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August 29, 2012

Ms. Marilyn Tavenner
Acting 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-1352-P, Medicare Program; Changes to the End-Stage Renal Disease Prospective Payment System for CY 2013, End-Stage Renal Disease Quality Incentive Program for PY 2014 and PY 2015 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) 2013, and End-Stage Renal Disease Quality Incentive Program (QIP) for PY 2014 and Payment Year (PY) 2015." 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 proposed provisions for daptomycin, Vascular Access Type, the National Healthcare Safety Network (NHSN) Dialysis Event Reporting Measure, Standardized Hospitalization Ratio (SHR) measure and the Standardized Mortality Ratio (SMR) measures as part of the PY 2015 ESRD QIP as proposed performance measures, along with a comment on data validation. We support the decision not to add new measures relevant to infection prevention and control for PY 2015.

Vascular Access Type Measure

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 Recommendation: APIC continues to support the Vascular Access Type Measure and efforts to promote the placement of arteriovenous (AV) fistulas for all patients, including pediatrics when feasible, on maintenance dialysis.

NHSN Dialysis Event Reporting Measure

We applaud CMS for continuing to promote the use of valid and reliable data through the CDC's NHSN reporting system, and to initiate inclusion of this data for quality purposes. We believe that NHSN is a clearly defined, scientifically sound system for reporting healthcare-associated infections (HAIs) that will ensure fair comparisons between facilities and enhance the accuracy of publicly reported data. These efforts will enable APIC members to evaluate organizational performance and set achievement and improvement thresholds which will ultimately improve patient outcomes. In addition, we are pleased that CMS has transitioned from claims-based administrative data to the CDC NHSN system for identification of infections. APIC would like to note that we are opposed to the use of administrative/ claims data as a single source of HAI identification. While claims data may be useful as a supplemental method to assist in finding records to be evaluated for possible HAI, it is essential that HAIs are validated by trained surveillance personnel using written standardized protocols. Because claims data do not provide precise identification of HAIs, nor do they provide information in a timely manner to provide effective treatment and prevention, they are of limited use in preventing HAIs.[4]

APIC Recommendation: APIC strongly supports the continuation of the NHSN Dialysis Event Reporting Measure with an expansion to a full 12 month reporting period for PY 2015.

Proposed Provisions for the ESRD PPS: Daptomycin

APIC acknowledges and supports the feedback that CMS has already received from other medical experts that daptomycin 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 compromised susceptible patient population.

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

NQF #1460: Bloodstream infection (BSI) measure

Once again we applaud CMS for using the NHSN system for collecting and reporting of HAI data. Measurement of positive blood cultures in outpatient dialysis centers is reliable and easy to collect. It may, however, 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. This would result in overestimating the frequency of BSI directly associated with dialysis. We acknowledge that those in charge of collecting these indicators in dialysis centers typically do not have formal training in infection prevention and control in order to make the aforementioned distinctions. Since this measure is easily collected and does not require formal training in infection prevention and control to complete accurately it is a good initial surrogate marker for dialysis-related BSI. However, for future reporting

periods, once outpatient dialysis centers gain more experience in collecting surveillance data, we would encourage CMS to also consider adding NHSN dialysis event specific indicators such as local access site infection, access-related bloodstream infection and vascular access infection. Choosing one or more of these indicators in a staggered approach would encourage centers to develop bundled measures and specific interventions to improve the quality of care in their specific populations.

> **APIC Recommendation:** APIC supports the use of NQF #1460. In addition we encourage consideration of adding measures more sensitive to intervention at the dialysis centers such as NHSN access-related BSI, NHSN local access-site infection or NHSN vascular access infection.

Measures under Consideration for Future Years of the ESRD QIP: SHR and SMR measures

While APIC acknowledges that standardized mortality and hospitalization ratios may reflect potentially avoidable outcomes, we express concern that these measures may need further risk adjustment considering the unique cultural, socioeconomic, and health factors unique to the ESRD population.

> **APIC Recommendation:** APIC supports not including the SHR and SMR in PY 2015 and recommends a pilot period in which only aggregate data is reported, giving individual facilities the opportunity to evaluate their own performance until a more thorough assessment and validation of this measure is assessed.

Pilot Data Validation Program

CMS recognizes the need for validation of HAI data and we support the use, application, and validation of the NHSN definitions for interfacility comparisons beginning in CY 2013. CMS proposes to sample records from 750 facilities and each facility would be required to produce approximately 10 records. CMS estimates it will take each facility approximately 2.5 hours to comply. APIC is concerned that the time stated may be underestimated and there is not adequate detail in the proposed rule on what records facilities will be required to submit. We encourage CMS to partner with CDC's NHSN program and state public health partners in developing a standardized process for validation of HAI data.

> **APIC Recommendation:** APIC recommends that CMS work collaboratively with CDC's NHSN program in developing standard validation processes for HAI data. In addition, 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 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 infection prevention opportunities for our patients. We appreciate the opportunity to express our comments to the CMS proposed rule for ESRD patients.

Sincerely,

Michelle Farber, RN, CIC
2012 APIC President

[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] 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/Resource_/TinyMceFileManager/Advocacy-PDFs/ID_of_HAIs_US_Hospitals_1010.pdf