



Health Data, Technology, and Interoperability (HTI-2) Proposed Rule: Information Blocking Information Session

**Patient Engagement, Information Sharing, and
Public Health Interoperability Proposed Rule**

August 8, 2024

Disclaimers and Public Comment Guidance

- The materials contained in this presentation are based on the proposals in the “Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability” 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.
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AGENDA

- Brief Review: purpose of HTI-2 Proposed Rule, What “Information Blocking” Is (and Isn’t)
- Information blocking proposals – Definitions
- Information blocking proposals – Existing Exception Updates
- Information blocking proposals – Proposed New Exceptions
- Where to learn more and how to submit comments

Purpose of HTI-2 Proposed Rule



Implementing the 21st Century Cures Act

- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking
- Establish the qualifications necessary for an entity to receive and maintain designation as a QHIN capable of trusted exchange pursuant to TEFCA



Achieving the Goals of the Biden-Harris Administration Executive Orders

- E.O. 13994 “Ensuring a Data-Driven Response to COVID-19 and Future High-Consequence Public Health Threats”
- E.O. 13985 “Advancing Racial Equity and Support for Underserved Communities Through the Federal Government” and E.O. 14091 “Further Advancing Racial Equity and Support for Underserved Communities Through the Federal Government”
- E.O. 14036 “Promoting Competition in the American Economy”
- E.O. 14058 “Transforming Federal Customer Experience and Service Delivery to Rebuild Trust in Government”



Leveraging Health IT and Advancing Interoperability

- HITECH Act
- Interoperability Advancement
- ONC Health IT Certification Program



Information Blocking Definition & Its Existing Exceptions

Quick Review: Elements of the Information Blocking Definition








To be “Information Blocking,” a practice (act or omission) must:




- Be done by actor regulated under the information blocking statute;
- Involve electronic health information (EHI);
- Be likely to interfere with access, exchange, or use of EHI;
- Be done with requisite knowledge by the actor;
- Not be required by law; and
- Not be covered by an exception.

Information Blocking Exceptions in Effect Today

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. Manner Exception
-  7. Fees Exception
-  8. Licensing Exception

Exceptions that involve practices related to actors' participation in TEFCA

-  9. TEFCA Manner Exception



Information Blocking Proposals in HTI-2

Overview of Information Blocking Proposals



Defined Terms Enhancements

- Health Care Provider, Health IT, Business Day
- Certain practices meeting “interference” definition



Existing Exceptions Updates

- Infeasibility – revise 2 conditions
- Privacy – expand 2 sub-exceptions
- TEFCA Manner – Request for Comment



Proposed New Exceptions

- Protecting Care Access
- Requestor Preferences



Information Blocking — Defined Terms Enhancements

“Health Care Provider”

PROPOSAL

Update the wording of the “health care provider” regulatory definition by adding explicit reference to the definitions of “laboratory” and “pharmacist” in the same section of the Public Health Service Act as the currently cited definition of “health care provider.”

BENEFITS

- Enhanced certainty for laboratories, pharmacists, and other interested parties of precisely what “laboratory” and “pharmacist” mean within the definition of “health care provider” for purposes of the information blocking regulations.

“Health Information Technology” or “Health IT”

PROPOSAL

Codify that for purposes of the information blocking regulations “health information technology” (and its short form “health IT”) have the same meaning as they do in ONC’s authorizing statute.

BENEFITS

- Enhanced certainty for actors and other interested parties as to what the term “health IT” means within the information blocking regulations.

“Business Day”

PROPOSAL

Codify that for purposes of information blocking regulations “business day” (or “days”) means Monday through Friday except for public holidays specified in U.S. code or declared a (federal) holiday by federal statute or executive order.

BENEFITS

- Would give actors and other interested parties certainty as to which days count as “business days” for purposes of information blocking regulations.
- Same days would count as “business days” under information blocking as (we propose) would count for purposes of ONC Health IT Certification Program regulations.

“Interfere With” or “Interference”

PROPOSAL

Add a new section (§ 171.104) to the information blocking regulations that would codify that certain practices (acts and omissions) constitute “interference” for purposes of the information blocking definition.

BENEFITS

- The proposal would give actors (and those who seek to interact with them to access, exchange, or use EHI) confidence that certain practices of the following general kinds will be “interference” for purposes of the information blocking definition:
 - Actions taken by an actor to impose delays on other persons’ access, exchange, or use of EHI;
 - Non-standard implementation of health IT and other acts to limit interoperability of EHI or the manner in which EHI is accessed, exchanged, or used by other persons;
 - Improper inducements or discriminatory contract provisions; and
 - Omissions (failures to act) when action is necessary to enable or facilitate appropriate information sharing, such as where access, exchange, or use of an individual’s EHI is required by law or where it is permitted by law and not subject to restrictions requested by the individual (to which an actor has agreed).
- Proposal would not set a fixed universe of practices that could constitute “interference,” leaving important room for case-by-case assessment across current variations in health IT and future innovations.

Certain Practices Constituting “Interference” for Purposes of the Information Blocking Definition

(a) The following constitute practices that are likely to interfere with the access, exchange, or use of electronic health information (EHI) for purposes of § 171.103:

(1) **Delay on new access.** Delaying patient access to new EHI, such as diagnostic testing results, so clinicians or other actor representatives can review the EHI.

(2) **Portal access.** Delaying patient access to EHI in a portal when the actor has the EHI and the actor’s system has the technical capability to support automated access, exchange, or use of the EHI via the portal.

(3) **API access.** Delaying the access, exchange, or use of EHI to or by a third-party app designated and authorized by the patient, when there is a deployed application programming interface (API) able to support the access, exchange, or use of the EHI.

(4) **Non-standard implementation.** Implementing health information technology in ways that are likely to restrict access, exchange, or use of EHI with respect to exporting electronic health information, including, but not limited to, exports for transitioning between health IT systems.

(5) **Contract provisions.** Negotiating or enforcing a contract provision that restricts or limits otherwise lawful access, exchange, or use of EHI.

(6) **Non-compete provisions in agreements.** Negotiating or enforcing a clause in any agreement that:

- (i) prevents or restricts an employee (other than the actor’s employees), a contractor, or a contractor’s employee
- (ii) who accesses, exchanges, or uses the EHI in the actor’s health IT
- (iii) from accessing, exchanging, or using EHI in other health IT in order to design, develop, or upgrade such other health IT.

Certain Practices Constituting “Interference”

(7) ***Manner or content requested.*** Improperly encouraging or inducing requestors to limit the scope, manner, or timing of EHI requested for access, exchange, or use.

(8) ***Medical images.*** Requiring that the access, exchange, or use of any medical images (including, but not limited to, photograph, x-rays, and imaging scans) occur by exchanging physical copies or copies on physical media (such as thumb drive or DVD) when the actor and the requestor possess the technical capability to access, exchange, or use the images through fully electronic means.

(9) ***Omissions.*** The following omissions:

- (i) Not exchanging EHI under circumstances in which such exchange is lawful;
- (ii) Not making EHI available for lawful use;

(iii) Not complying with another valid law enforceable against the actor that requires access, exchange or use of EHI;

(iv) A Certified API Developer (as defined in 45 CFR 170.404) failing to publish API discovery details as required by the maintenance of certification requirement in 45 CFR 170.404(b)(2);

(v) An API Information Source (as defined in 45 CFR 170.404) failing to disclose to the Certified API Developer the information necessary for the Certified API Developer to publish the API discovery details required by 45 CFR 170.404(b)(2).

(b) The acts and omissions that will constitute practices that are likely to interfere with the access, exchange, or use of electronic health information (EHI) for purposes of § 171.103 include acts and omissions beyond those listed in paragraph (a) of this section.

TEFCA and “Interference” – Complying With Required Provisions of the Common Agreement Likely Not an Interference

Proposed rule clarifies that it would likely not be interference for TEFCA Qualified Health Information Networks™ (QHINs™), Participants, or Subparticipants to comply with required provisions of the Common Agreement and the incorporated TEFCA Terms of Participation and TEFCA Standard Operating Procedures, respectively.

- In certain cases, QHINs, Participants, or Subparticipants may engage in practices not specifically required by the Common Agreement, terms of participation, and standard operating procedures. Our guidance does not extend to such permissible or optional practices.
- Not complying with a request for access, exchange, or use of EHI via the standards adopted in [45 CFR 170.215](#), including version(s) of those standards approved pursuant to [45 CFR 170.405\(b\)\(8\)](#), *could* be an interference, *could* implicate the information blocking definition, and would not be covered by the TEFCA Manner Exception (§ 171.403).
- In general and for clarity, any practice (act or omission) between TEFCA entities that is not one specifically required by the Common Agreement, including its terms of participation and standard operating procedures, as well as any practice involving or affecting non-participants in TEFCA *could* also be an interference.

For practices that are not required under TEFCA and/or that affect non-participants in TEFCA, which could constitute an interference, all of the other voluntary exceptions in part 171 would be available, as appropriate.



Request for Comment: TEFCA Manner Exception

Request for Comment – TEFCA Manner Exception

We finalized a new TEFCA Manner Exception in the HTI-1 Final Rule. We stated that the new TEFCA Manner Exception (§ 171.403) provides that an actor’s practice of limiting the manner in which it fulfills a request to access, exchange, or use EHI to be providing such access, exchange, or use to only via TEFCA will not be considered information blocking when it follows certain conditions (89 FR 1388).

We request comment on:

- **Fees & Licensing:** Whether there are drawbacks to applying the Fees and Licensing Exceptions, and if we should continue to apply them to the TEFCA Manner Exception as currently required in § 171.403(d).
- **API FHIR Limitation:** Should the limitation be expanded to include exchange based on versions of the FHIR standards that are more advanced than those adopted in 45 CFR 170.215 or approved through the 45 CFR 170.405(b)(8) “Standards Version Advancement Process – voluntary updates of certified health IT to newer versions of standards and implementation specifications”?
- **Alternative:** A Participant or Subparticipant who makes a request for access, exchange, or use of EHI via FHIR API will at first make such a request through a QHIN, but in time, a Participant or Subparticipant could directly request access, exchange, or use of EHI via FHIR API standards from another Participant or Subparticipant in a different QHIN.
 - Option 1: We could sunset the API FHIR limitation once all QHINs can support brokered FHIR.
 - Option 2: We could sunset the API FHIR limitation if all QHINs, Participants and Subparticipants support facilitated FHIR exchange.
 - Option 3: We could maintain the exception as is, regardless of FHIR API adoption among TEFCA entities.



Information Blocking — Existing Exceptions Updates

Privacy Exception Updates

Privacy Exception — “Individual” Definition

PROPOSAL

Correct typographical errors in the codified definition of the word “individual” within the Privacy Exception (§ 171.202)

BENEFITS

- Improves clarity for actors and other interested persons by including in each paragraph of the “individual” definition only the precise, accurate cross-references.
- Does not change the definition or how it would operate; merely corrects codified text to match the substance of the definition as explained in the ONC Cures Act Final Rules (85 FR 25846 through 25847)

Privacy Exception – Sub-Exception for Denying Individuals Access on “Unreviewable Grounds”

PROPOSAL

- Broaden the applicability of existing sub-exception (§ 171.202(d)) so that it would be available to any actor responding to a request for EHI under the same circumstances and subject to the same requirements an actor that is also a HIPAA covered entity or business associate could deny an individual access on “unreviewable grounds” without the denial constituting information blocking.
- Update name of sub-exception to be shorter and to align with proposed broader availability

BENEFITS

- Improved consistency for individuals, who may seek access to EHI from both actors who are required to comply with the HIPAA Privacy Rule and actors who are not required to comply with the HIPAA Privacy Rule.
- For actors not required to comply with the HIPAA Privacy Rule, assurance that they could choose to deny individual access on “unreviewable grounds” without committing information blocking (under the same circumstances and subject to the same requirements as an actor that is also a HIPAA covered entity or business associate could under the sub-exception as it stands today).
- Simpler exception for all actors.

Privacy Exception – Sub-Exception for Respecting Individual’s Request Not to Share EHI with Others

PROPOSAL

- Broaden the sub-exception’s availability by removing its existing limitation to individual-requested restrictions on EHI sharing that are permitted by other applicable law.
- Shorten the title of the sub-exception for ease of reference.

BENEFITS

- Improved assurance for any actor who elects to honor an individual’s request for restrictions on sharing of the individual’s EHI that applying those restrictions will not be considered information blocking if the requirements of this sub-exception are satisfied.
- Simpler exception that is easier for actors to avail themselves of, if they want to grant an individual’s request for restrictions.
- Enhanced assurance for individuals that information blocking regulations support actors’ choices to honor the individual’s request and not share EHI when the individual asks it not be shared.

Infeasibility Exception Updates

Infeasibility Exception — Overview

(a)(1) *Uncontrollable events...* (no change proposed)

(a)(2) *Segmentation* (update proposed)

(a)(3) *Third party seeking modification use* (update proposed)

(a)(4) *Manner exception exhausted* (no change proposed)

(a)(5) *Infeasible under the circumstances* (no change proposed)

(b) *Responding to requests* (must be met in complement to at least 1 condition from paragraph (a)) (update proposed)

Infeasibility Exception — Segmentation Condition Update

PROPOSAL

Expand application of the condition to circumstances where an actor cannot segment from other EHI the EHI that they cannot share or have chosen to withhold. Specifically, the *expansion* would make the condition applicable where the actor has chosen to withhold EHI consistent with:

- Privacy sub-exceptions applicable to denials of individual access on unreviewable grounds (§ 171.202(d)) or health IT developer of certified health IT not covered by HIPAA (§ 171.202(c))
- Proposed new Protecting Care Access Exception (§ 171.206)

BENEFITS

- Would accommodate more circumstances where another exception would apply to an actor choosing to withhold some EHI under an applicable exception but the actor cannot unambiguously segment that EHI from other requested EHI (that applicable law allows the actor to share).

Infeasibility Exception — *Third Party Modification Use Condition Update*

PROPOSAL

Revise the condition so it would not apply when third party modification use is sought:

- By any HIPAA covered entity or business associate from an actor that is their business associate
- By any health care provider who is not a HIPAA covered entity from an actor whose activities **would** make the actor a business associate of that same health care provider if that health care provider were a HIPAA covered entity.

BENEFITS

- Recognizes the need of covered entities and their business associates to regularly modify EHI held by other business associates of the same covered entity.
- Recognizes that health care providers who are not HIPAA covered entities often have similar relationships with actors who provide services that would make the actor a business associate if the health care provider were a HIPAA covered entity, and that these providers may need or want a third party to modify EHI held by such actors on their behalf.

Infeasibility Exception — *Responding to Requests Condition Update*

PROPOSAL

Revise the *responding to requests* condition (§ 171.204(b)) to offer actors a more flexible response timeframe where the reason(s) for infeasibility are consistent with the *manner exception exhausted* (§ 171.204(a)(4)) or *infeasible under the circumstances* (§ 171.204(a)(5)) conditions.

Retain existing ten-business-day response timeframe where reason(s) for infeasibility are consistent with the *uncontrollable events* (§ 171.204(a)(1)), *segmentation* (§ 171.204(a)(2)), or *third party seeking modification use* (§ 171.204(a)(3)) conditions

BENEFITS

- Would allow responding actors who initiate good-faith collaborative engagement with the requestor within ten business days of the actor receiving the request a flexible timeframe within which to discuss the potential infeasibility of the request as received and potentially feasible alternative ways to achieve information sharing.
- For requestors, in addition to more flexible time for discussions with the actor, would continue to provide for a response indicating reason(s) for infeasibility within 10 days of the actor's determination of infeasibility.
- For both actors and requestors, revised wording would offer enhanced clarity as to when the 10 business day timeframe for responding to requests infeasible for reasons consistent with the *uncontrollable events* (§ 171.204(a)(1)), *segmentation* (§ 171.204(a)(2)), or *third party seeking modification use* (§ 171.204(a)(3)) starts.

Infeasibility Exception — *Responding to Requests* Alternative Proposal

PROPOSAL

HTI-2 includes an alternative proposal would establish maximum timeframe(s) within which good faith discussions and negotiations must, in order for the *responding to requests* (§ 171.204(b)) to be met, reach a plan to proceed or an actor's determination that a particular requested access, exchange, or use of EHI is not feasible.

Under the alternative proposal, the maximum amount of time would be:

- 3, 5, 10, 20, or 30 business days after the date the actor receives any initial request; or
- one of those timeframes for any request that does not implicate the HIPAA Privacy Rule's individual right of access (45 CFR 164.524) and the maximum timeframe allowed under 45 CFR 164.524 for those requests that do also implicate it.

BENEFITS

- A maximum timeframe requirement would create additional clarity for actors and predictability for requestors.



Information Blocking — Proposed New Exceptions

New Protecting Care Access Exception

PROPOSAL

Under its specified conditions, the exception would apply to practices likely to interfere with EHI access, exchange, or use an actor believes in good faith could result in a risk of potential exposure to legal action, including investigation, that the actor believes could potentially be brought:

- under law in effect at the time the actor engages in the practice;
- against patients, health care providers, or those who help make providing or receiving care possible;
- for the mere fact that
 - a person sought, obtained, provided, or facilitated reproductive care that was lawful under the conditions in which it was provided; or
 - (where the patient protection condition applies) a patient has health conditions or history for which reproductive health care is often sought, obtained, or medically indicated.

BENEFITS

- Offers actors certainty that practices satisfying the exception will not be considered “information blocking”
- Assures patients that the information blocking regulations support actors limiting EHI sharing in response to risks that arise over time, while also continuing to support patients’ own access to their EHI and other sharing of EHI consistent with applicable law and patient preferences that fosters better patient care.
- Supports continued advances in digitization, interoperability, and public confidence in the nationwide health information technology infrastructure.

New Protecting Care Access Exception

OVERVIEW

An actor's practice implemented to reduce the risk of potential exposure to legal action would not be information blocking when the actor's practice satisfies at least 2 conditions:

Threshold



Patient Protection

< OR >

Care Access



- **Threshold Condition Requirements:**
 - 1) Belief (an actor holds in good faith)
 - 2) Tailoring (of practice)
 - 3) Implementation (of practice) based on actor's
 - organizational policy – or –
 - case-by-case determination
- **Patient Protection Condition** – applicable to practices actor believes could reduce the patient's risk of potential exposure to legal action based on mere fact reproductive health care sought/received or a health history or condition for which reproductive health care often sought, received, or medically indicated
- **Care Access Condition** – applicable to practices actor believes could reduce potential exposure to legal action of health care providers or other persons who provide care or are otherwise involved in facilitating reproductive health care that is lawful under circumstances provided

Proposed New Requestor Preferences Exception

New Requestor Preferences Exception

PROPOSAL

A proposed Requestor Preferences Exception (to be codified in 45 CFR 171). This exception would apply where an actor honors a requestor's preference(s) expressed or confirmed in writing for:

1. Limitations on the amount of EHI made available to the requestor;
2. The conditions under which EHI is made available to the requestor;
3. When EHI is made available to the requestor for access, exchange, or use.

BENEFITS

- The exception would offer actors certainty that, under the exception's specified conditions, an actor's honoring these requestor preferences would not constitute information blocking.
- Would apply to honoring preferences of any requestor, including individuals, health care providers, and any other requestor of access, exchange, or use (for permissible purposes) of EHI the actor has.
- Flexible to accommodate, to the extent the actor may be able and willing to do so, the considerable variety of unique preferences it is possible for a requestor to have in comparison even to similarly situated requestors.

Resources Available on HealthIT.gov!


RESOURCES AVAILABLE

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

- General Overview
- USCDI v4
- Electronic Prescription
- Information Blocking (Exceptions)
- Information Blocking (Definitions)
- Public Health Reporting
- TEFCAs
- Modular API
- Patient, Provider, and Payer API
- Key Compliance Dates

JULY 2024
Health Data, Technology, and Interoperability (HTI-2): Patient Engagement, Information Sharing, and Public Health Interoperability PROPOSED RULE

HTI-2 Proposed Rule Overview



Overview

Since the passage of the 21st Century Cures Act (Cures Act), the health IT and health care industry has made significant strides towards data interoperability throughout health care. The Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability (HTI-2) Proposed Rule builds on this foundation through new proposals that enable better and more equitable patient care through systemic improvements in the access, exchange, and use of data.

Key Proposals:

- A New Baseline Version of USCDI
- Minimum Standards Code Set Updates
- Bulk Data Enhancements
- Electronic Prior Authorization
- Information Blocking
- TEFCAs™
- New and Revised Standards and Certification Criteria Proposal

HTI-2 Proposed Key Dates

Health IT developers with a Health IT Module certified to any revised certification criterion, as defined in 45 CFR 170.102, must update their certified Health IT Module and provide such updated health IT to their customers in accordance with the timelines defined for a specific criterion and/or standard included in § 170.315. Below are key dates for the certification criteria we propose to revise in HTI-2. Note, the new certification criteria proposed in HTI-2 have specified timelines for adoption in the ONC Health IT Certification Program (Program), but have been purposefully omitted from this fact sheet.

We propose that by January 1, 2026, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

- § 170.315(d)(7) "privacy and security - health IT encryption"
- § 170.315(d)(8) "privacy and security - trusted connection"
- § 170.315(d)(12) "privacy and security - protect stored authentication credentials"

We propose that by January 1, 2027, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

- § 170.315(f)(6) "public health - antimicrobial use and resistance reporting - transmission to public health agencies"
- § 170.315(f)(7) "public health - health care surveys - transmission to public health agencies"

We propose that by January 1, 2028, a health IT developer of a Health IT Module certified to the following criteria must update their Health IT Module and provide the updated version to their customers in order to maintain certification of that Health IT Module.

<ul style="list-style-type: none"> • § 170.315(a)(2) "computerized provider order entry - laboratory" • § 170.315(a)(12) "family health history" • § 170.315(b)(1) "transitions of care" • § 170.315(b)(2) "clinical information reconciliation and incorporation" • § 170.315(b)(3) "electronic prescribing" • § 170.315(b)(6) "real-time prescription benefit" • § 170.315(c)(4) "clinical quality measures - filter" • § 170.315(d)(13) "privacy and security - multi-factor authentication" • § 170.315(e)(1) "patient engagement - view, download, and transmit to 3rd party" • § 170.315(f)(2) "public health - immunization registries" 	<ul style="list-style-type: none"> • § 170.315(f)(2) "public health - syndromic surveillance - transmission to public health agencies" • § 170.315(f)(3) "public health - reportable laboratory results" • § 170.315(f)(4) "public health - cancer registry reporting" • § 170.315(f)(5) "public health - transmission to public health agencies - electronic case reporting" • § 170.315(f)(9) "design and performance - application access - all data request - functional requirements" • § 170.315(g)(10) "design and performance - standardized API for patient and population services - data response"
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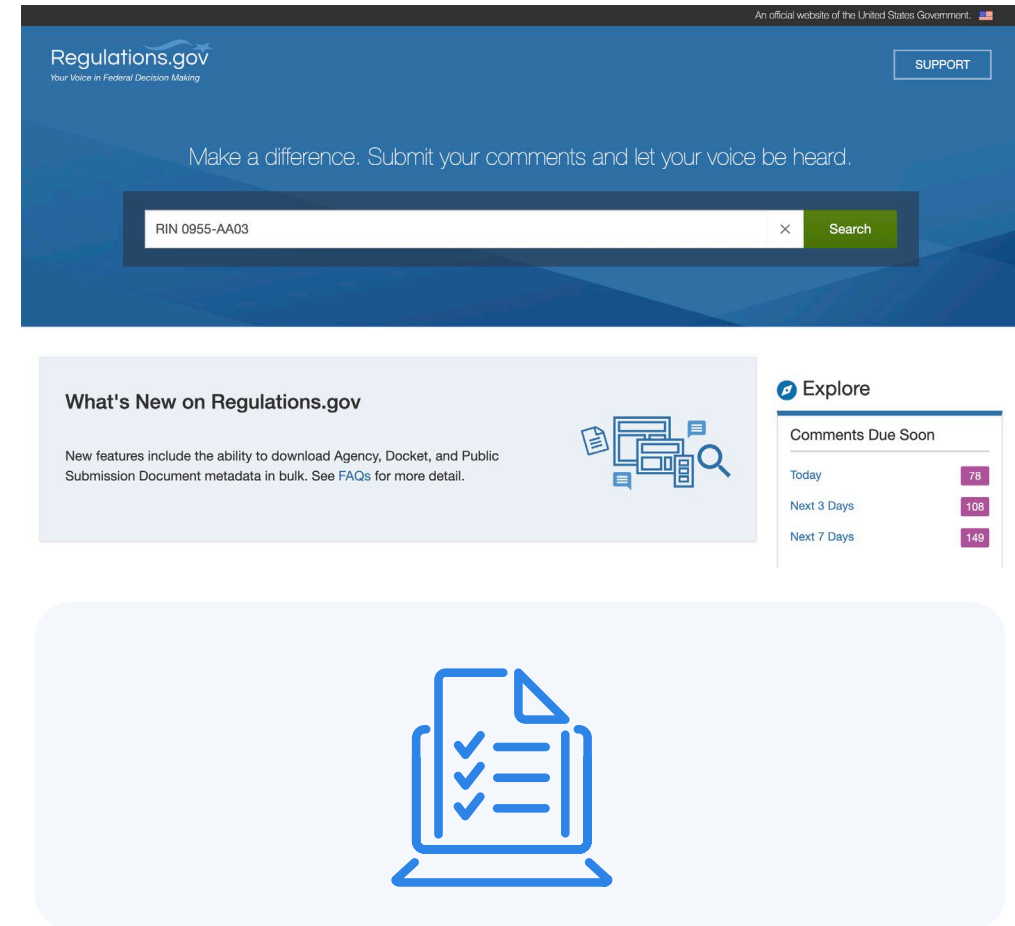
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Federal eRulemaking Portal

You may submit comments, identified by RIN 0955-AA06, through <http://www.regulations.gov>. Attachments should be in Microsoft Word, Microsoft Excel, or Adobe PDF; however, we prefer Microsoft Word.



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Wednesday July 17, 2024. at 2pm ET

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[Presentation Slides \[PDF - 2.2 MB\]](#)

HTI-2 Proposed Rule Public Health Information Session

Tuesday, July 30, 2024, at 2pm ET

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HTI-2 Proposed Rule Patient, Payer, Provider API Information Session

Thursday, August 15, 2024, at 2pm ET

[Register for the information session](#)



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