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Health IT Update – Reconciling HHS' Recent Proposed Rules Concerning Electronic Health Information with Connecticut's Information Blocking Statute

Connecticut Health Law

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Connecticut healthcare providers should give heed to three sets of recently proposed rules issued by the U.S. Department of Health & Human Services (HHS) interpreting some of the federal laws relating to electronic health record systems (EHRs) and prohibiting illegal restrictions on the use of electronic health information (EHI). The proposed rules are especially important to parties grappling with this State's own information blocking statute and other issues connected with this rapidly evolving area of health care compliance.

On October 17, 2019, HHS published its long-awaited proposed changes to the Anti-Kickback Statute (AKS) and the Physician Self-Referral Law (Stark) regulations that are intended to promote coordination of patient care in a value-based reimbursement environment. This included specific sections intended to clarify the existing AKS safe harbor and Stark exception concerning the donation of EHR systems and related support given to referring physicians which, among other things, prohibit donors from restricting the use or interoperability of donated EHR systems.

Most notably, HHS indicated its intent to align the concept of "information blocking" in the AKS and Stark regulations with the information blocking exceptions enumerated by the HHS Office of the National Coordinator for Health Information Technology (ONC) in Proposed Rules published on March 4, 2019. The ONC identified seven categories of practices that, despite interfering with the access, exchange, or use of EHI, are "reasonable and necessary" to advance other compelling policy interests concerning EHR. The permitted practices, each of which has detailed requirements, are intended to:

- protect patient safety;
- promote the privacy of EHI;
- promote the security of EHI;
- allow for the recovery of costs reasonably incurred;
- excuse an actor from responding to requests that are infeasible;

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- permit the licensing of interoperability elements on reasonable and non-discriminatory terms; and
- allow actors to make health IT temporarily unavailable for maintenance or improvements that benefit the overall performance and usability of health IT.

Under the ONC's proposed rules, if one of the above exceptions is satisfied, the actions taken by a regulated party in furtherance of such a goal would not be treated as information blocking and civil penalties and other disincentives enacted in 2016 under the federal 21st Century Cures Act (Cures Act) would not apply. The Cures Act defines information blocking as a practice that, except as required by law or specified by HHS as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI. For a health care provider to be found liable for information blocking, the provider must know that the practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI.

In 2015, Connecticut became one of the first states in the nation to explicitly prohibit this type of activity. Specifically, the Connecticut law defines health information blocking as:

(A) knowingly interfering with or knowingly engaging in business practices or other conduct that is reasonably likely to interfere with the ability of patients, health care providers or other authorized persons to access, exchange or use electronic health records, or (B) knowingly using an [EHR] system to both (i) steer patient referrals to affiliated providers, and (ii) prevent or unreasonably interfere with patient referrals to health care providers who are not affiliated providers, but shall not include legitimate referrals between providers participating in an accountable care organizations or similar value-based collaborative care models[.]

The law also made health information blocking an unfair trade practice and imposed special requirements on hospitals and health systems. However, since its enactment, there has been a paucity of guidance issued by Connecticut regulatory authorities or courts interpreting the language of the statute and its application to the type of "reasonable and necessary" practices covered by the proposed federal rules described above. This vacuum creates the possibility that, in the future, practices that are permitted by federal regulators could conflict with the enforcement of Connecticut's information blocking statute.

The ONC's proposed rules closed for public comment in May 2019. The proposed rules on the AKS and Stark exceptions are currently subject to a public comment period that expires on December 31, 2019. Connecticut health care providers and policymakers will be well served in paying attention to the developments of these proposed rules.

Tags: 21st Century Cures Act, U.S. Department of Health and Human Services (HHS)