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March 8, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: Medicare Value-Based Purchasing Program

Dear Dr. Berwick:

The Society for Healthcare Epidemiology of America (SHEA) appreciates the opportunity to provide guidance to the Centers for Medicare & Medicaid Services (CMS) on the formation of the national inpatient value-based purchasing program (VBP), per the Patient Protection and Affordable Care Act (ACA) of 2010.

SHEA was founded in 1980 and represents a growing and active membership of physicians and other healthcare professionals responsible for patient safety and quality improvement. The Society works to maintain the utmost quality of patient care and healthcare worker safety in all healthcare settings, applying epidemiologic principles and prevention strategies to a wide range of quality-of-care issues.

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. 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. 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 will concentrate comments provided here primarily in that area of the proposed program.

FY 2013 Measures

Process measures

Hospital-acquired infections SHEA believes that the measures CMS is proposing to include for payment in FY 2013 meet the criteria included in the Patient Protection and Affordable Care Act (ACA) of 2010. Specifically, we agree CMS' inclusion of the SCIP measures noted below fulfill the statutory requirement to include HAI "as measured by the prevention metrics and targets established in the HHS Action Plan to Prevent Healthcare-Associated Infections (or any successor plan)."

Recommendation: We concur with CMS' belief that the SCIP-Inf-1; SCIP-Inf-2; SCIP-Inf-3; and SCIP-Inf-4 measures meet the statutory requirements and should be included as infection measures in the FY 2013 VBP program.

Outcome Measures

Lack of inclusion of outcome measure: Central line-associated bloodstream infections (CLABSI)

With the implementation of CMS' Hospital Inpatient Quality Reporting (IQR) program, approximately 4000 hospitals in the U.S. will report data on CLABSI in ICUs through the CDC's National Healthcare Safety Network (NHSN), a process that began January 2011. In the FY 2011 IPPS, CMS required the use of NHSN as a method of collecting and providing CLABSI data using standardized definitions and methodology, with the stated intent that this measure was being added for public reporting and considered for reimbursement within the VBP program in FY 2013. CDC/NHSN is on schedule to provide data to CMS. Yet this measure is neither included nor mentioned by CMS in its proposed VBP program. In its proposal, CMS provided specific time periods for baseline reporting and performance data for FY 2013 and FY 2014 as statutory requirements to meet VBP criteria for payment for a number of measures. It is speculated that CMS did not comment due to these criteria which appear to delay use of the NHSN CLABSI data for VBP until after FY 2014. However without any comment, the intent of CMS is not clear.

Recommendation: SHEA requests that CMS provide some comment or explanation in light of the current requirement by CMS that data collection via NHSN begin January 2011 for CLABSI and surgical site infections to begin in 2012.

FY 2014 Measures

Hospital-Acquired Conditions (HACs)

CMS proposes to add three mortality, eight hospital-acquired conditions (HACs) and nine Agency for Healthcare Research and Quality (AHRQ) patient safety indicators (PSIs) and inpatient quality indicators (IQIs) measures to the VBP program for payment in FY 2014. SHEA has major reservations about the inclusion of any HAC measure CMS plans to integrate into the VBP program as quality measures, as well as their interaction with other payment policies. In particular, SHEA

views the two HAI HACs and their proposed use as quality measures in VBP as highly problematic.

- **Quality measure methodology disparities and confusion** SHEA supports the inclusion of risk-adjusted, rate-based measures in the VBP program. However, the HACs include two infections in which information is obtained from claims data: vascular-catheter associated bloodstream infections (abbreviated here as CA-BSI) and catheter-associated urinary tract infections (CAUTI). These claims-based HACs, specifically, the HAC CA-BSI will generate consumer confusion since they appear so similar to CLABSI data collected under the IPPS requirement using NHSN methodology. The methodology used in claims data to report these HACs cannot provide meaningful data to measure efforts to improve, nor make valid interhospital comparisons, and is true as well for CAUTI. (1) Further, CMS itself noted limited accuracy of the HAC claims measure to identify CAUTIs in past IPPS comment communications when measuring impact of “present-on-admission” codes.

SHEA believes CMS does understand that risk-adjusted and rate-based HAI measures such as CDC/NHSN defined CLABSI are true quality indicators that can measure improvement as promoted by HHS itself in its support of expanding programs such as Keystone’s HAI reduction program to all 50 states. SHEA has urged CMS in the past to remove HAI measures from HACs when HAI measures are reported as quality measures on Hospital Compare. In general, the process for selecting quality measures should not be based on unexamined claims data; such measures should undergo validation studies demonstrating their value, and be endorsed by the National Quality Forum (NQF).

Recommendations: 1) SHEA questions the accuracy of measures that rely on claims data for public reporting and payment purposes, and recommends that if CMS still intends to use some HACs in Hospital Compare and later in VBP, it should release revised, detailed measure specifications immediately and provide ample time for the field to verify the results. 2) SHEA urges the removal of all HACs, but *particularly* vascular-catheter associated bloodstream infections and catheter-associated urinary tract infections (CAUTI) from VBP based on their inappropriate use as quality measures. 3) SHEA also restates earlier requests to remove HAI-related measures from the category of HACs until validation studies can be performed demonstrating their value and endorsed by NQF.

- **Financial impact** Use of HACs for VBP also has major financial consequences to hospitals. The HAC list overlaps in its entirety with the existing CMS policy that prevents a HAC from qualifying as a case for a higher tier Medicare-Severity Diagnosis Related Group. As these measures are integrated into the Hospital IQR and VBP programs, CMS should discontinue them in the existing HAC policy to the extent that they overlap and should not consider them for the one percent payment reduction that will be implemented in FY 2015. SHEA agrees that CMS should retain the *low-frequency events* that do not lend themselves to rate-based measurement in the existing HAC policy such as air embolism and transfusion reactions. However, CMS should then exclude such HACs from the Hospital IQR and VBP programs. Adding HACs to a VBP program places the hospital at risk of not scoring sufficiently in both

the achievement and improvement ranges, and penalizes the hospital a second time for the same measure.

Recommendations: SHEA: **1)** urges CMS to structure the three policies that involve HACs reporting and reimbursement in a manner that ensures each one is mutually exclusive and hospitals are not penalized under more than one policy for the same HAC. **2)** SHEA supports maintaining low frequency events in the existing CMS HAC policy and not in VBP. SHEA therefore urges removal of the vascular-catheter associated bloodstream infections and catheter-associated urinary tract infections (CAUTI) HACs from VBP based on *both quality and financial considerations* until validation studies can be performed demonstrating their value and endorsed by NQF.

Agency for Healthcare Research and Quality (AHRQ)

Among the list of proposed AHRQ measures are the inclusion of AHRQ composite measures:

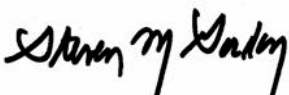
- Complication/patient safety for selected indicators (PSI composite)
- Mortality for selected medical conditions (composite)

The AHRQ PSI composite measure includes all of the proposed individual PSI measures, along with other measures not specifically proposed by CMS. Although the PSI composite measure is NQF endorsed, six of the eleven individual PSI measures have not been NQF endorsed and the composite includes infection-related measures. If CMS follows the current AHRQ methodology to calculate the PSI composite measure, the five measures proposed will account for sixty percent of the weighted composite. Thus, it appears that these measures will be doubly-counted within VBP for determining a performance standard and score for the hospital. Further, additional measures will be used to determine the score that were not explicitly called out in the proposed rule. A parallel process occurs with the mortality for selected medical conditions as well, with a similar impact.

Recommendation: SHEA urges CMS to include the AHRQ PSI and the mortality composite measure for public reporting purposes only, but remove them from the VBP reimbursement for reasons discussed.

We thank you for consideration of our concerns.

Sincerely



Steven M. Gordon, MD
SHEA President

(1) Zhan, Elixhauser, Baine et al. Identification of hospital-acquired catheter-associated urinary tract infections from Medicare claims: Sensitivity and positive predictive value, 2009. *Medical Care* 47(3): 364-369.