



## **ONC Proposed Rules Around Prohibiting Gag Clauses and other Restricted Communications Between Vendors, Providers & Others**

### **Background**

The 21<sup>st</sup> Century Cures (Cures) Act prohibits a developer, as part of their Conditions and Maintenance of Certification, from restricting communications around the following topics:

- The usability of the health information technology;
- The interoperability of the health information technology;
- The security of the health information technology;
- Relevant information regarding users' experiences when using the health information technology;
- The business practices of developers of health information technology related to exchanging electronic health information; and
- The manner in which a user of the health information technology has used such technology.

On March 4, 2019 ONC published their [proposed rule](#), “21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program.” In the rule, ONC lays out the parameters around which vendors may restrict the sharing of information related to their certified products (very limited) vs. under what circumstances providers (and others) are permitted to share information related to their purchased products, which in many cases has been tightly controlled by vendors through contracts. The discussion on this topic is contained under the “Communications” section of the [rule](#) beginning on page 167. ONC clearly states:

*Developers must not prohibit or restrict communications whether written, oral, electronic or by any other method if they concern protected communications, unless permitted otherwise by this Condition of Certification.*

ONC further confers that:

*A restriction or prohibition that does not satisfy this two-part test will contravene this Condition of Certification.*

### **ONC Proposals: When restricting information IS allowed by vendors**

In implementing this provision in the Cures Act, ONC has proposed the vendors must meet both pieces of a “two-part test” in order to ascertain whether they are permitted from restricting communications around their product. ONC says, “any prohibition or restriction not expressly permitted would violate the Condition,” of their certification. Further, the burden will be on the vendor to demonstrate they have met all of ONC’s requirements. ONC points out, however, that a customer’s dissatisfaction with a product is not necessarily indicative of the vendor engaging



in restricted or prohibited communications. The limited situations under which a vendor may restrict information are:

1. **Communications with unqualified protection:** Communications cannot fall into one of what ONC describes as “Communications with unqualified protection.” That means if the communication is related to a category ONC has established as being under this definition, then the vendor may not restrict communications. Said another way, vendors are prohibited from restricting communications that fall into one of the categories of unqualified protection; AND
2. **Permitted prohibitions and restrictions:** Communications must fall into a prescribed category of what ONC has deemed to be what they are referring to as “permitted prohibitions and restrictions.” These include:
  - a. Communications of their own employees;
  - b. Disclosure of non-user-facing aspects of the software;
  - c. Certain communications that would infringe the developer’s or another person’s intellectual property rights;
    - i. **NOTE:** On the topic of IP, ONC says:

*This Condition of Certification is not intended to operate as a de facto license for health IT users and others to act in any way that might infringe the legitimate intellectual property rights of developers... developers are not permitted to prohibit or restrict, or purport to prohibit or restrict, communications that would be a “fair use” of any copyright work comprised in the developer’s health IT. That is, a developer is not permitted to prohibit or restrict communications under the guise of copyright protection (or under the guise of a confidentiality or non-disclosure obligation) when the communication in question makes a use of the copyright material in a way that would qualify that use as a “fair use.” (page 196)*

- d. Publication of screenshots in very narrow circumstances; and
- e. Communications of information that a person or entity knows only because of their participation in developer-led product development and testing.

## **Vendor contracts**

### ***Contract language***

ONC proposes, “health IT contracts may include terms that govern the manner in which the parties conduct themselves, and those terms would not implicate this Condition of Certification unless the operative effect of a term was to restrict or prohibit a protected communication.” Also, ONC makes clear that vendor contracts must be “precise and specific.” They note that,



“Contractual provisions or public statements that support a permitted prohibition or restriction on communication should be very specific about the rights and obligations of the potential communicator. Contract terms that are vague and cannot be readily understood by a reasonable health IT customer will not benefit from the qualifications to this Condition of Certification.”

### ***Compliance Deadlines***

ONC has proposed developers must notify all customers with whom it has contracts within six months of the effective date of the final rule regarding any contract / communication that must be amended pursuant to these new rules where it contravenes what is already in place. Then, annually thereafter vendors would be required to notify customers thereafter concerning the need to make changes to contracts. Vendors would have up to two years to remove any contravening provisions related to communications.

### **What types of communications come with “Unqualified Protection” such that vendors CANNOT limit sharing of information?**

Vendors are prohibited from restricting communications, whether written, oral, electronic or by any other method, if they concern protected communications (unless expressly permitted as discussed elsewhere in this document). In addition to providers being afforded the ability to communicate about vendor products, so too are others, including “patients, health IT researchers, industry groups, and health information exchanges,” who would also “be able to make protected communications about the health IT free of impermissible prohibitions or restrictions.”

Examples of other protected communications include, but are not limited to:

- a post made to an online forum;
- the sharing of screenshots, subject to certain proposed restrictions on their general publication;
- an unattributed written review by a health IT user;
- a quote given by a healthcare executive to a journalist;
- a presentation given at a trade show;
- a social media post;
- a product review posted on a video-sharing service such as YouTube;
- the statements and conclusions made in a peer-reviewed journal; and
- private communications made between health IT customers about the health IT.

### **Protected Subject Areas Where Communications CANNOT be Restricted by Vendors**



ONC has proposed six classes of communications for which vendors could not restrict communications:

1. **Usability of Health Information Technology:** “Usability” of health IT is construed broadly to include both an overall judgment on the “usability” of a particular health IT product, as well as any factor that contributes to usability.
  - a. **Examples include:** the user interface (i.e., what a user sees on the screen, such as layout, controls, graphics and navigational elements); ease of use (e.g., how many clicks); how the technology supports users’ workflows; the organization of information; cognitive burden; cognitive support; error tolerance; clinical decision support; alerts; error handling; customizability; use of templates; mandatory data elements; the use of text fields; and customer support.
2. **Interoperability of Health Information Technology:** This would include communications regarding the “interoperability of health IT” including whether a health IT product and associated developer business practices meet the interoperability definition described in section 3000(9) of the Public Health Service Act (PHSA,) including communications about aspects of the technology or developer that fall short of the expectations found in that definition.
  - a. **Examples:** This will include communications about the interoperability capabilities of health IT and the practices of a health IT developer that may inhibit the access, exchange or use of electronic health information (EHI,) including information blocking.
3. **Security of Health IT:** Matters that fall within the topic of health IT security should be broadly construed to include any safeguards, whether or not required by the Security Rule, that may be implemented (or not implemented) by a developer to ensure the confidentiality, integrity, and security of the wider set of EHI (including ePHI), together with the health IT product’s performance regarding security.
  - a. **Examples:** A developer may not prohibit or restrict a potential communicator from communicating about, without limitation:
    - i. The approach to security adopted for the health IT at issue (e.g., architectural approach or authentication methodology);
    - ii. The resilience of the health IT;
    - iii. Identified security flaws in the developer’s health IT; or
    - iv. The response to cyber threats or security breaches by the developer.
4. **User Experiences:** To qualify as a “user experience,” the experience must be one that is had by a user of health IT. However, beyond this, ONC does impose any limitations. ONC states, “a ‘relevant user experience’ includes any aspect of the health IT user experience that could positively or negatively impact the effectiveness or performance of the health IT.”
  - a. **Examples:** User experiences would also include the experiences associated with configuring and using the technology throughout implementation, training and in



practice. It would include patients' and consumers' user experiences with consumer apps, patient portals and other consumer-facing technologies.

5. **Manner in which a User has Used Health IT:** This would encompass any information related to how the health IT has been used in practice and overlaps with the "user experience" category.
  - a. **Examples:**
    - i. information about a work-around implemented to overcome an issue in the health IT;
    - ii. customizations built on top of core health IT functionality;
    - iii. the specific conditions under which a user used the health IT, such as information about constraints imposed on health IT functionality due to implementation decisions; and
    - iv. information about the ways in which health IT could not be used or did not function as was represented by the developer.
6. **Business Practices Related to Exchange:** This broadly covers developer policies and practices that facilitate the exchange of electronic health information, and developer policies and practices that impact the ability of health IT to exchange health information. This includes the appropriate and timely sharing of electronic health information and the costs of switching health IT.
  - a. **Examples:**
    - i. Costs charged by a developer for products or services that support the exchange of electronic health information (e.g., interface costs, API licensing fees and royalties, maintenance and subscription fees, transaction or usage-based costs for exchanging information);
    - ii. Timeframes and terms on which developers will or will not enable connections and facilitate exchange with other technologies, individuals, or entities, including other health IT developers, exchanges and networks;
    - iii. Developer's approach to participation in health information exchanges and/or networks;
    - iv. Developer's licensing practices and terms as it relates to making available APIs and other aspects of its technology that enable the development and deployment of interoperable products and services; and
    - v. Developer's approach to creating interfaces with third-party products or services, including whether connections are treated as "one off" customizations, or whether similar types of connections can be implemented at a reduced cost.