[LSR NUMBER PENDING] - WORKING DRAFT

2027 SESSION

[LSR NUMBER PENDING] [DRAFTER CODE PENDING]

HOUSE BILL [NUMBER PENDING]

AN ACT relative to licensing clinical artificial intelligence providers and protecting patients.

SPONSORS: [SPONSOR OR SPONSORS PENDING]
COMMITTEE: [COMMITTEE REFERRAL PENDING]

ANALYSIS

This bill establishes a staged licensing system for legal entities that operate clinical artificial intelligence systems. It assigns patient-care responsibility to the licensed entity; requires independent evaluation, supervised deployment, incident reporting, public performance reporting, patient consent and human review; regulates material model changes; and authorizes enforcement, reciprocity, and rulemaking.

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Explanation: Matter added to current law appears in regular type because this working draft proposes an all-new chapter. Bracketed items are drafting placeholders for the Office of Legislative Services and are not final statutory citations, bill numbers, sponsors, committee referrals, or effective dates.

[LSR NUMBER PENDING]
[DRAFTER CODE PENDING]

STATE OF NEW HAMPSHIRE

In the Year of Our Lord Two Thousand Twenty Seven

AN ACT relative to licensing clinical artificial intelligence providers and protecting patients.

Be it Enacted by the Senate and House of Representatives in General Court convened:

1 New Chapter; Clinical Artificial Intelligence Providers. Amend RSA by inserting after chapter [RSA CHAPTER PENDING] the following new chapter:

CHAPTER [RSA CHAPTER PENDING]
CLINICAL ARTIFICIAL INTELLIGENCE PROVIDERS

[RSA]:1 Short Title.

This Act may be cited as the "Clinical AI Provider Licensing and Patient Safety Act."

[RSA]:2 Findings; Purpose.

I. Clinical AI can expand access and lower the cost of care, but patient-specific diagnosis, treatment, triage, and clinical orders are professional services that require accountability.

II. Existing medical-device and professional-licensure frameworks do not by themselves provide a complete state pathway for an AI-operated clinical service.

III. Regulation should be risk-based, technology-neutral, evidence-based, and focused on measurable patient outcomes rather than protection of incumbent business models.

IV. The purpose of this Act is to create a staged licensing pathway, preserve patient choice, assign legal responsibility, require continuous evidence, and allow safe expansion of clinical authority.

[RSA]:3 Definitions.

"Clinical AI provider" means a legal entity licensed under this Act that operates a clinical AI system and accepts professional responsibility for services delivered by that system.

"Clinical AI service" means a patient-specific service that assesses, predicts, diagnoses, triages, recommends, initiates, modifies, or discontinues a clinical action, treatment, medication, laboratory test, imaging study, referral, or medical device.

"Approved scope" means the exact combination of clinical function, condition, patient population, care setting, autonomy level, and exclusions stated on a license or endorsement.

"Material model change" means a change that may reasonably affect clinical output, calibration, failure modes, subgroup performance, escalation behavior, intended use, or approved scope, including a change to a foundation model, weights, system prompt, clinical policy, retrieval source, tool, or action layer.

"Serious reportable event" means death, serious injury, clinically significant delay, wrong-site or wrong-patient action, unauthorized prescription or order, privacy or security breach affecting care, material model malfunction, or a near miss reasonably capable of causing serious harm.

"Independent evaluator" means a person or organization with no financial interest in the applicant, qualified in clinical evaluation and AI assurance, and approved or accredited by the Department.

[RSA]:4 Administration; Independent Review.

I. The [Department of Health or Professional Licensing] shall administer this Act and issue, limit, suspend, and revoke licenses.

II. The Department shall appoint a Clinical AI Advisory Council including clinicians, patients, safety scientists, AI engineers, cybersecurity experts, health-equity experts, and at least two public members. No occupational group may hold a majority.

III. The Council advises on standards and public reports. Final licensing and enforcement authority remains with the Department.

IV. Members shall disclose financial conflicts and recuse from matters involving a current or recent employer, client, investment, or competitor.

V. The Department shall publish application status, license scope, restrictions, enforcement actions, performance summaries, and meeting materials, except protected patient information and narrowly defined trade secrets.

[RSA]:5 Licensing Ladder.

I. Level 0; information.

No license is required when a system provides only general health information, scheduling, documentation, or administrative support and is not represented or reasonably relied on for patient-specific clinical decisions. Level 0 systems remain subject to consumer-protection, privacy, and disclosure law.

II. Level 1; clinical support.

A Level 1 license permits patient-specific assessment and recommendations only when a licensed clinician independently accepts responsibility for the resulting clinical decision. The system may not independently issue or execute an order.

III. Level 2; supervised action.

A Level 2 license permits the system to execute only those low- or moderate-risk clinical actions expressly listed in the approved scope under a supervision protocol. The protocol must identify the supervising professional, intervention and review deadlines, override controls, escalation criteria, and downtime procedures.

IV. Level 3; bounded autonomous care.

A Level 3 license permits independent clinical action only within a narrow approved scope. Approval shall state each condition, function, patient population, care setting, permitted order or therapy, exclusion, referral threshold, and emergency limitation.

V. Level 4; expanded autonomous practice.

A Level 4 license consists of a Level 3 license plus one or more modular scope endorsements. Each endorsement requires its own evidence package. Evidence in one condition or population does not create authority in another.

VI. Prohibited inference.

Silence in a license is not authorization. A licensee may perform only acts affirmatively listed in its approved scope.

[RSA]:6 Application and Safety Case.

An applicant for Level 1 through Level 4 shall submit a public summary and confidential technical safety case containing:

I. the intended use, approved-scope request, exclusions, and foreseeable misuse;

II. the clinical evidence plan and comparison standard;

III. performance by age, sex, race and ethnicity where lawful and available, disability, language, insurance status, and other clinically relevant subgroups;

IV. calibration, sensitivity, specificity, false-positive and false-negative rates, abstention performance, and clinically meaningful outcome measures;

V. hazard analysis, red-team results, tool-use and action-layer testing, and adversarial-security testing;

VI. training and evaluation data provenance, leakage controls, and limits;

VII. escalation, human-review, emergency, continuity, and downtime plans;

VIII. versioning, logging, reproducibility, and change-control procedures;

IX. privacy, cybersecurity, access-control, and data-retention controls;

X. a named responsible officer and, for Levels 2 through 4, a state-licensed medical director;

XI. professional liability coverage and a patient-compensation bond proportionate to encounter volume and risk; and

XII. a wind-down plan providing continuity of care and interoperable transfer of records.

[RSA]:7 Evidence and Advancement.

I. Level 1 requires analytical and clinical validation appropriate to the intended use.

II. Level 2 requires prospective supervised deployment under an approved protocol and predefined stopping rules.

III. Level 3 requires independent evaluation and real-world evidence showing performance at least non-inferior to a reasonably prudent human clinician for the approved scope, with no material subgroup safety deficit.

IV. Level 4 requires sustained performance for a period set by rule, successful change-control history, and evidence for each new endorsement.

V. The Department may require stronger evidence for pediatric, pregnant, behavioral-health, oncology, emergency, or other vulnerable or high-risk populations.

VI. Controlled substances, involuntary treatment, surgery, and emergency stabilization may not be included in autonomous authority unless separately authorized by statute.

VII. The Department shall decide a complete application within 120 days. It may grant, deny, or issue a narrower license with written reasons. Inaction does not create a license.

[RSA]:8 Regulatory Sandbox.

I. Every initial Level 2 or Level 3 authorization is provisional for up to twenty-four months.

II. The Department may impose site, geography, encounter-volume, population, function, and duration limits.

III. A sandbox protocol shall state hypotheses, metrics, human-review rate, stopping rules, adverse-event thresholds, and a patient exit plan.

IV. A data and safety monitor independent of the applicant shall review performance at least quarterly for Level 3 deployments.
V. The Department may pause enrollment or clinical action immediately upon evidence of imminent risk.
VI. Graduation requires affirmative findings. Completion of time alone does not convert a provisional license.

[RSA]:9 Patient Rights.
I. Before service, the patient must receive a plain-language disclosure of the system's identity, license level, approved scope, material limits, supervision status, and how to reach a human.
II. Level 3 and Level 4 care requires affirmative consent. Consent may be withdrawn at any time without retaliation.
III. A patient may request timely human review of a diagnosis, denial, treatment, prescription, order, or escalation decision. Emergency review shall be available continuously when the approved scope includes time-sensitive conditions.
IV. A patient may obtain an interoperable copy of the record, including the system version and material basis for the action, in language a clinician can use.
V. A patient may file a complaint directly with the Department and shall receive notice of material corrective action affecting that patient's care.
VI. The clinical interface may not contain paid advertising or undisclosed steering to an affiliate. Financial relationships at the point of recommendation must be disclosed.

[RSA]:10 Clinical Duties and Accountability.
I. A clinical AI provider owes the patient the same duty of care applicable to a reasonably prudent licensed professional performing the same function.
II. The licensed entity is legally responsible for its system's acts and omissions. Responsibility may not be disclaimed by contract or shifted to the patient.
III. For Level 2, the supervising professional remains responsible for duties assigned by the supervision protocol; the entity remains responsible for system design, operation, monitoring, and disclosure.
IV. A licensee owes a duty of loyalty to the patient and shall not configure clinical logic to favor revenue over a clinically appropriate, safer, or materially lower-cost option.
V. A licensee shall maintain professional-liability coverage and tail coverage in amounts set by rule.

[RSA]:11 Monitoring, Incidents; Public Reporting.
I. Serious reportable events shall be reported to the Department within seventy-two hours; an event presenting ongoing imminent danger shall be reported within twenty-four hours.
II. Quarterly reports shall include encounter volume, abstentions, escalations, human overrides, complaints, adverse events, near misses, subgroup performance, uptime, major changes, and corrective actions.
III. The Department shall publish de-identified quarterly dashboards for Level 2 through Level 4 licensees.
IV. Licensees shall maintain immutable encounter logs, model and policy versions, tool calls, outputs, overrides, and clinical actions for the longer of seven years or the period required for comparable medical records.
V. The Department may conduct unannounced audits and require independent re-evaluation.
VI. Automatic safety triggers established by rule shall require a temporary restriction or pause pending review.

[RSA]:12 Material Changes; Model Drift.
I. A licensee shall operate a documented quality-management system covering development, validation, deployment, monitoring, and retirement.
II. A material model change requires notice and a change-impact assessment before deployment. A high-risk change requires prior Department approval.
III. Emergency security or safety patches may be deployed immediately when delay creates greater risk, but must be reported within seventy-two hours.
IV. The licensee shall continuously monitor drift in inputs, outputs, calibration, outcomes, escalation, and subgroup performance.
V. The Department may order rollback, restricted scope, additional supervision, patient notice, or revalidation.

[RSA]:13 Prescriptions, Tests, Devices; Referrals.
I. Level 2 and Level 3 authority may include non-controlled medications, laboratory tests, imaging, devices, and referrals only when each category is expressly endorsed.
II. The endorsement shall specify formularies, dose limits, repeat-order limits, contraindication checks, age limits, interaction checks, and required follow-up.
III. The Act does not supersede federal regulation of drugs and devices, laboratory law, pharmacy law, or controlled-substance law.
IV. Clinical orders shall identify the licensed clinical AI provider and responsible legal entity.

[RSA]:14 Privacy, Security; Interoperability.

I. A licensee shall comply with state health-privacy law and with HIPAA when applicable. Consumer-health data may not be sold or used for targeted advertising.

II. Cybersecurity controls shall include encryption, least-privilege access, multifactor authentication, vendor risk management, incident response, penetration testing, and software-bill-of-materials practices appropriate to risk.

III. A breach affecting clinical integrity shall be treated as a reportable event.

IV. Records and transition data must be exportable using nationally recognized interoperability standards where available.

[RSA]:15 Enforcement.

I. The Department may issue corrective-action plans, civil penalties, scope restrictions, probation, suspension, emergency suspension, or revocation.

II. Grounds include unlicensed practice, operating beyond scope, material misrepresentation, failure to report, obstruction of audit, unsafe drift, inadequate supervision, repeated subgroup harm, security failure, or breach of patient loyalty.

III. The Attorney General may seek restitution, injunctive relief, and penalties under consumer-protection law.

IV. Whistleblowers who report a reasonable safety concern are protected from retaliation.

V. Adverse actions are subject to the state's administrative procedure act, except that an emergency restriction may take effect immediately with a prompt hearing.

[RSA]:16 Reciprocity; Federal Alignment.

I. The Department may recognize another jurisdiction's license only after finding its evidence, patient-rights, monitoring, and enforcement protections substantially equivalent.

II. FDA clearance or approval may satisfy overlapping evidence requirements but does not by itself grant state practice authority.

III. The Department shall minimize duplicate reporting while preserving state access to encounter-level evidence needed for safety oversight.

[RSA]:17 Payment Neutrality.

A payer may not deny an otherwise covered and medically necessary service solely because it is delivered by a licensed clinical AI provider. Nothing in this section requires payment above an amount reflecting the service's cost, quality, and outcomes or creates federal-program recognition.

[RSA]:18 Rulemaking.

I. Within twelve months, the Department shall issue rules, application forms, evidence guidance, reporting schemas, and fee schedules.

II. Rules shall be proportionate to demonstrated risk, publicly explained, and reviewed at least every two years.

2 Transitional Authority. The department may accept supervised sandbox applications 6 months after enactment, subject to rules and available resources.

3 Effective Date. This act shall take effect [EFFECTIVE DATE PENDING].

WORKING-DRAFT NOTES FOR OLS AND LEGISLATIVE COUNSEL

1. This is a policy working draft, not an introduced bill. OLS should assign the LSR number, bill number, drafter code, RSA chapter and section citations, committee referral, sponsors, and effective date.

2. Conform the administering department, administrative appeals, record retention, malpractice, prescribing, laboratory, telehealth, privacy, and corporate-practice provisions to New Hampshire law.

3. Decide whether administration should sit in the Department of Health and Human Services, the Office of Professional Licensure and Certification, or another existing state entity. The draft uses an advisory council rather than creating a wholly new occupational board.

4. Set insurance, bond, fees, and civil-penalty amounts based on encounter volume and risk.

5. Review federal preemption and alignment with FDA device law, HIPAA, CLIA, pharmacy law, controlled-substance law, and reimbursement rules.

6. A fiscal note may be required because the bill creates a licensing, review, audit, reporting, and enforcement program. No fiscal impact has been estimated in this working draft.

Format reference: New Hampshire HB 201-FN (2025), as introduced, official General Court bill text.
https://gc.nh.gov/bill_status/legacy/bs2016/billText.aspx?id=36&sy=2025&txtFormat=html