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August 24, 2015

Via <http://www.regulations.gov>

Andrew M. Slavitt
Acting Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1628-P
P.O. Box 8010,
Baltimore, MD 21244-8010

RE: Medicare Program; End-Stage Renal Disease Prospective Payment System and Quality Incentive Program, Proposed Rule

SHEA represents more than 2,000 physicians, antibiotic stewardship experts, and other healthcare professionals globally with expertise in healthcare epidemiology and infection prevention. SHEA is dedicated to advancing the science and practice of healthcare epidemiology and preventing and controlling morbidity, mortality, and the cost of care linked to healthcare-associated infections (HAIs).

SHEA respectfully submits comments in response to the proposed rule for the End-Stage Renal Disease Prospective Payment System and Quality Incentive Program for calendar year (CY) 2016 published in the July 1, 2015 *Federal Register*.

Section III.G.2.c.ii - Proposed Full-Season Influenza Vaccination Reporting Measure

CMS is proposing to adopt a measure that is based on “ESRD Vaccination – Full-Season Influenza Vaccination” (Measure Applications Partnership #XDEFM) that assesses the percentage of ESRD patients > 6 months of age on October 1 and on chronic dialysis > 30 days in a facility at any point between October 1 and March 31 who either (1) received an influenza vaccination; (2) were offered but declined the vaccination; or (3) were determined to have a medical contraindication. SHEA agrees with studies demonstrating that encouraging closer evaluation of patients’ influenza vaccination status in the dialysis facility will increase influenza vaccination rates in the ESRD population which will in turn improve patient health and wellbeing.

CMS is also proposing facilities report data on patient influenza immunization status during the performance period using CROWNWeb.

CMS states that the measure specifications reviewed by the Measures Application Partnership do not include NHSN as a data source and that the data elements needed for this measure have already been developed in CROWNWeb. CMS also expresses concern over the potential burden incurred on facilities if they are required to report measure data to NHSN. Facilities are already familiar with the use and functionality of CROWNWeb to report data for other measures in the ESRD QIP.

Although SHEA agrees that reporting immunization data for performance measurement should not impose an unreasonable burden on dialysis facilities, SHEA disagrees that reporting these data to NHSN in addition to CROWNWeb would represent a burden. All facilities have to enroll in NHSN due to healthcare worker influenza vaccination reporting requirements; most are already enrolled to report dialysis events. ESRD census patient records from CROWNWeb can be uploaded into NHSN electronically. This does not require substantially more work for facilities compared to using CROWNWeb for this purpose.

Facilities will benefit from requiring NHSN reporting because it would allow them to obtain facility-level data which will in turn allow them to measure their performance against other dialysis facilities. Additionally, those data already available at the facility level can be made available at the organizational level (e.g., large dialysis organization; renal networks and public health via the “conferring rights” mechanism). SHEA respectfully requests that CMS require dialysis facilities report influenza vaccination data to NHSN. In order to provide incentives for reporting alone, SHEA recommends CMS allow facilities to receive bonus points for reporting immunization rates to NHSN.

Section III.F.4 - Data Validation Requirements for the PY 2018 ESRD QIP

CMS is proposing the continuation of the feasibility study for validating data reported to the NHSN Dialysis Event Module, and proposes to randomly select nine facilities to provide CMS with a quarterly list of all positive blood cultures drawn from their patients during the quarter, including any positive blood cultures collected on the day of, or the day following, a facility patient's admission to a hospital.

SHEA is concerned that the methodology proposed by CMS is not adequate. The sample size (nine facilities) is too small and the method for targeting, i.e. targeting patients with a positive blood culture is inadequate. SHEA recommends CMS perform validation in at least 5% of facilities. Record selection should not be restricted only to positive blood culture line-listings from the facility.

SHEA recommends CMS review the CDC-funded data validation project for dialysis events performed by the Tennessee Health Department as a case study and apply the lessons learned to the PY 2018 ESRD QIP program. CMS should also consider utilizing and funding state health departments to assist with local data collection and on site data validation in order to identify potential cases that were not reported. Further an examination of vaccination rate reporting could be conducted during an on-site visit. Finally, CMS should consider extending bonus points to facilities for reporting dialysis events.

SHEA thanks CMS for soliciting public comment on the proposed rule for the End-Stage Renal Disease Prospective Payment System and Quality Incentive Program for calendar year (CY) 2016. For future inquiries on this submission, please contact Lynne Batshon at 703-684-0761 or lbatshon@shea-online.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Anthony D. Harris". The signature is written in a cursive style with a large initial "A".

Anthony D. Harris, MD, MPH, FSHEA, FIDSA, President, SHEA