



# Current Regulatory Landscape of AI in Public Health & Health Care: A Brief Overview

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The purpose of this brief is to present the current federal regulatory landscape of artificial intelligence (AI) in health care and public health.<sup>1</sup> It details the statutes, regulations, and other exploratory actions taken by Federal agencies. As anticipated, the Department of Health and Human Services has been at the center of most AI regulatory activity related to health care. However, other entities, such as the Federal Trade Commission and the National Institutes of Standards and Technology also play integral roles.

## THE WHITE HOUSE

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The White House's Office of Science and Technology Policy (OSTP) oversees federal government activities related to AI and established the National AI Initiative Office in 2020. In recent years, the White House has taken steps to address AI in health care, including:

- In September 2022, the Biden administration published [Principles for Enhancing Competition and Tech Platform Accountability](#), which included a principle related to stopping discriminatory algorithmic decision-making.
- In October 2022, the Biden administration released the [Blueprint for an AI Bill of Rights](#) and related [fact sheet](#). Within the blueprint, the administration identified five principles: Americans should 1) be protected from unsafe or ineffective automated systems, 2) not face discrimination by algorithms, 3) be protected from violations of privacy, 4) know how and why an automated system is being used, and 5) be able to opt out

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<sup>1</sup> This brief does not cover cybersecurity.

from an automated system (where appropriate).

- January 2023 saw the publication of the National Artificial Intelligence Research Resource Task Force's (created by the National Artificial Intelligence Initiative Act of 2020 (Division E of [P.L. 116-283](#)) first report on "[Strengthening and Democratizing Artificial Intelligence Innovation](#)." Done in partnership with the National Science Foundation.
- In May 2023, the Select Committee on Artificial Intelligence issued its third update to the [National Artificial Intelligence Research and Development Strategic Plan](#) to guide federal investments across various sectors, including health care.
- Following a February 2022 Executive Order ([EO](#)) related to racial equity (which explicitly mentioned AI), in October 2023, the Biden administration took further executive action on AI: [Executive Order on the Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence \(fact sheet\)](#).

Within the EO, key activities related to health care include the following:

- To aid in the overall governance of AI, the EO establishes a White House Artificial Intelligence Council (White House AI Council), which includes the Secretary of HHS.
- Within 90 days of EO Publication (By January 28, 2024):
  - HHS will launch an AI task force to develop a strategic plan for a guide to responsible use of AI in health care.
- Within 180 days of EO Publication (By April 27, 2024):
  - HHS will (1) develop an AI assurance policy to evaluate AI-enabled healthcare tools and (2) encourage compliance with Federal non-discrimination and privacy laws as they relate to AI in health care.
  - The Director of OSTP, in coordination with HHS and other agencies, will establish a framework for identifying and mitigating risks related to biological sequences that may pose national security risks. And, within 180 days of the development of that framework (by October 24, 2024), agencies supporting life sciences research (including HHS) are tasked with implementing policies to ensure compliance, as a requirement of funding, with this framework.
  - HHS and USDA will publish plans to address the use of automated systems in the administration of public benefits.
- Within 1 year from October 30, 2023 (By October 30, 2024):

- HHS will (1) establish an AI safety program, building off the current work of Patient Safety Organizations and (2) develop a strategy for regulating AI within the drug development process.

## DEPARTMENT OF COMMERCE (DOC)

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### National Institute of Standards and Technology (NIST)

- In January 2023, NIST [released](#) the [AI Risk Management Framework \(AI RMF 1.0\)](#), a voluntary framework to equip organizations in their design, development and use of AI systems. NIST has since released a series of companion resources: the [NIST AI RMF Playbook](#), [AI RMF Explainer Video](#), [AI RMF Roadmap](#), [AI RMF Crosswalk](#), and various [Perspectives](#).
- In March 2023, NIST launched the [Trustworthy and Responsible AI Resource Center](#) to facilitate implementation of, and international alignment with, the AI Risk Management Framework.
- In April, 2023, the Coalition for Health AI built off NIST’s framework and issued a [Blueprint for Trustworthy AI Guidance and Assurance for Healthcare](#).
- In November 2023, NIST published a [Federal Register Notice](#) to announce the establishment of the “Artificial Intelligence Safety Institute Consortium”. The stated goal is to create a set of clear and reliable standards and metrics to support the development and responsible use of safe and trustworthy advanced AI systems.

## FEDERAL TRADE COMMISSION (FTC)

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- The FTC has the authority to take legal action against companies whose use of AI violates [section 5 of the FTC Act](#), which prohibits “unfair or deceptive acts or practices in or affecting commerce.”
- Section 13407 of ARRA ([P.L. 111-5](#)) [directed the FTC](#) in 2009 to established the [Health Breach Notification Rule](#) for all entities not covered by the HIPAA breach notification rule. Similar to the HIPAA breach notification rule, the FTC health breach notification rule details the circumstances in which an entity must notify individuals when their health information has been inappropriately disclosed. To aid in compliance with the various requirements, the FTC has issued [guidance](#) related to HIPAA, FTC Act, and the health breach notification rule.
- In February 2023, the FTC established a new [Office of Technology](#) to help the FTC keep pace with AI and other technology developments.

- In March 2023, the FTC issued [guidance](#) related to the risks of pixel tracking, invisible webpage trackers that gather and disseminate user information.

## DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS)

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HHS established [the Office of the Chief Artificial Intelligence Officer \(OCAIO\)](#) and published an [Artificial Intelligence Strategy](#) and [Trustworthy AI \(TAI\) Playbook](#) in 2021. OCAIO also maintains an inventory of [AI use cases](#). A public private partnership the “[Coalition for Health AI](#)” includes US Government observers from HHS agencies and the White House.

### Agency for Healthcare Research and Quality (AHRQ)

- Pursuant to the Patient Safety and Quality Improvement Act of 2005 ([P.L. 109-41](#)), AHRQ has created [patient safety organizations](#) (PSOs), [listed entities](#) that health care providers can report patient safety and quality information to without fear of legal liability. AHRQ disseminates information from the PSOs through the Patient Safety Network ([PSNet](#)). The [2023 Executive Order on AI](#) calls on HHS to collaborate with PSOs to establish an AI safety program within health care.
- Following a congressional request in 2020, AHRQ issued a Request for Information and commissioned an evidence-based examination of [health care algorithms and racial and ethnic disparities](#). AHRQ and the National Institute on Minority Health and Health Disparities (NIMHD) are also sponsoring [expert panels](#) to create guidelines for utilizing race and ethnicity data in health care algorithms.
- AHRQ recently released their [Digital Healthcare Research Division: 2022 Year in Review](#) that draws on decades of health IT research to inform the integration of AI in healthcare. The report notes that 17 percent of new grants funded under the division relate to health care AI research.
- In July 2023, AHRQ published an [issue brief](#) titled “Reimagining Healthcare Teams: Leveraging the Patient-Clinician-AI Triad To Improve Diagnostic Safety”.

### Assistant Secretary for Preparedness and Response (ASPR)

- ASPR has recognized the need to [leverage AI](#) and new data sources to improve its research, surveillance, and disease prediction capabilities. In recent years, the agency has utilized AI to enhance emergency response efficiency (*i.e.*, [emPOWER](#)), [improve trauma care](#) and [identify potential medical countermeasures](#).

## Centers for Disease Control and Prevention (CDC)

- CDC's [Data Modernization Initiative](#) leverages AI to enhance public health initiatives (e.g., forecasting trends in opioid overdose mortality and improving outbreak surveillance). The agency is also developing a [framework](#) for identifying and preventing biases in AI-integrated health tools.

## Centers for Medicare and Medicaid Services (CMS)

In recent years, CMS reimbursed some AI technologies and encouraged health care entities to mitigate biases in algorithms.

Through Medicare, CMS provides coding, coverage, and payment for [AI-enabled products](#) under the following [reimbursement mechanisms](#):

- Medicare Physician Fee Schedule (MPFS): CMS has created new Current Procedural Terminology (CPT) codes to reimburse AI products (e.g., IDx-RX, a new diagnostic tool for diabetic retinopathy).
- Inpatient Prospective Payment System (IPPS): CMS has utilized the New Technology Add-On Payment (NTAP) to enhance reimbursement for AI products (e.g., Viz.ai software, which facilitates diagnosis and treatment for certain strokes).
- Outpatient Prospective Payment System (OPPS): CMS has recognized new CPT “add-on codes” to provide additional payments for certain technologies (e.g., Software as a Services (SaaS)).

CMS has also taken steps to ensure safe utilization of algorithms within health care.

- In July 2022, as part of its proposed rulemaking [process](#), CMS issued a request for information (RFI) on preventing and mitigating bias in algorithms and predictive modeling. In April 2023, CMS issued a [final rule](#) requiring Medicare Advantage organizations to make medical necessity coverage decisions based on individual circumstances, rather than relying solely on generalized algorithms.

## Food and Drug Administration (FDA)

The FDA regulates food, drugs, medical devices, and other products. Within the FDA, two main centers have been most engaged with respect to AI: the Center for Devices and Radiological Health (CDRH) and Center for Drug Evaluation and Research (CDER).

### Center for Devices and Radiological Health (CDRH)

- CDRH's regulatory actions are primarily based upon the statutory authority under 201(h)(1) of the FFDCA [21 USC 321\(h\)\(1\)](#), which defines a device

as “intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals.”

- In 2017, CDRH [announced](#) a focus on digital health innovation. As part of its [strategic priorities for 2018-2020](#), CDRH highlighted the value of [collaborative communities](#) in which public and private entities work together to address medical device challenges. The FDA currently participates in the Digital Health Measurement Collaborative Community ([DATAcc](#)) and the [AI Global Healthcare Initiative Collaborative Community](#).
- Congress provided more specific authorities for AI-related activities through the 21st Century Cures Act ([P.L. 114-255](#)). Section 3060(a) of the 21st Century Cures Act added section 520(o), which excludes certain software functions from the device definition. These exclusions cover administrative support at healthcare facilities, specific lifestyle apps, electronic patient records, and certain apps for clinical laboratory and similar data assistance. Furthermore, software can be excluded from the device definition under section [520\(o\)\(1\)\(E\)](#) if it meets specific criteria. The FDA issued a [final](#) guidance document in September 2022 to clarify the scope of its statutory authority over clinical decision support software.
- In April 2019, the FDA released a [discussion paper](#) titled “Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning-Based Software as a Medical Device (SaMD)”. This framework introduced the concept of a predetermined change control plan (PCCP), which would allow for certain modifications to SaMD without the need for a renewed premarket review.
- In January 2021, the FDA issued the "Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) [Action Plan](#)." The action plan was developed based on previous FDA initiatives including, the [International Medical Device Regulators Forum](#) (IMDRF) [risk categorization framework](#) for [software as a medical device](#) (with FDA’s guidance document [here](#)), the FDA’s [risk-benefit framework](#) for certain devices, principles in the software modifications [guidance](#), and the total product lifecycle approach described in the Digital Health Software Precertification ([Pre-Cert](#)) Pilot Program. The action plan proposed five activities:
  1. Updating the framework for AI/ML-based SaMD, which includes issuing Draft Guidance on PCCPs, which would allow for certain modifications to SaMD without the need for an amendment to the premarket approval (PMA).
  2. Encouraging the development of Good Machine Learning Practice with guiding [principles](#).

3. Holding a public workshop on how device labeling supports transparency to users and enhances trust in AI/ML-based devices, building on the recent Patient Engagement Advisory Committee [meeting](#) in October 2021.
  4. Supporting regulatory science to develop methodology for evaluating and mitigating biases in machine learning algorithms and promoting algorithm robustness.
  5. Clarifying the process for monitoring real-world performance of AI/ML-based SaMD.
- The Consolidated Appropriations Act, 2023 ([P.L. 117-328](#)), which included the Food and Drug Omnibus Reform Act of 2022, added section 515C to the FDCA related to give FDA express authority to accept PCCPs. In response to this new authority, in April 2023, the FDA issued [draft](#) guidance on “machine learning-enabled device software functions” (ML-DSF). This draft guidance is based upon its 2021 [guiding principles](#). The FDA has now begun to accept PCCPs and establish standards for devices that rely on adaptive algorithms.
  - In October 2023, the FDA [announced](#) a new [Digital Health Advisory Committee](#). In citing the rationale for this new committee, the FDA noted the rapid pace of AI.
  - CDRH maintains a [list](#) of over 600 medical devices that are AI and machine-learning enabled.

### **Center for Drug Evaluation and Research (CDER)**

- CDER’s regulatory actions are based upon the statutory authority under 201(g) of the Federal Food Drug and Cosmetic Act (FDCA) ([21 USC 321\(g\)](#)) which defines the drug as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals.”
- CDER has developed three discussion papers on AI since 2022. The first paper, [AI and Machine Learning \(AI/ML\) for Drug Development](#), focuses on AI in drug discovery and development. The other two papers support CDER’s Framework for Regulatory Advanced Manufacturing Evaluation ([FRAME](#)) Initiative: [Artificial Intelligence in Drug Manufacturing](#) and [Distributed Manufacturing and Point-of-Care Manufacturing of Drugs](#). According to an [analysis](#) in 2022, from 2016 to 2021, drug sponsors have utilized AI/ML in over 200 drug and biologic applications.

### **Health Resources and Services Administration (HRSA)**

- HRSA [leads](#) HHS initiatives to expand and diversify the health care workforce. In light of the recent [announcement](#) of the first dual degree in AI and medicine, HRSA may be tasked to address AI education within the health-

care workforce through its grant, scholarship, and loan repayment programs. These initiatives include the National Health Service Corps, Title 7 and 8 programs (which provide grants to medical and nursing schools), and Title 5 maternal health programs.

## Office of the Assistant Secretary for Planning and Evaluation (ASPE)

ASPE published a [report](#) in September 2023 on the blueprint for HHS on “Trustworthy Artificial Intelligence (TAI) for Patient Centered Outcomes Research (PCOR).”

## Office of Civil Rights (OCR)

OCR enforces laws related to nondiscrimination, religious freedom, and health information privacy. OCR oversees provisions of the [Affordable Care Act \(ACA\)](#) and the [Health Insurance Portability and Accountability Act \(HIPAA\)](#) that have significant implications for AI applications in health care.

- Congress passed the ACA (P.L. 111-148) in 2009. Section 1557 of the ACA makes it illegal for health care providers and insurers that receive Federal assistance to discriminate against individuals based on race, color, national origin, sex, age, or disability (i.e., non-discrimination rule). HHS issued a [final rule](#) implementing this new law in June 2020. In August 2022, OCR and the Centers for Medicare and Medicaid Services issued a proposed [rule](#) that clarifies that covered entities 1) must ensure algorithms used in clinical decision-making do not discriminate, and 2) may be liable for decisions that rely on clinical algorithms. Section 1557 has undergone [significant back and forth revisions](#) by the agency and been marked by rulemaking and litigation, with several legal challenges and court decisions shaping its interpretation.
- Congress passed HIPAA (P.L. 104-191) in 1996, and HHS issued the [Privacy Rule](#) in 2000, to establish a foundation of Federal privacy and security safeguards for certain health information. HIPAA creates national standards related to the use of health information, including protected health information (PHI), limited datasets, and de-identified research data. In 2009, Congress enacted the Health Information Technology for Economic and Clinical Health (HITECH) Act—as part of the American Recovery and Reinvestment Act of 2009 (ARRA) (P.L. 111-5)—to strengthen HIPAA enforcement and establish the “breach notification rule,” which requires covered entities to inform patients when their PHI is improperly used or disclosed. In 2021, Congress amended the HITECH Act with the HIPAA Safe Harbor law (P.L. 116-321) and OCR published a [Notice of Proposed Rulemaking](#) to update the HIPAA Privacy Rule. Following OCR’s [guidance](#) regarding tracking technologies by HIPAA-covered entities, in July 2023 the FTC and HHS sent a [joint letter](#) to over 100 hospital systems and telehealth providers to



alert them to the risks of certain online tracking technologies that can lead to unauthorized PHI disclosures. In November 2023, the American Hospital Association (AHA) and three Texas hospital groups [filed a suit](#) challenging the OCR guidance.

- The comprehensive set of HIPAA regulations can be found in 45 CFR Code of Federal Regulations [Part 160](#), [Part 162](#), and [Part 164](#). For information on HIPAA and research, visit [here](#).

## Office of Human Research Protections (OHRP)

OHRP enforces the Federal Policy for the Protection of Human Subject Research, known as the [Common Rule](#). In recent years, OHRP has [discussed the impact of emerging technologies](#) such as AI on the application of the Common Rule.

## Office of the National Coordinator for Health IT (ONC)

Established by the HITECH Act of 2009, as part of the as part of the American Recovery and Reinvestment Act of 2009 (ARRA) ([P.L. 111-5](#)), ONC assists with the promotion and adoption of health information technology.

- In 2010, ONC developed the [Health Information Technology \(Health IT\) Certification Program](#), a voluntary initiative that certifies health IT products—including electronic health records—that meet certain standards for data exchange, privacy, and security. Within this program, the [Clinical Decision Support \(CDS\) certification criterion](#) validates programs that often incorporate AI to analyze patient data and provide personalized recommendations. Providers participating in certain Medicare and Medicaid programs must use certified health IT.
- In April 2023, ONC issued a [proposed rule](#) to implement several changes required by the 21<sup>st</sup> Century Cures Act ([P.L. 114-255](#)). As part of that rule, ONC proposed to update the Health IT Certification Program with new requirements for [algorithm transparency](#).
- ONC has also developed guidance documents and other AI-supportive material, including a [2018 Model Privacy Notice](#) for health technology developers and a 2023 [Social Determinants of Health Information Exchange Toolkit](#) to guide the integration of social determinants data across health IT systems.

## OTHER FEDERAL HEALTH CARE DELIVERY SYSTEMS

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*Indian Health Service (IHS)*

*Department of Defense's (DoD's) Military Health System*

*Department of Veterans Affairs' (VA's) Veterans Health Administration*

- In 2021, the VA launched the [AI@VA Community](#) to provide veterans with information about AI systems used in their healthcare.
- In 2022, the VA finalized a rule to implement a [Principle-Based Ethics Framework for Access to and Use of Veteran Data](#) and ensure AI risks are managed during human subjects research.
- In October 2023, the VA [announced](#) a \$1 million AI tech competition aimed to reduce health care worker burnout.
- The August 2023 [Defense Health Information Technology Symposium](#) focused on leveraging health IT—including artificial intelligence—to create a more patient-center health care delivery system. DoD is using AI and health data analytics to [facilitate disability-determinations](#).

## PATIENT-CENTERED OUTCOME RESEARCH INSTITUTE (PCORI)

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- Authorized by Congress in [2010](#) as part of the ACA and reauthorized in [2019](#), in 2021 as part of the Emerging Technologies and Therapeutics Reports, PCORI published a "[Narrative Review and Evidence Mapping of Artificial Intelligence in Clinical Care](#)."