



**FRESENIUS
MEDICAL CARE**

January 25, 2019

VIA ELECTRONIC SUBMISSION

Office of the National Coordinator for Health Information Technology
U.S. Department of Health and Human Services
330 C St SW
Floor 7
Washington, DC 20201
www.healthit.gov

RE: Strategy on Reducing Burden Relating to the Use of Health IT and EHRs

On behalf of Fresenius Kidney Care (FKC) we write today to provide comment on the Office of the National Coordinator for Health Information Technology's (ONC) Draft Strategy on Reducing Regulatory and Administrative Burden Relating to the Use of Health IT and EHRs (Draft Strategy). FKC is a division of Fresenius Medical Care North America (FMCNA) that focuses on renal replacement therapy through dialysis treatment either at home or in dialysis facilities. Collectively, FKC currently treats 193,336 patients in 2558 clinics nationwide and in Puerto Rico. FKC appreciates the work ONC is doing to find ways to reduce burdens on health care providers for the benefit of patients.

We support the Administration's goals to reduce the significant health IT-related burden associated with reporting and quality assessment programs. The End Stage Renal Disease Quality Incentive Program (ESRD QIP), Dialysis Five Star Program, Dialysis Facility Compare (DFC), Center for Disease Control (CDC) National Health Safety Network (NHSN) reporting mandate, ESRD Network Program, and other reporting and quality assessment programs require that dialysis facilities spend considerable staff time compiling and reporting the requisite data for each initiative. We take these quality, consumer satisfaction, and public health surveillance reporting obligations seriously and remain in compliance with our responsibilities under each. FKC appreciates the strategies and recommendations outlined in this report and particularly supports those that seek to simplify complicated requirements and streamline reporting across disparate programs.

Our comments on the Draft Strategy focus on requirements facing dialysis facilities that create health IT-related burden for clinic staff. Many of these requirements are fragmented, duplicative, or inconsistent, creating an unnecessary compliance challenge. As ONC works to finalize its draft recommendations, particularly as they relate to health IT usability and public health reporting, we hope consideration will be given to our experiences and incorporate our suggestions.

Specifically, our comments focus on regulatory and administrative burden created by:

- Disparate government websites for dialysis facility reporting;
- Individual ESRD Network mandates for Health Information Exchange;
- Disaster-related exemptions for the ESRD QIP and DFC;
- The CDC's Acute Kidney Injury (AKI) reporting mandate;
- Reporting requirements related to influenza;

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- CDC/NHSN Dialysis Event Surveillance Protocol for Infection Events; and
- CDC/NHSN Outpatient Dialysis Center Practices Surveys.

I. EHR Reporting and Health IT Usability

The Draft Strategy highlights burdens for clinicians related to the use of health IT as part of federal quality reporting, valued-based payment, APMs, and EHR programs. It points to challenges raised by providers related to lack of standardization in the current infrastructure and competing requirements in separate programs that necessitate the collection of the same information in different formats. As outlined below, our facilities face many of these challenges and we ask that HHS consider our recommendations for inclusion in the Draft Strategy.

1. Fragmented websites for dialysis quality and reporting programs

At present, FKC clinical staff must interact with three different websites to satisfy reporting obligations across quality programs. These websites include the CDC's NHSN website, CROWNWeb, and dialysisdata.org.

Navigating separate websites generates unnecessary burden on dialysis facility staff. Each site necessitates separate login credentials, registration requirements and user permissions. This creates unnecessary complexity for staff to simply maintain access to them. For example, a notary public verification is required for NHSN, while dialysisdata.org requires an annual Master Account Holder reset. As HHS considers strategies in the report to improve health IT usability, we encourage HHS to consider streamlining these websites with uniform registration requirements and permissions for participating facilities.

2. Individual ESRD Network mandates to join Health Information Exchanges

In the 2019 Statement of Work (SOW) for ESRD Networks, released in December 2018, CMS required that a percentage of dialysis facilities with the highest excess infection rates join a Health Information Exchange (HIE) or another information transfer system as approved by the Contracting Officer's Representative to receive information relevant to positive blood cultures during transition of care.

We understand the value of HIE, which is also our motivation for developing and executing a national interoperability strategy. Our corporate strategy is to move toward a trust framework that is efficient with connecting multiple providers to HIE's for patient information exchange as opposed to point-to-point agreements. The size and breadth of our organization mandates that we approach interoperability with the perspective of having an effective corporate strategy rather than the complexities presented by the varied options request by the ESRD networks. We are concerned that local facilities have no mechanisms to create such connections on their own and such requests distract clinic staff from their patient care responsibilities. Furthermore, facility-level determinations to join HIEs frustrate implementation of our previously approved corporate national interoperability strategy. As CMS considers strategies pertaining to Health IT interoperability, it should consider recommendations to remove well-meaning requirements that impede providers' broader organizational efforts to achieve interoperability.

3. Separate application processes to exclude facilities from the ESRD QIP and DFC during a disaster

There are separate processes in place to apply for exclusion from the ESRD QIP and the DFC in the event of a natural disaster. This creates needless administrative complexity for facilities that already face

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significant challenges in the aftermath of a disaster. It's critical that our patients maintain access to dialysis and we spend considerable effort and resources to ensure that our facilities are up and running in the event of a disaster with as little disruption as possible. Streamlining the procedures to apply for exclusion from CMS quality programs would represent a simple fix and provide welcome relief for facilities already facing significant logistical and operational challenges at these critical times.

II. Public Health Reporting

As ONC notes in the Draft Strategy, reporting related to population health data requires clinicians to “create and support numerous interfaces to public health entities, each of which may require custom changes to reports and/or duplicative entry into unique forms.” This is especially true for dialysis facilities that must gather and report data across multiple agencies, platforms and formats. One of ONC's strategies to reduce public health reporting burden would be to inventory reporting requirements for federal and public health programs in effort to reduce collection and reporting burden on clinicians. As HHS considers recommendations that would implement this strategy, we ask that it considers how public health reporting requirements for dialysis facilities particularly burden our staff.

1. Acute Kidney Injury reporting mandate

Dialysis facilities that treat acute kidney injury (AKI) patients are required to report Dialysis Event Surveillance data separately from ESRD patients to CDC's NHSN. The reporting requirements are very convoluted, costing staff precious time to comply. Moreover, this information is reported to CDC and is not used by CMS. The purpose of collecting this information is unclear as AKI patients are excluded from the ESRD QIP. We recommend that HHS consider strategies to eliminate NHSN reporting for AKI patients to reduce burden on clinicians and staff.

2. Influenza vaccine reporting

In the ESRD 2019 final rule, CMS retired the Healthcare Personnel Influenza Vaccination reporting measure from the ESRD QIP, effective Payment Year 2021. CMS noted that data indicated that ESRD facility performance on the measure was consistently high and that there is little room for improvement on this measure. CMS explained that measures like these may be at odds with the spirit of its Meaningful Measures Initiative.

While we agree with CMS' decision to remove the Healthcare Personnel Influenza Vaccination measure from the ESRD QIP, facilities in some states will continue to be responsible for reporting this data to CDC's NHSN. This seems inconsistent with the goals set out by the Cures Act to reduce regulatory and administrative burden relating to the use of health IT and alignment of quality measures across federal quality initiatives. Steps to reduce burden in one program do little to provide actual relief if the requirements are still in place in another program. We encourage CDC and CMS to work together to streamline these reporting requirements.

Patient influenza vaccination reporting also remains fragmented and burdensome for clinical staff. Several states mandate that dialysis facilities enter patient influenza vaccine information in their state registries. However, patient influenza vaccine data is reported to the government through CROWNWeb as well as available to CMS via Medicare claims. We encourage HHS to help break down data silos by supporting cross-departmental data sharing, encourage reuse of collected data for multiple purposes, and help decrease redundancy in data reporting by clinical staff.

3. Reporting for infection events outside of dialysis facilities

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Dialysis facilities are responsible for reporting the start of intravenous (IV) antibiotics or antifungals administered in an outpatient setting to the CDC's NHSN website as per the CDC's Dialysis Event Surveillance Protocol. Data collected for bloodstream infections are required for the ESRD QIP. In addition to outpatient hemodialysis centers, CDC considers long-term care facilities, skilled nursing facilities, and nursing homes as outpatient facilities; therefore, any infection event in these settings is reportable.

Reporting of events that occur in settings outside of dialysis clinics is problematic as dialysis facilities have little to no visibility to such events. Dialysis facilities are not always informed of IV antibiotic administration events that take place in skilled nursing homes. Furthermore, nursing home Dialysis Events would not be captured in FKC's clinical systems and would need manual entry into NHSN, resulting in additional clinic burden. The CDC already collects infection events in nursing homes through NHSN data submitted by long-term care facilities creating the possibility of duplicate reporting, thus we believe it is fair to discontinue, or make optional, this requirement for dialysis facilities. HHS should consider implementing the CROWNWeb model for NHSN, in order to prevent clinician reporting burden. Each patient in CROWNWeb is assigned a CROWN Unique Patient Identifier (UPI) number which allows the patient data and information transfer as patient relocates from one provider to another and eliminates duplicate reporting. Although there are still necessary enhancements to CROWNWeb that would improve reporting, we believe that streamlining interfaces through which facilities comply with various reporting requirements is central to reducing health-IT related burden.

4. NHSN Outpatient Dialysis Center Practices Survey

CDC Dialysis Event Surveillance Protocol requires the completion of an annual Outpatient Dialysis Center Practices Survey released in February of each year which is completed manually at the facility level. A significant amount of time is spent completing, tracking and ensuring 100 percent completion of the surveys. For example, we estimate that last year's survey took approximately 38,370 clinic staff hours across 2558 clinics. We believe that time could be better focused toward patient care activities.

Importantly, CDC does not share this survey data with CMS, although survey completion is required to allow users to submit data to NHSN that is required for the ESRD QIP. FKC is concerned that the CDC is preventing the reporting of important data to CMS for ESRD QIP and other purposes, and burdening dialysis clinical staff with paperwork production hours and manual data entry that deprive our teams of critical clinical time.

III. Conclusion

We appreciate the opportunity to provide comments on the Draft Strategy and hope HHS will consider the health IT burden reduction strategies we have outlined above as it works toward a final version. Please do not hesitate to contact Dr. Ahmad Sharif at 615-567-4823 or Ahmad.Sharif@fmc-na.com if you have any questions.



Ahmad Sharif, MD MPH SCPM

Senior Vice President, Chief Medical Information Officer

Fresenius Medical Care North America

Corporate Headquarters: 920 Winter St Waltham, MA 02451-1457 (781) 699-9000