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—

(1) Except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information; and

(2) If conducted by a health information technology developer, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information; or

(3) If conducted by a health care provider, such provider knows that such practice is unreasonable and is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

(b) Until May 2, 2022, electronic health information for purposes of paragraph (a) of this section is limited to the electronic health information identified by the data elements represented in the USCDI standard adopted in §170.213.

Subpart B—Exceptions That Involve Not Fulfilling Requests to Access, Exchange, or Use Electronic Health Information

§171.200 Availability and effect of exceptions.

A practice shall not be treated as information blocking if the actor satisfies an exception to the information blocking provision as set forth in this subpart B by meeting all applicable requirements and conditions of the exception at all relevant times.

§171.201 Preventing harm exception—when will an actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm not be considered information blocking?

An actor's practice that is likely to interfere with the access, exchange, or use of electronic health information in order to prevent harm will not be considered information blocking when the practice meets the conditions in paragraphs (a) and (b) of this section, satisfies at least one condition from each of paragraphs (c), (d), and (f) of this section, and also meets the condition in paragraph (e) of this section when applicable.

(a) *Reasonable belief.* The actor engaging in the practice must hold a reasonable belief that the practice will substantially reduce a risk of harm to a patient or another natural person that would otherwise arise from the access, exchange, or use of electronic health information affected by the practice. For purposes of this section, ''patient'' means a natural person who is the subject of the electronic health information affected by the practice.

(b) *Practice breadth.* The practice must be no broader than necessary to substantially reduce the risk of harm that the practice is implemented to reduce.

(c) *Type of risk.* The risk of harm must:

(1) Be determined on an individualized basis in the exercise of professional judgment by a licensed health care professional who has a current or prior clinician-patient relationship with the patient whose electronic health information is affected by the determination; *or*

(2) Arise from data that is known or reasonably suspected to be misidentified or mismatched, corrupt due to technical failure, or erroneous for another reason.

(d) *Type of harm.* The type of harm must be one that could serve as grounds for a covered entity (as defined in §160.103 of this title) to deny access (as the term ''access'' is used in part 164 of this title) to an individual's protected health information under:

(1) Section 164.524(a)(3)(iii) of this title where the practice is likely to, or in fact does, interfere with access, exchange, or use (as these terms are defined in §171.102) of the patient's electronic health information by their legal representative (including but not limited to personal representatives recognized pursuant to 45 CFR 164.502) and the practice is implemented pursuant to an individualized determination of risk of harm consistent with paragraph (c)(1) of this section;

(2) Section 164.524(a)(3)(ii) of this title where the practice is likely to, or