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:

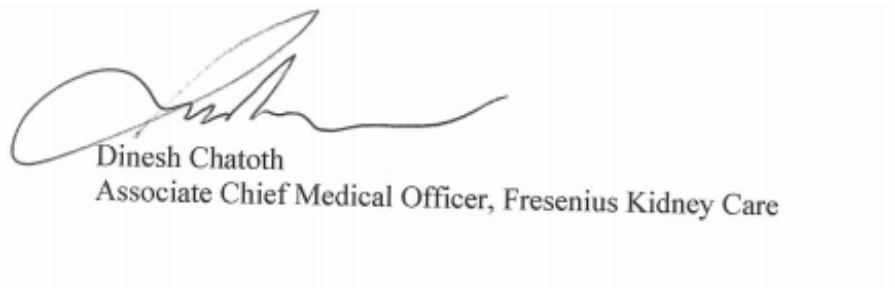
- **Positive blood cultures drawn within 24 hours of hospital admission.** Dialysis clinics have limited visibility to positive blood cultures drawn in the Emergency Room or in the hospital

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

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Re: United States Core Data for Interoperability (USCDI) Draft v2

Dear Mr Tripathi,

On behalf of CommonWell Health Alliance, we are pleased to submit comments on the Office of the National Coordinator's United States Core Data for Interoperability (USCDI) draft v2 as published January 2021. We support the ONC as it works to improve interoperability in the United States across providers, payers, patients and other stakeholders and we are aligned in the belief that we need standard data formats to accomplish the goal of seamless interoperability in healthcare nationwide.

CommonWell Health Alliance is a not-for-profit trade association made of various health IT and health care stakeholders. As a membership-based trade association, we provide an environment to openly work on interoperability improvements across many cornerstones of health care including but not limited to technology companies, payers, State and Federal agencies, providers, clearing houses, and patients. When the Alliance launched seven years ago, we started with services centered around Care Treatment and provided the ability for providers to query across other provider systems and retrieve data about a given patient. We have and continue to be a patient-centered network available nationwide and are proud to have added Patient Access use cases to give individuals the ability to find and access their data through patient portals, personal health records and other patient-centric applications.

CommonWell has a simple vision: health data should be available to individuals and caregivers regardless of where care occurs. Additionally, access to this data must be built into health IT at a reasonable cost for use by a broad range of health care providers and the people they serve. At CommonWell, together with our service provider and members, we have created and deployed a vendor-neutral platform that breaks down the technological and process barriers that inhibit effective health data exchange. We leverage existing standards and policies in order to enable scalable, secure and reliable interoperability as easily as possible for our members and their customers across the nation. We believe the ONC's Strategic Plan aligns with our mission and vision.

We believe the proposed USCDI v2 draft appropriately balances expanding the standard healthcare dataset while not creating significant burden on developers and providers to incorporate the additional data into their products and resultant data flows.

That said, we would like to endorse one proposed addition from one of our connected providers. Fresenius Medical Care is a national provider of services and products for patients with End Stage Renal Disease (ESRD). Currently, dialysis information is not well represented in the standard data and this information can be critical as patients with ESRD encounter planned or emergent transitions of care. Fresenius will be sending in their own comments regarding the specific data elements. We fully support the additions of these elements. We do recognize that dialysis related elements are not fully profiled yet and would encourage the ONC and the standards organization that complement the ONC's work to complete the appropriate profiles and include in the next readily available version of USCDI. If the profile

development can be completed in the near term, we agree it would be appropriate in v2. If it takes more than a couple months, we strongly endorse this being included in v3.

Note on Our Comments

These comments are reflective of the opinions of the Alliance and its members in regard to the objectives of CommonWell. It is not intended to represent the individual comments of each of our Members. Comments made here are not intended to represent the view of any particular member; and we expect some of our members to submit their own comment letters.

Final Comments

The Alliance remains committed to patient-centric interoperability on a national scale with the goal of ubiquitous, secure exchange of clinical data to the benefit of providers, patients, payers, public health and all other stakeholders in health care and beyond. We are encouraged by the mission and vision of the ONC and affirm our commitment to being a strong partner in executing on the vision.

On behalf of the CommonWell Health Alliance, thank you again for the opportunity to comment on the latest draft of v2 for USCDI. For any clarification or comments, please feel free to contact me at paul@commonwellalliance.org.

Sincerely,

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