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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-1526-P, Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2014, End-Stage Renal Disease Quality Incentive Program for PY 2016 and beyond, 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 "Medicare Program; Changes to the End-Stage Renal Disease (ESRD) Prospective Payment System (PPS) for Calendar Year (CY) 2014, and End-Stage Renal Disease Quality Incentive Program (QIP) for Payment Year (PY) 2016 and beyond." APIC is a nonprofit, multi-disciplinary organization representing over 14,000 infection preventionists 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 in hospitals and health systems who oversee infection prevention and control programs in dialysis centers. We have a vested interest in the effective operation of the ESRD Prospective Payment System and the prevention of infections in this patient population. Within this document, we will address the proposal to move the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure from a reporting measure to a clinical measure; the measures validation and performance and improvement thresholds, the CDC Core Interventions for bloodstream infection (BSI) prevention and the overall impact of the program.

NHSN Dialysis Event Reporting Measure
We applaud CMS for continuing to promote the use of valid and reliable healthcare-associated infection (HAI) data through the CDC's NHSN reporting system but do not support moving the NHSN Dialysis Event Reporting Measure to a clinical indicator. Measurement of positive blood cultures in outpatient dialysis centers is reliable and easy to collect. It is not, however, specific enough to detect HAIs related to care at individual dialysis centers. It may include blood cultures associated with a primary infection at another site as well as cultures that would be considered contaminated at the time of collection.

We share CMS's concern for the impact of HAIs on patients and the healthcare industry and their desire to quickly move forward with HAI indicators. However, we caution CMS that measuring positive blood cultures without controlling for other potential causes, like contamination at the time of culture, will result in overestimation of the frequency of dialysis-associated BSI and limit the capability to develop reliable benchmark data. The overestimation of dialysis-related BSI in this fashion would also make it difficult to assess the true impact of primary dialysis-associated bacteremia infection that can be measured over time to track improvement.

Converting the dialysis event measure from a reporting to a clinical measure creates the likelihood that dialysis centers would be penalized financially for infections that are not directly associated with dialysis. The CDC states that the goal of the dialysis event reporting is to capture data reliably, but that it will not perfectly capture all desired data completely, nor will it be captured without error.[1] APIC believes that this specific indicator should be refined further before transitioning it to a clinical indicator.

CMS states that they believe facilities are sufficiently versed in reporting this measure to NHSN. While facilities have become more familiar with this NHSN reporting measures, they have not yet been required to report a full 12 months of data. Monthly reporting of dialysis events requires designated staff to collect and report data into NHSN. Few ESRD facilities have staff dedicated solely to infection prevention and instead rely on facility staff or consultants to perform infection prevention and reporting duties in addition to their other tasks. For many dialysis facilities, the duration of reporting to NHSN will have been less than 12 months. The NHSN measure is sufficiently complex to require a longer period of acclimation to its requirements. Without 12 consecutive months of reporting, an accurate baseline rate cannot be calculated. This baseline data of greater than 12 months would serve as the foundation for the development of a reliable clinical measure that would achieve the intended goal of patient safety through prevention of HAIs. CMS proposes to use CY 2014 for baseline data and forgo setting improvement thresholds. APIC feels that any clinical indicator that ultimately affects reimbursement should have both appropriate performance and improvement thresholds established.

For future reporting periods, once outpatient dialysis centers gain more experience in collecting surveillance data, we would encourage CMS to consider adding NHSN dialysis event-specific indicators, such as local access site infection, access-related bloodstream infection and vascular access infection. These specific indicators should be implemented in a staggered approach and would better represent HAIs specific to dialysis centers. Choosing one or more of these indicators would encourage centers to develop bundled measures and specific interventions to improve the quality of care in their specific populations. This would also allow for a more appropriate ESRD national benchmark to be developed.

If a staggered approach were adopted, we would recommend beginning with access-related bloodstream infection, as this indicator is the most frequently identified and associated with the greatest morbidity and mortality. In addition, it is more amenable to already proven evidence-based bundled interventions to prevent bloodstream infection and more useful for directing performance improvement activities. This measure would more closely describe the incidence of infections associated with hemodialysis vascular access, as each culture would be identified with a suspected source of the positive culture. The 2013 update to the HAI National Action Plan to Prevent HAIs identifies "access-related bacteremia" as the measure that most closely describes actual incidence of infections associated with hemodialysis vascular access.

APIC Recommendations:

- APIC recommends that the dialysis event indicator remain a reporting measure and that appropriate benchmarks and robust data validation be established before transitioning to a clinical measure.
- APIC recommends that CMS transition to NHSN dialysis event specific indicators in a staggered approach beginning with access-related BSI.

CDC Core Interventions

CMS recognizes the importance of following the CDC core interventions for dialysis bloodstream infection prevention by encouraging facilities to adopt the measures, but stops short of requiring their implementation. Since these key interventions are known to reduce infections,[2,3] we encourage CMS to require their implementation. We acknowledge that considerable variation among facilities exists for core interventions 2 (hand hygiene observations), 4 (staff education and competency), 5 (patient education/engagement) and 9 (antimicrobial ointment to catheter exit sites) and would make auditing of these practices difficult. However, APIC believes that consideration should be given to requiring CDC core interventions 7 and 8; use of alcohol-based chlorhexidine >0.5%, the first line skin antiseptic for central line insertions and dressing changes (core intervention 7) and reducing risk of intraluminal biofilm by "scrubbing hubs" prior to accession or disconnection (core intervention 8). Questions regarding core interventions 7 and 8 could easily be added to the NHSN ESRD annual facility survey and validated on site visits.

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 via addition to the annual NHSN ESRD annual facility survey which can be validated during site visits.

Overall Impact

Section XI Regulatory Flexibility Act Analysis clearly identifies that the proposed rule will have a significant impact on a substantial number of small entities including small rural hospitals which may experience as much as a 10% decrease in payment. APIC is concerned that this will disproportionately affect the care of an already vulnerable population with limited healthcare resources. These facilities treat smaller numbers of patients; therefore, the infection rates of these facilities cannot be reliably compared to that of larger organizations with much higher patient volumes.

In the proposed rule, the NHSN Bloodstream Event in Hemodialysis Outpatient measure performance standards are based on percentile ranking of data from all of the eligible facilities. Establishing performance standards in this way gives a disproportionate disadvantage to smaller facilities. APIC encourages CMS to conduct further analysis of the impact on small entities and consider alternate performance indicators based on broader depth of data from dialysis centers. APIC recommends an approach that risk adjusts and controls for small data sets modeled after the Standardized Infection Ratio (SIR) currently in use in NHSN for BSI as well as other HAI indicators. The SIR is already the method for reporting for the HAI indicators in the Inpatient Prospective Payment System.

APIC Recommendations:

- APIC recommends that CMS work collaboratively with the CDC's NHSN program in developing standard validation processes for all HAI data.
- APIC recommends that CMS publish the processes that will be used for data validation, including more detail on what specific information centers will need to provide.

In conclusion, APIC appreciates CMS 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 scoring criteria 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.

Finally, we appreciate the opportunity to express our comments to the CMS proposed rule for ESRD patients.

Sincerely,

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

[1] CDC. Frequently Asked Questions about Dialysis Event. Available from http://www.cdc.gov/nhsn/dialysis/faq/FAQ-dialysis-event-reporting.html. Accessed August 15, 2013.

[2] Kallen AJ. Bloodstream infection rates in outpatient hemodialysis facilities participating in a collaborative prevention effort: A quality improvement report. *Am J Kidney Dis*, 62(2), 322-330.

[3] Kallen, A.J., Patel, P.R., Hess, S. (2011). Intolerance of chlorhexidine as a skin antiseptic in patients undergoing hemodialysis. *Infection Control and Hospital Epidemiology, 32*(11), 1144-1146.