes consist of both Medicare Part A and Part B charges and could incorporate Part D spending if data become available. In such an “all cost” environment, clinicians would not wish to have all costs attributed to them that are not directly related to care provided for the specific condition being treated. To account for this, each episode would require an episode-specific set of definitions for the series of relevant services plausibly associated with the given treatment or condition. Furthermore, using the CMS EGM would allow CMS the ability to use a single cost system to transition physicians from Fee-For-Service (FFS) to Alternative Payment Models (APMs) without creating burdens on practices to understand and manage different CMS cost allocation methodologies. We urge CMS to use the same methodology for all episode-based cost measures, both for hospital and physician measurement, and we see numerous advantages to utilizing the CMS EGM model.
**Risk Adjustment for Social Risk Factors**

For further comment on the inclusion of SES risk adjustment factors, please refer to the above section, Quality Methodology: Accounting for Social Risk Factors.

**PPS-Exempt Cancer Hospital Quality Reporting Program**

The PPS-exempt Cancer Hospital Quality Reporting (PCHQR) Program began in 2014 as a pay-for-reporting program, and there is no penalty or consequence if a PPS-exempt Cancer Hospital (PCH) fails to meet the reporting requirements. Many of the PCHQR policies are similar to the IQR Program, including the principles for selecting and removing measures and the procedures for hospital participation in the program. The initial program included five quality measures in 2014, and subsequent rulemaking has added and removed measures. A total of 17 measures were previously adopted for 2019.

For 2020, CMS proposes to remove three cancer-specific process measures because it has determined that they are topped out. CMS also explains that they believe that these measures do not meet the criteria for retention of an otherwise topped-out measure for the following reasons: they do not align with other HHS and CMS policy goals, such as moving toward outcome measures; do not align with other CMS programs; and do not support the movement to electronic clinical quality measures due to the chart extraction required to collect the data for these measures. CMS explains that if it determines at a subsequent point in the future that hospital adherence to these practices has unacceptably declined, it may propose to readopt these measures in future rulemaking. The measures proposed for removal are as follows:

1. Adjuvant Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis to Patients Under the Age of 80 with AJCC III (Lymph Node Positive) Colon Cancer (PCH-01/NQF #0223)
2. Combination Chemotherapy is Considered or Administered Within 4 Months (120 Days) of Diagnosis for Women Under 70 with AJCC T1c, or Stage II or III Hormone Receptor Negative Breast Cancer (PCH-02/NQF #0559)
3. Adjuvant Hormonal Therapy (PCH-03/NQF #0220)

The below table show the detail of the CMS topped-out analysis for the above measures in the Proposed Rule.
PCH-01, PCH-02 and PCH-03 are ACS measures tracked in the Rapid Quality Reporting System (RQRS), a program which is available to all Commission on Cancer (CoC)-accredited cancer programs. The RQRS is a rigorous, standardized system for reporting cancer measures. The ACS disagrees with the CMS determination that these measures are topped out, based on the ACS program compliance rates and the disparities in performance of these measures. Tables 1, 2, and 3 below detail mean RQRS measure compliance for 2014 and 2015 stratified by race, age, high school (HS) degree, insurance status and cancer program type. Rates include all RQRS participating programs (approximately 1,300 programs) calculated as of 5/23/2017. One concern is that CMS has determined that these measures are topped out based on the performance of only ten PCHs.

### Rapid Quality Reporting System (RQRS) Measure Compliance, Overall and Stratified

Table 1 ACT (PCH-01 NQF #0223) Adjuvant chemotherapy is considered or administered within 4 months (120 days) of diagnosis for patients under the age of 80 with AJCC Stage III (lymph node positive) colon cancer.

<table>
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<td>.0232</td>
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RQRS

<table>
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<tr>
<th>Overall Mean</th>
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<tr>
<td>Race</td>
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<tr>
<td>White</td>
<td>90.1 (89.4-90.7)</td>
<td>87.5 (86.8-88.3)</td>
</tr>
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<td>Black</td>
<td>85.5 (83.7-87.2)</td>
<td>83.8 (82.1-85.6)</td>
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<td>Hispanic</td>
<td>80.8 (78.0-83.6)</td>
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<tr>
<td>API</td>
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<td>Other</td>
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<td>Age</td>
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<tr>
<td>40-49</td>
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<td>70-79</td>
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### Table 2 (PCH-02; NQF #0559)

Combination chemotherapy is considered or administered within 4 months (120 days) of diagnosis for women under 70 with AJCC T1cN0M0, or stage IB - III hormone receptor negative breast cancer.

<table>
<thead>
<tr>
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</thead>
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<tr>
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<td>Medicaid</td>
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<tr>
<td>Private</td>
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<td>88.7 (87.8-89.6)</td>
</tr>
<tr>
<td>Medicare</td>
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<td>84.3 (83.3-85.4)</td>
</tr>
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<td>Other Government</td>
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<td>Unknown</td>
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<td>84.0 (78.6-89.3)</td>
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#### Quartile, No HS degree

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<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st quartile (greatest prop no HS degree)</td>
<td>85.2 (83.6-86.7)</td>
<td>82.7 (81.1-84.3)</td>
</tr>
<tr>
<td>2nd quartile</td>
<td>87.5 (86.3-88.8)</td>
<td>84.8 (83.4-86.2)</td>
</tr>
<tr>
<td>3rd quartile</td>
<td>90.0 (88.7-91.2)</td>
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<tr>
<td>4th quartile (lowest prop no HS degree)</td>
<td>90.8 (89.9-91.8)</td>
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#### Cancer Program Type

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</thead>
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<td>Community Cancer Program</td>
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<tr>
<td>Comp Com Can Program</td>
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<tr>
<td>Academic/Research Program</td>
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<td>85.1 (83.8-86.3)</td>
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#### Sex

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<tr>
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</table>

Rates include all RQRS participating programs (approx. 1300 programs) calculated as of 5/22/2017
<table>
<thead>
<tr>
<th>Race</th>
<th>2014</th>
<th>2015</th>
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<td>White</td>
<td>92.8 (92.6-93.0)</td>
<td>91.7 (91.5-91.9)</td>
</tr>
<tr>
<td>Black</td>
<td>86.7 (86.0-87.4)</td>
<td>84.7 (83.9-85.4)</td>
</tr>
<tr>
<td>Hispanic</td>
<td>85.4 (84.5-86.4)</td>
<td>84.7 (83.9-85.4)</td>
</tr>
<tr>
<td>API</td>
<td>91.3 (90.3-92.3)</td>
<td>89.4 (88.4-90.6)</td>
</tr>
<tr>
<td>Other</td>
<td>88.7 (87.3-90.1)</td>
<td>85.6 (84.2-87.0)</td>
</tr>
<tr>
<td>Age</td>
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<tr>
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<td>87.9 (86.7-89.1)</td>
<td>85.3 (84.0-86.5)</td>
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<td>88.7 (88.3-89.2)</td>
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<tr>
<td>50-59</td>
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<td>89.8 (89.5-90.2)</td>
</tr>
<tr>
<td>60-69</td>
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<td>70-79</td>
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<td>80+</td>
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<td>Insurance</td>
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<tr>
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<tr>
<td>Medicaid</td>
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<td>Private</td>
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<td>Medicare</td>
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<tr>
<td>Quartile, No HS degree</td>
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<td></td>
</tr>
<tr>
<td>1st quartile</td>
<td>87.9 (87.3-88.5)</td>
<td>85.8 (85.2-86.4)</td>
</tr>
<tr>
<td>2nd quartile</td>
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<td>89.2 (88.8-89.7)</td>
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<tr>
<td>3rd quartile</td>
<td>92.3 (91.9-92.7)</td>
<td>91.0 (90.6-91.4)</td>
</tr>
</tbody>
</table>

Table 3 HT (PCH-03; NQF #0220) Adjuvant Hormonal Therapy: Tamoxifen or third generation aromatase inhibitor is considered or administered within 1 year (365 days) of diagnosis for women with AJCC T1cN0M0, or stage IB - III hormone receptor positive breast cancer.

RQRS 2014          2015          Overall Mean 91.6 (91.4-91.8) 92.0 (91.6-92.4)

Quartile, No HS degree 1st quartile (greatest prop no HS degree) 87.9 (87.3-88.5) 85.8 (85.2-86.4)
2nd quartile 90.3 (89.9-90.7) 89.2 (88.8-89.7)
3rd quartile 92.3 (91.9-92.7) 91.0 (90.6-91.4)

Rates include all RQRS participating programs (approx. 1300 programs) calculated as of 5/22/2017.
Disparities in Tables 1, 2, and 3 are highlighted in yellow. PCH-01/NQF#0223 2015 RQRS compliance overall is 86.2 (compared to the CMS compliance of 98.2) but only 79.7 for Hispanic cancer patients, 83.8 for the 70-79 age range, and 82.7 for the population which has the greatest proportion with no high school degree. PCH-02/NQF#0559, 2015 RQRS shows an overall compliance of 92.2 (compared to the CMS compliance of 93.8), but only 86.2 for the Hispanic population, and 88.4 for the population which has the greatest proportion with no high school degree. PCH-03/NQF#0220 has an overall compliance of 92.0 in 2015 RQRS (compared to the CMS compliance of 93.8), but only 84.7 for the Hispanic population, 82.2 for the uninsured, and 87.9 for community cancer programs. The ACS expects a 90% compliance with our accountability measures, and there are clearly sub-populations which still do not have adequate compliance. Based on the discrepancies, we believe that these measures should be retained in the program as a composite measure. Measuring these processes together can be more meaningful than reporting singleton measures, telling a more complete story of patient care while allowing hospitals to continue to track disparities across patient cohorts.

It is also important to note the difference in the compliance rates in the RQRS program versus the CMS PCHQR program for overall measure performance. Similar to the discrepancies seen in the Surgical Site Infection: Colon and Abdominal Hysterectomy Comments harmonized measure when comparing NSQIP data to NHSN (discussed in VBP program), these measures are another example of how measuring the compliance with measure specifications is not adequate given the bias that can be introduced when the data is normalized, analyzed, ascertained, and reported consistently across different cohorts of patients (including registries and hospitals). ACS strongly urges CMS to consider the factors that introduce bias across different registries.

EHR Incentive Program

*Exception for Decertified EHR Technology for EPs, Eligible Hospitals, and CAHs Seeking to Avoid the Medicare Payment Adjustment*

As required under the 21st Century Cures Act, CMS proposes two policies that
would expand protections from payment adjustments under the EHR Incentive Program. First, CMS proposes to add a new exception from Medicare payment adjustments for participants that have not been able to comply with reporting requirements because their certified EHR technology (CEHRT) has been decertified under ONC’s Health IT Certification Program. CMS proposes this exception for the CY 2018 payment adjustment year, which is the final year of the payment adjustment for eligible professionals (EPs). An EP could qualify for this exception if their CEHRT was decertified either in the 12-month period preceding the applicable EHR reporting period for the CY 2018 payment adjustment year, or during the applicable EHR reporting period for the CY 2018 payment adjustment year. For example, if an EP intended to attest to meaningful use for a 90-day EHR reporting period beginning on April 1, 2016, the EP could apply for this exception if their CEHRT was decertified at any time during the 12-month period beginning on April 1, 2015 and ending on March 31, 2016, or if their CEHRT was decertified at any time during their 90-day EHR reporting period beginning on April 1, 2016. Under CMS’ proposal, an EP must demonstrate in its application and through supporting documentation, if available, that the EP intended to attest to meaningful use for a certain EHR reporting period and made a good faith effort to adopt and implement another CEHRT in advance of that EHR reporting period.

The ACS supports efforts to ensure that EPs are not penalized for circumstances beyond their control, including situations where CEHRT becomes decertified. We also appreciate that the policy would include CEHRT that was decertified prior to the reporting period, as well as during the reporting period. However, the use of a 12-month look-back period is confusing and would result in windows that would vary across EPs. Instead, the ACS encourages CMS to adopt a standard look-back window that would permit an EP to apply for this exception if their CEHRT was decertified at any time within the full calendar year prior to the reporting period, or during the reporting period itself. We also remind CMS that in situations where an EP’s EHR is decertified during the reporting period, it would be unreasonable to expect the EP to make a good faith effort to adopt and implement another CEHRT in advance of or even during the remainder of the reporting period. We request that CMS make this point of clarification when it finalizes this exception.

Ambulatory Surgical Center (ASC)-based Eligible Professionals
As mandated by the 21st Century Cures Act, CMS also proposes to implement a policy to provide that no Medicare payment adjustments will be made in 2017 and 2018 for EPs who furnish “substantially all” of their services in an ambulatory surgical center (ASC). Since the statute specifically refers to an EP who furnishes “substantially all” of his or her covered professional services in
an ASC, CMS proposes two alternative definitions for identifying ASC-based EPs:

- An EP who furnishes 75 percent or more of his or her covered professional services in sites of service identified by Place of Service (POS) code 24 in the calendar year that is two years before the payment adjustment year; and
- An EP who furnishes 90 percent or more of his or her covered professional services in sites of service identified by POS code 24 in the calendar year that is two years before the payment adjustment year.

ACS supports expanding this exception to ASC-based EPs since these professionals typically have little influence over their facilities’ decisions regarding EHR adoption and ongoing use, similar to EPs practicing in inpatient and emergency department settings. At the same time, we urge CMS to adopt consistent policies across programs and to ensure they align with newer programs such as the Merit-Based Incentive Payment System (MIPS). For example, currently, under the EHR Incentive Program, “hospital-based” is defined as when at least 90 percent of an EP’s claims are from an inpatient place of service (POS 21) or emergency department (POS 23). However, the definition of “hospital-based” for purposes of the Advancing Care Information (ACI) performance category under MIPS is at least 75 percent of the EP’s claims coming from POS 21, POS 23, or hospital outpatient (POS 22). The ACS recommends that CMS adopt the lower threshold of 75 percent to ensure consistency between the EHR Incentive Program and MIPS, but also to ensure that this exception is sufficiently inclusive of those EPs who have little control over EHR decisions in their practice.

More importantly, we urge CMS to adopt an exception policy across both programs that evaluates an EP’s “facility-based services” in total, rather than within any single setting. In other words, CMS should define EPs that are eligible for this exception as those for which at least a certain percentage of claims combined from any of the following settings: POS 21, POS 22, POS 23, or POS 24. This more comprehensive approach would better account for the clinical realities of practice, including the diversity and fluidity of surgical practice. Many surgeons are affiliated with multiple facilities and perform procedures in both outpatient hospitals and ASCs. Some practice in the outpatient setting, but take call in the inpatient setting. These surgeons might not satisfy the exception threshold based on any single facility-based place of service, but would likely qualify for the exception if CMS were to recognize services provided across the clinical care model and in multiple types of facilities.
For CY 2016, CMS found that only 404 EPs billed at least 75 percent of their covered professional services in POS 24, which equals approximately .08 percent of Medicare EPs. We do not believe that Congress intended to carve out an exception for such a small number of physicians. Rather, we believe that Congress intended to add POS 24 to the rest of the settings because of the frequency with which some physicians provide services in a facility (versus an office setting). Overall, the exception policy should recognize that facility-based clinicians face the same EHR barriers and lack control regardless of the specific setting and that “facility-based care” should be evaluated in the aggregate for purposes of determining who qualifies for protections from payment adjustments.

Certification Requirements for 2018
In this rule, CMS notes that it will continue to monitor the deployment and implementation status of technology certified to the 2015 Edition. If CMS identifies significant issues related to the 2015 Edition, it will consider flexibility in use of CEHRT in 2018 for all participants of the EHR Incentive Programs. We remind CMS that few EHR systems are currently certified to the 2015 Edition, especially for clinicians that provide more specialized surgical care, which will make it challenging for these clinicians to purchase or upgrade to the 2015 Edition by next year. As such, we recommend that CMS provide flexibility and allow for the use of technology certified to the 2014 Edition or the 2015 Edition (or a combination of both) for the 2018 EHR reporting period. This flexibility should apply to both the EHR Incentive Program, as well as to the Quality Payment Program.

PROPOSED CHANGES RELATING TO SURVEY AND CERTIFICATION REQUIREMENTS

Proposed 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)

Section 1865 of the Social Security Act allows health care facilities that are “provider entities” to demonstrate compliance with Medicare conditions of participation, conditions for coverage, or conditions for certification through accreditation by a program of a private, national accrediting organization (AO) that is approved by the Secretary. CMS has responsibility for oversight and approval of AO accreditation programs used for Medicare certification purposes, and for ensuring that providers and suppliers accredited under an AO accreditation program meet the quality and safety standards required by Medicare.
AOs perform their own surveys and issue their own survey reports that provide information on accredited facilities’ compliance with Federal regulations. These facilities participate in Medicare based on their accreditation from a CMS-approved AO and are not subject to routine surveys from State agencies. CMS has expressed concern regarding AO disparity rates based on the AO facility deficiency findings compared to deficiencies found by State survey agencies. CMS indicates that a significant number of health care facility survey reports and acceptable plans of correction (PoCs) are not currently available to health care consumers to assist them in their decision-making when selecting a facility.

CMS is proposing to require each national AO, including diagnostic imaging AOs, applying or reapplying for CMS-approval of its Medicare accreditation program provide a statement acknowledging that it agrees to make all Medicare provider or supplier accreditation survey reports as well as acceptable PoCs publicly available on its website. Survey reports and PoCs must be made available within 90 days after such information is released to the facilities under review.

We agree that public reporting of reliable and valid data plays a significant role in improving the quality of health care. However, rather than requiring AOs to make accreditation survey reports and facilities’ PoCs public, the ACS recommends that CMS initiate the creation of an effective public/private partnership with AOs, in which CMS performs its role as a public regulator while allowing private accreditors to facilitate improvement through confidential dialogue with health care facilities and providers. The ACS urges CMS to collaborate with AOs to ensure that accreditation surveys are designed and implemented to best identify needed areas of improvement in health care facilities, which will produce more benefit for consumers than simply making accreditation reports and PoCs public documents.

We appreciate the opportunity to comment on 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 Vinita Ollapally, Regulatory Affairs Manager, at vollapally@facs.org, or Jill Sage, Quality Affairs Manager, at jsage@facs.org.

Sincerely,

David B. Hoyt, MD, FACS
Executive Director