Kno2 Responds to New HHS Interoperability Rules from CMS & ONC

By now you have probably seen many news articles published about the new HHS interoperability rules. We want to provide some quick updates, a high-level overview of what is happening, and how Kno2 will help you handle these new requirements.

As you know, last year HHS released two proposed rules, both published in final form Monday, March 9th, 2020—one from ONC and one from CMS. After review of the final rules (which we have been tracking since the beginning), we are very pleased with the position of the Kno2 platform and our active work efforts to address all of the requirements from both rulings, placing our integrated partners in a position of leadership and strength. Please see below for callouts on the actionable items on each rule and our response.

CMS RULE

Summary:
CMS' rule (474 pages long) focuses on interoperability and patient access. This rule will give patients API access to claims and encounter information from payers beginning January 1, 2021. It also modifies the Medicare and Medicaid Conditions of Participation, requiring all hospitals to send electronic event notifications of a patient's admission and discharge or transfer to other healthcare facilities, community providers, or other practitioners. The ADT notification policy will apply 6 months after publication of the rule in the federal register (TBD, within a week or two of the release date: 3/9/2020).

Kno2's Response:

ADT/Event based notifications

As part of our participation in Carequality, we are proud to say we are actively working on this use case for subscription-based event notifications leveraging the existing Carequality trust framework. This new use case will be critical to many of you, providing an easy way for you to follow your patients as they are admitted to the hospital, and provide critical information for patients you are receiving post hospital discharge. The new use case was already expected to be finalized later this year, but this final rule from CMS may expedite that timeline. More details to come.

Digital Contact Information/NPPES

CMS will also be requiring all providers publish their "digital contact information" (such as FHIR endpoints or a Direct Address) to the National Plan and Provider Enumeration System (NPPES). They will begin publicly reporting in late 2020 those providers who have not done so. Ensuring that your providers have that digital contact information that they can publish will be critical. This requirement will easily be handled for any provider that already has a Direct Address through Kno2. Kno2 will continue to innovate and provide simple methods of management and publishing to our partners and end users in the upcoming months.

For More Info:
Further detail from CMS is available here: https://www.cms.gov/newsroom/fact-sheets/interoperability-and-patient-access-fact-sheet

ONC RULE

Summary:
ONC's rule deals with interoperability, information blocking, and updates to ONC's Health IT certification program. The rule is 1,244 pages long, plus many additional pages of supporting documentation also published this week from ONC. It will be a while before anyone has read through it all, so expect further updates as we learn more. All of that information can be found here: https://www.healthit.gov/curesrule/

Information Blocking:
Beginning at a high level, what does information blocking mean now and who is impacted? Compliance with the information blocking section of the final rule is not required for six months from the date of publication in the federal register.

Note that “information blocking” is defined in law and is illegal. The ONC rule provides exceptions, or cases where it is justified to not share information.

The proposed rule included four categories of "actors" of information blocking. In the final rule we now have three:

1. Health Care Provider - The rule provides a lengthy list of examples (e.g., hospital, SNF, home health, EMS agency, FQHC, dialysis facility, blood center, pharmacy, laboratory, etc.), ending with "and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the HHS Secretary." In short, if you are delivering patient care of any sort, you are a Health Care Provider.

2. Health Information Network or Health Information Exchange - These were two categories defined in the proposed rule that created confusion. The final rule combines them into one category. However, some of the confusion remains. This definition applies to any "individual or entity". Thus, a single person could be a Health Information Network (HIN) or Health Information Exchange (HIE). "…that determines, controls, or has the discretion to administer any requirement, policy, or agreement that permits, enables, or requires the use of any technology or service for access, exchange, or use of electronic health information"…

   As we read that, if you, as an individual, determine requirements around the use of technology for electronic health information, you are a Health Information Network and are potentially liable for information blocking if your decision is what caused information to not be shared. Hopefully we'll learn more about that one in some of ONC's public information webinars over the next few weeks.

3. Health IT Developer of Certified Health IT - This one largely remains the same as the proposal. If a vendor has any products certified, then all that vendor's products (including the non-certified ones) are liable for information blocking. A fully non-certified vendor would not apply. However, as we have commented previously, a Health Care Provider who uses a non-certified vendor product will still be liable for information blocking as a provider, and is essentially taking on all the risk of information blocking by choosing to use a non-certified vendor. We recognize many of our partners are non-certified due to lack of stimulus funding early on and believe Kno2 will provide some relief on this front as it relates to information exchange. Please see below.

Exceptions to Information Blocking:
In the proposed rule we were given seven exceptions to information blocking—cases where it is justified to not share information. In our comment letter we suggested a few additional exceptions. The final rule now has eight exceptions, with some being reworked and combined.

The exceptions include:

- Preventing Harm Exception – if sharing information would have a "reasonable" risk of harm to the patient
- Privacy Exception – if sharing information that requires patient consent and is not received, or if the patient has previously opted out of information sharing, etc.
- Security Exception – if the request does not meet organizational security policies tied to specific security risks
- Infeasibility Exception – Covers uncontrollable events (e.g., disasters, public health emergency, war, terrorist attack, etc.), also data segmentation, and "infeasibility under the circumstances" (which is a really broad category, but requires extensive additional proof and written documentation to prove infeasibility)
- Health IT Performance Exception – Covers "reasonable and necessary" measures that make health IT temporarily unavailable, such as routine system maintenance, performance improvements, etc.
- Fees Exception – Vendors and networks can charge fees, would not be information blocking if the fee has not been paid. Does not apply to patient request.
- Licensing Exception – Vendors and networks can license their interoperability elements, would not be information blocking if a provider has not licensed the required elements.
    - Note, this could still be information blocking against the provider who is blocking information because they have not licensed interoperability elements, but this would protect the vendor that makes interoperability elements available to any provider who has licensed them.
- Content and Manner Exception
    - Content – The rule specifically calls for the exchange of all Electronic Health Information (EHI). For the first 24 months from the date of publication in the federal register it is not information blocking if you only exchange USCDI, rather than all EHI.
    - Manner – If you are technically unable to respond to a request in the manner requested, it is not information blocking if you do respond in an approved alternative manner. (Note, this being the newest exception, we expect we'll learn a lot more about ONC's intentions here over the next few weeks)

Kno2's Response to Information Blocking:

<u>API Integration</u>

The core philosophy of Kno2 is and will remain to meaningfully connect to the entire care continuum for all use cases and provide access to this connectivity through a simple set of REST-based APIs or an online provider portal. Integrating your platform to these APIs will protect you and your end users from these claims, as you are supportive of all methods of exchange, including fax when need be.

<u>Certified Technology</u>

Recently, Kno2 integrated and expanded our Direct Secure Messaging platform to be supportive of XDR, allowing our technology to meet the latest certification requirements. Kno2 is scheduled to complete our re-certification to the latest requirements, and thus our partners will receive the benefit of this certification. In addition, Kno2 is in the final stages of technology that will provide the necessary CDA creation and FHIR resource availability, which will also be certified, allowing our health IT partners to have a modular certification package for interoperability.

Content – USCDI (US Core Data for Interoperability):
Additionally, the USCDI version 1 has been published by ONC. It has been modified from the proposed version to better align with both FHIR resources and C-CDA documents. Patient demographic requirements were also modified in order to better assist with patient matching. USCDI for patient demographics now includes current address AND previous address, phone number along with a specified phone number type, and email address.

USCDI will continue to be updated with priorities for new data elements/classes coming from stakeholder feedback. There will be a public website to submit recommendations. Participation **will be critical** because **the information** a post-acute provider may **care about is not always the same as what the hospitals** or other provider organizations care about. However, collectively pushing forward new elements into the USCDI will push others to support them as well, providing you with the information you need in these exchanges.

Kno2's Response on USCDI:

Kno2 has tracked closely to the guide for the USCDI and is ensuring our APIs are in full support of the new data elements and classes.

FHIR…FHIR….and more FHIR:
The focus of both final rules, especially around patient access, is on FHIR-based exchange. One of the big concerns with FHIR is the need to set up individual ("point-to-point") connections, especially when we're now talking about any number of patient apps being the requestor of FHIR data.

Kno2's Response to FHIR:

We have already been actively working with Carequality on a new use case for FHIR-based exchange. This use case will do for FHIR what it has already accomplished for query-based exchange with C-CDA documents, which also historically were point-to-point connections. A connection to Carequality through Kno2 will provide nationwide scalability for FHIR-based exchange, leveraging the existing governance and trust framework already in use for C-CDA document exchange. Like subscription-based notifications, this new Carequality use case was already in the works and expected later this year. That timeline may be expedited due to these new rules.

Kno2 is also in advanced planning with technology to provide CDA creation and FHIR resource tools to our EHR partners.

If you're still with us to this point, that is a lot of detail, while at the same time very high level and barely scratching the surface of these new rules and everything that we will learn about them in the coming weeks. It is Kno2's priority to provide interoperability services to any health IT vendor and/or healthcare organization through one simple set of APIs or through use of the portal.

Where You Need to Be

If you are not yet live with Direct Secure Messaging, start now. That will be critical for the CMS rule, allowing your providers to easily share their Direct addresses with other providers and with NPPES.

If you are not yet live on query-based exchange through Carequality, start now. C-CDA document exchange will still be critical for compliance with these rules. And with the new use cases coming for notifications and FHIR, getting started now on query-based exchange will put you in a great place to quickly adopt those new use cases as soon as we make them available through our APIs.

Finally, ensure your offering is sending and receiving faxes. Although it's 2020 and we're still talking about fax, if all else fails, it's critical your customers can easily release ALL parts of the applicable patient record minimally through fax. In addition, having your fax volume flow through our network will allow simple analysis of fax traffic so that we can easily move those faxes to Direct messaging and query-based exchange based on mapped endpoints to fax numbers, as well as moving fax volume to FHIR and other forms of exchange as those become available.

For any questions regarding these final rulings or Kno2's response, please contact Alan Swenson, Kno2 VP of Interoperability at aswenson@kno2.com.