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What to HIOs Need to Know about Patient Access in the 21st Century Cures Act

In one of the rare bi-partisan votes of 2016, Congress passed the 21st Century Cures Act, which President Obama signed into law on December 13th, 2016. 21st Century Cures is a wide ranging bill that covers everything from FDA approval processes to telemedicine to health IT and interoperability. Many may not realize that the final 21st Century Cures bill included most of the provisions of the Senate HELP Committee's Legislation to Improve Health Information Technology for Patients and Families, which was approved by the committee in early 2016 and contains many interoperability provisions. The 21st Century Cures Act attempts to address a number of interoperability and patient access issues, most of which will have an impact on health information organizations (HIOs). This is Part 1 of three white papers that will highlight the areas HIOs should pay attention to in the 21st Century Cures Act.

Patient Access

The bill includes three provisions around enabling easier patient access to their electronic medical information:

- HHS must use existing authorities to encourage providers and payers to work with HIOs to provide patients with access to their electronic health information that is longitudinal, secure, and can be updated automatically;
- The Office of Civil Rights (OCR) must provide education to providers on how they can work with HIOs to provide patients with access; and
- OCR must provide best practices and guidance to HIOs on how to provide patients with access.

There are a few existing authorities HHS could use to encourage the use of HIOs for patient access, and which authorities are used will depend on the new Secretary, Tom Price. The Quality Payment Program (QPP) is an obvious choice for encouraging the use of HIOs for patient access. The Advancing Care Information measures already encourage the use of HIOs for sending and receiving C-CDAs, and there is an Improvement Activity that specifically calls out the use of HIOs for bilateral data exchange between providers. An update to the QPP could include additional measures or improvement activities that promote the use of an HIO for patient access. Additionally, the Secretary could build requirements into alternative payment models (APMs), such as the Comprehensive Primary Care Plus (CPC+) program, that would push providers participating in the APM to use an HIO to provide patients with access to their health information. HIOs should keep an eye out for the updated final rule on QPP coming in 2017 for new requirements that are added and should closely monitor new Advanced APM models that CMS is developing for 2018.

On the education front, OCR has three main charges from the legislation. First, OCR must educate providers on how they can best work with HIOs. We believe this would likely include educating providers about the key capabilities of HIOs to provide patient access. Second, OCR must clarify any misunderstandings providers have about using HIOs. This may refer to providing HIPAA clarifications and educational materials on what is allowed under HIPAA when working with an HIO to provide patient access. OCR could also focus on patient authentication processes which have historically been difficult for HIOs to manage, since they don't have the primary relationship with patients. Finally, OCR would educate providers about specific HIOs or platforms (which we believe could include vendor products) who can provide patients access to their longitudinal health information and allow them to update it. It will be important for HIOs who provide these capabilities to ensure that ONC and OCR are aware of their capabilities as the educational materials are built.

Finally, OCR must develop and disseminate guidance for HIOs on the best practices for ensuring that patient information is private/secure, accurate, verifiable, and that consent and patient preferences for sharing data is easily exchanged. We believe that this guidance could get incorporated into the trust framework that ONC will be working with the industry on (we'll cover this in the next post), though OCR could of course develop separate guidance. HIOs should engage with ONC both on the trust framework and any guidance that they work with OCR to develop.

One other item of note that HIOs should pay attention to. The ONC certification program, currently has criteria that require health IT to meet certain standards for providing patients access to view, download, and transmit their health information (§170.315(e)(1)) or access it via APIs (§170.315(g)(7), (g)(8), and (g)(9)). The bill includes a provision that the certification program should certify the usability of health IT for patients and that health IT can provide patients access to a single longitudinal record that can be updated easily and automatically. With the wording of this provision mirroring the language on the capabilities an HIO can provide, HIOs should keep an eye out for future certification requirements geared towards their capabilities, if they are providing patients access. This is another area where HIOs should engage with ONC to ensure that any certification requirements can be implemented in the real-world.

[Click here for Part 2: Trusted Exchange Framework and Common Agreement.](#)