

PG Alert

To: Health Information and Technology; In-House Counsel; Physician Organizations; *and* Regulation, Accreditation, and Payment Practice Group Members

From: Health Information and Technology Practice Group Leadership

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ONC's De-Regulatory Announcement Aims at Enticing Industry to Adopt 2015 Edition Criteria By Scott Weinstein*

On September 21, the Office of the National Coordinator for Health Information Technology (ONC) announced that it is scaling back requirements for third-party certification of criteria related to certified electronic health record (EHR) technology (CEHRT). Specifically, ONC will permit health IT developers to self-declare their products' conformance with 30 of the 55 certification criteria it established in 2015 (2015 Edition criteria). Health IT developers will now only need to submit the remaining 25 criteria for third-party testing to obtain certification. Additionally, ONC will exercise discretion and not enforce the requirement that certification bodies conduct randomized surveillance of 2% of the health IT certifications they issue.

ONC stated that it made these changes to reduce burdens for health IT developers, certification bodies, and testing labs with the goal of allowing the industry to focus on certifying health IT products to the 2015 Edition certification criteria, and testing and improving the 2015 Edition features that are aimed at fostering interoperability.

Some industry watchers are concerned the changes may allow non-conformance with certification criteria to go undetected—turning the certification program into a set of guidelines rather than hard requirements. On the other hand, ONC appears to have recognized that the jump from "2014 Edition" to "2015 Edition" will be steep for many health IT developers. The Centers for Medicare & Medicaid Services (CMS) has already delayed until 2019 measures that would have required health care providers to adopt 2015 Edition products for participation in the Meaningful Use and Merit-based Incentive Payment System programs due, at least in part, to the lack of available 2015 Edition products in the market. ONC may see these deregulatory steps as necessary to encourage the development of 2015 Edition-certified products, which ONC believes will improve the overall interoperability of health IT products.

Background

The HITECH Act required the U.S. Department of Health and Human Services to create two programs to push forward the adoption and use of EHRs. The first program required ONC to create a certification process under which health IT developers would be able to certify their products' capabilities and conformance with required standards and implementation specifications. The second program required CMS to incentivize health care professionals and hospitals to adopt and "meaningfully use" CEHRT. CMS created measures defining "meaningful use," and established incentive payments and penalties based on whether meaningful use had been demonstrated.

As part of its certification program, ONC created testing labs and certification bodies to ensure that health IT products met ONC certification criteria.

Move to Self-Declaration

Under the 2015 Edition testing requirements, health IT developers will no longer be required to use third-party testing labs to test conformance to 30 of the 55 2015 Edition certification criteria as a condition of obtaining certification.

The features for which health IT developers may self-declare compliance include:

- Computerized provider order entry
- Drug-drug, drug-allergy interaction checks
- Offering patient-specific education resources
- Transmission to public health agencies - electronic case reporting
- Secure messaging
- Capture of information directly and electronically shared by a patient
- Privacy and security features such as auditable events and tamper resistance, automatic access time-out, trusted connection, and end-user device encryption.

According to ONC, these changes will reduce burdens for health IT developers and testing labs, and allow testing labs and developers to devote more of their resources to focus on interoperability-oriented test criteria. In its announcement, ONC noted that this self-declaration approach is used by other industry testing programs, including the Federal Motor Vehicle Safety Standards and the Federal Communications Commission.

Randomized Surveillance

ONC requires certification bodies to randomly select at least 2% of the products they have certified to evaluate their conformance with ONC's certification criteria as implemented in the field. The goal of this surveillance is to ensure that products implemented by health IT developers function in the field in the same way as they did when tested by the testing lab.

According to ONC's announcement, it will exercise enforcement discretion regarding the performance of randomized surveillance, and will not audit certification bodies' completion of randomized surveillance. Instead, ONC has directed certification bodies to focus on "reactive surveillance"-the initiation of surveillance (including, as necessary, in-the-field surveillance) when it becomes aware, through complaints or otherwise, of facts or circumstances that call into question the conformance of a health IT product with ONC's certification criteria.

ONC reasoned in its announcement that exercising enforcement discretion would allow certification bodies to better focus on certifying health IT to the new 2015 Edition certification criteria.

Analysis

Through its EHR incentive programs, CMS can encourage health care professionals and hospitals to adopt CEHRT that meets the updated standards and implementation specifications established by ONC. However, CMS has sometimes delayed the scheduled adoption of new "editions" of ONC's certification criteria due to the additional planning, costs, and transition time that professionals and hospitals have needed to meet new standards. Most recently, CMS targeted voluntary adoption of CEHRT by 2017 that met the 2015 Edition criteria, with required adoption by 2018. However, in proposed rules dated June 30, 2017 and August 2, 2017, CMS made the adoption of CEHRT meeting the 2015 Edition criteria optional in 2018 as well.

ONC views many of the additional capabilities required by the 2015 Edition criteria to be an important springboard for improving interoperability. For example, the 2015 Edition criteria will, for the first time, require health IT developers to offer application programming interfaces (APIs) that allow third party applications to interface with and obtain data from the EHRs. ONC hopes that the new capabilities within the 2015 Edition will allow patients to more easily direct the exchange of their health information between professionals and hospitals.

ONC is likely hoping that by making the testing and certification process less burdensome for health IT developers, it will entice more widespread adoption of the 2015 Edition criteria. It remains to be seen, however, whether these steps will influence the industry in that direction.

**We would like Scott A. Weinstein (McDermott Will & Emery LLP, Washington, DC) for authoring this Alert. We also would like to thank the Health Information and Technology Practice Group leadership for sharing this Alert with the In-House Counsel; Physician Organizations; and Regulation, Accreditation, and Payment Practice Groups.*

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