June 16, 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: 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 2012 Rates

Dear Dr. Berwick:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association comprised of 14,000 infection preventionists, wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed FY 2012 Hospital Inpatient Prospective Payment System (IPPS) and Long-Term Care Hospital Prospective Payment System changes. 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).

Our comments primarily reflect the concerns of our members in hospitals and health systems who oversee infection prevention and control programs and have a vested interest in the effective operation of the IPPS and the prevention of HAIs. We will primarily address the proposed quality measures for the Hospital Inpatient Quality Reporting (IQR) program for FY 2012 through FY 2015. APIC supports increased transparency, but we also note the need to educate consumers on this data and ensure that the information is truly meaningful in improving patient care outcomes.

We agree with CMS’s plan to retire SCIP-Inf-6 Appropriate Hair Removal for FY 2014 payment determination. We appreciate CMS’s effort to ease the burden of collection of chart-abstracted measures where appropriate thresholds have been obtained.

We are pleased that CMS is not adding any additional hospital-acquired conditions (HACs) in 2012. However, as APIC has noted in comments on earlier proposed rules relating to the Medicare HAC policy, we are concerned with the use of administrative/claims data to identify HAIs. For this reason, APIC 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 infections (CLABSIs) 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 note that the CMS FY 2012 IPPS proposed rule includes reporting of catheter-associated urinary tract infections (CAUTIs) through CDC/NHSN. We believe that this more accurate measurement approach should be applied to future infection prevention measures as well.

The use of claims data for the determination of HAI-HACs has limited value in improving patient care because claims data do not provide precise identification of HAIs, nor do they provide information in a timely manner to provide effective treatment and prevention. This results in questionable data comparison for end users whom these reported data are intended to 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. However, since vascular catheter-associated infection is still included on the CMS HAC list in the hospital value-based purchasing final rule and the FY 2012 hospital inpatient prospective payment system (IPPS) proposed rule, we again convey our concern with the confusion that results from continued use by CMS of both types of bloodstream infections in two separate documents. Furthermore, the addition of CAUTI reporting through both the CMS HAC list in Value-Based Purchasing and the FY 2012 IPPS rule creates additional confusion for end users. Both catheter-related bloodstream infections and CAUTIs have differing definitions and are reported using different kinds of data through different reporting systems.

**APIC recommendation:** APIC again recommends that CMS remove vascular catheter-associated infections and CAUTI conditions from the existing HAC policy once they are defined and transitioned into the Hospital IQR program.

### SSI Collection Beginning January 1, 2012.

CMS notes that the “Surgical Site Infection (SSI) measure is currently part of the FY 2014 Hospital IQR measure set, and data submission on the measure will begin with January 2012 events.” CMS has stated that they believe that phasing in the SSI measures will minimize the additional reporting burden on hospitals in States that do not currently mandate reporting of infection data to the CDC/NHSN, and will also allow time to address any measurement issues relative to the SSI measure. APIC supports CMS’s comment that it is important to phase in the SSI measures and that the select SSI measures be clearly defined.

**APIC recommendation:** APIC again recommends that CMS begins 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, before future expansions to add surgical procedures and additional measures proposed for FY 2014 and FY 2015.

### Proposed Measures for FY 2014 Payment Determination

CMS is proposing to adopt two additional HAI measures for the FY 2014 Hospital IQR measure set: (1) Central Line Bundle Compliance (NQF #0298): Central Line Insertion Practices (CLIP); and (2) Catheter-Associated Urinary Tract Infection (CAUTI) (NQF #0138).

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These proposed measures were developed and are currently collected by the CDC via the NHSN. Although CDC/NHSN is a web-based tool provided free of charge by the CDC to healthcare facilities, most facilities do not have surveillance technology that is capable of automated upload of data into CDC/NHSN. Use of Electronic Health Records (EHR), a platform that likely will facilitate efficient capture of key epidemiologic data elements, remains limited with estimates that as few as 9% of U.S. hospitals have a fully functional EHR. Even if and when EHR reaches a high proportion of implementation the most efficient collection of CLIP data elements will require an interface between CDC/NHSN with a facility’s EHR. This will also necessitate collaboration and allocation of resources by hospitals with vendors of healthcare informatics systems that currently coincide with major investments into EHR systems essential to meet meaningful use criteria. Therefore development and implementation of these systems requires extensive time and resource allocation. In addition, even use of surveillance technology, as highlighted by Grota and others, while making surveillance of HAIs more efficient, was available in only 23% of hospitals in California. More sophisticated systems such as a clinical data warehouse, which can enhance efficient collation of data that also supports meaningful use objectives, can require as much as 4,000 person hours to develop and make operational. This automation is increasingly critical for Infection Prevention programs as the number of HAI metrics CMS is adding or proposing continues to grow. To meet these additional requirements will require development, testing and refinement of automated surveillance technology that offers accurate case-mix adjustments and validation that such technology can capture criteria that meet epidemiologic HAI surveillance definitions from CDC/NHSN. Data that can be collected in an automated fashion, and that sync with other existing reported measures, not only make us better stewards of limited resources, but also allow for improvement efforts to be directed towards a specific data set. Given the person-hours currently required to input data, such systems are critical to reach that balance of prevention interventions and measurement as noted earlier. We note that this is an important consideration which is reflected in several of our comments regarding proposed measures for FY 2014 and FY 2015. We also note that HAI data requirements are not part of the early stages of meaningful use implementation, which may likely slow the process of adapting electronic data capture for HAIs.

Although CMS did not request comment on this issue APIC would like to point out its importance to the HAI measures CMS has finalized for FY 2012 and proposed for FY 2014 and FY2015. HAI surveillance has been considered a low priority in the staged meaningful use criteria. It currently sits as an optional consideration in Stage 3 (automated real-time surveillance and comprehensive patient data access) rather than as a core requirement in Stage 1 (public health reporting and quality reporting) or Stage 2. This delays financial incentives for hospitals to include HAI in their system selection criteria until 2015-2016. Hospitals need to have those informatics systems in place in 2011-2012 to meet current state and federal mandates for HAI reporting.

**APIC Recommendation**: CMS should align reporting requirements with the staging/timing of the National Coordinator for Health Information Technology (ONC) incentives for meaningful use.  

(1) Central Line Bundle Compliance (NQF #0298): Central Line Insertion Practices (CLIP)

Central Line Insertion Practice Adherence Percentage (CLIP) assesses the extent to which a facility employs insertion practices consistent with CDC’s Healthcare Infection Control Practices Advisory Committee (CDC/HICPAC) recommendations that are known to reduce CLABSIs. APIC strongly supports the reduction of CLABSIs as a national patient safety goal. We note however, that CMS appears to have
confused two different quality measures in its description of this measure. NQF measure #0298 is a measure developed by the Institute for Healthcare Improvement (IHI). It is very similar, but not identical, to a measure assessing central line insertion practices that has been developed by the CDC for use through the NHSN. The CDC measure is not NQF-endorsed. The IHI measure, which is NQF-endorsed, cannot be collected through CDC/NHSN.

On March 4, 2011 the CDC announced that in 2009 alone, an estimated 25,000 fewer CLABSIs occurred in U.S. intensive care units (ICUs) than in 2001, a 58% reduction. Although a substantial number of CLABSIs continue to occur outside the ICU setting, recent data suggests that these are due largely to access, maintenance and prompt removal of the line as opposed to insertion practices -- issues not addressed by the CLIP bundle. In one study, 9% of central lines outside of ICU were deemed as inappropriate. APIC has concerns for requiring reporting of a process measure which is highly labor intensive and which may not currently be part of the medical record. Since this measure is derived from direct observation, it is also not possible to validate observations.

APIC does not support adding this measure at this time for the following reasons:

- There is questionable value in requiring a process measure where outcome data is currently being collected and reported, and in which significant improvements in outcomes have already been observed.
- Very few users have automated surveillance technologies which are capable of transmitting data to CDC/NHSN.
- Collecting CLIP data on a large scale will be challenging, particularly in facilities with multiple ICUs, where central lines are usually placed.

(2) Catheter-Associated Urinary Tract Infection (CAUTI) (NQF #138)

CMS states that this NQF-endorsed CAUTI measure is currently collected by the CDC/NHSN as part of some state mandated reporting and surveillance requirements for hospitals. CMS also states that this proposed measure is currently risk stratified, and therefore is consistent with section 1886(b)(3)(B)(viii)(VIII) of the Social Security Act, and notes that risk stratification means that it is calculated using different categories of patients with varying risk of developing an infection.

**APIC recommendation:** APIC supports this outcome measure as long as it meets CMS criteria of risk stratification, using CDC/NHSN infrastructure and protocols for adult ICUs. That is, data collection would be limited to ICUs as defined by the NQF-endorsed measure.

**2014 summary:**
APIC understands the need for validated, evidence-based, risk-adjusted HAI measures and supports continuing CDC/NHSN CLABSI data for a baseline year. We also strongly urge starting with one or two SSI procedures as we also add monthly CAUTI for the adult ICUs. In light of the time needed to obtain vendor support we urge delay and evaluation for the need for the highly labor intensive process required of the CDC/NHSN CLIP adherence module.
Proposed Measures for FY 2015 Payment Determination

We note CMS’s proposed intention to retain all of the proposed measures for the FY 2014 payment determination measures for the FY 2015 payment determination and additional CDC/NHSN-based HAI measures for the 2015 Payment Determination.

CMS is proposing to adopt three additional HAI measures that are currently being collected by CDC via the NHSN. These measures are:

1. Methicillin-resistant Staphylococcus aureus (MRSA) Bacteremia measure;
2. Clostridium difficile Standardized Infection Ratios (SIR); and
3. Healthcare Personnel (HCP) Influenza Vaccination

(1) MRSA and (2) C. difficile:

Although the MRSA bloodstream infection rate and C. difficile SIR measures are not NQF-endorsed, we are aware of the expertise that has gone into the definitions and development of these laboratory-identified (Lab-ID) events. These are significant pathogens and it is important to assess the burden of these pathogens to facilitate prevention efforts.

Given that both of these CMS proposed measures utilize the laboratory event reporting option in CDC/NHSN, we recognize they have the greatest potential for reduced labor intensity for data collection because they draw primarily on data obtained from the microbiology laboratory. However, both measures highlight the importance of support from clinical informatics vendors and/or internal informatics personnel. Efficient use of laboratory information requires an interface with the patient admission-discharge-transfer (ADT) system that is not available from most laboratory information systems (LIS).

APIC recommendations: We believe these measures should be delayed until the majority of facilities can automate an interface between CDC/NHSN and the facilities’ LIS and/or electronic health records.

If one or both of these modules are still required by CMS before this time, we recommend that CMS require the facility to select one or two patient care units based on their risk assessment which can be identified and used for reporting these measures to CMS via CDC/NHSN.

(3) Healthcare Personnel (HCP) Influenza Vaccination (NQF #0431)

For the FY 2015 payment determination, CMS is also proposing to adopt one additional HAI measure that is currently collected by CDC via the NHSN module: Healthcare Personnel (HCP) Influenza Vaccination (NQF #0431). This NQF-endorsed measure assesses the percentage of HCP employed at the facility that received vaccination against influenza as part of an overall seasonal influenza prevention program.

Because healthcare personnel can unintentionally expose patients to seasonal influenza if the HCP have not been vaccinated, and such exposure can be dangerous to vulnerable patients, APIC recently issued a
position paper supporting mandatory HCP influenza vaccination as a condition of employment. APIC applauds CMS for adding this measure to the Hospital IQR program. We note that healthcare personnel in general continue to have low influenza vaccination rate. We support the public reporting of HCP vaccination rates; however, we are concerned that requiring the collection of this information through the current CDC/NHSN module is redundant and labor intensive. Most hospitals already have a database, maintained by the Employee/Occupational Health Department to record the vaccinations for tracking purposes and to report aggregated rates. CMS states that the current Influenza Vaccination and Management and Exposure Module may soon offer options for healthcare facilities to submit vaccination summary data and that CDC/NHSN plans to partner with vendor-based surveillance systems to permit periodic data extractions into CDC/NHSN, but hospitals will not be able to utilize that capability until hospital IT system issues are more fully addressed. We support the intent of this measure and agree that influenza vaccination data submitted to CDC will ultimately capture regional trends on the yearly uptake of the vaccine, prophylaxis and treatment for healthcare personnel, and the elements within yearly influenza campaigns that succeed or require improvement. At the state and national levels, the HCP component can aid in monitoring rates and trends.

**APIC Recommendation:** APIC strongly supports mandatory HCP vaccination, as well as public reporting of HCP vaccination rates. However, we encourage development of a system that would allow hospitals to submit summary data on HCP influenza rates, ideally drawn from existing databases, to avoid the need to input other extraneous information unrelated to this measure.

**Long-Term Care Hospital (LTCH):**

CMS proposes a new quality reporting program for long-term care hospitals for FY 2014, as required by the Patient Protection and Affordable Care Act of 2010. Under this proposal, CMS would collect data from October 1, 2012 through December 31, 2012 for the LTCH’s payment determination in FY 2014 and would likely continue into the following CY 2013 for FY 2015 reporting/payment. Infection-related quality measures include CAUTI, CLABSI, and pressure ulcers that are new or have worsened.

**CAUTI and CLABSI**

APIC again notes our support for the use of CDC/NHSN data for quality measures. However, we also note that both the CLABSI and CAUTI measures are not NQF-endorsed for LTCHs. Since patient populations vary across LTCHs, APIC cautions against the use of both CAUTI and CLABSI data that are not risk adjusted. We suggest that such data must be based upon the population at risk and type of LTCH unit. Given the estimated 1,200 LTCHs in the U.S., APIC is concerned that LTCHs that are not currently participating in CDC/NHSN for internal needs at this time may need major resources to enroll, receive training, and educate staff on the CDC/NHSN basics, including surveillance definitions and processes, for staff members who are responsible for data input. Similar challenges related to the EHR and vendor support as discussed for hospitals earlier in this document are of equal concern for LTCHs.

**APIC Recommendation:** APIC recommends that CMS consider one outcome measure, such as CLABSI or CAUTI, which can be phased in and tested for FY 2014 before adding additional measures. We also recommend that CMS limit data collection to a specific type or types of units
Consider those associated with the highest risk of infection such as long-term care ventilator units that may utilize either type of catheter more extensively.

**Consideration of future rulemaking measures related to ventilator care (NQF #0302, Ventilator Bundle)**

This comprehensive ventilator care-bundle process measure is designed to facilitate protocols such as weaning, and mitigate ventilator-related infections, such as ventilator-associated pneumonia. This measure is an IHI measure that specifically refers to patients in ICU settings. APIC questions the applicability of this measure in the long-term care setting, particularly in light of the fact that the process by which long-term care ventilator patients are managed and weaned is very different than the acute care setting. APIC also notes that this process measure is labor intensive and cautions against introduction of the measure prior to full implementation and integration of the EHR and evidence-based literature to support its implementation in the long-term care setting.

**New Technology for which CMS requests comment:**

PerfectCLEAN with Micrillon®: “UMF Corporation (the manufacturer) submitted an application for a technology called the PerfectCLEAN with Micrillon®. PerfectCLEAN is a cleaning textile product (or cleaning mat/wipe) with chlorine embedded or bound to the extruded fiber. The manufacturer asserts that PerfectCLEAN is intended to be used to trap and eliminate pathogens such as Methicillin-resistant staphylococcus aureus (MRSA), Clostridium difficile (C diff.) and the H1N1 flu virus from 99% of hard surfaces within the hospital (as well as other healthcare facilities and locations).”

The manufacturer stated that “PerfectCLEAN is an Environmental Protection Agency (EPA) approved antimicrobial/disinf ectant that will be available on the market in the first quarter of 2011 and maintains that PerfectCLEAN is subject to review and approval by the EPA but is not subject to review by the FDA. “CMS has determined that the registration process that the applicant is currently pursing will result in neither FDA approval nor clearance consistent with the current regulations. Therefore, CMS is concerned that PerfectCLEAN will not be eligible for new technology add-on payments under existing regulations. CMS also has several concerns about cost estimates, and notes that “If the PerfectCLEAN is a substitute for other cleaning mechanisms such as wiping down a hospital room with a spray and can produce significant savings across many cost centers, then CMS believes it would be appropriate to deduct some charges from the average charge per day in order to accurately reflect the cost to hospitals of this technology.” APIC’s concern is that the cost estimates are predicated on the implication that this product somehow will replace that of other compounds currently used in the hospital, implying that it has already been proven safe and effective. However none of this has yet been substantiated by either the company or available scientific, peer-reviewed evidence.

**APIC recommendations:** We strongly oppose any consideration of this product as warranting “New technology reimbursement”. No supporting data, including even peer-reviewed, in-vitro investigations have been cited by CMS in this proposal from CMS nor provided by the company as far as we can discern. It is noteworthy, by contrast, that almost all of the content in this proposal from CMS involving HAI measures is well supported by substantial scientific evidence and experience with surveillance methods applied by infection preventionists. A cursory review of information sources on this product, including the company’s own website, did not identify any scientific, peer-reviewed studies demonstrating efficacy against cross transmission – let

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alone prevention or mitigation of HAIs. We strongly urge CMS to not support reimbursement of this or any product that lacks scientific evidence of its efficacy using objective rigor that evaluates methodologic quality and strength of such evidence.

APIC appreciates the opportunity to comment on the proposed measures and continue to applaud CMS’s commitment to improving quality and promoting patient safety. We stand ready to assist CMS in an approach that ties payment to preventable HAIs based upon standardized validated measures and evidence based guidelines.

Sincerely,

Russell N. Olmsted, MPH, CIC
2011 APIC President


