



Overview of Four Types of Actors Eligible for Penalties Under Information Blocking Proposed Rule

I. Overview

The [21st Century Cures Act \(Cures Act\)](#) was signed into law on December 13, 2016. Among the many health IT-related provisions it contains is one related to “Information Blocking” in Section 3022. The law lays out four types of actors for whom information blocking provisions and enforcement by 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 as established in statute and the proposed rule are detailed below. Please see our [cheat sheet](#) on the seven information blocking exceptions listed in Cures and detailed in the ONC [proposed rule, “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program”](#) published on March 3rd. Listed page number below refer to the proposed rule.



II. Details on Four Types of Actors

“Actor”	Definition in ONC Rule	Cures Provision	Penalty/Structure	Notes
Provider	<p>Page 332</p> <ul style="list-style-type: none"> The term “health care provider” is defined in section 3000(3) of the PHSa. The PHSa definition is: (3) HEALTH CARE PROVIDER.—The term ‘health care provider’ includes a hospital, skilled nursing facility, nursing facility, home health entity or other long term care facility, health care 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-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 health care facility, entity, practitioner, or clinician determined appropriate by the Secretary. ONC proposes to adopt this definition for purposes of section 3022 of the PHSa when defining “health care provider” in § 171.102. ONC noted this definition is different from the definition of “health care provider” under the HIPAA Privacy and Security Rules. 	Not defined in CURES	Page 146 Section 4004 “(2) PENALTIES (B) PROVIDERS.— Any individual or entity described ... determined by the Inspector General to have committed 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.	HHS previously committed to not issue regulations around provider penalties until the Department issued the information blocking rule



<p>Health IT Developers¹</p>	<p>Page 332</p> <ul style="list-style-type: none"> • An individual or entity that develops or offers certified health IT. • 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: <ul style="list-style-type: none"> ○ Practices associated with any of the developer or offeror’s health IT products that <u>are certified</u> under the Program; and ○ Practices associated with any of the developer or offeror’s health IT products that <u>are not certified</u> under the Program. 	<p>Not defined in CURES</p>	<p>Sec. 4004 – page 146 “(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 nature and extent of the information blocking and harm resulting from such information blocking.</p>	<p>Page 335 of the ONC Rule: We are also considering additional approaches to help ensure that developers and offerors of certified health IT remain subject to the information blocking provision for an appropriate period of time after leaving the Program. The rationale for this approach would be that a developer or offeror of certified health IT should be subject to penalties if, following the termination or withdrawal of certification, it refused to provide its customers with access to the EHI stored in the decertified health IT, provided that such interference was not required by law and did not qualify for one of the information blocking exceptions.</p>
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¹ **NOTE:** There is a “drafting discrepancy” in the Cures Act. While the law outlines the four types of actors, under 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 Office of the Inspector General (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 rule as proposed.



<p>Health information network</p>	<p>Page 340</p> <ul style="list-style-type: none"> • ONC proposes a functional definition of “health information network” (HIN) that focuses on the role of these actors in the health information ecosystem. • ONC states the defining attribute of a HIN is that it enables, facilitates, or controls the movement of information between or among different individuals or entities that are unaffiliated. • ONC proposes that two parties are affiliated if one has the power to control the other, or if both parties are under the common control or ownership of a common owner. • The proposed definition would also encompass an individual or entity that does not directly enable, facilitate, or control the movement of information, but nonetheless exercises control or substantial influence over the policies, technology, or services of a network. 	<p>Not defined in CURES</p>	<p>t Sec. 4004 – page 146 “(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></p>	
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<p>Health Information Exchange (HIE)</p>	<p>Page 343</p> <ul style="list-style-type: none"> • ONC proposes to define a “health information exchange” (HIE) as an individual or entity that enables access, exchange, or use of EHI primarily between or among a particular class of individuals or entities or for a limited set of purposes. • HIEs include but are not limited to regional health information organizations (RHIOs), state health information exchanges (state HIEs), and other types of organizations, entities, or arrangements that enable EHI to be accessed, exchanged, or used between or among particular types of parties or for particular purposes. • HIEs may be established under federal or state laws or regulations but may also be established for specific health care or business purposes or use cases. • If an HIE facilitates the access, exchange, or use of EHI for more than a narrowly defined set of purposes, then it may be both an HIE and a HIN. 	<p>Not defined in CURES</p>	<p>Sec. 4004 – page 146 “(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 nature and extent of the information blocking and harm resulting from such information blocking.</p>	
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