Clark Hill

Telehealth Week 2025: Navigating Legal Changes and Future Trends for Healthcare Providers

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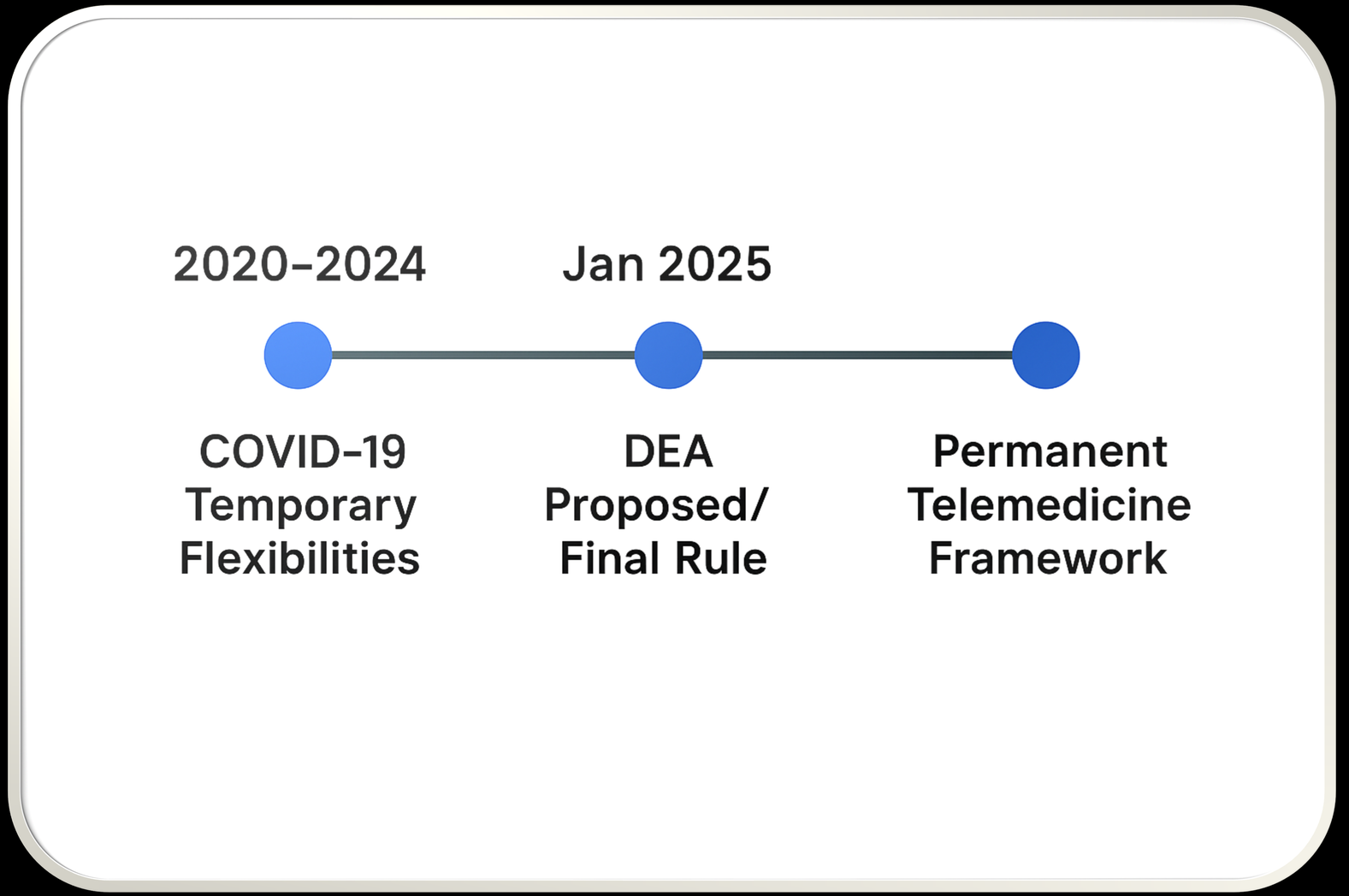
Agenda

- The Status of the DEA Final Rule
- Federal Reimbursement Concerns
- Navigating Interstate Compacts
- Compliance and Risk Management Best Practices

The Status of the DEA Final Rule


2020–2024
Jan 2025
COVID-19 Temporary Flexibilities
DEA Proposed/ Final Rule
Permanent Telemedicine Framework

The DEA Proposed Final Rule (Jan 2025) – Telemedicine & Controlled Substances

- Intended to establish permanent telemedicine prescribing rules following the expiration of COVID-19 flexibilities.
- Would apply to Schedule II–V controlled substances.
- Telemedicine prescribing would require patient evaluation via a DEA-compliant telehealth encounter.
- Prescribers must verify patient identity and conduct a medical evaluation consistent with in-person standards.
- Initial in-person visits may be required for certain substances depending on risk classification.
- Telehealth prescriptions must comply with DEA registration requirements and state licensing rules.

Compliance & Risk Management – DEA Telemedicine Rules

Provider Obligations:

- Maintain complete telehealth encounter documentation.
- Use DEA-registered telemedicine platforms that ensure secure prescribing.
- Confirm state and federal licensure before prescribing controlled substances.

Risk Mitigation:

- Implement audit logs for all telemedicine-controlled substance prescriptions.
- Regular staff training on DEA telemedicine requirements.
- Ensure cross-checks with Prescription Drug Monitoring Programs (PDMPs).

Potential Enforcement Risks:

- Non-compliance can trigger civil penalties, DEA investigations, license sanctions.
- Prescribing without meeting DEA or state telemedicine standards may be treated as illegal distribution.

What's Next For The DEA's Final Rule?

- No Final Rule announced (yet).
- The DEA appears to be starting over.
- The DEA withdrew from consideration all proposed rules and 38 other rules already approved in order to deregulate.

Federal Reimbursement Considerations

Federal Telehealth Reimbursement – Current Landscape

Medicare:

- Coverage for many services added during COVID-19 PHE (Primary care, behavioral health, chronic condition management)
- Audio-only visits remain reimbursable for certain behavioral health and evaluation/management (E/M) services.
- Patient location flexibility: home is recognized as originating site for covered services.

Medicaid:

- Telehealth coverage is state-specific; some states continue expanded access from the COVID PHE.
- Many states reimburse audio-only visits differently.

Telehealth Reimbursement – Current Risks & Considerations

Documentation & Compliance Risks:

- Incorrect telehealth modifiers (95, GT) → claim denials or overpayment recoupments
- Incomplete documentation of technology modality, patient consent, or location

Service Coverage Ambiguities:

- Post-PHE, some services reverted to in-person requirement; providers must track updates.
- Audio-only rules vary across payers and states.

Fraud & Abuse Exposure:

- Billing for non-covered telehealth services → potential False Claims Act (FCA) liability
- Misrepresentation of patient location or service type

Operational Considerations:

- Ensure billing staff and telehealth platform support current payer rules
- Maintain periodic review of federal, state, and commercial payer updates

Telehealth Reimbursement – Current Risks & Considerations

Unless Congress acts quickly, key telehealth flexibilities that were first put in place during the COVID-19 pandemic will expire on September 30, 2025.

What's at stake on October 1st if Congress doesn't extend telehealth access options:

- Providers would no longer be reimbursed for telehealth visits delivered to Medicare beneficiaries in their homes. Pre-pandemic rural and facility restrictions would return.
- Critical programs like Hospital at Home could face major disruption.
- Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) would no longer be able to serve as distant site providers for most telehealth services after December 2025.

Navigating Interstate Compacts

Key Discussion Points

- Cross-State Licensure Pathways
- The Impact of Licensure Compacts on Telehealth
- Overview of Interstate Licensure Compacts
- State Telehealth Registration Process
- How IMLC Differs from Other Compacts
- Interstate Compact Status by Profession

The Impact of Licensure Compacts on Telehealth

- Telehealth is generally considered rendered at the physical location of the patient.
- Interstate compacts simplify licensing by allowing providers to practice across state lines with a valid home-state license.
- Compacts are a key tool for enabling out-of-state practitioners to deliver care across state lines.

Cross-State Licensure Pathways

- Full State License
- Temporary Practice Laws
- Licensure Reciprocity
- Compacts
- Telehealth Registration

Overview of Interstate Licensure Compacts

- Definition of Compacts
- Purpose of Compacts
- How Compacts Work
- Compact Development Process
- Legal Considerations

State Telehealth Registration Process

Overview:

When a state has a **telehealth registration**, it allows out-of-state healthcare providers to deliver telehealth services to patients located in that state without requiring full in-state licensure. These registrations offer a more tailored and often quicker route.

Key Characteristics:

- **Oversight and jurisdiction:** The state maintains regulatory control over out-of-state providers.
- **Essential criteria:** Providers generally must have a valid, unrestricted license elsewhere, carry professional liability insurance, and be free of disciplinary actions
- **Scope limitations:** Registrants typically cannot open physical offices or provide in-person care in the state
- **Administrative requirements:** Annual renewals and fee submissions are common, along with documentation of compliance

How IMLC Differs from Other Compacts

Separate Expedited State Licenses

- Provides an expedited pathway to obtain multiple, full state medical licenses.
- Each IMLC license is issued and regulated by the individual state; renewals and requirements apply separately in each state.

Other Healthcare Compacts – Multistate Privilege or License

- Issues a single multistate license or "privilege to practice," allowing practice across all compact states under one set of credentials.
- Streamlined renewals, compliance, and practice rules for all member states.

Feature	IMCL	Other Compacts
License Type	Separate, expedited full licenses	Single multistate/privilege credential
Renewal	Done for each state individually	Single process or privilege renewal
Practice Rights	Full, per each state's scope/laws	Uniform privilege, some limits apply
Eligibility	Strict, centralized verification	Basic current licensure in a state

Interstate Compact Status by Profession

Operational Compacts

- Emergency Medical Services Compact (24 states)
- Interstate Medical Licensure Compact (42 states, D.C., Guam)
- Nurse Licensure Compact (43 jurisdictions)
- Physical Therapy Compact (35 states)
- Psychology Interjurisdictional Compact (42 states)

Activated Compacts Not Yet Operational

- Social Work (28 states)
- Counseling (25 states)
- Dentist & Dental Hygienist (10 states)
- Dietitian
- Occupational Therapy (31 states)
- Physician Assistants (19 states)
- Audiology & Speech-Language Pathology (36 states, 1 territory)

Not Activated Yet

- Advanced Practice Registered Nurse (4 states)

In Development

- Respiratory Therapists

As of September 2025, per compacts' websites

Compact Information Resources

- State Specific Compact Information
  - Center for Connected Health Policy (CCHP) – Licensure Compacts
- July 2024 Report on Out-of-State Telehealth Provider Policies
  - CCHP – The Cross-State Licensure Continuum: Out-of-State Telehealth Provider Policies
- State Map of Out-of-State Telehealth Provider Policies
  - CCHP - https://www.cchpca.org/policy-trends/
- August 2024 Webinar Cross-State Licensure & Compacts Webinar
  - CCHP - https://www.cchpca.org/resources/cross-state-licensure-compacts-webinar/
- Medicare Clarifies Recognition of Interstate License Compact Pathways
  - CMS.gov Medicare Learning Network - https://www.cms.gov/files/document/se20008.pdf
- National Center for Interstate Compacts Website
  - https://compacts.csg.org/
- Health Resources and Services Administration – Licensure Compacts Descriptions
  - https://telehealth.hhs.gov/licensure/licensure-compacts

Healthcare Interstate Compact Websites

Advanced Practice Registered Nurses Compact	https://www.aprncompact.com/about.page#map
Audiology & Speech Language Pathology Interstate Compact	https://aslpcompact.com/compact-map/
Counseling Compact	https://counselingcompact.org/map/
Dentist and Dental Hygienist Compact	https://ddhcompact.org/compact-map/
Interstate Medical Licensure Compact	https://www.imlcc.org/participating-states/
Nurse Licensure Compact	https://www.nursecompact.com/
Occupational Therapy Licensure Compact	https://otcompact.gov/compact-map/
Physical Therapy Compact	https://ptcompact.org/ptc-states
Physician's Assistant Licensure Compact	https://www.pacompact.org/
Psychology Interjurisdictional Compact (PSYPACT)	https://psypact.org/mpage/psypactmap
Social Work Licensure Compact	https://swcompact.org/compact-map/
The United States Emergency Medical Services Compact	https://www.emscompact.gov/

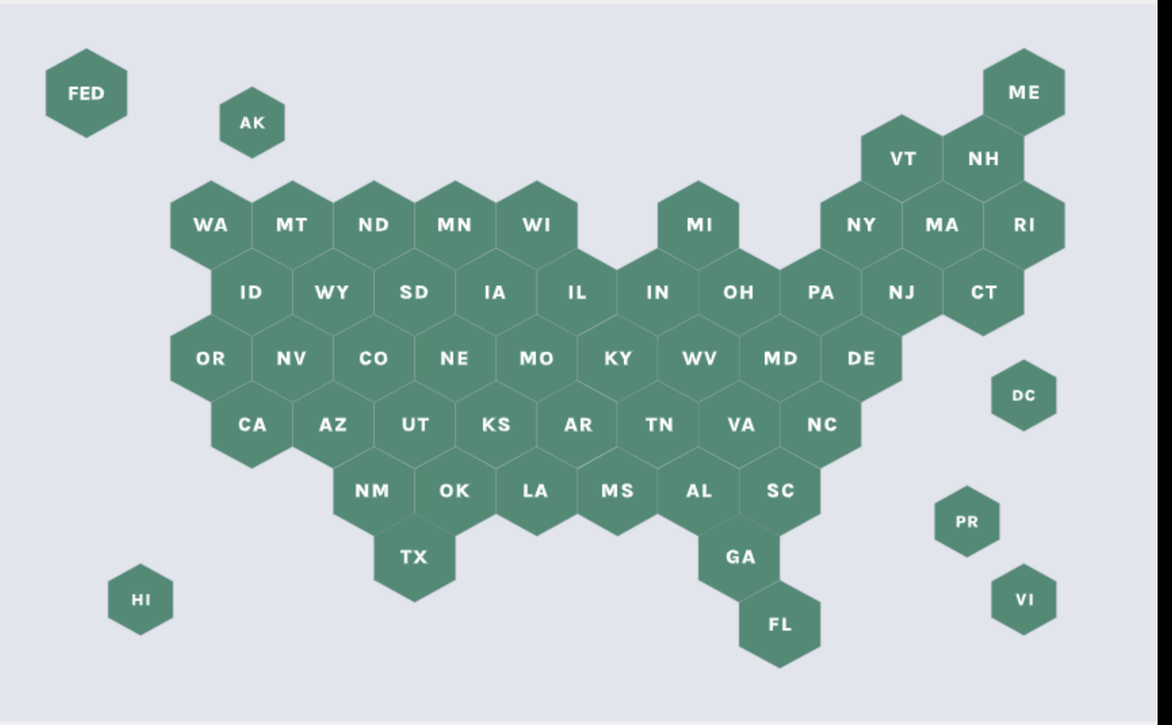
Center for Connected Health Policy

THE NATIONAL TELEHEALTH POLICY RESOURCE CENTER

PROFESSIONAL REQUIREMENTS

Cross-State Licensing

When telehealth is used, it is considered to be rendered at the physical location of the patient, and therefore a provider typically needs to be licensed in the patient's state. A few states have licenses or telehealth specific exceptions that allow an out-of-state provider to render services via telemedicine in a state where they are not located, or allow a clinician to provide services via telehealth in a state if certain conditions are met (such as agreeing that they will not open an office in that state). Still other states have laws that don't specifically address telehealth and/or telemedicine licensing, but make allowances for practicing in contiguous states, or in certain situations where a temporary license might be issued provided the specific state's licensing conditions are met.



CLICK THE MAP TO SCROLL DOWN TO THE STATE

https://www.cchpca.org/topic/cross-state-licensing-professional-requirements/

AI & Regulatory Compliance in Telehealth:

Navigating State AI Laws and FDA Oversight

Why AI Compliance Matters in Telehealth

AI is increasingly used for:

- Diagnostic support (e.g., arrhythmia detection)
- Predictive analytics (risk scoring, triage)
- Virtual assistants/chatbots for patient intake

Non-compliance risks:

- FDA enforcement for unapproved medical devices
- State restrictions on AI-driven clinical decision-making
- Data privacy violations (HIPAA, state AI/privacy laws)
- Scale balancing innovation vs. legal risk

FDA Oversight of AI/ML in Telehealth

AI as a Medical Device: regulated under 21 CFR Part 800–1299

Risk-based classification (Class I–III) depends on clinical impact

Key obligations for providers using AI in telehealth:

- Use only FDA-cleared or authorized devices
- Follow manufacturer instructions & maintain logs
- Report adverse events per 21 CFR Part 803 (MDR)

AI software updates: check whether “locked” vs “adaptive” affects regulatory obligations

State-Level AI and Telehealth Laws

California (CDPA/CPRA + AI transparency bills)

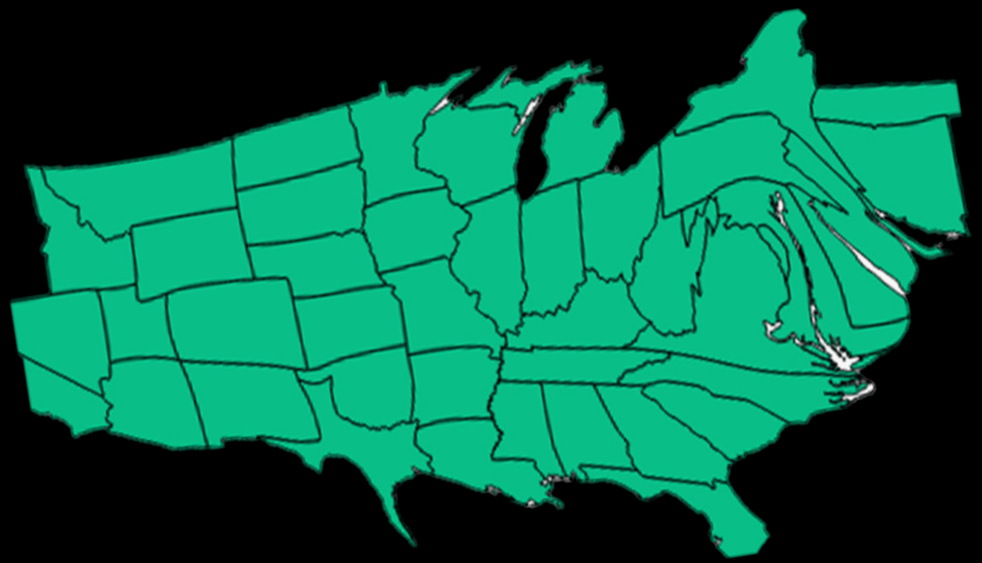
- Requirements for explainability, bias mitigation, and data handling

New York, Illinois, Texas, Virginia: Emerging AI legislation affecting:

- Clinical decision support transparency
- Patient consent for AI-assisted care

Multi-state telehealth providers must monitor:

- Licensing rules combined with AI usage restrictions
- Reporting obligations for AI errors or harm



Data Privacy & AI Risk in Telehealth

AI requires large patient datasets → privacy risks

Compliance requirements:

- HIPAA: AI data must be de-identified or protected under BAAs
- CPRA, CDPA: AI-generated inferences may be sensitive personal info

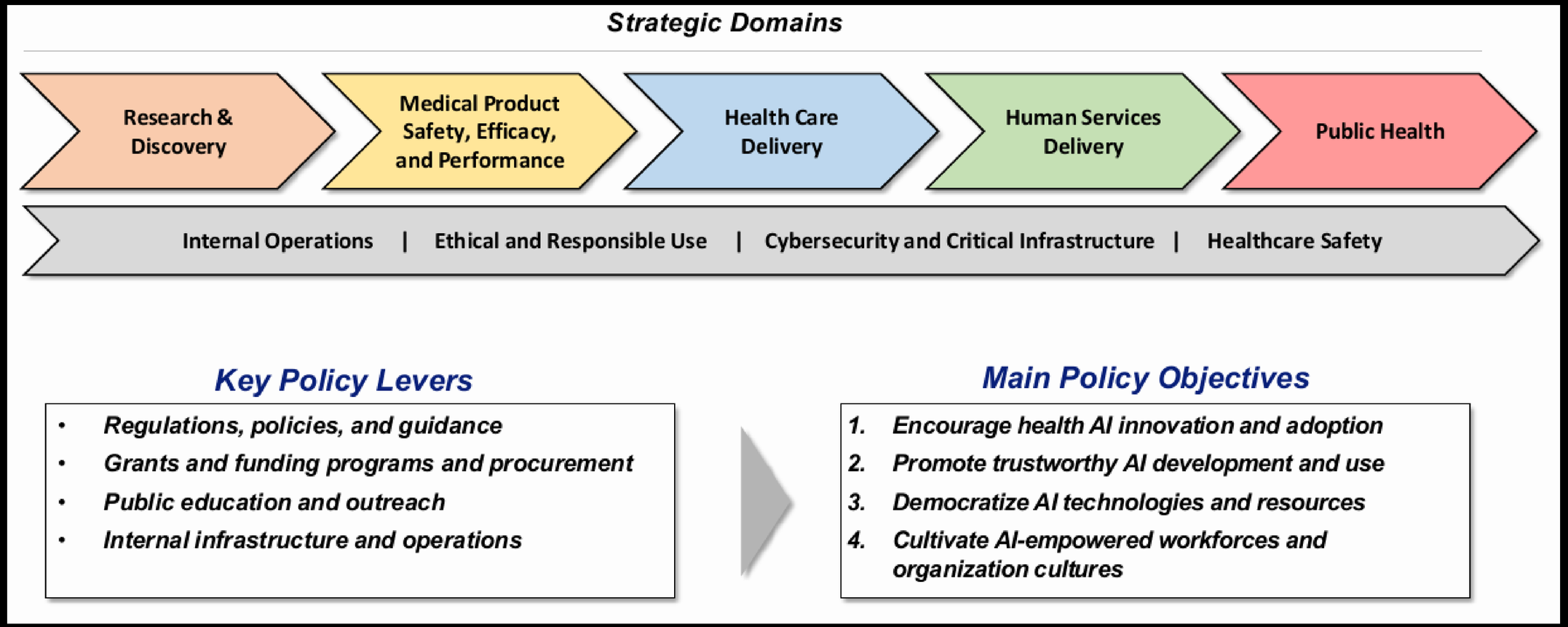
Implement technical/organizational safeguards:

- Access control, audit logging, encryption
- Policies to prevent AI re-identification of de-identified data

Fair	Does not exhibit prejudice or favoritism toward an individual or group based on their inherent or acquired characteristics
Appropriate	Outputs are well matched to produce results appropriate for specific contexts and populations to which they are applied
Valid	Outputs have been shown to estimate targeted values accurately and as expected in both internal and external data
Effective	Outputs have demonstrated benefits in real-world conditions
Safe	Use is free from any known unacceptable risks, for which the probable benefits of AI use outweigh any probable risks

FAVES Principles

HHS AI Strategic Plan



Health AI Regulation and Collaboration

Core Infrastructure

JULY 21, 2023

FACT SHEET: Biden-Harris Administration Secures Voluntary Commitments from Leading Artificial Intelligence Companies to Manage the Risks Posed by AI

BRIEFING ROOM › STATEMENTS AND RELEASES

U.S. National Science Foundation

National AI Research Resource

NIST

US AI Safety Institute

ASTP Assistant Secretary for Technology Policy

Health Care Products

FDA

Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) Action Plan

January 2021

ONC

HTI-1 Rule: Algorithm Transparency

Health Care Uses

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Office for Civil Rights

ACA Section 1557: Non-Discrimination in Health Programs and Activities

CMS.gov

February 06, 2024 06:04 PM

CMS outlines limits on Medicare Advantage AI usage

ALISON BENNETT

DECEMBER 14, 2023

Delivering on the Promise of AI to Improve Health Outcomes

BRIEFING ROOM › BLOG

28 providers and payers have joined today's commitments: Allina Health, Bassett Healthcare Network, Boston Children's Hospital, Curai Health, CVS Health, Devoted Health, Duke Health, Emory Healthcare, Endeavor Health, Fairview Health Systems, Geisinger, Hackensack Meridian, HealthFirst (Florida), Houston Methodist, John Muir Health, Keck Medicine, Main Line Health, Mass General Brigham, Medical University of South Carolina Health, Oscar, OSF HealthCare, Premera Blue Cross, Rush University System for Health, Sanford Health, Tufts Medicine, UC San Diego Health, UC Davis Health, and WellSpan Health.

Telehealth Provider Best Practices

Verify AI/ML software is FDA-cleared or appropriately authorized

Confirm state law compliance for AI use in clinical decisions

Implement AI governance program:

- Bias monitoring
- Explainability standards
- Adverse event tracking

Document patient consent specific to AI use

Risk Management & Auditing

Conduct internal AI audits: evaluate algorithms, patient outcomes, and vendor compliance

Maintain audit trails for AI decisions affecting patient care

Train staff on AI limitations, risks, and red flags

Develop incident response procedures for AI-related errors

Emerging Trends & Considerations

FDA AI/ML regulatory framework expected to expand:

- Adaptive AI/ML software
- Real-world performance monitoring

State laws likely to require:

- Bias audits, transparency reports, explainable AI
- Cross-border data restrictions may impact AI dataset access for telehealth

Thank You

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