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August 28, 2017

Ms. Seema Verma  
Administrator  
Centers for Medicare & Medicaid Services  
U.S. Department of Health and Human Services  
Room 445-G  
Hubert Humphrey Building  
200 Independence Avenue, SW  
Washington, DC 20201

***Re: CMS-1674-P, Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, and End-Stage Renal Disease Quality Incentive Program for Calendar Year (CY) 2018, proposed rule***

Dear Ms. Verma:

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 updating the End-Stage Renal Disease (ESRD) Prospective Payment System and Quality Incentive Program (QIP). APIC is a nonprofit, multidisciplinary 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 focus on issues related to prevention and reporting of healthcare-associated infections (HAIs) in the dialysis population.

**Aligning Extraordinary Circumstance Exception Policies (ECE) for all programs**

APIC agrees with the need to standardize the ECE processes across all CMS payment programs. We support the CMS proposals to (1) allow the facility to submit a form signed by the facility's CEO or designated personnel; (2) expand the reasons for which an ECE can be requested to include an unresolved issue with a CMS data system, which affected the ability of the facility to submit data, (3) specify that a facility does not need to be closed in order to request and receive consideration for an ECE, as long as the facility can demonstrate that its normal operations have been significantly affected by an extraordinary circumstance outside of its control, (4) clarify that CMS will strive to provide a formal response notifying the facility of its decision within 90 days of receipt of the facility's request.



### **Inclusion of Acute Kidney Injury (AKI) Patients in ESRD QIP**

APIC notes that CMS is indicating that, while it is not currently requiring facilities to report AKI patient data in any of the measures included in the ESRD QIP, including the National Healthcare Safety Network (NHSN) bloodstream infection (BSI) clinical reporting measure, it has a strong interest in collecting this data going forward. APIC supports inclusion of this population in future reporting requirements, especially as it relates to the NHSN BSI clinical reporting measure. This will allow for complete data collection and better risk stratification of the ESRD and AKI populations as it relates to BSIs. We believe that not including these patients within the ESRD QIP measures could result in under-reporting of BSI through inadvertent misclassification of patients, which would skew data trends as this population would be excluded from both denominator and numerator data.

### **Data Validation**

While APIC endorses the use of validation to ensure data accuracy, selection of only 35 facilities for the NHSN dialysis event validation study represents only one percent of facilities nationally. We feel strongly that a larger, more representative sample is needed for validation, especially considering this data is publicly available via Dialysis Compare. APIC applauds CMS for working with the Centers for Disease Control and Prevention (CDC) on the proposed methodology for data validation. APIC recommends that the sample size of facilities undergoing validation be increased to five percent, consistent with the dialysis facility validation sample size for CROWNWeb data. If financial barriers are a concern, APIC recommends that CMS consider requiring a self-validation exercise module for either all or a representative sample of dialysis facilities to perform. Self-validation exercises, while still a burden of labor on the facility, often provide useful information to both the regulatory agency and facility and would be considerably less resource intensive yet still provide useful validation data. The California Department of Public Health (CDPH) Healthcare-Associated Infections Program has several examples of such self-validation exercises on their website:

<http://www.cdph.ca.gov/programs/hai/Pages/UsingNHSNDataValidationforImprovedHAISurveillanceandReporting.aspx>

An additional consideration, despite the sample size, is to include a diverse group of facilities to ensure that the major providers are not overrepresented in the sample. Lessons learned from the CY 2017 data validation should be utilized when conducting the CY 2018 validation survey.

### **New Vascular Access Measures**

APIC appreciates the continued efforts to modify measures to ensure patient safety while recognizing the needs of the individual patient. We support the new National Quality Forum (NQF)-endorsed consensus-based vascular access measures (NQF #2977 and NQF #2978). We acknowledge the exclusion criteria and agree that while recognizing the infection risk associated with temporary access for maintenance dialysis, there are certain comorbidities and patient specific situations such as low life expectancy that should be considered in the measure.



**Proposed Performance Period**

APIC supports the influenza vaccination reporting measure performance period of October 1 through March 31. This is consistent with other quality reporting and value-based payment programs and we appreciate the coordination. Our members often have responsibility for infection prevention and control in more than one quality reporting or value-based payment program.

In conclusion, APIC appreciates CMS's attention to the concerns raised by stakeholders regarding reporting measures for bloodstream infections in the vulnerable ESRD population. APIC supports the proposal to include AKI patients in NHSN BSI Clinical Measure in the ESRD QIP Measure Set. While APIC applauds CMS for continued commitment to validation of data, APIC strongly recommends a five percent sample size for NHSN dialysis event data validation study. APIC is committed to ongoing 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.

Sincerely,

A handwritten signature in black ink that reads "Linda R. Greene".

Linda R. Greene, RN, MPS, CIC, FAPIC  
2017 APIC President