Office of the National Coordinator for Health Information Technology

HTI-1 Proposed Rule: Information Blocking Enhancements

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5/18/2023

Disclaimers and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the "Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing“ (HTI-1) proposed rule. While every effort has been made to ensure the accuracy of this restatement of those proposals, this presentation is not a legal document. The official proposals are contained in the proposed rule.

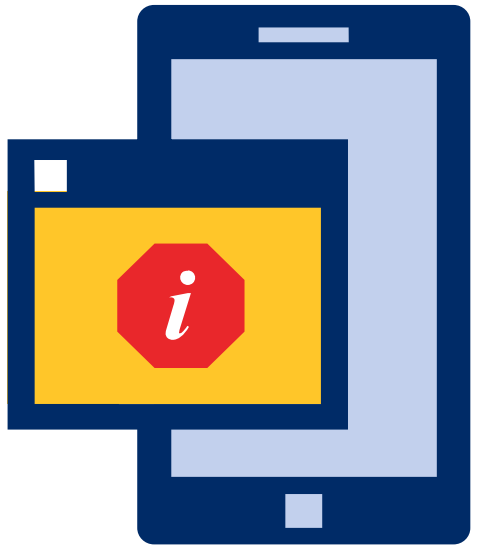
- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the proposed rule as it is contained in the proposed rule. ONC cannot interpret that information, nor clarify or provide any further guidance.

- ONC cannot address any comments made by anyone attending the presentation or consider any such comments in the rulemaking process, unless submitted through the formal comment submission process as specified in the Federal Register.

- This communication is produced and disseminated at U.S. taxpayer expense.

Context: Current Information Blocking Regulations

Overview of Information Blocking Elements



What Makes an Individual or Entity an Information Blocker?

- ❑ Actor regulated by the information blocking provision
- ❑ Involves electronic health information (EHI)
- ❑ Practice is likely to interfere with access, exchange, or use of EHI
- ❑ Requisite knowledge by the actor
- ❑ Not required by law
- ❑ Not covered by an exception

Information Blocking – Knowledge Standard

Health Care Providers

"…**knows** that such practice is **unreasonable** and is likely to interfere with the access, exchange or use of electronic health information…."

Health IT Developers of Certified Health IT and HINs/HIEs

"…**knows, or should know**, that such practice is likely to interfere with the access, exchange or use of electronic health information…."

Information Blocking – Definition of Electronic Health Information (EHI)

- EHI means **electronic protected health information (ePHI)** to the extent that the ePHI would be included in a **designated record set** as these terms are defined for HIPAA.
  - *Except for* psychotherapy notes (45 CFR 164.501) and information compiled in reasonable anticipation of, or for use in, a civil, criminal, or administrative action or proceeding.
- This is applicable whether or not the information is held by or for a HIPAA covered entity.

Definition of Information Blocking

45 CFR 171.103:

(a) Information blocking means **a practice** that—

(1) **Except as required by law** or covered by an exception, is likely to **interfere with** access, exchange, or use of **electronic health information** (EHI); and

(2) If conducted **by a health information technology developer, health information network or health information exchange**, such developer, network or exchange **knows, or should know**, that such practice is likely to interfere with access, exchange, or use of EHI; or

(3) If conducted by a **health care provider**, such provider **knows** that such practice is unreasonable and is likely to interfere with the access, exchange, or use of EHI.

~~(b) Until date specified in 45 CFR 171.103(b), EHI for purposes of § 171.103(a) is limited to the EHI identified by the data elements represented in the USCDI standard adopted in § 170.213.~~

Information Blocking Exceptions

Exceptions that involve not fulfilling requests to access, exchange, or use EHI

1. Preventing Harm Exception

2. Privacy Exception

3. Security Exception

4. Infeasibility Exception

5. Health IT Performance Exception

Exceptions that involve procedures for fulfilling requests to access, exchange, or use EHI

6. Content and Manner Exception

7. Fees Exception

8. Licensing Exception

Context: Information Blocking Enforcement

What Are the Consequences for Information Blocking?

"Actor"	Consequence
Health care providers	• Appropriate disincentives
Health information networks and Health information exchanges	• Civil monetary penalties (CMPs) up to $1 million per violation
Health IT developers of certified health IT	• Civil monetary penalties (CMPs) up to $1 million per violation • Certification action which could include a termination or ban

Notes on Enforcement:

- Civil monetary penalties (CMPs): enforcement dates will be established by current OIG rulemaking.
- Appropriate disincentives: to be established by future HHS rulemaking.

HHS/OIG "Information Blocking" Final Rule

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HHS/OIG **RIN:** 0936-AA09 **Publication ID:** Fall 2022

Title: Amendments to Civil Monetary Penalty Law Regarding Grants, Contracts, and Information Blocking

Abstract:

The final regulation modifies 42 CFR 1003 and 1005 by addressing three issues. First, the 21st Century Cures Act (Cures Act) provision that authorizes the Department of Health and Human Services (HHS) to impose civil monetary penalties, assessments, and exclusions upon individuals and entities that engage in fraud and other misconduct related to HHS grants, contracts, and other agreements. Second, the Cures Act information blocking provisions that authorize the Office of Inspector General to investigate claims of information blocking and provide HHS the authority to impose CMPs for information blocking. Third, the Bipartisan Budget Act of 2018 increases in penalty amounts in the Civil Monetary Penalties Law.

Agency: Department of Health and Human Services(HHS)
RIN Status: Previously published in the Unified Agenda
Major: No
CFR Citation: 42 CFR 1003 42 CFR 1005
Legal Authority: 21st Century Cures Act Pub. L. 114-255 secs. 4004 and 5003 Bipartisan Budget Act of 2018 (BBA 2018), Pub. L. 115-123, sec. 50412
Legal Deadline: None

Priority: Other Significant
Agenda Stage of Rulemaking: Final Rule Stage
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
NPRM	04/24/2020	85 FR 22979
NPRM Comment Period End	06/23/2020	
Final Action	03/00/2023	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0936-AA09

HHS/ONC Health Care Provider Disincentives Rulemaking

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HHS/ONC **RIN:** 0955-AA05 **Publication ID:** Fall 2022

Title: •Establishment of Disincentives for Health Care Providers who Have Committed Information Blocking

Abstract:

The rulemaking implements certain provisions of the 21st Century Cures Act to establish appropriate disincentives for health care providers determined by the Inspector General to have committed information blocking. Consistent with the 21st Century Cures Act, the rulemaking establishes a first set of disincentives using HHS authorities under applicable Federal law, including authorities delegated to the Centers for Medicare & Medicaid Services, and includes related policies necessary to implement these provisions.

Agency: Department of Health and Human Services(HHS)
RIN Status: First time published in the Unified Agenda
Major: Undetermined
CFR Citation: 45 CFR 171 42 CFR 495 42 CFR 413 42 CFR 41
Legal Authority: 42 U.S.C. 300jj–52 42 U.S.C. 1315a 42 U.S.C. 1395jjj 42 U.S.C. 1395ww 42 U.S.C. 1395f 42 U.S.C. 1395w–4 42 U.S.C. 1395yy 42 U.S.C. 1395rr 42 U.S.C. 1395f 42 U.S.C. 1395l 42 U.S.C. 195fff
Legal Deadline: None

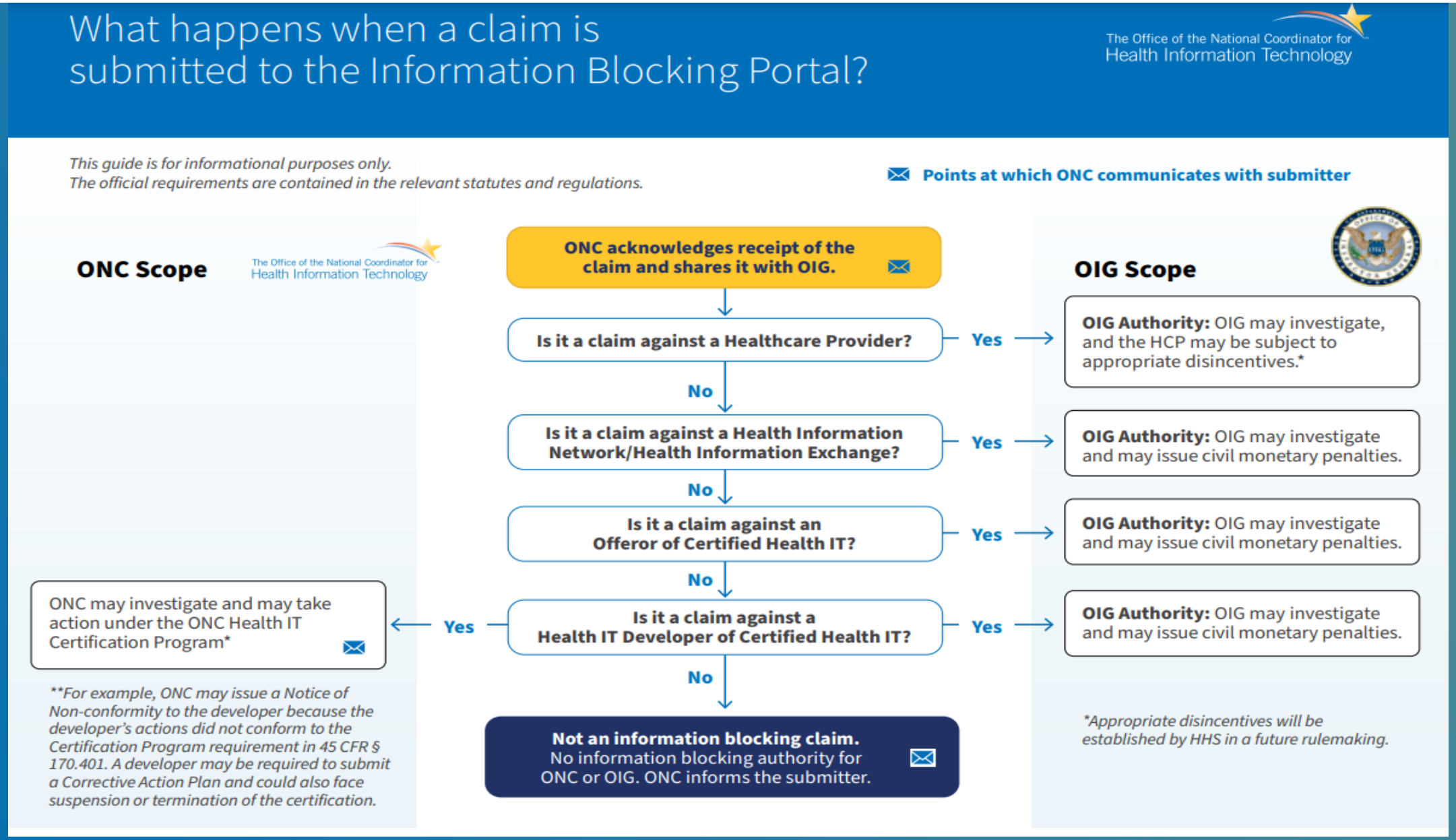
Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule Stage
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
NPRM	09/00/2023	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA05

Information Blocking Claims



https://www.healthit.gov/sites/default/files/page2/2021-11/Information-Blocking-Portal-Process.pdf

IB Claims: By the Numbers

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The Latest on Health Information Technology from ONC

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21st Century Cures Act, Information Blocking

Information Blocking Claims: By the Numbers

Rachel Nelson and Cassie Weaver | FEBRUARY 28, 2022

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The 21st Century Cures Act (Cures Act), signed into law by President Obama in 2016, directed ONC to implement a standardized process for the public to report claims of possible information blocking. The information blocking claims reporting process welcomes claims of possible information blocking from ***anyone*** who believes they may have experienced or observed information blocking. Any information received by ONC in connection with a claim or suggestion of possible information blocking and that could reasonably be expected to facilitate identification of the source of the information (claimant) is protected from disclosure under the Cures Act. The Cures Act authorizes the HHS Office of Inspector General (OIG) to investigate any claim of information blocking.

Today, we posted a **Quick Stat** visualization of data on the information blocking claims we have received through the **Report Information Blocking Portal** since April 5, 2021—the applicability date of the **information blocking regulations**. Moving forward, we generally plan to update these resources on a monthly basis and provide our data in two formats—a **web page** showing cumulative numbers to date and a **downloadable file [XLSX – 92 KB]** that shows what the cumulative counts were each month dating

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Information Blocking Claims: By the Numbers

Total number of portal submissions received, number of submissions that represent claims of possible information blocking, and number of claims by type of potential actor and type of claimant

Source

Submissions received through the Report Information Blocking Portal.

Citation

Office of the National Coordinator for Health Information Technology. 'Information Blocking Claims: By the Numbers,' Health IT Quick-Stat #59 https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers. May 2022.

Overview **Notes**

The 21st Century Cures Act (Cures Act), signed into law by President Obama in December 2016, directed ONC to implement a standardized process for the public to report claims of possible information blocking. This Quick Stats page displays data on claims or suggestions of possible information blocking[1] ONC has received through the Report Information Blocking Portal since April 5, 2021 – the applicability date of the information blocking regulations.

To best understand and use the information provided, it will be important to keep the following in mind:

- Information provided about the perspectives of those submitting claims and the types of potential actors alleged to be information blocking is based solely on an ONC analyst's inference from the facts and allegations as presented by the claimant.
- Any claim ONC receives is simply an allegation or suggestion that information blocking has occurred. Logging a portal submission as a claim does ***not*** imply that an investigation has occurred or been started, or that any determination has been made as to whether information blocking has occurred.
- Where a claim alleges or suggests that conduct implicating the information blocking definition in 45 CFR 171.103 could

https://www.healthit.gov/buzz-blog/21st-century-cures-act/information-blocking-claims-by-the-numbers

https://www.healthit.gov/data/quickstats/information-blocking-claims-numbers

Proposed Enhancements to Information Blocking Regulations

Overview of Information Blocking Enhancements

Definitions

- Offer Health IT
- Health IT Developer of Certified Health IT

Exceptions

- Infeasibility Exception – 1 revised and 2 new conditions
- Manner Exception – TEFCA condition

Requests for Information

- Additional exclusions from “offer” Health IT
- Practices required under the Common Agreement
- Data tagging and filtering capabilities of Health IT

Proposed Updated Definitions

Update Definition of Information Blocking – Proposal

§ 171.103

Information blocking.

(a) Information blocking means a practice that except as required by law or covered by an exception set forth in subpart B or subpart C of this part, is likely to interfere with access, exchange, or use of electronic health information; and

(b) If conducted by:

(1) A health IT developer of certified health IT, health information network or health information exchange, such developer, network or exchange knows, or should know, that such practice is likely to interfere with access, exchange, or use of electronic health information; or

(2) A health care provider, such provider knows that such practice is unreasonable and is likely to interfere with access, exchange, or use of electronic health information.

Current Definition: “Health IT Developer of Certified Health IT”

Health IT developer of certified health IT means an individual or entity, other than a health care provider that self-develops health IT for its own use, that develops or offers health information technology (as that term is defined in 42 U.S.C. 300jj(5)) and which has, at the time it engages in a practice that is the subject of an information blocking claim, one or more Health IT Modules certified under a program for the voluntary certification of health information technology that is kept or recognized by the National Coordinator pursuant to 42 U.S.C. 300jj–11(c)(5) (ONC Health IT Certification Program).

45 CFR 171.102

Defining "Offer Health IT"

Proposal

ONC is proposing to define what it means to *offer health IT* for purposes of the information blocking regulations.

- Generally includes providing, supplying, or otherwise making available certified health IT under any arrangement or terms except for certain beneficial and necessary activities that would be explicitly excluded.
- Would explicitly codify that we do not interpret individuals or other entities to offer health IT when they engage in activities such as certain donation and subsidized supply arrangements, specific implementation and use activities, and certain legal services arrangements.

Benefits

- Give clarity about the implications for an individual or entity's status under information blocking regulations of them making available funding subsidies for, or certain features or uses of, certified health IT.
- Encourage beneficial arrangements under which health care providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT.
- Give health care providers (and others) who use certified health IT certainty that implementing certain health IT features and functionalities, as well as engaging in certain practices that are common and beneficial in an EHR-enabled health care environment, will *not* be considered an offering of certified health IT (regardless of who developed that health IT).

Proposed Updates: Manner Exception

Manner Exception – Renumbered Existing Manner Requested and Alternative Manner Conditions

§ 171.301

Manner exception—When will an actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information not be considered information blocking?

An actor's practice of limiting the manner in which it fulfills a request to access, exchange, or use electronic health information will not be considered information blocking when the practice follows the conditions of this section.

(a) *Manner requested….*

(b) *Alternative manner...*

Manner Exception – Proposed TEFCA Manner Condition

Proposal

ONC proposes to add a TEFCA condition to the proposed revised and renamed Manner exception. The TEFCA condition would offer Qualified Health Information Networks (QHINs), participants, and subparticipants in TEFCA the ability to fulfill EHI requests from any QHIN, participant, or subparticipant in TEFCA using TEFCA means, even if the requestor would have preferred to use another means.

Benefits

- Aligns with the Cures Act's goals for interoperability and the establishment of TEFCA by acknowledging the value of TEFCA in promoting access, exchange, and use of EHI in a secure and interoperable way.
- Facilitates a responding actor reaching agreeable terms with a requestor to fulfill an EHI request and acknowledges that certain agreements have been reached for the access, exchange, and use of EHI.
- Provides a clear, efficient process for actors participating in TEFCA to prioritize the use of TEFCA means for fulfilling requests for access, exchange, and use of EHI from other TEFCA entities.

Manner Exception – Proposed TEFCA Manner Condition

(c) *TEFCA manner.* If an actor who is a QHIN, Participant, or Subparticipant offers to fulfill a request for EHI access, exchange, or use for any purpose permitted under the Common Agreement and Framework Agreement(s) from any other QHIN, Participant, or Subparticipant using Connectivity Services, QHIN Services, or the specified technical services in the applicable Framework Agreement available to both parties, then:

(i) The actor is not required to offer the EHI in any alternative manner;

(ii) Any fees charged by the actor in relation to fulfilling the request are not required to satisfy the exception in § 171.302; and

(iii) Any license of interoperability elements granted by the actor in relation to fulfilling the request is not required to satisfy the exception in § 171.303.

Manner Exception – Proposed TEFCA Manner Condition Definitions

(d) *Definitions.* The terms used in paragraph (c) of this section shall have the following meanings.

(1)(i) *Qualified Health Information Network* (*QHIN*) means a Health Information Network that is a U.S. Entity that has been Designated by the Recognized Coordinating Entity (RCE) and is a party to the Common Agreement countersigned by the RCE.

(ii) *Participant* means a U.S. Entity regardless of whether the entity is a Covered Entity or a Business Associate, that has entered into a Participant-QHIN Agreement whereby the QHIN agrees to transmit and receive information via QHIN-to-QHIN exchange on behalf of the party to the Participant-QHIN Agreement for the Exchange Purposes.

(iii) *Subparticipant* mans a U.S. Entity regardless of whether the entity is a Covered Entity or Business Associate, that has entered into either:

(A) a Participant-Subparticipant Agreement to use the services of a Participant to send and/or receive information; or

(B) a Downstream Subparticipant Agreement pursuant to which the services of a Subparticipant are used of the Common Agreement to send and/or receive information.

(iv) *Connectivity Services* means the technical services provided by a QHIN.

(v) *Framework Agreement(s)* means any one or combination of the Common Agreement, a Participant-QHIN Agreement, a Participant-Subparticipant Agreement, or a Downstream Subparticipant Agreement, as applicable.

(2) QHIN Services means any technical services provided within a QHIN.

Proposed Updates: Infeasibility Exception

Infeasibility Exception – Current Conditions

(a)(1) ***Uncontrollable events***… (revision proposed)

(a)(2) ***Segmentation*** (no change proposed)

(a)~~(3)~~ ***Infeasible under the circumstances*** (no substantive change; proposed to be redesignated (a)(5))

- To meet *infeasible under the circumstances*, actor must demonstrate six separate factors that led to its determination that complying with the request would be infeasible under the circumstances.
  - type of EHI and purpose; cost to the actor; financial and technical resources available to the actor; non-discriminatory practice; control over predominant technology; why the actor was unable to provide the EHI in an alternative manner.

(b) ***Responding to requests*** (must be met in complement to at least 1 condition from paragraph (a) – no change proposed)

Infeasibility Exception – Revised Uncontrollable Events Condition

Proposal

Revise the condition by replacing the words “due to” with “because of” to make clear that a causal connection is needed to use this exception

- The fact that an uncontrollable event occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception.
- The use of the words “due to” in the condition conveys that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI and the uncontrollable event.

Benefits

- Makes clear that the actor must demonstrate a causal connection between not providing access, exchange, or use of EHI and the uncontrollable event.
- Makes clear that the fact that an uncontrollable event specified in § 171.204(a)(1) occurred is not a sufficient basis alone for an actor to meet the uncontrollable events condition of the Infeasibility Exception.

Infeasibility Exception – Proposed Third Party Modification Use Condition

Proposal

A request to enable one or more third parties to modify EHI (including but not limited to creation and deletion functionality) could be considered infeasible unless the request is from a health care provider requesting such use from an actor that is its business associate.

Benefits

Reduces actor burden and uncertainty.

- Less documentation requirements compared under the “infeasible under the circumstances” condition
- No need to determine if another exception applies to the request, such as the Security Exception.

Note: Other exceptions, or other conditions of Infeasibility Exception, may apply where proposed Third Party Modification Use Condition is not met.

Infeasibility Exception – Proposed Third Party Modification Use Condition

Proposal

Available where the actor is asked to provide the ability for a third party (or its technology, such as an application) to modify EHI that is maintained by or for an entity that has deployed health information technology as defined in § 170.102 and maintains within or through use of that technology any instance(s) of any electronic health information as defined in § 171.102.

Not available when the request is from a health care provider requesting (directly, or through another business associate of the health care provider) such modification use from an actor that is its business associate.

Infeasibility Exception – Proposed Manner Exception Exhausted Condition

Proposal – Three Part Test

1. The actor could not reach agreement with a requestor in accordance with § 171.301(a) or was technically unable to fulfill a request for electronic health information in the manner requested;
2. The actor offered all alternative manners in accordance with § 171.301(b) for the electronic health information requested but could not reach agreement with the requestor; and
   - Alternative Proposal for # 2 discussed in preamble: "as few as two alternative manners"
3. **The actor does not provide the same access, exchange, or use of the requested electronic health information to a substantial number of individuals or entities that are similarly situated to the requester.**

•*Currently provides*	•*Substantial number*
•*Same*	•*Similarly Situated*

Benefits

- Provides certainty (do not have to demonstrate infeasibility under the circumstances)
- Reduces inappropriate or unnecessary diversion of actor resources
- Ensures actors reasonably allocate resources toward interoperable, standards-based manners

Requests for Information

Information Blocking RFI: Additional Exclusions from Offer Health IT

We seek comment on whether we should consider proposing in future rulemaking any additional exclusions from the *offer health information technology* or *offer health IT* definition proposed in § 171.102 of this proposal.

Information Blocking RFI: Possible Additional TEFCA Reasonable and Necessary Activities

We seek comment on whether any other particular practices that are not otherwise required by law but are required of an individual person or entity by virtue of their status as a QHIN, Participant, or Subparticipant pursuant to the Common Agreement pose a substantial concern or uncertainty regarding whether such practices *could* constitute information blocking as defined in 45 CFR 171.103.

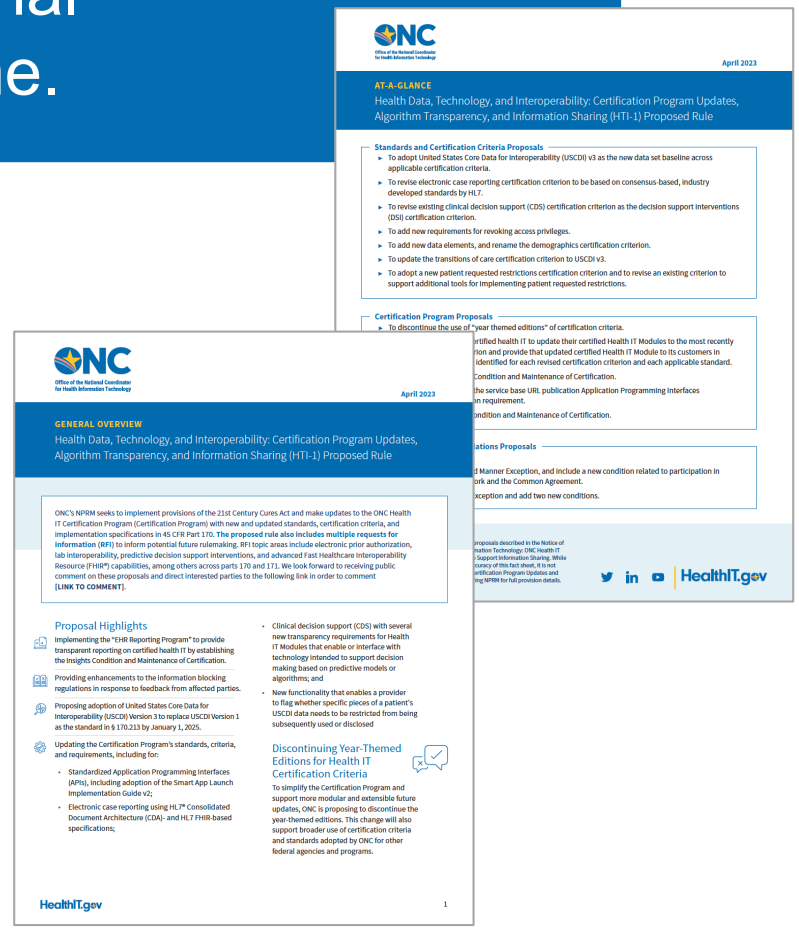
Information Blocking RFI: Health IT Capabilities for Data Segmentation and User/Patient Access

We seek comment to inform steps we might consider taking to improve the availability and accessibility of solutions supporting health care providers' and other information blocking actors' efforts to honor patients' expressed preferences regarding their EHI.

Opportunities to Learn More and Comment

Resources Available on HealthIT.gov!

Visit https://healthIT.gov/proposedrule for additional information. More updates will be added over time.



Fact Sheets

- General Overview
- At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- Update and Provide Certified Health IT
- Information Blocking

Measurement Spec Sheets

One for each of the 9 proposed Insights Condition measures

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Visit https://healthIT.gov/proposedrule for additional information. More updates will be added over time.

Upcoming Webinars

Impacts for Patients and Caregivers

June 1, 1:00 PM ET

Brief Overview/ Questions and Answers

TBD, 1:00 PM ET

HITAC HTI-1 Proposed Rule Task Force

Overarching Charge:
The HTI-1 Proposed Rule Task Force 2023 will evaluate and provide draft recommendations to the HITAC on the Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule.

- All Task Force meetings are open to the public
- Registration and meeting materials can be found at: https://www.healthit.gov/topic/federal-advisory-committees/hitac-calendar

How to Submit a Comment Online

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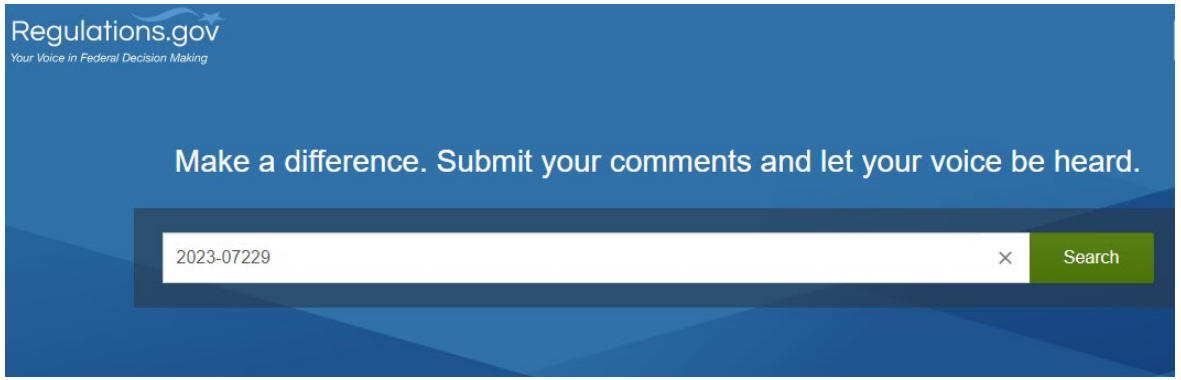
Or, at http://www.regulations.gov search by Federal Register docket number 2023-07229



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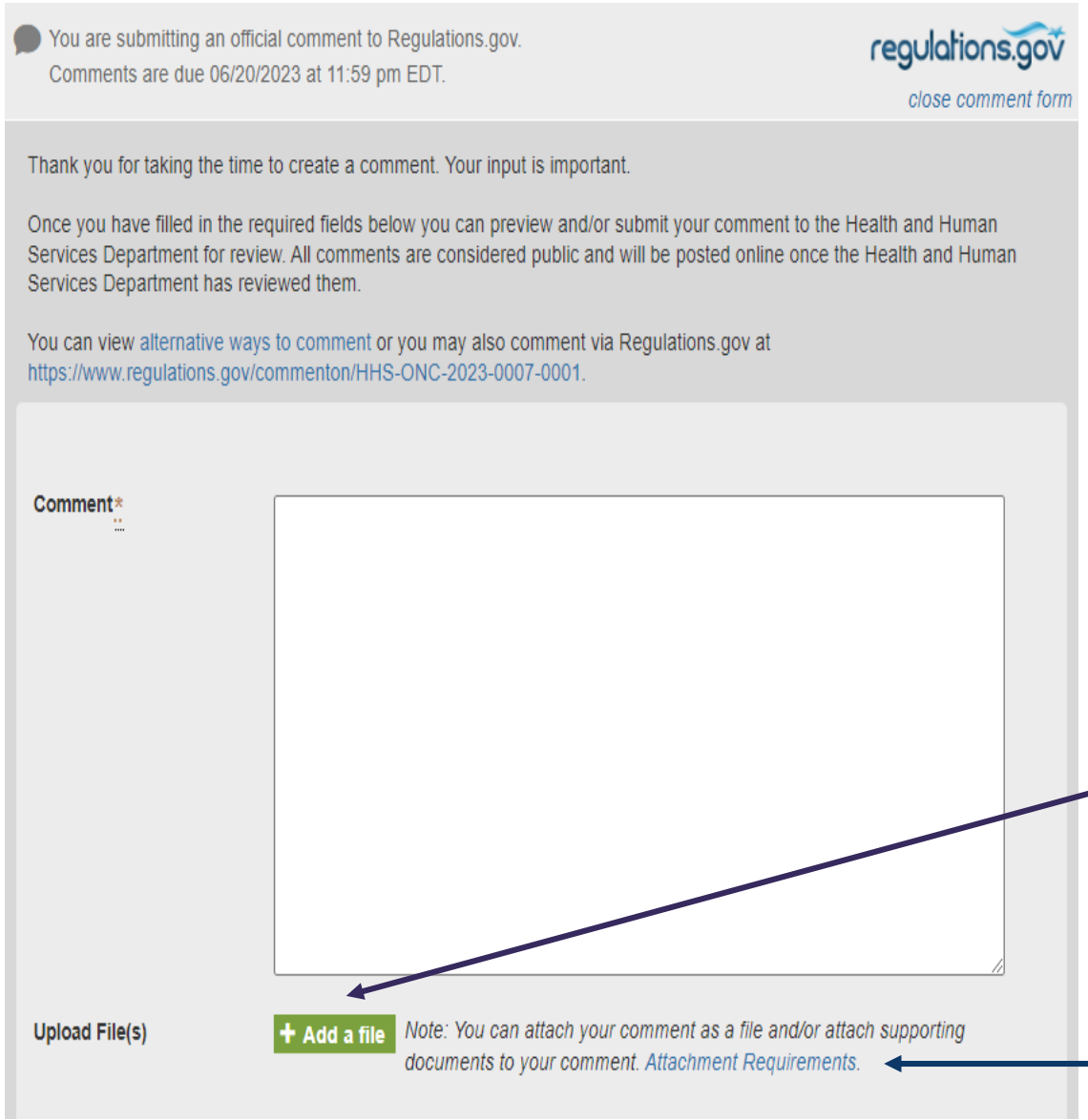

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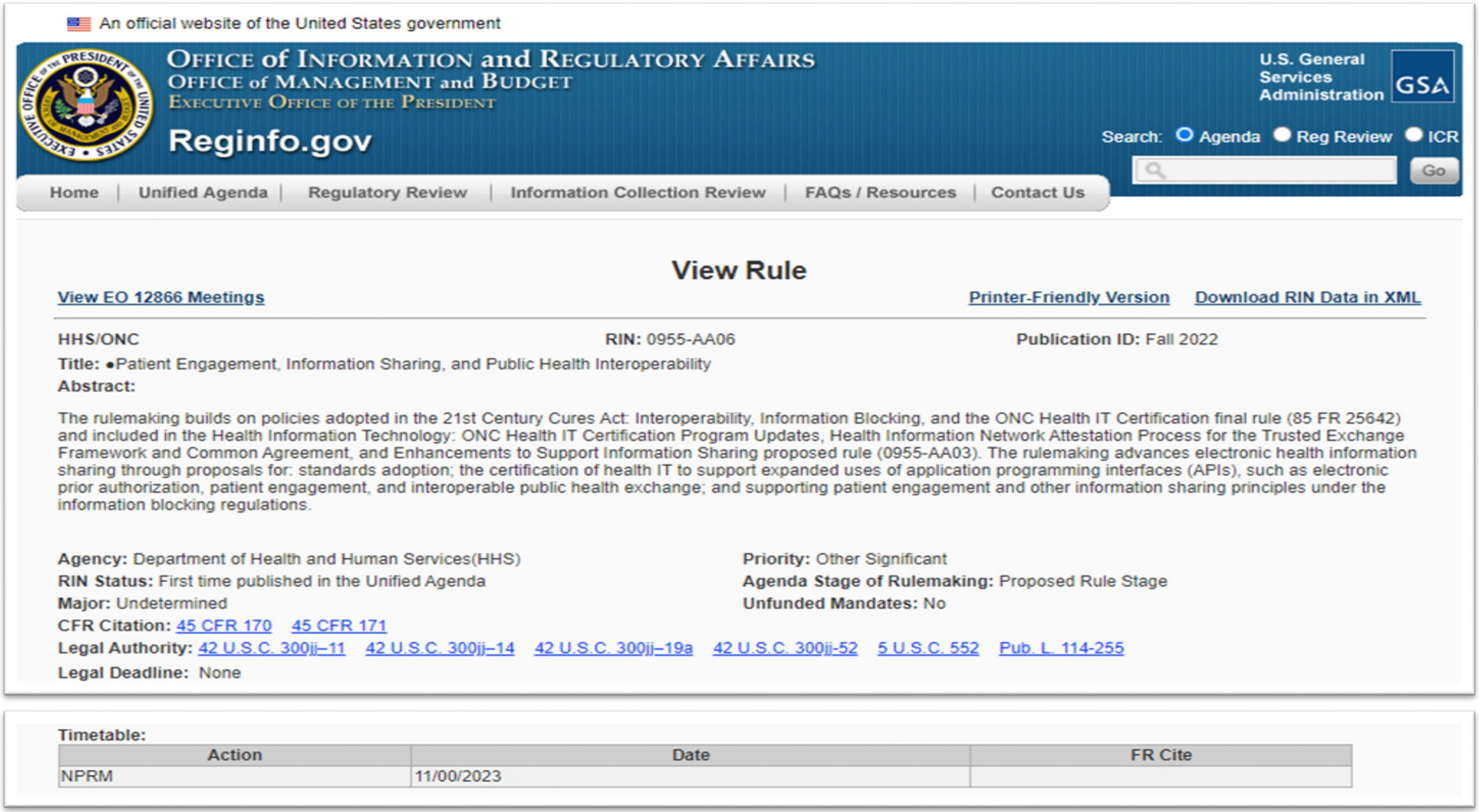
ONC HTI-2 Proposed Rule



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HHS/ONC **RIN:** 0955-AA06 **Publication ID:** Fall 2022

Title: •Patient Engagement, Information Sharing, and Public Health Interoperability

Abstract:

The rulemaking builds on policies adopted in the 21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification final rule (85 FR 25642) and included in the Health Information Technology: ONC Health IT Certification Program Updates, Health Information Network Attestation Process for the Trusted Exchange Framework and Common Agreement, and Enhancements to Support Information Sharing proposed rule (0955-AA03). The rulemaking advances electronic health information sharing through proposals for: standards adoption; the certification of health IT to support expanded uses of application programming interfaces (APIs), such as electronic prior authorization, patient engagement, and interoperable public health exchange; and supporting patient engagement and other information sharing principles under the information blocking regulations.

Agency: Department of Health and Human Services(HHS)
RIN Status: First time published in the Unified Agenda
Major: Undetermined
CFR Citation: 45 CFR 170 45 CFR 171
Legal Authority: 42 U.S.C. 300jj–11 42 U.S.C. 300jj–14 42 U.S.C. 300jj–19a 42 U.S.C. 300jj-52 5 U.S.C. 552 Pub. L. 114-255
Legal Deadline: None

Priority: Other Significant
Agenda Stage of Rulemaking: Proposed Rule Stage
Unfunded Mandates: No

Timetable:

Action	Date	FR Cite
NPRM	11/00/2023	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202210&RIN=0955-AA06

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