

Health Information Compliance Alert

Policy: ONC Proposed Rule 'Cures' HIT Certification Woes

Plus: Standardization and computability are at the heart of the proposals.

All practices are unique and require unique health IT solutions. Luckily, with so many different varieties of EHRs, software programs, and applications, organizations have a lot of options to choose from to meet the needs of their patients.

But, not all products are the same, nor do they all align with each other to ensure that health information exchange (HIE) is efficient and effective - and, that's a problem. The **HHS Office of the National Coordinator for Health Information Technology (ONC)** aims to fix the issue.

Nuts and bolts: On Feb. 11, ONC and CMS released coordinated proposals to address 21st Century Cures Act (Cures Act) provisions. The proposed rules, published in the Federal Register on March 4, contain much crossover material. However, ONC's policies are geared toward health IT certifications and industry standardization, while CMS troubleshoots Medicare's IT hotspots in its rule, as well as tying the proposals to federal healthcare programs' reimbursement and compliance.

"ONC's proposed rule to require secure open APIs [application programming interfaces], identify reasonable and necessary activities that are exceptions to information blocking, and update the Certification Program can serve as one of the largest steps necessary to make healthcare more transparent and patient accessible," says **Don Rucker, MD**, ONC national coordinator in a blog post on the rule.

Check Out the Details

A major part of the ONC proposed rule offers guidance on federal efforts to thwart information blocking in healthcare. The agency proposals outline requirements mandated in Section 4004 of the Cures Act to determine "reasonable and necessary activities that do not constitute information blocking," notes an ONC fact sheet. The proposed rule discusses seven exceptions to the rule, the reasoning behind data blocking, and who is allowed to sidestep new federal requirements (see Health Information Compliance Alert, Vol. 19, No.2).

Interoperability is the central theme of the policies mentioned in the rule, rolling out Cures Act allocations to target the influx of applications and products on the market. The proposed rule homes in with the following ideas to address problem spots in the health IT market:

APIs: ONC's proposals aim to change 2015 Edition certification standards for application programming interfaces (APIs) and "establish certain Conditions and Maintenance of Certification, implementing the Cures Act's requirement that health information from API technology be accessed, exchanged, and used 'without special effort,'" explain attorneys **Christine Moundas** and **Josiah Irvin** of national law firm **Ropes & Gray LLP** in legal analysis. "In doing so, ONC seeks to move the healthcare industry toward adoption of standardized APIs."

Other important mentions include:

- Fee restrictions for API technology suppliers.
- New API technical requirements for certification: the »use of the Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) standard; enhanced search and access capabilities; and more secure app connections.
- New API security requirements for certification: connection and registration protocols; put EHI-distribution in the hands of providers; and more patient-centered controls.
- Updated transparency, pro-competition, and maintenance requirements.

EHRs and EHI: ONC proposes to make the transfer of information more manageable with better EHI exports, the fact sheet suggests. As part of its new certification requirements, ONC proposes that developers "permit the export of EHI in computable, electronic format, both in the context of an individual patient request and when a healthcare provider chooses to transition or migrate information to another health IT system," Moundas and Irvin write.

USCDI: The agency wants to "move beyond the common clinical data set [CCDS]," says ONC guidance. As part of the nation's transition to value-based care, the feds want to replace the CCDS with the United States Core Data for Interoperability (USCDI) standard as part of the 2015 Edition certification.

Pediatric-specific HIT: Section 4001 of the Cures Act detailed the need for pediatric-centered health IT; the ONC proposed rule offers some "voluntary" criteria for 2015 Edition developers to make that happen. Some examples of software additions include age-appropriate clinical priorities, materials to encourage better EHI in pediatric settings, and better informational resources, the fact sheet notes.

Deadline: ONC is accepting public commentary on the rule through May 3, 2019.

Resources: See the ONC proposed rule at www.federalregister.gov/documents/2019/03/04/2019-02224/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification.

Find the ONC fact sheets at www.healthit.gov/topic/laws-regulation-and-policy/notice-proposed-rulemaking-improve-interoperability-health.