



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

August 26, 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-1614-P, Medicare Program; End-Stage Renal Disease Prospective Payment System, Quality Incentive Program, and Durable Medical Equipment, Prosthetics, Orthotics, and Supplies, 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 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 (IP) 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 end-stage renal disease (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 will address the National Healthcare Safety Network (NHSN) Bloodstream Infection Clinical Measure and the proposal to revise the measure to calculate facility performance using the Reliability-Adjusted Standardized Infection Ratio; the measure's validation; the Extraordinary Circumstances Exemption; the addition of the NHSN Healthcare Personnel (HCP) Influenza Vaccination Reporting Measure; and implementation of the Centers for Disease Control and Prevention (CDC) core interventions for dialysis bloodstream infection prevention.

NHSN Bloodstream Infection Measure

APIC applauds CMS for identifying the reduction of bloodstream infections in patients with ESRD as one of its highest priorities. We are encouraged that, for this reason, the agency proposes to place this measure alone in the Clinical Measure Safety subdomain beginning in payment year (PY) 2018.

We encourage CMS to consider adding NHSN dialysis event-specific indicators, such as local access site infection, access-related bloodstream infection, and vascular access infection, to the measure. These specific indicators should be implemented incrementally and would better represent HAIs specific to



dialysis centers. Incorporating these indicators would encourage centers to develop specific interventions to improve the quality of care in their specific populations. This would also allow for the development of a more appropriate ESRD national benchmark.

We recommend starting with access-related bloodstream infection, as this indicator is the most frequently identified in dialysis centers and has been associated with the greatest morbidity and mortality. In addition, access-related bloodstream infections are more amenable to evidence-based bundled interventions to prevent bloodstream infection and more useful for directing performance improvement activities. This measure has the potential to more closely describe the true incidence of infections associated with hemodialysis vascular access, as each positive culture would be identified with a suspected source of the positive culture.

APIC Recommendations:

- APIC recommends that CMS consider transitioning to NHSN dialysis event specific indicators which would better represent HAIs specific to dialysis centers.
- APIC recommends incremental implementation of event-specific indicators, beginning with access-related bloodstream infection.

Revision of the NHSN Bloodstream Infection in Hemodialysis Outpatients Clinical Measure to incorporate Reliability-Adjusted Standardized Infection Ratio

APIC supports the CMS proposal to adopt the Reliability-Adjusted Standardized Infection Ratio (SIR) for PY 2016 and future years. This will account for the variation in patient risk by vascular access type and the number of patients a facility treats in a given month. It will also provide a more reliable SIR and better reflect the differences in opportunity for HAI prevention in ESRD facilities.

APIC Recommendation: APIC supports the adoption of the Reliability-Adjusted Standardized Infection Ratio for calculating facility performance in the NHSN Bloodstream Infection Clinical Measure beginning in PY 2016, and we encourage monitoring and ongoing assessment of this ranking.

Validation of the NHSN Bloodstream Infection Clinical Measure

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 6,000 dialysis facilities reporting to NHSN. APIC is concerned 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: underreporting, 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 Clinical Measure is imperative because individual and aggregate facility data will be utilized to determine reimbursement. APIC believes that a feasibility study of nine centers is insufficient to accomplish that goal.

The CMS validation process should integrate the 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 dialysis centers that includes both small and large facilities, hospital-based and for-profit type centers, and facilities with paper and/or electronic medical records. Therefore, we recommend CMS reach out to researchers and professional organizations to access validation tools that have been developed and tested in the field, to put forth a more robust validation project. This will aid in the creation of outcome data that is informative and actionable for multiple stakeholders.

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.

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.

NHSN Healthcare Personnel Influenza Vaccination Reporting Measure for Payment Year 2018 and future payment years

APIC supports the CMS proposal to add HCP influenza vaccination to the ESRD quality reporting requirements. Because HCP can unintentionally expose patients to seasonal influenza if they have not been vaccinated and such exposure can be harmful to vulnerable patients, APIC supports mandatory HCP influenza vaccination as a condition of employment. We applaud CMS for adding this measure as we feel this will advance the strategy aimed at improving overall patient safety.

APIC Recommendation: APIC supports the CMS proposal to adopt the NHSN HCP Influenza Vaccination reporting measure for PY 2018 and future payment years.

Extraordinary circumstances exemption

APIC Recommendation: APIC supports the proposal to exempt ESRD facilities from QIP reporting requirements during the months in which they are forced to close due to a natural disaster or other extraordinary circumstances.

CDC core interventions for dialysis bloodstream infection prevention

CMS has recognized the importance of following the CDC core interventions for dialysis bloodstream infection prevention³ by encouraging facilities to adopt the measures. APIC continues to encourage CMS to require the implementation of these measures. Considerable variation among facilities exists for core measures 2, 4, 5, and 9. However, we feel that consideration should be given to requiring CDC core interventions 7 and 8 as clinical measures. When implemented, core interventions 7 and 8 protect catheter accesses from infection. Use of alcohol-based chlorhexidine >0.5% as the preferred skin



antiseptic for central line insertions and dressing changes (core intervention 7), and reducing risk of intra-luminal biofilm by “scrubbing hubs” prior to accession or after disconnection (core intervention 8) are essential for prevention of vascular access infection.

APIC Recommendation: APIC recommends that CMS require the implementation of core interventions 7 and 8 from the CDC core interventions for dialysis bloodstream infection prevention.

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 and on training, implementation and validation of reporting measures for ESRD facilities 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 "Jennie L. Mayfield". The signature is fluid and cursive, with the first letters of the first and last names being capitalized and prominent.

Jennie L. Mayfield, BSN, MPH, CIC
2014 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 U.S. Centers for Disease Control and Prevention. NHSN Dialysis Event Surveillance & Reporting Data Quality Evaluation – Project Implementation Guide. Available from <http://www.cdc.gov/nhsn/PDFs/dialysis/DE-Data-Quality-Evaluation-Implementation-Guide.pdf>. Accessed August 12, 2014.

³ U.S. Centers for Disease Control and Prevention. CDC Approach to BSI Prevention in Dialysis Facilities (i.e., the CDC Core Interventions for Dialysis Bloodstream Infection (BSI) Prevention). http://www.cdc.gov/dialysis/PDFs/Dialysis-Core-Interventions-5_10_13.pdf Accessed August, 12, 2014.