AI in Healthcare 2025:
A Toolkit for State Lawmakers

Nexus Policy Consulting

Introduction

The rapid advancement of artificial intelligence (AI) is transforming nearly every sector of our economy, and healthcare is no exception. AI-driven tools are already improving diagnostics, reducing providers' administrative burdens, and expanding access to high-quality care, especially in rural and remote areas of the world.

But while technology is evolving at an unprecedented pace, our healthcare policies are often stuck in the past—rooted in outdated regulatory frameworks that stifle innovation, limit competition, and slow the adoption of life-changing advancements.

As state lawmakers, you hold a unique and powerful role in shaping the future of AI in healthcare. While the federal government regulates aspects of drug and medical device approvals, the practice of medicine itself is a matter of state authority. This means states — not Washington — are best positioned to determine how AI can be safely and effectively integrated into healthcare delivery. From modernizing medical licensure and telehealth policies to ensuring AI-driven decision-making enhances the quality of care and expands access to critical services, states have the opportunity to lead where federal agencies lag behind.

This AI in Healthcare 2025: A Toolkit for State Lawmakers is not a final word on state policy levers on AI policy but rather a starting point for new ideas and innovations. It offers a framework for how states can harness AI to improve patient outcomes, lower costs, and expand access to care while ensuring appropriate guardrails are put into place.

→AI can empower doctors by enhancing their capabilities and improving patient outcomes.

→It can expand patient autonomy by providing more personalized and accessible care options for patients and their providers.

Introduction (cont'd)

→And it can break down barriers to care, laying the foundation for future innovations that will transform how we care for aging populations and deliver healthcare in the coming decades.

I encourage you to use this toolkit to start conversations, craft policy solutions, and explore what AI-driven healthcare can mean for your state. The future of medicine is being built today. With the right policies in place, states can ensure AI is used to advance — not restrict — medical innovation, delivering the promise of 21st century medical advances to patients and providers TODAY.

Naomi Lopez
Founder & Principal
Nexus Policy Consulting
naomi@nexuspolicyconsulting.com

TABLE OF CONTENTS

AI-Supported and AI-Driven Medicine

The Problem

Artificial intelligence (AI) is rapidly transforming healthcare delivery, providing physicians powerful tools to enhance patient care, improve diagnosis and treatment, and reduce administrative burdens. According to a recent survey by the American Medical Association, physician enthusiasm for AI is growing, with many in the field seeing its potential to enhance their clinical capabilities and streamline practice operations.[1]

The Food and Drug Administration (FDA) has already approved or certified more than 1,000 AI and machine learning (AI/ML) enabled medical devices, underscoring AI's growing and pivotal role in the transformation of modern medicine.[2] Despite this progress, many state laws governing the practice of medicine have not kept pace with technological advances, creating uncertainty around AI's use and limiting its full potential.

Current medical practice laws in most states were written in an era before AI-driven tools could assist in diagnosing illness, recommending treatments, or predicting patient decline. Today, therefore, these laws often do not define the role of AI in medical decision-making, leaving many providers, especially those working independent from major health systems or with limited financial or human resources, in unclear territory.

Without clear legislative or regulatory guidance, physicians may hesitate to adopt AI-based tools out of concern for liability or regulatory scrutiny. Similarly, state medical boards often do not have a framework to assess AI's role in clinical practice.

AI-Supported and AI-Driven Medicine (cont'd)

Today, AI can assist in interpreting imaging studies with greater accuracy than human radiologists, detect early signs of sepsis before clinical symptoms appear, and optimize treatment plans by analyzing vast medical datasets. While human clinical expertise and judgement is both needed and desired, laws that encourage AI integration into clinical practice can enhance medical providers' toolkits to provide cutting edge care to their patients.

AI-supported medicine and **AI-driven medicine** represent two distinct approaches for integrating artificial intelligence into healthcare. **AI-supported medicine** refers to the use of AI technologies to provide recommendations, analyses, or insights to a licensed healthcare provider while providers retain ultimate authority and responsibility for clinical decisions. In contrast, **AI-driven medicine** involves AI systems operating autonomously while making clinical decisions, including diagnosis, treatment, or other medical interventions, without prior review or oversight by a licensed healthcare provider. The distinction between these models is critical for regulatory and legislative considerations, ensuring that AI enhances medical practice while maintaining a balance of appropriate levels of human oversight and accountability.

This proposed law applies specifically to AI-driven and AI-supported medical devices that have obtained certification or approval from the FDA, ensuring that these technologies meet minimum safety and efficacy standards before deployment in clinical settings. When AI-driven medicine is used without direct management by a licensed healthcare provider, informed patient consent is required.

AI-Supported and AI-Driven Medicine (cont'd)

Patients must be clearly informed that the AI system operates independently and makes clinical decisions autonomously. Informed consent must be obtained by the healthcare provider before proceeding with care under these conditions, ensuring transparency and patient independence in the decision-making process.

Next Steps

What States Can Do

States can be at the forefront of supporting innovative care by acting now to modernize their laws and guidelines governing the practice of medicine to encourage AI-supported and AI-driven healthcare while ensuring patient safety and provider accountability. States have a critical opportunity to shape the future of AI in medicine by fostering an environment that encourages innovation while ensuring patient safety.

By modernizing outdated regulations, policymakers can enable AI to complement physicians, improving efficiency, expanding access to high-quality care, and ultimately saving lives by creating a new standard for innovation in healthcare. The rapid evolution of medical technology demands proactive legislative and executive action to prevent regulatory barriers from stifling life-saving advancements in AI-driven healthcare.

AI-Supported and AI-Driven Medicine (cont'd)

[1] American Medical Association, "AMA Physician Enthusiasm Grows for Health Care AI," available at https://www.ama-assn.org/press-center/press-releases/ama-physician-enthusiasm-grows-health-care-ai.

[2] U.S. Food and Drug Administration, "Artificial and Machine Learning (AI/ML)-Enabled Medical Devices," available at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices. Accessed February 20, 2025. See Appendix B for more insights and analysis.

VIEW MODEL LEGISLATION

Issue Experts

Taylor Barkley
Director of Public Policy
Abundance Institute
taylor@abundance.institute

Ted Cho
Physician, UCSF
Health Policy Research, Johns Hopkins
tedcho32@gmail.com

Joe Grogan
Founder
Fire Arrow, LLC
jgrogan@firearrowconsulting.com

AI-Supported and AI-Driven Medicine (cont'd)

Rea S. Hederman, Jr.
Vice President of Policy
The Buckeye Institute
rea@buckeyeinstitute.org

Brian J. Miller, MD
Nonresident Fellow
American Enterprise Institute
brian@brianjmillermd.com

Adam Thierer
Senior Fellow
R Street Institute
athierer@rstreet.org

Naomi Lopez
Founder & Principal
Nexus Policy Consulting
naomi@nexuspolicyconsulting.com

Patients' Medical Algorithm Rights

The Problem

Artificial intelligence (AI) is increasingly shaping modern healthcare, offering tailored diagnostic insights, treatment recommendations, and predictive analytics based on individual patient data. These AI-driven tools, when customized to a patient's unique medical profile, hold immense potential to improve clinical outcomes, enhance physician decision-making, and provide more precise and personalized care that continue to advance while being utilized.

While patients have long-standing legal rights to access and protect their medical records, they often lack comparable rights to access the algorithmic insights and decision-making processes used in their care. The "Patients' Medical Algorithm Rights Act" seeks to address this gap by ensuring patients have the right to access, control, and share their individualized medical information, including algorithm-generated insights.

Under this framework, healthcare providers and systems—whether digital or human—ensure patients have secure, user-friendly access to their curated medical data, including AI-generated outcomes and relevant clinical insights specific to their care. This access can be provided in a manner that preserves proprietary algorithms and protected technologies for developers while maintaining transparency in patient-specific results for patients and providers.

Patients' Medical Algorithm Rights (cont'd)

Adopting policies that ensure algorithmic access for patients is consistent with existing laws that grant patients the right to obtain their medical records. The Health Insurance Portability and Accountability Act (HIPAA) provides patients with the right to access their medical data, ensuring transparency in treatment history, diagnostic results, and physician notes.[1] Many states have expanded this precedent by enacting additional protections reinforcing and expanding patients' rights to their health information.

Extending these protections to algorithm-generated insights ensures patients receive the same level of transparency for AI-influenced decisions on par with traditional medical records. Just as patients can review physician notes and test results, the ability to review and understand AI-driven recommendations that affect their care can substantially expand understanding of care options with their providers.

Furthermore, as part of the 21st Century Cures Act, healthcare providers must grant patients electronic access to their health information, including structured data from health records.[2] Algorithmic insights, when used to guide clinical decisions, could logically fall under this requirement, ensuring that patients have meaningful management of the information shaping their diagnoses and treatments. Without such access, patients lose agency in the ownership of their personal medical information, undermining their autonomy and limiting their ability to make informed decisions, adhere to treatment protocols, and maintain trust in their care providers.

Patients' Medical Algorithm Rights (cont'd)

Next Steps

What States Can Do

States can take proactive steps to protect patients' rights by ensuring access to AI-generated medical insights. Just as HIPAA grants patients the right to obtain their medical records, similar legislation—such as the "Patients' Medical Algorithm Rights Act"—can establish a patient's right to access algorithmic information when it has been used to guide treatment plans.

By enacting these protections, states can take the lead in modernizing healthcare regulations where it matters most, keeping pace with AI's rapid advancement while ensuring patient rights and transparency guardrails remain at the core of medical decision-making. Algorithmic transparency is not just a technological issue—it is a fundamental healthcare right for which recognition and safeguarding equivalent to other types of medical records and information in the digital age is necessary to support effective treatment.

[1] Office of the National Coordinator for Health Information Technology. Your health information rights. HealthIT.gov. https://www.healthit.gov/topic/privacy-security-and-hipaa/your-health-information-rights. Accessed February 20, 2025.

[2] 21st Century Cures Act, Pub. L. No. 114-255, 130 Stat. 1033 (2016) (codified in various sections of 21 U.S.C. and 42 U.S.C.).

VIEW MODEL LEGISLATION

Patients' Medical Algorithm Rights (cont'd)

Issue Experts

Neil Chilson
Head of AI Policy
Abundance Institute
neil@abundance.institute

Naomi Lopez
Founder & Principal
Nexus Policy Consulting
naomi@nexuspolicyconsulting.com

Legalizing N-of-1 Treatments and Home Health Monitoring with AI/ML

The Problem

As states grapple with an aging population and rising Medicaid long-term care costs,[1] they can adopt new policies that leverage technology to make healthcare more accessible and, in many cases, allow older residents to remain in their communities. Advances in artificial intelligence and machine learning (AI/ML) have introduced game-changing innovations in medicine, particularly through personalized N-of-1 treatments and remote health monitoring.

Imagine a patient with diabetes using an FDA-certified AI-driven insulin pump that continuously monitors glucose levels and adjusts insulin delivery accordingly in real time before errors can occur. With remote monitoring capabilities, a healthcare provider can track a patient's condition in real time from the comfort of their own home, preventing dangerous blood sugar fluctuations without the patient needing frequent hospital visits. This technology allows individuals to manage conditions safely at home rather than in an long-term care or hospital setting.

A patient with congestive heart failure using a wearable AI-enabled device can track vital signs such as heart rate, oxygen levels, and fluid retention. The device can alert both patients and their doctors to early warning signs of deterioration, allowing for timely – and potentially less costly – intervention and reducing the need for emergency hospitalizations. By integrating these AI-driven solutions into healthcare, individuals can maintain their independence and receive proactive, personalized care in their preferred environment.

Legalizing N-of-1 Treatments and Home Health Monitoring with AI/ML (cont'd)

Unfortunately, outdated regulations that were adopted before these technologies existed, create uncertainty that could slow the adoption of these advancements by providers and patients. AI/ML-enabled medical devices offer tremendous potential to enhance patient care, particularly for older adults and individuals affected by chronic conditions. Many of these existing and emerging technologies enable real-time, personalized treatment decisions, allowing patients to receive high-quality care from the comfort of their own homes. These breakthroughs have the potential to dramatically expand living and care options for our aging population, allowing patients more options to age in community and, in some cases, maintain their independence for either a longer time period or the entirety of their remaining lives while increasing quality of life.

Many current laws, however, do not address the use of these devices outside of traditional healthcare settings, leaving healthcare providers and device manufacturers in a gray area – and patients reliant upon in-office visits and higher costs. Without clear guidance, patients may miss out on life-enhancing innovations, and providers may be hesitant to adopt new technology due to liability and coverage concerns. By implementing a well-defined legal framework — that includes regulatory oversight and patient protections — lawmakers can create new opportunities for patients to access cutting-edge treatment options and, in some cases, receive care in more convenient and familiar settings such as their own home to support quality of life as a priority in treatment advances.

Legalizing N-of-1 Treatments and Home Health Monitoring with AI/ML (cont'd)

Next Steps

What States Can Do

The AI-Driven Personalized Healthcare Act steps in to fill this gap. The bill directs state medical boards to formally recognize and authorize the use of FDA-certified AI/ML-enabled devices for N-of-1 treatments and remote health monitoring. This ensures these technologies are not just seen as futuristic possibilities but as legitimate and valuable tools that can be adopted as options for treatment in everyday healthcare scenarios.

The legislation also protects licensed healthcare providers from disciplinary actions when they use these devices in accordance with the standard of care. This provision reassures providers that they can integrate AI/ML innovations into their practice without fear of professional penalties, further providing new avenues for innovation in care that is patient-focused.

To ensure patient safety, the bill requires state medical boards to develop oversight protocols, including monitoring guidelines and adverse event reporting processes for AI/ML-enabled devices. To foster continued innovation while maintaining accountability, the bill establishes liability protections for manufacturers when their FDA-certified devices are used as intended. Healthcare providers are also shielded from liability, provided they obtain informed consent from their patients and follow accepted medical standards. State medical boards are responsible for creating the necessary rules to implement the bill's provisions within 12 months, ensuring a smooth transition into practice.

Legalizing N-of-1 Treatments and Home Health Monitoring with AI/ML (cont'd)

The AI-Driven Personalized Healthcare Act represents a practical, forward-thinking approach to modernizing state healthcare policy. By providing clear regulatory and enforcement frameworks, the bill allows patients to take advantage of cutting-edge treatment options safely and efficiently, supports providers in delivering high-quality care without the risk of liability, and encourages ongoing innovation in medical technology in patient-friendly care settings. Lawmakers have the opportunity to create access to new monitoring and treatment options, ensuring their constituents benefit from the future of medicine today.

[1] National Association of Medicaid Directors. "Top Five Medicaid Budget Pressures for Fiscal Year 2025." https://medicaiddirectors.org/resource/top-five-medicaid-budget-pressures-for-fiscal-year-2025/. Accessed February 20, 2025.

VIEW MODEL LEGISLATION

Issue Experts

Taylor Barkley
Director of Public Policy
Abundance Institute
taylor@abundance.institute

Joe Grogan
Founder
Fire Arrow, LLC
jgrogan@firearrowconsulting.com

Legalizing N-of-1 Treatments and Home Health Monitoring with AI/ML (cont'd)

Adam Thierer
Senior Fellow
R Street Institute
athierer@rstreet.org

Naomi Lopez
Founder & Principal
Nexus Policy Consulting
naomi@nexuspolicyconsulting.com

Reimbursement for AI/ML-Enabled Devices

The Problem

State governments run some of the largest health plans in the country, covering millions of employees, retirees, and their families. Unlike traditional private insurance or federally run programs like Medicare, many states operate self-insured health plans, whereby states themselves pay medical claims directly instead of paying premiums to an insurance company that assumes the risk.[1]

Self-insured health plans provide states a higher degree of flexibility when deciding what treatments, technologies, and reimbursement policies to adopt. Unlike private insurers, which are often bound by corporate profit guidelines and federal and state policies that limit programs like Medicare from adopt new policies and approaches, self-insured state plans have the ability to lead the way on innovation.

Healthcare treatments and innovations are rapidly moving forward, and one of the most promising frontiers is the integration of artificial intelligence (AI) and machine learning (ML) into medical devices. AI-assisted imaging can detect cancers earlier, machine learning-driven diagnostics can personalize treatment, and AI-enhanced predictive analytics can help doctors make more accurate diagnoses.

Despite these advances, many reimbursement policies across payer types are failing to keep pace. This is where self-insured state health plans have a unique opportunity to take the lead to cover meaningful advances for patients.

Unlike Medicare, which has begun reimbursing for AI-driven medical devices on a limited, case-by-case basis, state health plans have the opportunity to be more proactive in their coverage designs. Rather than waiting for

Reimbursement for AI/ML-Enabled Devices (cont'd)

slow-moving federal policies to catch up, they can adopt a forward-thinking approach by ensuring that any FDA-certified AI/ML medical device that meets established criteria for reimbursement is covered. This approach prioritizes medical necessity and patient outcomes rather than outdated rules that have yet to recognize and adopt the newest technologies.

Next Steps

What States Can Do

Allowing more AI-enabled devices to be considered by providers in diagnoses and treatment decisions can benefit both state employees and taxpayers. For example, AI-powered diagnostics and imaging tools can detect diseases earlier, leading to interventions that are at once more effective, less costly, and can greatly enhance patient quality of life and treatment outcomes.

The proposed AI/ML Device Reimbursement for State Health Plans Act provides a clear, common-sense approach for ensuring more diagnostic and treatment options are available to providers for their patients' treatment plans. The bill ensures devices will not be denied reimbursement simply because it utilizes AI, so long as the device is FDA-certified and meets standard medical necessity criteria.

The legislation also creates a streamlined reimbursement process for providers and constant evaluation feedback. States can consider, apply, and evaluate different reimbursement approaches, supporting goals to ensure every dollar of care is enhancing patient care and outcomes. [2] State health plans would be required to track costs, patient outcomes, and overall effectiveness,

Reimbursement for AI/ML-Enabled Devices (cont'd)

with independent evaluations conducted every two years to assess the impact of AI-driven medical technologies on patient outcomes.

AI is already transforming healthcare, and state-run self-insured health plans have a rare opportunity to lead the way. By embracing innovation, states can ensure their employees receive the best available care while also reducing long-term healthcare costs and improving overall efficiency. This is not just a reimbursement change — it is a chance to modernize healthcare delivery, enhance patient outcomes, and set a new standard for smart, innovative healthcare effectiveness.

[1] Forsberg, Vanessa C., Ryan J. Rosso, and Bernadette Fernandez. "Private Health Insurance: A Primer." Report R47507. Congressional Research Service, April 18, 2023. https://crsreports.congress.gov/product/pdf/R/R47507.

[2] Parikh, Ravi & Helmchen, Lorens. (2022). Paying for artificial intelligence in medicine. npj Digital Medicine. 5. 10.1038/s41746-022-00609-6. https://www.researchgate.net/publication/360731028_Paying_for_artificial_intelligence_in_medicine

VIEW MODEL LEGISLATION

Reimbursement for AI/ML-Enabled Devices (cont'd)

Issue Experts

Ted Cho
Physician, UCSF
Health Policy Research, Johns Hopkins
tedcho32@gmail.com

Joe Grogan
Founder
Fire Arrow, LLC
jgrogan@firearrowconsulting.com

Brian J. Miller, MD
Nonresident Fellow
American Enterprise Institute
brian@brianjmillermd.com

Naomi Lopez
Founder & Principal
Nexus Policy Consulting
naomi@nexuspolicyconsulting.com

Healthcare Spending Transparency and Accountability

The Problem

The current labyrinth of overlapping and duplicative healthcare programs and piecemeal initiatives is a relic of the past, patched together as a series of independent solutions — and far removed from what any state would design if starting fresh today creating a comprehensive system of care. It's time to move beyond Band-Aid fixes and build 21st-century solutions that address the needs of individuals to access effective care while delivering accountability for taxpayers.

Right now, overlapping, fractured federal and state healthcare programs usually operate in silos, weighed down by inefficiencies that drive up costs and can limit impact. Despite ever-increasing taxpayer funding, gaps in service persist, leaving eligible individuals without critical healthcare access and some areas of the country at critical disadvantages, while others receive redundant, abundant, or even misallocated benefits.

Bureaucratic red tape creates unnecessary hurdles for families and individuals who rely on multiple programs, forcing them to navigate a complex and outdated system just to access the support for which they qualify. Taxpayers, meanwhile, have little insight into how their money is spent on healthcare. Program budgets are allocated year after year with minimal visibility into whether those dollars are improving health outcomes or merely maintaining piecemeal and often inadequate care.

State agencies, bound by outdated evaluation methods, lack both the requirements to conduct and the ability to do real-time analysis on program impact to system reform and to individual outcomes. Decisions are often made based on static reports, rather than dynamic, data-driven insights that could allow for smarter, more responsive policymaking

Healthcare Spending Transparency and Accountability (cont'd)

to improve care and strengthen the healthcare system. The system isn't just inefficient — it's failing the people it's meant to serve.

Every state has the opportunity to harness innovation and modernize its healthcare programs by leveraging artificial intelligence (AI) and Application Programming Interfaces (APIs). AI-driven analysis can identify redundancies, enhance program innovations, and provide real-time, publicly accessible data on effectiveness. APIs can integrate systems across healthcare programs, creating a single-entry, one-stop eligibility platform that simplifies access and reduces bureaucratic confusion for individuals, families – and even state and federal agencies providing oversight of these programs.

AI has the power to analyze program participation, spending patterns, and service delivery gaps at a scale and speed that has never been seen. It can flag inefficiencies, identify underserved populations who qualify for assistance but may not be enrolled, and detect potentially improper payments before they happen. AI can also track trends over time, helping policymakers make proactive decisions that have real life implications rather than reacting to outdated reports and political inertia.

Next Steps

What States Can Do

The federal government already permits states to use federal funds for AI-driven evaluations and integrated data platforms.[1] That means states have a unique opportunity to modernize their healthcare oversight without increasing spending. The technology exists, the funding is available, and the need for reform is urgent.

Healthcare Spending Transparency and Accountability (cont'd)

By implementing AI-driven monitoring and analysis, lawmakers can ensure that taxpayer healthcare dollars are being spent wisely and healthcare programs are delivering real results that impact lives every day. With AI's ability to flag inefficiencies and improve targeting of effective or redundant outcomes, wasteful spending can be reduced, freeing up limited resources for those who need them most. A transparent, data-driven system will equip policymakers to track the effectiveness of their decisions in real time, rather than waiting years for traditional static evaluations.

This isn't just about modernization — it's about streamlining operations so governments can become more efficient – delivering results for the people they serve. Smarter oversight, real-time accountability, and a streamlined approach to healthcare assistance can create exponential benefits for taxpayers and policymakers alike. States have the chance lead in building a healthcare system that is more efficient, responsive, and accessible in delivering care to those who need it most. Now is the time to act.

[1] Office of Management and Budget. (2024, April 22). Guidance for federal financial assistance. Federal Register, 89(78), 29672-29794. https://www.federalregister.gov/documents/2024/04/22/2024-07496/guidance-for-federal-financial-assistance

VIEW MODEL LEGISLATION

Healthcare Spending Transparency and Accountability (cont'd)

Issue Experts

Rea S. Hederman, Jr.
Vice President of Policy
The Buckeye Institute
rea@buckeyeinstitute.org

Brian J. Miller, MD
Nonresident Fellow
American Enterprise Institute
brian@brianjmillermd.com

Naomi Lopez
Founder & Principal
Nexus Policy Consulting
naomi@nexuspolicyconsulting.com

Protecting AI-Generated Data as Free Speech

The Problem

As artificial intelligence revolutionizes healthcare, so do the risks of excessive or sweeping regulations that could stifle its innovation potential. While it is essential to protect the public from fraudulent misinformation, governments can aim to understand and properly integrate AI-generated speech rather than simply regulate it because it originates from an algorithm. AI-driven medical insights, when based on sound data and scientific methodology, can be an effective tool for enhanced patient outcomes and an extension of the knowledge-sharing that has always been fundamental to medical practice.

The First Amendment guarantees the right to free speech, but federal protections establish only a baseline. States have a history of establishing precedent in broadening speech rights.[1] Affirming AI-generated healthcare outputs, when they are truthful and non-misleading, can fall within these protections if states take the lead in providing expanded speech protections. If left unaddressed, vague or preemptive regulatory measures could lead to decreased access to critical AI-driven medical insights, slow innovation, and limit patients' and providers' abilities to access valuable health information when it matters most.

State lawmakers have a unique role in defining how AI integrates into healthcare, as states — not the federal government — hold the authority to regulate the practice of medicine. That means states can set clear legal guardrails to ensure AI-generated healthcare data is treated as protected speech unless there is a compelling and well-defined reason to regulate it in the areas of patient safety or data security – the benefits for positive patient outcomes far outweigh the risks.

Protecting AI-Generated Data as Free Speech

Protecting AI-generated healthcare speech ensures that doctors and patients have continued access to critical medical insights. AI is already being used to enhance clinical decision-making, identify early warning signs of disease, and tailor treatments based on a patient's unique biological makeup. If policymakers impose restrictions on AI-generated outputs without clear justification, they risk cutting off a valuable source of information that could improve patient outcomes and expand access to care, especially in remote or home-based settings. Equipping doctors and researchers with the opportunity to use AI-driven insights to inform their clinical decisions provides patients the access to the best available data they deserve when making choices about their health.

A balanced approach also promotes innovation in medicine. AI-powered tools are advancing rapidly, offering new avenues for the diagnosis and treatment of a range of conditions with unprecedented accuracy. If AI-generated speech is subject to excessive regulation, it could discourage healthcare innovators from developing new technologies and bringing them to market and inhibit incorporation into treatment plans for those already in the market. Ensuring that precise and effective AI outputs remain protected as free speech fosters an innovative environment where medical breakthroughs continue to develop, benefiting patients and providers alike.

AI-generated speech protections are fundamentally an issue of patient and provider autonomy. Healthcare decisions guided by medical expertise, patient preferences, and the best available evidence — not by government-imposed limitations on what information can be considered – are the most beneficial for improving healthcare outcomes.

Protecting AI-Generated Data as Free Speech (cont'd)

By adopting AI-generated healthcare speech guidelines that protect the principles of free expression, states can ensure patients and doctors retain the freedom to make informed healthcare choices without unnecessary and overly burdensome regulations.

Next Steps

What States Can Do

Policy and legislation around AI in healthcare are moving fast, and without clear policies in place, the risk of prohibitively broad or reactionary regulation grows. Such regulations could prevent patients from receiving critical AI-generated insights, hinder providers from making well-informed, real-time clinical decisions, and limit the ability of medical professionals to use cutting-edge tools already at their disposal.

By proactively establishing that truthful and non-misleading AI-generated healthcare outputs are protected speech, states can set the foundation for a regulatory environment that fosters innovation while ensuring patient safety. The Protection of Truthful and Non-Misleading AI-Generated Healthcare Speech Act provides a framework for striking this balance, ensuring AI-driven insights remain available to patients and providers while maintaining reasonable safeguards against possible harms. The risk is not just regulatory uncertainty — it is the loss of a future in which AI can help deliver better, more effective, and more personalized healthcare.

Protecting AI-Generated Data as Free Speech (cont'd)

[1] See, for example, Bradburn v. North Central Regional Library District (https://law.justia.com/cases/federal/district-courts/washington/waedce/2:2006cv00327/41160/120/), 231 P.3d 166, 172 (Wash. 2010) (Washington's free speech provision "is more protective of speech than the First Amendment . . . It is already settled that art. 1, § 5, is subject to independent interpretation."); Coleman v. City of Mesa (https://law.justia.com/cases/arizona/supreme-court/2012/cv-11-0351.html), 230 Ariz. 352, 361 n.5 (2012) (Arizona's Speech Provision "is in some respects more protective of free speech rights than the First Amendment"); and Los Angeles Alliance for Survival v. City of Los Angeles (https://law.justia.com/cases/california/supreme-court/4th/22/352.html), 22 Cal. 4th 352, 366 (2000) ("the California liberty of speech clause is broader and more protective than the free speech clause of the First Amendment").

VIEW MODEL LEGISLATION

Issue Experts

Neil Chilson
Head of AI Policy
Abundance Institute
neil@abundance.institute

Naomi Lopez
Founder & Principal
Nexus Policy Consulting
naomi@nexuspolicyconsulting.com

Appendix A
MODEL LEGISLATION

An Act to Define and Regulate AI-Supported and AI-Driven Medicine

Section 1. Title.

This Act shall be known and may be cited as the "AI-Supported and AI-Driven Medicine Regulation Act."

Section 2. Definitions

AI-Supported Medicine: The practice of medicine in which artificial intelligence (AI) technologies provide recommendations, analyses, or insights to a licensed healthcare provider who retains ultimate authority and responsibility for clinical decisions.

AI-Driven Medicine: The practice of medicine in which artificial intelligence systems operate autonomously to make clinical decisions, including diagnosis, treatment, or other medical interventions, without prior review or oversight by a licensed healthcare provider.

Artificial Intelligence: For the purposes of this Act, artificial intelligence refers to computational systems that perform tasks traditionally requiring human intelligence, such as data analysis, pattern recognition, decision-making, and natural language processing.

Informed Consent: A process through which a patient voluntarily agrees to medical intervention or treatment, having been provided with sufficient information about the purpose, risks, benefits, and alternatives of the intervention or treatment, including the use of AI.

Board of Medicine: The state regulatory authority responsible for licensing and oversight of healthcare providers and healthcare practices.

Section 3. Regulation of AI-Supported and AI-Driven Medicine

Disclosure Requirements:

If AI-Driven Medicine is used without review by a licensed provider, patients must be clearly informed that the system operates independently, making clinical decisions autonomously and without the oversight of

licensed healthcare provider. Patients must provide explicit consent for its use under these conditions.

Informed Consent:

a. Informed consent is required only when AI-Driven Medicine is used autonomously without provider review. Providers or entities must clearly inform patients before initiating care.

b. The following details must be included:

i. The nature of the AI system and its role in the patient's care.

ii. Potential risks, including system errors or limitations.

iii. Procedures for addressing errors or adverse outcomes arising from the AI system.

Certification:

AI systems used in healthcare that are certified or approved by the FDA, including those generating outputs for individual diagnoses or treatments, are exempt from certification requirements imposed by the state's Board of Medicine or its equivalent regulatory authority. However, this exemption does not extend to compliance with any other applicable laws.

Standards of Care:

a. The use of AI-Supported or AI-Driven Medicine shall meet or exceed the established standards of care in the state.

b. Licensed providers overseeing AI-Supported Medicine remain fully accountable for clinical decisions and patient outcomes.

Patient Recourse and Remedies:

Nothing in this Act shall alter or modify existing liability and insurance requirements.

Section 4. Reporting and Oversight

Providers and entities using AI-Driven Medicine in patient care must:

a. Submit annual reports to the Board of Medicine detailing:

i. The types of AI systems used.

ii. Instances of serious adverse events resulting directly from the use of the AI system.

iii. Measures taken to mitigate risks.

b. Notify the Board within 30 days of any major system failures or safety concerns directly related to AI use.

Section 5. Implementation and Enforcement

This Act shall take effect 90 days after its passage.

The Board of Medicine shall issue regulations necessary to implement this Act within 6 months of its passage.

Section 6. Severability

If any provision of this Act is found to be invalid or unenforceable, the remaining provisions shall remain in full force and effect.

An Act to Establish Patients' Medical Algorithm Rights

Section 1. Short Title

This Act may be cited as the "Patients' Medical Algorithm Rights Act."

Section 2. Purpose

The purpose of this Act is to ensure that patients have the right to access, control, and share their individualized, curated medical information, including the outcomes and insights derived from medical algorithms and data. This information shall be made available through secure, user-friendly Application Programming Interfaces (APIs) provided by healthcare providers—whether digital or human—that meet state medical board standards and, where applicable, adhere to liability insurance guidelines. This access shall not require the disclosure of trade secrets, proprietary algorithms, or other protected intellectual property but must transparently communicate the outcomes and clinical insights directly relevant to the patient's care.

Section 3. Definitions

As used in this Act, and unless the context otherwise requires:

"Patient" means any individual receiving healthcare services or who is a potential recipient of such services, including those whose data is stored, processed, or generated by healthcare providers or associated systems.

"Medical Algorithm" refers to a data-driven process, model, or system, including but not limited to AI-driven algorithms, used to analyze, interpret, or generate recommendations based on a patient's medical data or health history.

"Curated, Individualized Medical Information" means a patient's medical data that has been processed, analyzed, or synthesized to provide personalized recommendations, insights, or assessments based on the patient's unique medical history, genetic information, biological attributes, and other health-related factors.

"API" (Application Programming Interface) refers to a set of tools, protocols, and standards that allow for the secure and interoperable exchange of

medical information between systems or entities, enabling patients to access their curated medical data electronically.

"Healthcare Provider" means any licensed medical professional, healthcare institution, or digital health entity that provides direct or indirect healthcare services, diagnoses, or medical recommendations to patients.

"State Medical Board Requirements" refers to the standards set by the state's medical licensing authority or board, including requirements for the licensure and practice of healthcare providers.

"Liability Insurance Guidelines" refers to the requirements set by applicable liability insurance providers for coverage and practices related to the use of digital health tools, medical algorithms, and patient data sharing.

Section 4. Patients' Rights to Access and Control Their Medical Data

(a) Right to Access Curated Medical Information:

Patients shall have the right to access their curated, individualized medical information, including data and outputs generated through medical algorithms, via secure APIs. This information shall be provided by healthcare providers, whether digital or human, in accordance with applicable state medical board requirements and liability insurance guidelines.

(b) Right to Control Medical Data:

Patients shall have the right to access their curated medical information and to be informed about how it is used and shared, consistent with applicable state and federal laws, including HIPAA. For purposes beyond treatment, payment, and healthcare operations (TPO), patients may provide a general consent for the use of their data, which may include opt-in or opt-out preferences for specific activities, such as participation in clinical trials or data sharing for research purposes. Providers may implement standardized processes for collecting and managing patient consent, ensuring compliance with state and federal requirements while minimizing administrative complexity. Healthcare providers must make reasonable efforts to inform patients of their rights under this section and provide clear, simple mechanisms to adjust their preferences when appropriate.

(c) Secure and Interoperable Access:

Healthcare providers must provide patients with secure access to their curated medical information through interoperable systems that meet the technical requirements for patient data sharing and API access. These systems must comply with the state's data security standards and any applicable federal regulations (such as HIPAA or other privacy protections).

Section 5. Requirements for Healthcare Providers

(a) Provider Eligibility:

Healthcare providers, whether digital or human, must meet state medical board requirements to be eligible to provide curated, individualized medical information to patients through APIs. These providers must also ensure their practices conform to liability insurance guidelines that cover the use and sharing of patient data via digital tools.

(b) Compliance with Data Security and Privacy Laws:

All patient data shared through APIs must adhere to state and federal data privacy regulations, ensuring protection from unauthorized access or misuse.

(c) Data Integrity and Accuracy:

Providers shall make reasonable efforts to ensure that curated medical information shared with patients is accurate and up-to-date at the time it is provided. For algorithmically-generated recommendations, insights, or treatment suggestions, providers must disclose the source and limitations of such data, including whether it is subject to periodic updates. Providers are not required to retroactively correct data once shared but must update information in the normal course of care as clinically relevant changes occur.

Section 6. Liability and Accountability

(a) Provider Liability for Data Sharing and Algorithms:

Healthcare providers offering curated medical data via APIs are responsible for ensuring that the algorithms and data-sharing practices adhere to accepted standards of care, medical ethics, and relevant legal guidelines.

Providers may be held liable for any harm caused by the misuse or inaccurate representation of patient data shared through APIs.

(b) Patient Accountability:

Patients are empowered to make informed decisions regarding their curated medical data and the use of algorithm-generated recommendations. Healthcare providers must inform patients about the scope, limitations, and potential risks of the information they access through APIs. This includes any limitations in accuracy or applicability to their individual health situation. Patients must provide informed consent for the sharing and use of their medical data. Healthcare providers are also responsible for ensuring that patients understand their rights regarding privacy, data security, and the potential risks of sharing their medical information with third parties or relying on algorithm-generated recommendations.

Section 7. Interoperability and Data Standardization

(a) State-Level Standards for Interoperability:

The state may establish voluntary standards and protocols for ensuring that healthcare providers' systems are interoperable, enabling secure data sharing through APIs while preserving the integrity and confidentiality of patients' medical information.

(b) Encouraging Data Standardization:

The state encourages the adoption of widely recognized data standards and practices (such as HL7, FHIR, or others) that facilitate secure and efficient data exchange between providers, payers, and patients.

Section 8. Protection from Retaliation

No healthcare provider or entity shall retaliate against a patient for exercising their rights under this Act, including the right to access or control their curated medical data. This includes any attempt to restrict access or negatively affect the patient's care due to the use of their data through APIs.

Section 9. Effective Date

This Act shall take effect on January 1, [Year], and apply to all healthcare providers and systems offering curated, individualized medical information through APIs after that date.

Section 10. Severability

If any provision of this Act is found to be invalid or unconstitutional, the remainder of the Act shall remain in effect.

An Act to Promote N-of-1 Treatments and Remote Health Monitoring with AI/ML

Section 1. Short Title

This Act may be cited as the "AI-Driven Personalized Healthcare Act."

Section 2. Findings and Purpose(a) The legislature finds that:

(a) Advances in artificial intelligence and machine learning (AI/ML) have enabled highly personalized healthcare interventions, known as N-of-1 treatments, tailored to the unique characteristics of individual patients.

Remote health monitoring with FDA-certified AI/ML-enabled devices offers an opportunity to improve health outcomes, enhance convenience, and reduce healthcare costs.

Current regulatory frameworks may not adequately address effective use of these technologies in patient care.

(b) The purpose of this Act is to:

Authorize the integration of FDA-certified AI/ML-enabled devices for N-of-1 treatments and home health monitoring.

Establish patient protection guardrails to ensure the safety and efficacy of these treatments and technologies.

Provide liability protections to encourage innovation by manufacturers and developers of such technologies.

Section 3. Definitions. For the purposes of this Act:

"AI/ML-enabled device" means a device or software system that incorporates artificial intelligence or machine learning algorithms to assist in healthcare decision-making, monitoring, or treatment.

"N-of-1 treatment" refers to a personalized therapeutic or diagnostic intervention designed for and tailored to a single individual based on their unique clinical characteristics and data.

"FDA-certified" means a device or technology that has been approved or cleared by the United States Food and Drug Administration.

"Remote health monitoring" means the use of devices or systems to remotely monitor and record patients' health metrics in a non-clinical setting.

Section 4. Authorization for N-of-1 Treatments and AI/ML-Enabled Home Health Monitoring

(a) The state medical board shall:
Permit the use of FDA-certified AI/ML-enabled devices for the delivery of N-of-1 treatments.
Authorize the use of FDA-certified AI/ML-enabled devices for home health monitoring.
Facilitate the integration of these devices and technologies into clinical practice, subject to the protections outlined in this Act.

(b) Healthcare providers licensed under this state shall not be subject to disciplinary action solely for utilizing AI/ML-enabled devices for N-of-1 treatments or home health monitoring, provided such use complies with the provisions of this Act and applicable standards of care.

Section 5. Patient Protections

(a) The state medical board shall establish patient protection guidelines, which shall include:

Protocols for clinical oversight and monitoring of patient outcomes.

(b) Manufacturers of FDA-certified AI/ML-enabled devices must:

Maintain a process for reporting and addressing adverse events associated with their devices.

Section 6. Liability Protections

(a) Manufacturers and developers of FDA-certified AI/ML-enabled devices shall not be liable for any harm arising from their use, except in cases of gross negligence, willful misconduct, or fraud, provided the devices are used in accordance with their FDA-approved labeling and intended purpose.

(b) Healthcare providers utilizing such devices shall be shielded from liability related to their use if:

The devices are used in accordance with the manufacturer's instructions and applicable standards of care.

The providers have obtained informed consent from the patient.

Section 7. Implementation

The state medical board shall promulgate rules necessary to implement the provisions of this Act within 12 months of its enactment.

Section 8. Severability. If any provision of this Act or its application to any person or circumstance is held invalid, the remainder of the Act and the application of the provision to other persons or circumstances shall not be affected.

Section 9. Effective Date. This Act shall take effect 90 days following its enactment.

An Act to Require Reimbursement for FDA-Certified AI/ML Devices in Self-Insured State Health Plans

Sec. 1. Short Title

This Act may be cited as the "AI/ML Device Reimbursement for State Health Plans Act."

Section 2. Findings and Purpose

(a) The legislature finds that:

Artificial intelligence (AI) is increasingly integrated into medical devices, enhancing diagnostic accuracy, treatment efficacy, and overall patient outcomes.

State-sponsored self-insured health plans should foster innovation and ensure access, when recommended by the patient's medical provider, to medically necessary devices that utilize AI technologies.

(b) The purpose of this section is to ensure that devices utilizing AI technologies, which otherwise meet established criteria for reimbursement, are not excluded solely based on their use of AI.

Section 3: Definitions

For the purposes of this Act, the following definitions shall apply:

FDA-Certified AI/ML Devices: Any medical device or software application that uses artificial intelligence or machine learning algorithms, which has been certified or approved by the U.S. Food and Drug Administration (FDA) for medical use.

Self-Insured State Health Plans: Health insurance plans provided by the state for its employees and other covered individuals, where the state assumes the financial risk for providing healthcare benefits.

Patient's Informed Consent: Consent provided by the patient, acknowledging that they have been informed of the benefits, risks, and alternatives of using the AI/ML device, and that they voluntarily agree to its use in their care. This consent must be consistent with existing informed consent requirements.

Healthcare Provider: A licensed medical professional authorized to recommend or prescribe treatments, including AI/ML devices, based on the patient's medical needs.

Section 4. Reimbursement Requirements for AI-Enabled Medical Devices.

(a) A state-sponsored self-insured health plan shall provide reimbursement for any FDA-Certified AI/ML medical device that:

Is determined to be medically necessary and meets all applicable criteria for reimbursement under the health plan; and

Is otherwise reimbursable but incorporates artificial intelligence technologies as part of its functionality.

(b) Reimbursement for such devices shall not be denied solely on the basis that the device utilizes artificial intelligence technologies.

Section 5. Implementation Guidelines

(a) Regulatory Oversight:

The Department of Health or another designated state agency shall establish guidelines and procedures to ensure compliance with the reimbursement requirements outlined in Section 2.

(b) Claims and Reimbursement Process:

The state health plan shall create a streamlined process for healthcare providers to submit claims for reimbursement for FDA-certified AI/ML devices, ensuring that the reimbursement process is clear, timely, and efficient. Claims submitted under this process shall be reviewed, and a determination regarding approval or denial shall be provided to the healthcare provider within 30 calendar days of receipt of the claim.

(c) Patient Education and Consent:

Healthcare providers shall obtain verbal informed consent from patients or their authorized representatives prior to the use of AI/ML devices in their treatment, including the potential risks and benefits, in accordance with the standards and requirements outlined in [relevant state statute or code governing informed consent]. Documentation of verbal informed consent,

including the date, time, and a summary of the discussion, shall be included in the patient's medical record.

Section 6. Reporting and Evaluation

(a) Annual Reporting Requirement:

Each self-insured state health plan shall submit an annual report to the state legislature detailing the utilization of FDA-certified AI/ML devices, including:

The number of patients receiving AI/ML devices.

The overall cost savings or budget-neutral outcomes associated with the use of these devices.

Patient health outcomes and satisfaction related to the use of AI/ML devices.

(b) Independent Evaluation:

The state shall commission an independent evaluation every two years to assess the impact of AI/ML devices on patient care, cost savings, and overall healthcare quality within the self-insured state health plans.

Section 7. Effective Date

This Act shall take effect on January 1, [Year], and apply to all claims for reimbursement submitted after that date.

Section 8. Severability

If any provision of this Act is found to be invalid or unconstitutional, the remainder of the Act shall remain in effect.

An Act to Promote Healthcare Transparency and Accountability in Taxpayer-Funded Programs and Services

To mandate the use of artificial intelligence-driven methods for evaluating healthcare spending, program targeting, and program outcomes, ensuring transparency and accountability in the use of taxpayer resources for healthcare programs.

Sec. 1. Short Title

This Act may be cited as the "Healthcare Transparency and Accountability Act."

Section 2. Legislative Findings and Purpose

(a) Findings

The Legislature finds that:

- The Office of Management and Budget's (OMB) revised Uniform Guidance permits the use of federal funds for evaluation and data related organizational costs.
- Artificial intelligence (AI) offers advanced capabilities for analyzing healthcare spending, program targeting, and outcomes with greater precision and efficiency.
- Taxpayers deserve transparency and accountability regarding the allocation and effectiveness of healthcare resources.
- Current healthcare programs may fail to effectively reach uninsured and underserved populations, necessitating a reevaluation of resource use.

(b) Purpose

The purpose of this Act is to:

- Enhance the evaluation and administration of state healthcare programs using AI-driven methods.
- Increase transparency and promote accountability in healthcare spending.
- Provide taxpayers with accessible, data-driven insights into the performance and outcomes of publicly funded healthcare programs.

Section 3. Definitions

For the purposes of this Act:

(a) "Artificial Intelligence" means the use of machine learning, natural language processing, predictive analytics, and other advanced computational methods for data analysis and decision-making.

(b) "Healthcare Program" refers to any state-administered program funded in whole or part by taxpayer resources and intended to provide healthcare services or related support.

(c) "Evaluation Costs" include the costs of evidence reviews, feasibility assessments, program evaluations, and dissemination of findings.

(d) "Data Costs" include the costs associated with personnel, IT systems, integrated data platforms, data dashboards, and cybersecurity measures.

Section 4. Mandate for AI-Driven Evaluation and Transparency

(a) Evaluation Scope

(1) The Department of Health and Human Services (DHHS), in consultation with the Office of Technology and Innovation, shall integrate AI-driven methods for evaluating the efficiency, targeting, and outcomes of state healthcare programs.

- Analysis of healthcare spending patterns.
- Identification of gaps in resource allocation to underserved and uninsured populations.
- Assessment of program effectiveness in achieving stated outcomes.
- Evaluation of eligibility of program participants to ensure compliance with program criteria.
- Analysis of participation in multiple overlapping programs to identify redundancies or inefficiencies.
- Assessment of the accuracy of program targeting to ensure resources are directed toward the intended populations.
- Estimates of ineligible participants receiving program benefits.
- Estimates of eligible participants not currently participating in the programs.

- Calculation of average funding for each program beneficiary, an estimate of how much of each program dollar reaches the intended recipient, and an estimate of the average total funding for each program beneficiary across all programs they participate in.

(2) AI Evaluation Methods

The Department of Health and Human Services (DHHS), in consultation with the Office of Technology and Innovation, shall adhere to the following principles, methods, and practices for evaluation:

Utilize data from reliable, representative sources, in compliance with applicable privacy and security laws.

Ensure transparency by using interpretable models and publishing descriptions of methodologies and results.

Conduct validation, performance reviews, and bias audits at regular intervals to ensure reliability.

Measure program outcomes using predefined metrics, including cost reductions, health outcome improvements, and access to care.

Provide public reporting of findings and engage stakeholders to ensure accountability and inclusivity.

The agency shall adopt these methods within 12 months of enactment and update methodologies every 2 years to incorporate advancements in technology and feedback from stakeholders.

(b) IT and Data Capacity Development

Federal funds made available under OMB Uniform Guidance Section 200.455 (Subpart E) may be used to:

- Build or enhance integrated data systems.
- Develop and maintain data dashboards for public access.
- Implement robust cybersecurity measures to protect sensitive information.
- Data systems and dashboards shall present information in an accessible format for public and legislative review.

(c) Public Transparency

• Findings from AI-driven evaluations shall be made publicly available annually via an online portal,
with the first publication occurring no later than one year after the enactment of this Act.
• The portal shall provide taxpayers with detailed insights into:
• How healthcare funds are allocated and utilized.
• Disparities in access or service delivery.
• Progress toward addressing the needs of uninsured and underserved populations.

Section 5. Accountability and Reporting

(a) The DHHS shall submit an annual report to the Legislature detailing:

• Results of AI-driven evaluations.
• Recommendations for improving program performance and cost-effectiveness.
• Steps taken to address any identified inefficiencies or disparities.

(b) The Legislature shall conduct annual hearings to review the report and solicit public input on the findings and recommendations.

Section 6. Funding

(a) Federal funds authorized under Section 200.455 (Subpart E) of the OMB Uniform Guidance shall be prioritized for compliance with this Act.

(b) The Legislature may allocate additional state funds as necessary to support the implementation and sustainability of AI-driven evaluations and data transparency initiatives.

Section 7. Effective Date

This Act shall take effect immediately upon its enactment.

Section 8. Severability

If any provision of this Act is found to be unconstitutional or otherwise invalid, the remaining provisions shall not be affected and shall remain in full force and effect.

An Act to Protect Truthful and Non-Misleading AI-Generated Healthcare Speech

Section 1. Short Title

This Act may be cited as the "The Protection of Truthful and Non-Misleading AI-Generated Healthcare Speech Act."

Section 2. Purpose

It is the sense of the legislature that AI-generated speech, including healthcare data and outputs derived from an individual patient's history and biological attributes, constitutes free speech protected under the principles of truthful and non-misleading expression. Such speech should not be subject to regulation unless the potential harm resulting from such outputs constitutes an activity or danger that is already subject to regulation under existing laws.

Section 3: Definitions

As used in this Act, and unless the context otherwise requires:

"AI-generated health data and outputs" refers to any data or information that is produced or generated by an artificial intelligence system or algorithm, based on individual health-related inputs, including but not limited to a patient's medical history, biological attributes, or other personal health information.

"Free Speech" means the right to express, distribute, and disseminate information and ideas, including but not limited to medical, scientific, or treatment-related information, without undue government interference or regulation, as protected by the First Amendment of the United States Constitution and relevant state constitutional provisions.

"Biological and physiological attributes" refers to an individual's genomic, metabolic, cellular, molecular, and other biological data, including but not limited to DNA, RNA, proteins, enzymes, cellular signaling pathways, and other physiological characteristics relevant to health.

"Potential Harm" refers to a substantial risk of harm that is immediate, likely, and demonstrable in nature, and can be specifically identified in a manner consistent with public health, safety, or welfare concerns.

"Regulation" means any governmental restriction, control, or oversight on the dissemination or use of data, information, or communication, including laws, rules, or other forms of state authority.

"Individual's Medical History and Biological Attributes" includes personal health information, such as genetic data, medical records, and other biological or physiological data relevant to the individual's health.

Section 4: AI-Generated Health Data and Outputs as Free Speech

(a) Protection of AI-Generated Health Outputs as Free Speech:

AI-generated health data and outputs based on an individual patient's history and biological attributes shall be considered a form of free speech under the First Amendment to the United States Constitution and any applicable state constitutional provisions. Any governmental restriction or regulation of such outputs shall be subject to strict scrutiny and may only be upheld if it serves a compelling government interest, such as preventing clear, demonstrable, and specific harm to public health, safety, or welfare, and is narrowly tailored to achieve that interest using the least restrictive means. In the absence of such justification, AI-generated health data and outputs shall remain free from governmental interference, consistent with the principles of free speech and innovation.

(b) Right to Information:

Patients, healthcare providers, and others shall have the right to access, share, and disseminate AI-generated outputs derived from individual patient data, including medical history and biological attributes, for the purpose of informed decision-making, clinical care, and the advancement of medical and scientific knowledge, provided that such access, sharing, and dissemination is done with the patient’s consent and in conformity with existing patient privacy protections and applicable laws.

Section 5: Regulation of AI Outputs Not Presumed

(a) Regulation Only for Clear and Demonstrable Harm:

No government entity shall regulate AI-generated data and outputs unless it is demonstrated that such regulation addresses a substantial and clear risk of harm to individuals or society, such as fraud, misinformation,

or threats to public health or safety, and that the regulation is narrowly tailored to mitigate the specific harm and represents the least restrictive means of achieving the compelling governmental interest. In the absence of such demonstrated risk, AI-generated data and outputs shall remain free from governmental regulation, consistent with the principles of free expression and innovation.

Section 5: Regulation of AI Outputs Not Presumed

(a) Regulation Only for Clear and Demonstrable Harm:

No government entity shall regulate AI-generated data and outputs unless it is demonstrated that such regulation addresses a substantial and clear risk of harm to individuals or society, such as fraud, misinformation, or threats to public health or safety, and that the regulation is narrowly tailored to mitigate the specific harm and represents the least restrictive means of achieving the compelling governmental interest. In the absence of such demonstrated risk, AI-generated data and outputs shall remain free from governmental regulation, consistent with the principles of free expression and innovation.

(b) Burden of Proof for Regulation:

No regulation of AI-generated outputs based on patient data shall be valid unless it is established through a legislative sunrise process that such outputs cause substantial and specific harm, as defined in Section 4. The regulation must further demonstrate that it is the least restrictive means available to address the identified harm. Additionally, no regulatory body may impose regulations on AI-generated outputs without prior approval from the legislature.

Section 6: Non-Interference with Medical Decision-Making

Nothing in this Act shall be construed to interfere with the ability of healthcare providers to use AI-generated outputs, including those based on individual patient data, to make medical decisions or recommendations in accordance with professional standards and patient consent.

Section 7: Protection from Retaliation

No individual, healthcare provider, or entity shall be subject to retaliation or adverse action by the state or any regulatory body for utilizing, sharing, or disseminating AI-generated data or outputs, including those based on an individual patient's history or biological attributes, as long as the data and outputs are used in accordance with applicable laws and regulations governing patient privacy and consent.

Section 8: Effective Date

This Act shall take effect on January 1, [Year], and apply to all AI-generated data and outputs disseminated after that date.

Section 9: Severability

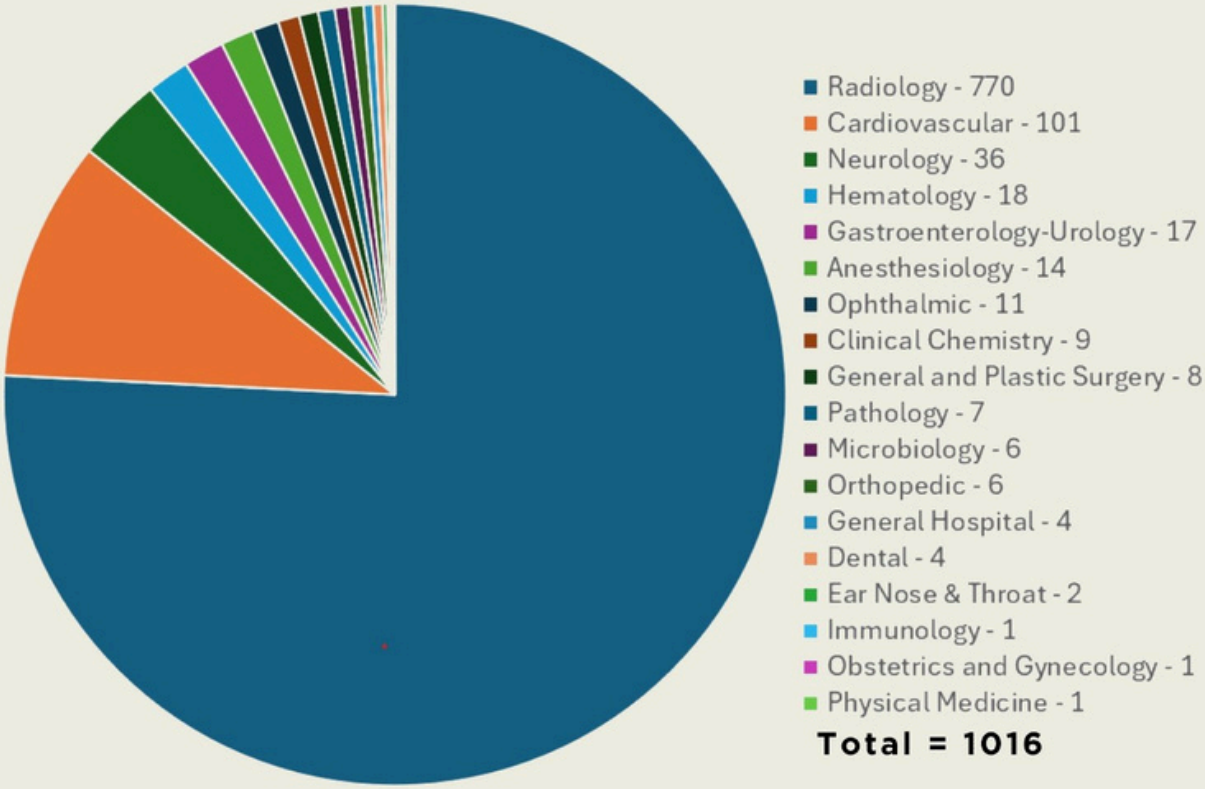
If any provision of this Act is found to be invalid or unconstitutional, the remainder of the Act shall remain in effect.

Appendix B

FDA-Authorized AI/ML-Enabled Medical Devices by Medical Application and Companies' Geographic Location & Ownership Status (as of January 6, 2025)

Number of FDA-Authorized AI/ML-Enabled Medical Devices by Primary Medical Application

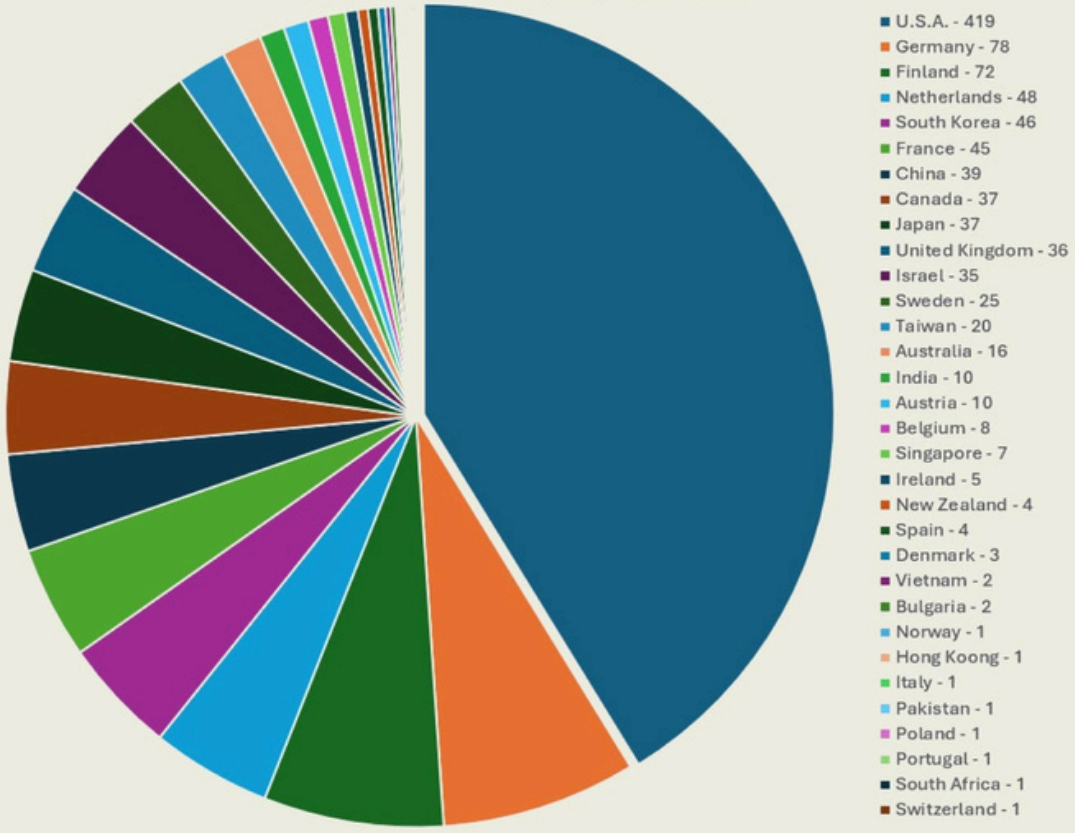
(accessed January 6, 2025)



Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Number of FDA-Authorized AI/ML-Enabled Medical Devices by Country

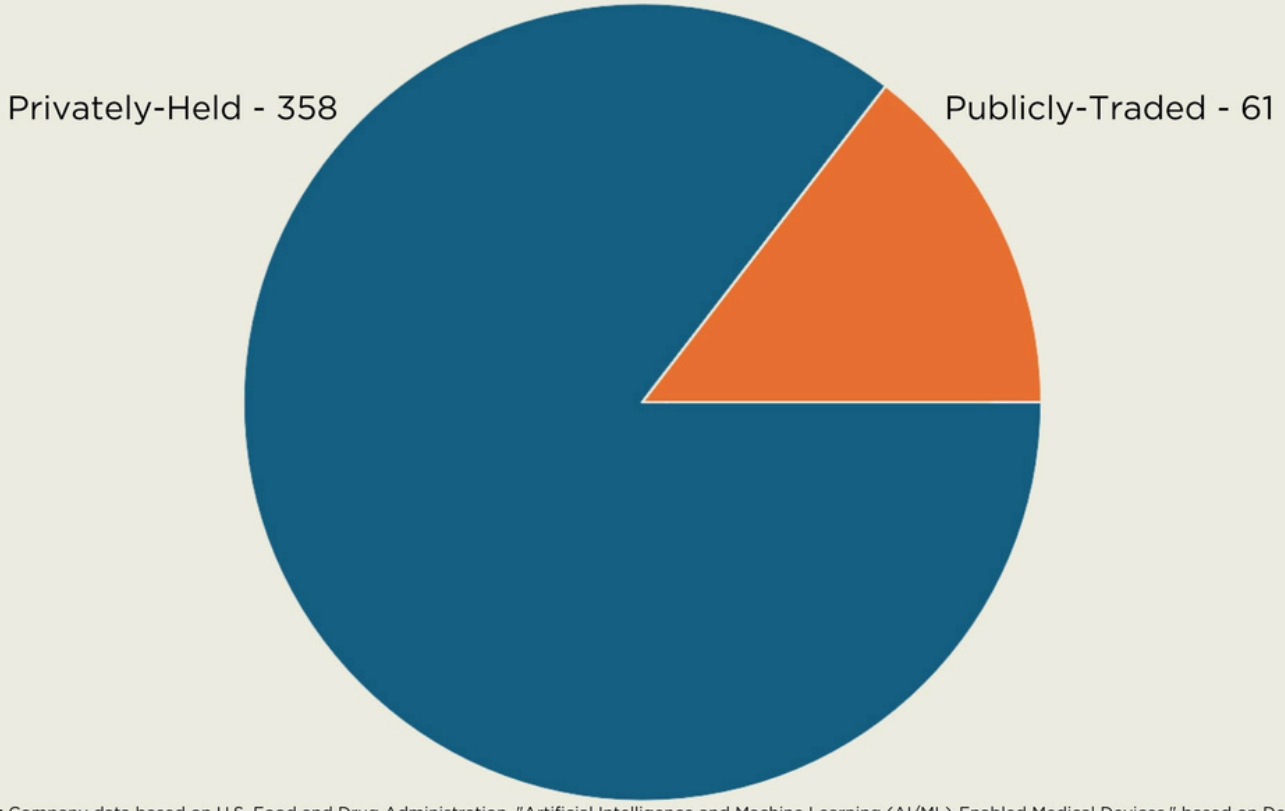
(accessed January 6, 2025)



Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Number of U.S.-Based Privately-Held vs. Publicly-Traded Companies with FDA-Authorized AI/ML-Enabled Medical Devices

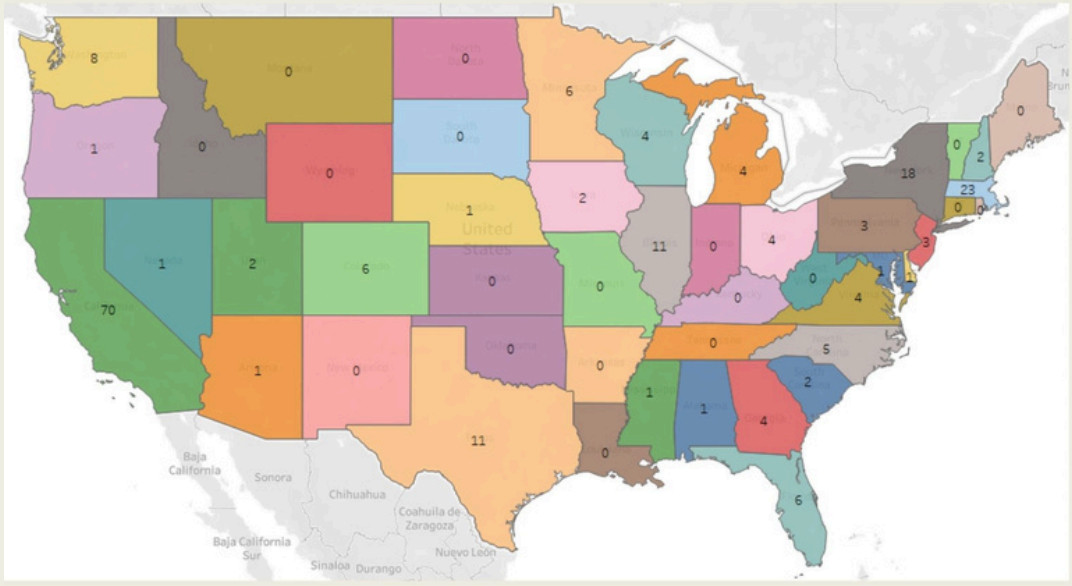
(accessed January 6, 2025)



Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Number of U.S.-Based Companies with FDA-Authorized AI/ML-Enabled Medical Devices by State

(accessed January 6, 2025)

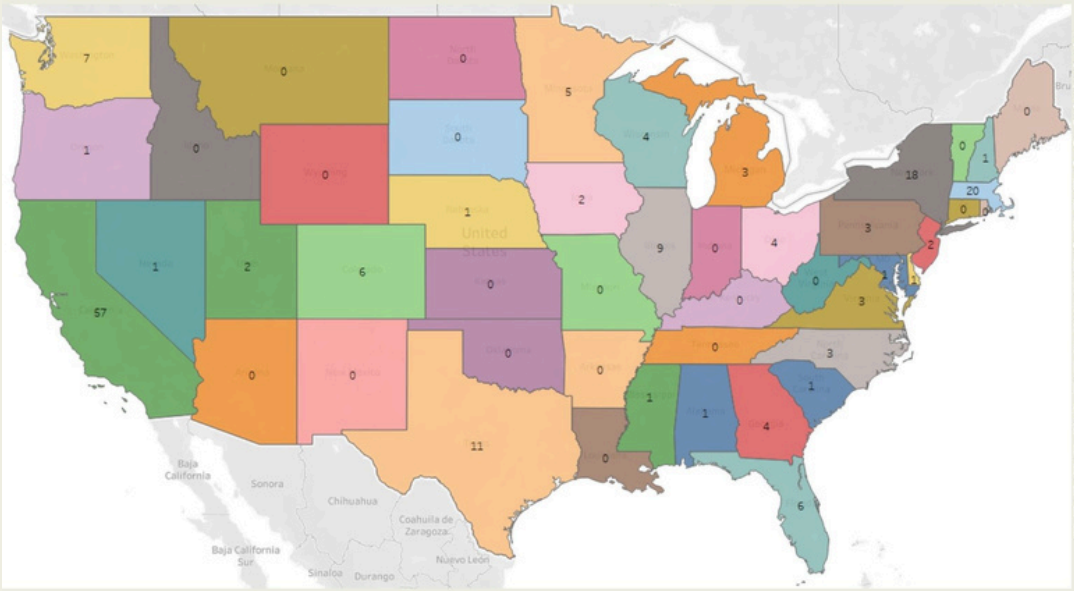


Alabama - 1
Alaska - 0
Arizona - 1
Arkansas - 0
California - 70
Colorado - 6
Connecticut - 0
Delaware - 1
District of Columbia - 1
Florida - 6
Georgia - 4
Hawaii - 0
Idaho - 0
Illinois - 11
Indiana - 0
Iowa - 2
Kansas - 0
Kentucky - 0
Louisiana - 0
Maine - 0
Maryland - 5
Massachusetts - 23
Michigan - 4
Minnesota - 6
Mississippi - 1
Missouri - 0
Montana - 0
Nebraska - 1
Nevada - 1
New Hampshire - 2
New Jersey - 3
New Mexico - 0
New York - 18
North Carolina - 5
North Dakota - 0
Ohio - 4
Oklahoma - 0
Oregon - 1
Pennsylvania - 3
Rhode Island - 0
South Carolina - 2
South Dakota - 0
Tennessee - 0
Texas - 11
Utah - 2
Vermont - 0
Virginia - 4
Washington State - 8
West Virginia - 0
Wisconsin - 4
Wyoming - 0

Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Number of U.S.-Based Privately-Held Companies with FDA-Authorized AI/ML-Enabled Medical Devices by State

(accessed January 6, 2025)

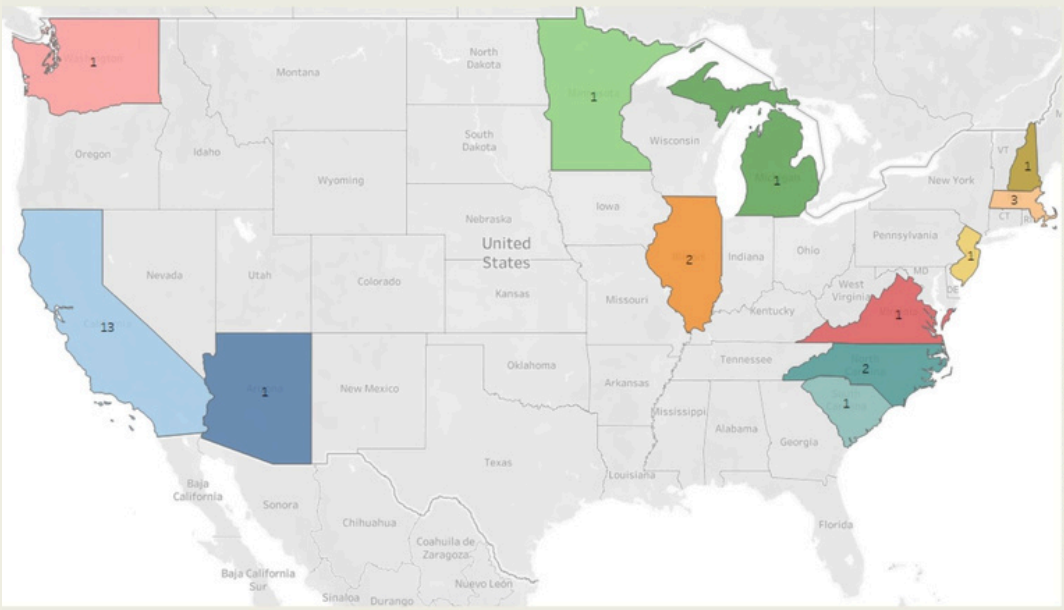


Alabama - 1
Alaska - 0
Arizona - 0
Arkansas - 0
California - 57
Colorado - 6
Connecticut - 0
Delaware - 1
District of Columbia - 1
Florida - 6
Georgia - 1
Hawaii - 0
Idaho - 0
Illinois - 9
Indiana - 0
Iowa - 2
Kansas - 0
Kentucky - 0
Louisiana - 0
Maine - 0
Maryland - 5
Massachusetts - 20
Michigan - 3
Minnesota - 5
Mississippi - 1
Missouri - 0
Montana - 0
Nebraska - 1
Nevada - 1
New Hampshire - 1
New Jersey - 2
New Mexico - 0
New York - 18
North Carolina - 3
North Dakota - 0
Ohio - 4
Oklahoma - 0
Oregon - 1
Pennsylvania - 3
Rhode Island - 0
South Carolina - 1
South Dakota - 0
Tennessee - 0
Texas - 11
Utah - 2
Vermont - 0
Virginia - 3
Washington State - 7
West Virginia - 0
Wisconsin - 4
Wyoming - 0

Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Number of U.S.-Based Publicly-Traded Companies with FDA-Authorized AI/ML-Enabled Medical Devices by State

(accessed January 6, 2025)

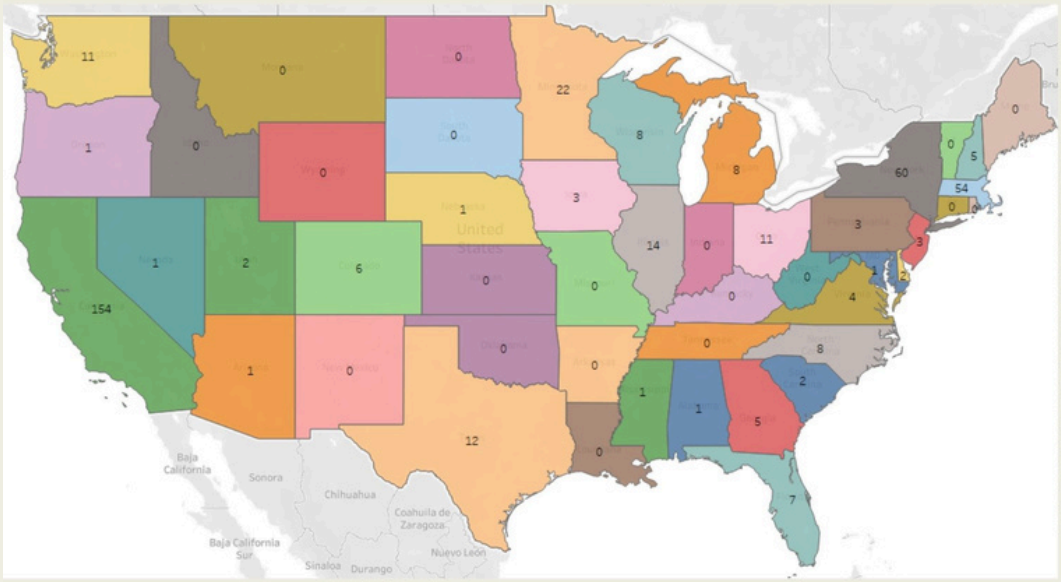


Alabama - 0
Alaska - 0
Arizona - 1
Arkansas - 0
California - 13
Colorado - 0
Connecticut - 0
Delaware - 0
District of Columbia - 0
Florida - 0
Georgia - 0
Hawaii - 0
Idaho - 0
Illinois - 2
Indiana - 0
Iowa - 0
Kansas - 0
Kentucky - 0
Louisiana - 0
Maine - 0
Maryland - 0
Massachusetts - 3
Michigan - 1
Minnesota - 1
Mississippi - 0
Missouri - 0
Montana - 0
Nebraska - 0
Nevada - 0
New Hampshire - 1
New Jersey - 1
New Mexico - 0
New York - 0
North Carolina - 2
North Dakota - 0
Ohio - 0
Oklahoma - 0
Oregon - 0
Pennsylvania - 0
Rhode Island - 0
South Carolina - 0
South Dakota - 1
Tennessee - 0
Texas - 0
Utah - 0
Vermont - 0
Virginia - 1
Washington State - 1
West Virginia - 0
Wisconsin - 0
Wyoming - 0

Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Number of U.S.-Based FDA-Authorized AI/ML-Enabled Medical Devices by State

(accessed January 6, 2025)

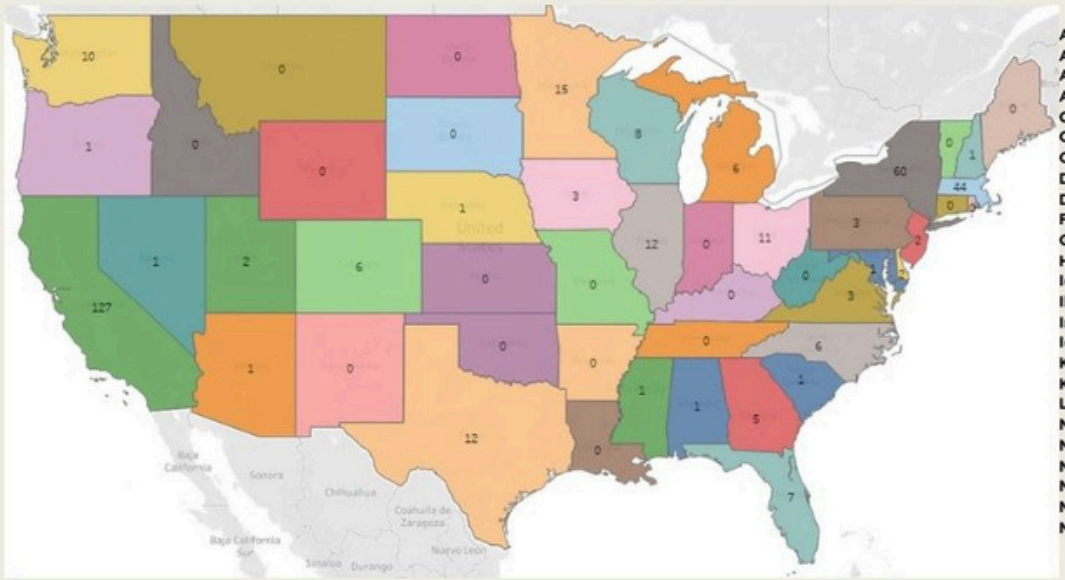


Alabama - 1
Alaska - 0
Arizona - 1
Arkansas - 0
California - 154
Colorado - 6
Connecticut - 0
Delaware - 2
District of Columbia - 1
Florida - 7
Georgia - 5
Hawaii - 0
Idaho - 0
Illinois - 14
Indiana - 0
Iowa - 3
Kansas - 0
Kentucky - 0
Louisiana - 0
Maine - 0
Maryland - 9
Massachusetts - 54
Michigan - 8
Minnesota - 22
Mississippi - 1
Missouri - 0
Montana - 0
Nebraska - 1
Nevada - 1
New Hampshire - 5
New Jersey - 3
New Mexico - 0
New York - 60
North Carolina - 8
North Dakota - 0
Ohio - 11
Oklahoma - 0
Oregon - 1
Pennsylvania - 3
Rhode Island - 0
South Carolina - 2
South Dakota - 0
Tennessee - 0
Texas - 12
Utah - 2
Vermont - 0
Virginia - 4
Washington State - 11
West Virginia - 0
Wisconsin - 8
Wyoming - 0

Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

Number of U.S.-Based Privately-Held FDA-Authorized AI/ML-Enabled Medical Devices by State

(accessed January 6, 2025)



Alabama - 0
Alaska - 0
Arizona - 1
Arkansas - 0
California - 13
Colorado - 0
Connecticut - 0
Delaware - 0
District of Columbia - 0
Florida - 0
Georgia - 0
Hawaii - 0
Idaho - 0
Illinois - 2
Indiana - 0
Iowa - 0
Kansas - 0
Kentucky - 0
Louisiana - 0
Maine - 0
Maryland - 0
Massachusetts - 3
Michigan - 1
Minnesota - 1
Mississippi - 0
Missouri - 0
Montana - 0
Nebraska - 1
Nevada - 1
New Hampshire - 1
New Jersey - 2
New Mexico - 0
New York - 60
North Carolina - 6
North Dakota - 0
Ohio - 11
Oklahoma - 0
Oregon - 1
Pennsylvania - 3
Rhode Island - 0
South Carolina - 1
South Dakota - 0
Tennessee - 0
Texas - 12
Utah - 2
Vermont - 0
Virginia - 3
Washington State - 10
West Virginia - 0
Wisconsin - 8
Wyoming - 0

Source: Company data based on U.S. Food and Drug Administration, "Artificial Intelligence and Machine Learning (AI/ML)-Enabled Medical Devices," based on December 20, 2024 update at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-aiml-enabled-medical-devices

ACKNOWLEDGEMENTS

I am deeply grateful to the Goldwater Institute legal team and the Abundance Institute policy team for their time and invaluable insights. I extend special thanks to Christina Sandefur, Jon Riches, Timothy Sandefur, and Patrick Bailey, MD, for their thoughtful critiques and guidance on legislative concepts and language. I also appreciate the helpful feedback and comments from Taylor Barkley, Bryce Chinault, Ahmad Nazeri, and Logan Whitehair. Thanks also go to Shelby Hockenberry, Ph.D. for her expert editing and strategic input. Any remaining errors are entirely my own.

Finally, I am especially grateful to Arvin Farber for his indispensable, all-encompassing assistance throughout this project.

ABOUT THE AUTHOR, NAOMI LOPEZ

Naomi is a nationally recognized healthcare policy expert with over 30 years of experience. She specializes in developing innovative policy solutions, crafting legislation and legislative strategies, and coordinating stakeholder groups to drive legislative change at both the federal and state levels.

She is the founder and principal of Nexus Policy Consulting and has held positions at the Goldwater Institute, Illinois Policy Institute, Pacific Research Institute, Institute for Socioeconomic Studies, and the Cato Institute. She is also the co-founder, alongside Joe Grogan, of the AI in Healthcare Working Group, a Public Advisor to the Paragon Health Institute, and a Senior Fellow at the Goldwater Institute.

She holds a B.A. in Economics from Trinity University, Texas, and an M.A. in Government from The Johns Hopkins University.

Nexus Policy Consulting
2501 Chatham Road, Ste. R
Springfield, IL 62704
nexuspolicyconsulting.com
(318) 422-0446