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August 22, 2016

Mr. Andrew M. Slavitt
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-1651-P: Medicare Program; End-Stage Renal Disease Prospective Payment System, Coverage and Payment for Renal Dialysis Services Furnished to Individuals with Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program Bid Surety Bonds, State Licensure and Appeals Process for Breach of Contract Actions, Durable Medical Equipment, Prosthetics, Orthotics and Supplies Competitive Bidding Program and Fee Schedule Adjustments, Access to Care Issues for Durable Medical Equipment; and the Comprehensive End-Stage Renal Disease Care Model; Proposed Rule

Dear Mr. Slavitt:

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. Our comments primarily focus on issues related to prevention and reporting of healthcare-associated infections (HAIs) in the dialysis population.

We are pleased that CMS continues to demonstrate its commitment to improving the quality of ESRD patient care. APIC applauds CMS for addressing stakeholder concerns regarding accuracy and validity of reporting that prompted proposed changes in the FY 2019 Quality Incentive Program. We have a vested interest in the effective operation of the ESRD QIP and the prevention of infections in this patient population.

Vaccines and their Administration

APIC supports the proposal to allow ESRD facilities the ability to administer vaccines to Medicare beneficiaries with acute kidney injury (AKI). APIC believes that this widened access to necessary vaccines goes far to support the health of Medicare patients in our nations ESRD facilities. In addition APIC strongly supports the use of the National Healthcare Safety Network (NHSN) for patient influenza



vaccination reporting. Inputting patient influenza vaccination data into NHSN allows for a bi-directional flow of data. Dialysis facilities are able to view their data and use it for improvement work at the same time regulatory agencies and local health departments can access it as well. This feature is not available with CROWNWeb. APIC supports annual influenza vaccination of both healthcare personnel and patients and feels strongly that NHSN should be the single repository for this data.

Proposed Reintroduction of the Expanded NHSN Dialysis Event Reporting Measure

APIC supports the proposal to reintroduce the expanded NHSN Dialysis Event Reporting Measure, and combine it with the NHSN Bloodstream Infection (BSI) Clinical Measure in the ESRD QIP measure set for PY 2019. BSIs are serious events in ESRD patients. The integrity of the data that is submitted is essential for accurate analysis and benchmarking to improve BSI prevention. Underreporting can be a serious hindrance to this data accuracy. Because this new measure set does not belong solely in either the Reporting or the Clinical Domains, APIC supports removing the Safety Subdomain from the Clinical Domain and establishing the new Safety Domain that includes the NHSN measure topic as a third domain along with the Clinical and Reporting Measure Domains. The new safety measure inclusion of the NHSN BSI Clinical Measure encourages improvement work while the NHSN Reporting Measure provides additional incentives for complete reporting.

Scoring the Proposed NHSN Dialysis Event Reporting Measure

APIC supports the modifications to scoring that reward dialysis facilities that have made investments to support robust surveillance programs allowing for monthly data input. The proposed scoring strongly encourages facilities to report twelve months of data to NHSN which serves to improve the data integrity. APIC agrees with CMS's statement that complete and accurate reporting is critical to maintaining the integrity of the NHSN surveillance system, and believes that finding the right balance between encouraging facilities to report accurate data to NHSN while at the same time encouraging reductions in the numbers of dialysis events goes far toward addressing the validation concerns with validity of data reported to NHSN.

Proposed NHSN BSI Measure Topic

APIC supports the proposed creation of a new NHSN BSI Measure Topic that would include the clinical measure of NHSN BSI's in dialysis patients as well as the NHSN Dialysis Event Reporting Measure. APIC supports the logic that went into the combination of these two measures into one measure topic as they encourage accurate NHSN reporting as well as the prevention of BSI's.

Proposal for Scoring the Proposed NHSN BSI Measure Topic

APIC agrees that CMS's proposed weighting formula of having the NHSN Dialysis Event Reporting Measure be weighted at 40 percent, and the NHSN BSI Clinical measure score weighted at 60 percent seems adequate to encourage both accurate NHSN reporting and strong clinical performance.

Data Validation

While APIC endorses the use of validation to ensure data accuracy, validation of only 35 facilities represents only 1 percent of facilities nationally. APIC recognizes that CMS has increased the number of



facilities proposed for validation since the last proposed rule; however, we feel strongly that a larger more representative sample is needed for validation especially considering this data will soon be publically available for the first time 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 Acquired Infections Program has several examples of such self-validation exercises on their website:

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

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 changes made to the NHSN BSI Clinical Measure in the ESRD QIP Measure Set, the reintroduction of the NHSN Dialysis Event Reporting Measure, and the establishment of the new safety domain with measures utilizing the NHSN BSI data. While APIC applauds CMS for continued commitment to validation of data, APIC strongly recommends a five percent sample size for data validation. 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 cursive script that reads "Susan Dolan".

Susan Dolan, RN, MS, CIC, FAPIC
2016 APIC President