

§ 170.400

(ii) *Delivery Notification in Direct*. Able to send and receive health information in accordance with the standard specified in §170.202(e)(1).

(2) *Direct Project, Edge Protocol, and XDR/XDM*. (i) Able to send and receive health information in accordance with:

(A) The standard specified in §170.202(a)(2), including formatted only as a “wrapped” message;

(B) The standard specified in §170.202(b), including support for both limited and full XDS metadata profiles; and

(C) Both edge protocol methods specified by the standard in §170.202(d).

(ii) *Delivery Notification in Direct*. Able to send and receive health information in accordance with the standard specified in §170.202(e)(1).

[80 FR 62747, Oct. 16, 2015, as amended at 80 FR 76871, Dec. 11, 2015; 85 FR 25941, May 1, 2020; 85 FR 47099, Aug. 4, 2020; 85 FR 70083, Nov. 4, 2020; 85 FR 78236, Dec. 4, 2020]

Subpart D—Conditions and Maintenance of Certification Requirements for Health IT Developers

SOURCE: 85 FR 25945, May 1, 2020, unless otherwise noted.

§ 170.400 Basis and scope.

This subpart implements section 3001(c)(5)(D) of the Public Health Service Act by setting forth certain Conditions and Maintenance of Certification requirements for health IT developers participating in the ONC Health IT Certification Program.

§ 170.401 Information blocking.

(a) *Condition of Certification requirement*. A health IT developer must not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj-52 and §171.103 on or after April 5, 2021.

(b) [Reserved]

[85 FR 25945, May 1, 2020, as amended at 85 FR 70084, Nov. 4, 2020]

§ 170.402 Assurances.

(a) *Condition of Certification requirement*. (1) A health IT developer must provide assurances satisfactory to the Secretary that the health IT developer

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will not take any action that constitutes information blocking as defined in 42 U.S.C. 300jj-52 and §171.103 of this chapter on and after April 5, 2021, unless for legitimate purposes as specified by the Secretary; or any other action that may inhibit the appropriate exchange, access, and use of electronic health information.

(2) A health IT developer must ensure that its health IT certified under the ONC Health IT Certification Program conforms to the full scope of the certification criteria.

(3) A health IT developer must not take any action that could interfere with a user's ability to access or use certified capabilities for any purpose within the full scope of the technology's certification.

(4) A health IT developer of a certified Health IT Module that is part of a health IT product which electronically stores EHI must certify to the certification criterion in §170.315(b)(10).

(b) *Maintenance of Certification requirements*. (1) A health IT developer must retain all records and information necessary to demonstrate initial and ongoing compliance with the requirements of the ONC Health IT Certification Program for:

(i) A period of 10 years beginning from the date a developer's Health IT Module(s) is first certified under the Program; or

(ii) If for a shorter period of time, a period of 3 years from the effective date that removes all of the certification criteria to which the developer's health IT is certified from the Code of Federal Regulations.

(2)(i) By December 31, 2023, a health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in §170.315(b)(10).

(ii) On and after December 31, 2023, a health IT developer that must comply with the requirements of paragraph (a)(4) of this section must provide all of its customers of certified health IT with the health IT certified to the certification criterion in §170.315(b)(10).

[85 FR 25945, May 1, 2020, as amended at 85 FR 70084, Nov. 4, 2020; 85 FR 70084, Nov. 4, 2020]