



## Overview of Three Types of Actors Eligible for Penalties Under Information Blocking Final Rule

### I. Overview

The [21<sup>st</sup> Century Cures Act \(Cures Act\)](#) was signed into law on Dec. 13, 2016. Included within the law are provisions related to “information blocking” contained within Section 3022. The law outlines the four types of actors for whom information blocking provisions are applicable and for whom enforcement actions by the Secretary for Health and Human Services and the Office of the Inspector General (OIG) apply: 1) Providers; 2) Health IT Developers; 3) Health Information Networks (HINs); and 4) Health Information Exchanges (HIEs). The definitions for each actor, established by the Office of the National Coordinator for Health Information Technology (ONC), are detailed below.

Healthcare providers, health IT developers of certified health IT, health information exchanges and health information networks must be in compliance with information blocking requirements as it relates to the sharing of electronic health information data (EHI) data starting Nov. 2, 2020.

In the final rule, [“21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program,”](#) published by ONC on May 1, 2020, the agency details eight information blocking exceptions. OIG also released a proposed rule, [“Grants, Contracts, and Other Agreements: Fraud and Abuse; Information Blocking; Office of Inspector General’s Civil Money Penalty Rules,”](#) on April 24, 2020 detailing the enforcement of information blocking for health IT developers, HINs and HIEs. The Department of Health and Human Services (HHS) has not yet issued enforcement policies for providers.

### II. **Key Points for Actors Considered “Healthcare Providers”**

- ✓ Healthcare providers who have HIEs/HINs are considered healthcare providers for the purpose of information blocking compliance. All actors with the exception of providers may be subject to civil monetary penalty (CMP) fines of up to \$1 million per information blocking violation.
- ✓ Definition of healthcare provider is expansive and exceeds those required to comply with Promoting Interoperability programs.
- ✓ Provider enforcement will begin no sooner than Nov. 2, 2020. While penalties for providers have not yet been laid out, it’s possible enforcement could be retroactive to the aforementioned date. Despite this deadline, vendors are not required to have certified products capable of an EHI export until Nov. 1, 2023. See our [cheat sheet](#) on compliance deadlines.
- ✓ Providers whose certified systems are not capable of handling export of all necessary EHI will be required to rely upon other systems to perform the needed export.
- ✓ Information blocking exception #6, the Content and Manner Exception, provides flexibilities for providers who may be incapable of exporting EHI. For more details, [go here](#).



**III. Definition of EHI**

Electronic health information is a new definition created in the 21<sup>st</sup> Century Cures Act, however lawmakers did not define it in statute. Rather, ONC crafted a definition. Although the definition initially proposed by ONC was overly broad, the agency narrowed it considerably to mean:

- 6-24 months (lasting through April 30, 2022) following publication of the final rule, EHI is defined as data elements in the U.S. Core Data for Interoperability (USCDI).
- Following 24 months (starting May 2, 2022), the definition changes to electronic protected health information (ePHI) as contained in a designated record set and as defined under 45 CFR 164.501.

**IV. Details on Three Types of Actors**

“Actor”	Definition in ONC Final Rule	Changes from Proposed Rule	Penalties	Notes and Clarifications in Final Rule
<b>Provider</b>	Page 25794 <ul style="list-style-type: none"> <li>• The term “healthcare provider” is defined in section 3000(3) of the Public Health Services Act (PHSA).</li> <li>• ONC adopts the definition at 3000(3) for purposes of the definition of healthcare provider for the information blocking section of the PHSA (Sec. 3022). This</li> </ul>	<ul style="list-style-type: none"> <li>• No changes from proposed rule.</li> <li>• ONC did not grant requested “exclusions” or “phase-in” for certain entities such as providers who were not eligible for</li> </ul>	<a href="#">21<sup>st</sup> Century Cures Act</a> , Page 146, Section 4004 <ul style="list-style-type: none"> <li>• “(2) PENALTIES (B) PROVIDERS.—Any individual or entity described ... determined by the Inspector General to have committed</li> </ul>	<ul style="list-style-type: none"> <li>• The Secretary has discretionary authority to expand the definition to any other category of providers determined appropriate.</li> <li>• ONC says they will consider expanding the</li> </ul>



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	<p>definition is different from the definition of “healthcare provider” under the Health Insurance Portability and Accountability Act (HIPAA) Privacy and Security Rules.</p> <p>The PHSA definition is:</p> <p><b>(3) HEALTHCARE PROVIDER.</b>—The term ‘healthcare provider’ includes a hospital, skilled nursing facility, nursing facility, home health entity or other long-term care facility, healthcare clinic, community mental health center (as defined in section 1913(b)(1)), renal dialysis facility, blood center, ambulatory surgical center described in section 1833(i) of the Social Security Act, emergency medical services provider, federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1861(r) of the Social Security Act), a practitioner (as described in section 1842(b)(18)(C) of the Social Security Act), a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe (as defined in the Indian Self-</p>	<p>HITECH monies and thus may not have certified EHRs.</p>	<p>information blocking shall be referred to the appropriate agency to be <u>subject to appropriate disincentives</u> using authorities under applicable federal law, as the Secretary sets forth through notice and comment rulemaking.</p> <ul style="list-style-type: none"> <li>As noted above, HHS has not yet issued enforcement policies for providers.</li> <li>At a minimum, the timeframe for enforcement would not begin sooner than the compliance date of the information blocking provision (Nov. 2, 2020) and will</li> </ul>	<p>definition in the future if the scope of healthcare providers subject to the information blocking provision does not appear to be broad enough in practice to ensure the provision applies to all healthcare providers that might engage in information blocking.</p> <ul style="list-style-type: none"> <li>ONC stated a “phase-in” approach for providers was unnecessary, citing how they have defined EHI.</li> <li>Nov. 2, 2020 through May 1, 2022 EHI will be limited to EHI identified in the <a href="#">USCDI standard</a> adopted in §170.213</li> </ul>



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	<p>Determination and Education Assistance Act), tribal organization, or urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act), a rural health clinic, a covered entity under section 340B, an ambulatory surgical center described in section 1833(i) of the Social Security Act, a therapist (as defined in section 1848(k)(3)(B)(iii) of the Social Security Act), and any other category of healthcare facility, entity, practitioner or clinician determined appropriate by the Secretary.</p> <p>Medical device manufacturers and community-based organizations generally would not meet the healthcare provider definition unless they are also a type of individual or entity identified in the definition.</p>		<p>depend on when the OIG civil monetary penalties (CMP) rules are final.</p> <ul style="list-style-type: none"> <li>An actor will not be subject to enforcement actions under the information blocking provision for CMP or appropriate disincentives if the actor’s practice satisfies at least one exception.</li> </ul>	<ul style="list-style-type: none"> <li>And, they rationalize that the information blocking “Content and Manner Exception” allows actors to make available a limited set of EHI (the USCDI) during the first 18 months after the 6-month delayed compliance date for part 171 (24 months after publication of the rule);</li> <li>The newly structured “Infeasibility Exception” addresses limited resources or limited access to health IT among actors (§ 171.204)</li> </ul>



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<b>Health IT Developers of Certified Health IT<sup>1</sup></b>	<p>Page 25795</p> <ul style="list-style-type: none"> <li>An individual or entity that develops or offers one or more Health IT Modules certified under the voluntary ONC Health IT certification program. ONC relies on the specific authority provided to OIG in section 3022(b)(1)(A) and (b)(2) to finalize this definition. The definition does not include a healthcare provider that self-develops health IT for its own use.</li> <li>Such individuals or entities could be subject to information blocking investigations based on actions they take that are likely to interfere with the access, exchange or use of EHI, including:</li> </ul>	<ul style="list-style-type: none"> <li>The definition was finalized largely as proposed but with minor modifications:               <ul style="list-style-type: none"> <li>ONC added “other than a healthcare provider that self-develops health IT for its own use;”</li> <li>Replaced the proposed phrasing “health information technology (one or more) certified” with “one or more Health IT</li> </ul> </li> </ul>	<p><u>21<sup>st</sup> Century Cures Act</u>, Sec. 4004 – page 146</p> <ul style="list-style-type: none"> <li>“(2) PENALTIES (A) DEVELOPERS, NETWORKS, AND EXCHANGES.— Following an investigation, the entity could be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which <u>may not exceed \$1 million per violation.</u> Such determination shall take into account factors such as the</li> </ul>	<ul style="list-style-type: none"> <li>ONC noted that in the market for certified HIT Modules, many of the customers of HIT developers or offerors are HIPAA-covered entities or HIPAA business associates (BAs). Because a contract for HIT products or services, and any associated BA agreements, could extend beyond a developer or offeror’s departure from the ONC HIT Certification Program, ONC believes such contracts and agreements can protect customers</li> </ul>

<sup>1</sup> **NOTE:** There is a “drafting discrepancy” in the Cures Act. While the law outlines the four types of actors, the section of the law that details the penalties for information blocking lists “health information technology developer of certified health information technology” as opposed to simply “health IT developers.” ONC has interpreted this to mean that the OIG only has enforcement authority to pursue charges of information blocking for developers with at least one product that has been certified by ONC. All other health IT developers would NOT be subject to possible penalties under the final rule.



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	<ul style="list-style-type: none"> <li>○ Practices associated with any of the developer or offeror’s health IT products that <u>are certified</u> under the program; and</li> <li>○ Practices associated with any of the developer or offeror’s health IT products that <u>are not certified</u> under the program.</li> <li>● ONC retained reference to the time at which the individual or entity that develops or offers certified health IT engages in a practice that is the subject of an information blocking claim to ensure understanding that a claim can be brought even if the developer no longer has certified HIT.</li> <li>● A developer or offeror of a single certified health IT product that has had its certification suspended will still be considered to have certified health IT.</li> </ul>	<p>Modules certified;”</p> <ul style="list-style-type: none"> <li>● Replaced “under the ONC Health IT Certification Program” with the finalized “under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj-11(c)(5) (ONC Health IT Certification Program).”</li> <li>● ONC considered but did <u>not</u> extend the definition of “health IT developer of</li> </ul>	<p>nature and extent of the information blocking and harm resulting from such information blocking.</p>	<p>against a HIT developer or offeror who has left the program refusing to relinquish EHI.</p>



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		<p>certified health IT” beyond the date on which a developer or offeror no longer has any health IT certified under the program.</p>		
<p><b>Health information network (HIN) and Health information exchange (HIE)</b></p>	<p>Page 25800</p> <ul style="list-style-type: none"> <li>The final rule combines the definitions of HIN and HIE to create one definition that applies to both statutory terms. The combined definition focuses on the functional activity of the individual or entity and not on title or classification of the person or entity.</li> <li>Specifically, a HIN or HIE means an individual or entity that determines, controls or has the discretion to administer any requirement, policy or agreement that permits, enables or requires the use of any technology or services for access, exchange or use of EHI:</li> </ul>	<ul style="list-style-type: none"> <li>ONC combined the definitions of HIN and HIE to create one functional definition that applies to both statutory terms in order to clarify the types of individuals and entities that would be covered.</li> <li>ONC also narrowed the definition in the following ways: <ul style="list-style-type: none"> <li>Removed the “substantially influences”</li> </ul> </li> </ul>	<p>Sec. 4004 – page 146 “(2) PENALTIES (A) DEVELOPERS, NETWORKS, AND EXCHANGES—</p> <ul style="list-style-type: none"> <li>Following an investigation, the entity could be subject to a civil monetary penalty determined by the Secretary for all such violations identified through such investigation, which <u>may not exceed \$1 million per violation.</u></li> </ul>	<ul style="list-style-type: none"> <li>The HIN/HIE definition is only applicable to the circumstances of an information blocking claim.</li> <li>ONC says this about providers who have an HIE/HIN, “a healthcare provider that may have ownership of a HIN/HIE, would not be considered a HIN/HIE, but instead a ‘health care provider’ with respect to situations that involve their behavior as a healthcare provider,</li> </ul>



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	<p>1) Among more than two unaffiliated individuals or entities (other than the individual or entity to which this definition might apply) that are enabled to exchange with each other; and</p> <p>2) That is for a treatment, payment, or healthcare operations purpose, as such terms are defined in 45 CFR 164.501 regardless of whether such individuals or entities are subject to the requirements of 45 CFR parts 160 and 164 (§ 171.102).</p>	<p>policies, technology, or services of a network element of HIN;</p> <ul style="list-style-type: none"> <li>○ Revised the definition to specify that to be a HIN or HIE there must be exchange among more than two unaffiliated individuals or entities besides the HIN/HIE that are enabled to exchange with each other;</li> <li>● Focused the definition on three activities: treatment, payment and</li> </ul>		<p>such as denying another healthcare provider’s ability to access, exchange or use EHI for treatment purposes or denying an individual’s access to their EHI via the healthcare provider’s patient portal.”</p> <ul style="list-style-type: none"> <li>● ONC clarifies that the reference to the three types of activities does not limit the application of the HIN/HIE definition to individuals or entities that are covered entities CEs or business associates (as defined in HIPAA); and the three activities serve as elements of the definition such that if an individual or entity meets them, then the</li> </ul>



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		healthcare operations, as each are defined in the HIPAA Rules.		individual or entity would be considered a HIN/HIE under the information blocking regulations for any practice they conducted while functioning as a HIN/HIE.