EXECUTIVE SUMMARY & OVERVIEW

THE AI CLINICAL SERVICES ACT: A Pro-Innovation, Pro-Safety Governing Philosophy

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1. The Core Philosophy

Most AI legislation today starts from a premise of risk avoidance: that artificial intelligence in healthcare should be slowed, restricted, or delayed until all uncertainty is eliminated. That approach, while well-intentioned, has produced predictable negative outcomes—regulatory paralysis, the proliferation of unregulated consumer tools, delayed access to care, and innovation migrating outside the healthcare system entirely.

The AI Clinical Services Act adopts a different, historically grounded philosophy. This Act recognizes that:

- **Inevitability:** AI will be used in healthcare regardless of legislative action; the only choice is whether it is used inside the system (regulated) or outside (unregulated).
- **Present Harm:** Provider shortages, access gaps, and wait times are present harms, not hypothetical ones. Delaying solutions is a choice to maintain these harms.
- **The Solution:** Patient safety is best protected not by prohibition, but by accountable, supervised deployment within the healthcare system.

Accordingly, the Act does not attempt to regulate artificial intelligence as a general technology, product, or computational resource. Instead, it regulates the **practice of medicine**—an area of law firmly within state authority—and asks a simple question:

> *When artificial intelligence performs clinical functions for a patient, who is accountable, under what standards, and with what safeguards?*

2. The Problem: A Structural Access Crisis

Healthcare faces a structural crisis that human capital alone cannot solve:

- **The Access Gap:** Rural hospitals are closing, specialists are scarce, and patients face dangerous wait times for critical diagnostics.
- **The Regulatory Gap:** Innovators are stuck between two extremes: waiting years for federal device approval or releasing unregulated "consumer apps" that do not integrate with clinical care.

- **The Payment Gap:** Without a licensure model, there is no reimbursement mechanism, forcing innovation into "cash-pay" models that exclude vulnerable populations or to sell to existing providers who use the technology to assist with clinical decision making.

3. The Solution: A "Fast-Lane" for Accountable Care

The Act answers these challenges by creating a new, state-licensed healthcare provider type: the **AI Augmented & Autonomous Service Provider (AAASP)**.

A. Structure & Accountability (The "Provider" Model) Instead of regulating code, we regulate the service. By treating sophisticated AI as a "Provider" rather than a "Device," the Act:

- **Creates a Licensed Pathway:** Establishes a clear route for AI to offer clinical services under state licensure (Class A License).
- **Mandates Insurance:** Requires malpractice equivalency and bonding, ensuring patients have recourse.
- **Enforces Transparency:** Requires explicit "Informed Consent to Innovation," ensuring patients know when they are treated by AI and preserving their right to human review.

B. The Regulatory Sandbox (Safe Deployment) Innovation in medicine has never occurred by freezing practice until certainty exists. It has occurred by allowing supervised use, measuring outcomes, and adjusting standards.

- **Provisional Licensure:** A 2-year "Sandbox" allows companies to launch safely under strict state supervision.
- **The "Shot Clock":** To prevent bureaucratic pocket vetoes, the Act imposes strict timelines (30 days for completeness /90 days for decision), guaranteeing a responsive government.
- **Data-Driven Safety:** Replaces theoretical fears with actual performance data, requiring AI to meet or exceed human safety benchmarks.

C. Economic & Legal Certainty

- **Reimbursement:** Mandates that private insurers recognize the new license type, turning AI from a cost center into a sustainable service.
- **Liability Cap:** Limits non-economic damages for Sandbox participants to encourage market entry while maintaining accountability for negligence.
- **Anti-Protectionism:** Explicitly prevents regulatory capture by requiring a super-majority vote for any rule that restricts AI scope of practice, ensuring decisions are based on safety data, not professional turf wars.

- **Market Certainty:** By defining liability, billing codes, and insurance requirements, we give investors the certainty they need to deploy capital here.

4. The Innovation Rationale

This is not deregulation. It is regulation that matches the reality of modern care delivery. Historically, medicine has advanced through supervised practice and continuous improvement. Telemedicine, nurse practitioners, and physician assistants all followed this path. The AI Clinical Services Act applies that same proven governance model to artificial intelligence.

Bottom Line: The AI Clinical Services Act does not ask regulators to trust technology blindly. **It asks them to govern it wisely.** By creating a lawful, accountable path for clinical AI deployment, the Act protects patients, strengthens the healthcare system, and positions the State as a trusted steward of safe progress.

SECTION-BY-SECTION SUMMARY

- **Section 1 (Findings & Purpose):** Asserts State sovereignty over the "practice of medicine" and establishes a legislative finding of "Anti-Protectionism," explicitly stating that regulations must not be used to protect the economic interests of human incumbents.

- **Section 2 (Definitions):** Adopts the "Role-Based" licensure framework (Informational vs. Autonomous) and "Condition-Based" risk tiers (Preventive vs. Critical). Defines "Clinical AI Service" to distinguish professional services from commercial devices.

- **Section 3 (Governance):** Creates the Board of Autonomous Clinical Practice. Key features include a diverse membership of technologists and clinicians and a two-thirds (2/3) super-majority vote requirement for any rule that restricts AI scope of practice or limits market entry.

AUTHOR'S NOTE

Consultation-Only Version: We also offer a version of this Act that utilizes a consultation process through a without a governing clinical AI board. It can operate through a state Department of Public Licensing or through other similar agency structures.

- **Section 4 (Licensure Framework):** Establishes license types (Class A, B, C) and Autonomy Modifiers (L0-L3). Imposes a "Shot Clock" for completeness reviews and guarantees a final decision within 90 days of a complete application.

- **Section 5 (Transparency):** Mandates a patient's "Right to Know" when an AI is treating them. Requires explicit disclosures for supervised services and affirmative acknowledgment for autonomous providers.

- **Section 6 (Clinical Integrity & Auditability):** Establishes a **Professional Duty of Loyalty** and a mandate for **Economic Stewardship**. Prohibits algorithmic steering for financial benefit and mandates a "Clean Interface" free of commercial content.

- **Section 7 (Regulatory Sandbox):** Creates a 2-year provisional licensure period for safe deployment. Establishes a State Centralized IRB for expedited ethical review and mandates "Wind-Down" plans for continuity of care.

- **Section 8 (Scope & Waivers):** Grants universal practice authority based on validated competency. Includes a limited corporate practice waiver and a liability safe harbor for sandbox participants in substantial compliance.

- **Section 9 (Enforcement):** Establishes penalties for unlicensed practice, misrepresentation of AI capabilities, or aiding and abetting unlicensed operations.

- **Section 10 (Public Finance):** Directs state payer programs to collaborate on reimbursement and creates a "Federal Firewall" to protect state-only funding until federal CMS guidance is issued.

- **Section 11 (Insurance Guidance):** Mandates that the Insurance Commissioner create a framework for private reimbursement, prohibiting discrimination against medically necessary services solely because they are delivered by a licensed AAASP.

- **Section 12 (Rule of Construction):** Codifies a presumption that AI services are authorized unless a specific risk is identified and requires that regulations be the least restrictive means available.

- **Section 13 (Severability):** Standard legal protection ensuring that the rest of the Act remains in effect if any specific provision is held invalid.

- **Section 14 (Effective Date):** Sets the timeline for the Act's commencement and the appointment of the Board.

REGULATORY REFERENCE TABLE

Exempt = No License Required (unless Voluntary L0) | L1/L2/L3 = AAASP License Required

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

*Supervised Autonomous for preventive is exempt unless the licensee will be ordering preventative labs, drugs or devices at which point it will need an L2 modifier.

MODEL LEGISLATION

STATE OF [STATE NAME]
BILL NO. []
A BILL TO BE ENTITLED
THE CLINICAL AI SERVICES ACT

AN ACT to establish the "AI Augmented & Autonomous Service Provider" (AAASP) as a recognized healthcare provider type; to create the Advisory Board of Autonomous Clinical Practice; to authorize fee collection; to establish a regulatory sandbox with expedited ethical review; to distinguish professional clinical services from commercial medical devices; to provide for provider identification and state-funded reimbursement; and for other purposes.

SECTION 1. TITLE, FINDINGS, AND PURPOSE

(a) Short Title. This Act shall be known and may be cited as the "Clinical AI Services Act".

(b) Findings and Purpose. This Act establishes the AI Augmented & Autonomous Service Provider (AAASP) as an independent, new class of healthcare provider to address provider shortages and improve patient outcomes. Through the state-regulated licensure pathway, the Act recognizes autonomous clinical AI as a professional clinical service rather than a federally regulated commercial device. The Act balances patient safety with responsible

innovation, ensuring that regulatory oversight protects public health rather than the economic interests of traditional healthcare professions.

SECTION 2. DEFINITIONS

(a) "Adverse event" means patient death, serious physical or psychological harm, or serious risk of harm reasonably associated with a Clinical AI Service, including inappropriate triage or failure to escalate care.

(b) "AI Augmented & Autonomous Service Provider" or "AAASP" means a corporate or legal entity licensed by the Division to operate Clinical AI Services that are subject to licensure under Section 4.

(c) "AI Operational Roles" defined.

1. **"Informational AI"** means artificial intelligence that provides data or information to a user but does not suggest a specific clinical action.
2. **"Advisory AI"** means artificial intelligence that analyzes patient-specific data to generate options, potential diagnoses, risk stratification, or therapeutic suggestions to a licensed healthcare provider or directly to a patient or user, where such output informs but does not substitute for independent clinical judgment, and where the provider or user is expected to determine how to proceed.
3. **"Supervised Autonomous AI"** means artificial intelligence authorized to execute a clinical action, diagnosis, or treatment plan under the supervision of a licensed human provider who retains intervening ability.
4. **"Fully Autonomous AI"** means artificial intelligence authorized to independently diagnose, treat, triage, or prescribe without the necessity of human supervision or intervention for each distinct case.

(d) "Clinical AI service" means any service, system, software, model, agent, or other technological mechanism that performs, is represented as performing, or is reasonably used to perform patient-specific clinical functions that would constitute the practice of medicine or other licensed clinical practice if performed by a licensed health care provider, to the extent otherwise permitted under applicable law.

1. A clinical AI service may operate with informational, advisory, supervised autonomous, or autonomous functionality. The degree of autonomy does not determine whether a service constitutes a clinical AI service under this Act.
2. A clinical AI service may be deployed through any medium, platform, device, communication method, or care delivery model, including software applications, digital agents, medical devices, telehealth systems, clinical information systems, robotic systems, or other technologies. The method of deployment does not alter whether a service constitutes a clinical AI service under this Act.
3. Patient-specific clinical functions include, but are not limited to, collecting, analyzing, interpreting, or synthesizing patient information; generating clinical assessments or diagnostic conclusions; recommending, initiating, modifying, monitoring, or discontinuing treatment; selecting, prescribing, dispensing, administering, or managing medications or medical devices; ordering, recommending, interpreting, or monitoring laboratory tests or diagnostic procedures; triaging patients; monitoring patient status; predicting clinical deterioration or improvement; communicating patient-specific clinical recommendations; or otherwise supporting or performing clinical decision-making for a specific patient.

4. A service shall be considered a clinical AI service if it is marketed, represented, offered, or reasonably used to independently perform patient-specific clinical functions.
5. "Clinical AI service" does not include software or systems whose sole function is administrative, financial, scheduling, billing, inventory management, claims processing, documentation assistance, generalized clinical education, population-level analytics, research, quality improvement, public health surveillance, or de-identified data processing, provided such systems do not independently perform or materially influence patient-specific clinical functions.
6. "Clinical AI service" does not include software or systems that solely transmit, store, display, route, or retrieve information without performing patient-specific clinical analysis, interpretation, recommendation, prediction, or decision support.
7. A system is not considered a clinical AI service solely because it provides informational or advisory clinical decision support to a licensed health care provider who retains independent authority and responsibility for clinical decision-making and clinical execution.

(e) "Board" means the Advisory Board of Autonomous Clinical Practice, an advisory regulatory body administratively within the Division of Occupational and Professional Licensing.

(f) "Clinical Conditions" means conditions under this Act shall be based on the patient's presentation and the clinical information reasonably available at the time of the service, not on retrospective diagnosis. A licensee acting in reasonable reliance on available clinical information shall not be deemed in violation due to later reclassification of the condition. For purposes of this act, clinical condition categories are defined as:

1. **"Preventive Condition"** means a measure, service, or intervention intended to reduce the likelihood of disease onset, progression, recurrence, or complications, whether applied to healthy individuals or individuals with risk factors or existing conditions, where the primary purpose is risk reduction or health maintenance, and where intervention is generally low-risk and consistent with accepted standards of care.
2. **"Chronic Condition"** means a condition, illness, or impairment that is persistent, recurrent, or reasonably expected to require ongoing or periodic clinical management, monitoring, or care. Chronic conditions are primarily managed through longitudinal care rather than emergency intervention.
3. **"Non-Critical Condition"** means a condition, illness, or injury, where delay in definitive diagnosis, initiation of treatment, or escalation of care would not reasonably be expected to result in serious adverse health consequences, permanent disability, or death. A non-critical condition does not present objective signs of physiologic instability, rapid deterioration, or the need for immediate emergency intervention.
4. **"Critical Condition"** means a disease, illness, injury, or physiologic state in which the condition presents a high probability of death, permanent disability, or serious irreversible harm without prompt medical intervention. A critical condition is characterized by physiologic instability, high acuity, or the need for intensive medical management to prevent catastrophic outcomes.
5. **"Time-Sensitive Condition"** means a medical condition or acute clinical presentation for which the effectiveness of diagnosis, treatment, or intervention is materially dependent on timely initiation, and for which a delay in care is reasonably expected to result in rapid clinical deterioration, irreversible morbidity, or death.

(g) "Designated Responsible Official" means a natural person designated by an AAASP who is authorized to bind the AAASP for compliance and administrative matters under this Act, receive legal process and Board notices, and certify filings and reports required by the Division. A Designated Responsible Official is not, solely by designation, deemed to be practicing a licensed healthcare profession.

(h) "Division" means the Division of Occupational and Professional Licenses.

(i) "Division Director" means the director of the Division of Occupational and Professional Licenses.

(j) "Materially influence" means having a reasonable likelihood of being relied upon to make, modify, or forgo a patient-specific clinical decision or action.

(k) "Medical Director" means a physician licensed and in good standing in this State who is designated by an AAASP to provide clinical oversight of the AAASP's clinical scope, safety protocols, escalation pathways, and quality assurance processes, as required by this Act or Division rule.

(l) "Reportable event" means an adverse event, a material near miss, a material malfunction affecting clinical output, or a material data integrity failure affecting patient-specific clinical decisions.

(m) "Sandbox Reciprocity State" means a jurisdiction recognized by the Division as having a substantially similar regulatory sandbox for health technology and/or Clinical AI.

SECTION 3. GOVERNANCE: ADVISORY BOARD OF AUTONOMOUS CLINICAL PRACTICE

(a) Establishment. There is hereby established the Advisory Board of Autonomous Clinical Practice, an advisory regulatory body administratively within the Division of Occupational and Professional Licensing. The Board's jurisdiction extends to Clinical AI Services, constituting the practice of medicine or other licensed clinical practice performing Clinical AI services as defined in Section 2.

(b) Composition. The Advisory Board shall consist of nine (9) voting members appointed by and serving at the pleasure of the Governor. Members may be removed by the Governor at any time, with or without cause. The board shall include:

1. Four (4) members who are actively licensed and in good standing to provide healthcare services in this state, each of whom has at least five (5) years of practice experience.
2. One (1) public member.
3. Four (4) Members-at-Large with demonstrated expertise in any of the following fields: health technology, ethicist, artificial intelligence, systems engineering, healthcare administration, patient safety, or regulatory affairs.

(c) Division Director & Staff.

1. **Division Director:** The Division Director shall serve as the chief administrative officer of the Board and shall be responsible for the administration and operation of the Board. The Division Director shall be considered a nonclassified employee, an executive employee, and an exempt employee.

2. **Staffing:** The Division Director may employ or contract for such other staff as necessary to carry out the duties of the Board, including the Board Ethicist required under Section 7(d).
3. **Powers and Duties:** Except as otherwise expressly reserved to the Board by statute or rule, the Division Director is authorized to take all actions reasonably necessary to carry out and enforce the laws and rules administered by the Board, including but not limited to the authority to:

(A) Employ, supervise, evaluate, and discipline Board staff and contractors;
(B) Enter into contracts, procure goods and services, and make expenditures within appropriated or authorized budgets;
(C) Establish internal organizational structure, operational procedures, and administrative systems;
(D) Receive, process, investigate, and resolve applications, registrations, filings, complaints, audits, and compliance matters;
(E) Conduct investigations, issue requests for information, and require the production of records as authorized by law;
(F) Administer examinations, reviews, assessments, certifications, or registrations authorized by law or rule;
(G) Take any other administrative or operational actions necessary to efficiently carry out the purposes of this Act.

(d) Fees & Funding.

1. **Authority:** The Division Director is authorized to adopt and charge reasonable fees for applications, provisional licenses, license renewals, and other administrative services.
2. **Fee Structure:** Fees shall be set at a level sufficient to offset the administrative costs of the regulatory sandbox and licensure monitoring.
3. **Appropriation:** The legislature may appropriate funds as necessary for the initial establishment and operation of the Board. Any such appropriation shall be temporary and shall terminate once fee revenue generated under this section is sufficient to support the ongoing administrative costs of the Board.

(e) Terms. Members shall serve staggered four-year terms. The Governor shall make appointments to promote regular turnover and avoid regulatory capture, and no member may serve more than two consecutive terms.

(f) Advisory Duties. The Division Director retains final authority for all licensing, regulatory, disciplinary, operational, and administrative actions under this Act unless expressly provided otherwise by statute. The Board shall advise and make recommendations to the Division Director regarding:

1. The granting, suspension, revocation, and monitoring of AAASP licenses;
2. The establishment and operation of a State Centralized Institutional Review Board (IRB);
3. Frameworks for Delegated Agreements, Collaborative Practice Agreements, and Supervision Agreements;
4. Algorithmic safety and bias auditing standards; and
5. Standards governing issuance and administration of the State Provider Identifier (SPI).

(g) Rulemaking. The Division Director may:

1. Adopt rules, in accordance with the state administrative procedure act, as necessary to administer, implement, and enforce this Act and consistent with the legislative intent and the authority expressly granted, including rules governing licensure standards, application procedures, renewal requirements, recordkeeping, reporting, inspections, audits, and compliance oversight;
2. Establish by rule minimum standards of professional conduct, operational compliance, and public protection applicable to licensees, within the scope and purposes of this act; and
3. Adopt rules prescribing fees, forms, and administrative processes necessary to carry out the duties of the Board.
4. No rule, benchmark, licensing condition of general applicability, or other regulatory standard proposed by the Division Director that materially restricts the scope of practice of an AAASP or imposes a new material barrier to market entry may be adopted unless:
(A) the Board approves the proposed regulatory action by an affirmative vote of at least two-thirds (2/3) of its voting members; and
(B) the Division Director issues written findings demonstrating that the restriction is supported by substantial evidence of a patient-safety risk and constitutes the least restrictive means of addressing that risk.

(h) Advisory Board Meetings and Organization.

1. The Board shall meet as necessary to carry out its duties and responsibilities under this Act.
2. A meeting of the Board may be called by the Chair, the Division Director, or upon written request of a majority of the Board members.
3. The Board shall annually elect from among its members a Chair and Vice Chair, who shall serve one-year terms and may be reelected.
4. A majority of the voting members of the Board shall constitute a quorum for the transaction of business. An affirmative vote of a majority of the members present at a meeting at which a quorum is present shall be required for official action of the Board, unless otherwise provided by law.
5. All meetings of the Board shall be open to the public and conducted in compliance with the state open meetings law and public records law. The Board may enter executive session only as authorized by law.
6. The Board shall permit public participation in meetings by teleconference or other electronic means, provided that public access and quorum requirements are satisfied.

(i) Investigations; Discipline; APA Procedures.

1. **Investigations.** The Division Director may receive complaints, conduct investigations, require the production of records reasonably related to compliance with this Act, and conduct audits as authorized by law and rule.
2. **Subpoenas.** The Division Director may issue administrative subpoenas for testimony and documents in furtherance of an investigation or contested case.

3. **Disciplinary Actions.** The Division Director may impose discipline, including reprimand, probation, restricted licensure, suspension, revocation, and administrative fines.
4. **Judicial Review.** Any denial, discipline, or adverse licensure action shall be a contested case subject to the [State Administrative Procedure Act] and judicial review as provided therein.
5. **Disciplinary Authority.** The Division Director constitutes the specific licensing authority for AAASPs and is authorized to pursue disciplinary action, including license suspension or revocation, if an AAASP fails to meet the applicable standard of care, or violates this Act or Division rules. Any denial, discipline, or adverse licensure action shall be subject to the State Administrative Procedure Act and judicial review as provided therein.

SECTION 4. LICENSURE FRAMEWORK

(a) Licensure Required. An AAASP License is required for any entity operating AI services that fall within the following risk categories:

1. **Critical Advisory AI:** Advisory AI require an AAASP license if the clinical conditions are critical or time-sensitive conditions that are intended, represented, or reasonably relied upon to guide clinical action in a manner that substitutes for, rather than merely informs, independent clinical judgment, and that does not satisfy the Clinical Decision Support Safe Harbor in Section 4(h).
2. **Supervised Autonomous AI:** services require an AAASP license if the clinical conditions are chronic and/or non-critical,critical, or time-sensitive conditions, or preventive conditions but only where the preventive service includes patient-specific clinical orders, including but not limited to, medication orders, laboratory orders, or device orders as part of a licensed professional service rendered within this State.
3. **Fully Autonomous AI**: All fully autonomous AI services, regardless of the clinical condition, require an AAASP license.

(b) Licensure Exemptions. The following categories of AI are exempt from licensure under this Act, dependent on the clinical condition. provided they do not exceed the scope defined herein:

1. **Informational AI** is always exempt regardless of the clinical condition
2. **Advisory AI** is exempt if the clinical conditions are **preventive** or **non-critical, chronic conditions.**
3. **Supervised Autonomous AI** is exempt if applied strictly to **preventive** conditions and if the service which is not issuing patient-specific clinical orders as part of a licensed professional service rendered within this state, including but not limited to medication orders, laboratory orders, or device orders.

(c) License Types.

1. **Provisional AAASP License (Sandbox):** The initial license issued to all new applicants. It restricts the licensee to operating within the regulatory sandbox subject to the oversight, geographic limitations, and data reporting requirements of Section 7.
2. **Full AAASP License (Unrestricted):** A standard license permitting statewide practice, issued upon successful completion from the sandbox.

(d) Voluntary Licensure. Licensed human providers utilizing exempt AI tools within their standard scope of practice are not required to obtain an AAASP license. However, an exempt AI

entity may voluntarily apply for AAASP licensure (designating as **Modifier L0**) to obtain standalone reimbursement or enter into clinical practice agreements.

(e) Classifications and Modifiers. The Division Director shall issue AAASP licenses with a Base Class and an Autonomy Modifier:

1. **Base Classes:**
(A) Class A (State Clinical Service): For Clinical AI Services delivered as patient-specific professional services and regulated by the State pursuant to its authority over the practice of medicine or other licensed clinical practice, including, but not limited to, services operating in a manner analogous to laboratory-developed tests (LDTs) or other proprietary algorithmic diagnostic, triaging, or therapeutic services, that do not rely on FDA clearance or approval as the basis for their lawful clinical use.
(B) Class B (Federal Device Reciprocity): For Clinical AI Services that have achieved FDA clearance, authorization, or approval as Software as a Medical Device (SaMD), and for which such federal authorization serves as the primary basis for the system's lawful clinical use.
(C) Class C (Therapeutic & Support): For Clinical AI Services providing non-diagnostic therapy, coaching, or monitoring. Class C services do not independently establish a diagnosis and operate on the basis of an existing diagnosis, referral, or patient-identified condition.
2. **Autonomy Modifiers:**
(A) Modifier L0 (Voluntary/Exempt): For AI systems otherwise exempt from licensure under Section 4(b) that voluntarily elect to obtain licensure.
(B) Modifier L1 (Advisory-Critical): For Advisory AI addressing critical or time-sensitive conditions.
(C) Modifier L2 (Supervised): For Supervised Autonomous AI requiring human oversight or CPA.
(D) Modifier L3 (Autonomous): For Fully Autonomous AI authorized for independent operation.

(f) Reciprocity.

1. **Sandbox Reciprocity:** A licensee in good standing in a sandbox reciprocity State, and not subject to any active or pending disciplinary action, shall be eligible for licensure by recognition in the state sandbox upon submission of a completed application.
2. **Federal Reciprocity:** An entity holding a valid FDA clearance for the specific use case applied for shall be automatically eligible for Class B licensure. The Division Director may impose State conditions of licensure under this Act, including transparency, reporting, auditing, pilot-zone, and sandbox requirements, to the extent not inconsistent with federal law, provided that they align benchmarks, post-market monitoring plans, and related guidelines already applicable to that provider to the maximum extent practicable.
3. **Licensure by Recognition – Substantially Similar Jurisdictions:** The Division Director shall grant an AAASP license to an applicant holding a current, unrestricted authorization to provide substantially similar clinical AI services in another state, unless the Division Director determines that:

(A) The originating jurisdiction's regulatory framework is materially less protective of patient safety than this Act;

(B) The applicant is not in good standing or is subject to pending disciplinary action; or

(C) The scope of practice or autonomy level requested in this State exceeds that authorized in the originating jurisdiction.

Licensure granted under this subsection shall not require satisfaction of provisional licensure requirements, except as necessary to verify good standing, scope equivalence, and compliance with reporting and transparency obligations under this Act.

4. The Division Director may require the applicant to submit documentation necessary to assess substantial similarity and may impose reasonable conditions or limitations to ensure patient safety and compliance with this Act.

5. **Modifier Escalation**: licensee may petition to upgrade from a lower Modifier to a higher Modifier (e.g., L2 to L3) upon submitting safety data from the sandbox demonstrating performance equivalent to or exceeding human benchmarks, to the extent such escalation is not inconsistent with federal law.

(g) Clinical Orders; Medications; Tests; Devices.

1. **Clinical Orders Generally.** A Modifier L2 AAASP and Modifier L3 AAASP may issue patient-specific clinical orders as part of a licensed professional service rendered within this State, including but not limited to medication orders, laboratory orders, or device orders, provided that such authority does not authorize the interstate marketing, distribution, or commercial sale of a medical device in violation of federal law.
2. **Prescription Drugs.** An L2 AAASP and L3 AAASP may issue medication orders for prescription drugs other than controlled substances within its approved scope. Dispensing and drug administration shall occur only through persons or entities authorized under State law to dispense or administer medications.

(h) Clinical Decision Support Safe Harbor. An Advisory AI system shall not require licensure under this Act, including under Modifier L1, when the system (1) does not independently initiate, execute, modify, or discontinue a clinical action, order, diagnosis, or treatment; and (2) is not intended, represented, or reasonably relied upon as a substitute for independent professional clinical judgment in the management of a critical or time-sensitive condition.

Nothing in this subsection exempts any system that otherwise meets the definition of Supervised Autonomous AI or Fully Autonomous AI.

(i) Timeliness of Licensure Actions

1. **Completeness Review:** Within thirty (30) days of receiving an initial application for licensure, the Division Director shall determine whether the application is complete and notify the applicant in writing.
(A) Notice of Deficiency: If the application is incomplete, the Division Director must specify exactly what information is missing.
(B) Deemed Complete: If the Division Director fails to notify the applicant of a deficiency within the thirty (30) day period, the application shall be deemed complete for the purposes of this Act. If an application is deemed complete by operation of law due to inaction, the Division Director may not subsequently deny the application based solely on the absence of information that it failed to request within the thirty (30) day review period, provided the applicant submits such missing documentation or information within ten (10) days of a written request.

2. Final Determination: Except as provided in paragraph (3), the Division Director shall grant or deny a license within ninety (90) days after the application is deemed complete.

3. **IRB Review Extension:** If the Board Ethicist determines that an applicant's proposed data collection constitutes "Human Subjects Research" requiring full review by the State Centralized IRB or an external IRB pursuant to Section 7(d), the Division Director may extend the review period by one (1) additional thirty (30) day increment. The Division Director must notify the applicant of this extension in writing prior to the expiration of the initial ninety (90) day period.

4. **Failure to Act (Automatic Provisional Status):** If the Division Director fails to issue a final determination within the applicable time period (ninety (90) days, or one hundred and twenty (120) days if extended for IRB review), a Provisional License shall be automatically issued to the applicant, upon submission by the applicant, through its Designated Responsible Official, of a sworn attestation under penalty of perjury that the applicant has satisfied all minimum insurance, bonding, safety, reporting, and compliance requirements required for provisional licensure under this Act, effective immediately, and valid for ninety (90) days or until the Division Director issues a final order, whichever occurs first.

SECTION 5. CONSUMER TRANSPARENCY & DISCLOSURE

(a) Right to Know. Patients have the right to know the type of healthcare provider delivering clinical services.

(b) Disclosure for Supervised Autonomous Services (Modifier L2). Prior to the time of service, an AAASP operating under Modifier L2 shall disclose to the patient, in plain language, that: "An Artificial Intelligence system will be used to generate and execute a clinical action, diagnosis, or treatment plan under the supervision of a licensed human provider who retains the ability to intervene. You have the right to request a human review of the decision, which may incur additional costs or time." The disclosure requirement does not apply to Advisory AI tools that provide recommendations, risk scores, alerts, or guidance to a licensed human healthcare provider who independently determines whether and how to act.

(c) Disclosure for Autonomous Services (Modifier L3). Prior to delivering services, an AAASP operating under Modifier L3 shall obtain affirmative patient acknowledgment that: "You are receiving care from an Autonomous AI Provider licensed by [State]. This provider is an artificial intelligence system and does not include routine human clinical oversight. You may seek additional or alternative care from a licensed human healthcare provider of your choice at any time."

(d) Provisional License Disclosure. In addition to subsection (c), a Modifier L3 AAASP operating under a provisional license shall disclose that: "This provider is operating under a provisional State license as part of a regulatory sandbox evaluating safety and effectiveness. By consenting to this service, you acknowledge that liability for non-economic damages may be limited under State law as provided in the Clinical AI Services Act."

SECTION 6. CLINICAL INTEGRITY, ALGORITHMIC LOYALTY, AUDITABILITY, PRIVACY REQUIREMENTS

(a) Professional Duty of Loyalty.

1. **Patient-First Mandate**: An AAASP holding a Modifier L2 or L3 license shall be bound by a professional duty of loyalty to the patient. The AAASP must act solely in the best clinical interest of the patient.
2. **Economic Stewardship**: The professional duty of loyalty includes a mandate for economic stewardship of the patient's resources. Stewardship requires the AAASP to prioritize the patient's overall welfare, including optimizing clinical outcomes, financial efficiency, care coordination, and patient convenience. An AAASP violates this duty if its clinical logic is configured to prioritize the financial interests of the AAASP or its affiliates over a substantially similar and clinically appropriate alternative that offers superior value, coordination, or efficiency to the patient.

(b) Prohibition on Embedded Commercial Content (The "Clean Interface").

1. **Clinical Sanctity**: The interface through which a Clinical AI Service interacts with a patient is deemed a clinical space.
2. **Advertising Ban**: It shall be unlawful for an AAASP to display, verbally articulate, or otherwise present paid commercial content, advertisements, "sponsored results," or third-party marketing messages within the context of a clinical encounter, diagnosis, or treatment plan.

(c) Algorithmic Neutrality and Transparency Standard

1. **Steering Defined**: An AAASP shall not utilize weights, biases, or prompt engineering to prefer an affiliated pharmacy, specialist, or manufacturer unless such preference is based on objectively verifiable clinical, economic, or coordination advantages for the patient, including but not limited to: lower out-of-pocket cost, faster time-to-treatment, superior validated outcomes, or enhanced convenience through vertical integration.
2. **Disclosure**: If an algorithm results in a recommendation for an affiliated entity, the AAASP satisfies its duty of loyalty, even if a human doctor might have reasonably chosen an alternative context, provided it discloses the financial affiliation in a clear and conspicuous manner at the point of recommendation.

(d) Clinical Output & Logic Integrity

1. **Required Output Logs:** For outputs used in clinical decisions, the licensee shall retain a system log containing the inputs, the final clinical output, and any structured metadata or explanations generated by the system **for a period of no less than six (6) years from the date the service was rendered, or for the duration required by [insert state] law for the retention of medical records, whichever is longer.**

2. **Deterministic Logic & Configuration Log:**

(A) If deterministic logic, hardcoded clinical rules, decision trees, or threshold values (including, but not limited to, clinical ranges, diagnostic boundaries, or prescribing parameters) are utilized to filter, modify, or direct the system's outputs, the licensee shall maintain an immutable log of such active rules and configurations, including the exact time periods they were in active use, **for a period of no less than six (6) years after the configuration is retired or modified.**

(B) This logging requirement shall apply to any configurable parameters, prompt templates, system instructions, or system-level constraints applied to a generative model or third-party component.
(C) This requirement does not require the disclosure or logging of proprietary source code, weights, or internal architecture of an inaccessible third-party platform or general-purpose Large Language Model (LLM) that functions as an underlying infrastructure component.

(e) Statistical Presumption and Pattern Audits

1. **"Market Variance" Audit**: The Division Director is authorized to perform statistical audits of an AAASP's referral and prescription patterns.
2. **Rebuttable Presumption**: A finding that an AAASP recommends an affiliate at a rate significantly higher than the regional average, or other appropriate clinical or economic benchmarks as determined by the Division Director, shall create a rebuttable presumption of unlawful steering.
3. **Safe Harbor**: An AAASP may rebut this presumption by demonstrating through its Clinical Logic Snapshots that the preference was driven by objective data—such as a showing that the affiliate provided superior care coordination, convenience, or the lowest-cost option for the patient.

(f) Privacy Requirements

1. Provider Designation: For the purposes of state law governing patient privacy, confidentiality, credentialing, reimbursement, and professional accountability as administered under this Act, an AAASP is deemed a health care provider.

2. **HIPPA Integration**: For the purposes of state-administered patient privacy, confidentiality, credentialing, and reimbursement laws, and for federal laws that expressly defer to state determinations of provider status, including the federal Health Insurance Portability and Accountability Act (HIPAA), an AAASP is deemed a health care provider, without creating or implying recognition for purposes of Medicare, Medicaid, or other federal payment programs.

3. **Privacy Compliance:** An AAASP shall be treated as a health care provider under all applicable state privacy and confidentiality laws and shall comply with HIPAA to the extent it functions as a covered entity or business associate.

4. Federal Limitation. This state provider designation is intended to satisfy federal laws that expressly defer to state determinations of provider status (including HIPAA), but does not imply recognition for federal Medicare, Medicaid, or other federal payment programs except as provided in Section 10.

SECTION 7. REGULATORY SANDBOX & ETHICAL OVERSIGHT

(a) Provisional Status & Duration.

1. **Term:** All initial licenses shall be Provisional for a minimum period of two (2) years, except as provided in paragraph (a)3. below.
2. **Conversion:** Upon completion of the two-year period, the provisional license shall be converted to a Full AAASP License upon an application and affirmative determination by the Division Director that the Licensee's performance meets or exceeds human benchmarks within their scope of services, and all other agreed upon and published safety benchmarks have been met.

3. **Expedited Conversion upon Application:** The Licensee may request expedited approval for a full AAASP license through an application for expedited approval of full licensure. The Division Director may approve upon determining that the provisional licensee has clearly demonstrated that it meets or exceeds safety and performance benchmarks.

(b) Authority to Restrict (Phased Deployment): The Division Director may impose restrictions on the scope of an AAASP's operations during the provisional or sandbox period, in order to ensure safe, controlled, and evidence-based deployment.

During the provisional or sandbox period, such restrictions may be used to facilitate phased deployment, data collection, and validation of safety and effectiveness. Permissible restrictions applicable to either provisional authorization include, but are not limited to, the following:

1. Geographic limitations, including restrictions to designated Health Professional Shortage Areas (HPSAs) or specific medically underserved counties;
2. Patient volume caps, such as a maximum number of active patients;
3. Scope limitations, including restriction of a clinical AI Service to specified disease states, clinical conditions, or clinical functions;
4. Phased supervised deployment, including requirements for physician review or confirmation of a defined number of patient interactions, diagnoses, or treatment recommendations prior to modification or removal of human-in-the-loop requirements.

(c) Patient Right to Try & Expanded Access. Notwithstanding any geographic, volume, or site-specific restrictions imposed under Subsection (b) on any provisional or full AAASP licensee, the licensee shall be authorized to provide services to any patient in the State who provides informed consent and meets at least one of the following "High-Need" criteria, as demonstrated by a referral or attestation from a licensed physician:

1. **HPSA Resident:** The patient resides in a federal Health Professional Shortage Area;
2. **Severe/Chronic Condition:** The patient has been diagnosed with a severe, life-threatening, or multiple chronic condition;
3. **Terminal Illness:** The patient has a condition from which death is likely to occur within six months;
4. **Severely Debilitating Condition:** The patient has a condition or disability that causes irreversible morbidity or likely substantial reduction in daily function;
5. **High-Risk Determination:** The patient has been determined by a licensed healthcare provider to be at high risk for a specific condition, disease, or diagnosis that the AAASP is designed to detect, diagnose, or treat; or
6. **Inadequate Access:** The patient is unable to obtain clinically appropriate access to an appropriate human clinician within a timeframe reasonably related to the patient's condition category.

(d) Ethical Review & Human Subjects Protections

1. **Determination of Status:** As part of the application process, every applicant must submit a determination to the Board Ethicist declaring whether their proposed data collection constitutes "Human Subjects Research" under 45 CFR 46 or is exempt/quality improvement.
2. **Board Ethicist Review:** The Board Ethicist shall review and sign off on the determination.

3. **IRB Requirement:** If the activity is determined to be Human Subjects Research, or if the applicant elects to treat it as such to support future federal applications, the applicant must obtain IRB approval prior to commencing data collection.
4. **State Centralized IRB:** The Division Director shall establish a State Centralized IRB to provide expedited, low-cost ethical review for sandbox participants. Applicants may elect to use this State IRB or an external accredited IRB (e.g., academic or hospital-based), or a network of external IRBs to maximize availability. The State Centralized IRB need not be a singular IRB but may be a coordinated network of IRB's to ensure maximum efficiency.
5. **IRB Review Deadline:** The State Centralized IRB shall complete its review and issue a determination within **thirty (30) days** of receiving a complete protocol submission to ensure compliance with the licensure timelines established in Section 4(i).
6. **Human Subject Obligations**: Nothing in this Section alters or waives any obligation under 45 CFR 46 or applicable FDA human-subject regulations when such obligations apply by virtue of federal funding, federal program participation, or other federal jurisdiction.

(e) Application Requirements. To ensure financial accountability and patient safety, all AAASP applicants must submit:

1. **Malpractice Insurance:** Proof of professional liability insurance coverage commensurate with human specialists in the same field and taking into account the scale of patient encounters (e.g., $1,000,000 per occurrence / $3,000,000 aggregate).
2. **Designated Responsible Official:** Each AAASP applicant and licensee shall maintain on file with the Division a current Designated Responsible Official and contact information. Failure to maintain a current designation is grounds for administrative action.
3. **Medical Director:** Each AAASP applying for or holding a Modifier L2 (Supervised) or L3 (Autonomous) license shall designate a Medical Director**.** The Medical Director shall be responsible for oversight of clinical scope, safety protocols, escalation procedures, and quality assurance related to patient care. The Designated Responsible Official and the Medical Director may be the same individual or different individuals, at the election of the AAASP.
4. **Background Checks:** The applicant shall submit to state and federal criminal background checks, in a form and manner prescribed by the Division, for:

    (A) any individual with direct or indirect ownership of ten percent (10%) or more of the AAASP;
    (B) the Designated Responsible Official;
    (C) the Medical Director;
    (D) any natural person who provides unsupervised direct patient care or who is authorized to independently initiate, modify, or execute patient-specific clinical actions on behalf of the AAASP.

The Division Director may, by rule, require additional background checks for other categories of personnel based on demonstrated risk to patient safety, data security, or program integrity.

5. **Consumer Protection Surety Bond:** A surety bond payable to the State Consumer Protection Fund in an amount determined by the Division Director, but no less than $50,000, to cover claims or operational failures not covered by insurance.

(f) Mandatory Wind-Down and Continuity Plan.

1. **Requirement:** As a condition of licensure, every AAASP applicant must submit and maintain a "Wind-Down and Continuity Plan" ("The Plan") approved by the Division Director. The Plan must detail procedures for the AAASP's insolvency, license revocation, or market exit.
2. **Data Custodianship:** The Plan must designate a "Successor Data Custodian" (e.g., an HIE or state repository). In a triggering event, the AAASP shall transfer all patient data to the Successor Custodian in an interoperable format within 72 hours.
3. **Escrow:** The AAASP must maintain a "Data Transfer Escrow" or bond sufficient to cover the technical costs of data migration.
4. **Tail Coverage:** The AAASP must carry "Tail Coverage" on its liability policy for a period equal to the state statute of limitations for malpractice plus one year.
5. **Execution:** The Division Director is authorized to seize the surety bond to execute the Plan if the AAASP fails to initiate it voluntarily.

(g) Safety and performance benchmarking.

1. **Establishment of Benchmarks:** The Division Director shall establish and publish objective safety and performance benchmarks that an AAASP must meet or exceed to qualify for licensure, to graduate from the regulatory sandbox or expanded authority or scope within the sandbox phase.
2. **Human Performance Standard:** Such benchmarks shall be designed to ensure that the AAASP demonstrates clinical competency, accuracy, and safety outcomes that meet or exceed the performance of a reasonably prudent human healthcare provider practicing in the same or similar specialty.
3. **Industry Standards:** Benchmarks may include clinically validated testing, subgroup performance evaluation, calibration, false positive and false negative rates appropriate to the intended use, and real-world outcome measures. The Division Director may recognize external evaluation frameworks by guidance and should align with federal benchmarks and monitoring methods for similar services and tools when possible. The Division Director may also choose to allow independent third party accreditation or certifications as recognition of meeting, exceeding or maintaining appropriate benchmarks.
4. **Post-Market Surveillance (Continuous Monitoring):** To maintain licensure, an AAASP must submit annual performance reports demonstrating that the model continues to meet the safety benchmarks established at licensure. The Division Director may suspend a license if data indicates "model drift" or a degradation in safety outcomes. Licensees shall report adverse and reportable events as defined in Section 2.
5. **Alignment with Existing Benchmarks and Monitoring Plans:** To minimize duplication and administrative burden to licensees, the Division Director shall, to the maximum extent practicable, align state benchmarks and post-market surveillance and monitoring plans (1) with federal benchmarks and post market surveillance plans established for Class B AAASP licensees, and (2) with other state sandbox or state licensing board benchmarks for AAASP licensees who are sandbox participants in another state or who hold a similar license in another state.

SECTION 8. SCOPE OF PRACTICE, WAIVERS & STANDARD OF CARE

(a) Universal Practice Authority. A Clinical AI Service or act is within the authorized scope of practice of a licensed AAASP if:

1. **Legal Consistency:** The act is consistent with and not expressly prohibited by this Act or the limitations of the specific License Class and Modifier held by the AAASP;

2. **Competency Consistency:** The act is consistent with the AI model's validated technical specifications, training data, intended use case, and performance parameters as submitted to the Division Director; and
3. **Standard of Care:** The performance of the act is within the accepted standard of care for the specific clinical task that would be provided in the same or similar clinical setting by a reasonable and prudent human healthcare provider with the same or similar specialty.

(b) Rule Harmonization. The Division Director shall review its administrative rules and modify or eliminate any provisions that are in conflict with the universal practice authority granted by this Section, ensuring that regulation focuses on clinical outcomes and safety rather than prescriptive technical methodologies.

(c) Limited corporate practice waiver. Any prohibition on the corporate practice of medicine or any other licensed clinical practice is waived solely to the extent necessary to permit an AAASP to hold an AAASP license and to bill for Clinical AI Services authorized under this Act. Nothing in this subsection authorizes a person or entity to control the independent professional judgment of a licensed human healthcare provider, nor does it alter corporate practice restrictions applicable to human clinical services.

(d) Provider–Patient Relationship. A provider–patient relationship exists when a licensed AAASP delivers a Clinical AI Service to a specific patient and the patient reasonably relies on that service for healthcare decision-making, and such relationship shall give rise to professional duty, standard of care, confidentiality, and civil liability under State law.

(e) Liability Safe Harbor. For AAASP sandbox participants in substantial compliance with this Act and the informed-consent requirements of Section 5, non-economic damages shall be limited to [State Cap Amount], except that this limitation shall not apply to acts or omissions constituting gross negligence, reckless disregard, or willful misconduct. Nothing in this subsection limits economic damages, injunctive relief, or Division Director disciplinary authority.

(f) No Expansion of Human Practice Authority. Nothing in this Act authorizes any natural person to engage in conduct outside the scope of that person's professional license, if any. Authority granted to an AAASP does not confer practice authority on any unlicensed individual involved in development, deployment, operations, or support of a Clinical AI Service.

(g) Exclusive Authority and Referral of Human Conduct.

1. The Division Director shall have exclusive authority to regulate, license, investigate, and discipline AAASPs and the delivery of clinical AI services authorized under this Act.
2. No other state licensing board shall impose licensure requirements, supervision requirements, disciplinary action, or rules of professional conduct that have the purpose or effect of restricting, prohibiting, or conditioning the lawful use of, reliance upon, or participation in services provided by a licensed AAASP acting within the scope of this Act.
3. Nothing in this subsection limits the authority of any State licensing board to regulate the independent professional conduct of natural persons within that board's jurisdiction. If, in the course of an investigation, the Division Director identifies evidence of potential misconduct by a licensed human practitioner that is independent of and not solely

attributable to lawful AAASP operation, the Division Director may refer such matter to the appropriate licensing board for review.

(h) Medical Director Role. Designation as a Medical Director does not, by itself, constitute the practice of medicine with respect to individual patient encounters conducted by an AAASP, and does not create per-se professional liability for the outputs of an AAASP acting within the scope of this Act.

SECTION 9. UNLAWFUL PRACTICE; TITLE PROTECTION; ENFORCEMENT.

(a) Unlawful Practice. A person or entity shall not offer, operate, market, or deploy a clinical AI service requiring licensure under Section 4 without a valid AAASP license issued under this Act.

(b) Misrepresentation. A person or entity shall not falsely represent that it holds an AAASP license, License Class, or Autonomy Modifier, or use any words, letters, or symbols that reasonably imply such licensure.

(c) Aiding and Abetting. A person or entity shall not knowingly aid, abet, or facilitate the unlicensed practice prohibited by this Section.

(d) Cease and Desist; Injunctive Relief. The Division Director may issue cease and desist orders and may request the Attorney General to bring an action for injunctive relief to enforce this Act.

(e) Civil Penalty. The Division Director may impose a civil penalty not to exceed $[X] per violation per day, in addition to any other remedy authorized by law.

SECTION 10. FINANCE & REIMBURSEMENT

(a) Collaboration Requirement. The State Medicaid Agency and the State Employee Health Plan shall collaborate with the Division Director to develop reimbursement codes, pilot programs, or coverage determinations for licensed AAASP sandbox participants. The State Medicaid Agency and [Agency administering the state employee health plan] may issue any rules necessary to carry out the duties of this section.

(b) State-Only Funding Firewall.

1. **State Provider Identifier (SPI):** The Division Director shall issue a unique State Provider Identifier to every licensed AAASP for use in claiming reimbursement from State Payer programs whenever a federal National Provider Identifier (NPI) is unavailable or technically inapplicable.
2. **Funding Source:** Reimbursement for claims submitted under an SPI by a provider without a corresponding federal National Provider Identifier (NPI) or CMS recognition shall be funded exclusively through state General Funds or other sources of non-federal funds unless the requirements of Section 10(b)(3) are met.
3. **Federal Matching:** To prevent federal clawbacks, no claims for AAASP services shall be submitted for federal matching funds (FMAP) unless and until the Centers for Medicare & Medicaid Services (CMS) issues written guidance confirming eligibility or otherwise makes clear through guidance or establishment of billing protocols that FMAP is available for these services.

(c) Payment Model.

1. **Default to Value:** Reimbursement for AAASP services shall be based on value-based care (VBC) or capitation models.
2. **Fee-For-Service Exception:** Fee-for-service (FFS) reimbursement is prohibited unless the payer and Division Director jointly determine VBC is impractical. Any determination to use FFS must be published in writing with justification.

SECTION 11. INSURANCE REIMBURSEMENT AND REGULATORY GUIDANCE

(a) Guidance Requirement. Not later than [180] days after the effective date of this Act, the [State] Insurance Commissioner shall issue regulations regarding the recognition of the AAASP license, the establishment of billing and coding standards, and outline standards for network participation, as necessary to clarify the application of the [State] Insurance Code to AI Augmented & Autonomous Service Providers (AAASPs) licensed under this Act.

(b) Reimbursement Framework. Such regulations shall, at minimum, ensure

1. **Non-Discrimination:** Prohibit health insurance carriers from denying coverage for a medically necessary service solely because the service was provided by a licensed AAASP, provided that the service would be covered if delivered by a human healthcare provider.
2. **Mandates:** Nothing in this section shall be construed as a benefit or coverage mandate.

(c) Applicability: This Section applies to health insurance coverage to the extent permitted by state and federal law, including the Employee Retirement Income Security Act of 1974 (ERISA).

SECTION 12. RULE OF CONSTRUCTION & FEDERAL COMPLIANCE

(a) Distinction from General Computing. Nothing in this Act shall be construed to prohibit, restrict, or require licensure for the mere development, ownership, or private operation of artificial intelligence models, provided such models are not marketed or deployed as clinical AI services for patient care.

(b) Federal Compliance. Nothing in this Act authorizes conduct that is expressly prohibited by federal law or that would place a licensee in unavoidable conflict with the Federal Food, Drug, and Cosmetic Act (FDCA) or the Controlled Substances Act (CSA).

(c) Professional Service Safe Harbor. Nothing in this licensure category shall be construed to authorize the distribution of a commercial medical device in violation of the FDCA. A Class C License authorizes the professional delivery of therapeutic services via artificial intelligence, which constitutes the practice of medicine within this state, distinct from the commercial sale of a medical device.

(d) Presumption of Authorization & Least Restrictive Regulation:

1. **Presumption:** It shall be the policy of this state that AI-enabled healthcare services within the scope of this Act are presumed authorized unless a specific, data-backed safety risk is identified.

2. **Least Restrictive Means:** In promulgating rules, the Division Director shall not impose a restriction on AAASP licensure or scope of practice that is more burdensome than necessary to address a specific, documented risk to public health.
3. **Burden of Proof:** The Division Director shall issue written findings supporting any material rule restriction, denial, or adverse licensure action, and such findings shall be supported by substantial evidence in the administrative record, consistent with the State Administrative Procedure Act.

SECTION 13. SEVERABILITY

(a) Savings Clause. If any provision of this Act or the application thereof to any person or circumstance is held invalid, such invalidity shall not affect other provisions or applications of the Act which can be given effect without the invalid provision or application, and to this end, the provisions of this Act are declared to be severable.

SECTION 14. EFFECTIVE DATE

This Act shall take effect on [Date], except that the Board shall be appointed and the Division Director may begin promulgation of rules no later than [Date].