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June 10, 2015

Andrew M. Slavitt
Acting 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-1632-P: Medicare Program: Hospital Inpatient Prospective Payment System for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment system for Fiscal Year 2016

Dear Mr. Slavitt:

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 2016 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: Proposed Changes FY 2016-2017

The proposed refinement to the pneumonia readmissions measure for FY 2017 involves expanding the cohort to include hospitalizations for patients with a principal diagnosis of aspiration pneumonia as well as patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that was present on admission. APIC agrees with CMS that refining this measure would better represent a more complete population of a hospital's patients that are being treated and managed for pneumonia, as well as ensuring that this measure accurately captures comparable populations across hospitals, and accounting for differences in coding practices across many hospitals. APIC believes this proposed refinement will improve the measures assessment of avoidable readmissions and supports the proposed refinement.

CMS has also proposed to adopt a Hospital Readmissions Reduction Program extraordinary circumstance waiver process for hospitals adversely impacted by circumstances beyond their control.

Similar to waivers currently present in the Value-Based Purchasing (VBP) Program and the Inpatient Quality Reporting (IQR) Program, these waivers would provide a hospital relief from reporting measures for the Hospital Readmissions Reduction Program for a period of time during which the hospital has experienced a disaster or other extraordinary circumstance. APIC appreciates the efforts of CMS to align the waiver process for all programs which will help reduce confusion and burden on facilities in unusual circumstances.

Recommendations

- *APIC supports the proposed refinement to the pneumonia readmissions measure for FY 2017.*
- *APIC supports the proposed hospital extraordinary circumstances waiver process for the Hospital Readmissions Reduction Program.*

Hospital Value-Based Purchasing (VBP) Program: Proposed Policy Changes for the FY 2018 Program Year and Subsequent Years

For the FY 2018 Program Year, CMS has proposed to readopt measures from prior programs for each successive year unless otherwise indicated. APIC concurs with CMS's belief that this policy aligns the VBP Program with the Hospital Inpatient Quality Reporting (IQR) Program. CMS has also proposed to remove the IMM-2 Influenza Immunization measure from VBP while continuing to include it in the IQR measure set. While APIC believes patient influenza vaccination is a high priority, we acknowledge that the measure is "topped-out" and concur with CMS that the continued inclusion of this measure in the IQR Program represents priorities identified in the National Quality Strategy.

APIC also supports the proposal by CMS to add the 3-Item Care Transition Measure (CTM-3) on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey. The inclusion of questions related to understanding of health maintenance and medications not only reflects patient experience, but could affect appropriate post-discharge use and administration of prescribed antimicrobials or early recognition of signs and symptoms of infection post-discharge. Engagement and understanding of patients and families in infection prevention is an important priority for APIC.

APIC notes that CMS has proposed to remove the Clinical Care-Process subdomain for the FY 2017 Hospital VBP Program due to the fact that two of the measures are proposed to be removed and no additional measures are currently proposed to be adopted in this domain. If the proposals are finalized, only one measure, PC-01 Elective Delivery, would remain in the Clinical Care-Process subdomain. CMS is proposing to move this one remaining measure to the Safety domain with the beginning of the FY 2018 program year. APIC supports this proposal. However, CMS is not explicit about incorporating new process measures into VBP in the future. Stakeholders may interpret the removal of the process domain to mean process measures will no longer be considered for inclusion in future years of the VBP program. We ask CMS to clarify their intentions for including future process measures in the VBP program.

CMS has proposed to calculate the current Centers for Disease Control and Prevention (CDC)'s National Healthcare Safety Network (NHSN) measures for use in the IQR and VBP program using the current

referent periods until the 2019 program years. APIC supports this strategy since it allows for accurate measurement between baseline and performance periods without readjusting data to align with the NHSN's new 2015 baseline period. APIC also supports the inclusion of the select non-Intensive Care Unit (ICU) Central Line-Associated Bloodstream Infection (CLABSI) and Catheter-Associated Urinary Tract Infection (CAUTI) measure expansion into the VBP program using 2015 as the baseline period. APIC notes that CLABSI and CAUTI are important targets for dedicated surveillance and prevention efforts outside the ICU setting and their inclusion in the VBP program represents a more robust reflection of overall organizational performance.

We note that CMS has proposed a 12-month performance period for the ICU CAUTI and CLABSI measures as well as the Surgical Site Infection (SSI), *Clostridium difficile* Infection (CDI) and Methicillin – resistant *Staphylococcus aureus* (MRSA) bacteremia measure with the baseline period 2014 and the performance period 2016. APIC concurs with this strategy.

Finally, CMS has proposed to increase the Safety domain's weight by five percentage points because CMS is proposing to add an additional measure to the domain and because CMS feels it should provide strong incentives to hospitals to perform well on measures of patient safety. APIC supports this proposal.

Recommendations

- *APIC supports removal of IMM-2 Influenza Immunization measure from the Value-Based Purchasing Program.*
- *APIC supports the addition of the 3-Item Care Transition Measure (CTM-3) on the Hospital Consumer Assessment of Healthcare Providers and Systems (HCAHPS) survey.*
- *APIC supports moving PC-01 Elective Delivery to the Safety domain and increasing the Safety domain weight to 25%.*
- *APIC requests that CMS clarify their intentions for including future process measures in the VBP program.*
- *APIC supports the proposal to calculate the current NHSN measures for use in the IQR and VBP program using the current reference periods until the 2019 program years.*
- *APIC supports the inclusion of the select non-ICU CLABSI and CAUTI measure expansion.*
- *APIC supports the use of a 12-month baseline period for all selected infection measures.*

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

For FY 2017 CMS is proposing an additional narrative rule for use in the FY 2017 program year. This additional narrative rule would be applicable to calculation for the Domain 2 score and would treat each Domain 2 measure independently when determining if a score of 10 (maximal score) would be assigned to the measure for non-submission of data without a waiver (if applicable). APIC supports the proposed changes to the narrative rule used in the calculation of the Domain 2 score. APIC believes that these

proposed changes will encourage greater transparency by encouraging hospitals to submit all available required data to NHSN on the different measures captured in the Domain 2 score.

CMS is also proposing to decrease the weighting of Domain 1 and increase the weighting of Domain 2. APIC would like to note that in past comments to CMS, APIC has encouraged the use of reliable and actionable measures to be utilized in determining a hospital's total HAC score. While APIC remains opposed to utilizing the AHRQ PSI-90 measures that are identified as infection indicators such as PSI-7 (Central Venous Catheter-Related Bloodstream Infection Rate), APIC applauds and supports the proposed changes for FY 2017 to move the weighting of Domain 1 to 15% and Domain 2 to 85%. This proposed change gives more weight to the CDC NHSN chart-abstracted measures utilizing standardized definitions that capture both data on Medicare as well as non-Medicare patients rather than measures that are obtained from claims-based data on Medicare patients only.

APIC also notes that CMS is proposing to include select ward (non-ICU) locations in certain CDC NHSN measures beginning in the FY 2018 program year. APIC agrees that the CLABSI and CAUTI measures should be inclusive of expanded, select medical wards in addition to the ICU locations in the overall HAC reduction program. APIC believes that CLABSI and CAUTI are important targets for dedicated surveillance and prevention efforts outside the ICU setting and their inclusion in the program represents a more robust reflection of overall organizational performance.

Recommendations

- *APIC supports the proposed changes to the narrative rule used in the calculation of the Domain 2 scores for the FY 2017 HAC Reduction Program.*
- *APIC supports the proposed adjustment for FY 2017 on the weighting of Domains 1 and 2 such that Domain 1 will be 15% and Domain 2 85%.*
- *APIC continues to oppose the use of infection measures in the AHRQ PSI-90 due to their being claims-based data capturing only Medicare patients.*
- *APIC supports the proposed measure refinements for the FY 2018 HAC Reduction Program to be inclusive of select medical wards as well as inpatient intensive care units.*

Hospital Inpatient Quality Reporting (IQR) Program

In the proposed rule, CMS notes that while IMM-2 Influenza Immunization (NQF #1659) has been determined to be statistically "topped-out", it will continue to retain the measure due to the benefits outweighing the disadvantages. CMS identifies that IMM-2 is the only Hospital IQR Program measure to address the Best Practices to Enable Healthy Living NQS Priority and CMS Quality Strategy goal. APIC supports the continued reporting of this measure.

CMS has also listed plans for removal of IMM-1 Pneumococcal Immunization (NQF #1653) due to new guidelines that were published and the determination of CMS that implementing the measure specifications would not be feasible given their complexity. CMS also notes they feel the measure,

updated by the new guidelines, would burden hospitals with data abstraction and yield results with only questionable meaningfulness and reliability. Finally, CMS emphasizes that while there is a proposal to remove IMM-1 from the Hospital IQR Program, there is value in the pneumococcal vaccine and that they expect hospitals to continue to provide pneumococcal vaccinations for their hospital populations. APIC appreciates the lengthy review and analysis CMS has provided in making this decision to remove IMM-1 measure and supports the removal at this time.

APIC notes that CMS has proposed to remove SCIP-INF-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300). The rationale described for this removal includes the unintended consequences that have occurred due to providers' enthusiasm to meet the measure and that the refined measure does not align with current guidelines and practice. APIC supports the removal of the SCIP-INF-4 measure at this time.

CMS is also notifying the public of the intent from CDC to update the standard population data (sometimes referred to by CDC as "national baseline") to ensure the NHSN measures' number of predicted infections reflect the current state of HAIs in the United States. Beginning in 2016, CDC will use the data collected for infection events that occurred in 2015 as the new standard population data for the HAI measures. APIC fully supports this plan to use the standard population data update since newer population data will help facilitate more accurate comparison of infection rates.

APIC also notes that CMS is proposing to refine the previously adopted Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization (NQF #0468) and to refine the Hospital 30-Day, All-Cause, Risk-Standardized Readmission (RSRR) following Pneumonia Hospitalization (NQF # 0506). The refinement involves expanding the measure cohort to include hospitalizations for patients with a principal diagnosis of aspiration pneumonia as well as patients with a principal discharge diagnosis of either sepsis or respiratory failure who also have a secondary diagnosis of pneumonia that was present on admission. APIC agrees with CMS that refining this measure would better represent a more complete population of a hospital's patients that are being treated and managed for pneumonia, as well as ensuring that this measure accurately captures comparable populations across hospitals, as well as accounting for differences in coding practices across many hospitals. This refinement proposal is also listed in the Hospital Readmissions Reduction Program proposals. APIC believes this proposed refinement will improve the measures assessment of mortality and readmission, align with the definition proposed for use in other CMS Programs, and supports the proposed change.

CMS identifies in FY 2018 it is proposing to adopt the Hospital Survey on Patient Safety Culture. It is noted that in the proposed measure, organizations will be able to use whichever patient safety survey tool they desire and thus, CMS will be able to understand what tools are being used. CMS will also gather information on how frequently the assessment is being completed and what response rates are for organizations. APIC supports the use of tools that can improve a culture of safety in hospitals and supports the addition of this measure.

Recommendations

- *APIC supports the continued reporting of IMM-2 Influenza Immunization (NQF #1659) as the benefit continues to be significant.*
- *APIC supports the removal of IMM-1 Pneumococcal Immunization (NQF #1653) and SCIP-INF-4 Cardiac Surgery Patients with Controlled Postoperative Blood Glucose (NQF #0300).*
- *APIC supports the plan to use the standard population data update for the HAI measures.*
- *APIC supports the refinement of both the Hospital 30-Day, All-Cause, Risk-Standardized Mortality Rate (RSMR) following Pneumonia Hospitalization (NQF #0468) and Hospital 30-Day, All-Cause, Risk-Standardized Readmission (RSRR) following Pneumonia Hospitalization (NQF # 0506).*
- *APIC supports the adoption of the Hospital Survey on Patient Safety Culture measure.*

PPS-Exempt Cancer Hospital Quality Reporting (PCHQR) Program

APIC notes that CMS is proposing a number of new quality measures beginning with the FY 2018 program.

The first is the CDC NHSN Facility-Wide Inpatient Hospital-Onset *Clostridium difficile* Infection (CDI) Outcome Measure (NQF #1717). APIC agrees with CDC that prolonged antibiotic exposure, a long length of stay in a healthcare setting, and the existence of a serious underlying illness or immunocompromised condition, increase the risk of CDI. In addition, chemotherapy and graft vs. host disease are associated with increased rates of CDI, especially in the early post-transplant period.[1] APIC supports reporting of this measure; however, we encourage CMS to monitor the evolution of the science related to the study of *C. difficile* in immunocompromised patient populations. The current version of molecular *C. difficile* tests in detecting colonization rather than true CDI in patients with frequent therapy related diarrhea raise uncertainty as to the significance of the test result even in a symptomatic patient. As this measure moves forward, future novel diagnostic strategies (e.g. measures of inflammation or host immune responses), as well as a better understanding of how these patients transition from colonization to disease, is crucial. APIC also acknowledges CMS's effort to support the Department of Health and Human Services *National Action Plan to Prevent Healthcare-Associated Infections (HAIs)* proposed 2020 goal to reduce CDI by 30 percent from the 2015 baseline.

CMS is also proposing to add CDC NHSN Facility-Wide Inpatient Hospital-Onset Methicillin-resistant *Staphylococcus aureus* (MRSA) Bacteremia Outcome Measure (NQF #1716). APIC agrees that cancer patients are at increased risk for MRSA infections and notes that California has required MRSA reporting for over 5 years with a subsequent decrease in MRSA bloodstream infection.[2] APIC supports the addition of this measure to the PCHQR Program.

Finally, CMS is proposing to add CDC NHSN Influenza Vaccination Coverage Among Healthcare Personnel (HCP) Measure (NQF #0431). APIC strongly applauds CMS for adding this measure, as influenza immunization of HCP is an important patient and employee safety issue supported by multiple infection

prevention societies, including APIC.[3,4] In addition, HCP vaccination has been associated with reduced worker absenteeism and fewer deaths among patients.

Recommendations

- *APIC supports the addition of all three new measures for reporting beginning with the FY 2018 program:*
    - *CDC NHSN Facility-Wide Inpatient Hospital-Onset CDI*
    - *CDC NHSN Facility-Wide Inpatient Hospital-Onset MRSA Bacteremia*
    - *CDC NHSN Influenza Vaccination Coverage Among HCP.*
- *APIC encourages CMS to monitor future novel diagnostic strategies for Clostridium difficile testing*

Long-Term Care Hospital Quality Reporting Program (LTCH QRP)

CMS proposes that beginning FY 2017 and for subsequent years, data submission deadlines be extended from 1.5 months to 4.5 months after the end of the calendar year quarter beginning quarter four, 2015. APIC supports the proposal as it aligns data reporting deadlines with the Inpatient Rehabilitation Facility Quality Reporting and the Hospital IQR Programs and standardizes data submission deadlines.

CMS also identifies that data validation is intended to provide assurance of the accuracy of the data that will be reported to the public. It notes that in this proposed rule CMS is not proposing any new policies related to data accuracy validation, but it may do so in future rulemaking cycles. CMS identifies that it wants to continue to explore methods and threshold policies that will limit the amount of burden and cost to LTCHs. APIC believes that training, auditing and validation are critical components of public reporting, especially for facilities without existing standardized surveillance systems. APIC appreciates CMS is demonstrating a continual dedication to reducing, as much as feasible, the data reporting burden by continuing to explore validation methods.

CMS notes they will begin publicly displaying performance data on the NHSN CAUTI Outcome measure, and NHSN CLABSI Outcome measure as well as two other measures. APIC supports the extension of transparency of LTCHs just as data from the Inpatient Quality Reporting Program is transparent. APIC believes the availability of quality outcome measures, like infection SIRs, not only allows consumers better knowledge for healthcare facility choice, but also promotes infection prevention programs in healthcare facilities. APIC also supports the use of SIRs in public reporting in order to standardize data presentation with facilities whose SIRs are already viewable by the public. APIC agrees the extension of the data submission timeline will allow ample time for data submission, review, and correction of submitted data.

Recommendations:

- *APIC supports the modification to the submission deadlines to align with other Quality Reporting Programs.*
- *APIC supports the display of the NHSN Outcome measures and also the use of the SIR.*

- *APIC agrees with the extension of the data submission timeline.*

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,

Mary Lou Manning, PhD, CRNP, CIC, FAAN, FNAP
2015 APIC President

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[1] Alonso, Carolyn D., et al. "Epidemiology and outcomes of Clostridium difficile infections in hematopoietic stem cell transplant recipients." Clinical infectious diseases 54.8 (2012): 1053-1063

[2] California Department of Public Health, Healthcare-Associated Infections in California Hospitals Report for January – December 2013: 2014. Accessed 6/5/15 at http://www.cdph.ca.gov/programs/hai/Documents/AnnualCaliforniaHospitalHAIReport2013FINAL3.13.15.pdf

[3] APIC Position Statement, Influenza vaccination as a condition of employment for healthcare personnel. January 27, 2011. Accessed 6/5/15 at http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/APIC_Influenza_Immunization_of_HCP_12711.PDF

[4] IDSA, SHEA, and PIDS Joint Policy Statement on Mandatory Immunization of Health Care Personnel According to the ACIP-Recommended Vaccine Schedule, December 2013. Accessed 6/5/15 at http://www.idsociety.org/HCW_Policy/