August 30, 2012

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

Attention: CMS-1589-P: Hospital Outpatient Prospective and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Electronic Reporting Pilot; Inpatient Rehabilitation Facilities Quality Reporting Program; Quality Improvement Organization Regulations

Dear Ms. Tavenner:

The Association for Professionals in Infection Control and Epidemiology (APIC) and the Society for Healthcare Epidemiology of America (SHEA) wish to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed CY 2013 Medicare hospital outpatient prospective payment system (OPPS) and ambulatory surgical center (ASC) payment system quality reporting programs. We are pleased that CMS continues to demonstrate its commitment to improving the quality of patient care and we believe CMS is moving in the right direction. We are writing to address issues raised by CMS related specifically to healthcare-associated infections (HAIs).

Hospital Outpatient Quality Reporting (OQR) Program Update

APIC and SHEA support CMS’s efforts to align the clinical quality measure requirements of the Hospital OQR and other programs, including those authorized by the Health Information Technology for Economic and Clinical Health (HITECH) Act, so that the burden of reporting is reduced. We emphasize that reducing the burden of reporting allows for enhancement of time spent on clinical infection prevention and control activities which can help improve patient outcomes. However we also need to be able to realistically evaluate the ability of facilities to submit such data electronically. A recent survey from New York State noted that only 15% of hospitals had adopted an Electronic Health Record (EHR) and many of those organizations that do have an EHR have not yet been able to validate the collection of denominator data electronically. While we recognize that outpatient facilities may be more advanced in their electronic capability than acute care hospitals, there may also be greater variability
and potentially less information systems and technology resources that need to be accounted for during implementation. It is also important to ensure that any data systems developed for submission accommodate pilot testing, reliability analysis, and validation components as part of the process.

*Recommendations:*

- APIC and SHEA support quality measure alignment to reduce the burden of reporting.
- APIC and SHEA recommend continued careful and thoughtful evaluation of electronic specifications for data submission through EHR technology.

**Proposed Process for Retention of Hospital OQR Program Measures Adopted in Previous Payment Determinations**

In this proposed rule, CMS notes that beginning with this rule, it is proposing to automatically continue any previously adopted measures for all subsequent year payment determinations unless it proposes to remove, suspend, or replace the measures. APIC and SHEA request that CMS continue to have a review and comment process on the retention of measures to allow for stakeholder input regarding the effectiveness and burden of the measure.

**Quality Measures for Calendar Year (CY) 2015 Payment Determination**

APIC and SHEA applaud CMS’s recognition of the time and effort to develop, align, and implement the infrastructure necessary to collect data as part of the Hospital OQR program. We also appreciate the recognition of the time and effort on the part of hospital outpatient departments which need to plan and prepare for these measures and thus support the proposal to not add any new healthcare-associated infection (HAI) measures.

*Recommendations:*

- APIC and SHEA support the proposal for no new additional measures for the CY 2015 payment determination.
- APIC and SHEA support the retention of the OP-6 (Timing of Antibiotic Prophylaxis) and OP-7 (Prophylactic Antibiotic Selection for Surgical Patients) for the CY 2015 payment determination.

**Possible Quality Measures under Consideration for Future Inclusion in the Hospital OQR Program**

APIC and SHEA continue to be interested in the ever-evolving current and future measure sets. We support CMS’s philosophy that these measures should evolve to include focused sets that are appropriate to the specific provider. It is of significant importance that the ability to risk adjust such measures to provide more meaningful and actionable focus must also be a continued part of measure set development. As stated in previous rules, APIC and SHEA support the use of measures based on alternative sources of data that utilize information already being reported by outpatient settings, provided that the data is based on standardized definitions and can also be risk adjusted and validated. The Centers for Disease Control and Prevention’s (CDC) National Healthcare Safety Network (NHSN) would be such an example. When considering new measures for the outpatient setting, one suggestion may be to add surgical site infection (SSI) following cholecystectomy. APIC and SHEA recommend
choosing a high volume procedure, following the NHSN selection criteria, and risk stratifying the data as appropriate.

APIC and SHEA again would also like to note that we are opposed to the use of administrative/claims data as a single source of HAI identification. While claims data may be useful as a supplemental method to assist in finding records to be evaluated for possible SSI, it is essential that HAIs are validated by trained surveillance personnel using written standardized protocols. Because claims data do not provide precise identification of HAIs, nor do they provide information in a timely manner to provide effective treatment and prevention, they are of limited use in preventing HAIs. There have been additional studies that reinforce our continued concern with use of claims versus clinician/epidemiologic data elements. This results in questionable data comparison for end users whom these reported data are intended to guide. While we applaud federal efforts to improve the quality and safety of patient care, we believe that the patients who receive that care would be better served by the use of more precise and accurate data to identify the conditions.

CMS also notes in this section that it is considering initiating a call for input to assess several measure domains including clinical quality of care, patient safety and population/community health. APIC and SHEA support initiating such a call and stand ready to assist in any manner possible.

**Recommendations:**
- APIC and SHEA recommend that CMS consider adding one surgical site infection HAI such as SSI following cholecystectomy. Use of NHSN selection criteria and risk stratification of outcome data would be required.
- We further recommend working in collaboration with CDC to understand the impact of implementation as it relates to other care settings, such as ASCs.
- APIC and SHEA strongly support CMS initiating a call for input to assess several measure domains and stand ready to assist CMS in this effort.

**Proposed Hospital OQR Program Validation Requirements for Chart-Abstracted Measures for the CY 2014 Payment Determination and Subsequent Years**

CMS notes that it is proposing to continue to utilize the number of randomly selected hospitals for validation of chart abstracted patient level data at 450. This is the same number that was utilized for the CY 2013 payment determination. APIC and SHEA support this continued approach as long as this remains sufficient representation of the breadth of hospital outpatient programs. CMS also continues to recognize the need for validation of HAI data and we support the use and application of the standardized NHSN definitions for interfacility comparisons.

**Recommendation:**
- APIC and SHEA support utilizing 450 randomly selected hospitals for validation of chart abstracted data and encourages CMS to work closely with NHSN in its validation development for any HAI measures.
Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program

In discussions within the proposed rule, CMS notes that while it is not intending to add any new measures at this time, it continues to evaluate the relevance and utility of measures compared to the burden on ASCs in submitting data. APIC and SHEA appreciate and support this effort because measure sets continue to evolve and should always be reflective of evidence-based practices and criteria as established in the medical literature.

APIC and SHEA also note that CMS has adopted Influenza Vaccination Coverage among Healthcare Personnel (NQF #0431) for the CY 2016 payment determination. Data collection for this measure would be via NHSN from October 1, 2014 to March 31, 2015. Because healthcare personnel can unintentionally expose patients to seasonal influenza if they have not been vaccinated, and such exposure can be dangerous to vulnerable patients, both APIC and SHEA have taken positions supporting mandatory HCP influenza vaccination as a condition of employment. We applaud CMS for adding this measure to the ASCQR program as we feel this will advance this strategy aimed at improving safety of patients. We note that healthcare personnel in general continue to have low influenza vaccination rates; however, while we support the public reporting of HCP vaccination rates, we advise CMS to continue to assess the CY 2016 timeframe as it relates to preparedness of ASCs, CMS and NHSN for the data submission and retrieval process. We support the intent of this measure and agree that influenza vaccination data submitted to CDC/NHSN will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, and the elements within yearly influenza campaigns that succeed or require improvement. At the state and national levels, the HCP component can aid in monitoring rates and trends.

Recommendations:
- APIC and SHEA support CMS’s proposal to not adopt any new measures at this time.
- APIC and SHEA strongly support mandatory HCP vaccination, as well as public reporting of HCP vaccination rates. We support CDC’s continuing efforts to develop an infrastructure and a system that would allow facilities to submit summarized, aggregate data on HCP influenza rates, ideally drawn from existing databases, to avoid the need to input other extraneous information unrelated to this measure.

Clarification Regarding the Process for Updating ASCQR Program Quality Measures

APIC and SHEA continue to support CMS utilizing a subregulatory process for making updates to measures that have already been adopted in order to ensure the most up-to-date scientific evidence and consensus standards. APIC and SHEA would also like to offer their input and expertise to the CMS Technical Expert Panels whenever needed or appropriate.

Proposed Requirements for Reporting of ASC Quality Data

CMS provides historical background that it has adopted claims-based measures for the CY 2014, CY 2015, and CY 2016 payment determination years. While there may certainly be appropriate claims-based measures for reporting of ASC quality data, APIC and SHEA again note, as above, that we are opposed to the use of administrative/claims data for identification of HAIs.
Proposed Inpatient Rehabilitation Facility (IRF) Quality Reporting Program Updates

As noted above with the ASC Quality Reporting and the Hospital OQR programs, APIC and SHEA support CMS using a subregulatory process for making updates to NQF-endorsed measures whereby the update is not substantially changing the nature of the measure. Significant changes to NQF-endorsed measures should continue to provide an opportunity for stakeholder input via the rulemaking process.

Adopted Measures for the FY 2014 Payment Determination

CMS notes that it has adopted the CDC measure, Urinary Catheter-Associated Urinary Tract Infection (CAUTI) rate per 1,000 urinary catheter days. CMS notes that the measure has since been updated to use a different calculation method, referred to as the standardized infection ratio (SIR) and that while this data calculation has changed, the way of reporting (via NHSN) has not. APIC and SHEA support this methodology and agree with CMS that it is a more accurate way to calculate the CAUTI measure for comparative purposes because it takes into account an IRF’s case mix. However, APIC and SHEA continue to be concerned with the small number of IRFs currently reporting to NHSN.

Recommendation:
- APIC and SHEA support the use of CAUTI for quality reporting in IRF; however, we suggest that CMS partner with IRFs currently enrolled in NHSN to precisely assess the resources necessary to collect and analyze CAUTI data. Because practices involving the use of indwelling urinary catheters differ greatly among patients or facilities based upon the demographics of the patient population and the required duration of catheterization, we recommend that data collection be limited to a specific type or types of patients within the IRF such as those who are associated with the highest risk of infection and who may utilize urinary catheters extensively.
- APIC also continues to support the exclusion of pediatric patients from this measure because it has not been NQF-endorsed for the pediatrics population due to low frequency of catheter use and difficulty in attributing UTIs.

APIC and SHEA appreciate the opportunity to comment on the proposed measures and continue to applaud CMS’s commitment to improving quality and promoting patient safety. Our organizations continue to support transparency in healthcare improvement efforts, and reporting of healthcare-associated infections as a means to that end. With the increasing volume of data reported, we believe it is integral that an assessment of the effects of public reporting on both the patient and the healthcare system are examined and shared. We stand ready to assist CMS in these assessments as well as all efforts to reduce preventable HAIs based upon standardized validated measures and evidence-based guidelines.

Sincerely,

Michelle Farber, RN, CIC  
President, APIC

Jan E. Patterson, MD, MS  
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