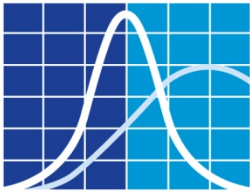

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June 6, 2011

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: 42 CFR Part 425: Medicare Program; Medicare Shared Savings Program for Accountable Care Organizations

Dear Dr. Berwick:

The Society for Healthcare Epidemiology of America (SHEA) is pleased that CMS is offering various healthcare incentive options including the proposed Accountable Care Organizations program which represents one of the best hopes for coordinating care in the fee-for-service system, while improving quality and reducing costs. Furthermore, SHEA appreciates the opportunity to provide input to the proposed rule on Medicare Shared Savings Program for Accountable Care Organizations.

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.

The Society welcomes federal efforts to improve the quality of patient care and appreciates that there are many major quality care aspects to the ACO proposal that deserve attention. SHEA

SHEA Headquarters *1300 Wilson Boulevard, Suite 300 • Arlington, VA 22209 • Phone: 703-684-1006 • Fax: 703-684-1009 • E-mail: info@shea-online.org*

looks forward to continuing to assist in these efforts by sharing our expertise in the prevention of healthcare-associated infections (HAI) and our comments will focus primarily on the HAI-related quality measures.

Value Metrics

CMS proposes to use 65 performance measures in year one of the ACO program, with ACOs required to report full and accurate data for those measures, but not meet any specific performance target. For subsequent performance periods, ACOs may also be expected to exceed certain minimum performance levels for each ACO performance measure then in use.

We believe that measurement is central to determining the success of the ACO program and monitoring for unintended consequences. However, measurement should be purposeful, meaningful and avoid undue burden on providers. CMS should focus on automated measures that assess the "value" of care. At this time, we do not have many outcomes-based, population-level measures across the continuum (including post-acute care, long-term care and hospice care) available that have been tested and validated. On the contrary, many of the existing measures focus on process of care and rely on the labor-intensive process of manually-abstracting data from medical charts.

> **SHEA recommends** that CMS should make it a priority to identify gaps and develop broad-based measures, including electronic specifications, which can be applied on a population basis.

Initial Measures - General

The magnitude of the proposed measures in the first year of the program is overwhelming. Although we appreciate that CMS has largely used measures with standard definitions that have been tested and are in wide use (including other Medicare programs), the number of measures required is far greater than the initial Physician Group Practice demonstration and Hospital Inpatient Quality Reporting (IQR) program, both of which have been in operation for more than five years. We recognize that the first year of the program is pay for reporting rather than performance, but this still poses a significant burden on newly formed partnerships that are forging new ground in interoperability.

> **SHEA recommends** CMS should reduce the number of measures in the initial measure set. **SHEA urges** CMS to identify the best initial measures for relevant populations and phase in new measures each year, similar to the Hospital Inpatient Quality Reporting Program.

Patient Attribution

One of the hallmarks of quality improvement is to identify the patient population toward which improvements will be targeted. We are concerned that, in the current ACO guidelines, patient attribution will be assigned retrospectively, after the performance period has passed. This will make it extremely difficult for ACOs to track and trend their progress over time and initiate rapid improvement methodologies.

SHEA suggests that patient populations be assigned prior to the start of measurement/reporting requirements.

For subsequent comments, SHEA will focus on infection-related measures only

Prevention Quality Indicators

The list of proposed AHRQ Prevention Quality Indicators (PQIs) includes:

- PQI #11 All non-maternal discharges of age 18 years and older with ICD-9-CM principal diagnosis code for bacterial pneumonia, per 100,000 population.
- PQI #12 All discharges of age 18 years and older with ICD-9-CM principal diagnosis code of urinary tract infection, per 100,000 population.

The AHRQ Guide to PQIs notes: "These indicators serve as a screening tool rather than as definitive measures of quality problems. They can provide initial information about potential problems in the community that may require further, more in-depth analysis." We are concerned that PQI measures would be used to assess the quality of care provided by an ACO rather than as a screening mechanism. Below is a table summarizing the sensitivity of the infection-related PQI measures:

Indicator Name (Number)	Risk Adjustment Incorporated	Literature Review Findings
Bacterial Pneumonia Admission Rate (PQI 11)	Age and sex.	? Proxy ? Unclear construct ? Easily manipulated ✓Unclear benchmark
Urinary Tract Infection Admission Rate (PQI 12)	Age and sex.	? Proxy ? Unclear construct ? Easily manipulated ✓Unclear benchmark

Notes under Literature Review Findings:

Proxy – Indicator does not directly measure patient outcomes but an aspect of care that is associated with the outcome; thus, it is best used with other indicators that measure similar aspects of care.

Unclear construct – There is uncertainty or poor correlation with widely accepted process measures.

Easily manipulated – Use of the indicator may create perverse incentives to improve performance on the indicator without truly improving quality of care.

Unclear benchmark – The "correct rate" has not been established for the indicator; national, regional, or peer group averages may be the best benchmark available.

? – The concern is theoretical or suggested, but no specific evidence was found in the literature.

✓– Indicates that the concern has been demonstrated in the literature.

SHEA does not support inclusion of these measures until CMS provides detailed measure specifications and risk standardization methodology.

Hospital Acquired Conditions (HACs)

Because composite measures of harm can vary with the degree of documentation, coding these measures may not be suitable for judging relative performance. Although composite measures

can be useful measures to monitor changes over time, such composite measures may not be suitable for judging relative performance.

> **SHEA recommends** that metrics of patient safety, specifically the HACs if used, be used for monitoring and not as part of the performance score.

However, if CMS does use HACs, SHEA continues to have concerns in their use as one of two quality measures for patient safety, and in particular, as an untested composite.

Use of claims data: As SHEA has noted in comments to CMS on earlier proposed rules relating to the Medicare HAC policy, we are concerned with the use of administrative/claims data to identify HAI. The use of claims data for the determination of HAI-HACs has limited value in improving patient care because claims data are shown to be inaccurate in the identification of HAIs, do not provide precise identification of HAIs, nor do they provide information in a timely manner to provide effective treatment and prevention. (1) This results in questionable data comparison for end users for whom these reported data are intended as a guide. While we applaud federal efforts to improve the quality 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. Until CMS conducts studies that are validated and endorsed by the National Quality Forum (NQF) as quality measures, we believe CMS should retain only low-frequency events that do not lend themselves to rate-based measurement in the existing HAC policy, such as air embolism and transfusion reactions.

Use of NHSN data: For this reason, SHEA strongly supported the provisions in the FY 2011 final rule on the annual update to the hospital inpatient prospective payment system (IPPS) which identified two HAIs – central line-associated bloodstream infection (CLABSI) and certain surgical site infections (SSIs) – to be reported through the Centers for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN), using standard definitions and methodology, for Medicare reimbursement. We believe that this more accurate measurement approach should be applied to future infection-related measures as well.

Confusion from mixing definitions/data sources: After review of the ACO proposed rule, we again convey our concern with the confusion that could result from inclusion of any indicator measuring bloodstream related infection other than NHSN CLABSI, since CMS' recent determination in the CMS FY 2011 IPPS rule to utilize "CLABSI" reporting through NHSN for Medicare reimbursement as part of the Hospital IQR program. Although CMS' intent to use various catheter-related bloodstream infection indicators aims to utilize reimbursement policies to improve the quality of patient care, they have differing definitions and therefore would be reported using different kinds of data through different reporting systems. NHSN CLABSI definitions should be used so that benchmarks are consistent and reimbursement policies are equitable.

Composite complications: If the proposed HAC list is utilized in a composite, this would only contribute to the confusion. Since CLABSI is already being collected through NHSN for inclusion in the hospital IQR program, we recommend CMS utilize only CLABSI for bloodstream infection measures in the Medicare IPPS or any other CMS reimbursement program.

Further, these same observations apply to catheter-related urinary tract infections (CAUTI). That is, the HAC-CAUTI is also retrieved from claims data and we recommend only NSHN-defined CAUTI be utilized for any CMS reimbursement program such as value based purchasing.

Measure #24

This patient safety measure is described as a "Health Care Acquired Conditions Composite." This composite is a compilation of infectious and non-infectious related measures and combining these very different, complex measures into one single composite is a major concern. This proposed "outcome measure" is further complicated by being a "composite of a composite." Specifically, #24 is a compilation of 9 selected CMS HACs combined with NQF #531 which is AHRQ PSI 90, *already a composite in itself of 8 measures*.

Table 1 also indicates that these data are retrieved/submitted from either administrative "claims" data ***or*** CDC's National Healthcare Safety Network (NHSN). We have major concerns regarding how this complex composite measure can *truly* measure patient safety, provide a picture of performance and permit the ACO to identify targeted areas for future improvement based on one composite score. We believe the applicability of this major composite to the full spectrum of patient populations involved in this program is highly questionable. Patient risk for multiple types of infection varies widely over the spectrum of acute, pre-and post-acute care settings. Quality measures are important but only useful if they fit the population at risk. The immunizations as noted in #26 and #27 are useful but apply only to specific populations, and are an example of the challenge to measure quality over multiple populations. However, we do not believe the composite can meet the intent any better. We list the components of the proposed composite below and offer some additional observations and recommendations.

Elements of Measure #24: Patient Safety - Health Care Acquired Conditions Composite (9 indicators plus one composite):

1. Foreign Object Retained After Surgery
2. Air Embolism
3. Blood Incompatibility
4. Pressure Ulcer, Stages III and IV
5. Falls and Trauma
6. Catheter-Associated UTI
7. Manifestations of Poor Glycemic Control
8. Central Line Associated Blood Stream Infection (CLABSI)
9. Surgical Site Infection
10. **AHRQ Patient Safety Indicator (PSI) 90 Complication/Patient Safety for Selected Indicators (a composite with 8 indicators in itself) – used for IQR reporting**
    - Accidental puncture or laceration
    - Iatrogenic pneumothorax
    - Postoperative DVT or PE
    - Postoperative wound dehiscence
    - Decubitus ulcer
    - Selected infections due to medical care (PSI #07: Central Venous Catheter-related bloodstream Infection)

- Postoperative hip fracture
- Postoperative sepsis

We note the following important observations based on the proposed #24 composite Measure above:

1. We are not aware that any set of HACs has ever been used and/or validated as a composite.
2. We are not aware that the combined set of HACs *plus* the ARHQ composite has ever been combined into a single composite and validated as a useful performance measure.
3. The selected 9 HACs do not include the HAC DVT post hip-knee surgery. We presume this HAC was not selected since it is part of the AHRQ PSI #90 composite as "Post-operative DVT or PE."
4. By the same logic (if a correct assumption) it seems inconsistent to include 'HAC pressure ulcers (Stages III and IV)' *as well as the* AHRQ PSI 90 which *also* includes 'decubitus ulcer.'
5. In the set of selected 9 HACs the HAC-HAI vascular catheter bloodstream infection appears to have been replaced by the NSHN defined central line-associated bloodstream infection (CLABSI) measure. The composite is instead complicated by the inclusion of yet another bloodstream measure from the AHRQ patient safety indicator set, PSI 90, which *also* includes PSI 07 Central Venous Catheter-Related Bloodstream Infection. Further, PSI 90 includes post-operative sepsis—a bloodstream infection. This mix of indicators simply adds confusion to what is actually being measured and at minimum overlaps and possibly duplicates bloodstream infection measurement. This approach to measuring catheter-related bloodstream infections magnifies the concerns expressed earlier for using and now mixing both claims and administrative data into a single composite to measure quality. SHEA continues to recommend use of only CDC defined CLABSI as CMS required as of January 1, 2011. We continue to support the consistent use of this specific measure in all proposed rules pertaining to HAIs.
6. The PS #24 HAC list includes HAC-HAI Catheter-Associated UTI and Surgical Site Infections from claims data. SHEA recommends standardization of all infection related measures by using the NHSN measurement system for data definitions and data submission. SHEA also recognizes that at the current time (though this is changing in the near future) the most easily retrievable NHSN data are the CLABSI data being submitted to CMS via CDC. We trust that CMS will gradually remove the rate-based, risk-adjusted vascular catheterization BSI, CAUTI and SSI from the HACs and place them in the IQR quality measure program as NHSN measures.
7. Given that the measurement requirement for ACOs is a significant undertaking, and one that should not be discounted due the need for sophisticated informatics capabilities, CMS should take great care not to exceed ACOs' capabilities in this area, especially given that most of the 65 measures cannot readily be extracted from the electronic health record (EHR) and this number is excessive.
8. The lack of risk adjustment for the claims data measures is notable especially in light of a composite score that will include numerous unrelated measures.

The proposed ACO quality measure set as a composite score lacks clarity and does not provide useful or timely information to improve performance. The lack of harmonization of these measures creates complexity and confusion.

Data sources: The HAI-HACs identified in the proposed quality measures include similarly named infections in which information is obtained from different sources using different definitions. Specifically PS1-07 - Central venous catheter blood stream infection is obtained from claims data while CLABSI data are collected using NHSN methodology.

SHEA recommendations for Patient Safety measure #24
In light of the current status of infection prevention measures and lack of interpretation of a "composite of a composite," SHEA urges CMS to:

1. Use for monitoring eight of these nine HAC measures (minus CLABSI) as currently defined in the IQR program from claims data but e*ach HAC should be submitted separately as currently required for IQR program.*
2. Use CLABSI from NHSN as noted—but data should be listed and submitted as a *separate patient safety measure altogether* much like the patient safety measure #25, the CLABSI Bundle.
3. Delete AHRQ PSI #90 since it overlaps with several HAC measures and imposes redundant, duplicative effort.

Proposed Measure #25: Patient Safety - Health Care Acquired Conditions:

CLABSI Bundle: This measure is listed as NQF #298 and as a process measure in which it is stated it can be retrieved/ submitted from either claims data or CDC National Healthcare Safety Network. The CLABSI Bundle is in fact an NHSN process measure: "adherence to central line insertion practices" or "CLIP". As a process measure it is not clear how this could be retrieved from claims data. It also needs wider implementation and validation. The CLIP measure is only now being considered for the IPPS 2012 quality measure.

SHEA Recommendation We suggest that this measure not be included at this time, given the volume of total quality measures and the recommendations for #24.

In conclusion, SHEA supports and proposes consideration of the following:

- HAI outcome indicators should be chosen from NHSN defined indicators, for example, central line-associated bloodstream infections as opposed to vascular catheter bloodstream infection *or* in this case, PSI 07 central venous catheter-related bloodstream infection, and data should be retrieved from the NHSN database.
- The exclusive use of administrative "claims" data is not a precise measure for identifying HAI and should not be used as a sole source for HAI identification.
- SHEA believes strongly that the measures in #24 should not be compiled into one composite. Our concerns center on the inability to obtain an accurate measure of patient safety and most importantly, a clear concise identification of areas that need to be

improved. The rapid and clear identification of areas for improvement would be beneficial to the ACOs and to facilities.

- We therefore ask that a review of the proposed measures in Table 1 be performed with the goal to eliminate duplicate measures as this duplication may cause confusion, inaccurate results and not enable involved organizations to measure improvement.
- It is recommended that when choosing an HAI-related quality indicator, CMS utilize the same methodology for data collection throughout all of its quality programs.
- Finally, ACOs are intended to increase quality and efficiency and better coordinate care. We believe, however, that the complexity and lack of validation for the composite scoring methodology, particularly combining HACs, NHSN data and AHRQ patient safety indicators will detract from this intent since it will be difficult to identify and target opportunities for improving patient outcomes thus discouraging organizations or groups from participation.

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

Sincerely,

Steven M. Gordon
President

References

1. Sherman ER, Heydon KH, St. John, KH et al. Administrative Data Fail to Accurately Identify Cases of Healthcare-Associated Infection. *Infection Control and Hospital Epidemiology*. 2006;27(4):332-37.