



Office of the National Coordinator  
for Health Information Technology

## EXPLAINED!

# The Communications Condition of Certification

**As part of the 21st Century Cures Act (Cures Act), Congress established seven conditions of certification. One of those conditions of certification, including its maintenance of certification requirements, focuses on communications about certified health IT that are now protected. These new regulatory provisions are part of the “Communications Condition of Certification” (Communications Condition) that ONC implemented at 45 CFR 170.403 as part of the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program Final Rule (85 FR 25642). The Communications Condition addresses practices by health IT developers that would otherwise prevent customers and other users of health IT from discussing issues concerning the health IT, such as through the use of “gag clauses” (i.e., restrictions on communications of certain information) in developer contracts.**

The Communications Condition only applies to health IT developer practices with respect to certified health IT.

This Explained! document is primarily for healthcare organizations, clinical staff, researchers, patients, and third-party services. It goes requirement-by-requirement and identifies what they mean in a simplified, paraphrased way and how they apply to developers of certified health IT to whom this Communications Condition is applicable. In order to fully understand this Explained! document, a reader should also review the applicable regulation at 45 CFR 170.403.

## Communications

**The rule says...** that certain communications regarding certified health IT are protected.

**This means...** that any communication identified as protected includes any form or medium of that communication, including visual communications (e.g., screenshots and video).

## Protected Communications

**The rule says...** that health IT developers generally, and subject to certain exceptions, cannot restrict communications about certified health IT when it comes to: usability, interoperability, security, user experiences, developer business practices related to exchanging electronic health information, and the manner in which a user of certified health IT has used such technology.

**This means...** that all users of certified health IT, including researchers, can openly discuss these topics with few prohibitions or restrictions. For example, developers can't prevent you from writing a blog post about a usability issue with your certified health IT, unless the discussion touches on matters that could be restricted. These limited restrictions include, for example, discussing non-user facing aspects or when the communication would infringe on intellectual property rights. However, developers may not prohibit any communication that would be "fair use" of copyrighted material.

You can provide [feedback](#) to ONC regarding attempts by developers of certified health IT to restrict your ability to communicate about their certified health IT.

## Unqualified Protection for Certain Communications

**The rule says...** that some protected communications about health IT when made to specified entities get "[unqualified protection](#)" and can't be restricted at all by developers when the communications are made to certain parties (generally government agencies and certain kinds of organizations). These include communications required by law, as well as communications about adverse events or unsafe conditions, cybersecurity threats and incidents, information blocking, or a health IT developer's failure to comply with ONC's Health IT Certification Program requirements.

**This means...** that users of certified health IT, including researchers, can communicate confidential or proprietary information to ONC or other government agencies if it involves patient safety or cybersecurity issues, or if the communication is related to information blocking or other ONC Health IT Certification Program requirements.



## Limited Restrictions Allowed on Certain Communications

**The rule says...** that, provided a communication about health IT does not receive “unqualified protection,” developers can place [limited prohibitions and restrictions](#) on certain protected communications about health IT, including those made by developer employees or that involve non-user facing aspects of the health IT, intellectual property (except in particular circumstances), pre-market testing and development, or screenshots and video (except in particular circumstances).

**This means...** that developers may place some restrictions on protected communications, but only if the communications are not ones that receive “unqualified protection.”

For example, one step a developer may take is to limit a user’s communication of screenshots or video to only the amount needed to communicate about the relevant health IT issue (e.g., an issue relating to usability or interoperability of certified health IT). However, any restrictions placed by a developer on intellectual property must not be broader than necessary, and developers must not restrict communications about work subject to copyright protection that would constitute a “fair use” of that work.



## Maintenance of Certification Requirements

**The rule says...** as a maintenance of certification requirement, [developers must send notices](#) informing customers and others with whom they have contracts or agreements that contain provisions violating this Communications Condition that they will not be enforcing those provisions.

**This means...** that anyone who has a contract or agreement with a developer of certified health IT that contains communication restrictions prohibited by this Communications Condition, including “gag clauses,” should have received a notice starting in 2021 that such provisions will not be enforced. These notices must be sent annually until the developer has removed or amended any contractual provisions that violate this Communications Condition.

## Maintenance of Certification Requirements (Cont.)

**The rule says...** as a maintenance of certification requirement, developers of certified health IT [cannot establish, renew, or enforce contracts violating this Communications Condition](#), and they must amend existing contracts violating this Communications Condition whenever those contracts are next modified for other reasons or renewed.

**This means...** that as of June 30, 2020, any new contracts you enter into with a developer of certified health IT must not have prohibited terms or provisions preventing you from communicating about the developer's health IT, including gag clauses. Further, if your current contract has such provisions, they must be removed whenever the developer renews or makes changes to the contract after June 30, 2020. To note, ONC exercised enforcement discretion for non-compliance with these requirements from June 30, 2020 until April 5, 2021 (85 FR 70064, 70071-72).