Artificial Intelligence in U.S. Healthcare: The Current Regulatory Landscape and Future Recommendations

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ABSTRACT

As a novel tool, AI raises significant regulatory challenges related to safety, efficacy, privacy, and ethics. As the global investment leader in digital health, the U.S. is experiencing a significant influx and adoption of AI technologies in various healthcare applications, from diagnostics and personalized medicine to administrative tasks and operations. While attracting substantial investment and fostering innovative developments boasts exciting potential, the rapid pace of AI development often outstrips existing regulatory frameworks, creating potential risks for patients and providers.

The integration of artificial intelligence (AI) within the United States healthcare system has the potential to revolutionize patient care, improve operational and administrative efficiency, and refine decision-making processes. As a novel tool, AI raises significant regulatory concerns related to safety, efficacy, privacy, and ethical use.

This poster presents findings from a policy review conducted by a HITLAB Delphi Intern to outline the current U.S. regulatory framework of AI in healthcare, identifies key challenges for integration, and recommends a cohesive regulatory framework to ensure the safe, effective, and equitable use of AI technologies in the U.S. healthcare system.
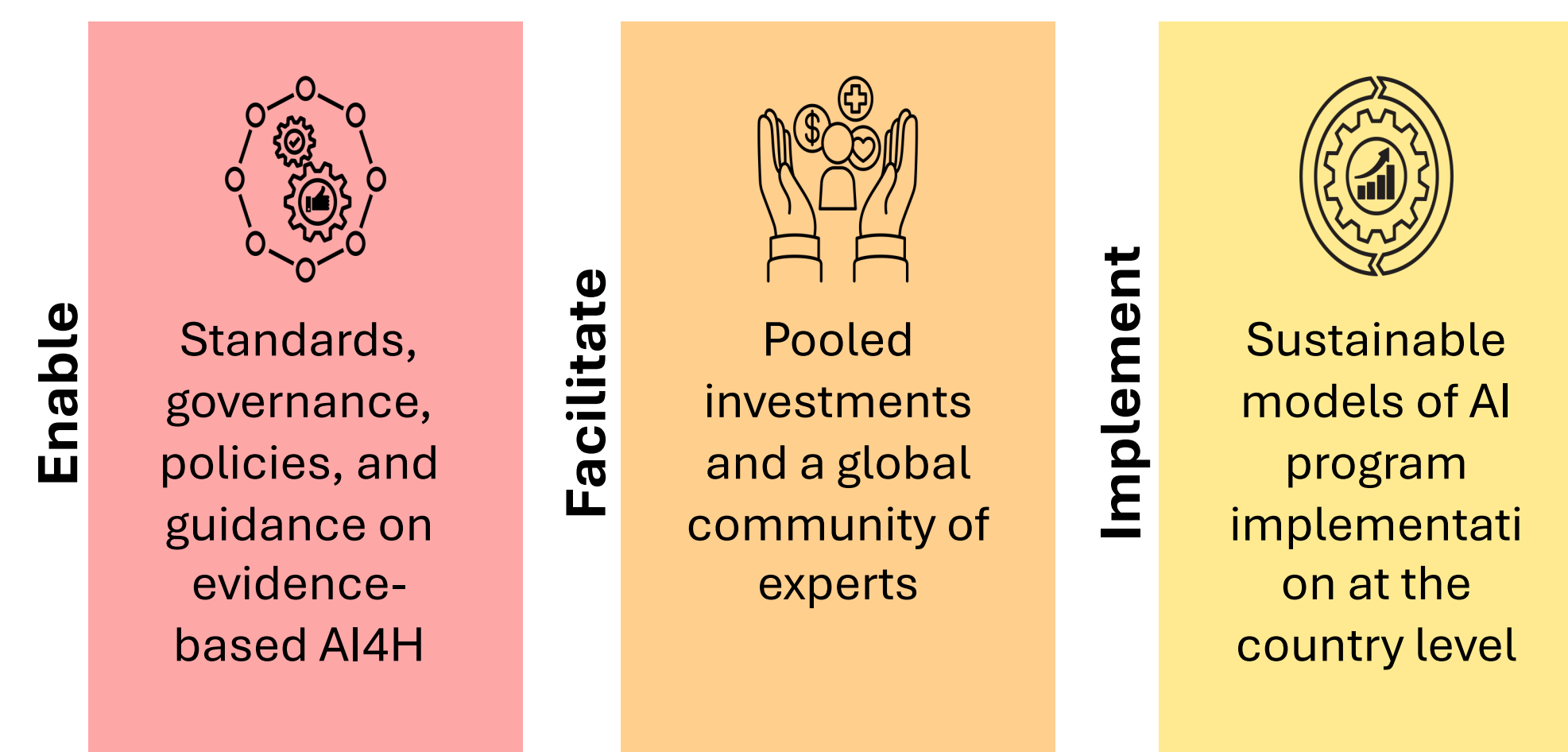
OBJECTIVES

- Understand the current United States regulatory framework of Artificial Intelligence in healthcare, including the different regulatory levels and agencies, stakeholders involved, and their respective interests, roles and impact.
- Identify the key challenges for the integration of AI in healthcare.
- Derive recommendations for guiding the development of future AI operational strategies and policy recommendations for the integration of AI in the U.S. healthcare system.
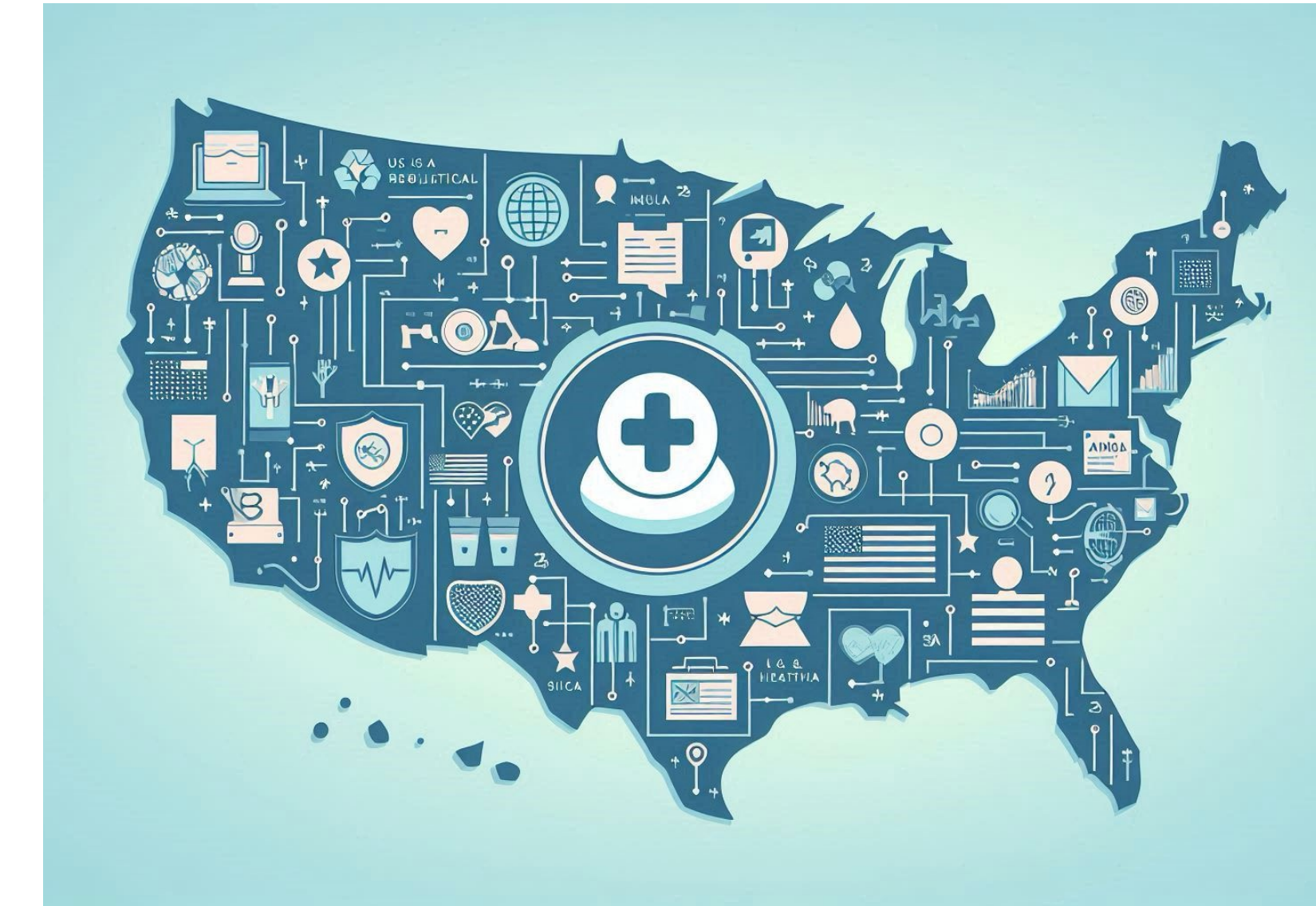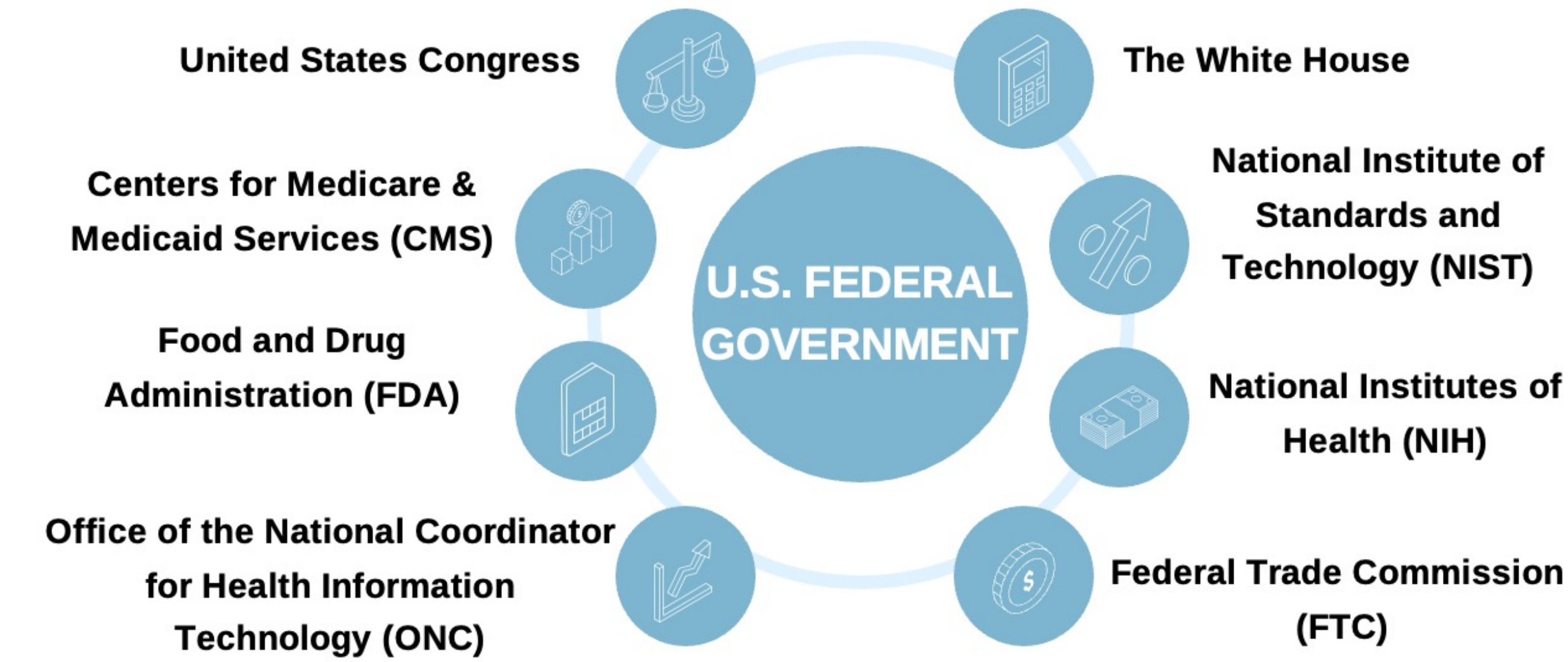
METHODOLOGY

- Comprehensive review: Conducted a multi-source review to understand the current regulatory environment of artificial intelligence in United States healthcare.

WHO's THREE PILLARS OF AI IN HEALTHCARE

Enable	Facilitate	Implement
Standards, governance, policies, and guidance on evidence-based AI4H	Pooled investments and a global community of experts	Sustainable models of AI program implementation at the country level

FEDERAL REGULATIONS

U.S. FEDERAL GOVERNMENT

- United States Congress
- The White House
- Centers for Medicare & Medicaid Services (CMS)
- National Institute of Standards and Technology (NIST)
- Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Office of the National Coordinator for Health Information Technology (ONC)
- Federal Trade Commission (FTC)

- **Congress**: Shapes AI regulation through legislative proposals such as HIPPA, the AI in Health Care Act, the 21st Century Cares Act, the Health Information Technology for Economic and Clinical Health (HITECH) Act, and Clinical Laboratory Improvement Amendments (CLIA).
- **FDA**: Oversees medical devices, including AI-driven technologies, and issues guidance documents and frameworks to streamline approval processes such as the Digital Health Innovation Action Plan and Breakthrough Device Designation.
- **The White House**: Produces guidance and initiatives regarding ethical use, emphasizing safety, fairness, transparency, and accountability including the AI Bill of Rights and President Biden's Executive Order on Artificial Intelligence.
- **FTC**: Enforces data security regulations for companies handling consumer health data and addresses privacy issues related to consumer data such as the collection and use of data by businesses operating across state lines, which is especially relevant for telehealth applications.
- **CMS**: Influences reimbursement policies for AI technologies in healthcare which can significantly affect adoption in clinical practice, especially in rural and low-income areas.
- **NIH**: Provides funding initiatives for research into AI applications in healthcare, promoting innovation while ensuring ethical standards.
- **NIST**: Promotes innovation and competitiveness by advancing science and technology to enhance economic security and quality of life.
- **ONC**: Establishes health IT interoperability standards, impacting how AI systems can integrate with existing healthcare technologies.

STATE AI REGULATIONS

Virginia HB 2307 Consumer Data Protection Act (2020)
Evaluates the impact of AI technologies on healthcare outcomes, highlights transparency needs in AI decision-making processes, and supports equitable access to care.

Illinois HB 3773 Illinois Human Rights Act - Amendment (2023)
Requires AI systems in healthcare to undergo bias assessments and regular audits of AI tools in clinical settings to prevent discrimination.

Washington SB 5838 Artificial Intelligence Task Force (2024)
Proposes a task force to study AI in healthcare and recommend best practices for ethical use, focusing on transparency, and clear communication about how algorithms function and impact patient care.

California SB 896 Generative Artificial Intelligence Accountability Act (2024)
Establishes ethical standards for automated decision-making technologies, emphasizes transparency, accountability, and requires company disclosure of algorithm decision-making.

STATE DATA PRIVACY REGULATIONS

California AB 375 Consumer Privacy Act (2018)
Grants rights to CA residents over personal data and requires businesses to disclose data collection practices and allow consumers to opt out of data selling.

Virginia SB 1392 Consumer Data Protection Act (2023)
Gives consumers control over their data, including health-related data, with requirements for transparency and data protection.

New York S5575B SHIELD Act (2019)
Expands data security requirements, mandating businesses to implement reasonable safeguards for personal data, including health information.

KEY CHALLENGES

DATA PRIVACY & SECURITY
Large datasets can pose significant risks to patient privacy, without proper regulatory compliance and cybersecurity measures.

SAFETY & EFFICACY
Traditional regulatory frameworks may not adequately address the unique challenges posed by AI, such as algorithmic bias and system malfunctions.

ETHICAL CONCERNS
AI integration raises questions related to informed consent, accountability, bias, transparency and equity, all essential for maintaining public trust.

MARKET ACCESS
Companies must consider varying state and federal regulations when developing products, potentially hindering innovation if overly restrictive.

DATA ACCESS & EXCHANGE
AI solutions need to integrate seamlessly with existing electronic health record (EHR) systems and healthcare technologies. A lack of interoperability can hinder the effectiveness of AI applications.

RECOMMENDATIONS

CLEAR METRICS AND APPLICATIONS
Create a risk-based classification system to ensure appropriate oversight based on potential impact and unified federal standards to close loopholes and reduce confusion. Include adaptable language to maintain regulatory integrity for market applications and judicial interpretation as technology develops.

ENHANCED POST-MARKET SURVEILLANCE
Implement robust post-market surveillance systems and standardized time frames to monitor performance and safety by collecting real-time data to identify issues post-implementation with regulatory oversight to ensure cohesive and successful applications.

TRANSPARENCY AND ACCOUNTABILITY
Include requirements to explain AI decision-making processes to help providers understand and trust AI recommendations. Develop ethical guidelines emphasizing fairness, accountability, and transparency to ensure proper informed consent. Implement public education and awareness campaigns.

STRENGTHENED DATA PRIVACY PROTECTIONS
Update HIPAA regulations to address unique challenges posed by AI and big data analytics such as data de-identification, data ownership and control, third-party access, accountability and liability for data breaches, and cybersecurity standards for data protection.

CROSS-SECTOR COLLABORATION AND INNOVATION
Incentivize Government, academic, and private sector collaboration to improve quality, innovation and regulatory decision-making. Continue federal funding to support safe and ethical use research, focusing on addressing bias and improving algorithms.