June 3, 2019

Donald Rucker, MD
National Coordinator for Health Information Technology
Office of the National Coordinate for Health Information Technology (ONC)
US Department of Health and Human Services (HHS)
330 C Street, SW
Washington, DC 20201

The Honorable Seema Verma, MPH
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Re: RIN 0955-AA01 & CMS-9115-P

Submitted electronically to http://www.regulations.gov

Dear Doctor Rucker and Administrator Verma:

Kno2 is pleased to provide comments in response to two interoperability proposed rules:

1- ONC – *21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program*
2- CMS – *Medicare and Medicaid Programs; Patient Protection and Affordable Care Act; Interoperability and Patient Access for Medicare Advantage Organization and Medicaid Managed Care Plans, State Medicaid Agencies, CHIP Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans in the Federally-facilitated Exchanges and Health Care Providers*

Given the high level of coordination between the two agencies in drafting these proposed rules, the extent to which these rules go hand in hand, and the need for future cooperation across

agencies and health care interoperability actors, we are providing a combined letter to cover comments for both proposed rules.

Kno2 is best known for working with providers who did not receive government incentives to implement electronic health records (EHRs) and were left behind in the transition to interoperable electronic exchange, including providers in the post-acute, long-term care, skilled nursing, and therapy settings. We also represent over 60% of emergency medical services, and are working with dental, vision, and others as well.

Kno2's Interoperability as a Service™ allows clinicians to utilize multiple methods of exchange all in one place, including cloud faxing, Direct messaging, referral networks, and also query-based record exchange through frameworks such as Carequality, CommonWell, state and local HIEs. We also work with some larger health systems and provider organizations that are using big-name certified EHRs, but still have interoperability gaps that we help them close, enabling them to eliminate all forms of fax and transition entirely to interoperable exchange of data.

Patient Summary Record

We are supportive of the proposal to adopt the HL7 CDA R2 IG: C-CDA Templates for Clinical Notes R1 Companion Guide, Release 1. Many EHR vendors already leverage the Companion Guide for their C-CDA document development and making that consistent across vendors would eliminate issues that occur today with variance between how documents are structured from one system to another – many of those issues occur today when receiving systems are unable to render received documents in a consistent manner due to variances in document structure from disparate senders. Additionally, as USCDI continues to expand, it will be critical that there be a consistent use of C-CDA across the industry in order to allow for mapping from USCDI data classes to C-CDA sections and discrete data structure.

While the Companion Guide does provide much needed clarity from the C-CDA Release 2.1, even among vendors that leverage the Companion Guide, there are inconsistencies. Recently Carequality and CommonWell Health Alliance formed a collaborative Joint Document Content Work Group to address some of this existing variance. A Document Content white paper has been published and the next iteration of that work group should be commencing later this year to create additional recommendations; those recommendations eventually being tied into requirements for participation within the Carequality Framework and the CommonWell Health Alliance Network. We recommend that such industry collaboration that builds upon and further

clarifies the C-CDA Templates for Clinical Notes R1 Companion Guide also be leveraged by ONC to drive industry-wide document consistency.
See: https://carequality.org/joint-document-content-work-group-recommendations-released/

The HL7 C-CDA Companion Guide includes 12 Document Templates, only 4 or 5 of which are consistently used, due to those being the Templates required by the 2015 Edition Certification Criteria. One of those 12 Templates we believe is critical to short term success in eliminating fax from health care – a challenge that has been commented on by both CMS and ONC, urging health IT vendors to eliminate fax. That Template is the Unstructured Document. Because it is not one of the few Templates required by the 2015 Edition Certification Criteria, there are many EHR vendors that do not support receipt of documents leveraging that Template, instead requiring that unstructured information be faxed. With the goal that USCDI expand over time, and the need for structured data to achieve true interoperability, it is our hope that all EHI will eventually be structured for exchange. That is likely many many years away, even with current ONC and CMS pushes for interoperability, including upcoming TEFCA-based exchange. Requiring support for the Unstructured Document Template within C-CDA would allow information that currently cannot be structured and is sent via fax to instead be sent using interoperable exchange methods, like other structured C-CDAs, as a glide path toward fully structured data, and allowing the industry to actually move toward elimination of fax today.

Electronic Health Information Export

We agree with the concept of an EHI export. There are many instances where this would be beneficial to patients and providers, enabling patients full access to their medical records, allowing providers to change EHR vendors while keeping their patients' clinical data, system consolidation with mergers and acquisitions, among other use cases. One concern we have with this proposal is the requirement that all EHI be exported, including structure and syntax that is in a computable format. Only a small subset of EHI is currently included in USCDI, and even within the Document Templates for C-CDA only a subset of EHI fits in the defined C-CDA sections. If the EHI export must be a computable format, that will require the defining of a standard for it, to ensure that a "computable format" from one EHR vendor is actually computable by the receiving system. We would propose that the EHI export require structure for any USCDI data elements/classes, and allow for the use of the C-CDA Unstructured Document Template for additional information that does not today have an industry-defined data structure, but could at least be presented in a human readable format as an Unstructured Document.

Real World Testing

Many EHRs have functionality that is never actually made available to users, is only developed for certification or for testing at a Connectathon, but never moved to Production for use by the health IT developer's customers. We are supportive of requiring real world testing of interoperability functionality, to ensure that such functionality is available to users and so that providers can trust that their certified EHR product will actually be able to do everything that it was certified for.

Information Blocking

Information blocking focuses on responding with data when requested, not on blocking the receipt of data that was sent. This is an important distinction, and we ask for clarification whether an actor that prevents others from sharing information with them would be an information blocker, just like an actor who does not share their own information with others.

For example, if a hospital wants to receive electronic data from an EMS agency transporting a patient, it could be information blocking if that EMS agency does not provide the requested information (assuming an information blocking exception is not otherwise met). However, if the EMS agency wishes to proactively share their information to the hospital, it is *not* information blocking for the hospital to refuse to accept Direct messages sent to the hospital from the EMS agency.

Likewise, many providers who were not included in federal incentive programs to adopt interoperability have begun moving toward interoperable exchange using Direct messaging as a replacement for fax, sending a PDF or C-CDA Unstructured Document (often with an embedded PDF). This is far more secure than fax. In the case of the C-CDA Unstructured Document it also allows the sharing of discrete patient demographic information to allow easier patient matching in the receiving system. However, many EHRs do not support the receipt of PDFs or C-CDA using the Unstructured Document Template (*see previous comments under Patient Summary Record*). LTPAC providers, EMS agencies, and others who *could* be sending a Direct message and eliminating fax, are instead required to keep faxing because the hospital or provider's office can't receive the Unstructured Document. But this inability to *receive* information interoperably is not currently considered information blocking, as the current definition and exceptions focus on responding to requests rather than ability to receive information when sent.

Many EHRs that were part of the Meaningful Use program developed Direct very narrowly to meet MU requirements, meaning that they are able to send referrals and discharges, but often

don't have workflows in place to handle receipt of information. Beyond unstructured information previously discussed, certified EHRs often also cannot receive information that requires action – e.g., a care plan needing physician signature. This requires the sending organization to again revert to fax, even though both sides are technically capable of interoperable exchange with Direct, or other standards.

§ 171.203 Promoting Security of EHI

We agree that security is critical in the interoperable exchange of EHI. We are concerned that this exception may require individual vetting of all possible connections, particularly any number of patient/consumer-facing applications. One possible solution would be to tie this exception to TEFCA-based exchange and the Common Agreement, allowing organizations to trust the security of TEFCA-based exchange without having to vet all other possible non-TEFCA-compliant connections. *See Information Blocking Exception for Compliance with TEFCA below*

§ 171.207 Maintaining and Improving Health IT Performance

The exception, as written focuses on planned downtimes (planned outages for maintenance, upgrades, etc.) Should consideration be given to unplanned outages (server crash, server performance issues due to load handling, etc.) either with timeline for unplanned outages to be resolved, or allowance to respond to a re-request post-outage without being an information blocker because of an outage?

RFI – Information Blocking Exception for Compliance with TEFCA

One area that is not covered by TEFCA as much as would be expected, given the focus of these ONC and CMS proposed interoperability rules, is patient access or consumer apps leveraging FHIR APIs. A major concern with the proposed access for patients in these rules is the burden that will place on providers, payors, and others to individually vet every possible consumer app that their patients may choose to connect with.

We believe that a TEFCA exception should be added, primarily to protect providers from that potentially massive burden of vetting consumer apps. Consumer apps need to be included in TEFCA. Once an app has been "validated" as TEFCA-compliant, and is live on a QHIN (directly, through a Participant, etc.) any other organization available through TEFCA exchange must exchange with that consumer app, at the patient's direction. An information blocking exception could be added such that if a patient uses an app that is not a party of the TEFCA (bound to the Common Agreement), the provider would not be an information blocker for refusing to exchange with that app. Without that exception, every provider organization will be required to

individually vet every possible consumer app. That is entirely infeasible. A vetting of apps through QHINs, under the direction of the RCE and ONC, would remove that burden entirely from the provider organizations (and payors, and anyone else a consumer app would want information from), allowing patients to trust that any consumer app of their choosing will be able to connect, as long as it is "certified"/"TEFCA compliant"/whatever label is given to those apps.

RFI - New Exceptions

We propose the creating of two additional information blocking exceptions:

(1) *Extended timeline for post-acute care (PAC) and other non-incentivized providers.* This could be considered either for an exception, specific to certain types of providers, or instead a clarification in defining to whom information blocking applies. For providers who were not included in federal programs to drive interoperability (e.g., Meaningful Use), their primary form of "interoperability" today may be the fax machine in the corner of the office. As we strive toward a fully interoperable healthcare ecosystem, it is critical that we include providers throughout the entire continuum of care. However, those providers who today have no, or limited, interoperability functionality should not be held to the same timeline as providers and hospitals that were previously incentivized to develop interoperable methods of exchange. While interoperability rules and information blocking may apply to all of these providers, they should be given an extended timeline in order to "catch up" with those who have the head start of previous federal incentives.

(2) *USCDI exception for exchanged information*. While the technical flow of exchange of information is handled fairly consistently across proposed rules, the actual data being exchanged is not. There are references to C-CDA documents, to FHIR resources, USCDI, and most broadly EHI. While a clear mapping is needed from USCDI to the C-CDA documents or FHIR resources in which that data is exchanged, we believe that a larger issue may be the discrepancy between references to USCDI versus EHI for data being exchanged. USCDI is a very small subset of EHI. USCDI is a great starting point and we are pleased to see the additions of Clinical Notes and Provenance combined with current elements from the Common Clinical Data Set (CCDS) to create USCDI v1. The intention of USCDI is to continually grow with new data elements being added, until it may eventually include all EHI. As USCDI grows, discrete coding systems will be identified or created for each data element. However, today much of EHI is not discretely coded,

or at least consistently with the same code system across EHRs. We recommend that an exception be added to information blocking such that an actor returning all available USCDI data is not information blocking if the requestor wants (but does not receive) additional EHI not presently included in USCDI. This would not prevent an actor from exchanging non-USCDI EHI that it is capable of returning, but an actor would not be an information blocker for any non-USCDI EHI that they technically cannot exchange.

Information Blocking Complaint Process

One potential issue with the complaint process for information blocking will be the knowledge of the complaint submitter of who is actually the information blocker. This will be true of any exchange, between providers, payors, and others – the accuser may not know how their system is connected to the system from which they are requesting information. Is information being blocked by the responding provider, by that provider's EHR, by a HISP or HIE or other 3rd party in the middle of the exchange, by the requestor's EHR, or potentially any number of other hops across the exchange? This is especially important when the requestor of data is the patient, and the patient believes their information is being blocked. How will the patient know who is responsible for the information blocking beyond simply blaming their provider? What will be the process of investigation to determine where the information blocking occurred when there may be a chain of connected systems from the patient's app to the provider's EHR, any of which could have blocked the flow of information. With the patient only seeing their app, and not able to get the information they want from their provider in the app, how will the process of investigation ensure that claims of information blocking do not add massive provider burden with each claim beginning at the provider, requiring providers prove their information sharing compliance?

Trusted Exchange Framework and Common Agreement – ONC RFI re: Health IT Developer Requirement to Participate

The current proposed structure of the TEFCA may not make sense to include as a requirement on health IT developers. Under the current draft proposal, there are health IT developers who may become a QHIN and others who might be a Participant of a QHIN, with their customers as their Participant Members. Still other health IT developers will not be a QHIN or a Participant, but simply the vendor to a QHIN or Participant (or Participant Member or Individual User). Requiring health IT developers to participate in the Trusted Exchange Framework and adhere to the Common Agreement would not make sense in all cases. A possible alternative solution would be to require health IT developers to show the capability of performing TEFCA-based exchange standards, though even then, the required exchange standards mostly apply to the

QHINs, and any given Participant, Participant Member, or Individual User could be using entirely different exchange standards in their connection to their QHIN. Even just certifying a health IT developer's support for exchange standards would either require that it only apply to health IT developers who provide technology to QHINs, or the TEFCA would need to require that all participants – QHINs, Participants, Participant Members, and Individual Members – use the same standards for exchange in all cases.

Patient Matching

One of the biggest challenges to interoperable exchange today is patient matching. Without a standard way to identify patients, consistent demographic information collected about patients, or any form of reliable patient identifier, health IT developers are required to create their own matching algorithms to achieve an acceptable "likelihood" for patient matches. Some vendors have complicated algorithms that give point values to all provided demographic elements, looking for a patient with a high enough score to determine a match. Others use simple string matching ("123 Main Street" does not match "123 Main St"). If we are to achieve true nationwide interoperability, without significantly increasing provider burden, we must address the issues of patient matching. The challenges we see today will only be magnified as TEFCA and patient access both drive continued growth of interoperable exchange.

ADT Notifications from Hospitals & Critical Access Hospitals

We agree that there are many benefits to sharing patient admit, transfer, and discharge information, however we are concerned with the proposed requirement for how Hospitals & Critical Access Hospitals must implement those ADT Notifications. Traditional HL7 ADT interfaces are not scalable and can be very costly to implement especially for PAC providers who may care for patients coming from many different hospitals. Organizations such as Carequality and CommonWell have already been working on solutions for providers (and payors, patient representatives, etc.) who need notifications of events occurring in other locations. These event notifications are built on a subscription model, where users who wish to receive notifications can "subscribe" to the patients and notification types they wish to receive. We encourage CMS and ONC to look toward these existing frameworks when requiring any form of cross-organizational notifications. This may also be a good use of TEFCA v2's Exchange Modality of QHIN Message Delivery.

Requirement Timelines

Both the CMS and ONC proposed rules, as currently written, include deadlines for achieving interoperability. There are requirements on payors to participate in a trusted exchange

framework, payors and providers to share information with patients, information blocking, providers sharing their electronic contact information, among others. Required timelines for interoperable exchange cannot be achieved if the underlying infrastructure is not yet in place. Many of the required exchanges could be facilitated through TEFCA-based exchange. We recommend that CMS and ONC base timelines on TEFCA implementation milestones, rather than seemingly arbitrary dates (e.g., January 1, 2020).

We appreciate your consideration of our comments and welcome the opportunity to meet with you to discuss these and other issues in greater detail.

Sincerely,

Alan Swenson
Vice President of Interoperability
Kno2
(208) 695-2378
aswenson@kno2.com