September 10, 2018

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1691-P
P.O. Box 8010,
Baltimore, MD 21244-8010

RE: CMS-1691-P Medicare Program; End-Stage Renal Disease Prospective Payment System, Payment for Renal Dialysis Services Furnished to Individuals With Acute Kidney Injury, End-Stage Renal Disease Quality Incentive Program

To Whom It May Concern:

As participants in the Adult Vaccine Access Coalition (AVAC), we appreciate the opportunity to comment on the Medicare Program End Stage Renal Disease Prospective Payment System and Quality Incentive Program proposed rule. We are deeply concerned the proposed rule seeks to remove the Influenza Vaccination Coverage Among Healthcare Personnel (NQF#0431) from the ESRD Quality Incentive Program (QIP) for PY2021. We also urge CMS to include a new composite measure for ACIP-recommended vaccines (influenza, pneumococcal and hepatitis B) in the ESRD Quality Incentive Program (ESRD QIP) to promote higher quality and more efficient health care for vulnerable ESRD patients at increased risk of vaccine preventable illness.

AVAC consists of over 50 organizational leaders in health and public health that are committed to addressing the range of barriers to adult immunization and to raising awareness of the importance of adult immunization. AVAC works towards common legislative and regulatory solutions that will strengthen and enhance access to adult immunization across the health care system. Our priorities and objectives are driven by a consensus process with the goal of enabling the range of stakeholders to have a voice in the effort to improve access and utilization of adult immunizations.

One of our key coalition priorities is to advocate for federal benchmarks and quality measures to encourage improved tracking and reporting of immunization status that will result in increased adult immunization rates. In 2016, AVAC released a White Paper outlining the value and imperative of quality
measures for adult vaccines. The report highlights the role of vaccine quality measures in preventing illness and death, reducing caregiving demands, avoiding unnecessary healthcare spending, and setting the foundation for healthy aging. Quality measurement programs through Medicare play a critical role in promoting improved quality and encouraging adherence to and consistent utilization of recommended adult vaccines.

The Department of Health and Human Services (HHS) recognizes that immunization is an important tool to keep people healthy and reduce avoidable health care costs. In its Strategic Plan FY 2018 –2022, HHS acknowledges that “infectious diseases are a major health and economic burden for the United States.” Additionally, strategic objective 2.1 makes a commitment to “support access to preventive services including immunizations and screenings, especially for high-risk, high-need populations.” Unfortunately, access to vaccines is not equal across a person’s lifespan. Despite the well-known benefits of immunizations, more than 50,000 adults die from vaccine-preventable diseases while adult coverage lag behind Healthy People 2020 targets for most commonly recommended vaccines: influenza, pneumococcal, tetanus, hepatitis B, herpes zoster, and HPV.

(p. 34339) Proposed Removal of the Healthcare Personnel Influenza Vaccination Reporting Measure From the ESRD QIP Measure Set

The proposed rule indicates that CMS originally adopted the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) in CY2015 because “we recognize that influenza immunization is an important public health issue and that vaccinating healthcare personnel against influenza can help to protect healthcare personnel and their patients (79 FR 66206 through 66208)”. According to the Centers for Disease Control and Prevention (CDC), individuals with chronic kidney disease have higher incidence or severity of some vaccine-preventable diseases due to altered immunocompetence. In fact, infectious disease is the second most common cause of death in late stage Chronic Kidney Disease (CKD) patients.

The Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) was adopted in the FY 2015 IPF PPS final rule, “due to public health concerns regarding influenza virus infection among the IPF population” and the measure addressed this concern “by assessing influenza vaccination in the IPF among healthcare personnel (HCP), who can serve as vectors for influenza transmission.”

2 https://www.hhs.gov/about/strategic-plan/index.html
However, CMS analysis of CY 2016 data in the proposed rule indicates, “ESRD facility performance on the measure was consistently high; 98 percent of ESRD facilities received the highest possible score on the measure (10 points) and the remaining 2 percent received no score on the measure because they did not report the required data. This finding indicates that influenza vaccination of healthcare personnel in ESRD facilities is a widespread practice and that there is little room for improvement on this measure.”

AVAC strongly disagrees with this contention. Removal of the Influenza Vaccination Coverage Among Healthcare Personnel measure (NQF #0431) from the ESRD QIP will send the impression to ESRD facilities that preventive health care services such as immunization are no longer a priority, despite the serious economic and health consequences of influenza outbreaks in this population. **The fact that the analysis of the measure for CY 2016 indicates that nearly every ESRD facility received the highest possible score is a clear indicator of the success of the measure.** Sustained widespread utilization of the influenza vaccine among healthcare personnel and the adoption of an adult immunization composite metric for ESRD patients should be an utmost priority for ESRD patients since, “these patients represent a high-risk group for developing infectious diseases.”

The proposal to remove this measure is also inconsistent with CMS’ own position and arguments with respect to this same measure in the inpatient hospital quality reporting program. The Hospital Inpatient Prospective Payment System proposed rule (CMS-1694-P) states with respect to the Influenza Vaccination Coverage Among Healthcare Personnel (HCP) measure (NQF #0431), it “promotes improved health outcomes among beneficiaries because: (1) health care personnel that have received the influenza vaccination are less likely to transmit influenza to patients under their care; and (2) vaccination of health care personnel reduces the probability that hospitals may experience staffing shortages as a result of illness that would impact ability to provide adequate patient care. Thus, we believe the costs associated with reporting this chart-abstracted measure outweighs the associated benefits of keeping it in the Hospital IQR Program.”

A recent commentary, *Influenza in long-term care facilities* notes, “a study of health care workers (HCW)s in an acute hospital during a mild epidemic season, found that 23% had serological evidence of new influenza infection during the season, implying a potential transmission risk to patients as between 28% and 59% of infected workers had subclinical infections and continued to work.” For ESRD patients with, “[c]o-morbidities such as diabetes mellitus and the inherent

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process of dialysis, where patients are frequently exposed to multiple pathogenic agents and potential cross-contamination from dialysis equipment in the health care environment, add to the susceptibility of this population.\textsuperscript{5}

AVAC strongly believes removal of this measure from the ESRD QIP would create greater inconsistency across quality reporting programs, add to provider reporting confusion and ultimately leave an extremely vulnerable population of Medicare beneficiaries more susceptible to vaccine preventable illness.

**Composite ESRD Vaccination Measure**

The HHS National Vaccine Program Office (NVPO) and the Centers for Disease Control and Prevention (CDC) in collaboration with the National Adult Immunization and Influenza Summit Quality Working group have spearheaded the development and testing of a new composite measure for end-stage renal disease patients covering influenza, pneumococcal and hepatitis B vaccines. A review of CMS fee-for-service claims data warrants the use of such a measure as current vaccination rates for the ESRD population fall well below recommended targets.\textsuperscript{6}

Research has shown that kidney care centers with vaccination protocols have demonstrated reduced infection rates and resulted in decreased morbidity and mortality\textsuperscript{7}. Vaccines, including hepatitis B and pneumococcal conjugate and pneumococcal polysaccharide, are specifically recommended for dialysis or CKD patients. However, like with other adult populations, vaccines are underutilized in CKD patients, who could benefit greatly from improved access to immunization services.\textsuperscript{8}

This work provides an important foundation for a composite measure for ACIP-recommended vaccines for ESRD patients and would be of great benefit to the ESRD QIP now in the future. The ESRD Quality Incentive Program (ESRD QIP) presents an important opportunity to promote higher quality and more efficient health care for Medicare beneficiaries. AVAC strongly believes the ESRD QIP should include a focused, concerted effort to improve access and utilization of adult immunizations as a means of improving the overall health of patients living with kidney disease. An ESRD composite measure would provide a sound, reliable and comprehensive means to assesses the receipt of routine adult

\textsuperscript{5} https://www.ncbi.nlm.nih.gov/pubmed/29132990

\textsuperscript{6} Ibid.

\textsuperscript{7} http://www.ncbi.nlm.nih.gov/pubmed/14717802

\textsuperscript{8} http://home.smh.com/sections/services-procedures/medlib/Pandemic/Pan_Renal/NLM_Kausz_14717802_050409.pdf
vaccinations recommended by the Advisory Committee on Immunization Practices (ACIP).

We look forward to working with CMS to ensure meaningful measures that reflect priority health care services, such as immunization, that also will streamline and reduce the reporting burden on providers, provide an accurate representation of ESRD facility performance in the least burdensome manner possible and provide meaningful data to the Medicare program on access to this important preventive service.

We appreciate this opportunity to share our perspective on this proposed rule. Please contact an AVAC Coalition Manager at (202) 540-1070 or info@adultvaccinesnow.org if you wish to further discuss our comments. To learn more about the work of AVAC visit www.adultvaccinesnow.org.

Sincerely,

Alliance for Aging Research
Asian & Pacific Islander American Health Forum (APIAHF)
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National Association of County and City Health Officials (NACCHO)
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