



The Office of the National Coordinator for
Health Information Technology

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Proposed Rule

Information Blocking (IB) – HITAC IB Task Force

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- Please submit comments through the formal process outlined in the Federal Register.

Roadmap

VIII. Information Blocking

A. *Background*

B. *Relevant Statutory Terms and Provisions*

C. *Proposed Exceptions to the Information Blocking Provision*

171.204 Recovering Costs Reasonably Incurred

171.206 Licensing of Interoperability Elements on Reasonable and
Non-discriminatory (RAND) Terms

Report to Congress

HHS FY 2015 Appropriations Act

- *Congress states “ONC should use its authority to certify only those products that...do not block health information exchange. ONC should take steps to decertify products that proactively block the sharing of information because those practices frustrate congressional intent, devalue taxpayer investments in CEHRT, and make CEHRT less valuable and more burdensome for eligible hospitals and eligible providers to use.”*
- *Congress requests a detailed report from ONC regarding the extent of the information blocking problem, including an estimate of the number of vendors or eligible hospitals or providers who block information. This detailed report should also include a comprehensive strategy on how to address the information blocking issue.*

ONC Report to Congress - Defining Information Blocking

Report Definition and Criteria

Information blocking occurs when persons or entities knowingly and unreasonably interfere with the exchange or use of electronic health information.

This definition requires three criteria be met:

- 1. Interference.** Information blocking requires some act or course of conduct that **interferes** with the ability of authorized persons or entities to access, exchange, or use electronic health information. This interference can take many forms, from express policies that prohibit sharing information to more subtle business, technical, or organizational practices that make doing so more costly or difficult.
- 2. Knowledge.** The decision to engage in information blocking must be made **knowingly**. An individual or entity does not engage in information blocking unless it knows (or should know under the circumstances) that its conduct is likely to interfere with the exchange or use of electronic health information.
- 3. No Reasonable Justification.** Not all conduct that knowingly interferes with electronic health information exchange is information blocking. Accusations of information blocking are serious and should be reserved for conduct that is objectively **unreasonable** in light of public policy. Conduct that is required to comply with federal or state privacy law would not be “unreasonable” and would not constitute information blocking under these criteria. Public policy must be balanced to advance important interests, including furthering the availability of electronic health information as needed for authorized and important purposes; protecting and promoting patient safety; maintaining the privacy and security of electronic health information; and protecting the legitimate economic interests and incentives of providers, developers, and other market participants to innovate and compete in ways that ultimately enhance technology, health care, and consumer health and welfare.

Interference?

Knowing?

Unreasonable?

INFORMATION BLOCKING

Information Blocking in the 21st Century Cures Act

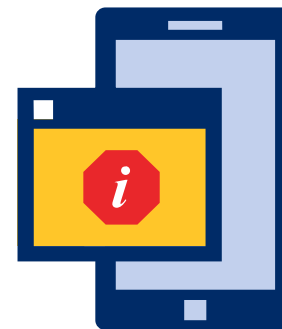
- **21st Century Cures Act, Section 4004:**
 - » Defines “information blocking” (§ 3022(a)(1), PHSA).
 - » Authorizes the Secretary to identify, through rulemaking, reasonable and necessary activities that do not constitute information blocking (§ 3022(a)(3), PHSA).
 - » Empowers the HHS Office of Inspector General (OIG) to investigate claims of information blocking (§ 3022(b)(1), PHSA) and provides referral processes to facilitate coordination with the HHS Office for Civil Rights (OCR) (§ 3022(b)(3)(A), PHSA).
 - » Prescribes penalties for information blocking (§ 3022(b)(2), PHSA).
 - » Charges ONC with implementing a complaint process for reporting information blocking, and provides confidentiality protections for complaints (§ 3022(d)(2) and (3), PHSA).



What Makes You an Information Blocker?

- **Information blocking definition**

A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.



- **Elements of information blocking**

- Actor regulated by the information blocking provision
- Involves electronic health information (EHI)
- Practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI
- Requisite knowledge by the actor
- Not required by law
- Not covered by an exception

Consequences of Being an Information Blocker

- **Cures Act prescribes penalties for information blocking (§ 3022(b)(2), PHSA)**
 - » Health IT developers of certified health IT (or other entity offering certified health IT), health information networks, and health information exchanges → Civil monetary penalties up to \$1 million per violation
 - » Health care providers → Appropriate disincentives
- **ONC proposes a certification ban (§ 170.581) under the ONC Health IT Certification Program for health IT developers**
 - » “Information Blocking” Condition of Certification (proposed § 170.401)
 - » Public listing of certification bans and terminations
- **CMS proposes public reporting of clinicians and hospitals who submit a “no” response to attestation statements related to information blocking**



"Actors" Regulated by the Information Blocking Provision

**Health Care
Providers**

**Health IT Developers
of Certified Health IT**



**Health Information
Networks (HIN)**

**Health Information
Exchanges (HIE)**

Health Care Providers

Who are they?

- a hospital
- skilled nursing facility
- nursing facility
- home health entity or other long term care facility
- health care clinic
- community mental health center
- renal dialysis facility
- blood center
- ambulatory surgical
- emergency medical services provider
- federally qualified health center
- group practice
- a pharmacist
- a pharmacy
- a laboratory
- a physician
- a practitioner
- a provider operated by, or under contract with, the Indian Health Service or by an Indian tribe, tribal organization, or urban Indian organization
- a rural health clinic
- a “covered entity” under certain statutory provisions
- an ambulatory surgical center
- a therapist
- any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary

Clarification/Request for Comment

We are considering adjusting the information blocking definition of “health care provider” to cover all individuals and entities covered by the HIPAA “health care provider” definition.

Health IT Developer of Certified Health IT

Who/What are they?

An individual or entity that develops or offers health information technology and which had, at the time it engaged in a practice that is the subject of an information blocking claim, health IT (one or more) certified under the Program.

Clarifications/Request for Comment

- The Cures Act does not prescribe that conduct that may implicate the information blocking provisions be limited to practices related to *only* certified health IT.
- The Cures Act does not impose a temporal nexus that would require that information blocking be carried out at a time when an individual or entity had health IT certified under the Program.
 - » We seek comment on methods to ensure that health IT developers of certified health IT will face consequences under the information blocking provision if they engage in information blocking in connection with EHI that was stored or controlled by the developer or offeror while they were participating in the Program.

Health Information Networks

Who/What are they?

An individual or entity that satisfies one or both of the following—

- Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.
- Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of EHI between or among two or more unaffiliated individuals or entities.

Clarifications and Examples

- 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.
- An entity is established within a state for the purpose of improving the movement of EHI between the health care providers operating in that state.
- A large health care provider (or other entity) functioning as a HIN.

Health Information Exchanges

Who/What are they?

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.

Examples and Clarifications

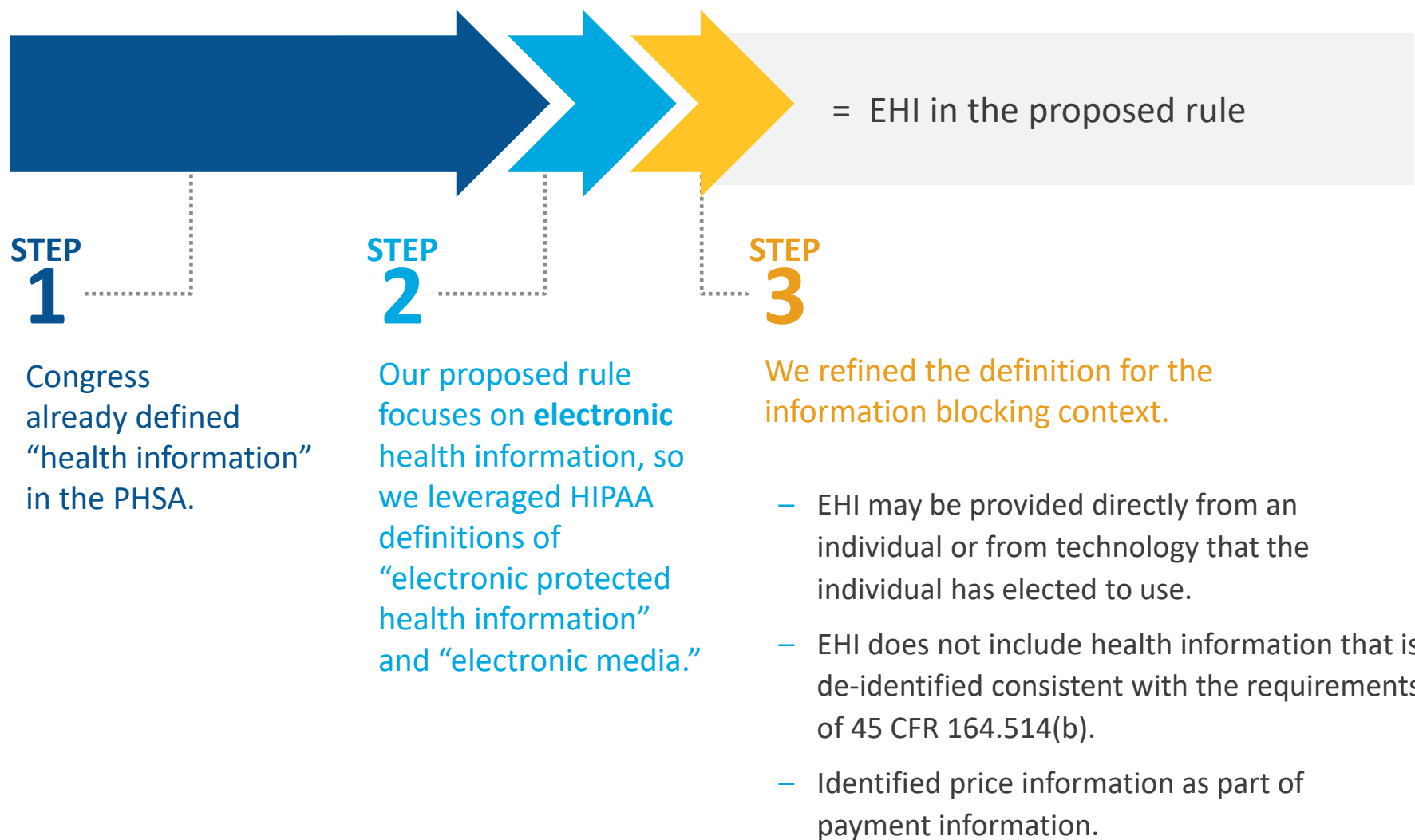
- HIEs include but are not limited to regional health information organizations (RHIOs), state health information exchanges (state HIEs), and other types of organizations, entities, or arrangements that enable EHI to be accessed, exchanged, or used between or among particular types of parties or for particular purposes.
- An HIE might facilitate or enable the access, exchange, or use of EHI for a limited scope of participants and purposes (such as a clinical data registry).
- 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.

Electronic Health Information



- We propose to define electronic health information (EHI) to mean electronic protected health information (as defined in HIPAA), and any other information that:
 - » is transmitted by or maintained in electronic media (as defined in 45 CFR 160.103);
 - » identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual; and
 - » relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

Electronic Health Information



Electronic Health Information

Observational Health Information

- “Observational health information” includes:
 - » Health information about a patient that could be captured in a patient record within an EHR and other clinical information management systems;
 - » Information maintained in administrative and other IT systems when the information is clinically relevant, directly supports patient care, or facilitates the delivery of health care services to consumers.
- Information blocking concerns are especially pronounced when conduct concerns EHI that is created or maintained during the practice of medicine or the delivery of health care services.

Additional information that could be considered EHI



- EHI that is created through aggregation, algorithms, and other techniques that transform observational health information into fundamentally new data or insights that are not obvious from the observational information alone. This could include, for example, population-level trends, predictive analytics, risk scores, and EHI used for comparisons and benchmarking activities.
- An individual’s health insurance eligibility and benefits.
- Billing for health care services.
- Payment information for services to be provided or already provided, which may include price information.

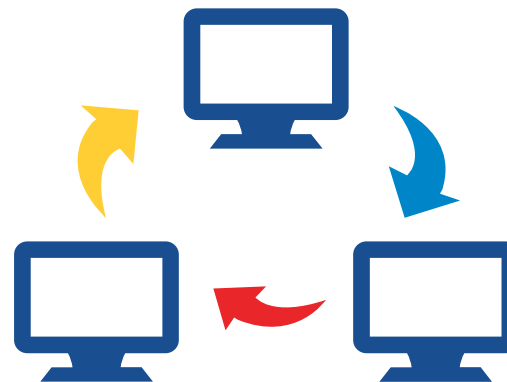
Price Information – Request for Comments and Information

- The fragmented and complex nature of pricing within the health care system has decreased the efficiency of the health care system and has had negative impacts on patients, health care providers, health systems, plans, plan sponsors and other key health care stakeholders.
- ONC has a unique role in setting the stage for such future actions by establishing the framework to prevent the blocking of price information.
 - » We seek comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking.
- Consistent with its statutory authority, the Department is considering subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors, and health care providers.
 - » The overall Department seeks comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care.



Interoperability Element

- We use the concept to analyze the likelihood of interference under the information blocking provision, and to structure some of the proposed exceptions.
- “Interoperability element” refers to any means by which EHI can be accessed, exchanged, or used.
 - » Includes functional elements, technical information, technologies, services, licenses, rights, privileges, and other conditions necessary to support the many potential uses of EHI.
- An actor who controls an interoperability element of health IT that could be used to access, exchange, or use EHI is at risk of violating the information blocking provision if the actor refuses to allow others to license or use that interoperability element on reasonable terms.
- This applies regardless of whether the person who requires use of the interoperability element might complement or compete with the actor’s own technology or services.



Interfere with Access, Exchange, or Use

“Interfere with, prevent, or materially discourage ”

- The terms “interfere with” and “interference” are used inclusive of prevention, material discouragement, and other forms of interference that implicate the information blocking provision.
- We interpret “interference” broadly and to take many forms.

“Access, exchange, or use”

- These concepts are closely related → EHI cannot be *used* unless it can be *accessed*, and this often requires that the EHI be *exchanged* among different individuals or entities and through various technological means.
- We propose to adopt interrelated definitions:
 - » “**Access**” means the ability or means necessary to make electronic health information available for use, including the ability to securely and efficiently locate and retrieve information from any and all source systems in which the information may be recorded or maintained.
 - » “**Exchange**” means the ability for EHI to be transmitted securely and efficiently between and among different technologies, systems, platforms, or networks in a manner that allows the information to be accessed and used.
 - » “**Use**” means the ability of health IT or a user of health IT to access relevant EHI; to comprehend the structure, content, and meaning of the information; and to read, write, modify, manipulate, or apply the information to accomplish a desired outcome or to achieve a desired purpose.



Practices That Implicate the Information Blocking Provision

OVERARCHING PRINCIPLE

To **implicate** the provision is not necessarily to **violate** it.

Practices that implicate the information blocking provision:

- » Imposing formal restrictions on access, exchange, or use of EHI
- » Imposing informal restrictions on access, exchange, or use of EHI
- » Disabling or restricting the use of a capability that enables users to share EHI with users of other systems
- » Implementing capabilities in ways that limit the timeliness of access, exchange, or use of EHI
- » Imposing terms or conditions on the use of interoperability elements that discourage their use
- » Discouraging efforts to develop or use interoperable technologies or services by exercising influence over customers, users, or other persons
- » Discriminatory practices that frustrate or discourage efforts to enable interoperability
- » Rent-seeking and opportunistic pricing practices
- » Implementing health IT in non-standard ways that substantially increase the complexity or burden of accessing, exchanging, or using EHI (for instance, not complying with section 3004 of the PHSA or consensus standards)

Knowledge Standard

Health Care Providers

“...**knows** that such practice is *unreasonable* and is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information...”
emphasis added.



Health IT Developers of Certified Health IT, HINs, and HIEs

“...**knows, or should know**, that such practice is likely to interfere with, prevent, or materially discourage the access, exchange or use of electronic health information...” emphasis added.



Required by Law

What does it means?

- It refers specifically to interferences with access, exchange, or use of EHI that are explicitly required by state or federal law.
- We have distinguished between interferences that are “required by law” and those engaged in pursuant to a privacy law, but which are not “required by law.”



Example – Privacy Practices Required by Law

- The HIPAA Privacy Rule requires that a covered entity must agree to the request of an individual to restrict disclosure of protected health information (PHI) about the individual to a health plan if the disclosure is for the purpose of carrying out payment or health care operations and not otherwise required by law and the PHI pertains solely to a health care item or service for which the individual, or person other than the health plan on behalf of the individual, has paid the covered entity in full. 45 CFR 164.522(a)(1)(vi).

Overview of Exceptions



- The seven categories of reasonable and necessary practices, and their corresponding conditions, are defined through the exceptions proposed at **45 CFR 171.201–207**.
- If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy one or more exception, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.

Proposed exceptions to the information blocking definition

- » **171.201** — Preventing harm
- » **171.202** — Promoting the privacy of EHI
- » **171.203** — Promoting the security of EHI
- » **171.204** — Recovering costs reasonably incurred
- » **171.205** — Responding to requests that are infeasible
- » **171.206** — Licensing of interoperability elements on reasonable and non-discriminatory terms
- » **171.207** — Maintaining and improving health IT performance

Exception: Recovering Costs Reasonably Incurred



OVERVIEW

Under the proposed exception, it will not be information blocking for an actor to recover its reasonable costs of enabling access, exchange, or use of EHI. The proposed exception does not prescribe the amount of fees that can be charged, but imposes conditions to ensure that an actor's method for recovering costs is reasonable and non-discriminatory.

To qualify for this exception, an actor must ensure that:

Its method for recovering costs complies with certain conditions

+

It is not seeking to recover costs that are specifically excluded

+

It complies with the Conditions of Certification at § 170.402(a)(4) or § 170.404, and the fee limitations imposed on health IT developers of certified health IT, if applicable

Objective



- Enable actors to recover the costs reasonably incurred to develop technologies and provide services that enhance interoperability, while not protecting rent-seeking, opportunistic fees, and exclusionary practices that interfere with access, exchange, or use of EHI.
- Would not prevent an actor from making a profit.

Exception: Recovering Costs Reasonably Incurred



Conditions Applicable to Cost Recovery Method

The method by which an actor recovers costs:

- ✔ **Must** be based on objective and verifiable criteria that are uniformly applied for all substantially similar or similarly situated classes of persons and requests;
- ✔ **Must** be reasonably related to the actor's costs of providing the type of access, exchange, or use to, or at the request of, the person to whom the fee is charged;
- ✔ **Must** be reasonably allocated among all customers to whom the technology is supplied, or for whom the technology is supported;
- ✘ **Must not** be based in any part on whether the requestor or other person is a competitor, potential competitor, or will be using the data in a way that facilitates competition with the actor; and
- ✘ **Must not** be based on the sales, profit, revenue, or other value that the requestor or other persons may derive from the access, exchange, or use EHI that exceeds the actor's reasonable costs for providing access, exchange, or use of EHI.

Exception: Recovering Costs Reasonably Incurred



Costs Specifically Excluded:

1. Costs that are incurred due to the health IT being designed or implemented in non-standard ways that unnecessarily increase the complexity, difficulty or burden of accessing, exchanging, or using EHI.
2. Costs associated with intangible assets (including depreciation or loss of value), other than the actual development or acquisition costs of such assets.
3. Opportunity costs, except for the reasonable forward-looking cost of capital.
4. A fee prohibited by 45 CFR 164.524(c)(4).
5. A fee based in any part on an individual's electronic access to their EHI.
6. A fee to perform an export of EHI via the capability of health IT certified to 45 CFR 170.315(b)(10) for the purposes of switching health IT or to provide patients with their EHI.
7. A fee to export or convert data from an EHR technology, unless such fee was agreed to in writing at the time the technology was acquired.

Exception: Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms



OVERVIEW

Under the proposed exception, it will not be information blocking for an actor to interfere with the access, exchange, or use of EHI by limiting access to an interoperability element, so long as the interoperability element is available for use by those that need it on reasonable and non-discriminatory (RAND) terms.

To qualify for this exception, an actor must demonstrate that it:

Timely responded to persons requesting to license or use an interoperability element

+

Offered an appropriate license with RAND terms

+

Met additional requirements relating to the provision of interoperability elements

+

Complied with relevant conditions of certification

Objective



- An actor that controls a functional element of health IT that could be used to access, exchange, or use EHI should make that interoperability element available to others that need it, but can impose RAND terms when doing so.
- Complying with this exception would not prevent an actor from making a profit.

Exception: Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms



Timely Response

Upon receiving a request to license or use interoperability elements, the actor must respond to the requestor within **10 business days** from receipt of the request by:

1. Negotiating with the requestor in a RAND fashion to identify the interoperability elements that are needed; and
2. Offering an appropriate license with RAND terms.

A RAND License:

- » Provides all rights necessary to access and use interoperability elements for the purpose of (as applicable):
 - Developing products or services that are interoperable with the actor's health IT, health IT under the actor's control, or any third party who currently uses the actor's interoperability elements to interoperate with such health IT;
 - Marketing, offering, and distributing interoperable products or services to potential customers and users; and
 - Enabling the use of interoperable products or services in production environments.
- » Imposes no more than a reasonable royalty for use of the interoperability elements.
- » Contains terms that are objective, verifiable, and uniformly applied, and are not based on whether the requestor is a competitor or the revenue the requestor may derive from the EHI obtained via the interoperability element.
- » Must not contain collateral terms that are anti-competitive.
- » Must not contain non-disclosure obligations that are broader than necessary to protect trade secrets.

Exception: Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms



Additional Requirements

To qualify for this exception, the actor must not engage in any practice that has any of the following purposes or effects:

- » Impeding the efficient use of the interoperability elements to access, exchange, or use EHI for any purpose for which a person is authorized, permitted, or required to access, exchange, or use the EHI under applicable law;
- » Impeding the efficient development, distribution, deployment, or use of an interoperable product or service for which there is actual or potential demand; or
- » Making changes to interoperability elements or health IT that “break” compatibility or otherwise degrade the performance of the licensee’s compatible technologies or services, unless the actor has afforded the licensee a reasonable opportunity to update its technologies or services to maintain interoperability.

Appendix

Health Care Provider Definition and Cross-Reference Table

Health Care Provider Definition

Public Health Service Act (42 U.S.C. 300jj)

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 300x–2(b)(1) of this title), renal dialysis facility, blood center, ambulatory surgical center described in section 1395l(i) of this title, emergency medical services provider, Federally qualified health center, group practice, a pharmacist, a pharmacy, a laboratory, a physician (as defined in section 1395x(r) of this title), a practitioner (as described in section 1395u(b)(18)(C) of this title), 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 [25 U.S.C. 450 et seq.]), tribal organization, or urban Indian organization (as defined in section 1603 of title 25), a rural health clinic, a covered entity under section 256b of this title, an ambulatory surgical center described in section 1395l(i) of this title, a therapist (as defined in section 1395w–4(k)(3)(B)(iii) of this title), and any other category of health care facility, entity, practitioner, or clinician determined appropriate by the Secretary.

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p style="text-align: center;">Community Mental Health Centers (as defined in 42 USC § 300x-2(b)(1))</p>	<p>(c) Criteria for mental health centers. The criteria referred to in subsection (b)(2) regarding community mental health centers are as follows:</p> <p>(1) With respect to mental health services, the centers provide services as follows:</p> <p>(A) Services principally to individuals residing in a defined geographic area (hereafter in this subsection referred to as a “service area”).</p> <p>(B) Outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of the service areas of the centers who have been discharged from inpatient treatment at a mental health facility.</p> <p>(C) 24-hour-a-day emergency care services.</p> <p>(D) Day treatment or other partial hospitalization services, or psychosocial rehabilitation services.</p> <p>(E) Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.</p> <p>(2) The mental health services of the centers are provided, within the limits of the capacities of the centers, to any individual residing or employed in the service area of the center regardless of ability to pay for such services.</p> <p>(3) The mental health services of the centers are available and accessible promptly, as appropriate and in a manner which preserves human dignity and assures continuity and high quality care.</p>
<p style="text-align: center;">Ambulatory Surgical Center (as defined in 42 USC § 296(9))</p>	<p>(9)The term “ambulatory surgical center” has the meaning applicable to such term under title XVIII of the Social Security Act [et seq.].</p>

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p>Physician (as defined in 42 USC § 1395x(r))</p>	<p>(r) Physician</p> <p>The term “physician”, when used in connection with the performance of any function or action, means (1) a doctor of medicine or osteopathy legally authorized to practice medicine and surgery by the State in which he performs such function or action (including a physician within the meaning of section 1301(a)(7) of this title (see below)), (2) a doctor of dental surgery or of dental medicine who is legally authorized to practice dentistry by the State in which he performs such function and who is acting within the scope of his license when he performs such functions, (3) a doctor of podiatric medicine for the purposes of subsections (k), (m), (p)(1), and (s) of this section and sections 1395f(a), 1395k(a)(2)(F)(ii), and 1395n of this title but only with respect to functions which he is legally authorized to perform as such by the State in which he performs them, (4) a doctor of optometry, but only for purposes of subsection (p)(1) and with respect to the provision of items or services described in subsection (s) which he is legally authorized to perform as a doctor of optometry by the State in which he performs them, or (5) a chiropractor who is licensed as such by the State (or in a State which does not license chiropractors as such, is legally authorized to perform the services of a chiropractor in the jurisdiction in which he performs such services), and who meets uniform minimum standards promulgated by the Secretary, but only for the purpose of subsections (s)(1) and (s)(2)(A) and only with respect to treatment by means of manual manipulation of the spine (to correct a subluxation) which he is legally authorized to perform by the State or jurisdiction in which such treatment is provided. For the purposes of section 1395y(a)(4) of this title and subject to the limitations and conditions provided in the previous sentence, such term includes a doctor of one of the arts, specified in such previous sentence, legally authorized to practice such art in the country in which the inpatient hospital services (referred to in such section 1395y(a)(4) of this title) are furnished.</p>
<p>Physician (as defined in 42 USC § 1301(a)(7))</p>	<p>(7) The terms “physician” and “medical care” and “hospitalization” include osteopathic practitioners or the services of osteopathic practitioners and hospitals within the scope of their practice as defined by State law.</p>

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p>Practitioner (as defined in 42 USC § 1395u(b)(18)(C))</p>	<p>(C) A practitioner described in this subparagraph is any of the following:</p> <ul style="list-style-type: none"> (i) A physician assistant, nurse practitioner, or clinical nurse specialist (as defined in section 1395x(aa)(5) of this title). (ii) A certified registered nurse anesthetist (as defined in section 1395x(bb)(2) of this title). (iii) A certified nurse-midwife (as defined in section 1395x(gg)(2) of this title). (iv) A clinical social worker (as defined in section 1395x(hh)(1) of this title). (v) A clinical psychologist (as defined by the Secretary for purposes of section 1395x(ii) of this title). (vi) A registered dietitian or nutrition professional.
<p>Clinical Nurse Specialist (as defined in 42 USC § 1395x(aa)(5))</p>	<p>(B) The term “clinical nurse specialist” means, for purposes of this subchapter, an individual who—</p> <ul style="list-style-type: none"> (i) is a registered nurse and is licensed to practice nursing in the State in which the clinical nurse specialist services are performed; and (ii) holds a master’s degree in a defined clinical area of nursing from an accredited educational institution.
<p>Certified Nurse Anesthetist (as defined in 42 USC § 1395x(bb)(2))</p>	<p>(2) The term “certified registered nurse anesthetist” means a certified registered nurse anesthetist licensed by the State who meets such education, training, and other requirements relating to anesthesia services and related care as the Secretary may prescribe. In prescribing such requirements the Secretary may use the same requirements as those established by a national organization for the certification of nurse anesthetists. Such term also includes, as prescribed by the Secretary, an anesthesiologist assistant.</p>
<p>Certified Nurse-midwife (as defined in 42 USC § 1395x(gg)(2))</p>	<p>(2) The term “certified nurse-midwife” means a registered nurse who has successfully completed a program of study and clinical experience meeting guidelines prescribed by the Secretary, or has been certified by an organization recognized by the Secretary.</p>

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p>Clinical Social Worker (as defined in 42 USC § 1395x(hh)(1))</p>	<p>(hh) Clinical social worker; clinical social worker services</p> <p>(1) The term “clinical social worker” means an individual who—</p> <p>(A) possesses a master’s or doctor’s degree in social work;</p> <p>(B) after obtaining such degree has performed at least 2 years of supervised clinical social work; and</p> <p>(C) (i) is licensed or certified as a clinical social worker by the State in which the services are performed, or (ii) in the case of an individual in a State which does not provide for licensure or certification—</p> <p>(I) has completed at least 2 years or 3,000 hours of post-master’s degree supervised clinical social work practice under the supervision of a master’s level social worker in an appropriate setting (as determined by the Secretary), and</p> <p>(II) meets such other criteria as the Secretary establishes</p>
<p>Clinical Psychologist (as defined in 42 CFR § 410.71)</p>	<p>d) Qualifications. For purposes of this subpart, a clinical psychologist is an individual who -</p> <p>(1) Holds a doctoral degree in psychology; and</p> <p>(2) Is licensed or certified, on the basis of the doctoral degree in psychology, by the State in which he or she practices, at the independent practice level of psychology to furnish diagnostic, assessment, preventive, and therapeutic services directly to individuals.</p>
<p>Indian Tribe (as defined in 42 USC § 300f(14))</p>	<p>(14) The term “Indian Tribe” means any Indian tribe having a Federally recognized governing body carrying out substantial governmental duties and powers over any area. For purposes of sections 300j–12, 300j–19a, and 300j–19b of this title, the term includes any Native village (as defined in section 1602(c) of title 43).</p>

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p>Urban Indian Organization (as defined in 25 USC § 1603)</p>	<p>29) Urban Indian organization</p> <p>The term “Urban Indian organization” means a nonprofit corporate body situated in an urban center, governed by an urban Indian controlled board of directors, and providing for the maximum participation of all interested Indian groups and individuals, which body is capable of legally cooperating with other public and private entities for the purpose of performing the activities described in section 1653(a) of this title.</p>
<p>Covered Entity (as defined in 42 USC §256b)</p>	<p>(4) “Covered entity” defined In this section, the term “covered entity” means an entity that meets the requirements described in paragraph (5) and is one of the following:</p> <p>(A) A Federally-qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act [42 U.S.C. 1396d(l)(2)(B)]).</p> <p>(B) An entity receiving a grant under section 256a [1] of this title. (for the development and operation of demonstration programs to provide patient navigator services to improve health care outcomes)</p> <p>(C) A family planning project receiving a grant or contract under section 300 of this title.</p> <p>(D) An entity receiving a grant under subpart II 1 of part C of subchapter XXIV (relating to categorical grants for outpatient early intervention services for HIV disease).</p> <p>(E) A State-operated AIDS drug purchasing assistance program receiving financial assistance under subchapter XXIV.</p> <p>(F) A black lung clinic receiving funds under section 937(a) of title 30.</p> <p>(G) A comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act [42 U.S.C. 701(a)(2)].</p> <p>(H) A Native Hawaiian Health Center receiving funds under the Native Hawaiian Health Care Act of 1988.</p> <p>(I) An urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act [25 U.S.C. 1651 et seq.].</p>

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p>Covered Entity (as defined in 42 USC §256b)</p>	<p>(J) Any entity receiving assistance under subchapter XXIV (HIV Health Care Services Program) (other than a State or unit of local government or an entity described in subparagraph (D)), but only if the entity is certified by the Secretary pursuant to paragraph (7).</p> <p>(K) An entity receiving funds under section 247c of this title (relating to treatment of sexually transmitted diseases) or section 247b(j)(2) 1 of this title (relating to treatment of tuberculosis) through a State or unit of local government, but only if the entity is certified by the Secretary pursuant to paragraph (7).</p> <p>(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act [42 U.S.C. 1395ww(d)(1)(B)]) that—</p> <p>(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act [42 U.S.C. 1395 et seq.] or eligible for assistance under the State plan under this subchapter;</p> <p>(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act [42 U.S.C. 1395ww(d)(5)(F)]) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act [42 U.S.C. 1395ww(d)(5)(F)(i)(II)]; and</p> <p>(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.</p>

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p>Subsection (d) Hospital (as defined in 42 USC §1395ww(d)(1)(B))</p>	<p>(B) As used in this section, the term “subsection (d) hospital” means a hospital located in one of the fifty States or the District of Columbia other than—</p> <ul style="list-style-type: none">(i) a psychiatric hospital (as defined in section 1861(f)),(ii) a rehabilitation hospital (as defined by the Secretary),(iii) a hospital whose inpatients are predominantly individuals under 18 years of age,(iv) a hospital which has an average inpatient length of stay (as determined by the Secretary) of greater than 25 days,(v)(I) a hospital that the Secretary has classified, at any time on or before December 31, 1990, (or, in the case of a hospital that, as of the date of the enactment of this clause, is located in a State operating a demonstration project under section 1814(b), on or before December 31, 1991) for purposes of applying exceptions and adjustments to payment amounts under this subsection, as a hospital involved extensively in treatment for or research on cancer,(II) a hospital that was recognized as a comprehensive cancer center or clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of April 20, 1983, that is located in a State which, as of December 19, 1989, was not operating a demonstration project under section 1814(b), that applied and was denied, on or before December 31, 1990, for classification as a hospital involved extensively in treatment for or research on cancer under this clause (as in effect on the day before the date of the enactment of this subclause), that as of the date of the enactment of this subclause, is licensed for less than 50 acute care beds, and that demonstrates for the 4-year period ending on December 31, 1996, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E), or

Health Care Provider Definition Cross-Reference Table

Cross-Referenced Term(s)	Definition
<p>Subsection (d) Hospital (as defined in 42 USC §1395ww(d)(1)(B))</p>	<p>(III) a hospital that was recognized as a clinical cancer research center by the National Cancer Institute of the National Institutes of Health as of February 18, 1998, that has never been reimbursed for inpatient hospital services pursuant to a reimbursement system under a demonstration project under section 1814(b), that is a freestanding facility organized primarily for treatment of and research on cancer and is not a unit of another hospital, that as of the date of the enactment of this subclause, is licensed for 162 acute care beds, and that demonstrates for the 4-year period ending on June 30, 1999, that at least 50 percent of its total discharges have a principal finding of neoplastic disease, as defined in subparagraph (E);</p> <p>(vi) a hospital that first received payment under this subsection in 1986 which has an average inpatient length of stay (as determined by the Secretary) of greater than 20 days and that has 80 percent or more of its annual Medicare inpatient discharges with a principal diagnosis that reflects a finding of neoplastic disease in the 12-month cost reporting period ending in fiscal year 1997;</p> <p>and, in accordance with regulations of the Secretary, does not include a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital (as defined by the Secretary). A hospital that was classified by the Secretary on or before September 30, 1995, as a hospital described in clause (iv) (as in effect as of such date) shall continue to be so classified (or, in the case of a hospital described in clause (iv)(II), as so in effect, shall be classified under clause (vi) on and after the effective date of such clause (vi) and for cost reporting periods beginning on or after January 1, 2015, shall not be subject to subsection (m) as of the date of such classification) notwithstanding that it is located in the same building as, or on the same campus as, another hospital.</p>
<p>Therapist (as defined in 42 USC § 1395w- 4(k)(3)(B)(iii))</p>	<p>(iii) A physical or occupational therapist or a qualified speech-language pathologist.</p>



Questions

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