1275 K Street, NW, Suite 1000
Washington, DC 20005-4006
Phone: 202/789-1890
Fax: 202/789-1899
apicinfo@apic.org
www.apic.org

June 27, 2014

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

Re: CMS-1607-P: Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and Long-Term Care Hospital Prospective Payment System for FY 2015, proposed rule

Dear Ms. Tavenner:

The Association for Professionals in Infection Control and Epidemiology (APIC) wishes to thank the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide input into its proposed FY 2015 Hospital Inpatient Prospective Payment System (IPPS) changes. APIC is a nonprofit, multi-disciplinary organization whose mission is to create a safer world through prevention of infection. 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. Our comments address issues raised by CMS related specifically to healthcare-associated infections (HAIs).

Hospital Value-Based Purchasing (VBP) Program

Measures for the FY 2017 Hospital VBP Program

For the FY 2017 Hospital VBP Program measure set, CMS indicates that it is proposing to remove PN-6, SCIP-Inf-2, SCIP-Inf-3, and SCIP-Inf-9 as they are now "topped-out." APIC supports the removal of these measures. We believe that only areas in need of improvement should be included in the program. Removing these measures will reduce the reporting burden on participating hospitals and ensure that only measures that allow valid statistical comparisons will be included.

CMS is also proposing to adopt several new measures into the VBP program including: Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia (NQF #1716) and *Clostridium difficile* (*C. difficile*) Infection (NQF #1717). Both will be reported via the Centers for Disease Control and Prevention's (CDC) National Healthcare Safety Network (NHSN). APIC agrees with CMS that both of these infections are very serious and can be associated with poor outcomes. APIC supports the addition of these measures to the Hospital VBP Program as both are part of the Hospital IQR program beginning with FY 2015 payment determination. We also appreciate the continued effort of CMS to align the Hospital Inpatient Quality Reporting (IQR) Program Measures with the Hospital VBP Program.

Finally, APIC notes that CMS proposes to add six episode-based standardized Medicare payment measures for future inclusion and expansion into the VBP under the Efficiency domain. Three of the measures under consideration address medical episodes, which would be triggered by an inpatient claim with a specified MS-DRG: (1) kidney/urinary tract infection; (2) cellulitis; and (3) gastrointestinal hemorrhage. The other three address surgical episodes: (1) hip replacement/revision; (2) knee replacement/revision; and (3) lumbar spine fusion/refusion. Medicare payments for services provided during an episode beginning three days prior to admission through 30 days after discharge would be attributed to the hospital at which the index admission occurred. APIC does not support inclusion of the episode-based standardized measures into VBP at this time. Urinary tract infection and cellulitis are often unrelated to an index inpatient admission. We feel that these measures need further clarity and discussion with stakeholders before they can be included in the VBP Program.

Recommendations:

- *APIC supports the removal of PN-6, SCIP-Inf-2, SCIP-Inf-3, and SCIP-Inf-9.*
- *APIC supports the addition of Methicillin-resistant Staphylococcus aureus (MRSA) bacteremia (NQF #1716) and Clostridium difficile Infection (NQF #1717) via NHSN reporting into the FY 2017 VBP program.*
- *APIC does not support the addition of the medical and surgical episodes into the Efficiency domain and recommends CMS provide further clarity and discuss with stakeholders before including in the VBP Program.*

Proposed Changes to the Hospital-Acquired Condition (HAC) Reduction Program

Updates on AHRQ PSI-90, and CDC/NHSN CLABSI and CAUTI Measures

APIC remains concerned about the approach of using composite measure scores for eight separate component indicators in the AHRQ PSI-90, for the measures do not identify specific areas that can be targeted for improvement efforts. However, APIC appreciates that CMS recognizes this measure is currently undergoing maintenance review by the National Quality Forum (NQF), along with the NHSN Catheter-Associated Urinary Tract Infection (CAUTI) and Central Line-Associated Blood Stream Infection (CLABSI) measures. APIC supports the stance by CMS that if changes to the measure are made, a notice would be issued to allow for comments prior to requiring reporting of the updated measure.

Criteria for Applicable Hospitals and Performance Scoring Policy

APIC supports the continued use of a scoring methodology that aligns with the achievement methodology that is used under the hospital VBP program and agrees that aligning the scoring methodologies reduces confusion.

APIC notes that for FY 2016, CMS is proposing to adjust the scoring methodology of Domain 2 and the weighting of Domains 1 and 2 due to the addition of CDC's NHSN Surgical Site Infection (SSI) measure. APIC agrees with the pooling approach to combining the standardized infection ratio (SIR) of the two SSI measures reported to NHSN as these SIRs will incorporate risk adjusted weighting of the surgical volume between the two measures.

Yet, while APIC supports the use of CDC/NHSN data in Domain 2, we believe that adding this new pooled SSI SIR to the existing CAUTI and CLABSI SIRs could lead to obtaining an average rate of the three that lacks specificity in determining a hospital's true HAI scores. Additionally, adding the MRSA bacteremia

and *C. difficile* SIR to the average for FY 2017 has the potential to further dilute this measure, much as the current Domain 1 composite AHRQ PSI-90 is now. At this time, we recommend that CMS assign each of the CDC/NHSN measures a separate percentage to total the Domain weight. Having each of the CDC/NHSN measures weighted individually will provide more specificity in determining a hospital's HAI score, and will guide specific areas for performance improvement.

For FY 2016, CMS is also proposing to decrease the weight of Domain 1 from 35% to 25% and increase the weight of Domain 2 from 65% to 75%. APIC strongly supports the proposed change to the weighting of Domains as this gives more weight to the chart-abstracted measures using standard definitions from CDC/NHSN rather than measures that are obtained from claims-based data.

Recommendations:

- *APIC supports a notice and comment period for any HAC measure with significant changes made during an NQF review process.*
- *APIC appreciates continued alignment in scoring methodologies to reduce confusion.*
- *APIC supports pooling the SIR for the two SSI measures reported to NHSN.*
- *However, APIC recommends instead of then averaging all 3 HAIs in Domain 2, CMS assign each HAI measure a separate percentage to total the Domain weight.*
- *APIC supports the change in Domain weights for FY 2016 to provide increased weight to Domain 2, which contains less claims-based data.*

Hospital Inpatient Quality (IQR) Program

Removal and Suspension of Hospital IQR Program Measures

In the proposed rule, CMS notes it is recommending a change to the criteria for determining when a measure is "topped-out". Specifically, CMS notes that it will be applying two criteria which were already adopted as part of the Hospital Inpatient VBP. As it pertains to HAI measures and infection prevention measures, APIC agrees with the proposal to align the definition of "topped-out" with the Hospital VBP Program to reduce confusion and promote consistency.

APIC additionally notes that in the proposed rule, several measures have been identified for removal for the FY 2017 payment determination. APIC supports the removal of:

- SCIP -Inf-1: Prophylactic antibiotic received within one hour prior to surgical incision
- SCIP-Inf-2: Prophylactic antibiotic selection for surgical patient
- SCIP-Inf-3: Prophylactic antibiotics discontinued within 24 hours after surgery end time (48 hours for cardiac surgery)
- SCIP-Inf-4: Cardiac surgery patients with controlled postoperative blood glucose
- SCIP-Inf-6: Surgery patients with appropriate hair removal (previously suspended)
- SCIP- Inf-9: Urinary catheter removed on Postoperative Day 1 (POD1) or Postoperative Day 2 (POD 2).

APIC also agrees with adding measures SCIP-Inf-1, SCIP-Inf-2, and SCIP-Inf-9 to the voluntary electronic reporting list.

APIC, however, would like to note that since CMS is proposing to continue to move toward including more clinical outcome measures, the loss of some of the current criteria, such as "availability of

alternative measures with a stronger relationship to patient outcomes", or "a measure that does not align with current clinical guidelines or practice", may be problematic going forward.

APIC also continues to emphasize the necessity to consider sufficient lead-in time for implementation of changes to measures, especially in regard to those measures impacting information technology requirements. Often this includes the need to budget for information technology support in given departments such as infection control, where limited budgets exist.

Recommendations:

- *APIC supports the alignment of the criteria for "topped-out" measures within the IQR program with that of the Hospital Inpatient VBP program.*
- *APIC recommends continued assessment of the effectiveness of newly proposed "topped-out" criteria that solely use statistical evaluation processes for determination.*
- *APIC supports the removal of the above identified SCIP measures as part of the "topped-out" criteria.*
- *APIC supports adding several of these "topped-out" measures to the voluntary electronic reporting list.*
- *APIC continues to recommend CMS maintain an alliance with Measure Applications Partnership (MAP) and other stakeholders such as APIC, to evaluate measure usefulness and relevancy of measures.*

Influenza Vaccination Coverage among Healthcare Personnel (HCP)

CMS clarifies in the proposed rule that beginning with the 2014-2015 influenza season, facilities should collect and report a single vaccination count for each healthcare facility by CMS Certification Number (CCN). APIC supports and endorses this proposal as a way to reduce the burden of data collection, instead of separating and reporting data by inpatient and outpatient setting. We appreciate the CMS response to our previous request for this approach given the difficulty, if not improbability, of obtaining accurate information by specific type of setting.

Recommendation:

- *APIC appreciates and supports CMS' clarification that facilities collect and report a single HCP influenza vaccination count for each healthcare facility by CCN.*

Proposed Refinement of Total Hip Arthroplasty and Total Knee Arthroplasty (THA/TKA) 30 Day Complication and Readmission Measures

In the proposed rule, CMS notes, it will refine the measure to exclude those patients who have a hip fracture coded as either a principal or secondary diagnosis during the index admission. APIC agrees with and supports the proposed modification to the algorithm. We agree with CMS that this modification should accurately exclude patients who were initially admitted for a hip fracture and who then subsequently underwent total hip arthroplasty, making their procedure non-elective.

Recommendation:

- *APIC supports the proposed refinement of this measure.*

Proposed Additional Hospital IQR Program Measures for FY 2017 Payment Determination and Subsequent Years

While CMS notes in the proposed rule that it may require measures that have not been endorsed, APIC would like to express our continued support for the use of NQF-endorsed measures, as opposed to those not endorsed by NQF. The process of appropriately developing, vetting, and maintaining measures is important to the validity and reliability of measures that are being used for reimbursement strategies as well as monitoring of adverse patient outcomes.

CMS also notes it is proposing to add Severe Sepsis and Septic Shock: Management Bundle (NQF #0500) as one of eleven measures for FY 2017 payment determination and subsequent years. While severe sepsis is certainly one of the leading causes of mortality, we have significant concerns with this measure as defined in the rule. The measure, as written, could lead to patients needlessly receiving a central venous catheter for measurement of central hemodynamic monitoring. Recent literature published on sepsis protocols has found no significant benefit from the mandated use of central venous catheterization and central hemodynamic monitoring in all patients.[1] As written, the proposed rule could lead to the unintended consequence of increased central line placement by recommending Central Venous Pressure (CVP) measurement as part of the bundle. By complying with this portion of the measure, for patients who could be managed effectively without a central line in place, facilities could inadvertently increase the risk of central line-associated bacteremia, or other significant complications. In addition, NQF has recently released for public comment a recommendation from the NQF Patient Safety Standing Committee that the item requiring measurement of central venous pressure be removed from this bundle.

Recommendation:

- *APIC supports use of NQF-endorse measures in CMS payment programs.*
- *APIC does not support the inclusion of the Severe Sepsis and Septic Shock Management bundle in its currently defined state, and urges CMS to reconsider after further review has been completed.*

Public Reporting of Electronic Clinical Quality Measures

For electronic clinical quality measure data submitted for FY 2016 payment determination, CMS is proposing that the data would be publicly reported as previously finalized. However, CMS notes that with the FY 2017 payment determination, hospitals that voluntarily report one year of electronic clinical quality measure data would have an option to have their data reported on *Hospital Compare* with a preview period prior to reporting.

Recommendation:

- *APIC supports giving hospitals the ability to preview any data, especially electronically submitted data, before the data are released to the public's attention. We also support adding a footnote next to voluntarily reported data that will identify it as such.*

Possible New Quality Measures and Topics for Future Years

While CMS notes that Electronic Health Record (EHR) technology is continuing to improve and moving towards electronic quality measure reporting may reduce administrative burden on hospitals, APIC would like to express concern with the proposal to require reporting of electronic clinical quality measures for the Hospital IQR Program beginning for the CY 2016 reporting period or FY 2018 payment

determination. HAI surveillance measures are not included in Meaningful Use until Stage 3, which is now scheduled to begin in 2017. Therefore, minimal IT support is currently available in many facilities for HAI-related measures. In addition, with many of the measures within the IQR program undergoing review and updating, any electronic reporting must take into account the time needed to develop and implement the appropriate electronic adaptations for such changes. We caution CMS about the timeframe for required electronic reporting of HAI data and encourage collaboration with CDC/NHSN and EHR vendors to determine this timeframe.

CMS also indicates it is considering the addition of Hepatitis B Vaccine Coverage Among all Live Newborn Infants Prior to Hospital or Birthing Facility Discharge (NQF #0475) as an electronic clinical quality measure starting October 1, 2016. APIC recognizes this measure is an important part of public health safety and supports the addition of this measure for reporting.

Recommendations:

- *APIC urges CMS to evaluate the timeframe for the role out of the electronic reporting requirement in collaboration with CDC/NHSN and EHR vendors.*
- *APIC supports the addition of the Hepatitis B Vaccine Coverage (NQF #0475) as part of the electronic clinical quality measure starting October 1, 2016.*

Form, Manner, and Timing of Quality Data Submission

CMS notes that for the FY 2016 payment determination and subsequent years, it wishes to clarify that all patient-level required data collected by CDC will be shared with CMS for Hospital IQR Program and Hospital VBP Program administration, monitoring and evaluation activities, including validation, appeals review, program impact evaluation, and development of quality measure specifications. CMS also proposes to receive access from CDC to voluntarily submitted name and race identifying information with respect to Hospital IQR Program required measures, and that this data will also be used for program administration, monitoring and evaluation activities, including validation, appeals review, program impact evaluation, and development of quality measure specifications.

APIC has significant concerns and does not support the release of all submitted patient-level data from NHSN as is set forth in this proposed rule. Although the intention to use the patient-level data for case-matching during the validation process is understood, APIC suggests that CMS evaluate the outcome and consequences of obtaining Medicare patient-level data via the newly submitted Medicare beneficiary number process before it requests the submission of all patient-level data in general.

APIC notes that this precedent-setting action of releasing patient-level data, without appropriate testing and vetting of process, has the potential to open itself to patient-level data being requested at other levels. Unintended consequences from use of that data in validation programs that may not be "mature" could result in poor quality monitoring and possible breaches in patient confidentiality. In addition, out of concern for the retrieval of this data, facilities may begin choosing not to submit the voluntary data to CDC/NHSN. APIC requests that CMS delay implementation of the proposal until it is able to provide clarification on how the data may be used and protected. In addition, APIC encourages CMS to collaborate with CDC/NHSN and other organizations on the retrieval and analysis of this data.

APIC is concerned that CMS is proposing to use NHSN data for development of quality measure specifications. The CDC/NHSN system is currently designed, developed, implemented, analyzed, evaluated, and used by subject matter experts in HAI surveillance, prevention and control. The system

should not be modified and/or new quality measure specifications identified without the explicit involvement and oversight of CDC. APIC is extremely concerned that modifications or additions of new HAI-related quality measures will undermine the credibility and/or utility of the NHSN, a globally recognized surveillance system for the prevention and control of HAIs.

Recommendations:

- *APIC does not support the release of all required or voluntarily submitted patient-level data until additional information and clarification can be reviewed.*
- *APIC encourages CMS to collaborate with CDC/NHSN and other organizations on the retrieval and analysis of this data.*

Proposed Modifications to the Existing Processes for Validation of Chart-abstracted Hospital IQR Program Data

CMS is proposing to change the timing of when the sample for validation of the HAI data is selected. Due to the proposal to change the timing of the validation itself, the sample selection timing must also change. APIC supports this proposal and agrees with CMS that this change will give facilities more time to complete the HAI validation template requirements.

CMS also notes that for FY 2017 payment determination and subsequent years, it will require hospitals to submit a mix of 40 charts to validate HAI measures and 32 charts to support clinical process-of-care measures (a total of 72 charts per year). This proposal is reflective of the greater impact the HAI measures will have on both the Hospital VBP and HAC Reduction programs. APIC supports the direction of this proposal.

Finally, we note that CMS is proposing to expand the options for secure transmission of electronic versions of patient medical record reporting, specifically allowing hospitals to submit digital images (PDFs) of patient charts via the QualityNet website. APIC fully supports this proposal as we believe it will streamline the validation process and the burden of work for hospitals, which is an important factor in healthcare cost efficiencies.

Recommendations:

- *APIC supports the change in timing when selecting a sample for validation of the HAI data.*
- *APIC supports the change in chart mix to validate more HAI charts as part of the greater impact the HAI measures have on CMS programs.*
- *APIC supports allowing secure transmission of digital images of patient charts via the QualityNet website.*

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

CMS is proposing to delay public reporting of NHSN Catheter-Associated Urinary Tract Infections (CAUTI) and Central Line-Associated Bloodstream Infection (CLABSI) data until 2017 for PPS-exempt cancer hospitals. CMS recognizes that a low volume of data is being produced and reported by facilities and CDC is unable to calculate reasonable and reliable baseline estimates or expected rates. APIC supports this delayed approach, and also urges CMS to be mindful of the same potential experience with the Harmonized Procedure Specific Surgical Site Infection (SSI) measure as well. We agree a minimum volume must be reported before meaningful analyses can be performed.

Recommendation:

- *APIC supports delaying the display of both NHSN CAUTI and CLABSI until 2017 due to the low volume of data produced, and urges CMS to evaluate the NHSN SSI data under the same standard.*

Long-Term Care Hospital Quality Reporting (LTCHQR) Program

Proposed Revisions to Data Collection Timelines and Submission Deadlines for Previously Adopted Quality Measures

CMS is proposing to revise the data collection timeline and submission deadline for the Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (Short Stay) measure (NQF#0680) to align with the reporting period for other measures being submitted into the LTCH CARE data collection instrument starting in FY 2016. APIC supports this alignment as it reflects the influenza season and will reduce the data entry time for LTCH staff.

CMS is also proposing three new LTCHQR program measures for the FY 2018 and subsequent years' payment determinations: 1) Percent of Long-Term Care Hospital Patients with an Admission and Discharge Functional Assessment and a Care Plan that Addresses Function; 2) Change in Mobility among Long-Term Care Hospital Patients Requiring Ventilator Support; and 3) National Healthcare Safety Network (NHSN) Ventilator-Associated Event (VAE) Outcome Measure. APIC notes that the burden of data collection must be considered to allow these facilities the time to acquire the resources to focus on improvement efforts and not solely on data collection and submission. The VAE measure in particular is resource intense for data collection, and some LTCHs may not have an EHR that would facilitate easy data gathering. APIC has continued concerns that limited existing resources in LTCHs will be moved from prevention to reporting activities.

In regard to the two proposed functional status quality measures, APIC agrees that improved functional status and improved, early mobility by those patients who are ventilated reduces the likelihood of infection, and significantly improves morbidity, mortality, cost, and quality of life in this vulnerable population.

In regard to the NHSN VAE Outcome Measure, APIC agrees that a portion of the LTCH population are on a ventilator and are at risk of developing a ventilator-associated event (VAE); however, APIC does not support the inclusion of this metric until the measure is evaluated and refined. Although APIC agrees that this standardized measure provides objectivity and reliability, we note that NHSN continues to modify the definition based upon assessment and user feedback. Furthermore, NHSN has not yet provided comparative data to enable facilities to set adequate targets or benchmarks. It is especially important to note that better data on VAEs and their responsiveness to quality improvement programs are necessary before they should be considered suitable metrics for inter-facility comparisons or pay-for-performance programs. Suitable risk adjustment strategies are also needed. As such, APIC believes that adoption of this metric for public reporting and pay-for-performance calculations should be delayed until the measure can be validated and until more is known about what portion of VAE is preventable.

APIC also notes that CMS is considering several future metrics that impact patient safety and infection prevention including measures addressing the Ventilator Bundle and Effective Clinical Process Management Bundles: Severe Sepsis and Septic Shock. APIC does not support the inclusion of the current Institute for Healthcare Improvement ventilator bundle, as several components of the bundle (daily sedation reduction and daily weaning of ventilator settings) may not be applicable to patients who

are on a long-term ventilator and may never be weaned. Additionally, work is currently underway to develop a new ventilator bundle that can more broadly address VAE. APIC also recommends additional review of Severe Sepsis/Septic Shock management bundles before proposing them as a formal measure. While sepsis is one of the leading causes of hospitalization and readmissions and results in significant morbidity, mortality, and increased cost in healthcare, the current bundle definition including central line placement and central hemodynamic monitoring may have other unintended consequences. We again note the NQF Patient Safety Standing Committee's recent recommendation that the item requiring measurement of central venous pressure be removed from this bundle. This recommendation is based on recent literature published on sepsis protocols which found no significant benefit of the mandated use of central venous catheterization and central hemodynamic monitoring in all patients.[1]

Recommendations:

- *APIC supports the alignment of the reporting period for Percent of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine with other metrics already being reported into LTCH CARE data collection instrument.*
- *APIC supports the inclusion of the two functional status quality measures, but we encourage CMS to evaluate the timing and introduction to allow for adequate training and resources for all data collection.*
- *APIC does not support the addition of NHSN VAE Outcome Measure at this time, as this measure has not been sufficiently validated and it is currently unclear what proportion of VAEs are preventable.*
- *APIC recommends CMS wait for the development of a new ventilator bundle that more specifically addresses VAE before including VAE as a required measure.*
- *APIC does not support the inclusion of the Severe Sepsis and Septic Shock Management bundle in its currently defined state, and urges CMS to reconsider after further review has been completed.*

APIC appreciates the opportunity to comment on the proposed measures and continues to applaud CMS' commitment to improving quality and promoting patient safety. Our organization continues to support transparency in healthcare improvement efforts and reporting of healthcare-associated infections as a means to that end. With the increasing volume of data reported, we believe it is essential that an assessment of the effects of public reporting on both the patient and the healthcare system are examined and shared. APIC stands ready to assist CMS in these assessments as well as all efforts to reduce preventable HAIs based upon standardized validated measures and evidence-based guidelines.

Sincerely,

Jennie L. Mayfield, BSN, MPH, CIC
2014 APIC President

[1] The ProCESS Investigators.A Randomized Trial of Protocol-Based Care for Early Septic Shock. N Engl J Med 2014;370:1683-93