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Clinical AI and the Future of Healthcare Access

A Pro-Innovation Regulatory Framework

The AI Medical Services Act

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Model legislation overview and implementation framework

The Healthcare Access Crisis

Human capital alone cannot solve the access gap.

- Most states face severe physician shortages.
- Rural hospitals and specialist access continue to decline.
- Patients wait weeks or months for diagnostics and treatment.
- Healthcare demand is rising faster than provider supply.
- Montana has prioritized the healthcare workforce as part of its Rural Health Transformation Program

Supply

Provider shortages and burnout constrain access even before demand growth is accounted for.

Access

Rural and underserved patients face the largest delays for diagnostics, triage, and specialist care.

Demand

An aging population and chronic disease burden increase clinical workload faster than staffing can expand.

AI is not optional - it is inevitable. The policy question is whether it operates inside the regulated healthcare system or outside it unregulated.

The Regulatory Gap

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Current law has no clear framework for clinical AI services.

Today, clinical AI sits between three different regulatory systems:

Regulatory Pathway	What It Governs
FDA Medical Device Regulation	AI software marketed as a medical device (SaMD)
Laboratory Developed Tests (LDTs)	AI used within clinical diagnostic services
Practice of Medicine (State Law)	Diagnosis, treatment, triage, prescribing

Problem

FDA regulates products.
State law regulates clinical practice.
Neither framework clearly governs AI delivering clinical services.

Result

Innovators default to consumer apps.
Clinical deployment is legally uncertain.
Patients lose the protections of the healthcare system.

The Core Idea

Regulate the service, not the software.

When AI performs clinical functions for patients, it should be licensed and accountable like any healthcare provider.

The Act establishes a new state-licensed entity:

AI Augmented & Autonomous Service Provider (AAASP)

This approach regulates clinical services delivered by AI, not the underlying code.

What Clinical AI Actually Does

Clinical AI services perform medical functions.

1. Analyze patient data

Clinical, biometric, diagnostic, and imaging inputs for a specific patient.

2. Generate conclusions

Diagnostic impressions, risk assessments, and treatment planning.

3. Monitor deterioration

Ongoing surveillance and early detection of worsening conditions.

4. Triage and escalate care

Prioritize patients, route them to the right level of care, and trigger human escalation when needed.

5. Recommend, initiate, or adjust treatment

Under defined autonomy levels, AI may support or execute medication, test, or care-plan decisions.

These activities constitute professional clinical services - not general-purpose software tools.

Risk-Based Governance

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Oversight scales with clinical risk.

Factor 1
AI autonomy level (L0-L3)

Factor 2
Clinical severity of the condition

Regulatory reference table

Condition Category	Informational (L0)	Advisory (L1)	Supervised Autonomous (L2)	Fully Autonomous (L3)
Preventive	**Exempt**	**Exempt**	**Exempt (or L2)***	**L3 Required**
Chronic or Non-Critical	**Exempt**	**Exempt**	**L2 Required**	**L3 Required**
Critical or Time-Sensitive	**Exempt**	**L1 Required**	**L2 Required**	**L3 Required**

*Preventive supervised AI is exempt unless ordering labs, drugs, or devices.

Oversight increases proportionally with clinical risk.

Safety and Accountability

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Patient protection is built into the model.

Malpractice coverage

Insurance and bonding create legal recourse when care goes wrong.

Right to Know

Patients receive transparency when AI is providing care.

Auditability

Adverse-event reporting and reviewable records support oversight.

Human escalation

Defined pathways preserve the right to human review and intervention.

Monitoring

Continuous performance measurement supports ongoing safety improvement.

Patients get accountability protections that do not exist with unregulated consumer AI apps.

The Act is designed to bring clinical AI inside the healthcare system with the same expectations of responsibility, traceability, and patient recourse that apply to other licensed care delivery models.

The Regulatory Sandbox

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Safe deployment through supervised innovation.

1. Provisional license

New providers begin in a 2-year sandbox period.

2. Supervised deployment

State oversight, safety monitoring, and real-world data collection.

3. Expanded scope

Scale only after proven safety and performance.

Shot clock

30 days
for completeness
90 days
for decision

What happens during the sandbox?

- Pilot planning, scaling and escalation
- State oversight and safety monitoring
- Independent review of outcomes
- Real-world evidence for regulatory decisions
- Wind-down planning and continuity of care expectations

Economic and Innovation Impact

The pro-innovation state strategy.

Clear rules create market certainty.

The Act is designed to attract capital and keep innovation inside the regulated healthcare system instead of pushing it toward consumer-only workarounds.

Payment pathway

Begins the process for a private-insurer reimbursement framework for licensed AI services.

Liability and billing clarity

Defined legal accountability and operational structures reduce uncertainty.

Anti-protectionism

A 2/3 super-majority vote is required to restrict AI scope of practice.

Expanded access

Rural and underserved communities gain additional capacity and service availability.

Investment and jobs

A predictable licensure model supports high-technology job creation and signals that the state welcomes responsible deployment.

The Policy Choice

The choice is not AI versus no AI.

Unregulated AI outside the healthcare system

- Consumer apps and cash-pay workarounds
- Limited accountability and recourse
- Fragmented integration with clinical care

OR

Licensed, accountable AI inside the healthcare system

- State licensure and oversight
- Transparency, recourse, and human escalation
- Integration with reimbursement and regulated care

The AI Medical Services Act chooses regulated integration.

THANK YOU!

QUESTIONS?