EXECUTIVE SUMMARY & OVERVIEW

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

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 Medical 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 decisionmaking.

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 Medical Services Act applies that same proven governance model to artificial intelligence.

Bottom Line: The AI Medical 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 Medical 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.

- **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 AI MEDICAL SERVICES ACT
AN ACT to establish the "AI Augmented & Autonomous Service Provider" (AAASP) as a recognized healthcare provider type; to create the Board of Autonomous Medical Practice; to provide for an Executive Director and staff; to authorize fee collection; to establish a regulatory sandbox with expedited ethical review; to distinguish professional clinical services from commercial medical devices; [**if applicable:** to harmonize regulations with the Right to Compute Act]; 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 "AI Medical Services Act".

(b) Findings. The Legislature finds that:

1. **Provider Status:** The patient-directed diagnostic, therapeutic, triaging, prescribing, or other clinical application of artificial intelligence, when offered as a Clinical AI Service, may constitute the practice of medicine or other licensed clinical practice subject to State regulation.
2. **State Sovereignty:** The Legislature affirms that laboratory-developed tests (LDTs) and professional diagnostic services utilizing proprietary methodologies, when offered and performed solely as patient-specific professional services within this State and not marketed or distributed as general-purpose commercial products, are professional services subject to state regulation, distinct from the commercial sale of medical devices regulated by the Federal Food, Drug, and Cosmetic Act (FDCA).
3. **Necessity:** To address critical provider shortages and improve patient outcomes, the State must establish a clear, safe licensure pathway for autonomous and augmented clinical services delivered through software, systems, or devices, complementing federal oversight where applicable.
4. **Compelling Government Interest:** The Legislature finds that the regulation of autonomous clinical decision-making is demonstrably necessary to protect the life, health, and safety of the citizens of this State. The licensure requirements established herein are narrowly tailored to regulate only the professional application of artificial intelligence in a clinical setting and do not restrict the general private ownership or non-clinical use of computational resources protected by the Right to Compute Act.
5. **5. Public Protection and Innovation:** The Legislature finds that the purpose of professional licensure and regulation is to protect the public health, safety, and welfare.

Nothing in this Act is intended to preserve or advance the economic interests, market share, or professional boundaries of any particular healthcare profession. This Act shall be construed to promote patient access to safe and effective artificial intelligence services and to encourage responsible innovation. Any regulatory requirement adopted under this Act that materially affects market entry or the availability of AI-enabled services shall be reasonably related to, and proportionate with, an identified risk to patient safety, and shall not impose restrictions greater than necessary to address such risk.

6. **Scope Neutrality:** Nothing in this Act expands or restricts the scope of practice of any human-licensed healthcare profession; it creates an independent licensure pathway for Clinical AI Services.

(c) Purpose. The purpose of this Act is to create a new class of healthcare provider, the AI Augmented & Autonomous Service Provider (AAASP), capable of practicing medicine under state licensure.

SECTION 2. DEFINITIONS

(a) "AI Operational Roles" defined.

1. **"Informational AI" (Inform):** Artificial intelligence that provides aggregated data, literature, or administrative information to a user but does not suggest a specific clinical action (e.g., search retrieval, transcription, back-office support).
2. **"Advisory AI" (Suggest):** 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 is intended to inform but not substitute for independent clinical judgment, and where the provider or user is expected to review, contextualize, and determine whether and how to act upon the suggestion for each patient encounter.
3. **"Supervised Autonomous AI" (Collaborate):** Artificial intelligence authorized 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.
4. **"Fully Autonomous AI" (Act):** Artificial intelligence authorized to independently diagnose, treat, triage, or prescribe without the necessity of human supervision or intervention for each distinct case.

(b) "Clinical Condition Categories" defined. Condition categorization 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 solely due to later reclassification of the condition. For purposes of this act, conditions categories are defined as:

1. **"Preventive":** Measures, services, or interventions intended to reduce the likelihood of disease onset, progression, recurrence, or complications, including wellness, fitness, primary, and risk-based preventive care, whether applied to healthy individuals or individuals with identified risk factors or existing conditions, where the primary purpose is risk reduction or health maintenance rather than treatment of an active acute pathology, and where the intervention is generally low-risk and consistent with accepted standards of care.
2. **"Chronic Condition":** A human disease, disorder, injury, or impairment that is persistent, recurrent, or reasonably expected to require ongoing or periodic clinical management, monitoring, or care to maintain function, prevent progression, mitigate symptoms, or reduce the risk of complications. Chronic conditions are primarily managed through longitudinal care rather than isolated emergency intervention and may experience episodic exacerbations requiring temporary escalation of care.
3. **"Non-Critical Condition":** A condition, illness, or injury, whether acute, subacute, stable chronic, or self-limiting, for which, based on reasonable clinical judgment and available clinical information, a 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, rapidly progressive deterioration, or the need for immediate emergency or life-preserving intervention.
4. **"Critical Condition":** A disease, illness, injury, or physiologic state in which one or more vital organ systems is impaired, failing, or at substantial risk of failure, or in which the condition presents a high probability of death, permanent disability, or serious irreversible harm without prompt and advanced clinical intervention. A critical condition is characterized by physiologic instability, high acuity, or the need for continuous monitoring, specialized resources, or intensive medical management to prevent catastrophic outcomes.
5. **"Time-Sensitive Condition":** 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. Time-sensitive conditions require accelerated recognition, triage, and escalation of care based on reasonable clinical judgment and available clinical information.

(c) "AI Augmented & Autonomous Service Provider" (AAASP).

1. Provider Designation: A corporate or legal entity licensed by the Board to operate Clinical AI Services that are subject to licensure under Section 4. For purposes of State law governing patient privacy, confidentiality, credentialing, reimbursement, and professional accountability as administered under this Act, an AAASP is deemed a healthcare provider.

2. HIPAA 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 HIPAA), an AAASP is deemed a "Healthcare 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 healthcare provider under all applicable state privacy and confidentiality laws and shall comply with the Health Insurance Portability and Accountability Act (HIPAA) to the extent it functions as a covered entity or business associate.

(d) Clinical AI Service" means any software system, algorithmic model, or automated service that, whether independently or in combination with human involvement, performs, supports, or materially influences functions that constitute the practice of medicine or other licensed clinical practice with respect to a specific patient, to the extent otherwise permitted under applicable law.

This definition encompasses AI systems across a spectrum of functionality and autonomy, including information-providing (assistive), advisory (augmentative), supervised autonomous, and autonomous systems, when such systems engage in patient-directed clinical activities as described below.

Such functions include, but are not limited to:

(a) Collecting, analyzing, interpreting, or synthesizing clinical data, biometric data, diagnostic data, laboratory data, imaging data, or patient-reported information for a specific patient;

(b) Generating or supporting clinical assessments, diagnostic conclusions, risk stratification, triage determinations, treatment plans, medication selection or dosing, or therapeutic initiation, modification, continuation, or discontinuation for a specific patient;

(c) Recommending, supporting, or interpreting laboratory tests, diagnostic procedures, or monitoring parameters for a specific patient;

(d) Monitoring patient status, detecting clinically meaningful changes, predicting clinical deterioration or improvement, or supporting clinical intervention workflows for a specific patient, whether in real time or asynchronously;

(e) Communicating clinical information, recommendations, alerts, or guidance intended to inform patient care or licensed clinician decision-making for a specific patient.

A Clinical AI Service may be deployed through any care delivery modality, including in-person care, telehealth, remote patient monitoring, asynchronous digital health platforms, embedded

clinical systems, or software-based agents. The mode of deployment does not alter whether a system constitutes a Clinical AI Service under this definition.

A Clinical AI Service does not include software or systems whose sole function is administrative, financial, scheduling, billing, inventory, 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 materially influence clinical decision-making for a specific patient.

Purely informational systems that only transmit, store, display, or route data without performing clinical analysis, interpretation, or decision support are also excluded, unless such systems materially influence patient-specific clinical functions described above. A system is considered deployed as a Clinical AI Service if it is marketed, represented, or reasonably used to independently perform patient-specific clinical decision-making or autonomous clinical action, and not when it merely provides advisory clinical decision support to a licensed human healthcare provider who retains independent authority for clinical decisions and execution.

(e) "Sandbox Reciprocity State." A jurisdiction recognized by the Board as having a substantially similar regulatory sandbox for health technology.

(f) "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 Board. A Designated Responsible Official is not, solely by designation, deemed to be practicing a licensed healthcare profession.

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

(h) "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.

(i) "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.

(j) "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 Board rule.

SECTION 3. GOVERNANCE: BOARD OF AUTONOMOUS MEDICAL PRACTICE

(a) Establishment. There is hereby established the Board of Autonomous Medical Practice ("The Board"), an independent regulatory body administratively attached to the [Department of Health or 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 Board shall consist of eleven (11) 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. One (1) Licensed Physician (MD/DO);
2. One (1) Registered Nurse or Advanced Practice Registered Nurse (APRN);
3. One (1) Licensed Pharmacist;
4. One (1) Licensed Psychologist;
5. One (1) Member representing Hospitals (such as a Hospital Association Employee or Hospital CEO);
6. One (1) Healthcare Ethicist with an advanced degree or significant professional experience in medical ethics or bioethics; and
7. One (1) public member to represent the interests and protections of consumers with respect to clinical artificial intelligence services.
8. Four (4) Members-at-Large with demonstrated expertise in any of the following fields: health technology, artificial intelligence, systems engineering, healthcare administration, patient safety, or regulatory affairs.

(c) Executive Director & Staff.

1. **Executive Director:** The Governor shall appoint an Executive Director who shall serve as the chief administrative officer of the Board and shall be responsible for the administration and operation of the agency. The Executive Director's compensation shall be funded through State appropriations. The Executive Director shall be considered a nonclassified employee, an executive employee, and an exempt employee.
2. **Staffing:** The Executive Director may employ 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 Executive 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 agency 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 chapter.

(d) Fees & Funding.

1. **Authority:** The Board 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 for the initial term of the board:** There shall exist an appropriation of [$500,000] for the purpose of initial cost associated with the establishment and initial operating cost of the board, until such time that fees may be sufficient to cover cost, or until such time this initial appropriation is expended.

(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) Duties. The Board shall:

1. Grant, suspend, revoke, and monitor AAASP licenses of all classes and types;
2. Establish and operate or contract for a State Centralized Institutional Review Board (IRB);
3. Authorize and develop frameworks for Delegated Agreements, Collaborative Practice Agreements (CPAs) and/or Supervision Agreements (collectively referred to herein "Clinical Practice Agreements");
4. Conduct or contract for algorithmic safety and bias audits; and
5. Issue the State Provider Identifier (SPI) for billing.

(g) Rulemaking. The Board may:

1. Adopt rules, in accordance with the state administrative procedure act, as necessary to administer, implement, and enforce this chapter and consistent with the legislative intent and the authority expressly granted to the Board, 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 chapter; and
3. Adopt rules prescribing fees, forms, and administrative processes necessary to carry out the duties of the Board.

(h) Board Meetings and Organization.

1. The Board shall meet at least quarterly and at such additional times as may be necessary to carry out the duties of the Board.
2. A meeting of the Board may be called by the Chair, the Executive 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.
7. No rule that materially restricts AAASP scope of practice or imposes a new material barrier to market entry shall be adopted without: (i) a two-thirds (2/3) affirmative vote of the Board; and (ii) written findings that the restriction is supported by substantial evidence of a patient-safety risk and is the least restrictive means to address that risk.

(i) Investigations; Discipline; APA Procedures.

1. **Investigations.** The Board may receive complaints, conduct investigations, require the production of records reasonably related to compliance with this Act, and conduct audits and inspections as authorized by law and rule.
2. **Subpoenas.** The Board may issue administrative subpoenas for testimony and documents in furtherance of an investigation or contested case.
3. **Disciplinary Actions.** The Board may impose discipline, including reprimand, probation, restricted licensure, suspension, revocation, and administrative fines.
4. **Procedure; 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 Board 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 Board 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) Exemptions. The following categories of AI are **exempt** from licensure under this Act,

provided they do not exceed the scope defined herein:

1. **All Informational AI:** Regardless of the clinical condition.
2. **Advisory AI** applied to **Preventive** or **Chronic/Non-Critical** conditions.
3. **Supervised Autonomous AI** applied strictly to **Preventive** conditions and 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.

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.

(b) 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 tools applied to **Critical & Time-Sensitive** conditions that is 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(a).
2. **Clinical Supervised AI:** Supervised Autonomous AI applied to **Chronic/Non-Critical** or **Critical & Time-Sensitive** conditions, or **Preventive conditions** but only where **the 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 systems, regardless of the condition category.

(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 & Modifiers. The Board 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(a) 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 Board 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 Board 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 Board 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 initial licensure requirements, except as necessary to verify good standing, scope equivalence, and compliance with reporting and transparency obligations under this Act.

4. The Board 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:** A 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.** A Modifier L2 AAASP and Modifier 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) Timeliness of Licensure Actions (The "Shot Clock").

1. **Completeness Review:** Within thirty (30) days of receiving an initial application for licensure, the Board shall determine whether the application is complete and notify the applicant in writing.
   (A) Notice of Deficiency: If the application is incomplete, the Board must specify exactly what information is missing.

(B) Deemed Complete: If the Board 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 Board inaction, the Board may not subsequently deny the application based solely on the absence of a document or information that it failed to request within the thirty (30) day review period, provided the applicant submits such missing information within [10] days of a written request.

2. **Final Determination:** Except as provided in Paragraph (3), the Board 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 Board may extend the review period by one (1) additional thirty (30) day increment. The Board 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 Board 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 Board issues a final order, whichever occurs first.

SECTION 5. CONSUMER TRANSPARENCY & DISCLOSURE

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

(b) Disclosure for Supervised Autonomous Services (Modifier L2). Prior to or at the time of service, an AAASP operating under Modifier L2 shall disclose to the patient, in plain language, that: "An Artificial Intelligence system was 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." This 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 the 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 AI Medical Services Act".

SECTION 6. CLINICAL INTEGRITY, ALGORITHMIC LOYALTY, AND AUDITABILITY
(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, which includes the optimization of 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.
3. **Prohibited Nudging**: An AAASP shall not use conversational prompts or "nudges" designed to persuade a patient to request a specific medication or optional commercial service for the sole purpose of financial gain.

(c) The "Algorithmic Neutrality" & 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 and Optionality**: 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:
    - (A) Discloses the financial affiliation in a clear and conspicuous manner at the point of recommendation; and
    - (B) Presents the patient with a choice of at least two (2) non-affiliated alternatives of similar clinical quality, where reasonably available, presented with equal visual prominence in the interface.

(d) Algorithmic Snapshots & Audit Integrity.

1. **Immutable Version Logs**: Every AAASP shall maintain an immutable "Clinical Logic Snapshot" for every version of its algorithm deployed in production, including the underlying weights, decision-logic, and prompt-engineering instructions.
2. **Two-Year Retention**: AAASPs shall retain these snapshots for a period of two (2) years to allow for retrospective "replay" of the logic used in any specific patient encounter during a Board audit.
3. **Anti-Tampering**: Once an AAASP receives formal notice of an investigation, it is prohibited from altering or deleting any snapshots related to the investigation period.

(e) Statistical Presumption and Pattern Audits.

1. **The "Market Variance" Audit**: The Board 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 Board, 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.

SECTION 7. REGULATORY SANDBOX & ETHICAL OVERSIGHT

(a) Provisional Status & Duration.

1. **Term:** All initial licenses shall be Provisional for a period of up to two (2) years.
2. **Automatic Conversion:** Upon completion of the two-year period, the Provisional License shall convert to a Full AAASP License upon an affirmative determination by the Board that published safety benchmarks have been met, unless the Board and the Licensee mutually agree to extend the Provisional period to collect further data. An extension of provisional licensure under this subsection is temporary in nature and shall

not be construed as a substitute for, or equivalent to, issuance of a Restricted Full License under subsection (b), nor as a determination that the applicable criteria for permanent licensure have been satisfied.

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

(b) Board Authority to Restrict (Phased Deployment). The Board may impose restrictions on the scope of an Artificial Intelligence–Assisted Autonomous Service Provider's (AAASP's) operations during the provisional or sandbox period, or as a condition of a Restricted Full License, 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. Upon issuance of a Restricted Full License, such restrictions may be maintained, modified, or removed to reflect the scope within which the AAASP has demonstrated sustained safety, effectiveness, and compliance.

Permissible restrictions applicable to either provisional authorization or a Restricted Full License include, but are not limited to, the following:

1. Geographic limitations, including restriction 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, 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 Sandbox 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 (or the Voting Healthcare Ethicist Member) 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 Board 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.
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(h).
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 Equivalency:** Proof of professional liability insurance coverage commensurate with human specialists in the same field (e.g., $1,000,000 per occurrence / $3,000,000 aggregate).
2. **Background Checks:** The applicant shall submit to state and federal criminal background checks, in a form and manner prescribed by the Board, 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 Board may, by rule, require additional background checks for other categories of personnel based on demonstrated risk to patient safety, data security, or program integrity.

3. **Designation Required.** Each AAASP applicant and licensee shall maintain on file with the Board a current Designated Responsible Official and contact information. Failure to maintain a current designation is grounds for administrative action.
4. **Medical Director Required.** Each AAASP applying for or holding a Modifier L2 (Supervised) or Modifier 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.
5. **Consumer Protection Surety Bond:** A surety bond payable to the State Consumer Protection Fund in an amount determined by the Board, but no less than $50,000, to cover claims or operational failures not covered by insurance.

(f) Mandatory Wind-Down & 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 Board. 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 their liability policy for a period equal to the State Statute of Limitations for malpractice plus one year.
5. **Execution:** The Board 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 Board shall establish and publish objective safety and performance benchmarks that an AAASP must meet or exceed to qualify for **Modifier L3** (Autonomous) licensure or to graduate from the Regulatory Sandbox.

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 Board may recognize external evaluation frameworks by guidance and should align with federal benchmarks and monitoring methods for similar services and tools when possible.
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 Board 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 Board 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 Board; 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 specialization.

(b) Rule Harmonization. The Board 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 Board 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 Board 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 Board identifies evidence of potential misconduct by a licensed human practitioner that is independent of and not solely attributable to lawful AAASP operation, the Board 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 Board 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 Board 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) Mandate to Collaborate. The State Medicaid Agency and the State Employee Health Plan shall collaborate with the Board 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 Board 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:** 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 Board 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) Mandate to Develop Guidance. Not later than [180] days after the effective date of this Act, the [State] Insurance Commissioner shall issue formal guidance, bulletins, or regulations as necessary to clarify the application of the [State] Insurance Code to Autonomous Artificial Intelligence Medical Service Providers (AAASPs) licensed under this Act.

(b) Reimbursement Framework. Such guidance or regulations shall:

1. **Recognition of Licensure:** Establish that an AAASP holding a valid Modifier L3 (Autonomous) license and Modifier L2 (Supervised Autonomous) constitutes a recognized provider type eligible for reimbursement under private health insurance policies and state-regulated health plans.
2. **Billing and Coding Standards:** Designate appropriate billing mechanisms, which may include the use of existing Current Procedural Terminology (CPT) codes with specific modifiers identifying the service as AI-delivered, or the adoption of new distinct billing codes as they become available.
3. **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.
4. **Network Participation:** Outline standards for including AAASPs in insurance provider networks, including credentialing requirements that are appropriate for automated systems rather than individual human history (e.g., waiving malpractice history questions that do not apply to software).

(c) Consultation. In developing these regulations, the Commissioner shall consult with the Board of Autonomous Medical Practice to ensure clinical consistency and with the Department of Health to ensure alignment with public health goals.

(d) 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) Alignment with Right to Compute. This Act constitutes a regulation of professional medical conduct and not a restriction on computational resources. It shall be interpreted in harmony with the Right to Compute Act to ensure that the fundamental right to compute is preserved while safeguarding public health.

(c) 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).

(d) 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.

(e) 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 Board 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 Board 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 begin

promulgation of rules no later than [Date].