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August 29, 2011

Donald Berwick, MD
Administrator
Centers for Medicare &
Medicaid Services
U.S. Department of Health and Human
Services
200 Independence Avenue, SW
Room 445-G
Washington, DC 20201

Re: Proposed Rule: CMS-1525-P Hospital Outpatient Prospective Payment; Ambulatory Surgical Center Payment; and Hospital Value-Based Purchasing Program

Dear Dr. Berwick:

The Society for Healthcare Epidemiology of America (SHEA) wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed rule "*Medicare Program; CMS-1525-P Hospital Outpatient Prospective Payment, Ambulatory Surgical Center Payment, and Hospital Value-Based Purchasing (VBP) Program for CY 2012*".

SHEA is a professional society representing more than 1,900 physicians and other healthcare professionals around the world with expertise in healthcare epidemiology and infection prevention and control. SHEA's mission is to prevent and control healthcare-associated infections and advance the field of healthcare epidemiology. The society leads this field by promoting science and research and providing high-quality education and training in epidemiologic methods and prevention strategies. SHEA upholds the value and critical contributions of healthcare epidemiology to improving patient care and healthcare worker safety in all healthcare settings.

We are pleased that CMS continues to demonstrate its commitment to improving the quality of outpatient care and support the quality programs in this expanding arena of care delivery. Our comments primarily reflect the concerns of our SHEA members who are dedicated to the elimination of healthcare-associated infections (HAI) in our hospitals and health

systems across all states, including outpatient settings. Our members provide leadership for HAI reduction, employing multiple initiatives to reduce HAI, and have been heavily engaged with the Centers for Disease Control and Prevention (CDC) and Department of Health and Human Services (HHS) in the development and implementation of the HHS Action Plan to Prevent Healthcare-Associated Infections, including outpatient care-delivery sites.

Since HAIs and their measured improvement in our organizations figure importantly in CMS' quality and reimbursement programs, our members have a vested interest in the effective operation of the VBP program and we will also comment on the proposed quality measure additions for the final VBP rule provided in the proposed outpatient rule here.

Hospital Outpatient Quality Reporting (Hospital OQR) Program

SHEA continues to support both the alignment and development of hospital outpatient quality reporting, and agrees as noted that "outcomes and...measures should be adjusted for risk factors or other appropriate patient population or provider characteristics." In addition, we also support the idea that the "collection of information burden on providers should be minimized to the extent possible." With the above premise in mind, we would also like to comment on the following.

Proposed New Hospital OQR Program Measures for Payment Determination

CY 2014

National Healthcare Safety Network (NHSN) Healthcare Associated Infection (HAI) Measure: Surgical Site Infection (NQF#0299)

Background

CMS states that this measure is among those collected by the CDC National Healthcare Safety Network (NHSN) and assesses the percentage of surgical site infections (SSIs) occurring within 30 days after an NHSN-defined operative procedure if no implant is left in place or within one year if an implant is left in place and the infection appears to be related to the procedure.

CMS proposes data submission for this measure would relate to events occurring between January 1, 2013 and June 30, 2013 for the CY 2014 payment. It would be reported using the NHSN infrastructure and protocols and references. Further, CMS proposed that because this SSI measure was adopted for the Hospital Inpatient Quality Reporting (IQR) Program for the FY 2014 payment determination, CMS views the proposed addition of this measure to the Hospital OQR Program as meeting the goal of aligning measures across programs where feasible. SHEA would like to note that admirable as this goal is, there are a considerable number of issues to consider.

Procedures alignment

SHEA has reviewed the final notice of the CMS IPPS decision published August 1, 2011. We note the selection of colon and abdominal hysterectomy procedures via NHSN for the FY 2014 payment determination and hospitals will be collecting the NHSN surgical procedures for the IPPS starting January 1, 2012, as required for the Hospital IQR Program FY2014. SHEA supports a surgical site infection measure, but as noted, CMS can achieve alignment of measures across programs *as feasible*. In this setting, the procedures selected for Hospital IQR reporting for FY 2014 payment determination – colon surgery and abdominal hysterectomy – are not appropriate measures for outpatient payment

determination. We do not believe these procedures generally fit hospital outpatient departments (HOPD) or ambulatory surgery centers (ASC).

HOPD and ASC have quite different procedures than hospitals, given same-day discharges. The approved list of NHSN procedures includes applicability of many for inpatient and outpatient settings.⁽¹⁾ However, even the CMS volume list of outpatient procedures in the OPPI proposal demonstrates that many of these procedures are not carried out in outpatient settings and are therefore not applicable.

NHSN existing modules

SHEA notes that CMS specifically proposed that HOPD use the *existing* NHSN infrastructure and protocols that are already in place for this measure for reporting in the OQR program. However, HOPD use CPT codes for procedures, meaning that current SSI modules in NHSN using ICD coding would not be easily applicable as they currently exist. We are aware of efforts by CDC to develop a module that *would* fit this setting, including ICD and CPT codes, as well as one that meets the needs of ASCs to be addressed later. However, this revised module is not currently available and not expected before CY 2013.

NHSN for HOPD /ASC

Most HOPD and ACS are not familiar with the NHSN modules for current surgical procedures, and as noted, without CPT codes, NHSN would not be an efficient tool. Once CMS finalizes this proposal, HOPD staff members would need time to plan for, enroll, train and educate themselves on NHSN. It should also be noted that surveillance practices in outpatient settings differ significantly from those used with inpatients, as can be seen from CMS' own list of highest volume HOPD procedures. This adds additional surveillance challenges to ensure the follow-up of each patient to determine *whether an infection developed*, and if so, *whether it meets the NHSN definition for SSI*.

NHSN data validation

Although SHEA noted the discussion in the proposed rule for other measures' validation procedures, we noted no mention of *NHSN validation processes*. We would appreciate a discussion of CMS plans on this issue similar to those that have been discussed in the IPPI for CLABSI, but with more detail on how HOPDs would submit a list of patients and what format would be used. The proposed process appeared to be a time-consuming manual record identification process. CMS should consider discussing with CDC a process for drawing the sample directly from the information submitted to NHSN.

SHEA recommendations:

- SHEA recommends that CMS begin with one or two of the NQF-endorsed CDC/NHSN outpatient surgical procedures, based on volume and risk to ensure the process for collection, transmission, and, importantly, validation, have been analyzed and assessed carefully.
- Given the requirement to use NHSN modules well before there are assurances of NHSN capabilities for this new usage (e.g., CPT codes), plus providing sufficient time to enroll, educate and train the many outpatient facilities, development of IT vendor support to interface with NHSN in this adapted module for HOPD, *we would urge delay of the CY 2014 payment determination to CY 2015, using data collected between January 1, 2014 and June 30, 2014.*

CY 2015

NHSN HAI Measure Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431)

Background

CMS proposes to add one more measure in CY 2016, Influenza Vaccination Coverage Among Healthcare Personnel (HCP) (NQF#0431). CMS noted its proposal includes the addition of this measure to the Hospital OQR Program for the FY 2015 payment determination, using the NHSN component for HCP and refers to its discussion of the rationale for using this measure.

SHEA agrees that HCP can unintentionally expose patients to seasonal influenza if the HCP have not been vaccinated, and such exposure can be dangerous to vulnerable patients. SHEA recently published a position paper supporting mandatory HCP influenza vaccination as a condition of employment. ⁽²⁾ SHEA applauds CMS for adding this measure to the OQR program, noting that HCP in general continue to have low influenza vaccination rates and this measure adds needed attention to improvement.

Although we support the public reporting of HCP vaccination rates as an effective way to capture regional trends and bring more attention to this public health issue, we must also acknowledge the complexity and labor intensity for the *collection* of this information in the current NHSN HCP module when one considers the NQF (0431) specifications. ⁽³⁾

The challenge for HOPD in collecting and reporting data for this measure is that it can require retrieval of information from not only HOPD employees but other non-employee departments such as credentialed medical staff and medical education departments (students/trainees). HOPD human resources departments are also challenged with collecting and reporting employee influenza immunization obtained outside the HOPD, such as physician offices or stores. Studies demonstrate that hospitals, ambulatory care centers (ACS) and other care sites are challenged in collecting numerator and denominator data for any groups beyond employees versus credentialed non-employees or other non-employees such as students and volunteers, given the current NQF specifications.

We note that in the CMS FY 2012 IPPS final rule published August 1, 2011, that the NHSN-HCP module is being modified to *accept aggregate data*, but believe it is critical to test how well this modification works for inpatient settings before requiring its use in HOPD. In light of all the additional OQR issues, we suggest that the HOPD 2015 payment determination, using data collection for immunizations from October 1, 2013 to March 31, 2014 be moved to coincide with the proposed *ASC 2016 payment determination, using data collected from October 2014 to March 2015*, since this will provide additional time for improving methods to collect information, experience needed from inpatient settings using the revised NHSN module, while also coinciding with the influenza season.

SHEA Recommendations:

- SHEA *strongly* supports mandatory HCP vaccination, as well as public reporting of HCP vaccination rates as evidenced by SHEA's position paper supporting mandatory HCP influenza immunization.
- SHEA recommends that the HOPD 2015 payment determination, using data collection for immunizations from October 1, 2013 to March 31, 2014 be moved to coincide with the proposed *ASC 2016 payment determination, using data collected from October 2014 to March 2015*.

Ambulatory Surgery Center (ASC) Quality reporting Program Measure Selection CY 2014-2015

Background

SHEA appreciates that CMS is requiring a quality program for ASCs for the first time, noting the program would begin with 2014 payment determinations. CMS states that in its view, ASC facilities are similar to HOPDs in that both provide many of the same surgical procedures, and therefore similar standards and guidelines with respect to surgical care improvement can be applied. CMS points out the measures proposed for 2014 align closely with those discussed in CMS' Report to Congress on a Medicare ASC Value Based Purchasing (VBP) implementation plan.

Therefore, CMS proposes data submission on the Surgical Site Infection Rate (NQF #0299) measure for the 2014 payment determination would begin with events occurring on or after January 1, 2013 through June 30, 2013 and would again use CDC's NHSN as the reporting mechanism.

SHEA refers to our remarks above regarding HOPDs since most issues are indeed similar. We note however, that ASCs are generally not aware of NHSN capabilities and processes, and clearly need a system that uses CPT codes as well as resources to address the challenges noted earlier, that is, NHSN enrollment, education and training beyond the basic surveillance programs needed to input data. We also recognize that ASCs may concentrate on one particular procedure that is very specific, such as eye surgery. Yet there may be no NHSN listed procedure in the list of 30 possible surgeries that is applicable to such specialized centers, such as eye surgery. ⁽¹⁾

Given these similar but greater challenges for ASCs that have not had an OQR before now, SHEA recommends a delay for this measure in ASC. SHEA notes that CMS proposes to retain the FY 2014 measures into 2015, but for SSI, *SHEA recommends that SSI measures be delayed to CY 2015 payment determinations beginning data collection January 1, 2014 through June 30, 2014.*

SHEA recommendations:

- SHEA recommends that CMS begin with one or two of the NQF-endorsed CDC/NHSN surgical procedures to ensure the process for collection, transmission, and, importantly, validation, have been analyzed and assessed carefully.
- Given the requirement to use NHSN modules well before there are assurances of NHSN capabilities for this new usage including CPT codes as well as time to enroll, educate and train the many ASC facilities, *SHEA urges delay to CY2015 payment implementation using data collected between January 1, 2014 and June 30, 2014.*

CY 2016

NHSN HAI Measure Influenza Vaccination Coverage among Healthcare Personnel (HCP) (NQF #0431)

In addition to retaining the 10 measures proposed for the 2015 payment determination, CMS proposes to add one more measure in CY 2016, "Influenza Vaccination Coverage Among Healthcare Personnel (HCP)" (NQF#0431). CMS noted its proposal includes the addition of this measure to the Hospital OQR Program for the FY 2015 payment determination, using the NHSN component for HCP and refers to its discussion of the rationale for using this measure. SHEA comments for HOPD apply here as well, including again our expression of strong support for HCP influenza vaccination.

We repeat our HOPD recommendation for ASC, but with the hope that the feasibility of using this NHSN module may be more realistic by CY 2016, particularly for availability of CPT codes but also increased availability of vendor support and time for enrollment and implementation after CPT codes are incorporated into the current NHSN module. CMS states that for the 2016 payment determination, data collection would apply to immunizations from October 1, 2013 to March 31, 2014.

In our HOPD comments we noted that in the CMS IPPS final rule, NHSN is being modified to accept *aggregate data*, but believe it is critical to test how well this works for the inpatient setting before requiring this measure in ASC. SHEA would recommend in light of all the additional ASC OQR issues, that *ASC 2016 payment determination use data collected between October 1, 2014 and March 31, 2015 which will still include that influenza season.*

SHEA recommendations:

- SHEA *strongly* supports mandatory HCP vaccination, as well as public reporting of HCP vaccination rates, noting again our support for mandatory HCP influenza immunizations.
- In light of all the ASC OQR issues, and until NHSN capability is fully tested in the inpatient settings to accept aggregate data, and receive proper training to implement NHSN, *SHEA recommends that the ASC 2016 payment determination use data collected between October 1, 2014 and March 31, 2015.*

Hospital Value-Based Purchasing (VBP) - Inpatient Measures for FY 2014

Background

CMS proposes additions to the Hospital VBP Program, which was established under section 3001(a) of the Affordable Care Act. The outcome measures included mortality measures, AHRQ patient safety and inpatient quality indicators, and Hospital Acquired Conditions (HACs).

SCIP – INF-9 Postoperative Urinary Catheter Removal on Postoperative Day 1 or 2

In this rule, CMS proposes to add the above as one clinical process of care measure. CMS states that information about this NQF-endorsed measure first appeared on *Hospital Compare* in December 2010 and is among the NQF SCIP infection prevention measures included in the HHS Action Plan to Prevent Healthcare Associated Infections. This SCIP measure meets the criteria for VBP.

SHEA recommendation:

- SHEA supports the inclusion of this measure.

HAC Measures

Background

CMS proposes a different performance standards methodology for the eight HAC measures that were adopted in the final rule for the FY 2014 VBP Program than the methodology used for the other measures. Citing data on the rarity of HAC occurrences, CMS reports that if the methodology that was

finalized for the mortality measures were used for the HACs, the achievement threshold for each of the measures would be zero. According to CMS, data for October 1, 2008-June 30, 2010 show that one-quarter of hospitals had no reportable occurrences of any of the HACs, and at least one-half had no occurrences on six of the eight HACs. CMS proposes that for the single combined HAC measure, achievement and improvement thresholds and benchmarks would be established based on hospital combined performance on seven or eight measures as applicable.

SHEA continues to have serious concerns with the CMS use of HAI-HACs as noted in past comments, to include vascular catheter-associated bloodstream infections (BSI) and catheter-associated urinary tract infections (CAUTI) among the HACs.

SHEA was pleased to see in the IPPS final rule addressing CAUTIs, that it is indeed considering retirement of claims-based version of CAUTIs as quoted in this comment from the Final FY 2012 IPPS rule: “because the topic of HAIs is of great importance, and a large quantity of data for the NHSN version of the measure will not be available to CMS for some time, we will continue to utilize the claims-based measure until such time as the NHSN version is available to CMS. *We will seek an appropriate time to retire the claims-based version of the measure taking into account the needs of, and impact on other programs, such as the Hospital VBP Program.*”


In the meantime, combining the HACs into a single measure may further complicate the meaning of the measure and be potentially misleading to consumers since the removal of claims-based version data will not occur for some time as noted above.

SHEA recommendation:

- SHEA urges CMS to consider the impact of a single measure that continues to include claims-based HAI data until NHSN rate-based data CLABSI and CAUTI meet the VBP criteria. Exclusion of HAI-HAC measures will likely not occur before FY 2015. *SHEA recommends removal of HAI-HACs from the seven or eight measures if combined into a single measure.*

SHEA appreciates the opportunity to provide input and we look forward to continuing to working with CMS as it continues efforts to improve the quality of healthcare delivery, contain costs and prevent HAI.

Sincerely,



Steven M. Gordon, MD
President

References

- (1) NHSN list of approved surgical procedures- Inpatient and Outpatient, 2011. Surgical Site Infection (SSI) Event, Table 1. *cdc.gov/nhsn*. August 10, 2011. Available from: <http://www.cdc.gov/nhsn/PDFs/pscManual/9pscSSICurrent.pdf>

- (2) Talbot T., Babcock H., Caplan A., Cotton D., Maragakis L., Poland G., Septimus E. Revised SHEA Position Paper: Influenza Vaccination of Healthcare Personnel. *Infect Control and Hosp Epidemiol* 2010; 31(10):987-995.
- (3) NQF specifications for NQF 0431. Influenza vaccination coverage among healthcare personnel (CDC) time-limited endorsement Appendix A—*Specifications of the National Voluntary Consensus Standards for Influenza and Pneumococcal Immunizations National Quality Forum, 2008*, National Quality Forum. Available from:
http://www.qualityforum.org/Publications/2008/12/National_Voluntary_Consensus_Standards_for_Influenza_and_Pneumococcal_Immunizations.aspx