“Just What the Doctor Ordered”

Regulations Affecting the Administrative and Back-Office Use of AI in Healthcare

October 24, 2024

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Agenda

- AI Experiences of Dr. Luehr
- AI Uses in Healthcare
- FDA Regulations and Exemptions
- Other Regulations Affecting AI in the Back Office
- Implementing Compliance – a Technical Perspective
- Q&A

AI Experiences of Dr. Luehr

AI in Healthcare

What AI Does Well

Recognize patterns

Analyze images/text/data streams

Make predictions

Support automation

Synthesize information

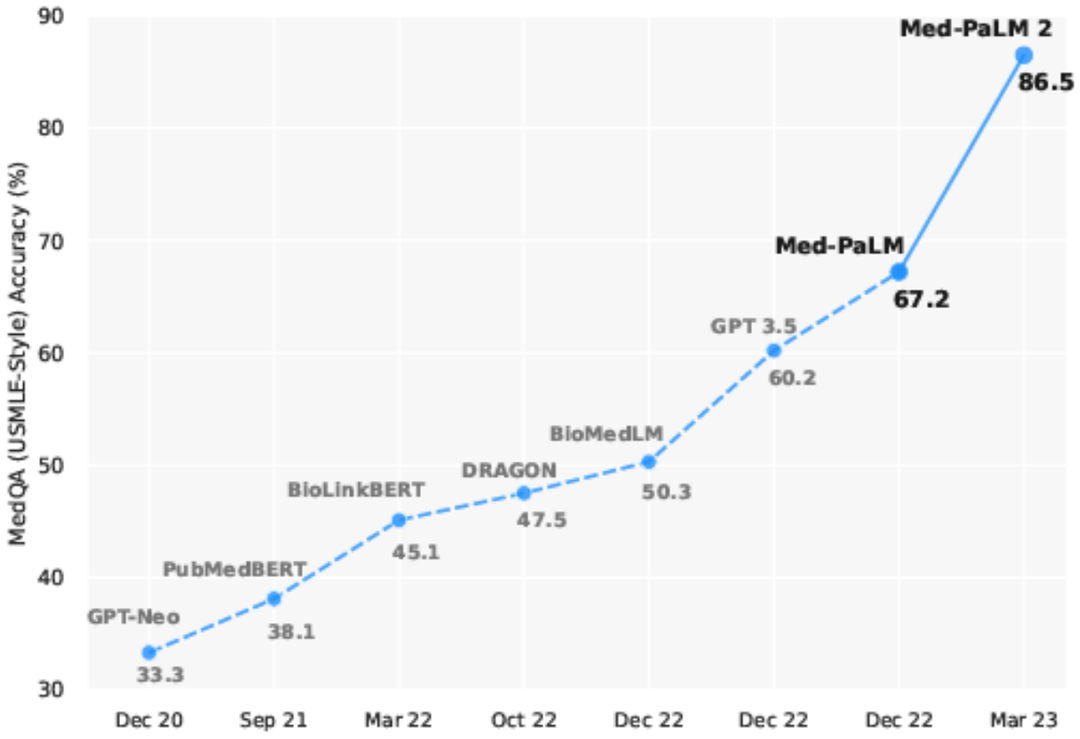
Translate

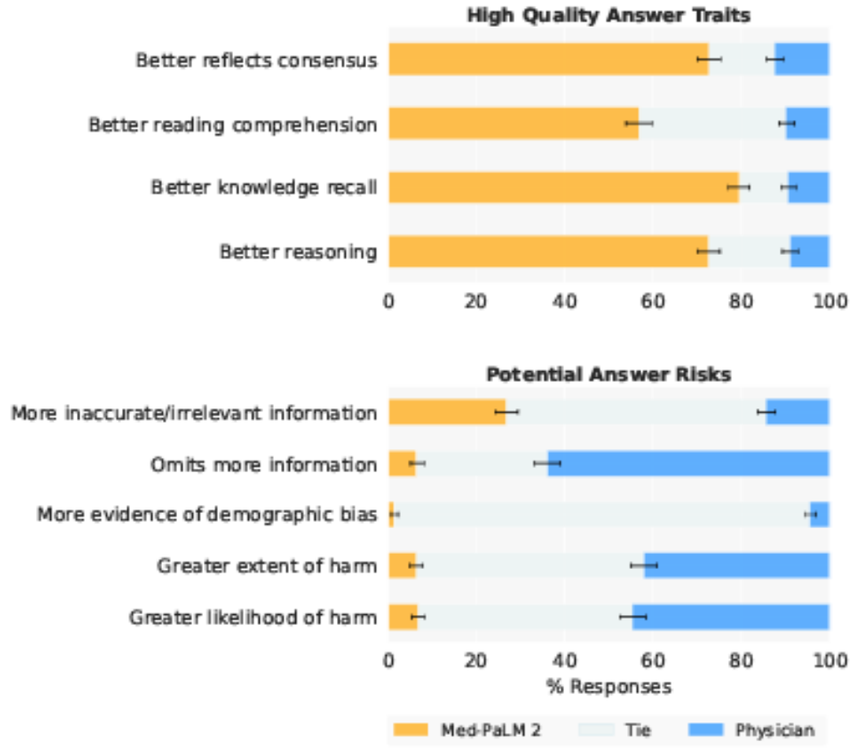
(between programming/spoken languages)

AI in Health Care: Accuracy on Medical Licensing Exam

AI performance is advancing rapidly.

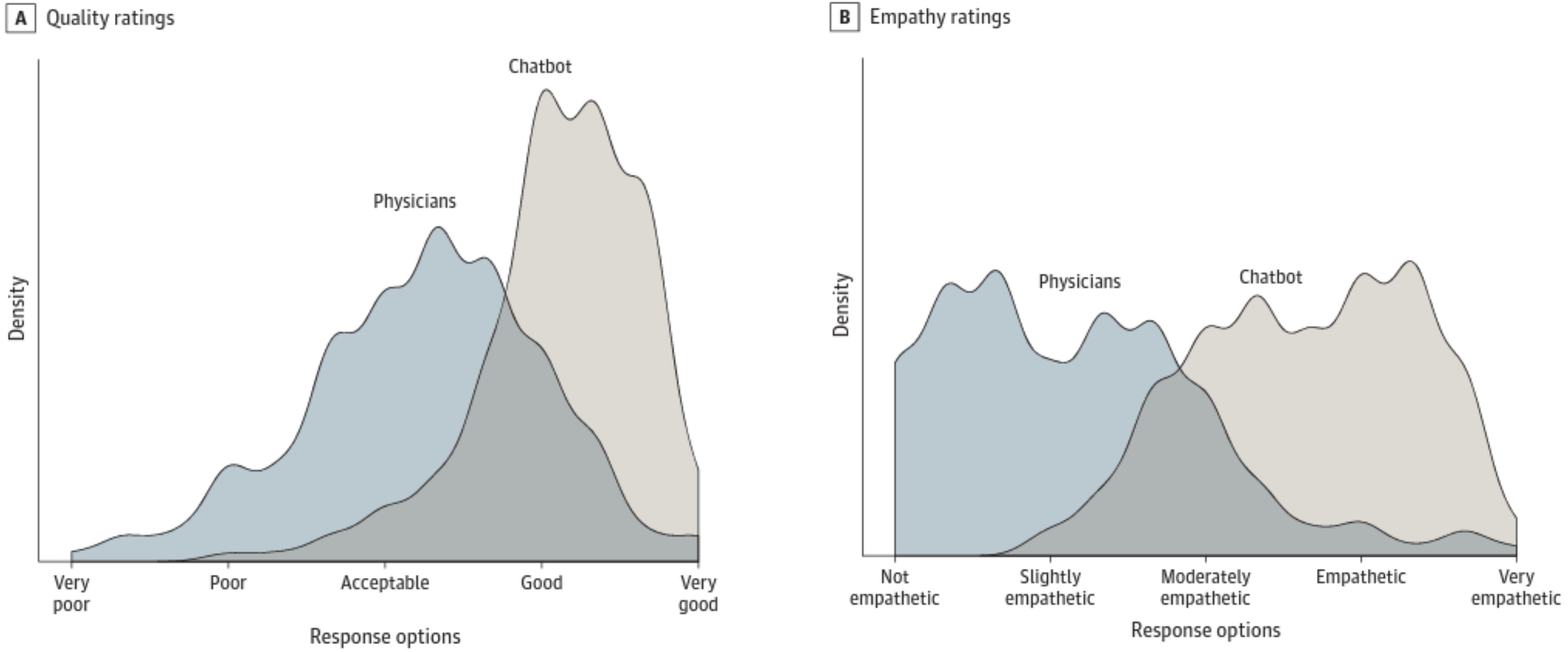
The latest models have 85+% accuracy on the exam, up from 33% only four years ago.





Source: Google. Toward Expert Level Medical Question Answering with LLMs.

Clinical Use Case: Chatbot (ChatGPT)



Source: *JAMA Intern Med.* 2023;183(6):589-596. doi:10.1001/jamainternmed.2023.1838

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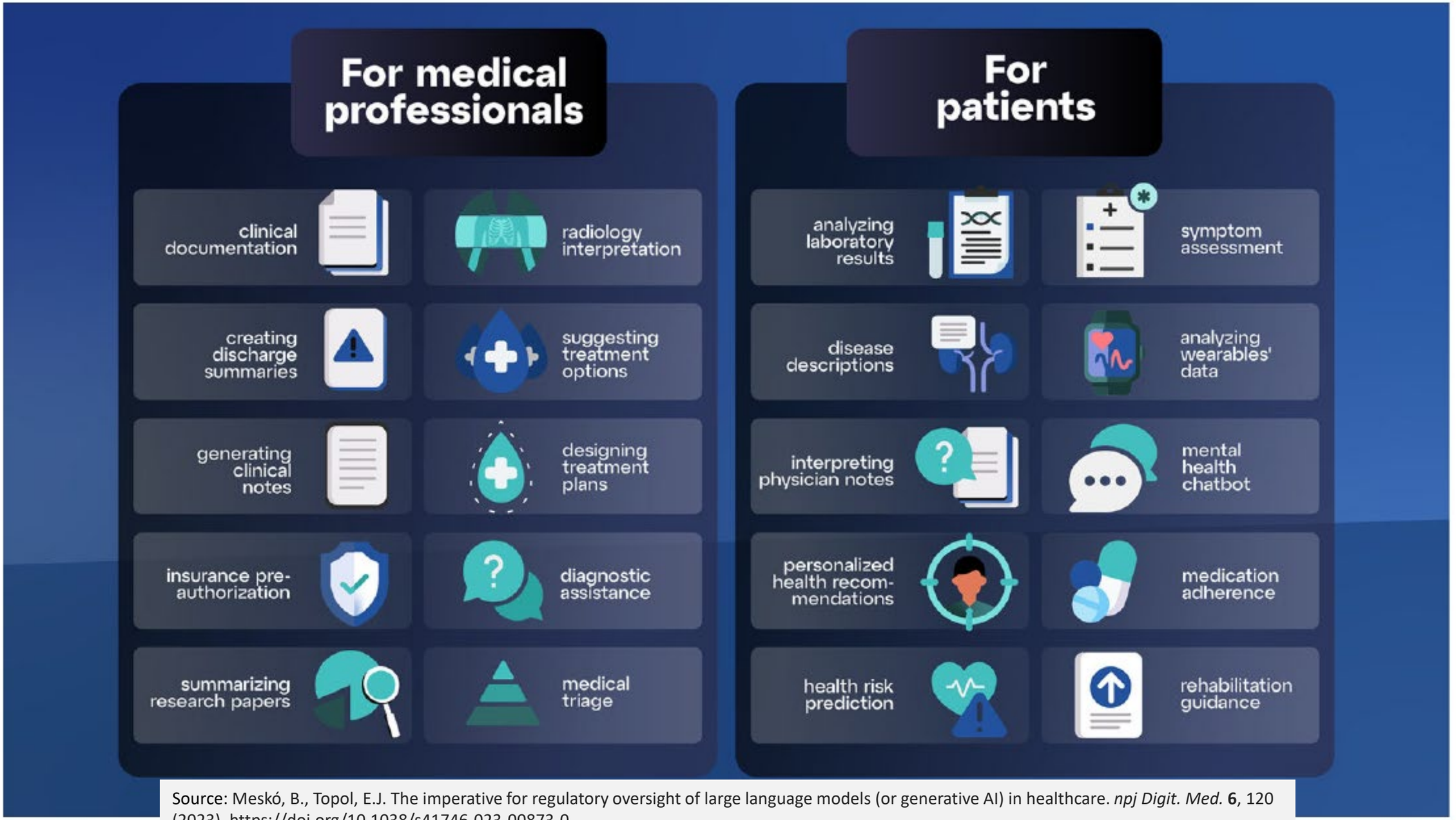
Administrative Use Case: Clinical Documentation

- Tested an AI Assistant with over 100 family medicine and other primary care providers for a month
- 72% reduction in median documentation time per note
- 3.3 hours per week per clinician saved
- Improved satisfaction with workload
- Improved satisfaction with overall practice

Source: Helio.com, “AI alleviates burnout, reduces documentation time by 72% in primary care,” March 20, 2023; AAFP, “Using an AI Assistant To Reduce Documentation Burden in Family Medicine,” Nov. 2021.

AI in Healthcare - Emerging Use of Generative AI



Source: Meskó, B., Topol, E.J. The imperative for regulatory oversight of large language models (or generative AI) in healthcare. *npj Digit. Med.* **6**, 120 (2023). https://doi.org/10.1038/s41746-023-00873-0.

“The irony of the current state of AI and the difficulties surrounding it, is that AI is supposed to make our business life easier, when in fact, it is the exact opposite.”

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Fortune 150 CISO

FDA Regulations and Exemptions

FDA Jurisdiction Over Medical Devices

Federal Food Drug and Cosmetic Act (FDCA)

Device Definition – intended use is key:

Intended for use:

- Diagnosis, cure, mitigation, treatment, or prevention of disease, in man or other animals, or

Intended to affect:

- Structure or
- Any function of the body of man or other animals

Software hook - "similar or related article"

Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is:
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
2. *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, or*
3. *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and*

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

FDA Regulation of Clinical Decision Support (CDS) Software

21st Century Cures Act excluded from definition of "medical device" in FDCA

"Software intended for . . . "

Administrative support of a health care facility, such as processing bills and claims, scheduling, inventory management, analysis of historical data to predict utilization, and determination of benefit eligibility.

Maintaining or encouraging a healthy lifestyle where the use is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition (i.e., general health and wellness).

Electronic patient records, if such records are created and used by health care providers and constitute health information technology as certified under Public Health Service Act § 3001(c)(5), and the software does not interpret or analyze patient records for the purpose of diagnosis, cure, mitigation, prevention, or treatment of a disease or condition.

Transfer, store, convert formats, or display (but not analyze) laboratory and device data, results, associated findings by a health care professional, and general background information about a test or device.

Clinical decision support ("CDS") software that displays/analyzes medical information and makes recommendations for health care professionals regarding prevention, diagnosis, or treatment of a disease/condition.

However, such software:

- Cannot be processing or analyzing medical images (e.g., CT scans, MRIs, X-rays), data from *in vitro* diagnostic devices, or "a pattern or signal from a signal acquisition system"; and
- Must be transparent and its recommendations reviewable, such that it does not serve as the sole basis for a health care professional's determination regarding a particular patient.

Source: Section 520(o), Federal Food, Drug, and Cosmetic Act; 21st Century Cures Act (P.L. 114-255), Section 3060(a).

FDA Jurisdiction Over Lab Developed Tests (LDTs)

- FDA has maintained it has regulatory authority over LDTs
  - traditionally exercised "**enforcement discretion**" over most LDTs
  - actively regulated commercial *in vitro* clinical tests as medical devices under Section 201(h) of the FDCA.

Per Section 201(h) of the Food, Drug, and Cosmetic Act, a device is:
An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is:

1. *recognized in the official National Formulary, or the United States Pharmacopoeia, or any supplement to them,*
2. *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, or*
3. *intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and*

which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes. The term "device" does not include software functions excluded pursuant to section 520(o).

FDA Jurisdiction Over LDTs – new Rule!

New Regulation: "[T]he LDT landscape has evolved significantly since 1976. Today, many LDTs increasingly rely on high-tech or complex instrumentation and software to generate results and clinical interpretations…

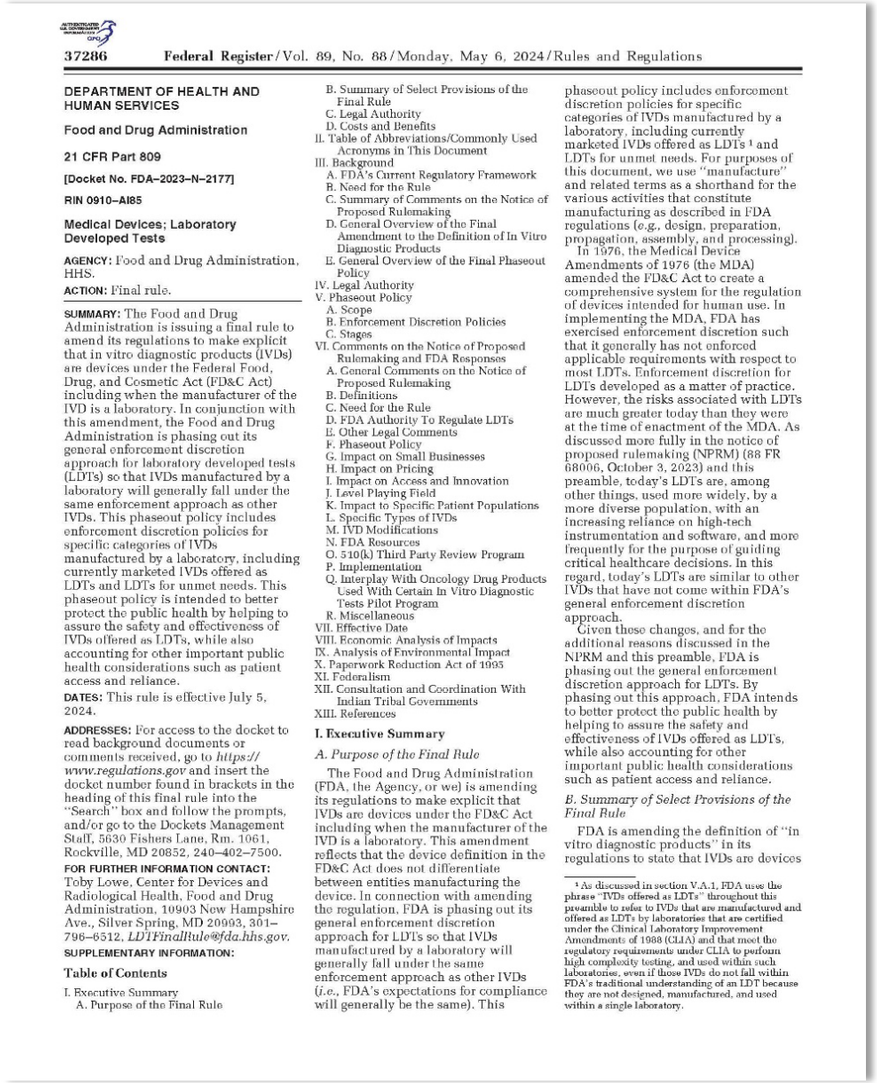
As a result of these evolutions in the testing landscape, FDA has long recognized the need for a change in the Agency's general enforcement discretion approach for LDTs."

- FDA issued final rule on May 6, 2024 declaring LDTs to be medical devices
- **21 CFR § 809.3 Definitions.**
- (a) ***In vitro diagnostic products*** are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (the act) and may also be biological products subject to section 351 of the Public Health Service Act, including when the manufacturer of these products is a laboratory.

FDA Jurisdiction Over LDTs – new Rule!

Fall-out from Rule Announcement

- Phases out enforcement discretion but carves out a few categories of tests that will be exempt from some or all regulations
- Final rule is being challenged in court
- Legislative proposals will likely surface to regulate LDTs under a different regime



37286 Federal Register / Vol. 89, No. 88 / Monday, May 6, 2024 / Rules and Regulations

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 809

[Docket No. FDA–2023–N–2177]

RIN 0910–AI85

Medical Devices; Laboratory Developed Tests

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration is issuing a final rule to amend its regulations to make explicit that in vitro diagnostic products (IVDs) are devices under the Federal Food, Drug, and Cosmetic Act (FD&C Act) including when the manufacturer of the IVD is a laboratory. In conjunction with this amendment, the Food and Drug Administration is phasing out its general enforcement discretion approach for laboratory developed tests (LDTs) so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs. This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs and LDTs for unmet needs. This phaseout policy is intended to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.

DATES: This rule is effective July 5, 2024.

ADDRESSES: For access to the docket to read background documents or comments received, go to *https://www.regulations.gov* and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Toby Lowe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301–796–6512, *LDTFinalRule@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

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I. Executive Summary

A. Purpose of the Final Rule

The Food and Drug Administration (FDA, the Agency, or we) is amending its regulations to make explicit that IVDs are devices under the FD&C Act including when the manufacturer of the IVD is a laboratory. This amendment reflects that the device definition in the FD&C Act does not differentiate between entities manufacturing the device. In connection with amending the regulation, FDA is phasing out its general enforcement discretion approach for LDTs so that IVDs manufactured by a laboratory will generally fall under the same enforcement approach as other IVDs (*i.e.*, FDA's expectations for compliance will generally be the same). This phaseout policy includes enforcement discretion policies for specific categories of IVDs manufactured by a laboratory, including currently marketed IVDs offered as LDTs [1] and LDTs for unmet needs. For purposes of this document, we use "manufacture" and related terms as a shorthand for the various activities that constitute manufacturing as described in FDA regulations (*e.g.*, design, preparation, propagation, assembly, and processing).

In 1976, the Medical Device Amendments of 1976 (the MDA) amended the FD&C Act to create a comprehensive system for the regulation of devices intended for human use. In implementing the MDA, FDA has exercised enforcement discretion such that it generally has not enforced applicable requirements with respect to most LDTs. Enforcement discretion for LDTs developed as a matter of practice. However, the risks associated with LDTs are much greater today than they were at the time of enactment of the MDA. As discussed more fully in the notice of proposed rulemaking (NPRM) (88 FR 68006, October 3, 2023) and this preamble, today's LDTs are, among other things, used more widely, by a more diverse population, with an increasing reliance on high-tech instrumentation and software, and more frequently for the purpose of guiding critical healthcare decisions. In this regard, today's LDTs are similar to other IVDs that have not come within FDA's general enforcement discretion approach.

Given these changes, and for the additional reasons discussed in the NPRM and this preamble, FDA is phasing out the general enforcement discretion approach for LDTs. By phasing out this approach, FDA intends to better protect the public health by helping to assure the safety and effectiveness of IVDs offered as LDTs, while also accounting for other important public health considerations such as patient access and reliance.

B. Summary of Select Provisions of the Final Rule

FDA is amending the definition of "in vitro diagnostic products" in its regulations to state that IVDs are devices

[1] As discussed in section V.A.1, FDA uses the phrase "IVDs offered as LDTs" throughout this preamble to refer to IVDs that are manufactured and offered as LDTs by laboratories that are certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and that meet the regulatory requirements under CLIA to perform high complexity testing, and used within such laboratories, even if those IVDs do not fall within FDA's traditional understanding of an LDT because they are not designed, manufactured, and used within a single laboratory.

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Other Regulations Affecting AI in the Back Office

Summary of Federal Health AI Activity

White House	AI Executive Order, AI Blueprint for an AI Bill of Rights, etc.
Congress	Bipartisan Task Force on AI, Bill to Create National AI Commission
OCR	Finalized Non-Discrimination Rule under 1557 of the Affordable Care Act
CMS	Regulatory guidance for Medicare Advantage plans regarding use of clinical algorithms for medical necessity determinations
ONC	Transparency and risk management requirements for certified health IT (HT-1 Rule)
FDA	Non-binding guidance on AI-driven clinical decision support tools that should be regulated as medical devices
DOJ	Pending litigation over alleged use of AI to deny Medicare Advantage claims

HHS Regulations Governing Use of AI in Health

Non-Discrimination

- **Regulations under Section 1557 of the Affordable Care Act**: Under new regulations at 45 CFR 92.210 "A covered entity **must not discriminate** on the basis of race, color, national origin, sex, age, or disability in its health programs and activities **through the use of clinical algorithms in its decision-making**".

Notable Implications for Providers

  - In this proposed rule, HHS notes that "[w]hile covered entities are not liable for clinical algorithms that they did not develop, they may be held liable under this provision for their decisions made in reliance on clinical algorithms."
  - Health care providers should ensure they understand how AI is being used within their organization, how the AI tools were developed, and demonstrate that their AI has been tested for bias and discrimination.

1557 Procedural History

- Final rule issued April 2024
- Effective date, July 5, 2024
- Gender ID provisions blocked in:
  - MS, FL
- Entire Rule blocked in
  - TX, MT
- Oct 9, 2024, HHS states 1557 will still be enforced.

Medical Necessity

- As part of 2024 Medicare Advantage (MA) final rule, CMS issued FAQs stating that Medicare Advantage Plans "must ensure that they are making **medical necessity determinations** based on the **circumstances of the specific individual,** as outlined at § 422.101(c), **as opposed to using an algorithm or software** that doesn't account for an individual's circumstances."

Sources: Nondiscrimination in Health Programs and Activities, 87 FR 47824; 88 FR 22120, 22195; Section 1557 Final Rule: Frequently Asked Questions | HHS.gov; CMS Letter: FAQ Related to Coverage Criteria and Utilization Management Requirements in CMS Final Rule (CMS-4201-F)

HHS/ONC "HTI-1" Rule - AI Transparency and Risk Management

In December 2023, HHS Office of the National Coordinator for Health Information Technology (ONC), finalized its "Health Data, Technology and Interoperability (HTI-1)" Rule

- **Purpose**: Promote the development of predictive algorithms that are fair, appropriate, valid, effective and safe (FAVES) and ensure that the AI used by health care providers can be trusted.

- **New Requirements for Developers of ONC-Certified HIT that use Predictive Decision Support Interventions (DSI)*** :

1. Transparency. If certified HIT* uses predictive DSI, the HIT developer must make available to the software users (i.e., providers) 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.

Health care providers should closely track predictive DSI requirements being imposed by the ONC; they may foreshadow how HHS may regulate health care providers' use of AI through other mechanisms (e.g., Medicare Conditions of Participation). ONC rules may serve as a blueprint for states.

2. Risk Management**.** Predictive DSI must be subject to: 1) an analysis of potential risks and adverse impacts associated with its validity, reliability, robustness, fairness, intelligibility, safety, security and privacy; 2) practices to mitigate risks; and, 3) policies and implemented controls for governance (including how data are acquired, managed and used).

*Note: The rule only pertains to developers of ONC-certified health information technologies. Predictive algorithms used by providers that are not offered as part of certified HIT are outside the regulation's scope. Predictive DSI is "technology that supports decision-making based on algorithms or models that derive relationships from training data and then produces an output that results in prediction, classification, recommendation, evaluation, or analysis (i.e., technologies that employ AI).

Source: HHS Final Rule, Manatt Health Newsletter

HHS proposed "HTI-2" rule in July 2024

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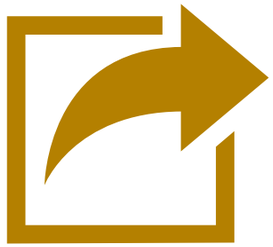
HHS Online Tracking Guidance

- **December 2022**, HHS issues Bulletin that sharing PHI with 3rd parties via pixels - without authorization and a BAA – violates the Privacy Rule and may constitute a Breach.
- **November 2023**, Hospital systems sue to enjoin enforcement of Bulletin.
- **March 2024**, HHS clarifies enforcement for authenticated, unauthenticated sites.
- **June 2024**, Texas federal court vacates Bulletin where an IP address relates to "unauthenticated" visits to public web pages about health conditions or providers.

HHS is now "evaluating its next steps."

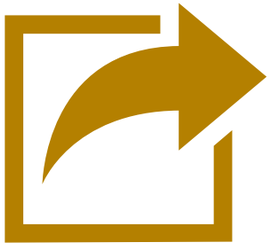


Source: Use of Online Tracking Technologies by HIPAA Covered Entities and Business Associates | HHS.gov

FTC Online Tracking Enforcement Actions

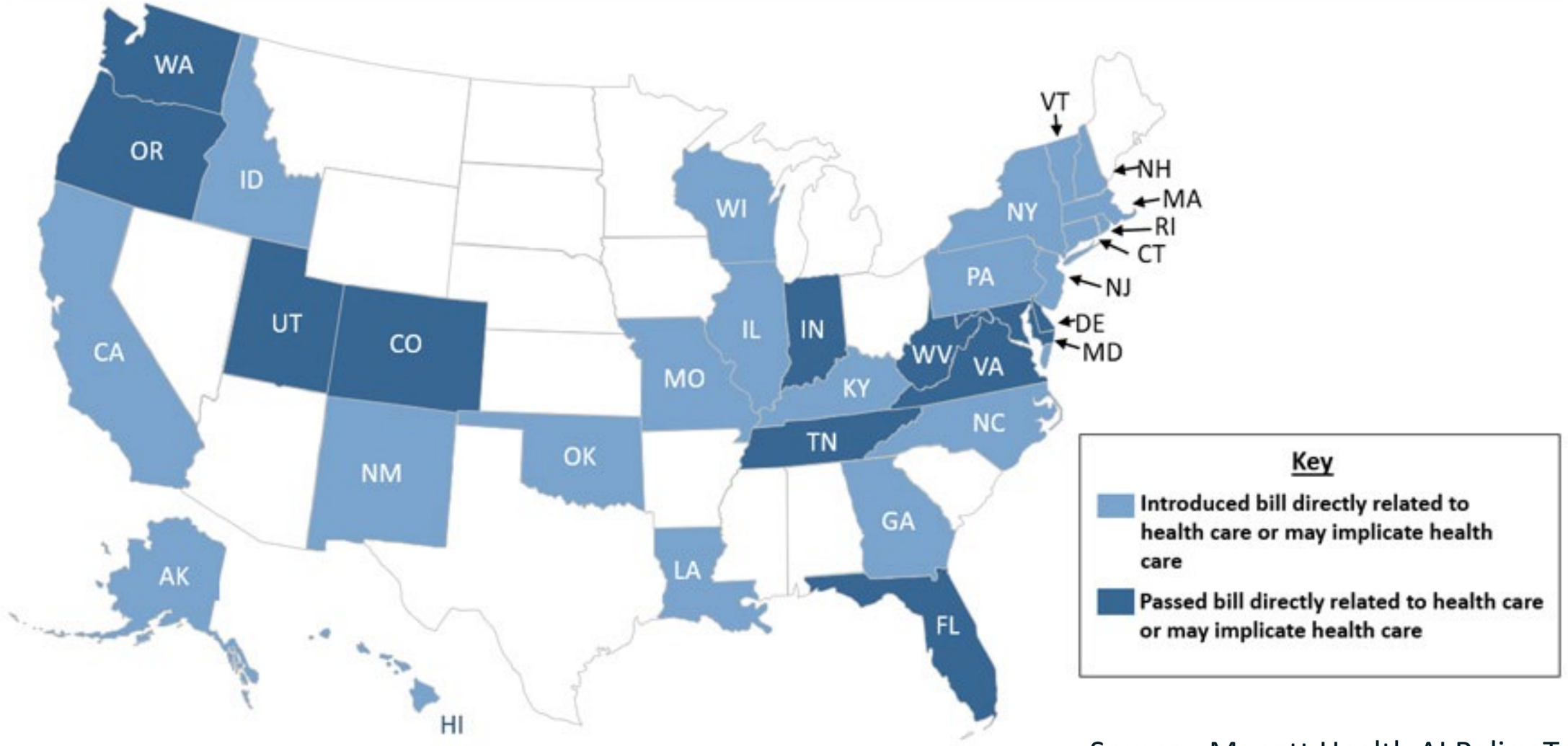
- **GoodRx (Feb. 2023),** enforcement action for sharing prescription medications and health conditions with companies like Facebook, Google, and Criteo. $1.5M penalty
- **BetterHelp (Mar. 2023),** action over violation of HBNR and disclosure of mental health data to Facebook and others for target marketing. $7.8M in restitution.
- **Easy Healthcare dba PreMom May 2023,** action over sharing of fertility information with AppsFlyer, Google and Chinese companies. $100K judgement.
- **Cerebral (Apr. 2024),** action over disclosure of sensitive health data to LinkedIn, Snapchat, and TikTok for advertising and data analytics. $7M settlement.
- **Monument (Apr. 2024),** action over disclosure of alcohol addiction information to Meta, Google and others. $2.5M suspended judgment

– **Health Breach Notification Rule (HBNR) (Apr. 2024),** finalized 16 CFR Part 318:



Source: FTC.gov

State Health AI Legislative Activity (January – June 2024)



Source: Manatt Health AI Policy Tracker

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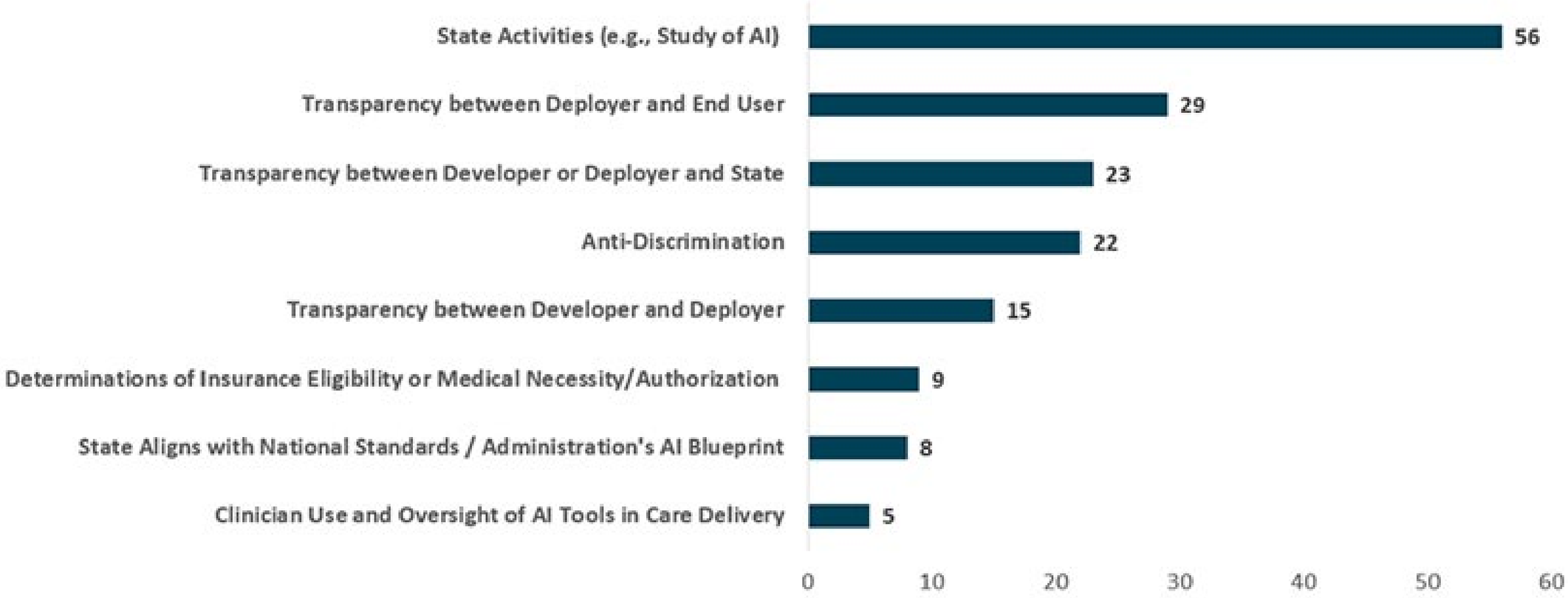
What is being regulated?

Bills introduced between January - June 2024



Source: Manatt Health AI Policy Tracker

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General Privacy, Cyber and AI Laws and Regulations

Washington BPPA

Oregon OCPA

Utah Consumer Privacy Act (UCPA)

Utah AI Policy Act

CCPA and CPRA

California Bot and AI Laws

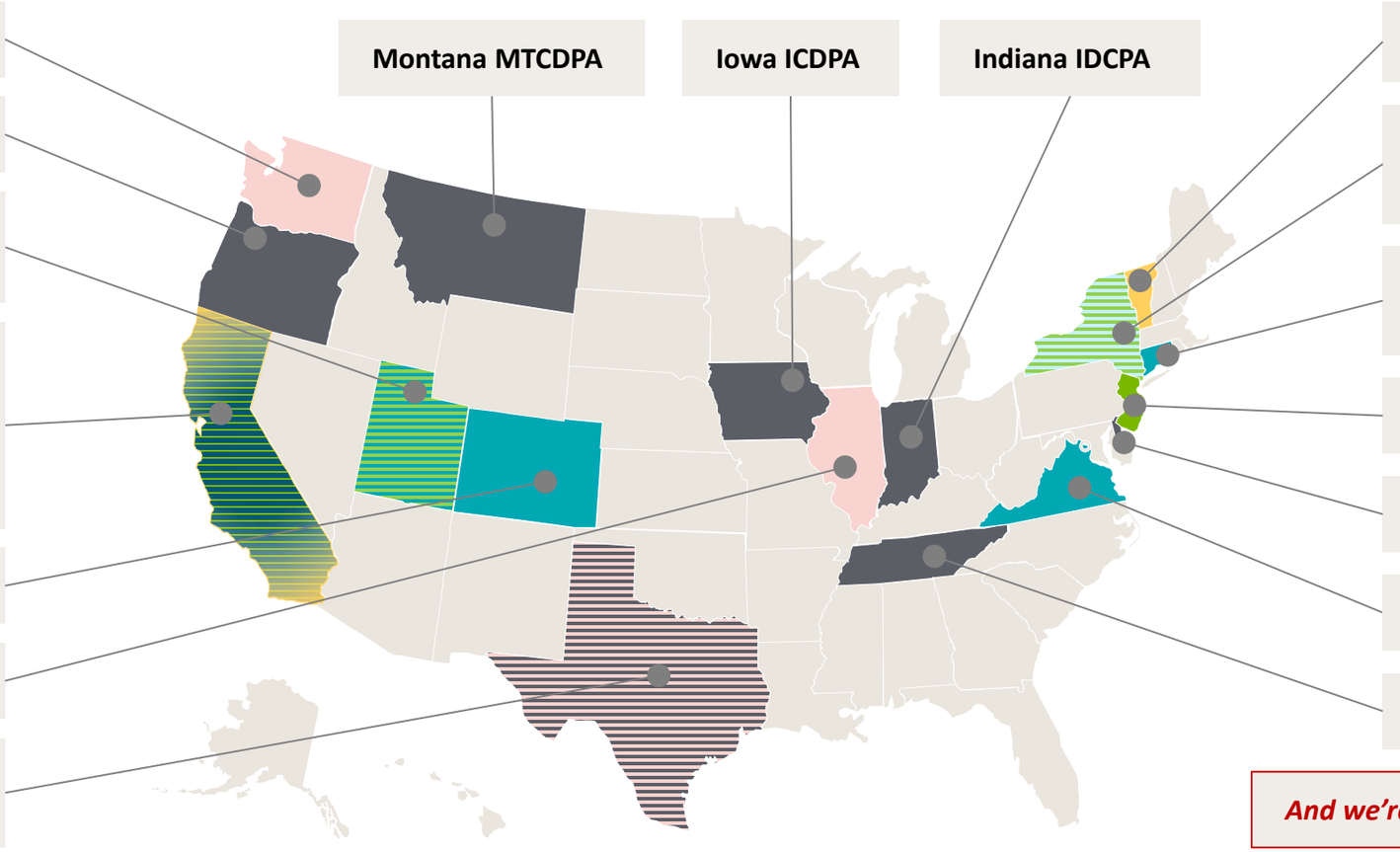
California Data Broker Law

Colorado Privacy Act (CPA)

Illinois BIPA

Texas Biometric Law

Texas TDSPA



Vermont Data Broker Law

New York's SHIELD Act

NYC Law 144 on AEDT

Connecticut Data Privacy Act (CTDPA)

New Jersey Bot Law

Delaware DPDPA

Virginia CDPA

Tennessee TIPA

And we're watching the Federal APRA, etc.

Legacy Comprehensive Privacy Law

New Privacy Law 2023 or 2024

Coming Privacy Law Late 2024 -26

Biometric Data Law

Data Broker Law

Stringent Cybersecurity Law

AI, Bot Disclosure Law

Legal and Regulatory Framework Governing AI

No federal law currently governs AI.

Many other existing laws and regulations govern a company's use of AI.

Consumer Protection Laws (FTC)	**HIPAA**	**Copyright and Trademark Laws**	**Employment Laws**
State Privacy Laws	**FDCA Act, Medical Research Laws**	**Laws Governing Professional Conduct**	**Anti-Discrimination Laws**

Source: https://www.ncsl.org/technology-and-communication/artificial-intelligence-2023-legislation ; https://www.manatt.com/insights/newsletters/privacy-and-data-security/regulation-of-ai-systems-is-already-here-look-to.

Risk Factors – based on NIST Framework

Accuracy	▪ Produces valid and reliable results ▪ Robust enough to address expected circumstance
Privacy and Confidentiality	▪ Protects personal information through consent, data minimization, limited use, etc. ▪ Protects business and partner information from unauthorized access or use
Intellectual Property (IP) Rights	▪ Does not ingest data into learning model without consent or infringe on IP rights ▪ Produces valuable results, even if IP is not protected
Ethics and Bias	▪ Does not rely on inaccurate, incomplete or biased historical data in its learning model ▪ Does not advance extremist views or perpetuate racist, sexist or harmful stereotypes
Transparency	▪ Provides adequate information about inputs, computer logic and testing ▪ Produces results that are explainable to and understood by end users
Safety and Security	▪ Protects personal information and confidential business data from unauthorized access ▪ Under human control and poses no danger to health or life, property or the environment

Chatbots

Risks

- Inadequate Notice
  - Chatbot laws
  - Wiretapping laws, CIPA
- Discrimination
  - HHS 1557, EEOC regulations
  - State AI laws
- Unauthorized Disclosure
  - HIPAA Privacy Rule
  - State privacy laws
  - FTC enforcement
- Professional liability

Mitigation

- Real-time, pop-up notice
  - "Automated responses generated by artificial intelligence"
  - "☐ I agree that my responses can be shared with xxy, this chatbot provider."
- Assessments, Bias Testing
  - Request Model and Data Cards
  - Conduct risk analysis and periodically retest accuracy, bias
- Signed BAA, if PHI is collected
- Fulsome privacy notice
- Disclaimer and human decision-making
  - "Responses are not medical advice. Please see your licensed professional for any healthcare concerns."

Compliance – a Technical Perspective

The Component Challenges of AI

Key AI Governance and Risk Concepts

Enterprise governance

AI governance starts with defining the corporate strategy for AI by documenting:

- Target operating models
- Compliance assessments
- Accountability processes
- Policies and procedures

Product governance

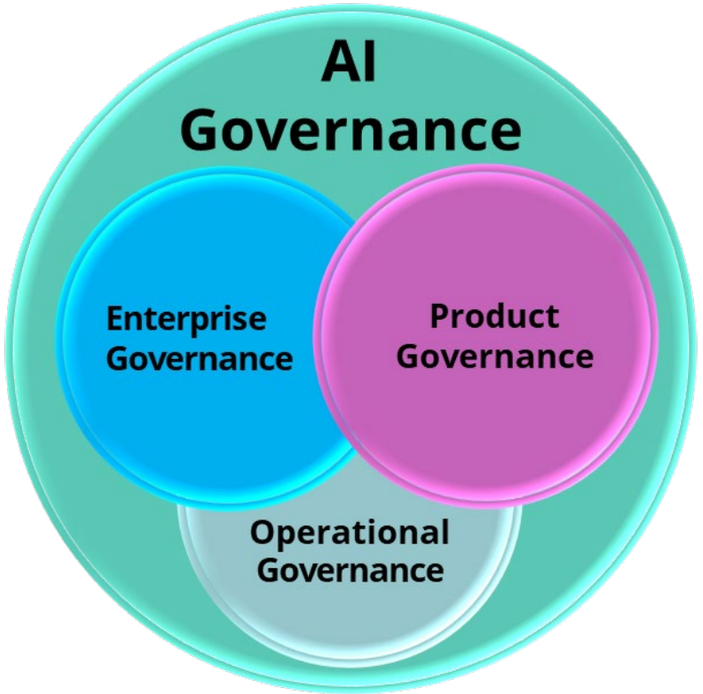
AI governance also requires enterprise policy standards to be applied at the product level. Organizations can ensure their AI products match their enterprise strategy by using:

- System impact assessments (AI IA)
- Quality management procedures
- Risk and controls frameworks
- Third-party due diligence

Operational governance:

The organization's AI strategy must ultimately be operationalized throughout the business through the development of:

- Performance monitoring protocols
- Transparency and human oversight initiatives
- Incident management plans



Key Data Governance Challenges

Accessing data and identifying data sources
Accessing data and identifying key data sources are critical components of effective AI data governance, ensuring data integrity, compliance, and ethical AI practices.

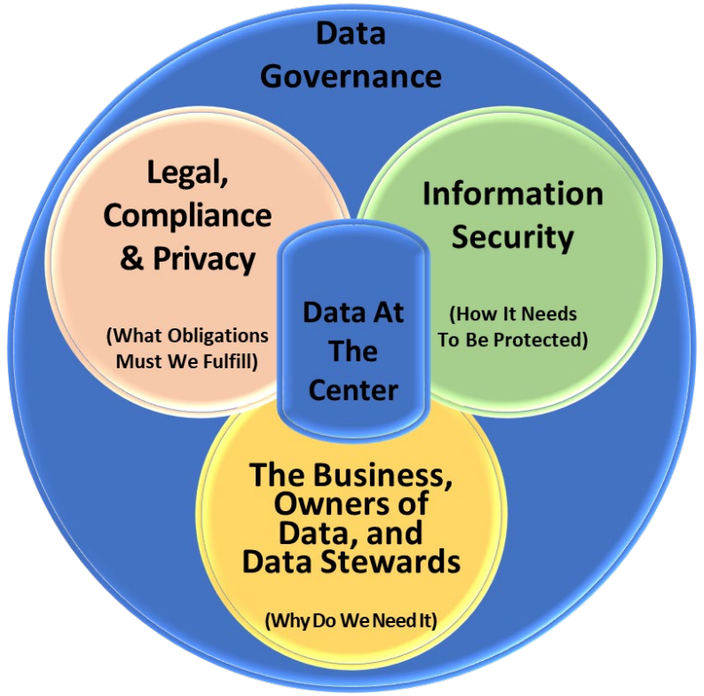
- **Data Access:** Compliant access protocols.
- **Data Sources:** Relevant to AI models.
- **Data Quality**: Accuracy, and consistency across sources.
- **Data Governance frameworks:** Manage data usage.
- **Regulatory:** Privacy and regulatory compliance.
- **Data Access:** Auditing and restricting
- **Data ethics**

Law and policy considerations
The topic of law and policy considerations for AI data governance involves the development and enforcement of legal frameworks and policies that ensure ethical, transparent, and secure management of data used in artificial intelligence systems.

- **Data Privacy:** Ensuring compliance with data protection **Transparency:** transparency in data collection.
- **Security Measures:** Robust data security protocols **Regulatory Compliance:** AI data practices align with existing and emerging regulations and designed to future legislative developments.

Business & Data Stewardship considerations

- **Ensures Data Integrity and Business Relevance**
- **Supports Data Governance and Accountability**
- **Strengthens Security and Data Protection**
- **Prepares Businesses for AI Scalability**



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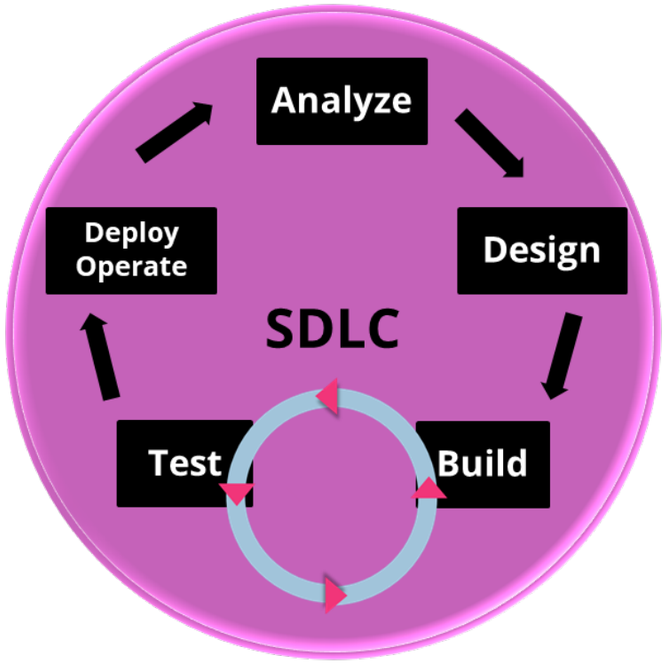
SDLC – Development Governance

AI DEVELOPMENT IS SOFTWARE DEVELOPMENT

SDLC Governance:

Emphasizing the **build-test-build-test iterative process** is critical to ensuring that the AI model works effectively and adapts to evolving data and business needs. Here's how it fits into the SDLC for AI development:

- **Rapid Prototyping and Initial Model Building**
- **Frequent Testing During Model Development**
- **Feedback Loop and Error Analysis**
- **Validation and Cross-Validation**
- **Automated Testing Pipelines**
- **Monitoring and Retraining in Production**



Take-Aways

- Set your strategy - listen to employees and determine best use cases
- Implement sound data governance, policies, and procedures
- Determine whether FDA medical device/software regulations apply
- Identify specific AI and healthcare laws that are applicable
- Identify generally applicable laws and principles
- Test and retest AI tools, especially for accuracy and bias


Q
A

Appendix

FDA Exemptions and Enforcement Discretion

Administrative Support of a Health Care Facility

- Processing and maintenance of financial records
- Claims or billing information
- Appointment schedules
- Business analytics
- Information about patient populations, admissions, practice and inventory management
- Analysis of historical claims data to predict future utilization or cost-effectiveness
- Determination of health benefit eligibility
- Population health management
- Laboratory workflow

- Other software used in a healthcare facility that is not a medical device
  - Videoconferencing software for use in telemedicine
  - Software that provides general patient education and to facilitate patient access to commonly used reference information
  - Medical education training software for health care providers

FDA Exemptions and Enforcement Discretion

Maintaining or Encouraging a Healthy Lifestyle/General Wellness

- An intended use that relates to maintaining or encouraging a general state of health or a healthy activity
  - Software would not be regulated as a device
  - Hardware would be considered a device but reviewed under wellness policy
- An intended use that relates the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition
- If the intended use of the software function is related to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition, then the product is not excluded from device definition
- Functions in software products that are for the purpose of logging workout activities, dietary logs, making exercise or posture suggestions, or providing daily motivational tips would not be considered a device

FDA Exemptions and Enforcement Discretion

Electronic Patient Records

- Intended to transfer, store, convert formats, or display the equivalent of a paper medical chart;
- Created, stored, transferred or reviewed by health care professionals or under their supervision;
- Certified health information technology; and
- NOT intended to interpret or analyze data or records for the purpose of diagnosis, cure, mitigation, prevention, or treatment of a disease or condition
- Not a medical device if the software provides patients with simple tools to organize and track their health information, provide easy access to information, or help patients document, show, or communicate potential medical conditions to HCPs
  - Example: Videoconferencing portals
    - On the other hand, an app intended for medical uses that uses the camera to document or transmit pictures is a device but is subject to enforcement discretion
  - Mobile apps that help asthmatics record inhaler usage, asthma episodes experienced, location of user at the time of an attack, or environmental triggers are no longer considered a device
  - Mobile apps that allow the user to record data, such as blood glucose, blood pressure, heart rate, weight, or other data from a device to eventually share with an HCP are no longer a device.

FDA Exemptions and Enforcement Discretion

Medical Device Data Systems

- Intended for transferring, storing, converting formats, or displaying:
  - Clinical laboratory test or other device data and results
  - Findings by a health care professional with respect to such data and results
  - General information about the clinician's findings
  - General background information about the laboratory test or device
- Examples of functions that are not a medical device:
  - Software that stores historical blood pressure information or displays a previously stored electrocardiogram;
  - Software that converts medical device data from one format to another in accordance with a preset specification - e.g. software that converts digital data generated by a pulse oximeter into a digital format that can be printed.
- Not exempt if the function is intended to interpret or analyze the data

FDA Exemptions and Enforcement Discretion

Clinical Decision Support

- Intended to provide decision support to a healthcare provider (HCP) for the diagnosis, treatment, prevention, cure, or mitigation of disease or other conditions
  - Not intended to acquire, process, or analyze a medical image or a signal from an in vitro diagnostic device or a pattern or signal from a signal acquisition system;
    - A signal acquisition system acquires an image or a physiological signal (e.g. electrocardiogram)
  - Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information;
  - Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition; and
  - Intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient
- If not exempt, FDA applies risk-based framework based on the significance of information provided by the software to the health care decision and the state of the health care situation or condition

FDA Exemptions and Enforcement Discretion

FDA exercises enforcement discretion for certain software that may meet the device definition, including functions that:

- Provide or facilitate supplemental clinical care, by coaching or prompting, to help patients manage their health in their daily environment
  - e.g. coaching to maintain healthy weight, exercise, manage salt intake or adhere to pre-determined medication dosing schedule by simple prompting
- Provide easy access to information related to patients' health conditions or treatments (beyond providing an electronic "copy" of a medical reference)
  - e.g. using patient's diagnosis to provide clinician with best practice treatment guidelines
- Make a checklist of common signs and symptoms and provide a list of possible medical conditions and advice on when to consult a HCP
- Help a patient keep track of medications and provide reminders for improved medication adherence
- Aggregate and display trends in personal health incidents