ROPES & GRAY ALERT

FDA Regulatory ▪ Health Care ▪ Digital Health

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21st Century Cures Act – Provisions Relating to Digital Health

On December 13, 2016, President Obama signed into law the 21st Century Cures Act (the Act), just days after it passed in the U.S. House of Representatives and Senate. With an overarching goal of advancing biomedical innovation, the Act makes numerous changes to laws that govern Food and Drug Administration (FDA) programs, clinical research regulations, and Medicare coverage and reimbursement rules.

To see Ropes & Gray's analysis of key provisions of the Act, please click on the hyperlinks below:

- Promoting Drug Development
- Development Incentives for Certain Classes of Drugs
- Medical Device Innovation
- Regulation of Clinical Research
- Reimbursement & Fraud and Abuse

Partners in Ropes & Gray's FDA Regulatory practice have also recorded a podcast to discuss some key implications of the Act for biopharmaceutical and medical device manufacturers. Click here to listen to the podcast.

This Alert highlights key changes related to the regulation and promotion of electronic health records (EHR) and other forms of health information technology (HIT). While the Act does not allocate additional funds for providers, developers, networks, or exchanges, it contains several provisions intended to promote interoperability of HIT networks, to reduce administrative and regulatory burdens preventing providers from adopting EHRs, and to improve patient access to information contained in EHRs.

Reducing Regulatory and Administrative Burden on Providers [Section 4001].[1]

The Act requires the U.S. Department of Health and Human Services (HHS) to develop, in consultation with providers and other stakeholders, a strategy for reducing regulatory and administrative burdens, including documentation and reporting requirements, relating to the use of EHRs. The Act directs HHS to prioritize, among other strategies, the use of incentive payments (including through "meaningful use" incentives for Medicare and Medicaid providers and the Merit-Based Incentive Payment System) and changes to certification standards for EHRs and other HIT.

The Act does not allocate additional funds to facilitate adoption of EHRs, and the practical benefit for providers will remain uncertain until HHS develops the strategy and recommendations required under the Act, which is to occur within one year of the date of enactment. There is, however, one immediate benefit to providers: the Act permits physicians to delegate, to the extent consistent with state law, applicable EHR documentation requirements to a person performing a scribe function, provided the physician reviews and signs the documentation.

[1] Cited sections refer to the relevant provisions in the Act.

Encouraging Interoperability of EHRs [Sections 4002 and 4003].

Under the Act, HHS must promulgate rules amending HIT certification standards by requiring developers (i) to publish application programming interfaces (APIs) that permit exchange of EHR and other health information between different HIT systems, (ii) to successfully test the "real world use" of interoperability technology, and (iii) to attest that they will not engage in "information blocking" (as defined below) or otherwise inhibit the appropriate exchange, access, and use of electronic health information.

In addition, the Act requires the Office of the National Coordinator for Health Information Technology (ONC) within HHS to develop, in consultation with appropriate stakeholders, a *voluntary* "trusted exchange framework" and common agreement for the secure exchange of health information between networks. (Such a framework might include common authentication methods, common rules for trusted exchange, and organizational and operational policies to enable exchange among networks.) The Act also establishes an HIT Advisory Committee within ONC that is charged with developing recommendations related to interoperability—which the Act defines as HIT that (i) enables the secure exchange of electronic health information "without special effort on the part of the user," (ii) allows for complete access, exchange, and use of all electronically accessible health information, and (iii) does not constitute information blocking" (see below). In adopting and implementing interoperability or other standards, ONC must "give deference" to standards developed in the private sector (*i.e.*, by standards development organizations or voluntary consensus-based standards bodies).

As a result of the HIT certification standard changes, including those requiring developers to publish APIs, it is expected that providers will find it easier to share patient records and exchange information with other health care providers for treatment purposes (or as otherwise allowed under applicable privacy laws).

Discouraging "Information Blocking" [Section 4004].

The Act authorizes the HHS Office of Inspector General (OIG) to investigate claims of information blocking, and to penalize practices found to be interfering with the lawful sharing of EHRs. Information blocking is broadly defined to include practices that prevent, interfere with, or burden information exchange. Such a broad definition risks penalizing providers, developers, and exchanges not only for egregious information blocking, but potentially for actions resulting from internal policies and industry best practices that vendors and providers have in place to protect the privacy and security of the entity and/or its patients. Providers may be especially susceptible to confusion, considering they historically have been given the ability to control the release of information based on professional judgment and business decisions.

The Act does attempt to protect providers by imposing a higher scienter requirement for providers than for HIT developers, exchanges, or networks: to be liable under the information blocking prohibition, a provider must "know[] that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information." The Act also clarifies that a provider does not violate the information blocking prohibition merely by utilizing HIT that fails to meet applicable certification requirements. Nonetheless, providers may wish to review their policies and procedures surrounding access and exchange of electronic health information to ensure they do not unreasonably restrict the transfer of information for treatment or other purposes permitted under HIPAA or other applicable state and federal law.

Leveraging EHRs to Improve Patient Care and Access to Information [Sections 4005 and 4006].

The Act requires certified EHRs to be capable of exchanging information with qualified "clinician-led clinical data registries," a requirement that may be of particular interest to physician groups. The Act defines such a registry as a clinical data repository that (i) is established and operated by a clinician-led or -controlled, tax-exempt, professional society or similar organization that is devoted to the care of a population defined by a particular disease, condition, exposure, or therapy; (ii) is designed to collect detailed, standardized data on an ongoing basis for medical

procedures, services, or therapies for particular diseases, conditions, or exposures; (iii) provides feedback to participants who submit reports to the repository; (iv) meets standards for data quality, including systematically collecting clinical and other healthcare data, using standardized data elements and having procedures in place to verify completeness and validity of those data, and being subject to regular data checks or audits to verify completeness and validity; and (v) provides ongoing participant training and support.

In addition, the Act attempts to improve patient access to information contained in EHRs by (i) supporting the certification and development of patient-centered EHRs that provide access to health information in a single, longitudinal format that is easy to understand and secure, and that may be updated automatically; (ii) requiring HHS to educate patients and providers on rights to, and best practices for, patient access to electronic health information, including through health information exchanges, patient portals, or other third-party applications; and (iii) clarifying that business associates that receive patient requests for access to protected health information may grant such access directly, including in an electronic format.

As with the other HIT-related provisions above, the Act does not allocate additional funds to assist providers in adopting or utilizing such patient-centered EHRs; providers may, however, notice changes implemented by developers to improve existing EHR capabilities or interfaces. Providers may also wish to review their business associate agreements to permit their business associates to provide access, upon requests from patients, to information contained in an EHR.

"Meaningful Use" Exceptions in the ASC Setting [Section 16003].

Recognizing the lack of certified EHRs for the ambulatory surgical center (ASC) setting, the Act creates an exception under applicable "meaningful use" requirements for physicians practicing in ASCs. Current law mandates that eligible professionals who fail to demonstrate meaningful use of EHRs receive reduced reimbursement for covered services, with the notable exception of hospital-based physicians. The Act creates a further exclusion for physicians who furnish substantially all of their Medicare services at ASCs. The provision will sunset three years after the HHS Secretary determines, through notice and comment rulemaking, that certified EHRs are available for the ASC setting.

If you have any questions, please contact any member of Ropes & Gray's FDA regulatory or health care practices or your usual Ropes & Gray advisor.