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June 24, 2019

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Room 445–G
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, DC 20201

Re: CMS-1716-P: Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System updates for FY 2020, proposed rule

Dear Ms. Verma:

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 on the FY 2020 Hospital Inpatient Prospective Payment System and Long-Term Care Hospital Prospective Payment System proposed rule. APIC is a nonprofit, multidisciplinary organization representing 16,000 infection preventionists (IPs) whose mission is to create a safer world through prevention of infection.

As we continue to assess the development and use of the Healthcare-Associated Infection (HAI) measures in the regulatory rules and payment programs, we would like to query CMS on how the present HAI measures will interact with any proposed measure sets/systems resulting from the work of the Core Quality Measures Collaborative (CQMC). We believe that HAI measures are important to consider in the core measure set discussions. However, we advocate to avoid duplication of measures in various programs and future quality measure work. Additionally, we continue to advocate for the use of National Healthcare Safety Network (NHSN)-defined HAI measures, as opposed to claims-based data or non-standardized and non-defined infection measures. APIC would appreciate ongoing dialogue and involvement in the Core Measure Set evolution, particularly since we note that the FY 2020 proposed rule addresses current HAI measure use out to FY 2025.

Hospital Value-Based Purchasing Program:

APIC agrees with CMS's proposal to adopt the same administrative policies/process for hospitals to report, review, and correct Centers for Disease Control and Prevention (CDC)/NHSN HAI measure data beginning with January 1, 2020 for the FY 2022 program year. We note that CMS is proposing to rely on the Hospital-Acquired Condition (HAC) Reduction Program validation process and data to ensure the

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accuracy of the CDC/NHSN HAI measure data in the Value-Based Purchasing (VBP) program. We agree with this approach in order to avoid any duplication of validation processes and efforts since the HAI measures continue to remain in two payment programs.

However, APIC expresses concern that the minimum number of cases for the Hospital VBP Program in the Safety Domain shifts measurement from a denominator of "number of cases" to the numerator of "number of predicted infections", for only the HAI measures. Our concern is that more facilities may be excluded from this measure if their predicted number of infections, based on Standard Infection Ratio (SIR) calculation, falls below one despite having over 25 cases. The SIR is a complex calculation that compares a facility's performance against itself. As fewer number of infections are reported the lower the facility's SIR will go. Moving this measure to predicted infections and away from a minimum number of procedures performed will change the landscape of who is included in this measure. We respectfully request ongoing dialogue on this methodology as it is used and evaluated in the FY 2020 scoring.

Hospital-Acquired Conditions (HAC) Reduction Program:

APIC recommends that CMS correct the term "infectious events", which is used several times in this section, to the more grammatically correct and accurate term "infection events."

Proposed Measure Removal Factors:
APIC supports the adoption of the eight measure removal factors and we appreciate CMS's alignment of the measure removal factor policy for the HAC Reduction Program with that of other quality and payment programs. As we noted in our comments on the FY 2019 IPPS/LTCH proposed rule, APIC agrees with the addition of Factor 8, to consider cost associated with a measure which outweighs the benefit of its continued use in the program and recommends that Factor 8 should be a consideration for measure removal in all the quality reporting and value-based purchasing programs. However, APIC encourages CMS to seek the input of stakeholders in the decision-making process when considering Factor 8 on a case-by-case basis as the associated cost/benefit relationship may be viewed differently by stakeholders.

Administrative Policies for the HAC Reduction Program for FY 2020 and subsequent years
As we noted in our VBP comments above, APIC agrees with the proposed clarification of administrative policies for data collection and validation of the CDC/NHSN HAI measures.

Proposed Change to Validation Targeting Methodology and Clarifications Regarding Validation Processes:
CMS is proposing to change the previously finalized selection methodology of 200 hospitals to be validated, to a new methodology of selecting "up to 200" hospitals for validation. APIC agrees with CMS that this allows for flexibility with the IQR and HAC Reduction Program selections and will not affect statistical reliability. CMS notes that the newly proposed random sample selection process will help avoid duplication efforts. APIC agrees with methodology to avoid duplication, as well as burden of work and resources for the validation process. However, many states also require validation processes and we ask that CMS consider this in its hospital selection process to avoid duplication.

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Proposed Clarification to Validation Filtering Methodology

APIC appreciates CMS's desire to scale validation to "true candidate events" and believes this should be a consideration for all HAI measures. We support the proposal to better target true events by eliminating positive blood and urine cultures collected on Day 1 or 2 of hospital admission from the selection process in determining a central line-associated bloodstream infection (CLABSI) or catheter-associated urinary tract infection (CAUTI) event. APIC appreciates CMS recognizing and including the recommendation from the Department of Health and Human Services (HHS) Office of the Inspector General to "make better use of analytics to ensure the integrity of hospital reported data and payment adjustment by identification of potential gaming or other inaccurate reporting."

APIC also appreciates CMS's testing of a filtering option to apply to colon and abdominal hysterectomy surgical site infection (SSI) cases to increase the yield rate and improve the power of the validation methodology. We look forward to working with CMS on this in future rulemaking cycles.

As CMS notes, it is important to understand the over-reporting and under-reporting of methicillin-resistant *Staphylococcus aureus* (MRSA) and *Clostridioides difficile* infection (CDI) rates. CDC created LabID methodology as a proxy measure for infection. The HAI is assigned a designation of either hospital-acquired or community-acquired, based solely on the date of the patient's admission and the date of culture. Designed to be implemented without clinical review, APIC is not surprised that the correlation between an NHSN-trained reviewer and the proxy measure is problematic. LabID measures are the only HAI measures that are not always reviewed by infection preventionists (IPs) before submission. APIC would encourage CMS to consider the LabID methodology to be more of the problem than the need for additional training of the facilities when seeking to improve the accuracy and validity of this measure.

Review of Cases Prior to Public Posting:

The process of reviewing CMS findings prior to public posting usually involves accessing findings via the *QNet* Secure Portal. APIC respectfully asks that improvement be made in providing sufficient case identification information in order to allow organizations to complete the review of these findings. Lack of sufficient case identification information can slow the process of review by organizations prior to public posting.

Burden Associated with Validation:

APIC appreciates CMS updating the hourly wage rate used to calculate cost burden to hospitals for the collection and submission of NHSN HAI data associated with the HAC Reduction Program to comply with updated data from the Bureau of Labor Statistics.

APIC Recommendations:

- APIC supports adoption of the measure removal factors for the HAC Reduction Program and appreciates the alignment of this policy with the other IPPS/LTCH quality and payment programs.

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- APIC encourages CMS to seek input from stakeholders when considering employing Factor 8 to justify removal of a measure.
- APIC supports the proposed clarification of administrative policies for data collection and validation of the CDC/NHSN HAI measures and appreciates administrative consistency with the Hospital VBP Program.
- APIC supports CMS utilization of a filtering methodology to validate true candidate events for CAUTI and CLABSI and supports CMS efforts to test a filtering methodology for colon and abdominal hysterectomy SSIs.
- APIC encourages CMS to develop a methodology to improve accuracy of the MRSA and CDI LabID event data.
- APIC encourages CMS to provide sufficient case identification information to facilitate hospital inspection of data prior to public reporting on *Hospital Compare*.
- APIC appreciates CMS recalculation of the hourly wage rate relative to NHSN HAI measure reporting.

Hospital Inpatient Quality Reporting Program – Hybrid Hospital-Wide Readmission Measure

APIC reads with interest the proposal to move forward with a hybrid All Cause Readmission measure. As we have discussed in previous comment letters, our experience is that claims-based data is not completely accurate in determining HAIs. Studies have concluded that administrative coded data might be valuable as a supplement to traditional HAI surveillance, but only after validation.[1,2] For this reason, we will continue to review the outcome of this hybrid measure, particularly regarding any infection-related data associated with the hybrid measure process and outcomes. We believe that validation is an important part of this process.

PPS-Exempt Cancer Hospital Quality Reporting Program

Public Display of NHSN HAI Measures:
APIC supports the public reporting of the NHSN Healthcare Personnel (HCP) Influenza Vaccination measure data on *Hospital Compare*. APIC has been a longtime supporter of HCP immunization as an important tool in protecting this vulnerable population.

APIC also supports the public display of MSRA bloodstream infections and colon and abdominal hysterectomy SSI data.

The public display of CDI data, with the current NHSN risk stratification, may not provide the public with helpful information. CDI infection rates increase with the use of chemotherapy and antibiotics; therefore, PPS-exempt cancer hospitals with large numbers of bone marrow transplants, leukemia, and lymphoma will have higher rates. There is also evidence these higher rates in oncology patients do not represent transmission, but rather induction as a result of their therapy regimen.[3,4,5]

APIC supports the CMS proposal to continue to delay public display of the CLABSI and CAUTI measure data for PPS-exempt cancer hospitals until a later date. As APIC has noted in earlier comments, the pool

of these facilities is very small and they are not homogeneous, so comparisons would be difficult. In addition, NHSN has made several changes to the mucosal barrier injury (MBI) organism list. This has created the situation where a CLABSI in 2017 would be classified as an MBI event in 2019. In addition, NHSN published a request for information on the Bloodstream Infection Module earlier this year, which would suggest there are more changes to come. Once the definitions and organism lists have been stabilized for a few years, APIC would support public display of these metrics.

APIC Recommendations:
- APIC supports public reporting of the NHSN HCP Influenza Vaccination, MRSA Bloodstream Infection, and colon and abdominal hysterectomy SSI measure data on *Hospital Compare*.
- APIC supports continued delay of public display of CLABSI and CAUTI measure data for PPS-exempt cancer hospitals on *Hospital Compare* until the definitions and organism lists have been stabilized.
- APIC does not support public display of CDI measure data on *Hospital Compare* because this information may be misleading and unhelpful to the public due to the nature of this infection in this population.

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

In the past, APIC has provided comment on the Federal Health Information Technology Strategic Plan[6] and the IMPACT Act transfer of information and medication profile.[7] We believe that data are powerful, but only when shared in a meaningful and reliable way. The Data Element Library should prove useful as a source of standardized data elements mapped to health information technology standards. APIC appreciates the ongoing HHS efforts to advance interoperability across all care settings. These efforts aim to improve the quality of patient care across the healthcare continuum regardless of the payor.

Proposed Transfer of Health Information to the Provider -- Post-Acute Care (PAC) Measure
While our focus is on antimicrobials (i.e., antibacterial, antifungal, and antiviral agents) APIC recognizes the importance of complete and accurate information for all medications at the time of a care transition. Medication profiles that include the indication, dose, duration, start and stop dates, route of administration, prescriber, and date and time of last dose before transition will ensure appropriate and timely treatment while reducing potential adverse drug reactions.

Along with medication information, transfer of additional information is necessary to facilitate appropriate infection prevention and control interventions during care transitions. APIC believes the following information should also be included in communications provided to the receiving facility or provider at the time of transition:
- Multidrug-resistant organism status, including specimen source;
- Current transmission-based precautions status and reason for precautions;
- Influenza and pneumococcal vaccination status; and
- Presence of indwelling devices (e.g. urinary catheters, tracheostomy tubes/ventilators, intravenous catheters).

APIC Recommendations:

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- APIC supports the Transfer of Health Information to the Provider -- PAC Measure.
- We acknowledge the importance of utilizing National Quality Forum (NQF) measures; however, given that the NQF measure only captures documentation of the medication and not the transfer of the medication information we urge CMS to submit the measure for NQF approval.
- APIC recommends that transfer information to the provider include information that would be helpful in preventing infections in addition to medication information.

Proposed Transfer of Health Information to the Patient -- PAC Measure
Medication use following transitions to home can be less controlled than when care transfers to a subsequent provider. Missed doses of an antimicrobial may result in readmission, while continuation of unnecessary antimicrobials can lead to emergence of resistant organisms and *Clostridioides difficile.* Because providing medication information as part of discharge planning is a Condition of Participation requirement for Medicaid and Medicare and the medication list can be generated from the electronic medical record, there should be no added burden to the long-term care hospital.

APIC Recommendations:
- APIC supports the Transfer of Health Information to the Patient -- PAC Measure.
- We recommend the submission of this measure to NQF for approval.

Medicare and Medicaid Promoting Interoperability Programs

APIC appreciates CMS's discussion regarding the value of electronic health records (EHRs) in today's healthcare environment, as well as the recognition that "reductions in persistent sources of technology-related burden" need to occur. As IPs implement HAI and communicable disease electronic surveillance systems, it is apparent that much more work and communication between vendors and IPs needs to happen. When electronic system developers and vendors actually sit down with practitioners to understand the workflows required, electronic systems can be optimized. APIC believes that more accountability on the part of electronic system vendors must be part of the future in order to make the systems more effective and truly represent the work flow of practitioners. Validation at the time of implementation of these systems, along with validation with any system upgrades is paramount to data accuracy. Future measures should include evidence of validation of electronic surveillance data by vendors and organizations in order to promote patient safety and data accuracy.

Thank you for the opportunity to provide input on programs impacting infection prevention and control in acute care and long-term care settings. We look forward to continuing to work the CMS as the agency continues this essential work.

Sincerely,

Karen Hoffmann, RN, MS, CIC, FSHEA, FAPIC
2019 APIC President

[1] Goto M, Ohl ME, Schweizer ML, Perencevich EN. Accuracy of Administrative Code Data for the Surveillance of Healthcare-Associated Infections: A Systematic Review and Meta-Analysis. *Clin Infect Dis* 2014;58:688–96.

[2] Stevenson KB, Khan Y, Dickman J, et al. Administrative coding data, compared with CDC/NHSN criteria, are poor indicators of health care associated infections. *Am J Infect Control* 2008;36:155–64.

[3] 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.

[4] Kamboj, Mini, et al. "Transmission of Clostridium difficile During Hospitalization for Allogeneic Stem Cell Transplant." *Infection Control & Hospital Epidemiology* 37.01 (2016): 8-15.

[5] Jain, Tania, et al. "Clostridium difficile colonization in hematopoietic stem cell transplant recipients: a prospective study of the epidemiology and outcomes involving toxigenic and nontoxigenic strains." *Biology of Blood and Marrow Transplantation* 22.1 (2016): 157-163.

[6] APIC comments to the National Coordinator for Health Information Technology. Federal Health Information Technology (IT) Strategic Plan for 2015-2020. Available at: http://www.apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/Federal_Health_IT_Strategic_Plan_final_2-4-15.pdf. Accessed May 28, 2019.

[7] APIC comments to CMS. Project Title: Quality measures to satisfy Improving Medicare Post-Acute Care Transformation Action of 2014 (IMPACT Act) domain of: Transfer of Health Information and Care Preferences When an Individual Transitions – Medication Profile transferred to Provider/ Medication Profile Transferred to Patient. CMS Contract No. HHSM-500-2013-13015I (RTI International) CMS Contract No. HHSM-500-2013-13001I (Abt Associates) Available at: https://apic.org/Resource_/TinyMceFileManager/Advocacy-PDFs/Advocacy_Updates/IMPACT_Medication_Profile_measures_final_5-1-18.pdf. Accessed May 28, 2019.