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August 10, 2011

Donald Berwick, MD
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
200 Independence Avenue, SW, Room 445-G
Washington, DC 20201

Re: CMS1-577-P, Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2012, end-Stage Renal Disease Quality Incentive Program for PY 2013 and PY 2014; proposed rule

Dear Dr. Berwick:

The Association for Professionals in Infection Control and Epidemiology (APIC), an international association comprised of greater than 14,000 infection preventionists, 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 CY 2012, and End-Stage Renal Disease Quality Incentive Program (QIP) for PY 2013 and PY 2014". We are pleased that CMS continues to demonstrate its commitment to improving the quality of ESRD patient care and we support this next step in the evolution of the ESRD program that began more than thirty years ago.

Our comments primarily reflect the views of our members in hospitals and health systems who oversee infection prevention and control programs in dialysis centers and 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 proposed elimination of Vancomycin restriction; Vascular Access Type; Vascular Access Infection and the National Healthcare Safety Network (NHSN) Dialysis Event measures as proposed performance measures, along with a comment on the Proposed Performance Standards.

Proposed Provisions for the ESRD PPS: Vancomycin

APIC acknowledges and supports the feedback that CMS has already received from other medical experts that Vancomycin is indicated for both ESRD and non-ESRD conditions, such as skin infections. APIC encourages CMS to continually consider, with the consultation of medical experts, the appropriateness of other anti-infective drugs and biologicals which could be used in the future for both ESRD and non-ESRD conditions, with a primary goal to help reduce drug resistance in this patient population that is so highly prone to antimicrobial resistance.

APIC Recommendation: APIC supports CMS' proposal to eliminate the restriction on Vancomycin to allow ESRD facilities to receive separate payment for these drugs when furnished to treat non-ESRD related conditions.

Proposed Performance Measures for PY 2014 ESRD QIP:

Proposed Vascular Access Type Measure

APIC supports the proposed Vascular Access Type Measure and efforts to promote the placement of arteriovenous (AV) fistulas for adult patients on maintenance dialysis. Evidence strongly supports the use of fistulas for all eligible patients and acknowledges reduced infection events in this population, compared to those with access via short- or long-term central venous catheters or ports.[1,2,3] APIC appreciates that CMS based this performance measure on two identified National Quality Forum (NQF)-endorsed measures (NQF #0257 and NQF #0256). We are unaware of any unintended consequences of combining these two measures into one overall score, especially if it ensures that facilities will not be penalized twice for the same event-related outcome.

We agree with the CMS determination that expanding collection of this data for all patients could be overly burdensome for ESRD providers and we support limiting the application of this measure to the Medicare hemodialysis patient population.

APIC appreciates CMS recognition of different treatment issues in different patient populations. As such, we support CMS' decision to exclude hemodialysis patients with acute renal failure, peritoneal dialysis patients, and patients under age 18 from this proposed measure.

Proposed Vascular Access Infections Measure

APIC applauds CMS' engagement in national efforts such as the National Patient Safety Initiative and the Partnership for Patients to reduce the number of preventable infections across healthcare settings. Infections, including bacteremia, are the second leading cause of death among hemodialysis patients. In a March 2011 publication, the U.S. Centers for Disease Control and Prevention (CDC) reported that in 2008, 37,000 bloodstream infections occurred among hemodialysis patients who had central venous catheters.[4] Among patients with a hemodialysis catheter, the rate of catheter-related bacteremias has been estimated to be 0.9 – 2.0 episodes per patient-year. Further, this report highlights that approximately 80% of ESRD patients in the United States initiate hemodialysis with a "temporary" central venous catheter, a proportion that exceeded that of eight of 10 other developed countries and was nearly threefold higher than in Germany (23%) and Japan (29%). Often, this is driven by preference expressed by the patient enrolled in ESRD. Interventions to improve arteriovenous fistula placement, including increased access to pre-ESRD nephrology care, are needed to reduce reliance on central venous catheters.

Measuring dialysis access related infection rates by assessing the number of months in which a monthly hemodialysis claim reports a dialysis access-related infection using Healthcare Common Procedure Coding System (HCPCS) modifier V8: As noted in previous APIC comments on the use of administrative data for quality purposes, we again note that the exclusive use of claims data for the determination of

vascular access infections as a proposed performance measure has limited value in improving patient care because claims data are unable to provide precise identification of healthcare-associated infections (HAIs), nor do they provide information in a timely manner to provide effective treatment and prevention.[5] Claims data, used in isolation for measuring quality of care, result in questionable data comparison for end users whom these reported data are intended to guide. While we applaud federal efforts to improve the quality of ESRD patient care, we believe that the patients who receive that care would be better served by the use of more precise and accurate data from the CDC/NHSN to identify clinical conditions/outcomes.

APIC also highlights a concern regarding duplicative reporting when using claims data for measuring vascular access bloodstream infections. A single patient that encounters a recurrent (same organism) bloodstream infection the month following the initial infection will be counted as two infections (one in each month) when using claims data. This penalizes a facility twice for the same event. The CDC/NHSN definition, however, uses a 21 day rule for recurrent bloodstream infections in the same patient and counts these events only once.

APIC also supports exclusion of pediatric and peritoneal dialysis patients from this measure.

> **APIC Recommendation**: APIC acknowledges that a transition period exists between the use of claims data and the use of actual data submissions into the CDC/NHSN database. We recommend that CMS move from vascular catheter-associated infections identified using claims data to the use of the CDC/NHSN dialysis event reporting module, thereby promoting the use of well-defined HAI data to improve prevention strategies in the ESRD patient population.
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> **APIC Recommendation**: APIC supports the recommendation to convene an expert panel to address the unique needs of the pediatric and peritoneal dialysis patient populations and offers APIC expertise when these panels are convened.

Proposed NHSN Dialysis Event Reporting Measure

APIC applauds the Department of Health and Human Services agencies, including CMS, in their partnering with the CDC to encourage providers to report to NHSN in the tracking of HAIs. Prior to participation in the NHSN reporting program, facilities must meet certain technical requirements (i.e., Internet access, a valid e-mail address, and ability to download a digital certificate) and make a commitment to follow the data collection protocol, complete an annual practices survey, and report dialysis events and denominator data for at least 6 months in a given year. APIC appreciates CMS' acknowledgment of the time it takes facilities to become familiar with, and utilize the reporting process.

> **APIC Recommendation**: APIC supports the initial limited reporting measure to assess whether providers/facilities enroll and complete any training required by CDC/NHSN.
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> **APIC Recommendation**: Implementation of a NHSN Dialysis Event Reporting Measure should be timed to allow ESRD dialysis centers to meet NHSN reporting requirements and to meet NHSN's ability to bring all ESRD centers on board.

Proposed Performance Standards for PY 2014 ESRD QIP

APIC, in past comments to CMS, has expressed concern over the composite scoring approach to the evaluation of infection-related indicators. Grouping infection-related performance measures with other non-infection-related performance measures, limits the ability to identify opportunities for improvement and develop relevant prevention strategies based upon the population at risk.

> **APIC Recommendation**: APIC supports the need to establish performance and improvement standards and compare data to a baseline period. Additionally APIC supports comparing both the performance and the improvement standards to the national performance and improvements rates, but recommends that a composite scoring approach not be used for infection-related measures.

In conclusion, APIC appreciates CMS's thoughtful approach to expanding the ESRD Quality Incentive Program to begin to include HAI-related measures. 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,

Russell N. Olmsted, MPH, CIC
2011 APIC President

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[1] Hoen B, Paul-Dauphin A, Hestin D, et al. EPIBACDIAL: a multicenter prospective study of risk factors for bacteremia in chronic hemodialysis patients. J Am Soc Nephrol 1998;9:869–76.

[2] Taylor G, Gravel D, Johnston L, Embil J, Holton D, Paton S. Prospective Surveillance for Primary Bloodstream Infections Occurring in Canadian Hemodialysis Units. Infect Control Hosp Epidemiol 2002;23:716-20.

[3] Dopirak M, Hill C, Olesksiw M, Dumigan D, Arvai J, English E, et al. Surveillance of Hemodialysis-Associated Primary Bloodstream Infections: The Experience of Ten Hospital-Based Centers. Infect Control Hosp Epidemiol 2002;23:721-4.

[4] Centers for Disease Control and Prevention. Vital Signs: Central Line--Associated Blood Stream Infections --- United States, 2001, 2008, and 2009. Morb Mortal Wkly Rep 2011; 60(08);243-248. Available from http://www.cdc.gov/mmwr/preview/mmwrhtml/mm6008a4.htm. Accessed August 4, 2011.

[5] APIC Position Paper: The Use of Administrative (Coding/Billing) Data for Identification of Healthcare-Associated Infections (HAIs) in US Hospitals. Washington DC:APIC. October 12, 2010. Available at: http://www.apic.org/Content/NavigationMenu/GovernmentAdvocacy/PublicPolicyLibrary/ID_of_HAIs_US_Hospitals_1010.pdf