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August 24, 2015

Mr. Andrew M. Slavitt
Acting Administrator
Centers for Medicare and 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-1628-P: Medicare Program; End-Stage Renal Disease (ESRD) Prospective Payment System, and Quality Incentive Program for CY 2016, Proposed Rule

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 rule “End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies.” APIC is a nonprofit, multi-disciplinary organization representing over 15,000 infection preventionists (IPs) 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 ESRD patient care.

Our comments primarily reflect the views of our members who oversee infection prevention and control programs in dialysis centers. We have a vested interest in the effective operation of the ESRD Quality Incentive Program (QIP) and the prevention of infections in this patient population. Our comments address issues related specifically to healthcare-associated infections (HAIs) in the dialysis population.

ESRD Quality Incentive Program (QIP) Reporting

APIC supports the ongoing requirement for utilization of the Centers for Disease Control and Prevention’s (CDC) National Healthcare Safety Network (NHSN) for infection-related reporting. This standardized reporting system allows for robust data analysis and risk stratified comparison among facilities nationwide, drives improvement, and promotes patient safety. APIC supports the use of a single system for reporting quality metrics whenever feasible to prevent redundancy and confusion.

Data Validation

APIC commends CMS for continuing to recognize and acknowledge the need for validation of HAI data and we support the use, application, and validation of the NHSN definitions for inter-facility comparisons. There are currently approximately 6000 dialysis facilities reporting to NHSN. APIC

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continues to have concerns that the proposed, nine-facility feasibility study is not robust enough to evaluate true validation concerns. Based on the results of NHSN dialysis event surveillance validation studies performed in Colorado,¹ the following data quality concerns need to be evaluated: under-reporting, access type errors (for example, inclusion of peritoneal as an "other" access type), application of the NHSN criteria (especially the 21-day rule), accessibility of reports of positive blood cultures from inpatient facilities to outpatient dialysis facilities, and the accuracy of manual- vs. electronically-submitted data. The CDC has already developed a Data Quality Evaluation Guide for NHSN dialysis event surveillance.² Validation of the NHSN Bloodstream Infections (BSI) Clinical Measure is imperative because individual and aggregate facility data will be utilized to determine reimbursement. APIC continues to believe that a feasibility study of nine centers is insufficient to accomplish that goal.

The CMS validation process should integrate evaluation of quality concerns identified by validation projects already completed by the State of Colorado and the CDC. It would also need to include a representative sample of small and large dialysis centers, hospital-based centers and for-profit type centers. Validation should also be done in centers with both paper and electronic medical records. APIC encourages CMS to collaborate with others, using established validation tools to put forth a more robust validation project. A robust surveillance validation process will generate data that is informative and actionable for multiple stakeholders outside of CMS.

In addition, given that positive blood cultures are only one of three metrics in the NHSN dialysis event surveillance definition (the other two events being IV antimicrobial start; and pus, redness, or increased swelling at the vascular access site) it is unclear how only obtaining the positive blood culture data will lead to comprehensive validation of data reported to NHSN.

APIC agrees that the requirement for facilities to provide positive blood culture reports on a quarterly basis is reasonable and should not be a burdensome task for IPs, especially when the expectation is known in advance; however, given this is a feasibility study of a validation methodology, those facilities chosen should not be penalized with a deduction in Total Performance Scores as a result of non-compliance. APIC recommends that this penalty be delayed until full validation is in place.

APIC Recommendations:

- APIC recommends that CMS develop a more robust data validation process modeled after the CDC Data Quality Evaluation Guide in order to detect true validation concerns.
- APIC recommends that CMS work collaboratively with the CDC/NHSN program in developing standard validation processes for all HAI data.
- APIC recommends postponing TPS penalties during the feasibility study until full validation is implemented

PY 2018 Measures Continuing for PY 2019 and Future Payment Years

APIC supports the continuation of the NHSN HCP influenza vaccination and NHSN Bloodstream Infection in Hemodialysis Outpatients in the ESRD QIP. We applaud CMS for continuing these measures as we feel these will continue to advance the strategy aimed at improving patient safety.

APIC supports the ongoing use of a pay-for-performance metric to drive improvement via the ESRD QIP. However, we are concerned that the ESRD QIP now includes the NHSN BSI in Hemodialysis Outpatients as a clinical measure, but no longer includes the NHSN reporting measure. Based on the QIP system for point allocation, a substantial proportion of facilities that have met all NHSN reporting requirements for



12 consecutive months will receive 0 points on the NHSN measure. Payment programs for all other care settings include an incentive for NHSN reporting. The Hospital Inpatient Prospective Payment System (IPPS) includes both a pay-for-reporting program (Hospital Inpatient Quality Reporting Program) and pay-for-performance programs (such as Value-Based Purchasing). However, the ESRD QIP program no longer includes an incentive for NHSN reporting. Establishing a structure for surveillance and reporting BSI measure data into NHSN requires considerable expense and effort on the part of the facility. APIC believes that the lack of a payment incentive for BSI measure reporting undervalues this effort and could potentially cause facilities to disengage from NHSN participation, undermining the prevention objectives that would lead to quality improvement.

APIC encourages CMS to consider implementing a QIP scoring system that assigns value to NHSN reporting, independent of the actual SIR. Some options for this include:

- Reinstatement of the NHSN dialysis event reporting measure in the QIP so that facilities can earn points simply for reporting, or
- Modify the scoring structure so that facilities get a certain number of points on the NHSN measure for reporting and additional points based on the SIR value.

APIC Recommendations:

- APIC supports the NHSN Influenza Vaccination reporting measure for PY 2019 and future payment years.
- APIC supports the CMS NHSN Bloodstream Infection in Hemodialysis Outpatients clinical measure for PY 2019 and future payment years.
- APIC recommends that CMS revise the QIP scoring system to include an incentive for NHSN reporting.

Proposed Full-Season Influenza Vaccination Reporting Measure beginning in PY 2019

APIC notes that CMS has proposed reporting influenza immunization rates for inpatients age six months and older, as part of the ESRD QIP beginning in PY 2019. APIC supports this proposal. Though the measure is not National Quality Form (NQF)-endorsed, APIC believes that the screening for and administration of influenza vaccine to at-risk patients in any setting should be a standard of practice in healthcare. Due to this, the proposed measure is an appropriate assessment of the quality of care furnished in ESRD, as related to HAI prevention.

However, APIC disagrees with the proposal to report patient influenza vaccination through CROWNWeb. ESRD facilities are already required to report healthcare personnel (HCP) influenza vaccination through NHSN beginning with the 2015-16 influenza season. NHSN also has the capacity to support patient influenza vaccination data reporting. APIC strongly recommends CMS utilize NHSN as the standard reporting system for both healthcare personnel and patient vaccination data. NHSN allows both the ESRD facility and CMS to run analysis on the reported data to drive improvement rather than just a one-way flow of this information to CMS for payment determination. In addition, use of NHSN for both metrics will simplify the requirement for ESRD facilities and prevent confusion.

APIC Recommendations:

- APIC supports the adoption of the Full-Season Influenza Reporting measure for PY 2019 and future years.



- APIC supports the reporting period and deadlines as proposed as they align with the NHSN HCP Influenza Vaccination reporting measure.
- APIC encourages CMS to consider the use of NHSN for reporting of patient influenza vaccination data, as this will avoid confusion of reporting data into different systems, and allows for use of information for quality improvement as well as payment determination.

In conclusion, APIC appreciates CMS's prioritization of the implementation of HAI-related measures in the vulnerable ESRD population. APIC stands ready to work with CMS to establish meaningful performance measures, reporting methodology, and validation design for the ESRD patient population in order to obtain accurate data that will promote the most strategic prevention opportunities for our patients. We welcome the opportunity to work collaboratively as part of an expert panel to explore measures for the pediatric and peritoneal dialysis patient populations.

Sincerely,

A handwritten signature in black ink that reads "Mary Lou Manning".

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

¹ Hoxworth T, Angbanzan R. Validation of National Healthcare Safety Network (NHSN) Dialysis Event Data [Abstract]. Presented at 2013 Annual CSTE Conference. June 10, 2013. Pasadena, CA. Available from: <https://cste.confex.com/cste/2013/webprogram/Paper1472.html>

² NHSN Dialysis Event Surveillance & Reporting Data Quality Evaluation – Project Implementation Guide <http://www.cdc.gov/nhsn/PDFs/dialysis/DE-Data-Quality-Evaluation-Implementation-Guide.pdf> Accessed August 12, 2014.