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# Navigating Health Tech: Regulations for AI/ML in Medical Devices and Software

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# Presenters

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Benjamin has counseled numerous  software as a medical device (“SaMD”) developers and software as a service (SaaS) companies, especially those designing software that incorporates artificial intelligence (AI) or machine learning (ML) functionalities, on FDA regulatory strategy, including preparing for pre-submission meetings with FDA, submitting applications for marketing authorization, and responding to agency requests for additional information.

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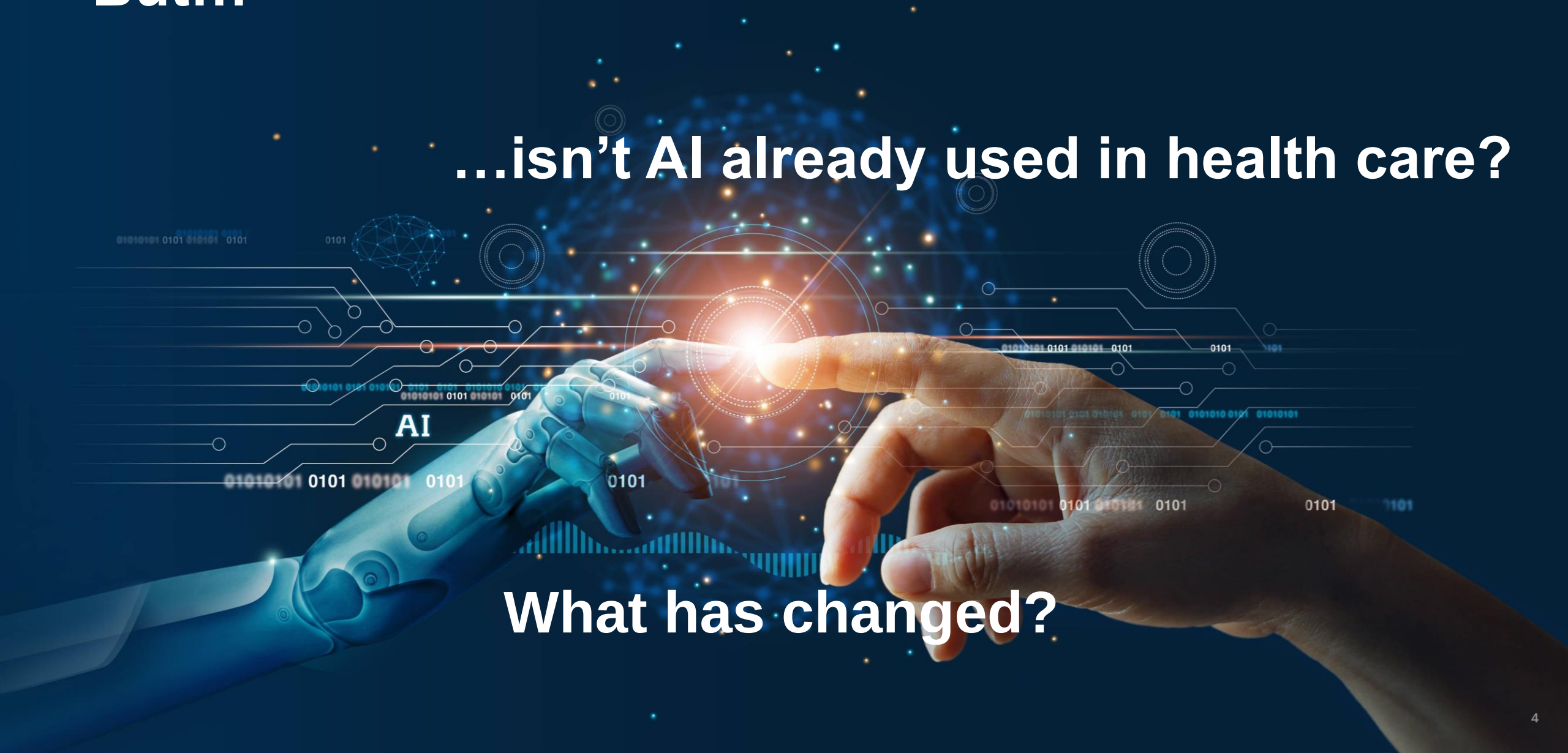
Pat advises clients on a broad spectrum of health care regulatory, clinical trial, data privacy, health care technology, and transactional matters. Among his areas of focus is the Office of the National Coordinator for Health Information Technology (“ONC”) Health IT Certification Program and the associated regulatory structure for health IT developers and health care providers, including algorithm transparency requirements, information blocking rules, and the interoperability and exchange of health care data.


AI is changing our
WORLD
(and health care is no exception)

# But…

## …isn’t AI already used in health care?




## What has changed?

# Health care presents many compelling use cases

- Administrative & Billing
- Disease Prevention & Management
- Diagnosis & Prognosis
- Care Coordination & Prioritization
- Clinical Intervention
- Medication Management
- Population Health

## …but what will the regulatory framework look like?

# Multiple Legal and Policy Effects on AI/ML

**Clinical Application**

**Care Coordination**

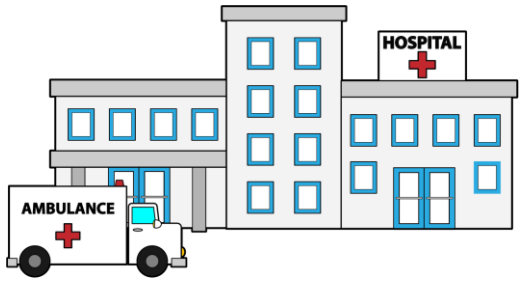
**User Experience**

## Federal Law

- Statutes
- Executive orders
- Federal lawsuits
- Agency rules

## State Law

- Statutes
- State lawsuits
- Medical Boards




## Institutional Policy

- AI/ML policies and procedures
- Practice-specific guidelines

# FDA Regulation of AI/ML: Where We've Been and Where We Are Now

# FDA Medical Device Regulations

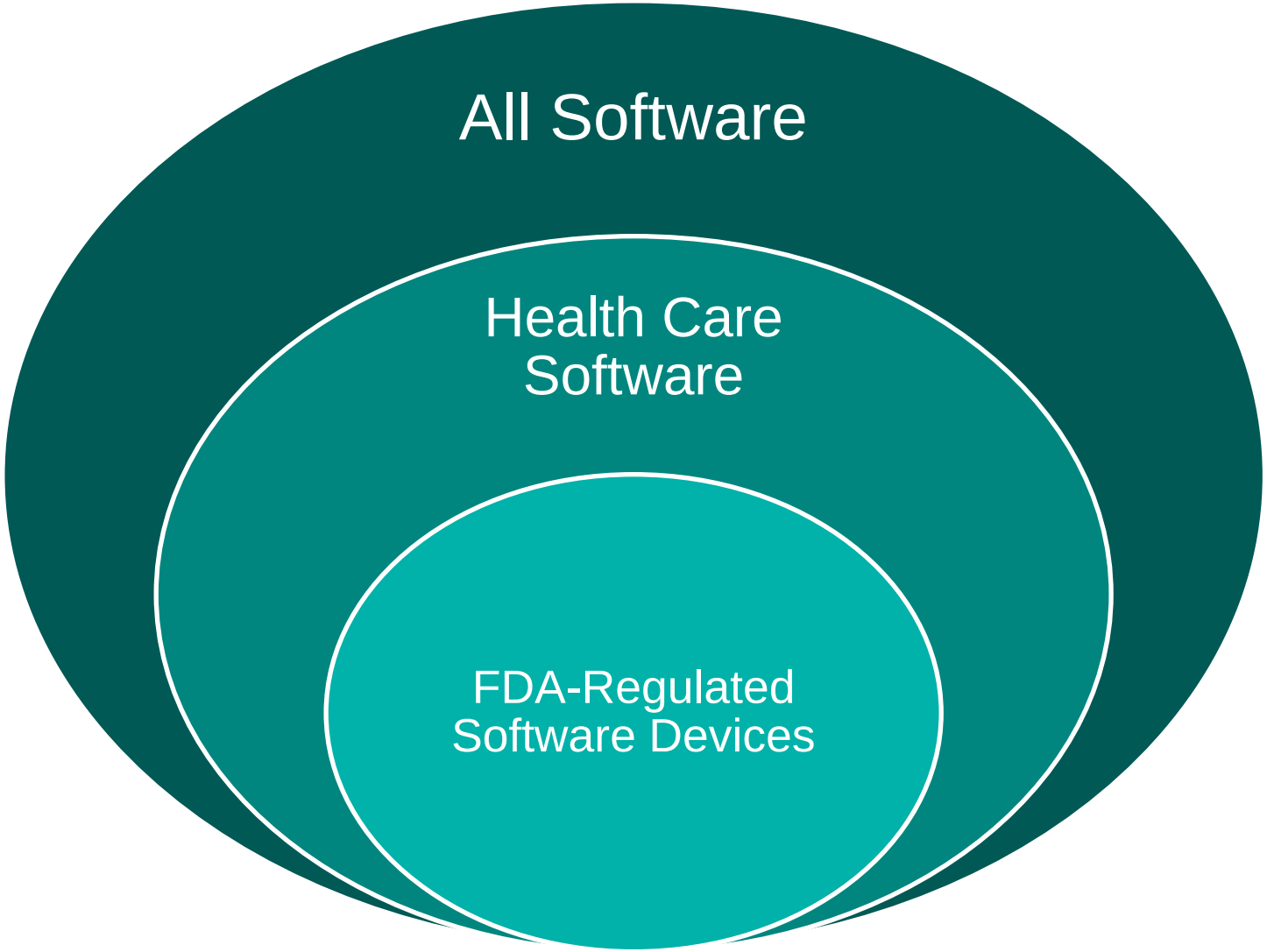
- Medical devices include anything intended to diagnose, cure, mitigate or prevent diseases or conditions or to affect the structure or function of the human body
  - Includes hardware and software
  - Software can be regulated as an integral part of a hardware platform or as a standalone device (SaMD)
- Digital health technologies intended for general wellness, medical practice administration, data storage or display or communication with patients are **not** devices
- FDA regulates software and digital health technologies as traditional devices
  - Classified on same risk-based spectrum (class I, II or III)
  - Same authorization pathways (510(k), De Novo, PMA)
- Certain exceptions:
  - 21st Century Cures Act
  - FDA enforcement discretion policies

# 21st Century Cures Act Amendments

5 types of software functions are expressly excluded from the FD&C Act “device” definition, codified at 21 U.S.C. § 360j(o), when such functions are intended

1) for administrative support of health care facility, including laboratory workflow
2) for maintaining or encouraging a healthy lifestyle and are unrelated to diagnosis, cure, mitigation, prevention, or treatment of disease or condition
3) to serve as electronic patient records for transferring, storing, converting formats, or displaying patient information (but do not “interpret or analyze” patient records or medical image data)
4) for transferring, storing, converting formats, or displaying lab test or other device data/results (but do not “interpret or analyze”); OR
5) for certain clinical decision support purposes, so long as the following criteria are met:
    - Not processing or analyzing a medical image or signal,
    - Displays information about a patient,
    - Supports or provides recommendations to health professionals, AND
    - Enables HCPs to independently review the basis for the software’s recommendations

# FDA Does Not Regulate All Health Care Software



# FDA Regulation of Device Software Functions

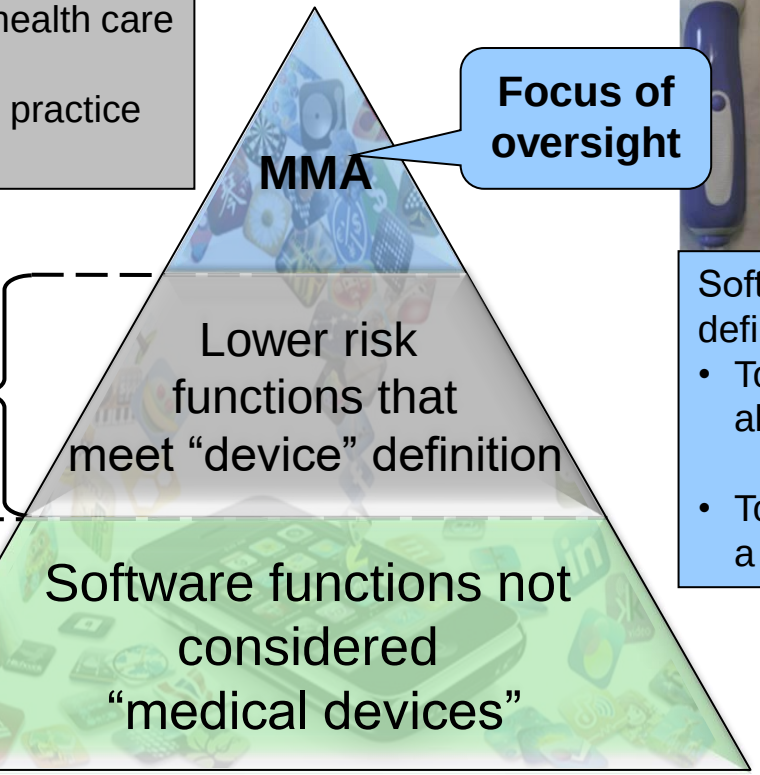
- Patient self-management functions
- Tools to organize and track health information (not for treating or adjusting medications)
- Tools to access to health information document and communicate with health care providers
- Tools that automate simple clinical practice tasks





**No FDA regulatory requirements**

**Enforcement Discretion**




**Focus of oversight**

Software functions that meet “device” definition that are either intended

- To be used as an accessory to already regulated medical device

**OR**

- To transform a mobile platform into a regulated medical device



C·D·R·H Center for Devices and Radiological Health



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# AI/ML Software Is Treated Like Other SaMD

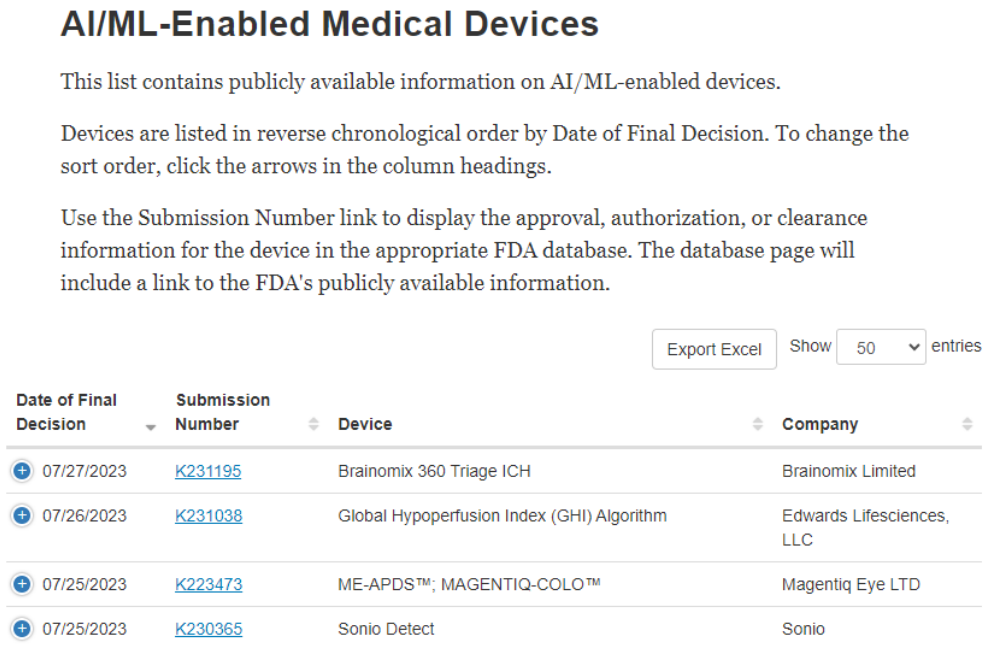
- Prior to 2020, FDA required AI/ML-based SaMD manufacturers to lock device function algorithms prior to marketing authorization and commercialization
  - Device regulations require manufacturers to assess each proposed modification or improvement to a device (including SaMD) to determine whether a separate 510(k) or PMA submission is necessary
- In 2020, FDA began authorizing unlocked AI/ML algorithms accompanied by predetermined change control plans (PCCPs)
  - A PCCP describes certain intended modifications to the AI/ML-based software and the associated method of implementation and must be authorized by FDA as part of a premarket submission
- FDA issued a draft guidance on preparing a PCCP for inclusion in a marketing submission in April 2023
  - Description of modifications
  - Modification protocol (development, validation, and implementation)
  - Impact assessment

# FDA's Authorization Process

- The FD&C Act limits FDA to the following authorization pathways for all non-exempt devices:
  - Premarket notification (510(k))
  - Premarket approval (PMA)
  - De novo classification
- PCCPs are an additional submission requirement for AI/ML-enabled SaMD with learning algorithms
  - Affects the substantial equivalence analysis for the 510(k) pathway
- FDA could further modify authorization process to require
  - Additional testing, including human factors studies
  - Post-marketing requirements

# FDA Has Reviewed Many AI/ML-Enabled Devices

- The agency maintains a list of all AI/ML-enabled devices it has reviewed



## AI/ML-Enabled Medical Devices

This list contains publicly available information on AI/ML-enabled devices.

Devices are listed in reverse chronological order by Date of Final Decision. To change the sort order, click the arrows in the column headings.

Use the Submission Number link to display the approval, authorization, or clearance information for the device in the appropriate FDA database. The database page will include a link to the FDA's publicly available information.

Export Excel Show 50 entries

| Date of Final Decision | Submission Number | Device | Company |
|---|---|---|---|
| 07/27/2023 | K231195 | Brainomix 360 Triage ICH | Brainomix Limited |
| 07/26/2023 | K231038 | Global Hypoperfusion Index (GHI) Algorithm | Edwards Lifesciences, LLC |
| 07/25/2023 | K223473 | ME-APDS™; MAGENTIQ-COLO™ | Magentiq Eye LTD |
| 07/25/2023 | K230365 | Sonio Detect | Sonio |

https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

- There are currently 692 devices listed, going back to 1995
- FDA updates the list periodically

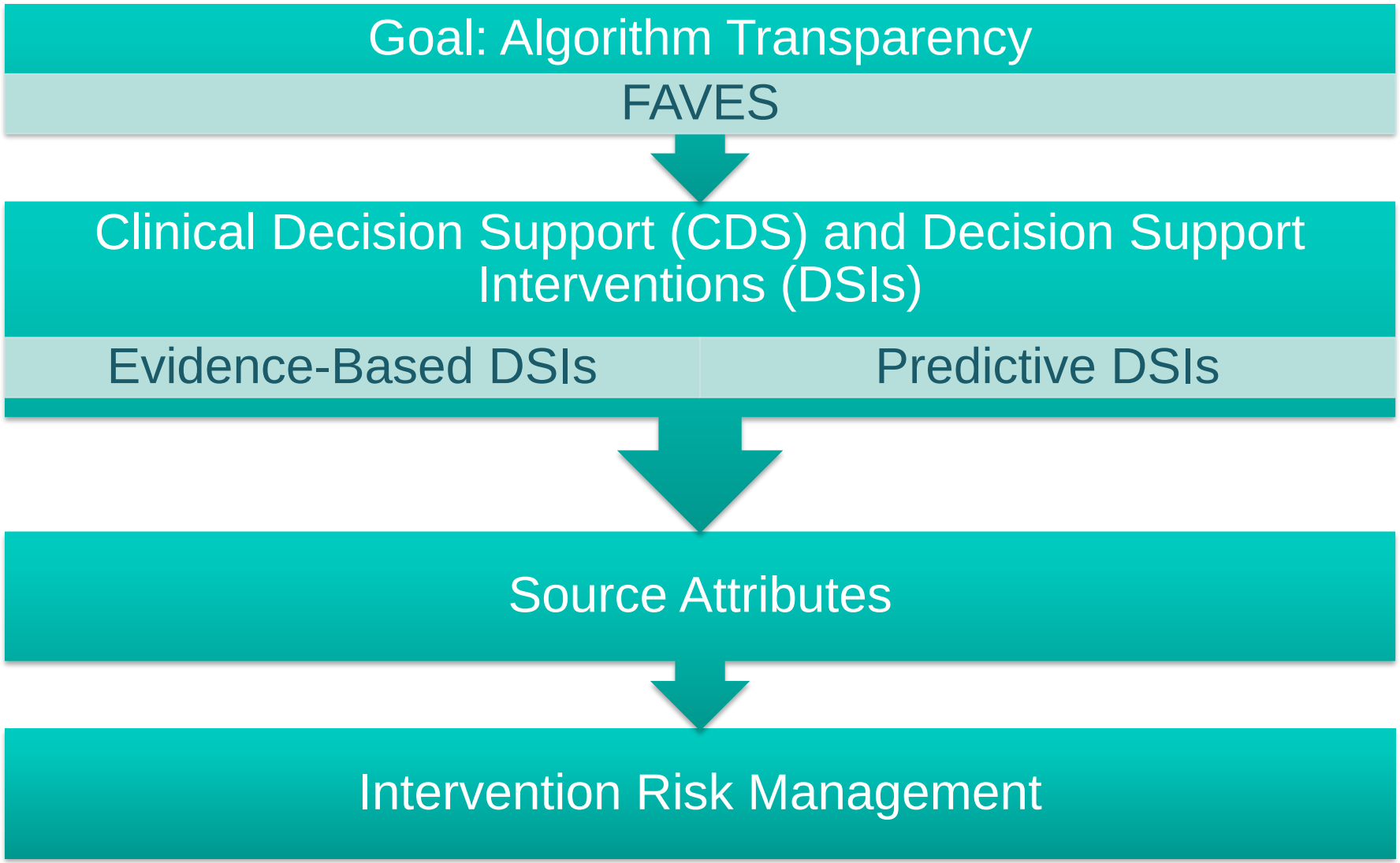
# What Are FDA's Plans for Regulating AI/ML?

- **April 2019** Proposed Regulatory Framework for Modifications to Artificial Intelligence/ Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD)
- **January 2021** Artificial Intelligence and Machine Learning Software as a Medical Device Action Plan
- **October 2021** Good Machine Learning Practice for Medical Device Development: Guiding Principles
- **May 2023** Using Artificial Intelligence and Machine Learning in the Development of Drug and Biological Products

  Artificial Intelligence in Drug Manufacturing
- **October 2023** Predetermined Change Control Plans for Machine Learning-Enabled Medical Devices: Guiding Principles
- **March 2024** Artificial Intelligence and Medical Products: How CBER, CDER, CDRH, and OCP are Working Together

# Emerging Regulatory Landscape for AI/ML in Health Care

# HTI-1 Final Rule Overview



# ONC-FDA Interaction

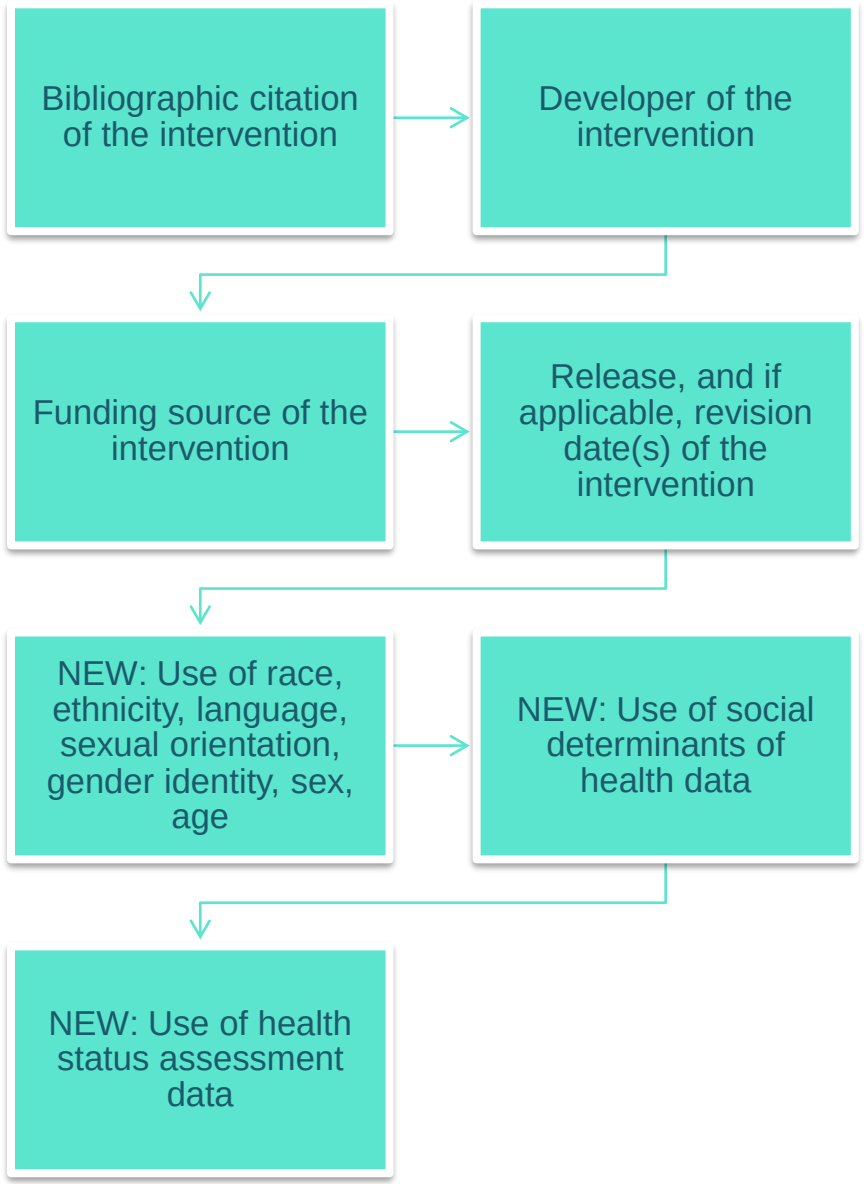
**ONC/HHS worked closely with the FDA on development of HTI-1 Final Rule**

**ONC/HHS sought alignment with the FDA's recent Clinical Decision Support Guidance for Industry (CDS Guidance)**

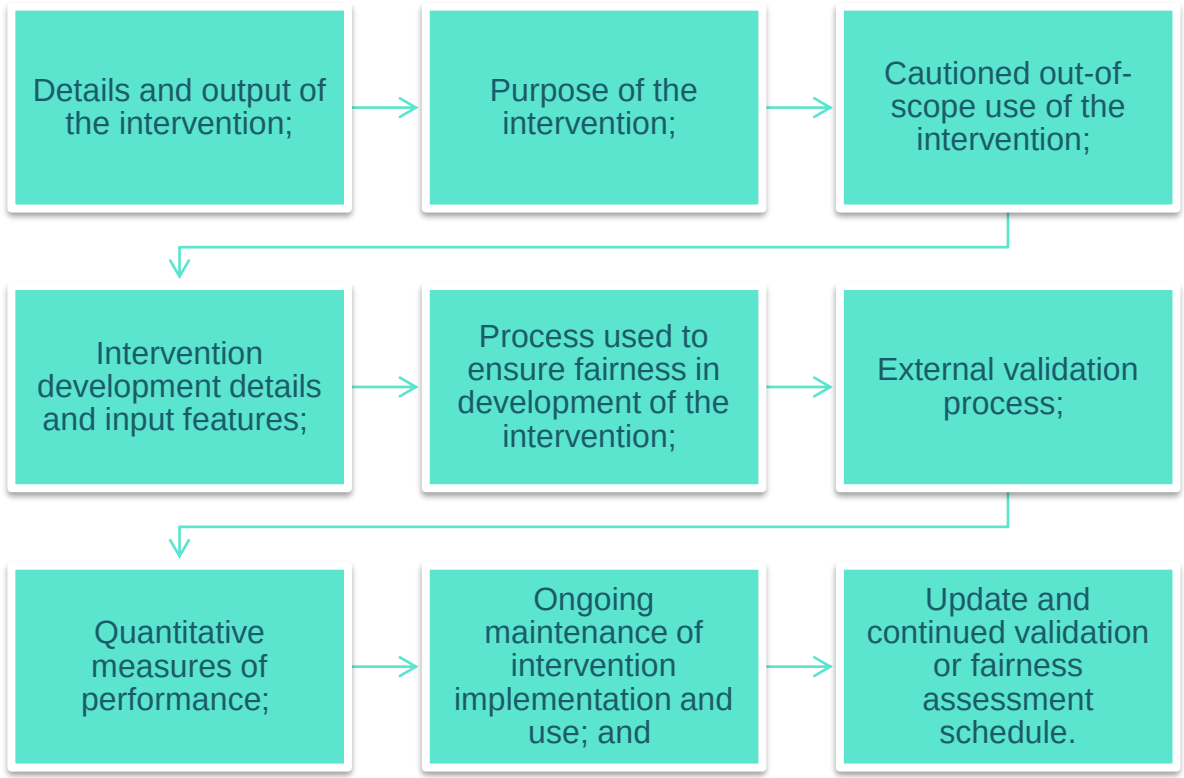
**ONC/HHS stated that its requirements are complementary to FDA's Content of Premarket Submissions for Device Software Functions guidance**

**Predictive DSIs may be considered Non-Device CDS, be considered CDS with device software functions, or lie outside of FDA's purview**

# Evidence-Based DSI Source Attributes



# Predictive DSI Source Attributes



# Intervention Risk Management (IRM)

## IRM Practices

- **Risk Analysis** – Predictive DSIs must be subject to analysis of potential risks and adverse impacts associated with “validity, reliability, robustness, fairness, intelligibility, safety, security, and privacy”
- **Risk Mitigation** – Predictive DSIs must also be subject to practices to mitigate the risks above.
- **Governance** – Predictive DSIs must also be subject to governance control policies, including how data are acquired, managed, and used.

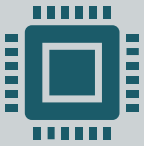
## Required Characteristics for Risk Analysis and Risk Mitigation

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

# OCR NPRM: Nondiscrimination in Health Programs and Activities (ACA Section 1557)

**Clinical algorithms may as tool to augment decision-making, but not as a replacement of clinical judgment**

**OCR: Once providers use information required by FDA/ONC to make decisions, they are active participants.**



**What decisions and actions were taken by the covered entity in reliance upon a clinical algorithm in its decision-making?**

# AI-Enabled Tools and Medicare Advantage Plans

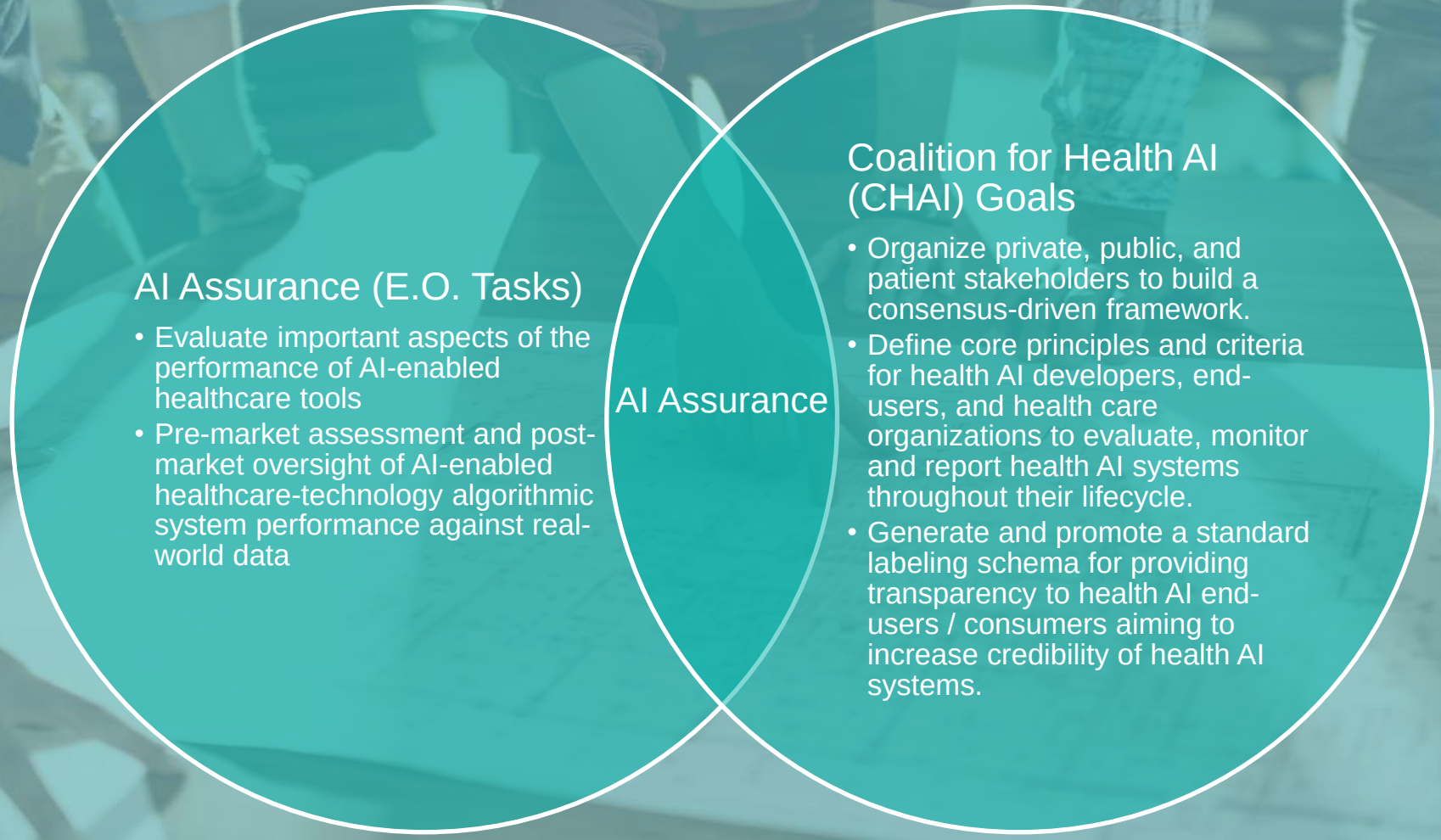
**CMS Final Rule released April 12, 2023**: Effective January 1, 2024, Prohibits MA organizations from using an algorithm or software that does not account for an individual's circumstances when making medical necessity determinations.

**CMS FAQs released February 6, 2024**: An algorithm or software tool can be used to assist MA plans in making coverage determinations, but it is the responsibility of the MA organization to ensure that the algorithm or artificial intelligence complies with all applicable rules for how coverage determinations by MA organizations are made.

# E.O. 14110: Health Care-Specific Tasks

- Develop AI Task Force (90 days of E.O. date)
- Develop AI Assurance Policy (180 days of E.O. date)
- Advance Compliance with Federal Nondiscrimination and Privacy Laws (180 days of E.O. date)
- Develop AI Safety Program (365 days of E.O. date)
- Create Strategy for Regulating AI-Enabled Tools in Drug-Development Processes (365 days of E.O. date)
- Develop Grant-Making/Awards to Advance AI-Enabled Tools
- Create VA AI Tech Sprint Competitions
- Develop plan addressing use of automated or algorithmic systems in the implementation by States and localities of public benefits/services administered by HHS (180 days of E.O. date)

# AI Assurance



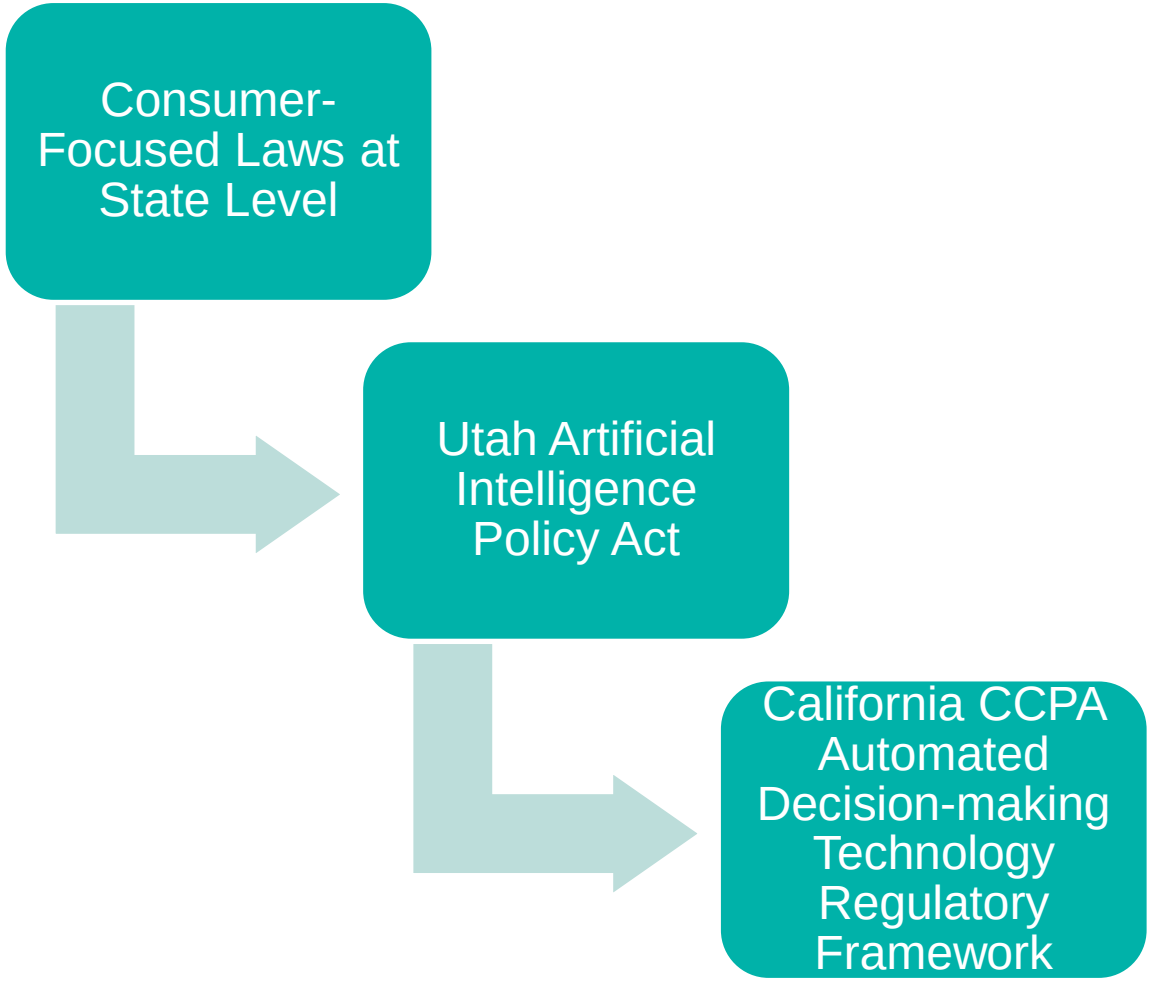
# Proposed Federal Legislation

**Federal Artificial Intelligence Risk Management Act of 2024** – requires Federal agencies to use the Artificial Intelligence Risk Management Framework developed by the National Institute of Standards and Technology with respect to the use of artificial intelligence.

**Eliminating Bias in Algorithmic Systems Act of 2023** – requires agencies that use, fund, or oversee algorithms to have an office of civil rights focused on bias, discrimination, and other harms of algorithms, and for other purposes.

**Algorithmic Accountability Act of 2023** – directs the Federal Trade Commission to require impact assessments of automated decision systems and augmented critical decision processes, and for other purposes.

# State Laws Relevant to AI in Health Care



# AI Frameworks and Resources

- NIST AI Risk Management Framework (RMF)
- Biden-Harris Administration *Blueprint for an AI Bill of Rights*
- Health Equity Across the AI Lifecycle (HEAAL) Framework
- Government Accountability Office (GAO) Accountability Framework for Federal Agencies and Other Entities

# Questions?