# HTl-1
# Health Data, Technology, and Interoperability, Certification Program Updates, Algorithm Transparency, and Information Sharing

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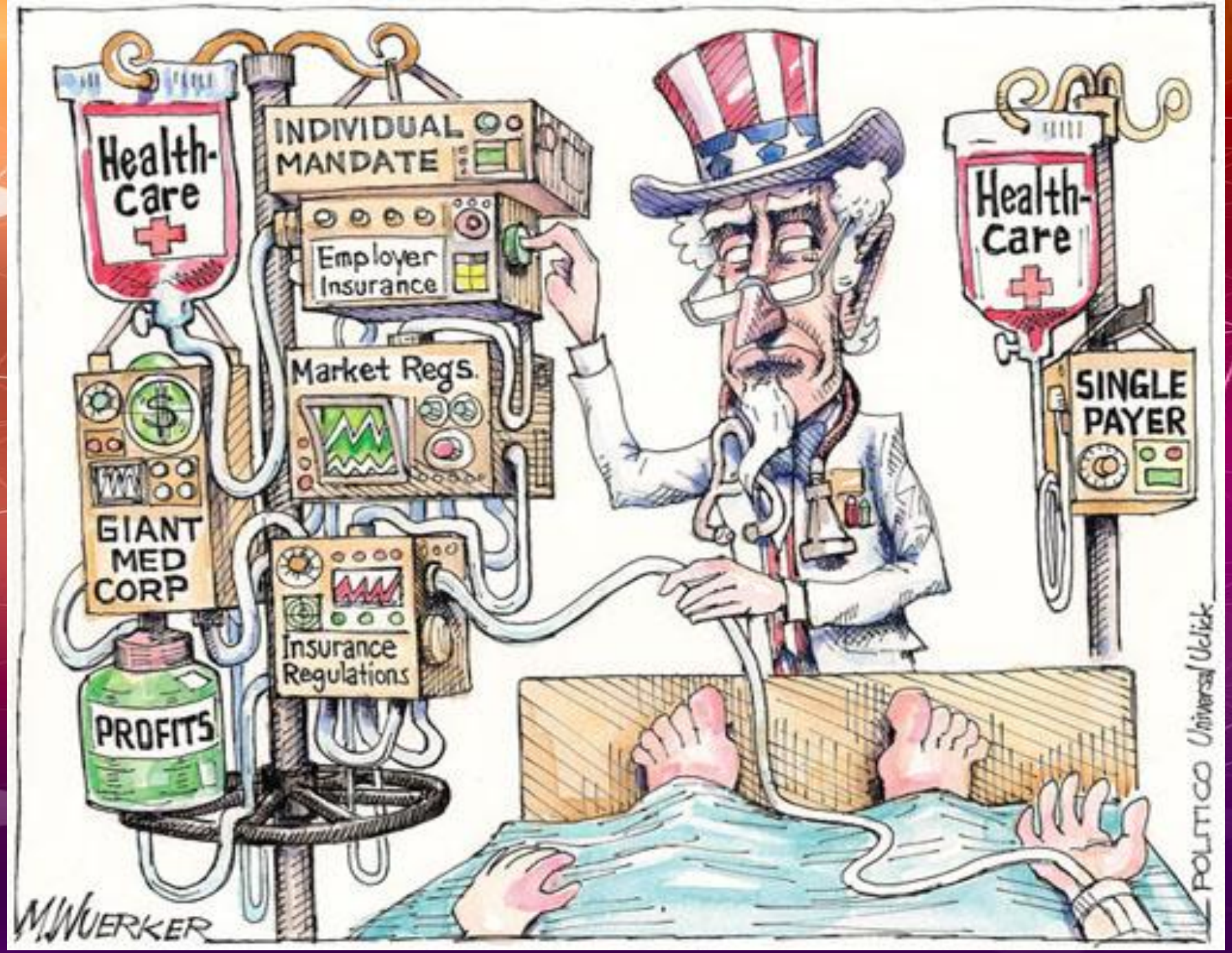
Health-Care
INDIVIDUAL MANDATE
Employer Insurance
Market Regs.
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Insurance Regulations
PROFITS
Health-Care
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# Agenda

- Overview
- ONC Certification Criteria for Health IT (edition-less)
- 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 Public Health Threats”
- E.O. 13985 and E.O.14091 “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

# Establishing Applicability and Expiration Dates for Certification Criteria and Standards

**HTI-1 Final Rule**

- **Discontinues the year-themed editions and establishes a single set of certification criteria, "ONC Certification Criteria for Health IT"**
- Clinical Decision Support is eliminated **December 31, 2024**
- Predictive Decision Support intervention **January 1, 2025**

- Ensures that customers are provided with timely technology updates

How will the vendors achieve those dates?
\re we really going to move forward without decision support?

# 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

# Concerns

- Timelines for Vendors
- Will in increase clinical charting burden
- ???  In the Chat please

# United States Core Data for Interoperability (USCDI) v3

- Adopted USCDI v3 as the new baseline for certification.
- Increasing the data elements by 20 and 2 additional data classes included in USCDI increases the amount of data available to be used and exchanged for patient care.
- Health IT Modules certified to criteria that reference USCDI would need to update to USCDI v3 by the **January 1, 2026**

➢ Use applicable US Core IG and C-CDA Companion Guide: See Notes

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

# USCDI Version 3

The Office of the National Coordinator for Health Information Technology

**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

- 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 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.

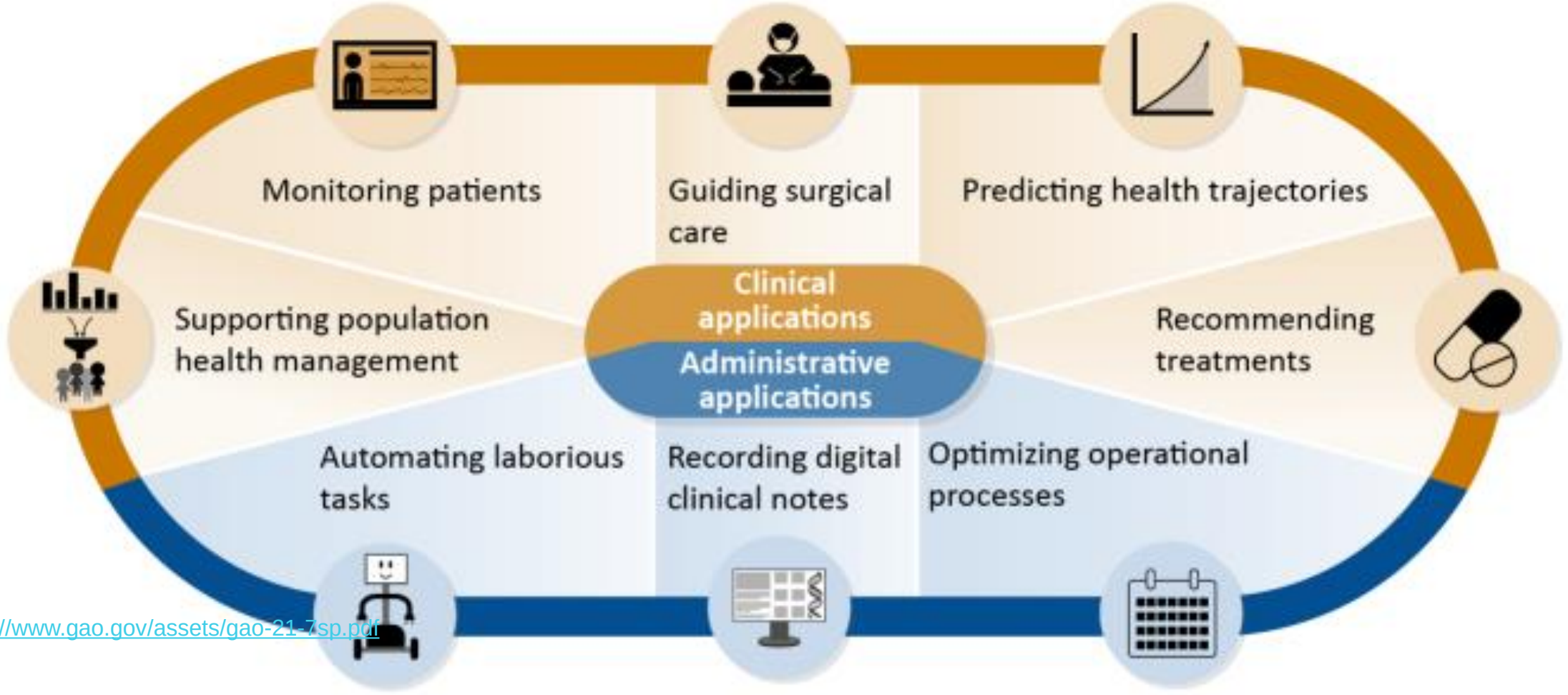
Your Portal !!!

# Where is your provider organization?

- Do you currently collect all the USCDI v3 elements?
- Are you working with your vendor?
- Is someone in your organization responsible ?  Compliance?

# Decision Support Interventions

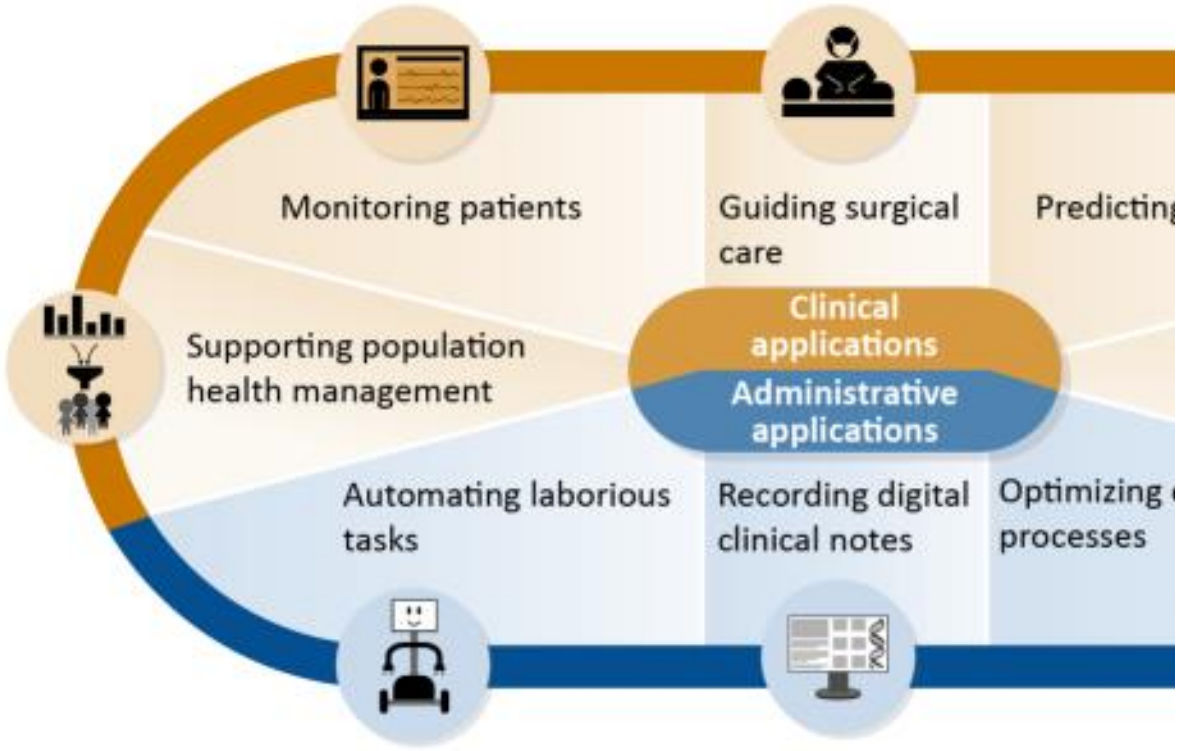
# How can AI be used in healthcare?




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

: GAO. | GAO-21-7SP

# 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

# Predictive Decision Support Interventions

**Predictive Decision Support Intervention or Predictive DSI means technology that:**

- 1. Supports decision-making based on algorithms or models that
- 2. Derive relationships from training data and then
- 3. Produces an output that results in prediction, classification, recommendation, evaluation, or analysis

• **The ONC Definition for Predictive DSI is**

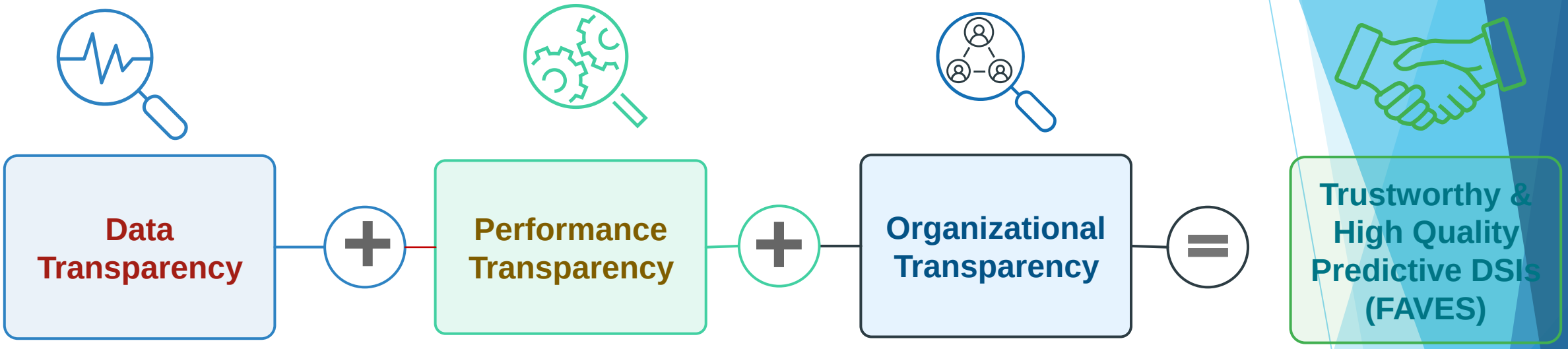
- **Broad in scope:** a variety of techniques from algebraic equations to machine learning from relatively simple risk calculators (ASCVD or APACHE IV) to deep neural networks and LLMs
- **Use case inclusive**: clinical, payer, research, administrative use cases • Risk independent: high-risk, low-risk, unknown risk
- **Developer agnostic**: certified EHR company, health system, academic research lab, consumer technology firm …

# The Why?

- Today: Algorithms used without knowledge of population data
- Today:  Last maintenance unknown
- Today:  Absolute Value, Benefits and Risks unknown

SO …

# 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

# FAVES

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

- Fair (unbiased, equitable) - Works across similar groups
- Appropriate - Well matched to context and populations
- Valid -Targeted values are accurate to internal/external data
- Effective - Benefits and Results happen in real world
- Safe – Benefits outweigh probable Risk

# 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

# 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

# Thirty-One Predictive DSI Source Attributes

## 1 General Description and Outputs

1) Identify Developer
2) Funding Source
3) Value of Output
4) Type Of Output

## 2 Purpose

5) Intended use;
6) Intended patient population(s;
7) Intended user(s)
8) Intended decision-making role of intervention

## 3 Cautioned Out-of-Scope Use

9) Tasks, situations, or populations not appropriate uses
10) Known risks, inappropriate settings &, uses, known limitations.

## 4 Development and Input Features

11) Exclusion and inclusion criteria;
12) Use of variables
13) Description of demographic representativeness
14) Relevance of training data

## 5 Process used to ensure fairness

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

## 6 External Validation Process

17) Description of the data source, clinical setting
18) Party that conducted external testing
19) Demographic representatives
20) External validation

## 7 Quantitative Measures of Performance

21) Validity of intervention in test data
22) Fairness of intervention in test data
23) Validity of intervention in data external data
24) Fairness of intervention external data
25) References to evaluation of use of the intervention on outcomes

## 8 Ongoing Maintenance of Intervention

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

## 9 Validation or Fairness Schedule

30) Process and frequency by which the intervention is updated;
31) Frequency the intervention's performance is corrected for risk & fairness related to validity

# In a nutshell:

- If certified HIT does use predictive DSI, the HIT developer must make available to the software users detailed information about the predictive DSI, including:
- The purpose of the intervention;
- Funding sources for the intervention's development;
- Exclusion and inclusion criteria that influenced the training data set;
- The process used to ensure fairness in development of the intervention; and
- A description of the external validation process.

# What will result?

- Impact on Innovation
- Impact on use of Predicative Decision Support Interventions
- Please put some ideas in the chat.

# Interesting Footnotes

- Predictive algorithms used by health care providers that are not offered as part of certified HIT are outside the regulation's scope

- Therefore, large language models (LLMs) like ChatGPT would only be subject to the rule to the extent they are offered by a developer of certified HIT.

- Similarly, AI used by health insurers to determine whether to approve a certain service—which has been the subject of recent litigation—is not subject to the rule.

# Information Sharing

# 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**

# 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

# My Suggestion in this component of the regulations

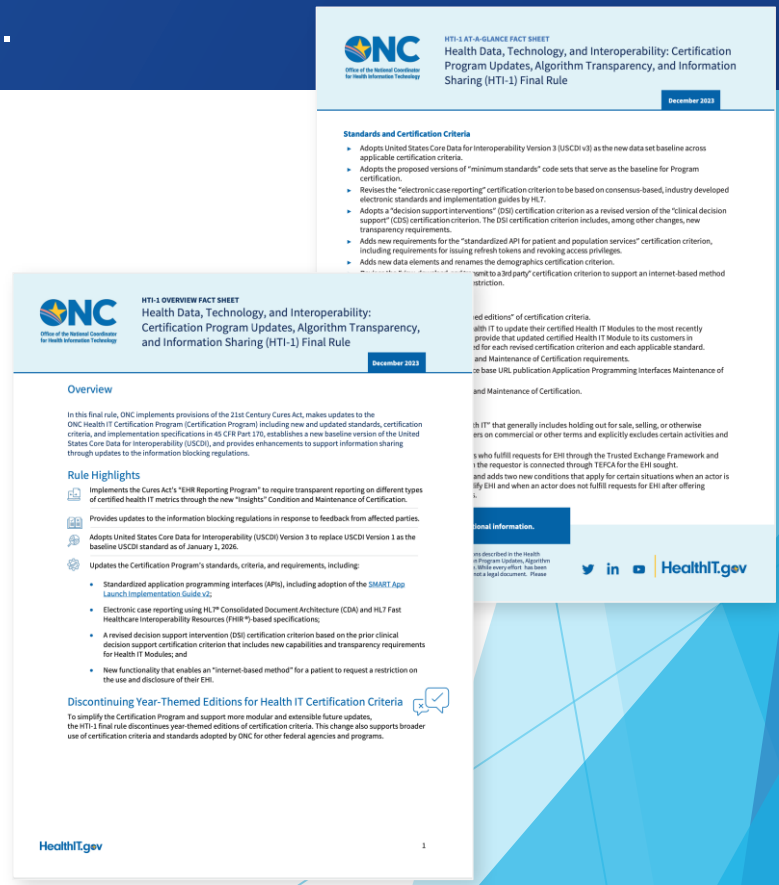
- Identify owner of Information Sharing/Blocking in your organization
- Start with Health Information Management
- Share this information.

# Let's review

- No more new Certified Health IT Editions
- Clinical Decision Support retires 12/31/24
- Predictive and Non-Predictive Clinical Decision Interventions begin 1/1/25
- United States Core for Interoperability v3 is effective 1/1/26
- FAVES is the latest ONC acronym
- This is the beginning of managing AI
- New Information blocking exceptions or redefinitions

# 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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## View Rule

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

**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

# Thank you

# Predictive Decision Support Interventions

# 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

# 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

# Predictive Decision Support Intervention (Predictive DSI) Definition

- 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
  - scope Predictive DSI remains largely unchanged
  - broad and inclusive of a wide array of technologies and use cases
  - applies equally to technologies with perceived level of risk
  - not dependent on which entity or party that developed the Predictive DSI

# 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)

# 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.

# 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

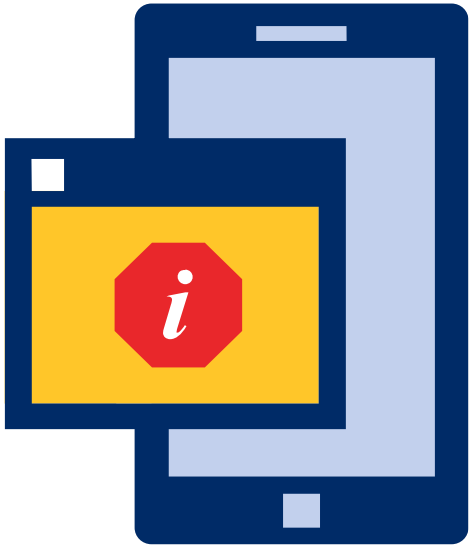
# Health IT Developer of Certified Health IT Definition - Updated

***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

# Information Sharing/Blocking

# Overview of Information Blocking Elements

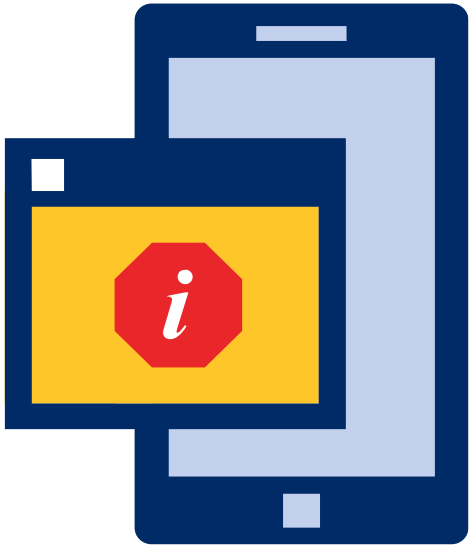


## What Makes an Individual or Entity an Information Blocker?

- 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.

# Overview of Information Blocking Elements



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

# 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