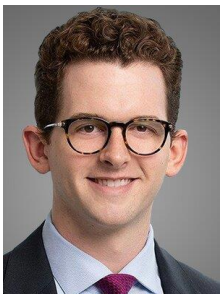
Health Care Info Blocking Rule Changes To Watch For

By **Sara Shanti, Paul Werner and CJ Rundell** (June 29, 2023)

Sara Shanti

Paul Werner



CJ Rundell

As the Office of the National Coordinator for Health Information Technology proposes to make certain revisions[1] to the federal information blocking rules — Title 45 of the Code of Federal Regulations, Part 171[2] — the delay in publishing enforcement rules continues to frustrate health care stakeholders.

This frustration stems in part from ongoing anti-competitive conduct by some "actors" — defined under the rules to include health IT developers of certified health IT — as well as health information networks and health information exchanges, and health care providers in the absence of any imminent threat of enforcement.

A new proposed rule published by the ONC in April would, among other things, offer some relief to actors by modifying certain exceptions to the rules.

However, actors and industry stakeholders are still awaiting the final enforcement rules, which the U.S. Department of Health and Human Services, Office of Inspector General, has yet to issue.

Further, a proposed rule from HHS and the ONC regarding "appropriate disincentives" for health care providers has been delayed.

Actors should be aware of the potentially beneficial changes to come from the ONC's proposed rule, but frustrated stakeholders will continue to endure the current information blocking environment while awaiting the final enforcement rules from the OIG.

Additional relief may be on the horizon, as regulatory review of the OIG's final rule was completed June 2.

Stakeholders Are Frustrated, Some Flex in the Silence

The pendency of the final enforcement rules has fostered a corollary lack of incentive to comply with the rules.

Some actors are engaging in opportunistic behavior to further solidify their market share and stymie the advancement of interoperability by emerging stakeholders with innovative products — conduct that is precisely what the rules were intended to prevent.

In some instances, established developer actors are threatening emerging companies that offer promising interoperability solutions and those companies' customers with implicit violations of the rules and terms of use breaches.

In addition, health care providers, such as clinical laboratories, feel stuck in the middle between having to comply with the rules, wishing to follow the treating providers' direction and needing to protect themselves against entities and individuals still engaging in

information blocking.

These industry stakeholders are concerned that they have little to no recourse against anti-competitive behavior that likely violates the rules absent the threat of enforcement — especially with limited resources.

However, bad actors beware: Industry stakeholders do have options to protect and enforce their rights while awaiting agency enforcement.

The avenues of recourse for stakeholders may include reporting Health Insurance Portability and Accountability Act right of access violations to the HHS Office for Civil Rights — ensuring their contracts prohibit information blocking, and leveraging available claims for tortious business interference, unfair competition, defamation or breach of contract.

These options may not be a sustainable alternative to agency enforcement of the rules since they require expending significant resources and funds to protect evolving rights.

Added Complexity of State Laws Has Actors Feeling Overburdened

Some actors, and in particular health care providers such as clinical laboratories, are concerned that recently passed state laws contribute to the complexity of information blocking compliance.

Actors are particularly frustrated with having to shoulder the cost of navigating this increased complexity.

For example, the Kentucky Disclosure of Lab Results Act requires that certain clinical laboratory, pathology and radiology tests and reports not be disclosed to a patient for 72 hours after they are finalized, unless a health care provider otherwise directs the release.[3]

As the ONC has recently reiterated, practices that are required by law, including state law, are excluded from the definition of information blocking under the rules.[4]

As such, actors within the scope of this Kentucky law must defer to its restrictions on the release of tests and reports.

In addition, California enacted its own information blocking law in 2021, the California Data Exchange Framework, which imposes additional obligations on certain actors in California.[5] Health care providers and other actors must monitor for other applicable federal, state and tribal laws that could change or add to their information blocking obligations.

The ONC Proposes Limited and Impactful Updates to the Rules

On April 18, the ONC published a proposed rule that would, among other things, make limited changes to the rules, including clarifying a portion of the definition of a developer actor, revising the infeasibility exception, and updating the content and manner exception to include a Trusted Exchange Framework and Common Agreement, or TEFCA, condition.

First, with regard to the definition of a developer actor, the ONC proposed to define what it means to "offer health IT" to further clarify and limit the definition in response to industry stakeholder concerns regarding the apparent breadth of the definition.

In particular, the definition outlined would carve out the provision of funding for obtaining or maintaining certified health IT and codify that the ONC does not interpret health care providers or other health IT users to offer health IT "when they engage in certain activities customary and common among both health care providers that purchase certified health IT from a commercial developer or reseller and health care providers that self-develop certified health IT," such as implementing application programming interface or portals for clinician or patient access.[6]

Significantly, the ONC also proposed to exclude from offering health IT the inclusion of health IT in a comprehensive package of services for administrative or operational management of a health care practice or provider offered by a management consultant.

This addition would exclude management and administrative services agreements from offering health IT, which often include the provision of health IT.

Second, the ONC proposed to revise the infeasibility exception by adding two new conditions and revising one existing condition.

The first new condition would permit an actor to deny a third party's request to enable use of electronic health information to modify EHI — e.g., creation and deletion functionality — provided the request is not from a health care provider requesting such use from an actor that is a business associate.

The second new condition would apply where an actor has exhausted the manner exception, and the actor does not currently provide a substantial number of individuals or entities similarly situated to the requestor with the same requested access, exchange or use of the requested EHI.

Further, the ONC proposed to revise the "uncontrollable events" condition to clarify that an actor must demonstrate a causal connection between the actor's inability to fulfill the request and the uncontrollable event.

Third, the ONC proposed to add a TEFCA condition to the manner exception to support and promote national health care interoperability via TEFCA means of exchange.

This new condition would — subject to a certain enumerated conditions — allow an actor that is a "Qualified Health Information Network," "Participant" or "Subparticipant" to prioritize the use of TEFCA mechanisms of exchange, even where alternative mechanisms, i.e., alternative manners, are available for sharing EHI with requestors who have also chosen to become a part of the TEFCA ecosystem.

Enforcement Rules Are Coming

The 21st Century Cures Act empowered the OIG to investigate all actors for alleged violations of the rules and directly enforce against developer actors and health information networks and health information exchanges, and the appropriate agency to enforce against health care providers with appropriate disincentives to be defined by HHS.

While the Cures Act does not specify whether enforcement should be only prospective from the date of the final enforcement rules, the OIG has proposed to delay enforcement until 60 days after its final enforcement rule is published.

The OIG's Proposed Enforcement Rule

HHS OIG published a proposed enforcement rule in April 2020.[7]

Under that rule, the OIG proposed a maximum penalty per violation of the rules not to exceed $1 million. The OIG further proposed to define a "violation" as each practice that constitutes information blocking.

When imposing a civil monetary penalty against an individual or entity for committing information blocking, the OIG would need to consider the nature and extent of the information blocking and harm resulting from such information blocking, including, where applicable, the number of patients affected, the number of providers affected, and the number of days the information blocking persisted

Regarding the effective date for enforcement, the OIG proposed to exercise its enforcement discretion by delaying enforcement until 60 days after its final rule is published. Although the OIG included this enforcement timeline in its proposal, it could change course given ongoing anti-competitive conduct in the market that may indicate a clear disregard for the rules during the pendency of the enforcement rules.

The OIG has yet to publish a final rule, however, the U.S. Office of Information and Regulatory Affairs completed its regulatory review of the final rule on June 2,[8] so the final rule may be published soon.

Appropriate Disincentives Yet To Be Determined by HHS and the ONC

The Cures Act empowered HHS to set forth appropriate disincentives for health care providers using existing authorities under applicable federal law.

HHS and the ONC have yet to define appropriate disincentives for health care providers and, in its press release[9] for the April proposed rule that would modify the rules, HHS reiterated that this enforcement rule is still in the works.

While HHS and the ONC have not yet indicated what appropriate disincentives may include, enforcement under other programs may provide some insight. Based on existing authorities, such disincentives reasonably could include civil fines and suspension, termination or exclusion from participation in federal health care programs.

Industry Stakeholders Will Have To Wait and See What the Final Enforcement Rules Include

Although the ONC's proposed rule provides some relief to actors under certain exceptions to the rules, industry stakeholders will have to wait for the final enforcement rules for direct regulatory recourse against anti-competitive and other conduct that violates the rules.

It remains to be seen whether the enforcement rules will come this year, particularly for health care providers.

The OIG has yet to publish its final rule, but as noted, the final rule may be published soon now that the U.S. Office of Information and Regulatory Affairs has completed its regulatory review.

The proposed rule for appropriate disincentives is currently slated to be published in September, based on the 2022 fall regulatory agenda.[10]

Sara Shanti and Paul Werner are partners, and CJ Rundell is an associate, at Sheppard Mullin Richter & Hampton LLP.

[1] 88 Fed. Reg. 23746 (Apr. 18, 2023).

[2] 45 C.F.R. Part 171.

[3] See KY Rev. Stat. § 333.152.

[4] https://www.healthit.gov/buzz-blog/information-blocking/information-blocking-regulations-work-in-concert-with-hipaa-rules-and-other-privacy-laws-to-support-health-information-privacy.

[5] https://www.cdii.ca.gov/committees-and-advisory-groups/data-exchange-framework/.

[6] 88 Fed. Reg. at 23754.

[7] 85 Fed. Reg. 22979 (Apr. 24, 2020).

[8] https://www.reginfo.gov/public/do/eoDetails?rrid=309561.

[9] https://www.hhs.gov/about/news/2023/04/11/hhs-propose-new-rule-to-further-implement-the-21st-century-cures-act.html.

[10] https://www.hhs.gov/about/news/2023/04/11/hhs-propose-new-rule-to-further-implement-the-21st-century-cures-act.html.