To: Micky Tripathi, Ph.D. M.P.P., National Coordinator for Health Information Technology

From: Fresenius Medical Care North America (FMCNA)

Date: April 15, 2021

Re: United States Core Data for Interoperability Draft Version 2

Fresenius Medical Care North America (FMNCA) welcomes the opportunity to comment on the draft version 2 United States Core Data for Interoperability (USCDI V2). FMNCA is the largest integrated supplier in the US of services and products for patients with End Stage Renal Disease (ESRD) undergoing dialysis treatment both in an outpatient clinic and at home. As a national provider with more than 200,000 patients with serious illness, we support the Office of the National Coordinator's (ONC) goals for nationwide interoperable health information exchange. Together with other ESRD providers, this represents a collective population of over 700,000 patients, most of whom are in Medicare. As this population accounts for a disproportionate amount of Medicare fee-for-service spending, we believe there are important opportunities to realize savings to the healthcare system through improved care coordination and reduced hospitalizations. To that end, we participate as members in organizations dedicated to improving health outcomes through interoperability such the CommonWell Health Alliance Network and eHealth Exchange.

A key priority for FMNCA is to reduce hospital readmissions for ESRD patients. We believe improved exchange of dialysis information between the dialysis clinic and other providers would further this goal. Almost 34% of patients with ESRD are re-hospitalized within 30 days, which is nearly twice the rate in the general Medicare population.[1] ONC has an opportunity to reduce readmissions for dialysis patients by including health data classes and data elements to the USCDI that are specific to the dialysis treatment. Such dialysis-specific data elements would facilitate care coordination when a dialysis patient is transferred from an acute care setting and eliminate time lag in the communication of critical information that is unique to dialysis patients. In addition, there are several CMS initiatives to improve care and lower costs for Medicare beneficiaries with ESRD through better-coordinated, value-based approaches to care. Those initiatives include the Comprehensive ESRD Care (CEC) Model initiative and the Comprehensive Kidney Care Contracting models. These initiatives require extensive semantic interoperability to facilitate the effective coordination of care. Expanding the USCDI V2 specifications to include key renal data elements would directly and positively impact this important program.

Currently, when a patient is transferred from the hospital, critical dialysis treatment information may be missing, potentially delaying necessary treatment and compromise patient safety. Certain dialysis parameters are very important for a dialysis clinician to know when a patient returns after a hospitalization because certain common elements may be altered during the hospital stay. The dialysis clinic staff will have difficulty dialyzing the patient without access to this data. Incoming continuity of

[1] United States Renal Data System. 2020 *USRDS Annual Data Report: Epidemiology of kidney disease in the United States.* End Stage Renal Disease: Chapter 4. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020. https://adr.usrds.org/2020/end-stage-renal-disease/4-hospitalization#:~:text=Rates%20of%20hospital%20readmission%20within,not%20rehospitalized%20and%20died%2C%20respectively

care documents (CCD) from hospitals that provided dialysis treatment to a patient in the acute setting often do not contain critical data elements that could be of lifesaving importance, such as current dialysis treatment prescription, dialysis medications, last dialysis treatment related information (vitals, dry weight, stability) and lab results. Conversely, dialysis treatment information should also be made available to hospital staff when a patient is admitted to the hospital.

To facilitate seamless transitions of care and reduce rehospitalizations for ESRD patients, FMNCA believes updates to the USCDI guidelines should begin to incorporate data elements specific to the dialysis treatment. Based on ESRD Implementation Guidelines developed by a consortium of ESRD stakeholders, FMNCA has developed its own renal-specific CCD to share with participating providers containing common data elements imperative to dialysis care. Dialysis providers who participate in Health Information Exchanges use elements in the ESRD Implementation Guidelines on their outgoing CCD documents. Hospitals that have provided dialysis treatments in the acute setting, however, do not contain any of those critical data elements in their outgoing CCD documents. In many cases, what happens is the dialysis nurse or the nephrologist will have to call the hospital and try to obtain dialysis specific information before the patient can be dialyzed.

We recommend the following data classes and data elements, which impact patient safety, should begin to be incorporated in the USCDI starting with Version II and in future updates:

Dialysis treatment prescription

- Dialysis treatment time
- Dialysate
- Dialysate flow rate
- Blood flow rate
- Estimated dry weight
- Vascular access
- Heparin dose
- Intradialytic medications and dose

Last dialysis treatment related information

- Vital signs
- Dialysis access assessment
- Post treatment weight
- Amount of fluid removed
- Patient stability

Other

- Most recent lab results prior to discharge
- Antibiotics administered during hospitalization

In addition, the following data elements which impact care coordination should also be considered:

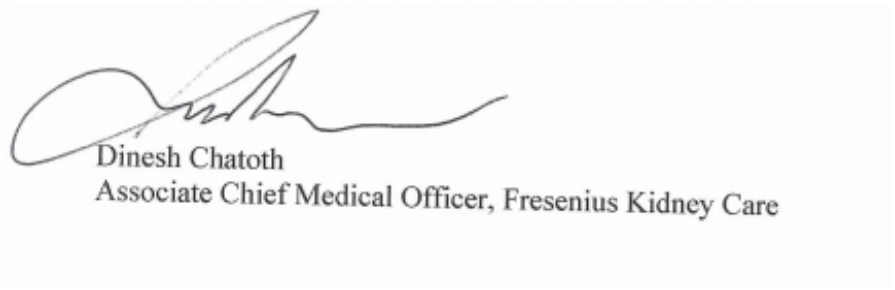
- **Positive blood cultures drawn within 24 hours of hospital admission.** Dialysis clinics have limited visibility to positive blood cultures drawn in the Emergency Room or in the hospital

which are reportable to the Centers for Disease Control and Prevention's National Health Safety Network

- **Transplantation referral and waitlisting data.** The lack of transplantation data exchange increases the risk that potential candidates for transplantation may not be offered a referral. Transplantation is a key CMS focus, and the new ESRD Treatment Choices (ETC) Model encourages increased kidney transplants for Medicare beneficiaries with ESRD, while reducing Medicare expenditures.

We serve a very vulnerable population and see a great need to share information electronically between common care providers to give the best care possible based on the longitudinal patient record. Incorporating the dialysis data elements mentioned above into the USCDI would significantly improve continuity of care, patient safety and potentially prevent hospital admissions and readmissions. FMCNA appreciates having the opportunity to provide comment. We look forward to working with ONC to address the recommendations we have made in this letter.

Sincerely,



Dinesh Chatoth
Associate Chief Medical Officer, Fresenius Kidney Care

Statement of Support: eHealth Exchange

eHealth Exchange, the nation's largest Health Information Network, enthusiastically supports Fresenius Kidney Care's suggestions to adjust USCDI v2 to include critical data elements for patients with End Stage Renal Disease. If enacted, I'm confident Fresenius' requests would dramatically improve clinical outcomes and decrease CMS and other payor expenditures for these patients. Hospitals, nephrologists, and dialysis providers currently have very little visibility to critical dialysis treatment related data elements that affect patent safety during transitions of care. While we have already made substantial progress in data exchange, there are still a few critical fields that can greatly contribute to optimal outcomes in patients with ESRD.

Jay Nakashima

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Executive Director, eHealth Exchange