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17025,” IBR approved for §§170.520(b) and 170.524(a).

(4) ISO/IEC 17025:2017(E)—General requirements for the competence of testing and calibration laboratories (Third Edition), 2017–11, “ISO/IEC 17025,” IBR approved for §§170.520(b), and 170.524(a).

(5) ISO/IEC 17065:2012(E)—Conformity assessment—Requirements for bodies certifying products, processes and services (First Edition), 2012, “ISO/IEC 17065,” IBR approved for §§170.503 and 170.523(a).

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AUTHORITY: 42 U.S.C. 300jj–52; 5 U.S.C. 552.

SOURCE: 85 FR 25955, May 1, 2020, unless otherwise noted.

Subpart A—General Provisions

§ 171.100 Statutory basis and purpose.

(a) *Basis.* This part implements section 3022 of the Public Health Service Act, 42 U.S.C. 300jj–52.

(b) *Purpose.* The purpose of this part is to establish exceptions for reasonable and necessary activities that do not constitute information blocking as defined by section 3022(a)(1) of the Public Health Service Act, 42 U.S.C. 300jj–52.

§ 171.101 Applicability.

(a) This part applies to health care providers, health IT developers of certified health IT, health information exchanges, and health information networks, as those terms are defined in §171.102.

(b) Health care providers, health IT developers of certified health IT, health information exchanges, and health information networks must comply with this part on and after November 2, 2020.

§ 171.102 Definitions.

For purposes of this part:

Access means the ability or means necessary to make electronic health information available for exchange or use.

Actor means a health care provider, health IT developer of certified health IT, health information network or health information exchange.

API Information Source is defined as it is in § 170.404(c).

API User is defined as it is in § 170.404(c).

Certified API Developer is defined as it is in § 170.404(c).

Certified API technology is defined as it is in § 170.404(c).

Electronic health information (EHI) means electronic protected health information as defined in 45 CFR 160.103 to the extent that it would be included in a designated record set as defined in 45 CFR 164.501, regardless of whether the group of records are used or maintained by or for a covered entity as defined in 45 CFR 160.103, but EHI shall not include:

(1) Psychotherapy notes as defined in 45 CFR 164.501; or

(2) Information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.

Exchange means the ability for electronic health information to be transmitted between and among different technologies, systems, platforms, or networks.

Fee means any present or future obligation to pay money or provide any other thing of value.

Health care provider has the same meaning as “health care provider” in 42 U.S.C. 300jj.

Health information network or *health information exchange* 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 electronic health information:

(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

(2) That is for a treatment, payment, or health care 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.

Health IT developer of certified health IT means an individual or entity, other than a health care provider that self-develops health IT for its own use, that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified 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).

Information blocking is defined as it is in § 171.103.

Interfere with or *interference* means to prevent, materially discourage, or otherwise inhibit.

Interoperability element means hardware, software, integrated technologies or related licenses, technical information, privileges, rights, intellectual property, upgrades, or services that:

(1) May be necessary to access, exchange, or use electronic health information; and

(2) Is/Are controlled by the actor, which includes the ability to confer all rights and authorizations necessary to use the element to enable the access, exchange, or use of electronic health information.

Permissible purpose means a purpose for which a person is authorized, permitted, or required to access, exchange, or use electronic health information under applicable law.

Person is defined as it is in 45 CFR 160.103.

Practice means an act or omission by an actor.

Use means the ability for electronic health information, once accessed or exchanged, to be understood and acted upon.

§ 171.103 Information blocking.

(a) Information blocking means a practice that—