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June 24, 2013

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-1599-P: Medicare Program; Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System for FY 2014

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 2014 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 Readmissions Reduction Program-Fiscal Years 2014 and 2015

APIC notes the readmission reduction measures are intended to capture unplanned readmissions that arise from acute clinical events requiring urgent hospitalization within 30 days of discharge. The population of focus for these measures should be on those readmissions which are unplanned (i.e. for treatment due to a complication), as planned readmissions do not necessarily signal poor quality of care. While APIC supports the addition of total hip arthroplasty (THA) and total knee arthroplasty (TKA) to the readmission measure, we do not want to see facilities unfairly penalized if the readmission was a planned part of the care process. Therefore, APIC supports CMS's attempt to develop an algorithm to identify those planned readmissions and exclude them from the measures.



Recommendation: We understand that CMS is in the process of developing an algorithm to exclude planned readmissions from the hospital readmission reduction measures. APIC supports this effort.

Hospital Value-Based Purchasing (VBP) Program -- Fiscal Year 2016

CMS identifies in the proposed rule that it intends to remove PN-3b: Blood Cultures Performed in the Emergency Department Prior to Initial Antibiotic Received in Hospital from the FY 2016 Hospital VBP Program in part because the measure is no longer endorsed by the National Quality Forum (NQF), was not recommended for use by the Measure Applications Partnership (MAP), and due to the fact that there have been significant issues with documentation of the timing of blood cultures and the electronic health record.

Recommendation: APIC supports the removal of this measure.

CMS is proposing to adopt several new measures into the VBP program including:

- Influenza Immunization (IMM-2, NQF #1659) as a chart abstracted prevention measure that assesses whether patients over 6 months of age were screened for seasonal influenza immunization status and were vaccinated prior to discharge if appropriate.
- Catheter-Associated Urinary Tract Infection (CAUTI, NQF #0138) in adult intensive care units (ICU) as a healthcare-associated infection measure reported via the National Healthcare Safety Network (NHSN).
- Surgical Site Infection (Colon Surgery and Abdominal Hysterectomy) (SSI, NQF #0753) as a healthcare-associated infection measure reported via NHSN.
- NHSN-based Central Line-Associated Bloodstream Infection (CLABSI) measure in ICU patients in its current state (was previously adopted).

And for FY 2017:

- Methicillin-resistant *Staphylococcus aureus* (MRSA) bacteremia standardized infection ratio (SIR)
- *Clostridium difficile* (*C. difficile*) SIR

APIC supports the addition of the above measures and recognizes that all of these measures are now NQF-endorsed. We note that while the Centers for Disease Control and Prevention (CDC) has submitted the reliability-adjusted version of the CLABSI measure to NQF for endorsement, CMS is not proposing to adopt this version of CLABSI measurement at this time. APIC supports this approach and will comment on the reliability-adjusted SIR if proposed in future rulemaking. We also appreciate the integration of the VBP program with the Hospital Inpatient Quality Reporting (IQR) program and the intent to align the two programs. Aligning the two programs with measurements and reporting structure should allow hospitals to better incorporate this information into their quality improvement programs.



Although we support the additional measures, we express a note of caution that there may be differences in the definitions used in the baseline and performance periods. For example, for the FY 2015 CLABSI measure there are differences in the NHSN definition for the baseline period (January – December 2011) versus the performance period (February – December 2013). Because of the differences in definitions, the baseline period may not be sufficient in establishing valid achievement scores for the performance period. APIC is concerned that healthcare institutions that use this information to direct resources may be making decisions with deficient and unsatisfactory information. APIC notes that the baseline and performance periods for CLABSI for FY 2016 are not stated and requests clarification.

In addition, APIC identifies a significant discussion by CMS in the proposed rule on aligning the VBP, IQR and Electronic Health Record (EHR) Incentive Program with the National Quality Strategy (NQS) domains beginning with the FY 2017 Hospital VBP Program. Specifically, this would place the HAI measures into the Safety domain. APIC believes this direction is appropriate for these measures at this time.

Finally, CMS has proposed to adopt a Hospital VBP program extraordinary circumstance waiver process for which hospitals could apply at the same time a waiver is sought for the Hospital IQR program. These waivers would allow CMS to “waive” all applicable quality measure data from a performance period, and thus, exclude a hospital from the VBP program for a fiscal year during which the hospital has experienced a disaster or other extraordinary circumstance.

Recommendations:

- APIC supports the addition of the global measure for influenza immunization, ICU CAUTI, ICU CLABSI and SSI for colon surgery and abdominal hysterectomy into the VBP Program for FY 2016.
- APIC supports the addition of MRSA bacteremia and *C. difficile* SIR for FY 2017 VBP, while urging CMS to evaluate the timing of these additions in context with ongoing efforts to improve the risk adjustment and comparison analysis.
- APIC requests CMS provide additional detail on baseline and performance periods for CLABSI in FY 2016 as well as additional clarification on how it would account for differences in baseline and performance periods when the measurement definition changes.
- APIC supports the alignment of the VBP program with the NQS domains and specifically supports placement of the HAI measures into the Safety domain.
- APIC supports the adoption of an extraordinary circumstance waiver process for the VBP program.

Proposed Implementation of the Hospital-Acquired Condition (HAC) Reduction Program for FY 2015

In identifying the general framework for the HAC Reduction Program, APIC recognizes that CMS is not required to address specific measure scoring methodologies in notice and comment rulemaking, yet has



done so in an effort to allow the public to understand how the measures are discussed and finalized. APIC appreciates this effort and applauds CMS for its transparency.

CMS notes that it plans to use two Domains and separate out the AHRQ Patient Safety Indicators (PSI) from the CDC/NHSN measures due to several major differences in data source, collection and calculation. In addition, APIC generally would be opposed to the use of any of the AHRQ measures that are identified as infection indicators (such as PSI-7 central venous catheter-related bloodstream infection rate), as the AHRQ data captures events that occur only among Medicare fee-for-service discharges and is based on claims data. The CDC HAI measures capture data on both Medicare and non-Medicare patients and are chart abstracted using standardized definitions and reported quarterly.

APIC agrees with the proposal to separate the two domains and agrees it would provide a more reliable scoring model. For Domain 1, APIC favors the proposed approach of using the six individual AHRQ PSIs as opposed to the alternative approach which incorporates one composite of 8 component indicators. As we have previously commented to CMS, composite measures lack specificity and relevance and do not allow intended audiences to focus on specific, meaningful prevention strategies. APIC applauds CMS efforts to publish data that is meaningful and can support provider efforts to impact clinical change at the bedside. Due to this, we do not support the alternative measure set that includes AHRQ PSI-90, for it is a composite measure and it incorporates PSI-7 central venous catheter-related blood stream infections rate, which would be reported via a different collection measure in Domain 2. Having different definitions associated with bloodstream infections (one collected via administrative data as in the alternate approach to Domain 1 and one collected via epidemiological surveillance as in Domain 2) can cause confusion and has the potential for misdirection of finite resources.

APIC appreciates CMS's use of CDC/NHSN, rather than claims-based data for the Domain 2 measures of CLABSI and CAUTI (FY 2015, FY 2016, FY 2017); SSI – Colon Surgery and Abdominal Hysterectomy (FY 2016, FY 2017); and MRSA bacteremia and *C. difficile* (FY 2017).

APIC also agrees with the use of the CDC/NHSN SIR for Domain 2 HAI measures; however, we caution that inpatient units with low volume/low device utilization can have data (SIRs) that are disproportionately high due to low denominators. This may, in fact, be an inadvertent benefit to units that have not aggressively made attempts to decrease catheter utilization days.

Finally, APIC agrees that the process used to review and correct information through the existing Hospital IQR program would be an acceptable format for updating performance rather than reviewing and correcting data in two different programs. APIC appreciates the effort of CMS to reduce the burden on hospitals in this portion of the proposal.

Recommendations:

- APIC supports separating the AHRQ and CDC measures into two separate domains.



- APIC supports the proposal for Domain 1 over the alternative approach.
- APIC supports the use of the CDC/NHSN definitions for all measures in Domain 2; however, APIC urges CMS to review the context of units that may have lower device utilization. APIC does not want to see facilities unfairly penalized for reducing risk by the lowering number of days devices are in place.
- APIC supports the use of the existing Hospital IQR process for review and correction of information in the Hospital VBP program.

Hospital Inpatient Quality (IQR) Program

CMS notes that as part of its ongoing work to update and modify the display of this publicly reported data, it is proposing to make the individual PSI indicators that are part of the PSI-90 composite measure available to the public. APIC believes this display, which would include the individual display of PSI-7 central venous catheter related bloodstream infection rate, could potentially be more confusing to consumers in that this measurement differs significantly from another measure in the Hospital IQR Program with a very similar name: the CDC/NHSN CLABSI measure. This could provide the public, and healthcare facilities that must make decisions about finite resources, with confusing and conflicting information. Individual indicators are more relevant if properly determined. APIC would recommend that CMS not display the individual composite measures to the public at this time.

CMS also proposes to remove or suspend measures that were supported in previous rulemaking, specifically:

- Remove PN-3b: Blood Culture Performed in the Emergency Department Prior to First Antibiotic Received in the Hospital Measure (no longer NQF-endorsed)
- Remove IMM-1: Immunization for Pneumonia Measure (rapidly changing guidelines that are difficult to adapt and update within the system)
- Remove SCIP-Inf-10: Surgery patients with perioperative temperature management (measure topped out)
- Continued suspension SCIP-Inf-6: Appropriate hair removal (measure topped out)

APIC supports the removal and continued suspension of these measures, and also supports CMS's stance which identifies that despite removal of the pneumonia vaccination measure, hospitals should continue to keep up with vaccination recommendations for various populations.

Recommendations:

- APIC does not support display of the individual PSI indicators under the PSI-90 composite.
- APIC supports the removal or suspension of PN-3b, IMM-1, SCIP-Inf-10, and SCIP-Inf-6.
- APIC appreciates that CMS continues to encourage hospitals to appropriately vaccinate their patient populations.



Proposed Refinements to Existing Measures in the Hospital IQR Program

In the rule, CMS proposes to expand the CLABSI and CAUTI measures to select non-ICU locations (medical, surgical and medical/surgical wards) on or after January 1, 2014. APIC supports the expansion of these measures consistent with NQF endorsement, with several additional concerns and considerations:

- Hospitals are still in various phases of electronic health record implementation. Retrieval of this data electronically is still in a transitional phase, and manual retrieval could result in diverting resources from performance improvement activities that are in progress for the ICU-related measures. Finding a balance in data retrieval and being able to direct prevention and improvement activities is absolutely necessary with the limited resources in healthcare.
- APIC additionally expresses significant concern over the forthcoming (early 2014) changes to the CDC/NHSN CAUTI definition in relationship to implementing expansion of these indicators beyond the ICU. Measure definition changes also provide a challenge to facilities that rely on electronic surveillance to assist in their data capture as the data system must receive the updated requirements from CDC, update their systems and then pass these changes on to the end user. APIC is concerned that expanding the surveillance of CAUTI at the same time the definition changes could increase confusion and decrease the reliability of data collected. The data will not be comparable over time to assess the improvement or declining performance for public and healthcare administration determinations. APIC recommends the introduction of the new CAUTI definitions for a time frame of at least one year prior to expansion outside of the ICU.
- Therefore, APIC recommends that CMS consider a phased-in approach to this expansion, adding the CLABSI measure **before** the CAUTI measure and expanding the CAUTI measure **after** CDC has revised its definition and has sufficient time to assess the impact of the changes.

As mentioned earlier in our comments on the Hospital VBP Program, APIC also expresses concern regarding the low volume/low utilization device days in many patient locations that may result in higher comparative rates potentially masking a successful program where device utilization and timely removal of invasive devices is an organizational priority.

CMS also identifies in this section of the proposed rule it plans to refine SCIP-Inf-4: Controlled 6 AM Glucose for Cardiac Surgery Patients (NQF #300), as this measure has undergone extensive changes as part of the NQF endorsement maintenance process. While APIC supports this measure in general, we would suggest that the terminology “corrective action to be documented for post-operative glucose over 180mg/dl”, be changed to reflect a more clinically acceptable terminology rather than “corrective



action” (e.g. documentation of clinical attempt of glucose control) as “corrective action” may not always be achievable for some patients.

Recommendations:

- APIC supports a phased-in approach of expansion with CLABSI and CAUTI beyond the ICUs, specifically recommending that CLABSI expansion be transitioned first, followed by CAUTI after surveillance definitions have been updated and implemented.
- APIC supports the refinement of the SCIP-Inf-4 measure, but recommends the language “corrective action” be replaced with “documentation of clinical attempt of glucose control.”

Data Submission Requirements for Quality Measures That May be Voluntarily Electronically Reported for the FY 2016 Payment Determination

APIC appreciates the attempt of CMS to begin to align the quality measure reporting under the Hospital IQR and Medicare Electronic Health Record (EHR) programs. APIC supports the proposed voluntary participation in electronic submission of one quarter of quality data measures, but reminds CMS that HAIs are not part of Stage 1 or Stage 2 Meaningful Use, so many hospitals will be at variable levels of capability with HAI data via electronic submission. APIC also agrees with the proposal to give “Pioneer Designation” to encourage participation in the program.

Proposed Modifications to the Validation Process for Chart-Abstracted Measures under the Hospital IQR Program

CMS proposes to better align itself with NHSN definitions by replacing the requirement to note a “central venous catheter” (CVC) on its CLABSI validation template with the requirement to note a “central line”. In addition, CMS proposes to exclude from the CAUTI validation template all urine cultures with more than 2 organisms, even if they have greater than or equal to 1,000 colony-forming units (CFUs)/ml as often these cultures would indicate contamination. APIC supports both of these proposals as they align with current CDC/NHSN definitions.

CMS also proposes to adopt a sub-regulatory process for handling details of the definition specifications. While APIC supports this proposal, we also respectfully request that CMS involve APIC, Infection Preventionists (IPs) and CDC/NHSN experts in the discussion process. As refinement of the CDC/NHSN definitions continues, we can anticipate the process will require both IPs and validators to carefully match the cases and to learn from the process. APIC encourages dialogue and learning opportunities for all stakeholders in this validation and sub-regulatory process.

Regarding the addition of MRSA bacteremia and *C. difficile* to the validation process, APIC agrees that this validation needs to be accomplished and appreciates the proposal from CMS to randomly assign half of the randomly selected hospitals (approximately 300 of the 600 selected) to submit templates for



CLABSI and CAUTI and the other half (the other 300 hospitals) would submit templates on MRSA and *C. difficile* infection (CDI) for validation. We agree this may reduce burden to hospitals and continue to respectfully request that CMS place into context the burden of data retrieval/validation work that is being requested as a whole for IPs throughout the country. As measures continue to expand and additional validation becomes necessary, resource limitations could serve to focus infection control programs solely on data retrieval and submission, rather than on prevention and improving outcomes.

APIC also appreciates and supports the proposal to reduce the number of validation records from 48 to 36, as well as an exclusion for those outlier patients with a length of stay greater than 120 days. Certainly having valid and reliable data is important, and APIC is grateful that CMS recognizes the work intensity by all in the validation process for HAIs.

CMS identified criteria for selecting hospitals for validation in previous rules. In this year's rule, CMS is proposing an additional criterion that would target for validation any hospital that failed to report to NHSN at least half of actual HAI events detected as determined during the previous year's validation effort. This would provide an additional incentive for properly reporting HAI events that should have been reported to NHSN. APIC agrees with CMS that the Hospital VBP Program may give hospitals an unintended incentive to underreport HAI events and supports the addition of this targeting criterion.

In addition, APIC recognizes that many states have health departments that already provide validation as part of their state reporting requirements. APIC believes State Health Departments are an important stakeholder in prevention and reporting efforts and should lead validation work nationally. This validation work should be coordinated with CMS and their needs to validate NHSN reporting.

Finally, APIC endorses a secure method of electronic submission of records for the validation process and recognizes CMS's effort to define pathways for submitting such records. The cumbersome submission of paper records needs to be streamlined for hospitals as well as validators. Extreme volumes of patient medical records can also be misleading and result in inaccurate validation. In addition, as hospitals rapidly adopt EHR systems as their primary source of information, electronic submission will become necessary.

Recommendations:

- APIC supports the alignment of the validation templates with CDC/NHSN current definitions.
- APIC supports the use of the sub-regulatory process to update measures and validation templates, but encourages CMS to consult with stakeholders, including APIC and CDC/NHSN experts.
- APIC supports a "split" validation of CLABSI, CAUTI, MRSA and CDI as well as the exclusion of patients with a length of stay greater than 120 days, and the reduction of validation charts from 48 to 36, all efforts which will reduce the validation burden to hospitals and IPs.



- APIC supports additional targeting criteria for those who underreport by 50% or greater during the previous year's validation.
- APIC supports continued efforts to establish electronic submission of records for the validation process.

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program: Proposed New Quality Measures

For the PCHQR program beginning with FY 2015, CMS is proposing to adopt one new measure: the NHSN HAI measure of Surgical Site Infection (SSI), and for FY 2016, proposes to adopt the six measures of the Surgical Care Improvement Project (SCIP). As all of these are NQF-endorsed, APIC supports these additions and believes they are appropriate for the cancer hospital setting. APIC appreciates the display of the NHSN HAI SSI measure will include the SIR which will be consistent with other facilities that are reporting this data. In addition, APIC also acknowledges CMS is deferring the public reporting of three measures finalized as part of the FY 2014 PCHQR Program, including the NHSN CLABSI outcome measure and the NHSN CAUTI outcome measure, as CMS is in the process of testing and assessing the data quality. APIC supports this approach in that data displayed for the public should always be identified as both reliable and valid.

Recommendations:

- APIC supports the addition of the NHSN SSI measures for FY 2015.
- APIC supports adoption of the six SCIP measures for FY 2016.
- APIC supports deferral of public reporting of the FY 2014 measures that have not yet been sufficiently tested or assessed for reliability and validity.

Long-Term Care Hospital Quality Reporting (LTCHQR) Program

CMS proposes to move the Influenza Vaccination Coverage among Healthcare Personnel measure (NQF #0431) reporting period to align with the influenza vaccination season defined by the CDC. APIC supports this recommendation as it aligns with current recommended reporting practices.

In addition, CMS identifies it is proposing to delay the start of the collection and submission of data on the measure Percentage of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine (NQF #0680) from January 1, 2014 to April 1, 2014. This delay is requested as it is necessary to allow time and opportunity for LTCHs and vendors to train, plan for and incorporate changes into their data collection and entry systems. APIC agrees this approach makes sense, although it will allow three fewer months of data collection to be considered for payment determination for FY 2016.

CMS is proposing a number of new LTCHQR Program measures for the FY 2017 and FY 2018 payment determinations. Introducing several of these -- including the NHSN MRSA Bacteremia Outcome Measure



(NQF #1716), NHSN *C. difficile* Infection (CDI) Outcome Measure (NQF #1717), All-cause Unplanned Readmission Measure for 30 day Post Discharge, and the Application of the Percent of Residents Experiencing One or More Falls with Major Injury (NQF #0064) -- over the space of two years in facilities should be undertaken with caution. APIC notes that the burden of data collection must be considered in order to allow these facilities to acquire the resources to focus on improvement efforts and not completely on data collection and submission alone. Although CMS acknowledges the desire to build on the LTCH CARE data set to avoid the burden of data collection, we have concerns that the limited existing resources will be moved from prevention activities to reporting activities.

In addition, CMS is seeking feedback on several proposed measures and measure topics under consideration for the LTCH Quality Reporting Program. APIC questions the relevance of considering an SSI measure for a LTCH facility where surgical procedures, such as colon and hysterectomy, are not routinely performed.

Finally, APIC agrees a portion of the LTCH population are on a ventilator and thus are at risk for development of a ventilator-associated event (VAE), including ventilator associated pneumonia (VAP). However, several of the pieces of the proposed VAP prevention bundle, such as 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 from the ventilator. Collection of this information then will be an unnecessary use of limited resources. NQF has recently decertified the traditional VAP measure used within NHSN and is currently monitoring the development and use of ventilator-associated events (VAE). Therefore, APIC recommends that CMS wait until NQF has endorsed this newly defined CDC/NHSN VAE measure and look to this outcome measure for potential expansion into the LTCH population.

Recommendations:

- APIC supports the alignment of the reporting period of Influenza Vaccination Coverage Among Healthcare Personnel Influenza with the influenza season.
- APIC supports the delay of one quarter for Percentage of Residents or Patients Who Were Assessed and Appropriately Given the Seasonal Influenza Vaccine.
- While APIC supports the expansion of reporting of HAI measures within the LTCH setting, we encourage CMS to evaluate the timing of introduction to allow for adequate training and resources for all data collection.
- APIC does not support the addition of SSI or of the VAP prevention bundle in the LTCH setting and instead urges CMS to wait for the NQF endorsement of the VAE measure as a possibility for future reporting opportunity.



Proposed Change to the Medicare Hospital Conditions of Participation (CoPs) Relating to the Administration of Pneumococcal Vaccines

CMS is proposing an update by which it would delete the term “polysaccharide” from the current CoP standard for the nursing services condition for preparing and administering drugs in reference to the pneumococcal vaccine. This deletion would allow a hospital to include any type of pneumococcal vaccine as part of its physician-approved policy for administration by nurses without a prior practitioner order, as long as the vaccine has been approved by the FDA for the patient population to which the facility intends to administer it. Therefore APIC supports the proposed change to delete the word “polysaccharide” from the text of regulation in order to add clarity to the policy that a hospital may include any type of FDA-approved pneumococcal vaccine in its physician-approved policy for administration by nurses without a prior practitioner order.

Recommendation: APIC supports deleting the word “polysaccharide” from the CoP in reference to pneumococcal vaccine.

APIC appreciates the opportunity to comment on the proposed measures and continues to applaud CMS’s 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,

A handwritten signature in blue ink that reads "Patricia S. Grant". The signature is fluid and cursive, with the first name being the most prominent.

Patricia S. Grant, RN, BSN, MS, CIC
2013 APIC President