



The Office of the National Coordinator for
Health Information Technology
Health IT Advisory Committee

Information Blocking Task Force Meeting

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Agenda

- Task Force Charge
- Progress and Draft Recommendations
 - » Work Group 1 – Relevant Statutory Terms and Provisions
 - » Work Group 2 – Exceptions
 - » Work Group 3 – Information Blocking, Assurances, and Communications Conditions and Maintenance of Certification and Enforcement
- Questions and Feedback

Information Blocking Task Force Charge

- **Overarching Charge:** Provide recommendations on policies related to information blocking; the “information blocking,” “assurances,” and “communications” conditions and maintenance of certification requirements; and the enforcement of all the conditions and maintenance of certification requirements.
- **Specific Charges:** Provide recommendations on the following topics:
 - Information Blocking:
 - **ONC definitions/interpretations of certain statutory terms and provisions, including the price information request for information**
 - Seven exceptions to the information blocking definition, and any additional exceptions (request for information)
 - **Complaint process**
 - **Disincentives for health care providers (request for information)**
 - **“Information blocking,” “assurances,” and “communications” conditions and maintenance of certification requirements**
 - **Enforcement of all the conditions and maintenance of certification requirements**

Relevant Statutory Terms and Provisions

§ 171.102

Definition of Electronic Health Information

ORIGINAL TEXT

Electronic Health Information (EHI) means—

- (1) Electronic protected health information; and
- (2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

MARKUP FROM ORIGINAL

Electronic Health Information (EHI) means—

- (1) Electronic protected health information ([as defined in HIPAA](#)); and
- (2) Any other information that identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual and is transmitted by or maintained in electronic media, as defined in 45 CFR 160.103, that relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment(s) for the provision of health care to an individual., [and](#)
- [\(3\) On the one year anniversary of the effective date of the final rule, an individual's consent directives including privacy, medical treatment, research, and advanced care.](#)

PRINCIPAL DISCUSSION POINTS

- Belief that Congress intended 21CC to be wide in remit, and to promote information sharing to further patient care as much as is reasonable
- Original proposed definition of EHI is strong, and with minor amendments can be stronger
- Desire for “EHI” to be “HIPAA plus”
- “Information” should be both machine readable (e.g. coded) and human readable form, update preamble to make clear
- Consent is considered by the Task Force an important class of data that should not be blocked despite concerns over how this would be implemented

Request for Comment and Request for Information Price Information

PRINCIPAL DISCUSSION POINTS

- Task Force believes that Price Transparency is a desirable goal that is achievable
- Further believe that policy levers are required to move the healthcare ecosystem in that direction given the nature of reimbursement
- Tying together Information Blocking regulations too tightly with the regulations required to promote Price Transparency may have the unintended consequence of slowing down Information Blocking regulation finalization
- Recognize that Price Transparency regulation drafting and consideration is underway
- Prices included in EHI should reflect all services and payment information by all parties including any contract terms, rebates or other forms of incentive payment or other form of remuneration
- Recognize many different players, for example, health care providers, health plans, contractors, administrators, pharmacy benefit managers (PBMs), pharmacies, group purchasing organizations (GPOs), technology companies, health IT developers, laboratories, medical devices, brokers and other similar market players)
- The definition of Electronic Health Information encapsulated within the draft regulations includes clear reference to “...or the past, present, or future payment(s) for the provision of health care to an individual”. This ensures that the right information is being exchanged for Price Transparency Regulations could be built upon a solid interactive base
- Potential for ONC to instantiate through HITAC a Task Force under SEC.3002.b.D specifically charged with producing recommendations for regulations to specifically to address improving Price Transparency across the healthcare ecosystem

§ 171.102

Definitions of Health Information Exchange and Network

ORIGINAL TEXT

Health Information Exchange or HIE means an individual or entity that enables access, exchange, or use of electronic health information primarily between or among a particular class of individuals or entities or for a limited set of purposes.

Health Information Network or HIN means an individual or entity that satisfies one or both of the following—

(1) Determines, oversees, administers, controls, or substantially influences policies or agreements that define business, operational, technical, or other conditions or requirements for enabling or facilitating access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

(2) Provides, manages, controls, or substantially influences any technology or service that enables or facilitates the access, exchange, or use of electronic health information between or among two or more unaffiliated individuals or entities.

PROPOSED TEXT

Health Information Exchange or HIE means the act of accessing, transmitting, processing, handling, or other such use of Electronic Health Information, or the organization or entity conducting that act.

Health Information Network or HIN means an individual or entity that satisfies one or several of the following—

(1) Determines, oversees, administers, controls, or defines policies or agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more individuals or entities.

(2) Provides, manages, or controls, any technology or service that enables or facilitates Health Information Exchange between or among two or more individuals or entities.

PRINCIPAL DISCUSSION POINTS

- Considerable discussion across members
- Multiple uses of “health information exchange” within 21CC, capitalized and otherwise, with differing contexts
- Recognize that “exchange” and “network” have multiple common uses in industry right now
- Believe that promoting consistency of usage is advantageous
- Focus upon “exchange” as an act and “network” as an organizational construct
- Need to fit within the bounds of 21CC usage, especially as enforcement is built around that
- Additional preamble to provide usage examples

§ 171.102

Definitions of Health Information Exchange and Network

PROPOSED TEXT

Health Information Exchange or HIE means the act of accessing, transmitting, processing, handling, or other such use of Electronic Health Information, or the organization or entity conducting that act.

Health Information Network or HIN means an individual or entity that satisfies one or several of the following—

- (1) Determines, oversees, administers, controls, or defines policies or agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange between or among two or more individuals or entities.
- (2) Provides, manages, or controls, any technology or service that enables or facilitates Health Information Exchange between or among two or more individuals or entities.

MARKUP FROM ORIGINAL

Health Information Exchange or HIE means ~~the act of an individual or entity that enables~~ accessing, transmitting, processing, handling, exchange, or other such use of eElectronic ~~h~~Health ~~i~~Information, or the organization ~~primarily between or among a particular class of individuals or entity~~ conducting that act. ~~ies or for a limited set of purposes.~~

Health Information Network or HIN means an individual or entity that satisfies one or ~~both~~ several of the following—

- (1) Determines, oversees, administers, controls, or defines ~~substantially influences~~ policies or agreements that define business, operational, technical, or other conditions or requirements for Health Information Exchange ~~enabling or facilitating access, exchange, or use of electronic health information~~ between or among two or more unaffiliated individuals or entities.
- (2) Provides, manages, or controls, ~~or substantially influences~~ any technology or service that enables or facilitates Health Information Exchange ~~the access, exchange, or use of electronic health information~~ between or among two or more unaffiliated individuals or entities.

PRINCIPAL DISCUSSION POINTS

- Considerable discussion across members
- Multiple uses of “health information exchange” within 21CC, capitalized and otherwise, with differing contexts
- Recognize that “exchange” and “network” have multiple common uses in industry right now
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Practices that may implicate the information blocking provision

PRINCIPAL DISCUSSION POINTS

- Patient Access
 - “Open” patient access to EHI about them is likely to implicate the Information Blocking rule.
 - Obligation of actors to provide such access in real-time, and free of charge (beyond approved fee exemptions) is not one that is widely understood or implemented now (even in a “paid” manner)
 - Providing patients with the tools to appropriately parse EHI to ensure it is understandable to them may potentially implicate and ONC should investigate whether this is the case.
- Pricing Information
 - Could readily implicate the Information Blocking rule
 - This information is not routinely exchanged, and will require focus from multiple actors to ensure that the intent of Congress is met
- Actors vs Information type
 - Information Blocking provision is designed to ensure that patient information moves without hindrance across the healthcare ecosystem with appropriate authorization to facilitate the provision and reimbursement of care services to patients
 - These services are likely to be provided by an increasingly broad series of organizations, and these regulations must be structured so that these new entrants to the market are appropriately covered by the conditions herein
 - It would not be advantageous to improving patient outcomes if some actors were implicated (through inclusion) and others were not (by the regulations being mute) as the regulations should be focused upon the blocking of information vs the entity performing the blocking.

Parties affected by the information blocking provision

PRINCIPAL DISCUSSION POINTS

- Healthcare is moving forward, and our traditional view of what/whom is a “Provider”, and how and where they provide care is changing
- Health IT Developers
 - Included if one or more products are “certified”
 - Requiring compliance based upon another products certification potentially problematic
 - Suggestion to focus upon utility of product for processing EHI
 - Potential to required certification for such products?
- The workgroup recommends that that the definition of “Actors” be augmented to include a functional component followed by illustration of common-names for those actors.
- In addition, clarity is sought around those Health IT Developers who have elected for Certification as Certified Health IT vs those developers of health IT that do not seek Certification. Belief that this will be an ever increasing number over the coming years, for a number of reasons.
- New entrants to the health IT market that provide niche services to patients may not seek certification, especially if they are consumer focused vs clinical. New and existing entrants may not seek certification as they adopt alternative business models which reduce the cost of Health IT to end users, and thus have reduced incentive for certification. We need to clarify that a developer of Health IT is a developer because they create IT designed to perform the exchange, use, or access of EHI whether or not that IT is Certified.
- Organizations which may have some degree of ambiguity about whether they are considered an actor would include Retail Pharmacies, Line Insurance Companies, Life Insurance Companies, Retailers who develop and sell home health IOT devices – which might be alleviated by adopting a position of inclusion based upon their handling of Electronic Health Information.

Exceptions

Exceptions

- Workgroup still underway and drafting recommendations
- Will be circulated during next few days

Information Blocking, Assurances, and Communications Conditions and Maintenance of Certification and Enforcement

§ 170.401

Information Blocking

ORIGINAL TEXT

(a) Condition of Certification. 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.

(b) Maintenance of Certification. [Reserved]

MARKUP FROM ORIGINAL

No changes

§ 170.402

Assurances 1/2

ORIGINAL TEXT

(b) Maintenance of Certification.

(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 each of a developer's health IT 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.

MARKUP FROM ORIGINAL

(b) Maintenance of Certification.

(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 each of a developer's health IT 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~~-or~~

(iii) If for a shorter period of time and not due to de-certification, a period of 3 years from the date of withdrawal by the health IT developer of a certified health IT product from certification.

PRINCIPAL DISCUSSION POINTS

- Records should be retained concerning compliance with the Certification Program
- Desire to clarify timeframe for withdrawal

§ 170.402

Assurances 2/2

ORIGINAL TEXT

(b) Maintenance of Certification.

(2) 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) within:

- (i) 24 months of this final rule's effective date, or
- (ii) 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition.

MARKUP FROM ORIGINAL

(b) Maintenance of Certification.

(2) 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) within:

- (i) 24 months of this final rule's effective date, or
- (ii) 12 months of certification for a health IT developer that never previously certified health IT to the 2015 Edition.

(3) [ONC will preserve in an appropriate, publicly accessible format a list of the start and end dates of each previously certified health IT product.](#)

PRINCIPAL DISCUSSION POINTS

- Desire to ensure that a historic list of product certification dates is maintained
- This would codify the CHPL practice already put in place by ONC and ensure it is maintained

§ 170.402

Request for information on participation in the TEF/CA

PRINCIPAL DISCUSSION POINTS

- The Task Force believes it would not be responsible to make recommendations within this RFI until the next draft of TEF is available.

PROPOSAL

- Revisit this area to make recommendations when revised drafts of TEFCAs are published (or have the other TEF Task Force address it).

§ 170.403 Communications 1/7

Whistleblower Protection

ORIGINAL TEXT

(a) *Condition of Certification ...*

(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 or materials 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, or with any other requirement of this part, to ONC or an ONC-ACB.

MARKUP FROM ORIGINAL

(a) *Condition of Certification ...*

(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.

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- (A) Making a disclosure required by law;
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- (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, or with any other requirement of this part, to ONC or an ONC-ACB.

[Any person who makes a communication covered by \(2\)\(i\) to an appropriate entity must not be subject to retaliatory action which could reasonably be considered due to their whistleblowing activity.](#)

§ 170.403 Communications 2/7

Whistleblower Protection

PRINCIPAL DISCUSSION POINTS

- In (2)(i)(A), the group felt that it was reasonable for health IT developers to request that they be notified when a disclosure required by law takes place, and that this was accommodated in the current regulatory text.
- In (2)(i)(C), the group felt that notification to health IT developers prior to (or simultaneous with, if prior was not possible) public reporting would be beneficial for resolving security vulnerabilities prior to the knowledge being widespread.
- In (2)(i)(E) the group felt that a specific protection might be called for those individuals who highlight information blocking practices, and identify them to the appropriate authorities so that the individual is not subject to retaliatory action by the actor identified by the whistleblower. Obviously would need to phrase that a whistleblower would not be able to leverage this as mechanism to avoid sanctions for other activities (e.g. performance etc.).

§ 170.403 Communications 3/7

Unprotected Communications

ORIGINAL TEXT

(a) *Condition of Certification ...*

MARKUP FROM ORIGINAL

(a) *Condition of Certification ...*

(3) Unprotected Communications. Specific communications are not extended the protections or restrictions in this section, where those communications are considered unprotected in that that are either:

(i) protected by other legislation or regulation; or

(ii) false or unlawful

PRINCIPAL DISCUSSION POINTS

- The Task Force suggested an additional category of communications that would not be protected (neither receiving unqualified protection nor their restriction necessitating a permitted restriction).
- The intent was that this category would include communications such as false communications, things protected by attorney-client privilege, and so forth.
- The Task Force did not intend for false communications such as libel to be protected as an unintended consequence.
- Other examples of unprotected communications might include communications sent by a person who improperly obtained the information or received it from somebody who did not have the right to provide the information, such as a hacker..

§ 170.403 Communications 4/7

Intellectual Property Fair Use and Screenshots Pt 1

PROPOSED TEXT

(ii) Permitted prohibitions and restrictions ...

(C) Intellectual property. A health IT developer may prohibit or restrict communications that would reasonably infringe the intellectual property rights existing in the developer's health IT (including third-party rights), provided that—

(1) A health IT developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; and

(2) A health IT developer does not prohibit the communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section.

MARKUP FROM ORIGINAL

(ii) Permitted prohibitions and restrictions ...

(C) Intellectual property. A health IT developer may prohibit or restrict communications that would reasonably infringe the intellectual property rights existing in the developer's health IT (including third-party rights), provided that—

(1) A health IT developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work; and

(2) A health IT developer does not prohibit the fair use communication of screenshots of the developer's health IT, subject to the limited restrictions described in paragraph (a)(2)(ii)(D) of this section, and with the understanding that any actor disclosing the screenshots are responsible for ensuring that each use is being put to "fair use."

PRINCIPAL DISCUSSION POINTS

- Administrative functions of HIT could unintentionally reveal significant intellectual property of health IT developers
- Concerns of sharing screenshots, inherent intellectual property of UI design vs valid reasons why screenshots are both required to be shared and could also be considered "fair use".
- The goal was that the communications should not permit unintended use, such as using screenshots to attempt to copy screen designs from a competitor.
- The restriction that screenshots be permitted to be communicated under fair use principles is not in the regulatory text and the group felt that it deserved further consideration.

§ 170.403 Communications 5/7

Screenshots Pt 2

PROPOSED TEXT

(ii) Permitted prohibitions and restrictions...

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

(2) Not infringe the intellectual property rights of any third parties, provided that —

(i) The developer has used all reasonable endeavors to secure a license (including the right to sublicense) in respect to the use of the third-party rights by communicators for purposes of the communications protected by this Condition of Certification;

(ii) The developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work;

(iii) The developer has put all potential communicators on sufficient written notice of each aspect of its screen display that contains third-party content that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights; and

(iv) Communicators are permitted to communicate screenshots that have been redacted to not disclose third-party content; and

MARKUP FROM ORIGINAL

(ii) Permitted prohibitions and restrictions...

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

(2) Not infringe the intellectual property rights of any third parties, provided that —

(i) The developer has used all reasonable endeavors to secure a license (including the right to sublicense) in respect to the use of the third-party rights by communicators for purposes of the communications protected by this Condition of Certification;

(ii) The developer does not prohibit or restrict, or purport to prohibit or restrict, communications that would be a fair use of a copyright work;

(iii) The developer has put all potential communicators on sufficient written notice ~~of each aspect of its screen display that contains third-party content~~ of a list of third-party content included in the health IT that cannot be communicated because the reproduction would infringe the third-party's intellectual property rights; and

(iv) Communicators are permitted to communicate screenshots that have been redacted to not disclose third-party content; and

PRINCIPAL DISCUSSION POINTS

- Attempting to enumerate on a screen what might be third party content that was the intellectual property of a third party was infeasible
- Preferred approach would be for developers to provide a list of third party content that might be present.

§ 170.403 Communications 6/7

Timelines for Contract Updates

ORIGINAL TEXT

(b) Maintenance of Certification

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

(b)(2)(ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, agree to amend the contract or agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.

MARKUP FROM ORIGINAL

(b) Maintenance of Certification

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

(b)(2)(ii) If a health IT developer has a contract or agreement in existence at the time of the effective date of this final rule that contravenes paragraph (a) of this section, then the developer must in a reasonable period of time, but not later than two years from the effective date of this rule, agree with the relevant client on a plan to amend the contract or an agreement to remove or void the contractual provision that contravenes paragraph (a) of this section.

(b)(2)(iii) The plan required by paragraph (ii) of this section must be completed within five years of the effective date of this rule.

PRINCIPAL DISCUSSION POINTS

- There was concern that ONC's timeline for updates to contracts was insufficient and that the work was significantly underestimated by ONC's regulatory impact analysis.
- There was an example raised from a member of the group of needing to hire four additional lawyers to complete the work in that timeframe.
- The intent was to instead have health IT developers propose a plan for contract updates in 2 years, and update contracts at next renewal or within 5 years.

§ 170.403 Communications 7/7

One Final Point

RECOMMENDED UPDATE

- **Proposed recommendation:** Adjust definitions to clarify that administrative functions of HIT could be “non-user facing aspects” based on the assessment that those communications are not matching the purpose described in 21st Century Cures and also affect a limited set of users.

§ 170.580 ONC review of certified health IT or a health IT developer's actions

PRINCIPAL DISCUSSION POINTS

The Task Force was concerned with the idea that direct review communications could be serious in consequence and email alone would not be a sufficient communication medium

PROPOSED REGULATORY TEXT

§ 170.505 Correspondence.

(a) Correspondence and communication with ONC or the National Coordinator shall be conducted by email, unless otherwise necessary or specified. The official date of receipt of any email between ONC or the National Coordinator and an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart is the date on which the email was sent.

(b) In circumstances where it is necessary for an applicant for ONC-ACB status, an applicant for ONC-ATL status, an ONC-ACB, an ONC-ATL, health IT developer, or a party to any proceeding under this subpart to correspond or communicate with ONC or the National Coordinator by regular, express, or certified mail, the official date of receipt for all parties will be the date of the delivery confirmation to the address on record.

(c) Notices initiating direct review, of potential non-conformity, of non-conformity, of suspension, of proposed termination, of termination, of ban, or concerning the appeals process will be issued simultaneously via certified mail and email.

Public listing of certification bans and terminations

PRINCIPAL DISCUSSION POINTS

- Indefinite communication of past records (ban with start and end date, if lifted) seems appropriate.
- The sense of the Task Force was that knowledge of past bans was important for stakeholders.
- We do not recommend establishing a minimum time period over which a ban must last, even if the health IT developer is a repeat offender.
- The sense of the Task Force was that a minimum ban time period could have unintended consequences.

Applicability of Conditions and Maintenance of Certification for self-developers

PRINCIPAL DISCUSSION POINTS

- The provisions of information blocking and assurances would apply to self-developers also.
- Most of the provisions of Communications would also apply to self developers.
- The Task Force identified one area that would require modification for self-developers, which was in (a)(2)(ii)(A) where the Task Force noticed that employees of a developer can have their communications restricted, but that this could have the consequence of limiting communications of users of the self-developed health IT for the reasons identified under Cures.

PROPOSED REGULATORY TEXT

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

[Healthcare organizations self-developing certified systems are not permitted to restrict the communications of their user employees with respect to these provisions.](#)



The Office of the National Coordinator for
Health Information Technology

Health IT Advisory Committee

Questions and Feedback



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