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June 17, 2010

Ms. Marilyn Tavenner
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

Re: CMS-1498-P, *Medicare Program; Proposed Changes to the Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Proposed Fiscal Year 2011 Rates; Proposed Rule,* May 4, 2010.

Dear Ms. Tavenner:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association comprised of 13,000 infection preventionists, wishes to thank the Centers for Medicare and Medicaid Services (CMS) for the opportunity to provide input into its proposed 2011 Inpatient Prospective Payment System (IPPS) changes.

While 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 several issues raised by CMS related to healthcare-associated infections (HAIs).

Our comments primarily reflect the concerns of our members in hospitals and health systems who oversee infection prevention programs and have a vested interest in the effective operation of the IPPS and the prevention of HAIs. We will primarily address the infection-related hospital-acquired conditions (HACs) and the proposed quality measures for Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) for 2011 and 2012 that involve HAIs, including the proposal to begin using Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN) data for payment determination for selected HAIs beginning in FY 2013.

Background

The Deficit Reduction Act (DRA) of 2005 required CMS to identify by October 1, 2007 at least two preventable complications of care that could cause patients to be assigned to a complication or co-morbidity (CC) diagnosis-related group (DRG). The conditions must be high-cost, high-volume or both, result in the assignment of a case to a DRG that has a higher payment when present as a secondary diagnosis, and be reasonably preventable through the application of

evidence-based guidelines. This CMS reimbursement policy currently covers 10 hospital-acquired conditions (HACs).

Current status

This year, CMS is not proposing to add or remove HACs. Rather, the agency stated it is focused on evaluating the impact to date of the HAC policy. We note that CMS had provided analysis of nine months of present on admission (POA) coding and we find the data to be focused on cost impact of POA codes. APIC encourages CMS to consider its POA analyses to ensure retained conditions are, indeed, high cost and/or high volume. For example, the high proportion of catheter-associated urinary tract infections (CAUTI) coded as POA (83%) may be a better indicator of coding inconsistencies than high rates of HAIs. The appended article by Meddings et al. may be useful in this analysis. In addition, we would like to encourage CMS to review the impact of findings related to over-culturing on admission, antimicrobial use, and other admission screening for multidrug resistant organisms.

(Meddings et al. *Infect Control Hosp Epidemiol* 2010; 31(6):627-633).

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- **APIC supports the CMS evaluation of the HAC policy and believes a robust program evaluation must continue to be conducted before CMS considers adding any additional categories of HACs.**

- **APIC suggests these data indicate the need for sufficient training on new codes used in claims reporting and believes these results demonstrate the need for sufficient time for training on any new electronic media.**

APIC appreciates that CMS laid out its vision for the Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) program for FYs 2012, 2013 and 2014 in the proposed rule as suggested by APIC in previous years. Specifically, CMS proposes to retire one measure for FY 2011, add 10 measures in FY 2012, and add three measures in FY 2013, as well as requiring participation in one of four registries and adding four measures in FY 2014. However, the plan continues to lack sufficient detail to provide well informed comments. For example, while CMS lists eight possible HAC "measures" for FY 2012 there are no details on how the measures would be constructed. We are also concerned that, while CMS is developing a rule encouraging the meaningful use of electronic health records (EHRs), this IPPS rule does not outline the relationship between hospital quality reporting in the RHQDAPU program and meaningful use of EHRs going forward. The long-term goal should be to transition from RHQDAPU to meaningful use of EHRs.

- **Recognizing that at this time most facilities do not have EHRs and those that do may have systems in their infancy, APIC continues to urge CMS to follow a more methodical framework to prioritize and integrate measures into one program, in**

order to reduce the burden on hospitals trying to implement both programs and measures at the same time.

Measures for FY 2011

APIC agrees with the CMS proposal to retire the Agency for Healthcare Research and Quality (AHRQ) mortality measure for Selected Surgical Procedures Composite for FY 2011. AHRQ itself noted in a June 2009 report that the measure is not appropriate for comparing hospitals' performance.

Measures for FY 2012

CMS proposes eight hospital-acquired conditions (HAC) out of 10 HAC measures:

- Foreign Object Retained After Surgery,
- Air Embolism,
- Blood Incompatibility,
- Manifestations of Poor Glycemic Control,
- Pressure Ulcers Stages III & IV,
- Vascular Catheter-Associated Infection,
- Catheter-Associated Urinary Tract Infection, and
- Falls and Trauma.

Although six of these conditions represent one-time events, two of the conditions – vascular catheter-associated infection and catheter-associated urinary tract infection – are rate-based conditions. CMS proposes moving these two infection-related conditions from the HAC policy to the RHQDAPU program beginning in FY 2012. APIC supports the *concept* of including HAI-HACs in RHQDAPU, while retaining the non-risk adjusted conditions under the existing HAC policy. However, CMS has not clearly specified how these metrics would be constructed. For example, CAUTI is endorsed by the National Quality Forum (NQF), but it is unclear if CAUTI is the same as the nursing sensitive measure "Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients per 1000 catheter-days" (NQF 0138) or how vascular catheter-associated infections would overlap with "Central line-associated blood stream infection (CLABSI)" (NQF #0139). In addition, CMS proposes collection of HAI measures through NHSN.

- **APIC supports data collection through NHSN (see discussion under "Measures for FY 2013" below), but we are concerned that publishing administrative data via the HAC list and having hospitals report to NHSN while collecting data in another format could lead to confusion for all stakeholders involved.**

- **APIC urges CMS to remove vascular catheter-associated infections and CAUTI conditions from the existing HAC policy once they are defined and transitioned into RHQDAPU.**

CMS invites comments on the retirement of selected Surgical Care Improvement Project (SCIP) measures:

APIC believes that retirement should occur when the standard of care has changed, when performance of the preponderance of hospitals is at or very near perfect, or when an outcome measure is integrated that can take the place of a process measure (e.g. urinary tract infection rates versus catheter removal timing). Data collection should not continue, due to burden, unless there is a compelling argument that the standard of care may deteriorate if collection and monitoring does not continue. Thus, APIC agrees that the following measure is currently reported as highly reliable and should be retired:

- SCIP-Infection-6: Appropriate hair removal for surgery patients

The performance of the following measures are not highly reliable; however, current literature shows the measures in their current format may not be impactful on reducing surgical morbidity and mortality. We therefore urge CMS to review current literature and either modify or retire these measures:

- SCIP-Infection-2: Prophylactic antibiotic selection for surgical patients
- SCIP-Infection-4: Cardiac surgery controlled post-operative glucose
- PN-3b Blood culture performed before first antibiotic received in hospital

Measures For 2013

CMS proposes requiring hospitals to participate in NHSN by January 1, 2011 and publicly report in FY 2013

1. Central Line Associated Blood Stream Infection (CLABSI) (NQF #0139)
2. Surgical Site Infection (SSI) (NQF # 0299)

APIC is a proponent of NHSN, a free, publicly available system, and supports participation in NHSN which can transfer data directly to CDC. It also supports the use of data mining systems that further assist hospitals to electronically transfer NHSN data to the CDC, and then to the CMS QualityNet without reentry of data.

CMS notes that currently 21 states mandate public reporting of infections through NHSN; however, it is not clear if all 21 states mandate reporting of CLABSI, and which procedures of the 37 categories of NHSN operative procedures are monitored for SSI in a given state. Further, hospitals that are not currently participating in NHSN did not budget for the needed staff or data products to assist in the NHSN data input process. This timeframe would provide less than five months for most hospitals to acquire equipment and staff for which they did not budget, provide training, and begin data collection using a new reporting system by January 1, 2011 to submit beginning October 1, 2012 (FY 2013) for reimbursement. APIC is concerned about CDC's capacity to bring on more than 1,000 hospitals in this short timeframe *and* establish a connection between CMS and CDC for the agencies to share this information.

In addition, enactment of the Patient Protection and Affordable Care Act (healthcare reform) established a hospital value-based purchasing (VBP) program beginning in FY 2013 that sets

incentive payments under the Medicare program to hospitals that meet certain performance standards. HAIs, as measured by the metrics and targets in the Department of Health and Human Services (HHS) HAI Action Plan, are included in the initial set of measures. The plan includes CAUTI, Methicillin-resistant *Staphylococcus aureus* (MRSA), *Clostridium difficile* infection (CDI), ventilator-associated pneumonia (VAP), surgical site infections (SSI) and CLABSI, but notes that the measures are at different stages of development. Given the number of HAI measures that will be required from the HHS HAI Action plan to be in place for the VBP program eligibility by FY 2013, use of NHSN will be overwhelming and participation will be labor intensive since each data accession requires patient and chart assessment. The processes to directly link electronic surveillance activities and electronic health records to NHSN, and techniques that are rapidly evolving to further automate this data collection process are close, but not yet complete. In addition, we believe CMS should consider, as mentioned earlier, that few hospitals have advanced EHRs or data mining systems.

In order to comply with the requirements of the healthcare reform law and support CMS's transition to using NHSN data for Medicare payment determination for HAIs, APIC recommends incremental movement of HAIs to the RHQDAPU program by adding NQF-defined SSIs and CAUTI in FY 2012, which are NQF-endorsed and risk-adjusted. We also look to CMS for assurance that NHSN data will be validated by personnel with experience in infection prevention processes. *It is important that hospitals are able to continue using the NHSN software or other systems that generate reports to submit to NHSN without the need for full manual abstraction of data to satisfy this requirement or joining a registry.*

- **Given these hurdles, and the lack of advance warning to hospitals, APIC believes CMS should not require more than one measure starting January 1, 2011 for payment in FY 2013. In order to satisfy the Congressional mandate, yet balance the concerns stated above, APIC believes CMS should finalize its proposal to collect *only* CLABSI for data collection starting January, 2011 since CLABSI is the *only* measure that is sufficiently through the consensus process and can be adopted quickly to meet the statutory requirement without unduly burdening hospitals.**

- **APIC strongly urges CMS to ensure that the existing HAC policy, the infections in VBP, and the one percent reduction to payments for HACs starting in FY 2015 remain mutually exclusive policies with separate conditions in each. The long-term goal of infection data collection and reporting should be to cultivate more global hospital-wide assessments of harm in order to improve patient safety and healthcare quality, rather than targeting individual organisms or conditions.**

The other HHS HAI Action Plan measures (CAUTI, SSI, CDI, MRSA, and VAP) are not yet ready for inclusion in the RHQDAPU and VBP programs and should be phased in over time. Each of these can be collected through NHSN once the measures are further developed and the remainder of the hospitals begin participating in NHSN. However, at this point it would be essentially impossible to include MRSA, CDI and VAP in the programs. These require clinically enhanced data to sufficiently identify whether the infections are community- or hospital-

acquired, and such measures are still in development. In addition, VAP still lacks a clear definition. CMS should consider SSI and CAUTI as the second wave of infections to be included in RHQDAPU and then value-based purchasing, as these are well-specified and many hospitals have experience in reporting these measures.

CMS also proposed that hospitals collect SSI in 2011. However, we do not believe that hospitals can undertake this measure in 2011 given the constraints outlined above. The HHS HAI Action Plan never intended hospitals to collect data on *all* surgical procedures, and CMS has not defined which procedures will be required. The manual collection of these infections through chart-abstraction for all conditions would be overwhelming to most facilities. It is critical for hospitals to select surgical procedures and determine priorities based on risks of their population and programs. NHSN provides the capacity to select procedures that fit large academic, as well as community and specialty hospitals with different populations and surgical procedures. Given the extensive elements that need to be collected to determine SSIs, hospitals need to balance the burden of prospective surveillance coupled with chart review for all *other* HAI measures proposed by CMS. APIC recommends that CMS and CDC undertake data analyses to determine which infection measurements are most likely to positively affect improvement, and then clearly provide options for selecting infections pertinent to each hospital's population and programs for submission to satisfy the requirement.

- **APIC recommends that CMS, with assistance from CDC, publish the top 10 high risk/high volume procedures as provided by published NHSN SSI rates and permit hospitals to select a subset (for example, one to three procedures) that fit their population.**

- **Clarification should be made whether any or all surgical procedures apply to specific populations like adult or pediatric populations, or both, such as those in non-children's hospitals.**

APIC hopes that HHS will release a revised HAI Action Plan later this year that provides some additional information on the measures and an appropriate implementation schedule and that CMS follows with a concrete plan within its future rulemaking.

Summary of APIC's proposed incremental submission plan:

We understand the intent of Congress is to submit HHS HAI Action Plan measures by October 1, 2012 (FY 2013) for eligibility in the VBP program. Given the constraints as outlined above and being aware of the efforts CDC is making to simplify the enrollment process for this web-based program, we propose the following submission plan:

1) **CLABSI** (NQF 0139) using the NHSN (NQF-endorsed nursing sensitive measure) for ICU and high-risk nursery (HRN) patients [for non-children's hospitals]: Central line-associated bloodstream infections per 1000 catheter days.

- Data collection January 1, 2011, with submission October 1, 2012 (FY 2013)

2) **Surgical site infections** (NQF 0299): Percentage of surgical site infections occurring within thirty days after the operative procedure if no implant is left in place, or within one year if an implant is in place, in patients who had an NHSN operative procedure performed during a specified time period, and the infection appears to be related to the operative procedure. (For the number of procedures to be determined, see APIC's earlier recommendation**.)**

- Data collection January 1, 2012, with submission October 1, 2013 (FY 2014)

3) **CAUTI** Nursing sensitive measure (NQF 0138): Urinary catheter-associated urinary tract infection for intensive care unit (ICU) patients per 1000 catheter-days.

- Data collection January 1, 2012, with submission October 1, 2013 (FY 2014)

4) **Remaining HHS HAI Action Plan measures** should be considered after further input and refinement from CDC, since they are either not yet NQF-endorsed or do not have clear definitions (such as VAP).

- **APIC believes it is prudent on all sides to address only one NQF-endorsed, measure (CLABSI) collected via NHSN for submission in FY 2013 until there is assurance that all hospitals are enrolled in NHSN. APIC recommends delay in the submission of SSI and CAUTI measures until FY 2014 for the reasons outlined above.**

- **APIC understands that during the transition of SSI and vascular catheter-associated infection from the HAC policy to the RHQDAPU program, these measures may require payment under the current HAC policy until the transition to RHQDAPU or VBP is complete. Once that system is in place we would expect that retrieval from claims data would cease.**

Registry overlap

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- **APIC strongly recommends the reconciliation of overlapping measures between NHSN and registries. The fields, though similar, must be exactly the same to avoid duplication of effort and confusion over interpretation through any participating database (registry) system.**

<u>Measures for 2014</u>

CMS proposes two vaccination measures:

1. Global Influenza Immunization
2. Global Pneumococcal Immunization

APIC supports influenza and pneumococcal vaccinations; however, implementation of these measures is quite complicated when applied to all populations. Recording the assessment of each patient for level of risk and contraindications, and assigning a status level needs to be considered and neither measure is NQF-endorsed at this time.

- **APIC urges that these two measures be reviewed by NQF before CMS determines if they should be considered for adoption.**

Measures for 2015

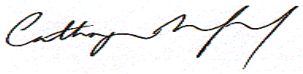
CMS proposes Influenza Vaccination of Healthcare Personnel

APIC applauds CMS for adding this measure to the RHQDAPU program. We note that "healthcare personnel" (HP) in general continue to have low influenza vaccination rates and support the addition of this measure to the RHQDAPU program. However, APIC suggests that the definition of HP be clearly defined. In recent CDC analyses it was noted that vaccination rates among hospital personnel were much higher than overall healthcare personnel rates. Although they all need to be higher, careful consideration of definition is imperative, given the impact on reimbursement just for hospitals. A threshold would need to be developed and exemptions must be made for facilities at times of vaccine shortage.

- **APIC recommends this measure be considered for future reporting but with much more specification and definition.**

We thank CMS for working to improve the quality of patient care. APIC stands ready to assist CMS with an approach that ties payment to prevention of HAIs based on associated actionable evidence-based practice guidelines. Please feel free to contact Denise Graham, APIC Executive Vice President, at 202-454-2617 or dgraham@apic.org.

Sincerely,



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