§ 170.403 Communications.

(a) *Condition of Certification requirements.* (1) A health IT developer may not prohibit or restrict any communication regarding—

(i) The usability of its health IT;

(ii) The interoperability of its health IT;

(iii) The security of its health IT;

(iv) Relevant information regarding users' experiences when using its health IT;

(v) The business practices of developers of health IT related to exchanging electronic health information; and

(vi) The manner in which a user of the health IT has used such technology.

(2) A health IT developer must not engage in any practice that prohibits or restricts a communication regarding the subject matters enumerated in paragraph (a)(1) of this section, unless the practice is specifically permitted by this paragraph and complies with all applicable requirements of this paragraph.

(i) *Unqualified protection for certain communications.* A health IT developer must not prohibit or restrict any person or entity from communicating any information whatsoever (including proprietary information, confidential information, and intellectual property) when the communication is about one or more of the subject matters enumerated in paragraph (a)(1) of this section and is made for any of the following purposes:

(A) Making a disclosure required by law;

(B) Communicating information about adverse events, hazards, and other unsafe conditions to government agencies, health care accreditation organizations, and patient safety organizations;

(C) Communicating information about cybersecurity threats and incidents to government agencies;

(D) Communicating information about information blocking and other unlawful practices to government agencies; or

(E) Communicating information about a health IT developer's failure to comply with a Condition of Certification requirement, or with any other requirement of this part, to ONC or an ONC–ACB.

(ii) *Permitted prohibitions and restrictions.* For communications about one or more of the subject matters enumerated in paragraph (a)(1) of this section that is not entitled to unqualified protection under paragraph (a)(2)(i) of this section, a health IT developer may prohibit or restrict communications only as expressly permitted by paragraphs (a)(2)(ii)(A) through (E) of this section.

(A) *Developer employees and contractors.* (*1*) A health IT developer may prohibit or restrict the communications of the developer's employees or contractors.

(*2*) A self-developer must not prohibit or restrict communications of users of their health IT who are also employees or contractors.

(B) *Non-user-facing aspects of health IT.* A health IT developer may prohibit or restrict communications that disclose information about non-user-facing aspects of the developer's health IT.

(C) *Intellectual property.* A health IT developer may prohibit or restrict communications that involve the use or disclosure of intellectual property existing in the developer's health IT (including third-party intellectual property), provided that any prohibition or restriction imposed by a developer must be no broader than necessary to protect the developer's legitimate intellectual property interests and consistent with all other requirements of paragraph (a)(2)(ii) of this section. A restriction or prohibition is deemed broader than necessary and inconsistent with the requirements of paragraph (a)(2)(ii) of this section if it would restrict or preclude a public display of a portion of a work subject to copyright protection (without regard to whether the copyright is registered) that would reasonably constitute a "fair use" of that work.

(D) *Screenshots and video.* A health IT developer may require persons who communicate screenshots or video to—

(*1*) Not alter the screenshots or video, except to annotate the screenshots or video or resize the screenshots or video;

(*2*) Limit the sharing of screenshots to the relevant number of screenshots

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needed to communicate about the health IT regarding one or more of the six subject areas in paragraph (a)(1) of this section; and

(*3*) Limit the sharing of video to:

(*i*) The relevant amount of video needed to communicate about the health IT regarding one or more of the six subject areas in paragraph (a)(1) of this section; and

(*ii*) Only videos that address temporal matters that cannot be communicated through screenshots or other forms of communication.

(E) *Pre-market testing and development.* A health IT developer may prohibit or restrict communications that disclose information or knowledge solely acquired in the course of participating in pre-market product development and testing activities carried out for the benefit of the developer or for the joint benefit of the developer and communicator. A developer must not, once the subject health IT is released or marketed for purposes other than product development and testing, and subject to the permitted prohibitions and restrictions described in paragraph (a)(2)(ii) of this section, prohibit or restrict communications about matters enumerated in paragraph (a)(1) of this section.

(b) *Maintenance of Certification requirements*—(1) *Notice.* Health IT developers must issue a written notice to all customers and those with which it has contracts or agreements containing provisions that contravene paragraph (a) of this section annually, beginning in calendar year 2021, until paragraph (b)(2)(ii) of this section is fulfilled, stating that any communication or contract provision that contravenes paragraph (a) of this section will not be enforced by the health IT developer.

(2) *Contracts and agreements.* (i) A health IT developer must not establish, renew, or enforce any contract or agreement that contravenes paragraph (a) of this section.

(ii) If a health IT developer has a contract or agreement in existence as of June 30, 2020, that contravenes paragraph (a) of this section, then the developer must amend the contract or agreement to remove or void the contractual provision that contravenes paragraph (a) of this section whenever the contract is next modified for other reasons or renewed.

(c) *Communication, defined.* ''Communication'' as used in this section means any communication, irrespective of the form or medium. The term includes visual communications, such as screenshots and video.

[85 FR 25945, May 1, 2020, as amended at 85 FR 43711, July 20, 2020; 85 FR 70084, Nov. 4, 2020]

§ 170.404 Application programming interfaces.

The following Condition and Maintenance of Certification requirements apply to developers of Health IT Modules certified to any of the certification criteria adopted in § 170.315(g)(7) through (10).

(a) *Condition of certification requirements*—(1) *General.* A Certified API Developer must publish APIs and allow electronic health information from such technology to be accessed, exchanged, and used without special effort through the use of APIs or successor technology or standards, as provided for under applicable law, including providing access to all data elements of a patient's electronic health record to the extent permissible under applicable privacy laws.

(2) *Transparency conditions*—(i) *Complete business and technical documentation.* A Certified API Developer must publish complete business and technical documentation, including the documentation described in paragraph (a)(2)(ii) of this section, via a publicly accessible hyperlink that allows any person to directly access the information without any preconditions or additional steps.

(ii) *Terms and conditions*—(A) *Material information.* A Certified API Developer must publish all terms and conditions for its certified API technology, including any fees, restrictions, limitations, obligations, registration process requirements, or other similar requirements that would be:

(*1*) Needed to develop software applications to interact with the certified API technology;

(*2*) Needed to distribute, deploy, and enable the use of software applications in production environments that use the certified API technology;

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