



August 28, 2013

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

***Re: CMS-1601-P, Medicare and Medicaid Programs: Hospital Outpatient prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs, proposed rule***

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 Calendar Year (CY) 2014 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 Updates**

APIC and SHEA recognize that CMS has implemented quality measure reporting programs for multiple settings of care. Reporting focused on quality measures that have high impact and support national priorities for improved quality and efficiency of care for Medicare beneficiaries is of significant benefit. We continue to urge CMS to support, where appropriate, the adoption of HAI measures that are consistent with epidemiological events and have aligned data elements with the Centers for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN). In addition, APIC and SHEA support CMS's goals of aligning outpatient measures with established clinical quality measure requirements and utilizing, where feasible, electronic specifications to enable the collection of this information as part of care delivery.

Aligning HAI measures and moving towards electronic data capture will potentially reduce the burden of data collection and reporting for facilities, yet must be undertaken in a thoughtful manner to account for the massive infrastructure development for such electronic health record (EHR) requirements. APIC and SHEA recommend reaching out to key stakeholders including CDC, infection preventionists, healthcare epidemiologists, direct care

providers, vendors of EHR systems and other stakeholders who are able to provide input and feedback in development of appropriate elements that relate to HAIs.

*Recommendation:* APIC and SHEA support transparency through reporting of meaningful clinical data and urge CMS to reach out to key clinical stakeholders during development of electronic reporting requirements and additional HAI-related data elements. In particular, CMS has the ability to promote incorporation of key elements and operability of EHR systems that will facilitate improved performance and outcomes under the meaningful use initiative.<sup>1</sup>

### **Proposed Quality Measures for the CY 2016 Payment Determination and Subsequent Years**

CMS notes it is proposing to adopt several new measures for the Hospital OQR Program including one HAI measure – Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431), currently collected by the CDC through NHSN – and a chart-abstracted measure identified as Complications within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564).

APIC and SHEA applaud the proposed addition of the HCP influenza vaccination measure. This measure is high impact and complies with the targets of the National Action Plan to Prevent Healthcare-Associated Infections. It is also consistent with existing measures under other quality reporting programs and demonstrates alignment with the importance of this measure and the protection of patients against influenza in the outpatient setting as in other settings. Studies continue to highlight the ongoing gap between the current and optimal level of influenza vaccination among personnel in many settings across the healthcare delivery network.<sup>2</sup>

In addition, we are pleased that data submission and reporting standard procedures will be through the NHSN. This will allow for the continued use of the standardized definition of HCP<sup>3</sup> and will enhance the validity and reliability of the outcome measure. APIC and SHEA also appreciate that CMS is accepting those HCP who receive the vaccine during the time from October 1 or when the vaccine becomes available, as this encourages programs to vaccinate earlier and not delay for reporting purposes. We would like to encourage CMS to align HCP influenza vaccination surveillance and reporting strategies across the continuum of healthcare settings to allow for comparison data and to ease the burden on those who collect and report the data to NHSN.

APIC and SHEA note, however, that outpatient services provided within acute care facilities are often provided by the same staff in the same units as inpatient services. Therefore, it will be impossible to differentiate which HCP to report under the Hospital Inpatient Quality Reporting Program and which to report under the Hospital OQR program. CMS addressed a similar concern in the FY 2014 Inpatient Rehabilitation Facility (IRF) PPS final rule by acknowledging that over-reporting will occur when IRF units are located within acute care facilities. However, unlike IRF units, outpatient services may not have separate units. Although APIC and SHEA support transparency in quality reporting, we are concerned about the level of confusion among the public consumers of Hospital Compare that may arise as a result of this level of over-reporting. We request that CMS clarify reporting requirements for facilities whose staff provide both inpatient and outpatient services.

CMS has also proposed the addition of Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564). APIC and SHEA note that while this is an NQF-endorsed measure, we believe the frequency of complications is quite low. This is particularly true for infectious complications such as endophthalmitis, which is rare in frequency and typically is episodic involving a cluster associated with source from an index patient or personnel with a viral eye infection.<sup>4</sup> The literature describes a non-infectious complication, toxic anterior segment syndrome (TASS) that appears to be associated with reprocessing of surgical instruments or

other products/medications used during surgery, although this is also rare and identification of contributing risk factors remain elusive.<sup>5,6,7</sup> Therefore the effort put into surveillance and reporting of adverse outcomes following this surgery may not meet the intent of assessing performance by measuring complications given their very low frequency.

Recommendations:

- APIC and SHEA support the addition of the Influenza Vaccination Coverage Among Healthcare Personnel (NQF #0431) as a patient safety measure and request clarification on reporting requirements for facilities whose staff provide both inpatient and outpatient services when a differentiation cannot be made between staff because staff simultaneously care for both.
- APIC and SHEA suggest engaging a group of stakeholders to review the topic of complications following cataract surgery and delay implementation of the measure until further analysis can be completed.

**Possible Hospital OQR Program Measure Topics for Future Consideration**

APIC and SHEA recognize CMS is attempting to identify measures that help further the goal of achieving better healthcare and improved health for Medicare beneficiaries who receive healthcare in hospital outpatient settings. We would therefore like to recommend several areas for consideration as patient quality measure topics for both hospital outpatient and ambulatory care settings:

- Safe Injection Practices. This critical safety initiative emerged out of observation of prior and ongoing outbreaks of infection transmitted by unsafe practices by providers, especially evident in ambulatory care settings across the United States.<sup>8,9</sup> The CDC has issued a *Guide to Infection Prevention for Outpatient Settings*<sup>10</sup> that offers excellent examples of key processes and monitoring that providers in ambulatory settings can employ to improve patient safety. Additional guidance and resources are also available from the Safe Injection Practices Coalition.<sup>11</sup> In addition, CDC has collaborated with CMS to provide interpretive guidelines for ASC surveyors under CMS Conditions for Coverage. The “triangulation” of encouraging providers to track key processes around safe injection practices plus findings from CMS validation surveys and OQR validation seems a logical and powerful tool to improve patient care. Analogous to promoting safe injection practices, maintaining sterility when compounding medications onsite, and adequate disinfection of devices between patients for point of care glucose testing are essential in reducing the risk of organism transmission.
- Surgical Instrument Reprocessing and Cleaning/Disinfection. Effective disinfection and sterilization is an important component of any infection prevention and control program. There have been noted lapses in infection control, including instrument reprocessing in ASCs.<sup>12</sup> Appropriate care and management of surgical equipment is a complex process that requires expertise and oversight to ensure patient safety. We encourage CMS to engage providers, APIC, SHEA, CDC, and accreditation agencies to develop and test measures that are efficient and effective while avoiding overly burdensome, rigid measures. There are some existing items in CMS survey tools for outpatient care areas that may be worth reviewing.
- Outcomes following Surgical Care. While patients, payers, and providers have the most interest in outcomes, the frequency and sampling strategy are critical to provide meaningful surveillance data. For example, we understand that the top three types of outpatient care involve endoscopy, ophthalmic surgery, and pain therapy. Adverse outcomes, especially infection, are exceedingly rare among these types of care and the effort to detect adverse outcomes involving infections would involve substantial

surveillance resources with low yield. As an alternative, we recommend CMS collaborate with key professional organizations like APIC, SHEA, and those representing surgeons and perioperative professionals, i.e. the Association of periOperative Registered Nurses (AORN), to identify a roster of surgical procedures that are high volume, and lend themselves to incorporation into the NHSN reporting modules. This will allow standardization, risk stratification and ultimately dissemination of findings.

#### **Extraordinary Circumstance Extension or Waiver**

APIC and SHEA note CMS's proposal to grant extensions or waivers with respect to the reporting of required quality data during an "extraordinary circumstance beyond the control of the hospital" or when a systemic problem with one of the data collection systems directly or indirectly affects the ability of the hospital to submit data.

*Recommendation:* APIC and SHEA support this proposal.

#### **Hospital Value-Based Purchasing (VBP) Program Updates**

##### **Proposed Performance and Baseline Periods for Certain Outcome Measures for the FY 2016 Hospital VBP Program**

APIC and SHEA thank CMS for including the FY 2016 performance and baseline period proposals in this rule as this was something we wished to review that was inadvertently missing from the Hospital Inpatient Prospective Payment System proposed rule. While APIC and SHEA support the use of surveillance data via NHSN over administrative data, we wish to note there were significant changes in the central line-associated bloodstream infection (CLABSI), catheter-associated urinary tract infection (CAUTI) and surgical site infection (SSI) surveillance definitions between the baseline collection period in 2012 and the proposed performance period in 2014. This may be a confounder when assessing future performance. In addition to the definitional changes to CLABSI, CAUTI and SSI in the baseline collection periods, it is anticipated that additional definition changes to CAUTI will occur in 2014.

*Recommendation:* APIC and SHEA encourage CMS to consider the data instability when comparing collection periods.

##### **Proposed Requirements for the Ambulatory Surgical Center Quality Reporting (ASCQR) Program**

APIC and SHEA note that CMS has proposed similar measures aligned with the Hospital OQR program. While we appreciate the alignment, we suggest further review and analysis of Complications Within 30 Days Following Cataract Surgery Requiring Additional Surgical Procedures (NQF #0564). As we noted above in our comments on the Hospital OQR program, the frequency of complications from the NQF-endorsed measure is low and we wonder whether the effort to comply with this measure may exceed the benefit gained from it.

*Recommendation:* APIC and SHEA suggest engaging a group of stakeholders to review the topic of complications following cataract surgery and delay implementation of the measure until further analysis can be completed.

##### **Proposed Requirements for the CY 2016 Payment Determination**

In the proposed rule, CMS is allowing ASCs an extended deadline of August 15, 2015 to submit HCP influenza vaccination data for the 2014-2015 influenza season. APIC and SHEA note that the data submission deadline for this measure in other care settings is May 15. We encourage CMS to align the data submission deadline for ASCs

with that of quality reporting programs in other settings, and we encourage ASCs that are able to do so, to submit their data by May 15, 2015 to maintain consistency with HCP influenza vaccination reporting in other care settings.

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 HAIs 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,



Patricia S. Grant, RN, BSN, MS, CIC  
2013 APIC President



Daniel Diekema, MD  
2013 SHEA President-Elect

---

<sup>1</sup> U.S. Department of Health and Human Services (HHS). EHR Incentives and Certification; How to attain meaningful use. Available at: <http://www.healthit.gov/providers-professionals/how-attain-meaningful-use>. Accessed 08/13/13.

<sup>2</sup> Lee SJ, Harrison R, Rosenberg J, et al. Influenza vaccination among health care personnel in California: 2010-2011 influenza season. *Am J Infect Control*. 2013 Aug;41(8):e65-71.

<sup>3</sup> U.S. Centers for Disease Control and Prevention (CDC). Toxic anterior segment syndrome after cataract surgery--Maine, 2006. *MMWR* 2007;56(25):629-30.

<sup>4</sup> CDC. Adenovirus-Associated Epidemic Keratoconjunctivitis Outbreaks — Four States, 2008–2010. *MMWR* 2013; 62(32):637-641.

<sup>5</sup> CDC. Toxic anterior segment syndrome after cataract surgery--Maine, 2006. *MMWR* 2007;56(25):629-30.

<sup>6</sup> Eydelman MB, Tarver ME, Calogero D, et al. The Food and Drug Administration's Proactive toxic anterior segment syndrome Program. *Ophthalmology*. 2012 Jul;119(7):1297-302.

<sup>7</sup> Sengupta S, Chang DF, Gandhi R, et al. Incidence and long-term outcomes of toxic anterior segment syndrome at Aravind Eye Hospital. *J Cataract Refract Surg*. 2011 Sep;37(9):1673-8.

<sup>8</sup> CDC. Invasive *Staphylococcus aureus* infections associated with pain injections and reuse of single-dose vials--Arizona and Delaware, 2012. *MMWR* 2012;61:501-4.

<sup>9</sup> Schaefer MK, Jhung M, Dahl M, et al. Infection control assessment of ambulatory surgical centers. *JAMA*. 2010;303:2273-9.

<sup>10</sup> CDC. Guide to Infection Prevention for Outpatient Settings. Available at <http://www.cdc.gov/HAI/pdfs/guidelines/standatds-of-ambulatory-care-7-2011.pdf>. Accessed 8/15/13.

<sup>11</sup> Safe Injection Practices Coalition. One & Only Campaign. Available at: <http://www.oneandonlycampaign.org/> Accessed 08/13/13.

<sup>12</sup> Schaefer, *op. cit.*