April 18, 2018

Kate Goodrich, MD
Director and CMS Chief Medical Officer
Center for Clinical Standards and Quality
U.S. Centers for Medicare & Medicaid Services
7500 Security Blvd, Baltimore, MD 21244

Re: Advancing Immunization Measures for End-Stage Renal Disease Patients: Recommendations of the National Adult and Immunization Summit (NAIIS)

The undersigned participants of the National Adult and Influenza Immunization Summit (NAIIS) appreciate the opportunity to provide the following recommendations. The NAIIS comprises more than 130 public and private organizations from the healthcare industry: public health and private medical sectors, vaccine manufacturers and distributors, consumers, and others interested in preventing illness, disability, and deaths through the use of recommended vaccines. Through our Quality and Performance Measures Workgroup (QPM WG)\(^1\), we provide this set of recommendations to CMS on potential means to improve End Stage Renal Disease (ESRD) quality programs in this important patient population.

I. Composite Measure: We recommend that CMS consider developing and implementing an ESRD vaccination composite measure, with reporting on individual measures for influenza, pneumococcal, and hepatitis B. There is an opportunity to include such a measure within ESRD quality programs.

Our research on CMS Fee-For-Service claims data\(^2\) shows gaps in influenza, pneumococcal, and hepatitis B vaccination rates within the dialysis population that are sufficient enough to warrant the use of such measures, and to introduce incentives for dialysis centers to close immunization gaps. We have observed significant and positive shifts in providers’ performance when comparable metrics have been introduced within federal quality and performance measure sets (especially those associated with incentives), and when there is support for implementing these metrics from a systems level. For example, the influenza metric within the Medicare Advantage Star Ratings measure set has shown a steady improvement trend average across Medicare Advantage plans since its implementation in 2010, moving from 65% average performance in 2010 to 72% performance in 2016. If a composite measure is not appropriate, use of three individual measures may suffice.

---

\(^1\) The ESRD Subgroup of the WG was formed to identify a composite measure including influenza, pneumococcal, and hepatitis B vaccination measures for individuals with kidney failure/end-stage renal disease (ESRD). Members of this subgroup are comprised of broad range of partners such as provider groups, quality improvement organizations, and advocacy groups. This subgroup has several parallel goals that align with the CMS ESRD quality programs: 1) investigate the extent to which ESRD-specific immunization measures are present and utilized in the marketplace; 2) determine the suitability of these measures to be used within a composite measure for ESRD populations, and pursue a plan for the development of such a measure, if applicable; and 3) identify an implementation pathway for the metric within an appropriate measure set.

II. **Measure Harmonization:** We encourage CMS to harmonize rather than duplicate efforts where possible, and to consider using existing measures where appropriate.

For example, the NQF 0226—Influenza Immunization in the ESRD Population is currently maintained by the Kidney Care Quality Alliance (KCQA) and may not explicitly align with the current CMS ESRD measure under development. Moreover, other immunization measures both currently developed and currently in development by the National Committee for Quality Assurance (NCQA), the Pharmacy Quality Alliance, and others (for example, CMS has commissioned NCQA to develop a new pneumococcal metric), should be mindful of harmonization.

III. **Interoperability & Data Source:** We encourage CMS to use multiple currently available databases (e.g., CROWNWeb, immunization information systems (IIS, also called immunization registries), and the National Healthcare Safety Network (NHSN)) as sources for their immunization metrics and support data-sharing of these systems.

Recognizing that data sources have inherent limitations and missing data, the use of multiple sources can increase the quality of data used for clinical decision-making. Although accessibility and data quality of each database is varied by facility and jurisdiction, current immunization quality measures take this variability into account. Thus, CMS should align their data sources to coincide with those currently used by other measure developers. In recognition of the limitations of a single data source to inform a metric, the NCQA has introduced new methods of electronic data sourcing for metrics and applied these methods in immunization measures currently being co-developed with NAIIS for the HEDIS measure set. Data sources for these measures include claims data, health information exchange (HIE) and registry data, electronic medical record (EHR) data, and case management system data. Interoperability of these databases will enable a more comprehensive patient history and improve the quality of care.

IV. **Data Reporting:** We encourage CMS, within your current authority, to require both the submission of vaccine administration records to the appropriate IIS for all vaccines administered within dialysis centers, and to institute a functional requirement for a query of the IIS to be available prior to a vaccine being administered, where appropriate.

This structural requirement (versus a process measure) for the CROWNWeb system would bring CROWNWeb in harmony with current national EHR technical requirements. As part of Meaningful Use Stages II and III, and included within the Merit-based Incentive Payment System (MIPS) resulting from the Medicare Access and CHIP Reauthorization Act of 2015, requirements have emerged for EHR functionality. These requirements facilitate both the reporting of administered vaccinations to the IIS, as well as the ability to query the IIS. In EHRs where this functionality is available, reporting of administered vaccinations is performed automatically either through daily batch reporting or real time submissions. Live query of patient immunization records within the IIS is typically revealed as a fully integrated “immunization history” tab within the patient profile. In 2010, the Community Preventive Services Task Force deemed use of the IIS a best practice based on strong evidence found in 108 published studies and 132 conference abstracts. The evidence showed that the IIS are effective in increasing vaccination rates and reducing vaccine-
preventable disease. Reporting vaccines and querying vaccination histories is a best practice also recommended by the National Vaccine Advisory Committee, the US Preventive Services Task Force, and is included in the National Adult Immunization Plan (where CMS is a stakeholder). Utilization of IIS data can itself lead to improved data quality. As immunizers learn the benefits of IIS data use through experience, they identify data gaps or errors in individual records and are motivated to submit corrections. In addition, they increase their focus on accurate reporting and often identify easily corrected system errors—all of which can lead to improved data quality. Utilization of IIS data can also help CMS reduce over-vaccination by avoiding the administration of duplicate vaccines that patients already received outside of dialysis centers, and aid clinicians at dialysis facilities in identifying vaccination gaps among ESRD patients.

These recommendations stem from our WG activities since 2015 and through an in-depth gap analysis in measures related to adult immunizations, the development of appropriate performance measures, and the application of such measures to increase the overall rates of adult immunization. The ESRD Subgroup has benefited tremendously from CMS’ previous work, expertise, and the participation of broad range of stakeholders in the development of these recommendations.

As CMS considers the above recommendations, we encourage CMS to consult organizations and institutions involved in direct patient care delivery and healthcare payments and reimbursement (e.g. managed care organizations, dialysis providers, and health care insurance carriers). This is especially important because the transition period from chronic kidney disease to end stage renal failure and dialysis ranges from six months to one year, with many uncertainties in terms of provider responsibility and accountability for vaccine delivery.

Sincerely,

American Academy of Physician Assistants
Alexandria, Virginia
American Association of Nurse Practitioners
Austin, Texas
American Immunization Registry Association
Washington, D.C.
California Immunization Coalition
Sacramento, California
Dynavax
Berkeley, California
Every Child By Two
Washington, D.C.
Gerontological Society of America
Washington, D.C.
GlaxoSmithKline
Philadelphia, Pennsylvania
Immunization Action Coalition
Saint Paul, Minnesota
Imunize Nevada
Reno, Nevada
National Alliance of State Pharmacy Associations
North Chesterfield, Virginia
Sanofi Pasteur
Swiftwater, Pennsylvania
Scientific Technologies Corporation
Phoenix, Arizona
Virginia Department of Health
Richmond, Virginia
Zero Hour Health, A Corporate Wellness Company
Stamford, Connecticut