

(B) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

(2) *Alternative manner.* If an actor does not fulfill a request described in paragraph (a) of this section in any manner requested because it is technically unable to fulfill the request or cannot reach agreeable terms with the requestor to fulfill the request, the actor must fulfill the request in an alternative manner, as follows:

(i) The actor must fulfill the request without unnecessary delay in the following order of priority, starting with paragraph (b)(2)(i)(A) of this section and only proceeding to the next consecutive paragraph if the actor is technically unable to fulfill the request in the manner identified in a paragraph.

(A) Using technology certified to standard(s) adopted in part 170 that is specified by the requestor.

(B) Using content and transport standards specified by the requestor and published by:

(1) The Federal Government; or

(2) A standards developing organization accredited by the American National Standards Institute.

(C) Using an alternative machine-readable format, including the means to interpret the electronic health information, agreed upon with the requestor.

(ii) Any fees charged by the actor in relation to fulfilling the request are required to satisfy the exception in § 171.302.

(iii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is required to satisfy the exception in § 171.303.

[85 FR 25955, May 1, 2020, as amended at 85 FR 70085, Nov. 4, 2020]

**§ 171.302 Fees exception—When will an actor's practice of charging fees for accessing, exchanging, or using electronic health information not be considered information blocking?**

An actor's practice of charging fees, including fees that result in a reasonable profit margin, for accessing, exchanging, or using electronic health information will not be considered infor-

mation blocking when the practice meets the conditions in paragraph (a) of this section, does not include any of the excluded fees in paragraph (b) of this section, and, as applicable, meets the condition in paragraph (c) of this section.

(a) *Basis for fees condition.* (1) The fees an actor charges must be—

(i) Based on objective and verifiable criteria that are uniformly applied for all similarly situated classes of persons or entities and requests;

(ii) Reasonably related to the actor's costs of providing the type of access, exchange, or use of electronic health information to, or at the request of, the person or entity to whom the fee is charged;

(iii) Reasonably allocated among all similarly situated persons or entities to whom the technology or service is supplied, or for whom the technology is supported; and

(iv) Based on costs not otherwise recovered for the same instance of service to a provider and third party.

(2) The fees an actor charges must not be based on—

(i) Whether the requestor or other person is a competitor, potential competitor, or will be using the electronic health information in a way that facilitates competition with the actor;

(ii) Sales, profit, revenue, or other value that the requestor or other persons derive or may derive from the access, exchange, or use of the electronic health information;

(iii) Costs the actor incurred due to the health IT being designed or implemented in a non-standard way, unless the requestor agreed to the fee associated with the non-standard design or implementation to access, exchange, or use the electronic health information;

(iv) Costs associated with intangible assets other than the actual development or acquisition costs of such assets;

(v) Opportunity costs unrelated to the access, exchange, or use of electronic health information; or

(vi) Any costs that led to the creation of intellectual property, if the actor charged a royalty for that intellectual property pursuant to § 171.303

§ 171.303

45 CFR Subtitle A (10-1-23 Edition)

and that royalty included the development costs for the creation of the intellectual property.

(b) *Excluded fees condition.* This exception does not apply to—

(1) A fee prohibited by 45 CFR 164.524(c)(4);

(2) A fee based in any part on the electronic access of an individual's EHI by the individual, their personal representative, or another person or entity designated by the individual;

(3) A fee to perform an export of electronic health information via the capability of health IT certified to §170.315(b)(10) of this subchapter for the purposes of switching health IT or to provide patients their electronic health information; and

(4) A fee to export or convert data from an EHR technology that was not agreed to in writing at the time the technology was acquired.

(c) *Compliance with the Conditions of Certification condition.* Notwithstanding any other provision of this exception, if the actor is a health IT developer subject to the Conditions of Certification in §170.402(a)(4), §170.404, or both of this subchapter, the actor must comply with all requirements of such conditions for all practices and at all relevant times.

(d) *Definition of Electronic access.* The following definition applies to this section:

*Electronic access* means an internet-based method that makes electronic health information available at the time the electronic health information is requested and where no manual effort is required to fulfill the request.

**§171.303 Licensing exception—When will an actor's practice to license interoperability elements in order for electronic health information to be accessed, exchanged, or used not be considered information blocking?**

An actor's practice to license interoperability elements for electronic health information to be accessed, exchanged, or used will not be considered information blocking when the practice meets all of the following conditions.

(a) *Negotiating a license conditions.* Upon receiving a request to license an interoperability element for the access,

exchange, or use of electronic health information, the actor must—

(1) Begin license negotiations with the requestor within 10 business days from receipt of the request; and

(2) Negotiate a license with the requestor, subject to the licensing conditions in paragraph (b) of this section, within 30 business days from receipt of the request.

(b) *Licensing conditions.* The license provided for the interoperability element(s) needed to access, exchange, or use electronic health information must meet the following conditions:

(1) *Scope of rights.* The license must provide all rights necessary to:

(i) Enable the access, exchange, or use of electronic health information; and

(ii) Achieve the intended access, exchange, or use of electronic health information via the interoperability element(s).

(2) *Reasonable royalty.* If the actor charges a royalty for the use of the interoperability elements described in paragraph (a) of this section, the royalty must be reasonable and comply with the following requirements:

(i) The royalty must be nondiscriminatory, consistent with paragraph (b)(3) of this section.

(ii) The royalty must be based solely on the independent value of the actor's technology to the licensee's products, not on any strategic value stemming from the actor's control over essential means of accessing, exchanging, or using electronic health information.

(iii) If the actor has licensed the interoperability element through a standards developing organization in accordance with such organization's policies regarding the licensing of standards-essential technologies on terms consistent with those in this exception, the actor may charge a royalty that is consistent with such policies.

(iv) An actor may not charge a royalty for intellectual property if the actor recovered any development costs pursuant to §171.302 that led to the creation of the intellectual property.

(3) *Non-discriminatory terms.* The terms (including royalty terms) on which the actor licenses and otherwise provides the interoperability elements