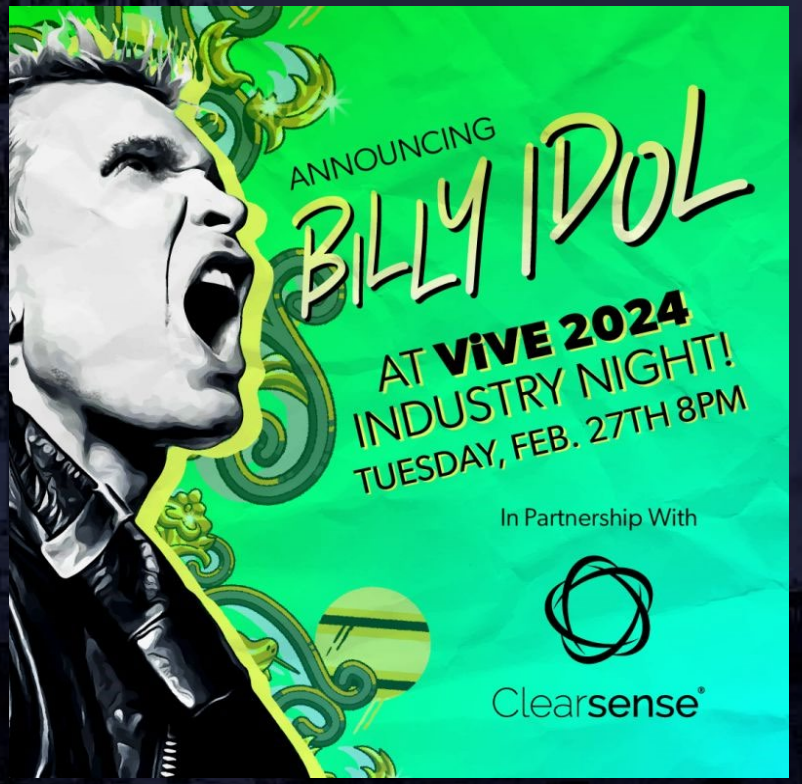
CHIME Public Policy team's Cheat Sheet on the final rule here: https://chimecentral.org/content/chime-cheat-sheet-on-hti-1-final-rule and email policy@chimecentral.org if you have any questions!

ViVE 2024



Learn more at: https://chimecentral.org/events/vive-event and email policy@chimecentral.org if you would like to meet with the team in LA!

CHIME PUBLIC POLICY
WORKING FOR YOU IN WASHINGTON

Office of the National Coordinator for Health Information Technology

HTI-1 Final Rule Overview

Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

2/6/2024

Disclaimers

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.

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

Agenda

- Overview
- ONC Certification Criteria for Health IT (edition-less)
- Certification Compliance Timeframes
- United States Core Data for Interoperability (USCDI) – USCDI v3 Baseline
- Patient Requested Restrictions
- DSI Criterion and Condition and Maintenance of Certification Requirements
- Information Sharing

Purpose of HTI-1 Final Rule

Implementing the 21st Century Cures Act

- EHR Reporting Program
- APIs that allow EHI to be accessed, exchanged, and used without special effort
- Reasonable and necessary activities that do not constitute information blocking

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. 14110 “Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence”

Leveraging Health IT and Advancing Interoperability

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

Discontinuing Year-Themed "Editions"

HTI-1 Final Rule

Discontinues the year-themed editions and establishes a single set of certification criteria, "ONC Certification Criteria for Health IT"

Benefits

- Allows the Certification Program and health IT developers to more effectively utilize new and updated standards and functionality in a timely manner
- Allows users of health IT to work in partnership with health IT developers to update their systems for new standards or functionality in the manner that works best for their unique needs
- Assists health care industry participants in other HHS programs that reference Certification Program standards and criteria, such as CMS's Promoting Interoperability Program, by ensuring developers provide timely updates for any new or updated certification criteria
- Supports users of health IT by reducing potential confusion of tracking use of different editions of certified health IT

Establishing Applicability and Expiration Dates for Certification Criteria and Standards

HTI-1 Final Rule

- Establishes the dates by which a prior version of a criterion is no longer applicable when a revised version (including new and revised standards) of that criterion is adopted
- Establishes applicable timelines, including expiration dates, for the adoption of standards when a new, revised, or updated version of the standard is adopted for the same purpose

Benefits

- Supports establishment of clear timelines associated with the specific criterion or standard

- Facilitates ease of reference for federal, state, local or tribal programs seeking to align their program requirements to the standards and implementation specifications available in certified health IT
- Ensures that customers are provided with timely technology updates

United States Core Data for Interoperability (USCDI) v3

- Adopted USCDI v3 as the new baseline for certification.
- Expanding the data elements and data classes included in USCDI increases the amount of data available to be used and exchanged for patient care.
  - ONC is expanding the USCDI by moving from USCDI v1 to the adoption of USCDI v3 in 45 CFR 170.213(b) by **January 1, 2026**. Until that time, both versions will be accepted as in compliance with the USCDI standard in § 170.213.
- Health IT Modules certified to criteria that reference USCDI would need to update to USCDI v3 by the January 1, 2026, using the applicable US Core IG and C-CDA Companion Guide:

- § 170.315(b)(1): Transitions of Care
- § 170.315(b)(2): Clinical Information Reconciliation and Incorporation
- § 170.315(b)(9): Care Plan*
- § 170.315(e)(1): View, Download, and Transmit 3rd Party
- § 170.315(g)(6): Consolidated CDA Creation Performance
- § 170.315(g)(9): Application Access-All Data Request
- § 170.315(g)(10): Standardized API for Patient and Population Service

* § 170.315(b)(9) is only updated to the C-CDA Companion Guide

USCDI v3


Allergies and Intolerances
Substance (Medication)
Substance (Drug Class)
Reaction
Assessment and Plan of Treatment
Assessment and Plan of Treatment
SDOH Assessment
Care Team Member(s)
Care Team Member Name
Care Team Member Identifier
Care Team Member Role
Care Team Member Location
Care Team Member Telecom
Clinical Notes
Consultation Note
Discharge Summary Note
History & Physical
Procedure Note
Progress Note
Clinical Tests
Clinical Test
Clinical Test Result/Report
Diagnostic Imaging
Diagnostic Imaging Test
Diagnostic Imaging Report
Encounter Information
Encounter Type
Encounter Diagnosis
Encounter Time
Encounter Location
Encounter Disposition
Goals
Patient Goals
SDOH Goals
Health Insurance Information
Coverage Status
Coverage Type
Relationship to Subscriber
Member Identifier
Subscriber Identifier
Group Number
Payer Identifier
Health Status/ Assessments
Health Concerns
Functional Status
Disability Status
Mental Function
Pregnancy Status
Smoking Status
Immunizations
Immunizations
Laboratory
Test
Values/Results
Specimen Type
Result Status
Medications
Medications
Dose
Dose Units of Measure
Indication
Fill Status
Patient Demographics/ Information
First Name
Last Name
Middle Name (Including middle initial)
Name Suffix
Previous Name
Date of Birth
Date of Death
Race
Ethnicity
Tribal Affiliation
Sex
Sexual Orientation
Gender Identity
Preferred Language
Current Address
Previous Address
Phone Number
Phone Number Type
Email Address
Related Person's Name
Related Person's Relationship
Occupation
Occupation Industry
Problems
Problems
SDOH Problems/Health Concerns
Date of Diagnosis
Date of Resolution
Procedures
Procedures
SDOH Interventions
Reason for Referral
Provenance
Author Organization
Author Time Stamp
Unique Device Identifier(s) for a Patient's Implantable Device(s)
Unique Device Identifier(s) for a patient's implantable device(s)
Vital Signs
Systolic blood pressure
Diastolic blood pressure
Heart Rate
Respiratory rate
Body temperature
Body height
Body weight
Pulse oximetry
Inhaled oxygen concentration
BMI Percentile (2 - 20 years)
Weight-for-length Percentile (Birth - 24 Months)
Head Occipital-frontal Circumference Percentile (Birth - 36 Months)
New Data Classes and Elements
Data Element Reclassified
Name and Other Changes to Existing Data Classes/Elements

Patient Requested Restrictions

Background

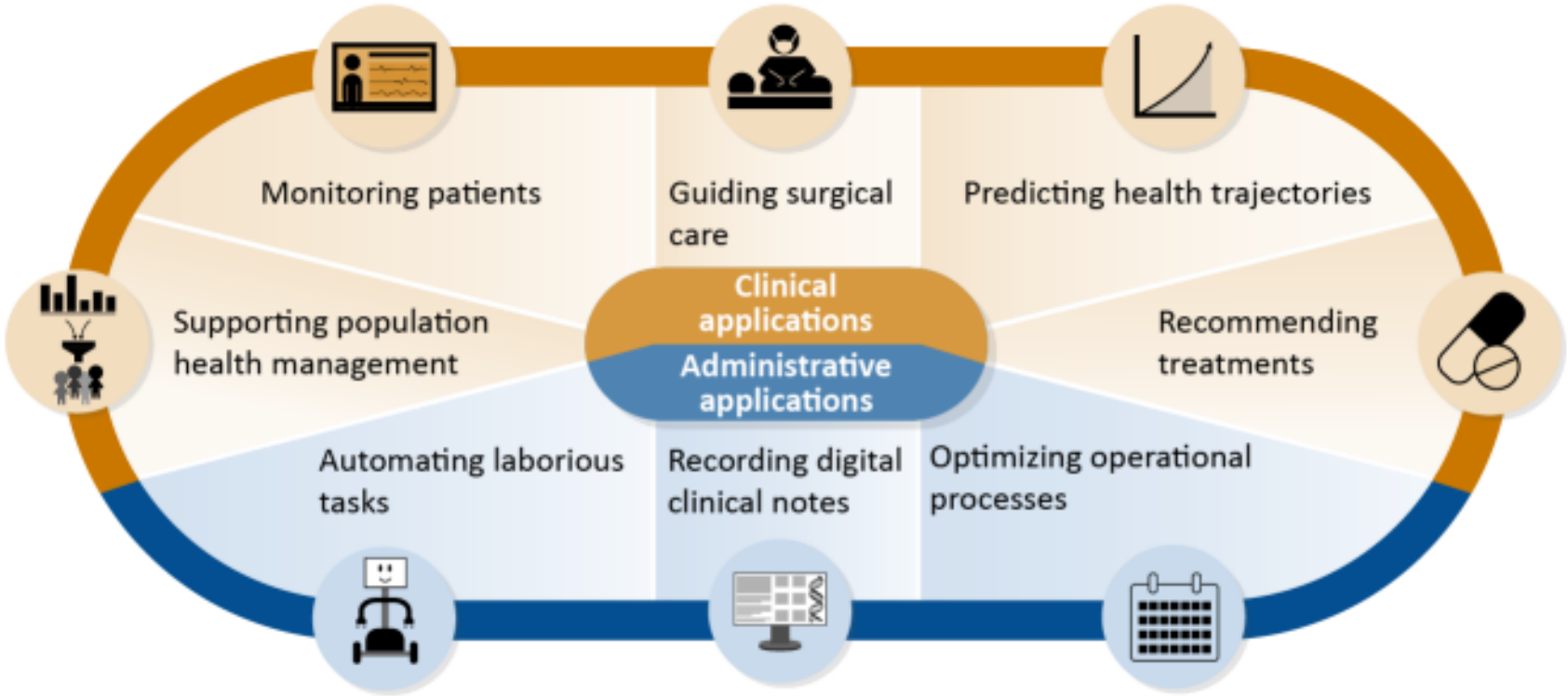
- The Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule provides individuals with several legal, enforceable rights intended to empower them to be more active participants in managing their health information.
- In the HTI-1 Proposed Rule, we made several proposals in support of the HIPAA Privacy Rule's individuals' "right to request a restriction" on certain uses and disclosures of their PHI (*see also* 45 CFR 154.522(a)).

HTI-1 Final Rule

- In the HTI-1 Final Rule, we require support for an "internet-based method" for patients to request a restriction on the use or disclosure of their data in § 170.315(e)(1) (VDT) by 01/01/26.
- Based on feedback received and readiness of the technology, we have decided not to finalize the remainder of the proposals for new criteria.
- We will continue to monitor efforts in the industry related to technological advancement to support patient-requested restrictions.

Decision Support Interventions

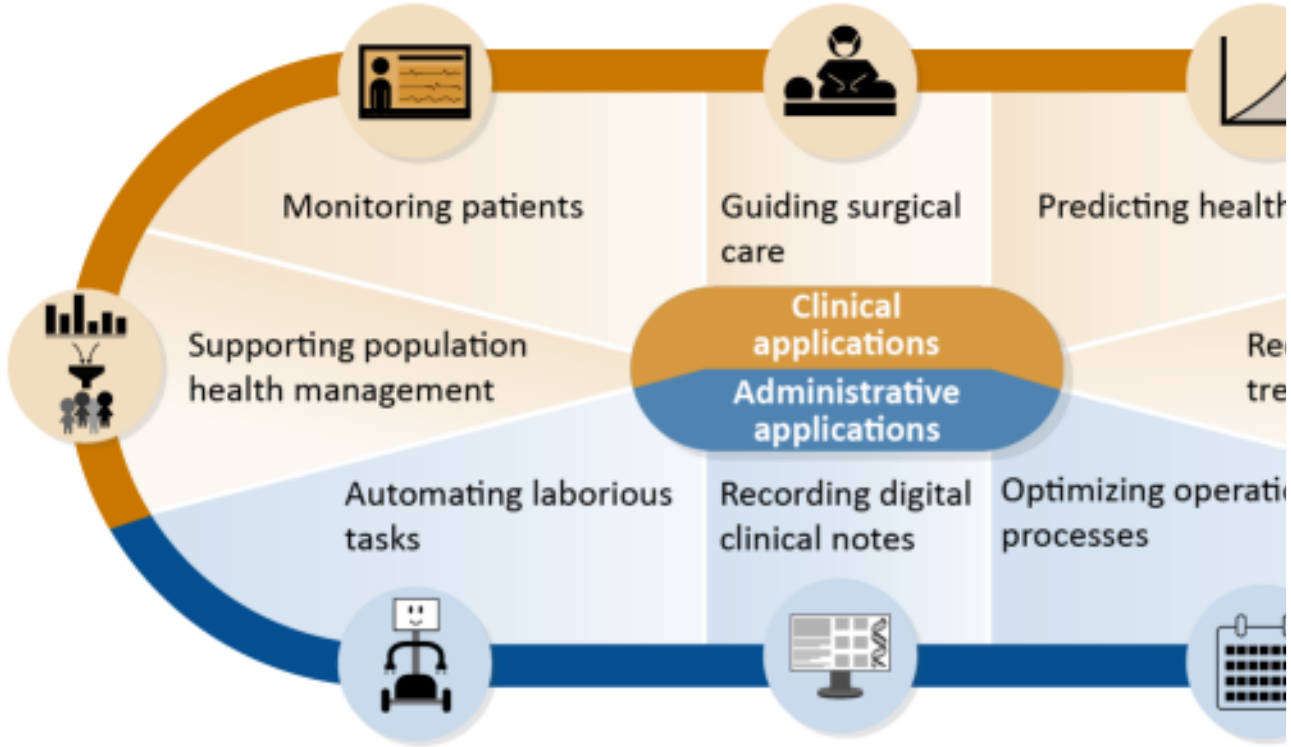
How can AI be used in healthcare?



: GAO. | GAO-21-7SP

https://www.gao.gov/assets/gao-21-7sp.pdf

What are the challenges?



: GAO. | GAO-21-7SP

- **Amplify** implicit and structural biases
- **Magnify** ethical, legal, and social concerns related to data collection and use
- **Reinforce** common, non-evidence-based practices
- **Solidify** existing inexplicable differences in health outcomes
- **Perpetuate** information asymmetries regarding a model's quality
- **Lead** to recommendations that are ineffective or unsafe

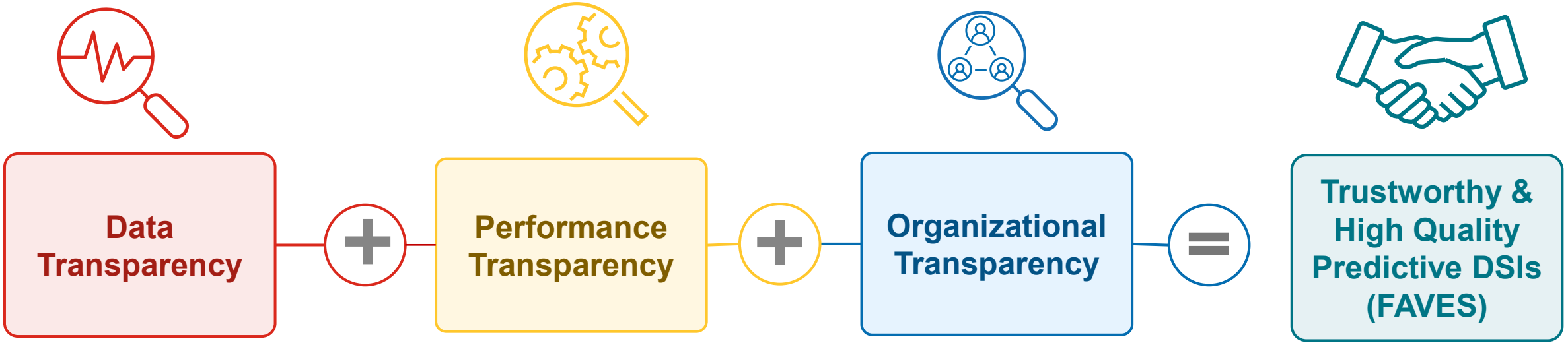
Source: *"Getting the Best out of Algorithms in Health Care." Health IT Buzz blog. June 15, 2022*

An inclusive framing of how to address challenges

FAVES describes the characteristics of “high-quality” algorithms and communicates how we may get the best out of predictive models in health care

- **F**air (unbiased, equitable) - Model does not exhibit biased performance, prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics. The impact of using the model is similar across same or different populations or groups.
- **A**ppropriate - Model is well matched to specific contexts and populations to which it is applied.
- **V**alid - Model has been shown to estimate targeted values accurately and as expected in both internal and external data.
- **E**ffective - Model has demonstrated benefit and significant results in real-world conditions.
- **S**afe – Model use has probable benefits that outweigh any probable risk

ONC's View: Transparency Is a Prerequisite for Trustworthy AI



Data Transparency

Requirements enable users to know when a DSI uses specific data elements relevant to health equity

Performance Transparency

Enable users to have consistent and routine electronic access to technical, and performance information on Predictive DSIs

Organizational Transparency

Requirement for Certified Health IT developers to apply intervention risk management for each Predictive DSI they supply as part of their Health IT Module

Predictive DSI definition

- Predictive Decision Support Intervention means
  - Technology that supports decision-making based on algorithms or models that derive relationships from training data and then produce an output that results in prediction, classification, recommendation, evaluation, or analysis
- The scope of the definition for Predictive DSI remains largely unchanged
- Finalized definition is broad and inclusive of a wide array of technologies and use cases
- Definition applies equally to technologies with perceived level of risk (i.e., does not treat “high-risk” definitionally different from “low risk” Predictive DSIs)
- Definition is not dependent on which entity or party that developed the Predictive DSI (e.g., health system vs. tech company vs. payor vs. certified health IT developer, etc.)

When is a developer responsible for source attribute content and risk management practices?

- Is the Predictive DSI supplied by the certified health IT developer?
  - Yes = Source attribute information must be complete and up-to-date and risk management practices must be applied
  - No = No requirements for source attribute information/content but source attribute categories must still be available for customers to use
    - Customers must be able to select a Predictive DSI that they self-develop or that they want to use from a third/other party
    - No requirements to apply risk management practices
- There are no requirements for customers that self-develop or purchase from a third party a Predictive DSI to provide source attribute information to their certified health IT developer
  - Unless that Predictive DSI is subsequently supplied by the developer of certified health IT as part of its Health IT Module

Reduced configuration nexus for Predictive DSIs & Health IT Modules

Finalized Configuration Nexus for 170.315(b)(11)

“Supplied by the health IT developer as part of its Health IT Module”

- Includes Predictive DSIs that are authored or developed by the certified health IT developer
- Includes Predictive DSIs that are authored or developed by other parties if those Predictive DSIs are sold, marketed, or otherwise explicitly included as part of a Health IT Module
- Supplied by means that
  - Certified health IT developer has taken on stewardship and accountability for that Predictive DSI for the purposes of the Health IT Module
  - Knowledge of its use is known by the certified Health IT developer

Requirements for Predictive DSI source attribute content

NES EHR

NES-developed Hypertension Predictive Model

NES EHR *Now With*: Zelda's Hypertension Predictive Model

Predictive DSIs authored, developed, or supplied by a certified health IT developer are subject to ONC requirements

Developers are not required to author, develop, or supply a Predictive DSI to be certified

And / Or

No Predictive DSI authored, developed, or supplied by developer of certified health IT

Health IT Modules certified to (b)(11) must enable a user to select evidence-based and Predictive DSIs

NES EHR

Enable selection of evidence-based DSI

Enable selection of Predictive DSI

+

Support all source attribute category fields

The developer must create the source attribute fields and support the functionality to access and modify those fields

- Source attributes fields for both evidence-based and Predictive DSIs must be supported
  - 13 source attributes for evidence-based DSIs
  - 31 source attributes for Predictive DSIs
- The developer is not responsible for the content of these source attributes unless the Predictive DSI is “supplied by” the certified health IT developer as part of its Health IT Module
- Source attribute information (content) for evidence-based DSIs and “supplied” Predictive DSIs must be:
  - Accessible by a limited set of identified users
  - Complete and up-to-date
  - Plain language descriptions

13 Source Attributes for Evidence-based DSIs

Already required as part of CDS criterion

1. Bibliographic Information
2. Developer of the intervention
3. Funding source of the technical implementation for the intervention's development
4. Release, an if applicable, revision date(s) of the intervention

Use of data elements salient to health equity

5. Use of race in the intervention
6. Use of ethnicity in the intervention
7. Use of language in the intervention
8. Use of sexual orientation in the intervention
9. Use of gender identity in the intervention
10. Use of sex in the in the intervention
11. Use of age (date of birth) in the intervention
12. Use of social determinants of health in the intervention
13. Use of health status assessments data in the intervention

Nine Predictive DSI Source Attribute Categories

1. Details and output of the intervention
2. Purpose of the intervention
3. Cautioned Out-of-Scope Use of the intervention
4. Intervention development details and input features
5. Process used to ensure fairness in development of the intervention
6. External validation process
7. Quantitative measures of performance
8. Ongoing maintenance of intervention implementation and use
9. Update and continued validation or fairness assessment schedule

Thirty-One Predictive DSI Source Attributes

1 General Description and Outputs

1) Name and contact information for the intervention developer;
2) Funding source of the technical implementation for the intervention(s) development;
3) Description of value that the intervention produces as an output; and
4) Whether the intervention output is a prediction, classification, recommendation, evaluation, analysis, or other type of output.

2 Purpose

5) Intended use of the intervention;
6) Intended patient population(s) for the intervention's use;
7) Intended user(s); and
8) Intended decision-making role for which the intervention was designed to be used/for.

3 Cautioned Out-of-Scope Use

9) Description of tasks, situations, or populations where a user is cautioned against applying the intervention; and
10) Known risks, inappropriate settings, inappropriate uses, or known limitations.

4 Development and Input Features

11) Exclusion and inclusion criteria that influenced the data set;
12) Use of variables in paragraph (b)(11)(iv)(A)(5)-(13) as input features;
13) Description of demographic representativeness including, at a minimum, those used as input features in the intervention;
14) Description of relevance of training data to intended deployed setting;

5 Process used to ensure fairness

15) Description of the approach the intervention developer has taken to ensure that the intervention's output is fair; and
16) Description of approaches to manage, reduce, or eliminate bias.

6 External Validation Process

17) Description of the data source, clinical setting, or environment where an intervention's validity and fairness has been assessed, other than the source of training and testing data
18) Party that conducted the external testing;
19) Description of demographic representativeness of external data including, at a minimum, those used as input features in the intervention;
20) Description of external validation process.

7 Quantitative Measures of Performance

21) Validity of intervention in test data derived from the same source as the initial training data;
22) Fairness of intervention in test data derived from the same source as the initial training data;
23) Validity of intervention in data external to or from a different source than the initial training data;
24) Fairness of intervention in data external to or from a different source than the initial training data;
25) References to evaluation of use of the intervention on outcomes, including, bibliographic citations or hyperlinks to evaluations of how well the intervention reduced morbidity, mortality, length of stay, or other outcomes;

8 Ongoing Maintenance of Intervention

26) Description of process and frequency by which the intervention's validity is monitored over time;
27) Validity of intervention in local data;
28) Description of the process and frequency by which the intervention's fairness is monitored over time.
29) Fairness of intervention in local data; and

9 Validation or Fairness Schedule

30) Description of process and frequency by which the intervention is updated; and
31) Description of frequency by which the intervention's performance is corrected when risks related to validity and fairness are identified.

Organizational transparency on risk management of Predictive DSIs

Intervention risk management practices must be applied for each Predictive DSI supplied by the health IT developer as part of its Health IT Module

1. Validity
2. Reliability
3. Robustness
4. Fairness
5. Intelligibility
6. Safety
7. Security
8. Privacy

- Predictive DSI(s) must be subject to
  - Analysis of potential risks and adverse impacts
  - Practices to mitigate identified risks
  - Policies and implemented controls for governance, including how data are acquired, managed, and used
- Final Rule preamble describes each characteristic and associated approaches that can be taken to assess and mitigate risks
  - Note: many of the terms and concepts in the IRM requirements rely on the National Institute of Standards and Technology (NIST) AI Risk Management Framework
- Summary information of risk management and governance to be publicly available

Implementation Timeline & requirements

Health IT Developers

- Will have one year to update their certified health IT to support capabilities in 170.315(b)(11)
- Will need to provide updated technology to their customers by December 31, 2024
- Will need to provide summary IRM practice information to their ONC-ACB before December 31, 2024
- Will need to keep source attribute information and risk management information up-to-date as an ongoing maintenance of certification requirement
- Will need to include as part of Real World Testing Plans and Results

Providers

- As of their 2025 performance period for CMS payment policy, certified health IT will support providers' ability to access and modify detailed source attribute information for evidence-based and Predictive DSIs they use

Industry

- The 31 source attributes finalized offers an industry-wide baseline from which more detailed "model cards" and other industry consensus can be formed
- Transparency provisions are likely to incentivize the creation and support of fairer, better validated algorithms in healthcare

ONC requirements foster a nascent information ecosystem for Predictive DSI performance and quality

- Establishes a consistent, industry-wide foundation of performance and quality information
- Provides ingredients for model card “nutrition labels”
- Balances prescriptiveness and flexibility to accommodate varied applications, contexts, and use cases
- Supports information related to local settings and post-deployment performance information
- Supports customer users that self-develop Predictive DSIs or use *other party*-developed Predictive DSIs
- Supports ongoing standardization, customization, and enhancements to source attributes
  - Accommodates emerging source attributes that may be more fit-for-purpose for specific uses (e.g., stratification), settings (e.g., oncology), and Predictive DSI types (e.g., LLMs and other generative AI)

Scope of DSIs considered evidence-based for purposes of the Program

- Enable a user to provide electronic feedback data for **evidence-based decision support interventions** and make available such feedback data, in a computable format, including at a minimum the intervention, action taken, user feedback provided (if applicable), user, date, and location

- For purposes of requirements in § 170.315(b)(11), we finalized that evidence-based DSIs are limited to only those DSIs that
  - Are actively presented to users in clinical workflow to enhance, inform, or influence decision-making related to the care a patient receives
- This has implications for DSIs that Health IT Modules must
  - Enable selection (i.e. activation) of
  - Enable users to access source attributes for
  - Support “feedback loop” functionality for

Assurances Condition and Maintenance of Certification requirements

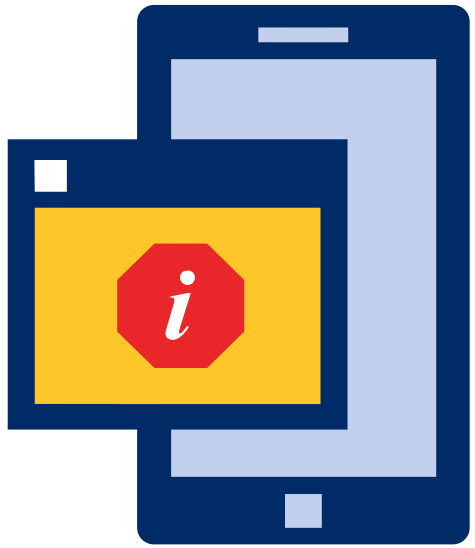
- Finalized a DSI criterion-specific instantiation of general Certification Program expectations as new Maintenance of Certification Requirements
- Builds on three specific existing Assurances Condition of Certification requirements
- Establishes ongoing obligations for developers of certified health IT that supply Predictive DSIs as part of their Health IT Modules to
  - Enable user access to updated descriptions of source attribute information
  - Review and update as necessary IRM practices that must be applied for each Predictive DSI the health IT developer supplies as part of its Health IT Module
  - Ensure the ongoing public accessibility of updated summary IRM practice information as submitted to their ONC-ACB via hyperlink
- Recognizes that such ongoing requirements would best fit under the Program as a developer-level responsibility, rather than a product-level responsibility

How ONC fits into the larger HHS Health AI Picture

Health AI Areas of Activity	U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES Office for Civil Rights	FDA	ONC
Applicable Federal Policies	**Nondiscrimination in Health Programs and Activities Proposed Rule (Section 1557 of the Affordable Care Act)**	**CDS and Device Software Function-related Guidance Documents**	**ONC Health IT Certification Program *(HTI-1 rulemaking)***
Who Must Comply?	*Health care provider and health plan using AI to support decision-making in covered health programs and activities*	*Manufacturer of device software functions (e.g., AI-enabled software that meets the definition of medical device)*	*Developers of certified health IT that supply a predictive DSI as part of its Health IT Module*
What Must Be Done?	Not use clinical algorithms in discriminatory ways	Receive FDA-approval for demonstrating the device software function's safety and effectiveness	Provide transparency information about predictive DSI's to clinical customers and engage in risk management practices

Information Sharing

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

Interfere with or ***interference*** means to prevent, materially discourage, or otherwise inhibit.

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.

Exceptions: Reasonable and Necessary Activities

Promote confidence in health IT infrastructure

- Privacy and security
- Patient safety

Promote competition and innovation

- Usability and modernization of technology
- Greater value, more choices, reduced burden

Promote standardization and interoperability

- Greater accessibility, including for research
- Better quality and equitable health outcomes

Exceptions Policy

1. Identify certain **reasonable and necessary activities** that do not constitute information blocking

2. Address practices of **significant risk** for actors not engaging in them due to uncertainty about the information blocking regulations

3. Through appropriate conditions, **limit to protect and not extend** beyond, reasonable and necessary activities

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

New - Exceptions that involve practices related to actors' participation in TEFCA

9. New TEFCA Manner Exception

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

HHS/OIG "Information Blocking" Final Rule

An official website of the United States government Here's how you know

U.S. Department of Health and Human Services
Office of Inspector General

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Information Blocking

Last Updated: 09-14-2023

View the Final Rule

On June 27, 2023, HHS-OIG posted its final rule implementing information blocking penalties. The final rule establishes the statutory penalties created by the 21st Century Cures Act. If OIG determines that an individual or entity has committed information blocking, they may be subject up to a $1 million penalty per violation.

The final rule does not impose new information blocking requirements. OIG incorporated regulations published by the Office of the National Coordinator for Health Information Technology (ONC) as the basis for enforcing information blocking penalties. For more information on ONC's information blocking regulations see: Information Blocking.

To report complaints about information blocking, please visit the ONC Information Blocking Portal or the OIG Hotline.

OIG Information Blocking Fast Facts

Enforcement

Enforcement of the information blocking penalties will begin September 1, 2023.

OIG will not impose a penalty on information blocking conduct occurring before September 1, 2023.

Enforcement Priorities

- patient harm
- significantly impacted a provider's ability to care for patients
- of long duration
- cause financial loss to Federal health care programs, other government/private entities or
- was performed with actual knowledge.

https://oig.hhs.gov/reports-and-publications/featured-topics/information-blocking/

HHS/ONC Health Care Provider Disincentives Rulemaking

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View Rule

View EO 12866 Meetings | Printer-Friendly Version | Download RIN Data in XML

HHS/ONC **RIN:** 0955-AA05 **Publication ID:** Fall 2023

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 (Cures Act) to establish appropriate disincentives for health care providers determined by the HHS Inspector General to have committed information blocking. Consistent with the 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.

Agency: Department of Health and Human Services(HHS)
Priority: Substantive, Nonsignificant
RIN Status: Previously published in the Unified Agenda
Agenda Stage of Rulemaking: Proposed Rule Stage
Major: No
Unfunded Mandates: No
CFR Citation: 45 CFR 171 42 CFR 414 42 CFR 425 42 CFR 495
Legal Authority: 42 U.S.C. 300jj–52 42 U.S.C. 1302 42 U.S.C. 1306 42 U.S.C. 1395hh 42 U.S.C. 1395jjj 42 U.S.C. 1395rr(1) 5 U.S.C. 552.2
Legal Deadline: None

Timetable:

Action	Date	FR Cite
NPRM	11/01/2023	88 FR 74947
NPRM Comment Period End	01/02/2024	

https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=202310&RIN=0955-AA05

HTI-1 Final Rule - Enhancements to Information Blocking Regulations

Overview of Information Blocking Enhancements

Definitions

- Offer Health IT
- Health IT Developer of Certified Health IT
- Business Associate
- Information Blocking

Exceptions

- Infeasibility Exception – 1 revised and 2 new conditions
- Manner Exception – renamed, removed obsolete “content” condition
- TEFCA Manner Exception – new

Health IT Developer of Certified Health IT Definition - Updated

Health IT developer of certified health IT means an individual or entity, other than a health care provider that self-develops health IT **that is not offered to others**, 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

New Definition: “Offer Health IT”

- Establishes what it means to “offer health IT.” In general, it includes: providing or supplying, or offering to provide or supply, certified health IT for deployment by or for other individuals or entities under any arrangement or terms not consistent with an exclusion codified as part of the definition.

- Explicitly codifies that we do not interpret certain activities as offers of health IT: funding donation and subsidy arrangements; implementation and use activities; health IT selection and implementation consulting; legal services and certain operations management services arrangements. These are described in the exclusions (paragraphs of the definition).

Some Examples of Benefits

- Encourages beneficial arrangements under which health care providers in need can receive subsidies for the cost of obtaining, maintaining, or upgrading certified health IT by giving funding sources certainty that making ***funding*** available for this purpose does not make them an offeror of health IT.

- Gives health care providers (and others) who deploy certified health IT certainty that implementing certain health IT features and enabling certain uses of the health IT they deploy will *not* be considered offering certified health IT (regardless of who developed that health IT).

- Establishes certainty for outside counsel that neither representing a client in negotiations or other matters with health IT vendors nor facilitating use of a client’s health IT for legal discovery purposes is considered an offering of health IT.

Infeasibility Exception – Third Party Seeking Modification Use Condition

Third party seeking modification use. The request is to enable use of EHI in order to modify EHI provided that the request for such use is not from a health care provider requesting such use from an actor that is its business associate.

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.

- An actor may choose to verify that the modification use request came from the health care provider themselves or accept the third party's representation of a request as coming from a health care provider.

Benefits

Reduces actor burden and uncertainty.

- Less documentation requirements compared to 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 the Infeasibility Exception, may apply where *third party seeking modification use* condition is not met.

Infeasibility Exception – Manner Exception Exhausted Condition

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 **at least two alternative manners** in accordance with § 171.301(b), one of which must either be certified health IT or via published content and transport standards; and
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*
- *Same*
- *Substantial number*
- ***Similarly Situated****

*Shall not discriminate based on whether the requestor is an individual or competitor (or facilitates competition) or based on the health care provider type and size

Benefits

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

NEW Subpart D: Exceptions That Involve Practices Related to Actors' Participation in TEFCA

ONC added a new subpart to the information blocking regulations.

§ 171.400: Purpose and Effect of Exceptions

§ 171.401: Reserved (potential definitions)

§ 171.402: Reserved

§ 171.403: TEFCA 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 to only via TEFCA not be considered information blocking?

NEW TEFCA Manner Exception

An actor may limit the manner in which it fulfills a request for access, exchange, or use of electronic health information to only via TEFCA **IF**:

1. The actor and requestor are both part of TEFCA.
2. The requestor is capable of such access, exchange, or use of the requested electronic health information from the actor via TEFCA.
3. The request for access, exchange, or use of EHI is not via the standards adopted in 45 CFR 170.215 (**FHIR**), including version(s) of those standards approved pursuant to 45 CFR 170.405(b)(8) (**SVAP**).
4. The actor complies with the Fees and Licensing Exceptions.

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.
- 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.

“Stacking” Exceptions

- **Available to all actors**
- **Not something new or limited to a specific combination of exceptions**
- **Not limited to one exception per practice**

Example: Actor has agreed to patient request to have certain EHI withheld from some or all sharing (Privacy Exception). Health care provider cannot segment this EHI from other EHI they could under applicable law make available (Infeasibility Exception)

Request for Advisory Opinion Authority

HHS Office of the National Coordinator for Health IT
FY 2024 President's Budget: Justification of Estimates to the Appropriations Committee

Proposed Law

1. Advisory Opinions for Information Blocking

   Provide HHS the authority to create an advisory opinion process and issue advisory opinions for information blocking practices governed by section 3022 of the Public Health Service Act (PHSA), 42 USC 300jj-52. The opinion would advise the requester whether, in the Department's view, a specific practice would violate the information blocking statutory and regulatory provisions; it would be binding on the Department, such that the Department would be barred from taking enforcement action against the practice. In addition, provide ONC with the authority to collect and retain fees charged for issuance of such opinions, and to use such fees to offset the costs of the opinion process.

https://www.healthit.gov/sites/default/files/page/2023-03/FY%202024%20ONC%20508%20%28002%29.pdf

Resources Available on HealthIT.gov!

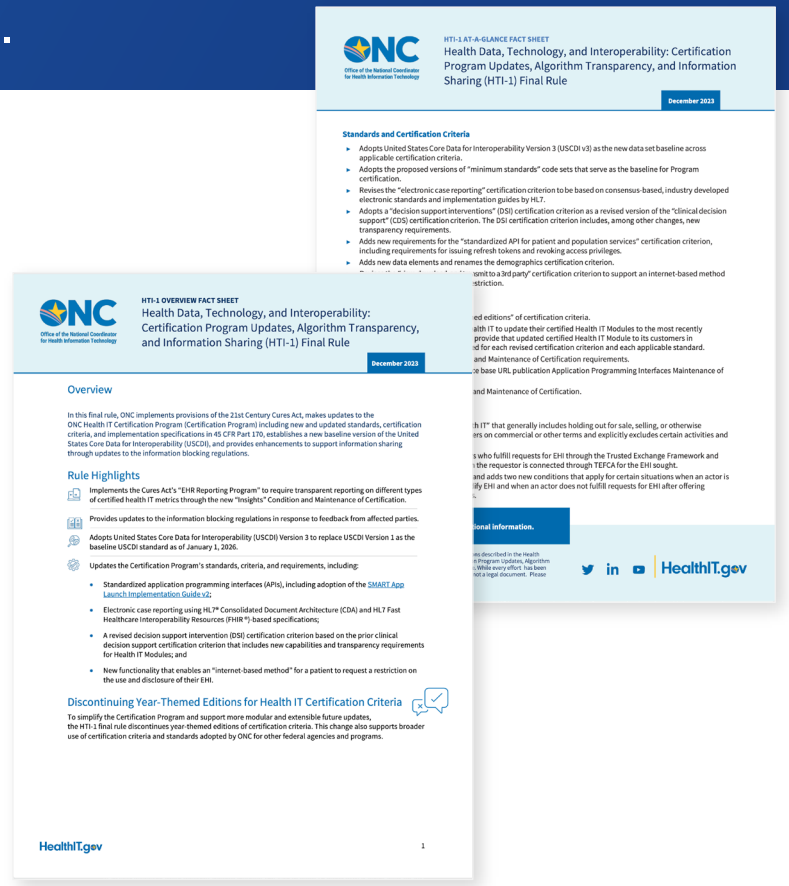
Visit https://healthIT.gov/HTI-1 for additional information.

Fact Sheets

- General Overview
- Final Rule At-a-Glance
- Decision Support Interventions and Predictive Models
- Insights Condition
- HTI-1 Information Blocking
- HTI-1 Key Dates

Measurement Spec Sheets

- For each of the Insights Condition measures



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)
Priority: Other Significant
RIN Status: First time published in the Unified Agenda
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Legal Deadline: None

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NPRM	11/00/2023	

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