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Mr. Andy Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-3321-NC
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

**Re: Comments to the CMS Quality Measure Development Plan:
Supporting the Transition to the Merit-based Incentive Payment
System (MIPS) and Alternative Payment Models (APMs) (DRAFT)**

Dear Mr. Slavitt:

On behalf of the more than 80,000 members of the American College of Surgeons (ACS), we appreciate the opportunity to respond to the *CMS Quality Measure Development Plan: Supporting the Transition to the Merit-based Incentive Payment System (MIPS) and Alternative Payment Models (APMs) (DRAFT)* that was published by CMS on December 18, 2015. 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.

For more than 100 years, ACS has led national and international initiatives to improve quality in hospitals as well as the more specific fields of surgical quality, trauma, and cancer. The ACS Inspiring Quality Campaign was more recently launched to drive awareness of innovative quality improvement programs across the country including the Commission on Cancer, the Committee on Trauma and the ACS National Surgical Quality Improvement Program (ACS NSQIP). These initiatives are built on the following key principles: setting clinical standards, building the right infrastructure, using the right data, and verifying with outside experts. ACS has translated years of expertise into a modern framework of quality measurement. The below practices describe ACS approach to surgical measurement, and will help set the context for our comments to the CMS Quality Measure Development Plan (MDP):

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- Include measures that are meaningful to surgeons and their patients;
- align with the federal incentive programs;
- represent composites across the surgical care continuum (preoperative, perioperative, intraoperative, postoperative, and post-discharge);
- use key processes, risk adjusted outcomes, and patient reported outcome measures (PROMs);
- rely on clinical data (not solely administrative data);
- reduce data burdens by allowing for automated data flow;
- be transparent in quality measurement to accurately define “what, when and why”;
- provide surgeons reporting options to drive improvement;
- promote ACS clinical data registries;
- secure data and performance measures for: authenticity, integrity, reliability and validity; and
- include seamless measurement in surgical workflows at the point of care.

Together, these practices implemented through our various clinical data registries and quality improvement programs form a continuous loop of quality improvement in which organizations and providers learn to improve and keep improving in real time.

Our comments appear in the order in which they are listed in the draft MDP.

Operational Requirements of MACRA

ACS strongly urges CMS to distribute Medicare Access and CHIP Reauthorization Act (MACRA) funding included in section 102 for quality measure development. MACRA specifically authorizes \$15 million per year for each of fiscal years 2015 through 2019, for a total of \$75 million, to fund the development of physician quality measures for use in the MIPS. We encourage CMS to give priority to efforts generated by or in collaboration with the medical profession—this will be key to achieving the legislation’s goal of the availability of an adequate portfolio of appropriate quality measures.

Multi-Payer Applicability of Measures

CMS explains that quality measures currently in use by public and private payers include multiple measures for the same topic resulting in redundancy

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and variability, leading to administrative burden for providers while limiting the ability to measure outcomes across populations. In response, CMS has supported efforts to create aligned core measures across payers including the National Quality Forum Measures Application Partnership (NQF MAP), the Core Quality Measures Collaborative, and the Health Care Payment Learning and Action Network (HCPLAN).

ACS has been an active participant in the NQF MAP and the HCPLAN but we are concerned about the lack of transparency of the Core Quality Measures Collaborative. It is our understanding that the Core Quality Measures Collaborative developed core measures sets with CMS without input from ACS, and very little input from other surgical societies. The result is a set of core measures that are inconsistent with the continuum of surgical care. In general, we support a framework which measures care across the five phases of surgical care including preoperative, perioperative, intraoperative, postoperative, and post-discharge care. We discuss this framework in more detail below. Input from the surgical specialty societies is critical in determining whether the core measure framework is relevant to surgical care. In general, we are concerned that core measures may be too narrow and could lead to the disengagement of surgeons and surgical patients. Core measures sets also seem to be inconsistent with CMS' intention to leverage a data-driven approach to integrate earlier and broader access to clinical data and metadata originating from patient registries, clinical data repositories, and common data models. Moving forward, we encourage a more transparent and inclusive process, and look forward to participating in future discussions and iterations of core measures sets to determine their relevancy to surgery.

Evidence Base for Non-Endorsed Measures

CMS states that as part of the MDP, they plan to use the rating criteria established by NQF to evaluate the quality, quantity and consistency of the evidence for the development of quality measures. ACS supports valid and reliable evidence based measurement but warns CMS that the NQF construct was developed to determine the gold-standard of claims-based measures which measures a single, isolated moment. Given CMS' strategic vision to allow for a data-driven approach which encourages continuous measurement in real time, the current NQF framework may not be appropriate for seamless measurement in surgical workflows at the point of care. It is possible that evidence basis that

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can more closely follow the continuum of care may differ from the traditional NQF measurement science. ACS supports measurement science which develops composites based on valid clinical metrics and shared attribution. This approach allows for accountability and drive toward meaningful improvement. ACS is currently engaging the NQF to consider quality measurement across the care continuum in order to advance measure science to align with the implementation of MACRA.

CMS also notes that they will continue to require measure developers to submit a well-crafted case for measures to be included in federal programs. CMS specifically notes that as part of the submission they are looking for a demonstration of the impact of a measure in terms of lives saved and cost saved. We have concern with the request for demonstrating lives saved because this is not applicable to all types of care provided, especially conditions that are not life-threatening. We believe that quality-adjusted life years may be more broadly applicable, but ultimately we support the demonstration of quality or financial impact.

Quality Domains and Priorities

MACRA specifies the following quality domains: clinical care, safety, care coordination, patient and caregiver experience, population health and prevention. CMS explains that the MIPS performance category of clinical practice improvement activities includes a subcategory of care coordination. CMS notes that they support the development of measures using hybrid data sources to link information between care settings. ACS seeks clarification on how CMS defines “hybrid data.”

CMS Strategic Vision – Measure Development Priorities

The ACS believes that registry-based quality measures which encompass five phases of surgical care: preoperative, perioperative, intraoperative, postoperative, and post-discharge, along with care coordination will be meaningful and important to both surgeons and surgical patients. Every surgical patient in each specialty walks through the phases of surgical care, and each of these phases involves key processes, critical care coordination with primary care physicians and anesthesia, as well as the technical side of surgical care that relates to safety, outcomes and preventing avoidable harms.

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Therefore, to optimally design a value-based surgical care system, a framework that values these phases is required.

Defining process 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. These phases begin with the decision to operate in a preoperative phase. During this preoperative care initial assessment and optimization of comorbid conditions, medications and informed consent are addressed. Care coordination and optimal patient preparation for surgery are universal for all patients. The perioperative phase includes a pre-check 72 hours prior to and upon admission and prior to surgery. The intraoperative phase includes the conduct with the entire surgical team, the technical procedure and coordination with anesthesia. The postoperative phase considers acute care in the postsurgical window, including initial recovery and in-hospital clinical pathways. The post-discharge phase considers the recovery plan and re-entry of the patient into care coordination with the primary care team. Recognition of these phases with clinical metrics and registries would build a safer, higher quality of care as a standard.

The American College of Surgeons has defined a set of metrics to span across the various phases of surgical care that align with a patient's clinical flow. This 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 seek input from stakeholders to build upon this framework—feedback from patients will be especially critical for improving patient centrality.

Phases of surgical care measures:

1. Surgical Plan and Goals of Care
2. Identification of Major Co-Morbid Medical Conditions
3. Preventative Care and Screening: Tobacco Screening and Cessation Intervention
4. Preoperative Key Medications Review for Anticoagulation Medication
5. Patient-Centered Surgical Risk Assessment and Communication
6. Patient Frailty or Functional Index
7. Perioperative Composite
8. Postoperative Care Coordination and Follow-up
9. Unplanned Hospital Readmission within 30 Days of Principal Procedure

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10. Participation in a National Risk-adjusted Outcomes Surgical Registry

These metrics are different from measures in the current PQRS because they span across the various phases of surgical care and when measured together they can have a real impact at the point of care. ACS firmly believes that the current measure approach is narrow, complex, costly and sluggish. It is also important to recognize that a single set of measures for “general surgery” is very difficult to translate to an individual general surgeon due to the diversity of procedures general surgeons perform. Procedures vary from surgeon to surgeon based on their patient population, subspecialty, and geographical location. Furthermore, the current approach will likely slow down the ability to drive quality and improvement, which seems inconsistent with the goals of MACRA. ACS supports clinical metrics that are meaningful and actionable for improving surgical care and which matter to surgeons and their patients.

Consideration for Electronic Specifications

As required by MACRA, CMS must consider whether measures chosen for MIPS and APMs appear viable for electronic specification. We commend CMS for stating the intention to integrate earlier and broader access to clinical data and metadata originating from patient registries, clinical data repositories, and common data models. We strongly support the broad use of common data models with standardized data and believe that this critical step toward enabling real-time measurement in a way that is meaningful to surgeons and their patients. However, we strongly encourage CMS to expand its focus beyond electronic clinical quality measures (eCQMs). **ACS strongly believes that the entire clinical data ecosystem must operate with open architecture to promote secure, accessible sharing of data as necessary to facilitate the future of quality measurement, not a narrow focus on eCQMs.** eCQMs serve their purpose by supporting document “exchange” and interoperability among electronic health records (EHRs). However, a data “exchange” only provides an “as last requested” version of information and therefore does not create the conditions necessary to yield the real-time data required for this goal. Open architecture allows for clinical use case applications to improve the quality of patient care and optimize the functioning of the health care system as a whole.

Standards and Tools

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Open architecture framework and data exchange will greatly enhance measure proliferation while reducing the burden of data aggregation and further securing patient confidentiality. The explosion of health data, driven partially by adoption of EHRs and clinical data registries, coupled with advances in technology such as Platform as a Service (PaaS), has led entities in the private sector to create standards and build systems (open architecture) that can harness the massive amounts of data collected on a daily basis and use it to promote real-time measures for leading and lagging indicators that improve care and aid in preventing harms. This technology is currently utilized to improve patient care in places such as the LSU Health Care Services Division and Intermountain Health and the Beth Israel Deaconess Medical Center. These systems have used PaaS to analyze data from multiple EHR vendors, government health programs and other sources to provide researchers, health care providers and even patients, with valuable, real-time information. In this case, data is output to the end user through applications in a process comparable to that used by smartphones and other mobile devices.

Smartphones do not store the data—the application programming interface (API) of each platform, such as Android, IOS or Windows for mobile devices provides the programmatic instructions, tools and common data definitions, for the usage of apps on the phone. Data is entered once and repurposed many times.

Extending this example to health care, apps could be used track hemoglobin A1c or surgical site infections, for example. Through use of this technology, data entered in the EHR could be fed into the registry, provided to the patient, and also used to meet reporting requirements with minimal additional effort from the provider. Open architecture will allow this data to flow back from the registry to the EHR. This can be accomplished in the cloud through virtual analysis where data can remain housed at its source in a distributive model, obviating the need for data aggregation. The ability to imbed measures within an EHR or an API to highlight critical decision points within surgical workflow across the phases of surgery (as described above) can transform care. In order to allow for this level of exchange and interoperability, universal use of a repository is needed to define official versions of vocabulary value sets for clinical quality measures—one example of this is the National Institutes of Health Value Set Authority Center (VSAC). Systems would be required to have the tools to regularly update the VSAC in order to enable sharing. **The universal use of standards within a central repository would be a leap**

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forward in enabling advanced health analytics and expanding interoperability while optimizing workflow. In order to accomplish this, it is also absolutely critical that any ONC-certified platform must have the ability to imbed applications, regardless of the platform.

Challenges in Quality Measure Development and Potential Strategic Approaches

Engaging Patients in the Measure Development Process

CMS states that in 2012, they began to require measure developers to include one or more patients in the measure development process. Although ACS has included patients in the development of many of its measures, ACS is unfamiliar with this as a CMS requirement and requests clarity in the final MDP.

Reducing Provider Burden of Data Collection for Measure Reporting

CMS notes that they strive to minimize provider burden by collecting data that are part of the existing clinical workflow, as well as prioritizing the development of measures based on data from EHRs. As mentioned above, ACS strongly supports full interoperability with open architecture which is not limited to EHRs. Removal of outdated documentation guidelines (promulgated for an age of paper records) and enhanced efficiencies through digitized workflow will improve clinical care while reducing administrative burden.

Shortening Time Frame for Measure Development & Streaming Data Acquisition for Measure Testing

ACS agrees that integration of the Measure Authorizing Tool (MAT) and VSAC have the ability to reduce measure development time. However, we also encourage flexibility in measure development through the use of clinical innovation laboratories. For example, measure development could be accelerated by applying measures across ten different delivery systems to demonstrate improvement. This will be easily accomplished with full interoperability.

Identifying and Developing Meaningful Outcome Measures

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CMS explains that they are participating in an NQF pilot project to evaluate incorporation of sociodemographic factors into risk adjustment models, and the Office of Assistant Secretary for Planning and Evaluation is conducting research specific to risk adjustment. ACS is extremely concerned with CMS' ability to implement outcome measures in MIPS and APMs due to their current inability to accept risk adjusted data as part of the Physician Quality Reporting System (PQRS) program. Part of the challenge is the capability to compare different populations across different data sources (such as different registries) due to a lack of defined risk variable definitions and statistical methods. These problems were recently demonstrated in CMS' inability to accept risk adjusted metrics for the American College of Surgeons PQRS General Surgery Measures. CMS accepted risk adjusted rates for PQRS performance of the General Surgery Measures for the 2014 performance year but explained that because of the 2015 Value Modifier—and the need to rate performance across individual providers—they could not accept risk adjusted rates for 2015. This is because not all providers who reported this measures group submitted risk adjusted results.

Following this discovery, ACS ran a comparison of the Surgeon Specific Registry (SSR) 2015 raw data vs 2015 risk adjusted data for the surgical site infection (SSI) measure in the PQRS General Surgery Measures Group. The results of our analysis indicate that 50% of the poor performers were misclassified when risk adjustment is not applied. ACS is currently working with CMS to find a solution to the technical issues regarding risk adjustment by sharing our methodology and variable definitions. However, this has raised a red flag and we strongly encourage additional resources and engagement of stakeholders to help CMS implement risk adjusted rates in short order, given the quick timing of MACRA implementation.

Developing PROMS and Appropriate Use Measures

CMS explains that these types of measures have been difficult to develop due to challenges in validity without placing excessive burden on the patient. For PROMS, the infrastructure to collect and store data has not been widely available, affordable, or standardized. CMS specifically solicits comments on ways to capture patient-reported data in a manner that does not create undue burden. ACS believes that interoperability is the solution to PROM data aggregation with the ability for patients to access data on demand.

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For appropriate use measures, CMS explains that the availability of data has constrained measure development. ACS agrees with the lack of available data, but adds that there must be an investment in measures science for appropriateness measures.

Developing Measures that Promote Shared Accountability Across Settings and Providers

ACS agrees that as payment systems evolve toward population-based payments, CMS must adapt measures that reflect shared accountability which will require provider coordination across care settings and interoperability. ACS has encouraged CMS to consider a range of APMs in which a broad group of diverse specialists could participate such as procedure-specific APMs, condition-specific APMs, or capitated payments for care of a population related to a specific condition, patient population, or desired health outcome. For example, a condition-specific APM could be developed around breast cancer. The time window could be one year from the breast cancer diagnosis and could include all the Part B services provided to a patient in that time window related to the diagnosis. An example of a population-based APM on the other hand could be an ongoing “per member per month” payment for total breast care for each individual covered under the model regardless of diagnosis. This would be similar to a managed care model but is limited to a specific service line of care.

In these examples, measures would need to be developed to promote shared accountability among providers as well as to ensure patients have access to the care they need. The ACS believes that the measures developed to follow the five phases of surgery are an example of the College’s commitment to shared accountability. As noted above, each surgical patient walks through five phases of surgical care, involving not only the technical side of surgical care that relates to safety, outcomes and avoidable harms, but also key processes related to care coordination with primary care physicians and anesthesia among others. Instituting these measures would incentivize better coordinated care and shared accountability, especially in a population-based APM.

CMS has stated that shared accountability will also require improved access to data from multiple sources. As noted above, ACS strongly urges CMS to go beyond its current position on health information exchange (HIE) and interoperability to support a clinical data ecosystem operating on an open

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architecture that allows secure, accessible sharing of data as necessary to facilitate the future of quality measurement. To drive quality improvement and shared accountability will require more than document “exchange” and interoperability among EHRs based on a static “as last requested” version of information. If the physicians treating a patient have incomplete or outdated data, their ability to influence outcomes are limited, and physicians should only be held accountable for outcomes they are able to influence. A clinical data ecosystem built on open architecture would be more capable of providing physicians of diverse specialties with this real-time, actionable data.

We appreciate the opportunity to comment on draft MDP. 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 the ACS Division of Advocacy and Health Policy at jsage@facs.org.

Sincerely,

David B. Hoyt, MD, FACS

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