Common Health Coalition

Model State Legislation: Vaccine Provider Protection

Health care providers may be limiting vaccine administration because of uncertainty around liability protections as a result of recent changes to federal immunization recommendations. As those recommendations are narrowed, gaps are expected to appear between evidence-based medical practice and what federal liability frameworks cover.

THE GAP IN FEDERAL PROTECTION

Two primary federal liability programs — the Vaccine Injury Compensation Program (VICP) and the Public Readiness and Emergency Preparedness (PREP) Act — were designed to protect patients and providers when vaccines are recommended at the federal level. When federal recommendations change, however, those protections do not automatically follow the science or clinical practice. That can leave providers exposed to uncertainty and patients with fewer clear pathways for compensation.

Specifically, current federal frameworks do not cover:

- **Vaccines removed from federal injury tables.** If a vaccine is no longer listed on the VICP injury table, families may lose access to the no-fault compensation system, and providers may lose the predictable liability protections tied to that listing — even if the vaccine remains medically appropriate for certain patients.

- **Services provided after PREP Act emergency declarations expire.** During a declared public health emergency (such as the COVID-19 pandemic), the PREP Act provides broad liability protections. Once that declaration ends, those protections end as well — even if the disease continues to circulate and vaccination remains clinically recommended for some populations.

- **New vaccines not yet incorporated into federal schedules.** When new vaccines are developed, there can be a lag before they are formally added to federal injury tables or fully integrated into coverage frameworks. During that interim period, providers may face ambiguity about whether federal liability protections apply.

- **Preventive immunizing agents that do not meet statutory definitions of "vaccine."** Some newer preventive products — such as monoclonal antibodies designed to prevent infectious disease in infants or immunocompromised individuals — may function like vaccines in practice but fall outside existing statutory definitions. As a result, they may not be clearly covered under VICP or PREP Act protections.

In practical terms, these gaps mean that a clinician may follow current medical evidence and professional guidance, but still face uncertainty about whether federal liability protections apply. That uncertainty can influence whether providers continue offering certain immunizations — particularly in smaller practices or underserved communities — potentially affecting access for children and families.

THE STATE SOLUTION

This model bill creates a state-controlled framework that activates *only when federal programs do not apply*. It protects providers following medical guidelines while ensuring fair compensation for rare injuries, while limiting state financial exposure.

MODULAR DESIGN — States Choose What Works

The bill offers flexible, layered options across three categories:

1. **Routing Claims Away From Providers**
   - **State substitution:** State becomes sole defendant, providers not in litigation;
   - **No-fault compensation fund:** VICP-like administrative pathway;
   - **Certificate of merit:** Early screening of frivolous claims;
   - **Professional discipline safe harbor:** For following guidance.

2. **Provider Protections in Court**
   - **Statutory civil immunity:** Categorical immunity for guideline-compliant care;
   - **Safe harbor affirmative defense:** Shifts burden of proof;
   - **Excess liability fund:** Caps catastrophic provider exposure beyond insurance.

3. **Patient Compensation**
   - **Administrative fund option:** Streamlined VICP-like compensation;
   - **Judicial pathway option:** Litigation against state, not providers;
   - ***Note:*** *Provider immunity without patient remedies is legally and politically fragile*

Cost Control is Built in

- Vaccine injuries are extremely rare (≈1 per million doses);
- States control compensation caps, eligible injuries, deadlines, attorney fees;
- Multi-state compact option shares administrative costs;
- Mandatory actuarial review and reserve requirements.

KEY DIFFERENCES FROM VICP

VICP focused on *manufacturer* stability through federal mandate and excise taxes. This bill focuses on *provider* confidence and patient access.

THE BOTTOM LINE

Federal vaccine liability protections have widening gaps. This bill gives states a fiscally controlled tool to preserve vaccine access, protect responsible providers, and fairly compensate injured patients—operating *only where federal law does not*.

A gap-filler, not a system overhaul. State authority preserved.

Common Health Coalition

Model Vaccine Provider Protection Act

SECTION 1. SHORT TITLE

This Act shall be known and may be cited as the "[State Name] Vaccine Provider and Patient Protection Act of [Year]."

SECTION 2. LEGISLATIVE FINDINGS AND DECLARATIONS

The [State] General Assembly finds and determines that:

(1) Immunization against preventable diseases is one of the most significant public health achievements of the modern era, having been a primary driver in the dramatic increase in average human life expectancy over the last century, contributing significantly to the reduction of premature mortality across all age demographics,and preventing incalculable suffering;
(2) Widespread immunization programs have not only eradicated or controlled once-deadly diseases, but have fundamentally extended the productive life years of the citizenry, thereby fostering greater economic stability and reducing the long-term public health burden on the State;
(3) The safety and efficacy of vaccines have historically been rigorously evaluated through federal approval processes, including those from the Food and Drug Administration (FDA), ongoing safety monitoring, and recommendations from expert medical bodies including the federal Advisory Committee on Immunization Practices (ACIP), the American Academy of Pediatrics (AAP), the American Academy of Family Physicians (AAFP), and other recognized medical specialty organizations;
(4) Healthcare providers in [State] who administer vaccines in accordance with recognized medical standards and evidence-based guidelines are practicing within the standard of care for their profession;
(5) The federal National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 et seq., and the Vaccine Injury Compensation Program (VICP) established thereunder, provide critical liability protections and no-fault compensation for injuries related to vaccines covered under that federal program;
(6) Similarly, the Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d, authorizes liability protections for covered countermeasures during public health emergencies, and the Countermeasures Injury Compensation Program (CICP) established pursuant thereto provides a federal compensation mechanism for serious physical injuries or deaths directly caused by the administration or use of such covered countermeasures;
(7) However, the VICP covers only vaccines specifically listed in the federal Vaccine Injury Table, and the CICP covers only countermeasures during declared public health emergencies and only when administered or used in accordance with a PREP Act declaration. Changes to the federal Vaccine Injury Table in response to narrowing ACIP recommendations, or the expiration or non-renewal of PREP Act declarations, whether based on new scientific evidence, shifting federal priorities, or other factors, could render certain vaccines or patient populations ineligible for VICP or CICP coverage, even when administration of such vaccines remains consistent with evidence-based medical practice and the standard of care;

(8) Preventive immunizing agents other than traditional vaccines are increasingly used in accordance with evidence-based medical guidelines and should be treated consistently for liability-protection purposes when administered within the standard of care.
(9) When vaccines fall outside VICP or CICP coverage, healthcare providers face potential civil liability even when acting in full accordance with professional medical standards;
(10) The threat of civil liability for vaccine administration that follows evidence-based medical guidelines but falls outside federal program coverage creates a substantial disincentive for healthcare providers to offer certain immunizations, thereby reducing patient access to potentially life-saving preventive care;
(11) Residents of [State], including infants, children, adolescents, and adults, benefit from timely access to vaccines recommended by medical experts, and such access should not be compromised by gaps in liability protection when providers follow recognized medical standards;
(12) The State has a compelling interest in ensuring that healthcare providers can deliver immunization services in accordance with the standard of care without fear of civil liability when federal protections are unavailable;
(13) Patients who suffer injuries from vaccines deserve fair, timely, and predictable compensation through mechanisms that avoid the delays, expenses, and uncertainties of traditional litigation;
(14) A comprehensive liability protection framework that supplements federal protections while providing equitable compensation for vaccine injuries serves the public health interests of [State] and promotes both provider confidence and patient access to immunization services.
(15) This Act is not intended to regulate, supplant, supplement, or provide an alternative forum for any vaccine-related injury that is adjudicable under the VICP or CICP, but instead is intended solely to address injuries, administrations, and circumstances that fall outside the scope of federal coverage.
(16) In establishing procedures for the resolution of vaccine injury claims under this Act, the General Assembly intends to preserve appropriate judicial oversight over any mechanism that diverts, substitutes, or conditions access to civil litigation, while allowing initial review and administrative functions to be exercised by entities within the executive or judicial branch, consistent with the Constitution and laws of this State.

Therefore, the General Assembly declares that the purposes of this Act are to:

(1) Supplement, and not replace or diminish, the protections and compensation provided under the federal National Childhood Vaccine Injury Act and VICP, or under the PREP Act and CICP;
(2) Ensure that healthcare providers in [State] who administer vaccines in accordance with recognized medical guidelines and professional standards are protected from civil liability when such administration falls outside the scope of federal protection;
(3) Maintain patient access to evidence-based immunization services by removing disincentives for providers to offer vaccines that follow the medical standard of care;
(4) Provide fair and efficient compensation to individuals who suffer vaccine-related injuries in circumstances not covered by federal programs;
(5) Establish clear procedural mechanisms to resolve vaccine injury claims expeditiously while minimizing the burden on both patients and healthcare providers;
(6) Protect the [State] healthcare workforce, including physicians, pharmacists, nurses, and other qualified professionals, in delivering immunization services consistent with their scope of practice and professional standards;
(7) Preserve and strengthen public confidence in the safety and availability of vaccines as essential public health tools.

SECTION 3. DEFINITIONS

As used in this Act:

(1) "ACIP" means the Advisory Committee on Immunization Practices of the federal Centers for Disease Control and Prevention, or any successor entity.
(2) "ACIP Recommendations" means the immunization recommendations published by ACIP, as such guidelines may be updated from time to time.
(3) "CICP" means the Countermeasures Injury Compensation Program established under the Public Readiness and Emergency Preparedness Act, 42 U.S.C. § 247d-6d and § 247d-6e.
(4) "Covered vaccine administration" means
    (a) the prescription, ordering, dispensing, furnishing, counseling regarding, or administration of a vaccine or immunizing agent by a healthcare provider or other individual authorized under the laws of this State to perform such acts**,** or pursuant to federal law that expressly authorizes such acts notwithstanding state law, including shared clinical decision-making concerning whether, when, and to whom a vaccine or immunizing agent should be provided, when such conduct is performed in accordance with Recognized Medical Guidelines;
    (b) provided, however, that covered vaccine administration does not include any injury or death that is not associated with the act of administration of the vaccine or immunizing agent, but instead arises from independent acts, omissions, or conditions, including:
        (i) Defective, malfunctioning, or improperly maintained medical equipment, devices, or supplies;
        (ii) Improper storage, handling, transportation, preparation, reconstitution, dilution, or expiration of a vaccine or immunizing agent, including failure to comply with manufacturer storage specifications or cold-chain requirements; or
        (iii) Contamination, adulteration, or degradation of a vaccine or immunizing agent occurring prior to administration. For purposes of this definition, “contamination” or “adulteration” does not include any ingredient, component, excipient, preservative, adjuvant, or formulation element that is included on the vaccine’s FDA-approved label or otherwise authorized under federal law at the time of administration.
    (c) For purposes of this Act, references to the "administration" of a vaccine or immunizing agent include all clinical acts and omissions encompassed within covered vaccine administration, including prescribing, recommending, counseling, ordering, furnishing, timing, and clinical decision-making related to vaccination, and are not limited to the physical act of injection or delivery.
(5) “Designated Adjudicatory Authority” means the entity designated by the State pursuant to Section 4 to exercise initial jurisdiction over claims arising from covered vaccine administration, which may be:
    (a) A Vaccine Injury Review Panel or administrative body housed within the executive branch; or
    (b) A statutorily created tribunal, special master, or other adjudicatory body housed within or adjunct to the judicial branch.
(6) "Designated State Agency" means the agency or agencies designated pursuant to Section 4 to administer the provisions of this Act.
(7) “Fund” “Pooled Fund” means,
    (a) “State Fund” means a vaccine injury compensation fund established and administered by a Member State pursuant to Section 9 or Section 10 of this Act;
    (b) “Pooled Fund” means a trust fund established and administered by the Commission pursuant to this Compact, including the Multi-State Table Injury Compensation Pool and the Multi-State Excess Coverage Pool; and

(c) References to a “fund” shall be construed according to context to refer to a State Fund or a Pooled Fund, as applicable.

(8) "Gross negligence" means an act or omission that demonstrates a reckless disregard for the safety of the patient or a conscious indifference to the patient's welfare.

(9) "Healthcare facility" means any:
   (a) Facility licensed or certified under [State] law where vaccines or immunizing agents are stored, prescribed, or administered, including but not limited to hospitals, clinics, community health centers, pharmacies, long-term care facilities, schools, and
   (b) Public Health Entity acting in a clinical vaccination capacity.

(10) "Healthcare provider" means any
   (a) Individual licensed, certified, or otherwise authorized under [State] law to prescribe, order, dispense, furnish, or administer vaccines or immunizing agents, including but not limited to physicians, physician assistants, advanced practice registered nurses, pharmacists, registered nurses, and other healthcare professionals acting within their scope of practice,
   (b) Officer, employee, agent, volunteer, or contractor of a Public Health Entity when acting in a clinical vaccination capacity; and
   (c) Officer, employee, agent, volunteer, or contractor of a healthcare facility when engaging in covered vaccine administration.

(11) "Immunizing agent" means any preparation intended and administered primarily to produce active or passive immunity to disease for preventive purposes, including but not limited to vaccines, toxoids, immune globulins, and monoclonal antibodies.

(12) "Individual" means a natural person of any age, and includes a minor who is authorized under [State] or federal law to consent to the administration of a vaccine or immunizing agent.

(13) “Injury” means any physical injury, illness, condition, significant aggravation, disability, or death, including death resulting from such injury, illness, condition, or disability.

(14) "Off-label use" means administration of a vaccine or immunizing agent in a manner, dosage, age group, or for an indication that differs from the labeling approved by the federal FDA, but that is consistent with Recognized Medical Guidelines and the standard of care.

(15) “Public Health Entity” means any governmental entity or instrumentality of the State or a political subdivision thereof that is authorized by law to administer vaccines or immunizing agents, including but not limited to state or local health departments, boards of health, public hospitals or clinics, school-based health programs, and public health emergency response entities. For purposes of this Act, a Public Health Entity acts in a clinical vaccination capacity when engaging in covered vaccine administration through its officers, employees, agents, volunteers, or contractors.
   (a) Nothing in this definition shall create any new cause of action or abrogate any immunity provided under [State Tort Claims Act] except to the extent expressly provided in this Act.

(16) "Recognized Medical Guidelines"
   (a) means:
      (i) Guidelines, recommendations, or immunization schedules published by ACIP;
      (ii) Guidelines, recommendations, or immunization schedules adopted by the [State Board of Health] or [State Department of Health]; or
      (iii) Evidence-based clinical practice guidelines published by nationally recognized medical specialty organizations, including but not limited to the American Academy of Pediatrics, the American Academy of Family Physicians, the Infectious Diseases Society of America, the American College of Obstetricians and Gynecologists, and the American College of Physicians.
   (b) Recognized Medical Guidelines do not include recommendations, protocols, or statements issued by organizations that lack a nationally recognized medical specialty role or whose guidance is not based on systematic review of scientific evidence.

(c) For purposes of this Act, compliance with Recognized Medical Guidelines:
    (i) shall be determined based solely on the guidelines in effect on the date the vaccine or immunizing agent was administered; and
    (ii) shall be deemed compliance with the applicable professional standard of care.

(17) “Significant aggravation” means any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health.

(18) "State Board of Health" means the [State Board of Health] or equivalent body established under [cite State statute].

(19) "State Table Injury" means a vaccine-related injury or condition that meets the criteria specified in the [State] Vaccine Injury Table established pursuant to Section 9 of this Act.

(20) "Vaccine" means any preparation of killed or attenuated living microorganisms, or fraction thereof, that upon administration stimulates immunity to protect against disease.

(21) “Vaccine Injury Review Panel” means:
(a) An administrative, judicial, or quasi-judicial body designated under Section 4(12) to conduct initial review and claim-routing determinations under this Act;
(b) Includes the State Vaccine Injury Compensation adjudicatory process established under Section 9, if adopted; and
(c) Includes the Multi-State Vaccine Injury Review Panel established pursuant to Section 23, if the State is a Member State of the Compact.

(22) "VICP" means the federal Vaccine Injury Compensation Program established under 42 U.S.C. §§ 300aa-10 to 300aa-34.

(23) "Willful misconduct" means an act or omission that is taken:
(a) Intentionally to achieve a wrongful purpose;
(b) Knowingly without legal or factual justification; and

(24) In disregard of a known or obvious risk that is so great as to make it highly probable that harm will follow.

SECTION 4. STATE DIRECT ACTION, SUBSTITUTION, AND DEFENSE

[Note to States: This section provides the most comprehensive protection for healthcare providers and serves two distinct functions: 1) procedural substitution to remove claims from court and route them to a Vaccine Injury Review Panel where such a panel exists; and 2) establishment of a no-fault state obligation to compensate covered vaccine injuries where no such panel exists. This Section does not impose fault-based liability on the State and does not substitute the State as a tortfeasor standing in the place of a healthcare provider.States with established State Tort Claims Acts and sovereign immunity protections should consider this option. If adopted, Sections 4 and 5 can work together to provide robust provider protection.]

(1) **Direct Action Against the State.**
(a) An individual alleging injury or death arising from covered vaccine administration for which no Vaccine Injury Review Panel has primary jurisdiction under this Act, may bring a civil action directly against the State under this Act, without naming any healthcare provider or healthcare facility as a defendant, but only after exhaustion of any Vaccine Injury Review Panel process where such a panel has jurisdiction.

(b) In any action brought pursuant to this subsection, the State shall be the sole defendant, and no healthcare provider or healthcare facility shall be named, joined, or impleaded.
(c) Any action brought under this subsection shall proceed exclusively under the [State Tort Claims Act], as modified by this Section, and shall be subject to all limitations, defenses, procedural requirements, and damage caps applicable to actions against the State thereunder.
(d) The filing of an action under this subsection constitutes an irrevocable election to proceed against the State and a waiver of any civil action against a healthcare provider or healthcare facility arising from the same covered vaccine administration.
(e) No certificate of merit shall be required for an action brought solely against the State under this subsection.
(f) An action brought under this section shall constitute a no-fault statutory compensation action. Recovery shall not require proof of negligence, breach of the standard of care, or causation in fact. An action brought under this subsection shall constitute a no-fault statutory compensation action, with compensation determined pursuant to subsection (9).
(g) In any action under this section, the State acts solely as a statutory obligor. The State shall not be deemed a tortfeasor, shall not be vicariously liable for the acts or omissions of any healthcare provider or healthcare facility, and shall not be subject to fault-based liability.
(h) An action brought under this subsection shall provide a meaningful, non-illusory remedy. At a minimum, the court shall have authority to award reasonable compensation for medical expenses, lost income, and non-economic injury, consistent with subsection (9), upon a showing, by a preponderance of the evidence, that the injury is plausibly associated with covered vaccine administration, consistent with standards adopted by the [State Department of Health].

(2) **Designation as State Agents.**
(a) Any healthcare provider or healthcare facility that engages in covered vaccine administration shall be deemed to be acting as an agent of the State solely for the procedural purposes of substitution, defense, and claim routing under this Section.
(b) This subsection applies only where a healthcare provider or healthcare facility is named as a defendant in lieu of, or in addition to, the State.
(c) Designation as a State agent under this subsection shall not create respondeat superior liability, vicarious liability, or any admission of fault by the State.

(3) **Substitution of State as Defendant.**
(a) In any civil action brought against a healthcare provider or healthcare facility based on allegations arising from covered vaccine administration, the court shall lack primary jurisdiction to adjudicate the merits of the claim as a fault-based civil action unless and until the procedures in subsection (3)(b) are satisfied, and the State shall be substituted as the sole defendant upon judicial confirmation for the limited purpose of mandatory removal of the claim from fault-based judicial adjudication and routing the claim to the:
(i) Appropriate Vaccine Injury Review Panel, if one exists, or
(ii) No-fault compensation process or adjudication under subsection (1), where no such panel exists, upon the filing of a certification by the [Attorney General] or [State Department of Health] that the administration at issue constitutes covered vaccine administration as defined in this Act.
(b) Substitution shall become effective only upon entry of an order by the court confirming that:
(i) The certification filed by the [Attorney General] or [State Department of Health] establishes, on its face, that the administration at issue constitutes covered vaccine administration; and
(ii) Routing the claim pursuant to this Section does not deprive the claimant of a meaningful remedy.

(c) The healthcare provider or healthcare facility originally named as a defendant shall be immediately dismissed from the action as to that provider or facility with prejudice upon substitution.

(d) Upon substitution, the action shall not proceed as a fault-based tort action and shall proceed exclusively either:

(i) Before the applicable Vaccine Injury Review Panel, if one exists; or

(ii) As a no-fault claim against the State under subsection (1).

(e) For purposes of claims arising solely from covered vaccine administration under this Act, the State hereby waives sovereign immunity to the extent necessary to permit substitution under Section 4, subject to all limitations, caps, defenses, and procedures applicable under the [State Tort Claims Act].

(f) Substitution under this subsection shall not require, imply, or permit adjudication of negligence, breach of duty, or fault by the court.

(4) **State Defense and Indemnification.**

(a) The [Attorney General] shall provide legal defense for all claims subject to this Section.

(b) The State shall indemnify and hold harmless any healthcare provider or healthcare facility, only to the extent substitution applies under this Section, for any judgment, settlement, or costs arising from covered vaccine administration.

(c) Healthcare providers and healthcare facilities shall have no obligation to participate in discovery, depositions, trial, or any other aspect of litigation for claims subject to this Section, except that a provider may voluntarily cooperate in providing factual information regarding the vaccine or immunizing agent administration.

(5) **Certification Process.**

(a) Within ninety (90) days of service of a complaint alleging injury from vaccine or immunizing agent administration, the named healthcare provider or healthcare facility shall notify the [State Department of Health] and [Attorney General] of the action.

(b) The [State Department of Health], in consultation with the [Attorney General], shall review the allegations and determine whether the vaccine or immunizing agent administration constitutes covered vaccine administration within forty-five (45) days of notification.

(c) If the [State Department of Health] determines that the administration constitutes covered vaccine administration, the [Attorney General] shall promptly file the certification required under subsection (3).

(d) The determination shall be based solely on whether the vaccine or immunizing agent administration constitutes covered vaccine administration as defined in this Act, without regard to whether injury actually occurred, whether the provider complied with the professional standard of care, or whether the provider's actions caused any alleged injury. Any determination under this subsection shall be preliminary and procedural only and shall not be binding on the court with respect to jurisdiction, constitutional questions, or the availability of judicial remedies.

(e) A healthcare provider may satisfy the notice requirement of this subsection at any time, including after the expiration of any specified time period and at any stage of a claim, administrative proceeding, or civil action. Late or supplemental notice shall be deemed effective for all purposes under this Act. Failure to provide notice under this subsection shall not:

(i) Affect the applicability of any immunity, safe harbor, defense, substitution, or indemnification provided under this Act; or

(ii) Give rise to civil liability.

(6) **Relationship to State Tort Claims Act.**

(a) Claims proceeding under this Section shall be subject to all provisions, limitations, procedures, and immunities provided under the [State Tort Claims Act], including but not limited to:

(i) Damage caps or limitations;

(ii) Notice and procedural requirements;
(iii) Limitations on types of recoverable damages;
(iv) Immunities for discretionary functions or policy decisions;
(v) Statute of limitations provisions.

(b) Nothing in this subsection shall be construed to require proof of negligence, breach of duty, or causation as a condition of recovery where this Section establishes a no-fault compensation obligation.

(7) **Non-Availability for Willful Misconduct or Gross Negligence.**

(a) The protections of this Section shall not apply if:
(i) The healthcare provider or healthcare facility engaged in willful misconduct or gross negligence; or
(ii) The healthcare provider or healthcare facility failed to obtain legally required informed consent in accordance with Section 14(2) of this Act, except where such consent was not required by law or was not reasonably obtainable under emergency circumstances.

(b) In such circumstances, the State shall not be substituted as defendant, and the provider or facility may be held personally liable.

(8) **Coordination with Statutory Immunity Under Section 5.**

(a) If this Act includes both this Section 4 (State Direct Action, Substitution and Defense) and Section 5 (Statutory Civil Immunity), Section 4 shall be the primary procedural mechanism for routing and resolving claims arising from covered vaccine administration.

(b) Upon service of a complaint alleging injury from vaccine or immunizing agent administration, the healthcare provider or healthcare facility shall immediately comply with the notification requirements of subsection (5)(a) of this Section.

(c) The healthcare provider or healthcare facility may not file a motion to dismiss based on immunity under Section 5 until the earlier of:
(i) The [State Department of Health] completing its review and issuing a determination under subsection (5)(b) of this Section; or
(ii) Forty-five (45) days elapsing from the date of notification under subsection (5)(a) without a determination being issued.

(d) If the [State Department of Health] certifies that the administration constitutes covered vaccine administration:
(i) The State shall be substituted as defendant under subsection (3) of this Section;
(ii) The healthcare provider or healthcare facility shall be dismissed with prejudice; and
(iii) Any pending motion to dismiss under Section 5 shall be denied as moot.

(e) If the [State Department of Health] determines that the administration does NOT constitute covered vaccine administration, or fails to issue a determination within the time period specified in subsection (5)(b):
(i) The State shall not be substituted as defendant;
(ii) The healthcare provider or healthcare facility may then file or proceed with a motion to dismiss based on immunity under Section 5; and
(iii) The [State Department of Health]'s determination shall not be binding on the court's independent evaluation of whether the healthcare provider or healthcare facility is entitled to immunity under Section 5, but may be considered as evidence by the court.

(f) Waiver of Derivative Immunity. If the State is substituted as the defendant under this Section:
(i) The State may not assert any immunity that would have been available to the healthcare provider or healthcare facility under Section 5 as a defense to the State's liability;
(ii) The State's liability shall be governed solely by the provisions of the [State Tort Claims Act] and subsection (6) of this Section; and

(iii) Any damage caps, procedural requirements, or immunities applicable to the State under the [State Tort Claims Act] shall apply in lieu of any protections that would have been available to the healthcare provider or healthcare facility under Section 5.

(g) This coordination mechanism ensures that healthcare providers and healthcare facilities are removed from litigation at the earliest practicable stage and that claims are resolved through the appropriate no-fault or administrative process.

(h) Section 5 shall operate solely as a residual immunity defense in actions where substitution under this Section does not apply.

(9) Compensation Framework Where No Vaccine Injury Review Panel Exists.

(a) Where a claim proceeds under subsection (1) because no Vaccine Injury Review Panel has primary jurisdiction, compensation shall be awarded pursuant to this subsection and not pursuant to fault-based tort principles.

(b) Compensable categories shall include, at a minimum:

(i) Reasonable and necessary medical expenses;

(ii) Rehabilitation and long-term care costs;

(iii) Lost income or loss of earning capacity;

(iv) Pain and suffering; and

(v) Death benefits, including survivor compensation.

(c) Compensation under this subsection shall be subject to the following caps, which shall apply per claimant:

(i) Medical and rehabilitation expenses: [$____];

(ii) Lost income or earning capacity: [$____];

(iii) Pain and suffering: [$____];

(iv) Death benefits: [$____].

(d) The [State Department of Health], in consultation with the [Attorney General] and relevant medical experts, shall adopt and periodically update a State Vaccine Injury Table identifying covered vaccines, recognized injuries, and presumptive timeframes, which shall be used to guide compensation determinations under this subsection.

(e) A claimant awarded compensation under this subsection may elect to:

(i) Accept the award as final, in which case the claim shall be resolved with prejudice; or

(ii) Reject the award and pursue any otherwise available civil action against a healthcare provider or healthcare facility, in which case state substitution, defense, and indemnification under this Section shall not apply.

(f) An election under subsection (e) shall be irrevocable once made.

(10) Election and Rejection of No-Fault Determination.

(a) A claimant who receives a final award or adverse determination under subsection (1) may elect to accept or reject such determination.

(b) Acceptance of a determination under subsection (1) shall be final and shall bar any civil action against a healthcare provider or healthcare facility arising from the same covered vaccine administration.

(c) Rejection of a determination under subsection (1) shall restore the claimant's right to pursue a de novo civil action against a healthcare provider or healthcare facility as otherwise permitted by law.

(d) Upon rejection under this subsection:

(i) State substitution, defense, and indemnification under this Section shall not apply;

(ii) Any prior dismissal of a healthcare provider or healthcare facility shall be without prejudice for purposes of the de novo action; and

(iii) The action shall proceed as a fault-based civil action subject to all applicable defenses and procedural requirements.

(11) Preservation of De Novo Judicial Action Following Panel Rejection.

(a) Notwithstanding any other provision of this Section, nothing in this Section shall be construed to limit, bar, or condition the right of a claimant who rejects a final determination or award of a Vaccine Injury Review Panel to pursue a de novo civil action against a healthcare provider or healthcare facility as otherwise permitted by law. In such an action, state substitution, defense, and indemnification under this Section shall not apply.

(b) Nothing in this Section shall be construed to preclude judicial review of a final determination arising from the no-fault compensation process established under subsection (1), including review of constitutional claims, questions of law, or final agency action, as provided under the [State Administrative Procedure Act] or other applicable law. Judicial review under this subsection shall include review of any determination or certification that resulted in substitution, routing, or dismissal of a healthcare provider, and shall be conducted by a court of competent jurisdiction independent of the Designated Adjudicatory Authority.

(12) **Institutional Placement of Initial Review:**

(a) For purposes of this Section, this State adopts the following structure for initial review and claim routing of covered vaccine injury claims:

(i) **[Select one:]**

[Initial review and claim-routing determinations under this Section shall be conducted by a review panel or administrative body within the executive branch, as provided in Section 9 of this Act, if adopted, or otherwise as provided by law.]

[Initial review and claim-routing determinations under this Section shall be conducted by a statutorily created tribunal, special master, or other adjudicatory body within or adjunct to the judicial branch, as provided under this Act or other applicable law of this State.]

(b) Regardless of the structure adopted under the previous paragraph, no claimant shall be divested of access to a civil action, and no healthcare provider shall be dismissed or the State substituted as defendant in a civil action, except pursuant to an order of a court of competent jurisdiction.

[Implementation Note.

(13) Section 4 includes alternative options for the institutional placement of initial review and claim-routing determinations at subsection (12). States adopting the judicial-branch option may need to establish a tribunal, special master, or other adjudicatory mechanism consistent with their constitution and judicial administration laws. States adopting the executive-branch option may assign these functions to an existing or newly created administrative body. The substantive standards and procedures of this Act apply regardless of institutional placement.]

SECTION 5. STATUTORY CIVIL IMMUNITY

[Note to States: This section provides absolute immunity and may be adopted as an alternative to Section 4, or as a supplemental "backstop" protection. States concerned about fiscal exposure from Section 4 may prefer this immunity-only approach. However, it does not provide as robust protections for providers, who will need to hire counsel to raise these defenses on their behalf.]

(1) **Grant of Immunity.**

(a) Except as provided in subsection (2), a healthcare provider or healthcare facility is immune from civil liability for any injury to an individual caused by an act or omission in connection with covered vaccine administration.

(2) **Scope of Immunity.**

(a) The immunity granted under this Section applies only to acts or omissions arising out of or directly related to covered vaccine administration, including, but not limited to:

(i) Any act or omission in the prescription, ordering, dispensing, furnishing, or administration of a vaccine or immunizing agent;

(ii) Clinical decisions regarding the appropriateness of vaccine or immunizing agent administration for a particular patient;

(iii) The provision of information or counseling regarding vaccines or immunizing agents;

(iv) Recordkeeping, reporting, or documentation related to vaccine or immunizing agent administration; and

(v) Any other act or omission directly related to covered vaccine administration.

(b) The immunity extends to:

(i) Healthcare providers acting in their individual capacity;

(ii) Healthcare facilities and their employees, agents, and contractors;

(iii) Professional corporations, limited liability companies, partnerships, or other business entities through which healthcare providers deliver services;

(iv) Supervising healthcare providers for acts of those they supervise within the scope of supervision; and

(v) Employers of healthcare providers, and any persons or entities alleged to be vicariously liable for acts or omissions of healthcare providers, including but not limited to officers, employees, agents, volunteers, or contractors, when such acts or omissions occur in the course of covered vaccine administration.

(c) The immunity provided under this Section does not apply if:

(i) The healthcare provider or healthcare facility engaged in willful misconduct or gross negligence;

(ii) The vaccine or immunizing agent was administered to an individual despite a known, documented, and absolute contraindication specific to that individual as recognized in the manufacturer's FDA-approved labeling and Recognized Medical Guidelines;

(iii) The healthcare provider or healthcare facility failed to obtain legally required informed consent in accordance with Section 14(2) of this Act, except where such consent was not required by law or was not reasonably obtainable under emergency circumstances; or

(iv) The vaccine or immunizing agent administration did not constitute covered vaccine administration as defined in this Act.

(3) **Burden of Proof.**

(a) In any action in which immunity under this Section is claimed:

(i) The healthcare provider or healthcare facility shall have the burden of establishing that the vaccine or immunizing agent administration constituted covered vaccine administration;

(ii) Once the healthcare provider or healthcare facility establishes that the administration was covered vaccine administration, the burden shifts to the plaintiff to establish by clear and convincing evidence that one of the exceptions in subsection (2) applies.

(4) **Motion to Dismiss.**

(a) A healthcare provider or healthcare facility may file a motion to dismiss based on immunity under this Section at any time after the complaint is filed. The court shall rule on such motion expeditiously and before requiring the healthcare provider or healthcare facility to respond to the complaint on the merits.

(5) **No Abrogation of Other Immunities.**

(a) Nothing in this Section shall be construed to abrogate or diminish any other immunity or limitation of liability provided to healthcare providers or healthcare facilities under [State] or federal law.

SECTION 6. SAFE HARBOR AFFIRMATIVE DEFENSE

[Note to States: This section provides a fallback defense, but providers remain exposed to litigation costs.]

(1) **Rebuttable Presumption of Non-Negligence.**

(a) In any civil action alleging negligence arising from vaccine or immunizing agent administration, there shall be a rebuttable presumption that the healthcare provider or healthcare facility was not negligent if:

(i) The vaccine or immunizing agent administration constituted covered vaccine administration; and

(ii) The healthcare provider or healthcare facility followed Recognized Medical Guidelines applicable to the patient's circumstances.

(b) This presumption shifts the burden to the plaintiff to prove by clear and convincing evidence that the healthcare provider deviated from applicable Recognized Medical Guidelines.

(c) This rebuttable presumption shall apply only to healthcare providers and healthcare facilities. It shall not apply in any action brought directly against the State or in which the State is substituted as defendant pursuant to Section 4, which establishes a no-fault statutory compensation process.

(2) **Motion for Summary Judgment.**

(a) A healthcare provider or healthcare facility may assert the safe harbor affirmative defense at any time, including in a motion to dismiss (where appropriate) or a motion for summary judgment, supported by appropriate evidentiary materials.

(b) Upon the filing of a motion asserting the safe harbor affirmative defense, all merits discovery unrelated to the safe harbor defense shall be stayed pending resolution of the motion. The court may permit limited discovery solely as necessary to resolve material factual disputes relevant to the safe harbor defense.

(c) For purposes of the safe harbor defense, compliance with Recognized Medical Guidelines shall be determined based on objective evidence, including contemporaneous medical records and the applicable guidelines in effect at the time of administration.

(d) If the provider establishes compliance with Recognized Medical Guidelines, the burden shifts to the plaintiff to establish clear and convincing evidence, that:

(i) The provider materially deviated from all applicable Recognized Medical Guidelines; or

(ii) The Recognized Medical Guidelines were inapplicable to the patient due to clearly documented, patient-specific contraindications or exceptional clinical circumstances.

SECTION 7. PROFESSIONAL DISCIPLINE SAFE HARBOR

(1) **Safe harbor.**

(a) No healthcare provider or healthcare facility shall be subject to professional discipline, licensure action, or adverse credentialing action by a state licensing board or professional regulatory authority solely on the basis of conduct constituting covered vaccine

administration, where such conduct was performed in compliance with Recognized Medical Guidelines.

(2) Non-reportability of protected proceedings.

(a) The filing, existence, review, adjudication, or resolution of any claim, petition, or proceeding arising from covered vaccine administration, including but not limited to proceedings before a Vaccine Injury Review Panel, actions in which the State is substituted as defendant under Section 4, or claims resolved through any no-fault compensation mechanism established under this Act, shall not be required to be disclosed, reported, or identified in any application for licensure, license renewal, certification, hospital privileging, credentialing, or recredentialing, and shall not constitute an adverse event, disciplinary history, or negative factor for any professional or institutional review purpose.

(3) **Limitations**.

(a) Nothing in this Section shall be construed to limit the authority of any licensing board or regulatory body to investigate, charge, or discipline conduct involving:

(i) fraud or misrepresentation;
(ii) gross negligence or willful misconduct;
(iii) incompetence, impairment, or unprofessional conduct;
(iv) improper storage, handling, preparation, or administration of vaccines or immunizing agents outside Recognized Medical Guidelines;
(v) falsification of medical records or required reporting; or
(vi) conduct outside the scope of covered vaccine administration.

SECTION 8. CERTIFICATE OF MERIT REQUIREMENT

(1) **Certificate Required.**

(a) In any civil action alleging injury arising from vaccine or immunizing agent administration in which a healthcare provider or healthcare facility is named as a defendant, or in any action in which the State is substituted as the defendant pursuant to Section 4, the plaintiff shall file with the complaint a certificate of merit executed by a qualified expert witness.

(2) **Content of Certificate.**

(a) The certificate of merit shall:

(i) Be executed by a healthcare provider who is licensed and possessing training or clinical experience in a relevant specialty;
(ii) State that the expert:
(A) Has reviewed all relevant medical records and information available to the plaintiff at the time of filing;
(B) Is actively engaged in clinical practice and has personally administered, within the two (2) years preceding execution of the certificate, the same category of product at issue in the action (either vaccines or immunizing agents) to patients in a clinical setting;
(C) Is familiar with Recognized Medical Guidelines applicable to the vaccine or immunizing agent administration at issue; and

(D) Has concluded, based on the medical records and applicable clinical standards, that there exists a reasonable medical basis to believe the claim is not frivolous and that the alleged injury is plausibly associated with the vaccine or immunizing agent.

(iii) Specifically identify the clinical basis for the expert's conclusion, including clinically relevant departures from the Recognized Medical Guidelines, without requiring a determination that the applicable legal standard of care was violated;

(iv) Attest that the expert has not executed more than [ten (10)] certificates of merit for vaccine or immunizing agent-related claims in the preceding [twelve (12)] months; and

(v) Include a statement that the expert understands that providing a false certificate of merit may subject the expert to professional discipline and sanctions under applicable court rules.

(3) **Qualified Expert Witness.**

(a) For purposes of this Section, a qualified expert witness must:

(i) Be a healthcare provider licensed in any State, the District of Columbia, or a territory or possession of the United States;

(ii) Possess training or clinical experience relevant to the vaccine or immunizing agent at issue (e.g., pediatrics, family medicine, infectious diseases, internal medicine);

(iii) Have clinical experience administering the type of vaccine or immunizing agent at issue;

(iv) Be in active clinical practice, meaning the expert has devoted at least [thirty (30)] percent of the expert's professional time to direct patient care within the two (2) years preceding the execution of the certificate;

(v) Not have been subject to disciplinary action by any state medical board or professional licensing authority within the preceding [five (5)] years; and

(vi) Disclose any material financial, professional, or personal interest that could reasonably be expected to affect the expert's objectivity, provided that the existence of such an interest shall not, by itself, disqualify the expert, but may be considered by the court in assessing credibility and weight.

(4) **Filing and Service Requirements.**

(a) The certificate of merit shall be filed simultaneously with or before the complaint is filed.

(b) The complaint shall not be served on any defendant unless accompanied by the certificate of merit.

(c) Failure to file and serve the certificate of merit as required shall result in automatic dismissal of the action without prejudice.

(5) **Opportunity to Cure Deficiency.**

(a) If a complaint is filed without the required certificate of merit, or if the certificate is deficient, the court shall dismiss the complaint without prejudice.

(b) The plaintiff shall have sixty (60) days from the date of dismissal to file a new complaint accompanied by a compliant certificate of merit.

(c) If the plaintiff fails to file a compliant certificate within sixty (60) days, the dismissal shall be converted to a dismissal with prejudice.

(d) Notwithstanding subsections (a) through (c), the court may, in the interests of justice, permit the plaintiff to cure a deficient certificate of merit by amendment without dismissal where the deficiency is technical or non-substantive.

(6) **Sanctions for Frivolous Certificates.**

(a) If a court determines, after a hearing, that a certificate of merit was executed without reasonable basis and for an improper purpose such as harassment or delay, the court may:

(i) Impose monetary sanctions on the expert who executed the certificate, the attorney who filed it, or both;

(ii) Refer the expert to the appropriate professional licensing board for disciplinary proceedings;
(iii) Award reasonable attorney's fees and costs as a sanction, consistent with Section 13 and in addition to any prevailing-party fee award.
(iv) Take such other action as the court deems appropriate.

(b) In determining whether sanctions are appropriate, the court shall consider whether the expert conducted an adequate review of available records, whether the expert was familiar with applicable guidelines, and whether the expert's conclusions were objectively reasonable based on the information available.

(7) **Tolling.**

(a) Any applicable statute of limitations shall be tolled during the pendency of a court's review of a timely filed certificate of merit under this Section.

(8) **Confidentiality.**

(a) The certificate of merit and all materials submitted in connection with the certificate shall be treated as confidential and shall not be admissible in any subsequent proceeding, except:
(i) In proceedings to determine whether the certificate satisfies the requirements of this Section;
(ii) In proceedings regarding sanctions under subsection (6); or
(iii) In professional disciplinary proceedings against the expert who executed the certificate.

SECTION 9. STATE VACCINE INJURY COMPENSATION FUND [OPTION A: COMPREHENSIVE NO-FAULT SYSTEM]

[Note to States: This section establishes a robust no-fault compensation system for severe vaccine injuries. It requires significant upfront investment but provides the most comprehensive protection for providers and fairest outcomes for patients. States with strong budgets and commitment to comprehensive protection can adopt this option.]

(1) **Establishment of Fund.**

(a) There is hereby created the [State Name] Vaccine Injury Compensation Fund (the "Fund"), which shall be maintained as a separate fund in the State Treasury.

(b) The Fund shall be administered by the [State Department of Health] in consultation with the [State Treasurer] and [Attorney General].

(c) The Fund is established to provide no-fault compensation to individuals who suffer Table Injuries as a result of covered vaccine administration.

(2) **State Vaccine Injury Table.**

(a) The [Designated State Agency], in consultation with medical experts in immunization, pediatrics, infectious diseases, and vaccine and immunizing agent safety, shall establish and maintain a State Vaccine Injury Table identifying:
(i) Specific vaccines and immunizing agents covered by the Fund;
(ii) Injuries, disabilities, illnesses, and conditions caused by such vaccines and immunizing agents; and
(iii) Time periods within which the first symptom or manifestation of onset of each such injury must occur after covered vaccine or immunizing agent administration to qualify for compensation.

(b) The Table shall be based on medical and scientific evidence and shall include only injuries that are:
    (i) Severe and result in significant permanent impairment or death;
    (ii) Causally associated with vaccine or immunizing agent administration based on credible medical evidence; and
    (iii) Likely to result in medical costs exceeding [$XX] or permanent disability lasting longer than [six (6) months].
(c) Table Injuries shall include, but need not be limited to:
    (i) Death occurring within a specified time period after vaccine or immunizing agent administration;
    (ii) Anaphylaxis requiring emergency medical intervention and hospitalization for more than twenty-four (24) hours;
    (iii) Encephalopathy or acute encephalitis;
    (iv) Paralysis, including Guillain-Barré syndrome;
    (v) Seizure disorders;
    (vi) Chronic inflammatory demyelinating polyneuropathy;
    (vii) Intussusception;
    (viii) Shoulder injury related to vaccine or immunizing agent administration; and
    (ix) Such other injuries as the Designated State Agency determines meet the criteria in subsection (b).
(d) The Designated State Agency shall review and update the Table at least every two (2) years to reflect current medical and scientific evidence.
(e) The Table and any amendments thereto shall be promulgated through rulemaking in accordance with [State Administrative Procedure Act].

(3) **Vaccine Injury Review Panel Designation.**
(a) The claim review and adjudication process established under this Section shall constitute the State's "Vaccine Injury Review Panel" for purposes of this Act.
(b) The Department of Health, including any special masters, hearing officers, or adjudicatory bodies designated pursuant to subsection (4), shall exercise the powers of the Vaccine Injury Review Panel, including initial review, claim-routing determinations, and issuance of determinations subject to judicial review as provided by law.
(c) For States adopting this Section but not participating in the Multi-State Vaccine Injury Compact, the Vaccine Injury Review Panel shall be deemed an executive-branch administrative body.

(4) **Eligibility for Compensation.**
(a) An individual who suffers a State Table Injury as a result of covered vaccine or immunizing agent administration is eligible for compensation from the Fund without regard to fault.
(b) To qualify for compensation, the claimant must demonstrate:
    (i) The individual received a vaccine or immunizing agent that is covered by the Fund;
    (ii) The individual suffered an injury listed in the [State] Vaccine Injury Table;
    (iii) The first symptom or manifestation of onset of the injury occurred within the time period specified in the Table; and
    (iv) The injury resulted in medical expenses exceeding [$XX] and/or resulted in permanent impairment lasting longer than [six (6) months].
(c) There shall be a rebuttable presumption that an injury listed in the Table that occurs within the specified time period was caused by the vaccine or immunizing agent.

(5) **Claim Filing and Review.**
(a) Claims for compensation shall be filed with the [State Department of Health] on forms prescribed by the Department.

(b) Claims must be filed within [five (5) years] of the date of first symptom or manifestation of onset of the injury or death of the individual, whichever is later. For injuries sustained by a minor, a claim must be filed within six (6) years of the date of first symptom or manifestation of onset of the injury, provided that no claim may be filed later than eight (8) years after the date of covered vaccine administration.
(c) The Department shall review claims and make determinations regarding eligibility and compensation amounts.
(d) The Department may appoint special masters or hearing officers with medical expertise to assist in reviewing claims.
(e) Claimants shall have the right to be represented by counsel and to present medical evidence.
(f) The Department shall endeavor to issue an initial determination within one hundred twenty (120) days of receipt of a complete claim.
(g) If the Department has not issued a final determination within one (1) year of receipt of a complete claim, the claimant may elect to:
    (i) Continue pursuing compensation from the Fund; or
    (ii) Deem the claim constructively denied and pursue remedies as provided under subsection (8).
(h) The Department may utilize internal medical reviewers or contract medical experts to assist in evaluating claims.
(i) The certificate-of-merit requirement set forth in Section 8 shall not apply to claims filed with the Fund under this Section.

(6) **Compensation Awards.**
(a) Compensation may include:
    (i) Medical Expenses: All reasonable and necessary medical expenses incurred or reasonably expected to be incurred as a result of the injury, including hospitalization, physician services, medications, medical devices, rehabilitation, and long-term care;
    (ii) Lost Wages: Compensation for lost past and future earnings resulting from the injury, subject to reasonable actuarial calculation;
    (iii) Pain and Suffering: A fixed award for pain and suffering not to exceed [$XX];
    (iv) Death Benefit: For claims resulting in death, a fixed death benefit of [$XX] to be paid to the estate or designated beneficiaries; and
    (v) Attorney's Fees and Costs: Reasonable attorney's fees and costs incurred in preparing and presenting the claim, up to [fifteen percent (15%)] of the total compensation awarded. Attorney's fees awarded under this subsection are compensable administrative expenses and shall not be subject to, or affected by, Section 13 of this Act.
(b) Compensation for medical expenses and lost wages shall be paid directly to the claimant or claimant's estate.
(c) Total compensation from the Fund, excluding attorney's fees and costs, shall not exceed:
    (i) [$XX] per claim for living claimants; or
    (ii) [$XX] for death claims.

(7) **Offset and Subrogation.**
(a) Compensation paid from the Fund shall be reduced by the amount of any payments received or entitled to be received from:
    (i) The federal Vaccine Injury Compensation Program;
    (ii) Any other state or federal compensation program;
    (iii) Any settlement or judgment in a civil action related to the vaccine or immunizing agent injury; or
    (iv) Any health insurance, disability insurance, or other third-party payor for the same medical expenses or lost wages.

(b) The Fund shall be subrogated to any right of recovery the claimant may have against third parties, including vaccine manufacturers, for injuries compensated by the Fund.
(c) Any amounts recovered through subrogation shall be returned to the Fund.

(8) **Appeals.**
(a) A claimant who is dissatisfied with a determination by the Department may appeal to the [State District Court / Appropriate Court] within thirty (30) days of the determination.
(b) Review shall be de novo with respect to both eligibility for compensation and the amount of compensation awarded, and the claimant shall have the burden of proving eligibility by a preponderance of the evidence.
(c) Appeals shall be expedited and decided within [ninety (90) days], if practicable.

(9) **Exclusive Remedy.**
(a) For individuals who suffer Table Injuries and receive compensation from the Fund, such compensation shall be the exclusive remedy, and no civil action may be filed against the healthcare provider or healthcare facility that administered the vaccine or immunizing agent.
(b) Acceptance of compensation from the Fund constitutes a complete release of all claims against such healthcare provider or healthcare facility arising from the vaccine or immunizing agent administration.
(c) Rejection of compensation shall not affect eligibility for compensation under any other applicable law.
(d) This Section does not affect any rights or limitations applicable to claims against vaccine or immunizing agent manufacturers under federal or state law.

(10) **Election.**
(a) If a claimant is eligible for compensation from the Fund for a State Table Injury, the claimant must elect whether to:
(i) Accept compensation from the Fund, thereby waiving any right to file a civil action against the healthcare provider or healthcare facility; or
(ii) Decline compensation from the Fund, and may then pursue a civil action, if permitted under this Act.
(b) The election must be made within [ninety (90) days] of receiving notice of eligibility for compensation.
(c) Once made, the election is irrevocable.
(d) If a claimant fails to make an election within the period specified in subsection (b), the claimant shall be deemed to have rejected compensation from the Fund and may pursue a civil action as otherwise permitted under this Act.
(e) The election period shall not begin to run until the claimant has received written notice of the determination and of the consequences of acceptance or rejection.

(11) **Tolling.**
(a) Any applicable statute of limitations for a civil action arising from the same injury shall be tolled from the date a claim is filed with the Fund until:
(i) The claimant accepts compensation from the Fund; or
(ii) The claimant rejects compensation or treats the claim as constructively denied under this Section.

(12) **Administration.**
(a) The [State Department of Health] shall adopt rules governing the administration of the Fund, including procedures for filing claims, standards for determining causation, methods for calculating compensation, and procedures for appeals.
(b) The Department shall prepare an annual report detailing:
(i) The number and types of claims filed;
(ii) The number and amounts of awards made;

(iii) The financial status of the Fund;
(iv) Trends in vaccine and immunizing agent injury claims; and
(v) Recommendations for any necessary changes to the Table or compensation structure.

(c) The report shall be submitted to the [Governor] and [State Legislature] by [December 1] of each year and made publicly available.

SECTION 10. EXCESS VACCINE LIABILITY FUND

[Note to States: This section implements a system where private insurance covers initial liability and the state fund covers catastrophic provider exposure. This reduces state costs while incentivizing private insurance market participation. May be combined with Vaccine Injury Compensation Fund, which acts as a mechanism to compensate patients.]

(1) **Establishment of Excess Vaccine Liability Fund.**
(a) There is hereby created the [State Name] Excess Vaccine Liability Fund (the "Excess Fund"), which shall function as a secondary layer of coverage for vaccine and immunizing agent-related liability.
(b) The Excess Fund shall provide coverage for judgments or settlements arising from covered vaccine administration that exceed the limits of the healthcare provider's or healthcare facility's primary professional liability insurance.

(2) **Relationship to Vaccine Injury Compensation Fund and Scope of Coverage.**
(a) This Section is structurally distinct from, and subordinate to, the Vaccine Injury Compensation Fund established under Section 8, and is intended solely to provide excess indemnification protection for healthcare providers and healthcare facilities in cases where a claimant elects not to accept compensation from that Fund.
(b) This Section governs excess indemnification of healthcare providers and healthcare facilities and does not create, modify, or limit any right of action by claimants.

(3) **Primary Insurance Requirement.**
(a) A healthcare provider or healthcare facility is eligible for protection from the Excess Fund only with respect to covered vaccine administration for which the provider or facility maintains professional liability insurance covering the same category of product (vaccine or immunizing agent, as defined in this Act), with minimum limits of
(i) [Two Hundred Fifty Thousand Dollars ($250,000)] per occurrence; and
(ii) [Seven Hundred Fifty Thousand Dollars ($750,000)] annual aggregate.
(b) Proof of such insurance must be provided to the [State Department of Health] annually.

(4) **Excess Coverage.**
(a) The Excess Fund shall pay:
(i) The amount of any judgment or settlement that exceeds the primary insurance coverage; up to
(ii) A maximum state contribution of [Five Hundred Thousand Dollars ($500,000)] per occurrence.
(b) Total recovery from primary insurance plus the Excess Fund shall not exceed [Seven Hundred Fifty Thousand Dollars ($750,000)] per occurrence.

(5) **Nature of Payments. No Direct Claim by Claimants.**

(a) Payments from the Excess Fund shall be made solely for the purpose of indemnifying healthcare providers or healthcare facilities for amounts they are legally obligated to pay in excess of primary professional liability insurance.
(b) No claimant shall have any legal or equitable interest in the Excess Fund or in any payment made therefrom.

(6) **Claims Process.**
(a) Civil actions proceed normally against the healthcare provider or healthcare facility.
(b) If a judgment or settlement exceeds primary insurance limits, the Excess Fund shall pay the excess amount subject to the caps in this Section.
(c) The [Attorney General] may participate in the defense of any action where Excess Fund exposure is likely.
(d) For purposes of this section, an "occurrence" shall be determined in accordance with the terms and conditions of the applicable primary insurance policy, and multiple claims or causes of action arising from the same insured event shall be treated as a single occurrence to the extent so treated under such policy.

(7) **Administration and Oversight.**
(a) The [State Department of Health], in consultation with the [Attorney General], shall adopt rules governing verification of eligibility for Excess Fund coverage, coordination with primary insurance, and prevention of duplicative recovery.
(b) Determinations regarding Excess Fund payments shall be subject to judicial review in accordance with [State Administrative Procedure Act] or applicable law.

SECTION 11. FUNDING FOR COMPENSATION FUNDS AND STATE DEFENSE COSTS

[Note to States: States may choose any combination of funding mechanisms.]

(1) **Funding Structure.**
(a) **Allocation of Funding Sources.**
(i) The Vaccine Injury Compensation Fund established under Section 9 and the Excess Coverage Fund established under Section 10 are hereby funded through the mechanisms set forth in this Section.
(ii) The Legislature hereby elects the following funding allocation for the Vaccine Injury Compensation Fund under Section 9:
(A) [__%] General Fund appropriations under subsection (b);
(B) [__%] Provider assessments under subsection (d);
(C) [__%] Private insurance assessments under subsection (c);
(iii) The Legislature hereby elects the following funding allocation for the Excess Coverage Fund under Section 10:
(A) [__%] General Fund appropriations under subsection (c);
(B) [__%] Provider assessments under subsection (d);
(C) [__%] Private insurance assessments under subsection (e);
(iv) Percentages may be adjusted by subsequent legislative enactment but shall total one hundred percent (100%) for each Fund.

(v) All assessments and contributions authorized under this Section are regulatory fees imposed pursuant to the State's police powers and are intended to defray the costs of administering vaccine-related liability protections and compensation mechanisms, and shall not be construed as taxes.

(b) **General Fund Appropriation for Patient Compensation.**

(i) General Fund appropriations under this subsection shall be deposited into the Vaccine Injury Compensation Fund.

(ii) The Legislature has elected that General Fund appropriations:

(A) [Fully fund all compensation payable under Section 9;] [or]

(B) [Supplement other funding mechanisms, including coverage for:

(I) VFC-eligible individuals;

(II) Medicaid or CHIP beneficiaries;

(III) Uninsured or underinsured individuals; or

(IV) Actuarially projected shortfalls.]

(iii) Appropriations under this subsection shall be based on actuarial projections and included in the annual budget request of the [State Department of Health] or other administering agency.

(iv) This subsection is intended to ensure equitable access to compensation regardless of insurance status and to avoid conflicts with federal VFC funding restrictions.

(c) **General Fund Appropriation for Excess Coverage.**

(i) The Legislature may appropriate General Fund revenues to the Excess Coverage Fund to supplement or replace other funding mechanisms.

(ii) Amounts appropriated under this subsection shall be used solely for the indemnification of healthcare providers or healthcare facilities and shall not constitute compensation to claimants.

(iii) General Fund support under this subsection does not create or expand any right of action against the State and does not constitute an admission of liability.

(d) **Provider Assessment for Excess Coverage.**

(i) Each healthcare provider and healthcare facility licensed in the State shall be subject to an annual regulatory assessment for the purpose of supporting the administration and sustainability of vaccine-related liability protections and compensation mechanisms established under this Act.

(ii) The assessment shall:

(A) Be collected at the time of initial licensure or annual license renewal by the applicable licensing authority;

(B) Be remitted to the [State Treasurer] for deposit in the Excess Coverage Fund.

(C) Be initially set at [$X] per licensed provider, and [$X] per licensed facility, subject to adjustment pursuant to subsection (5).

(iii) The administering authority may, by rule and based on actuarial analysis, establish different assessment amounts or classes for categories of providers or facilities, including differentiation based on license type, scope of practice, volume of vaccine administration, or claims exposure.

(iv) Payment of the assessment shall not be a condition of eligibility for liability protection, immunity, substitution, defense, indemnification, or any other protection under this Act.

(v) Failure to pay the assessment may be enforced solely through administrative mechanisms, including late fees, interest, civil penalties, or licensure enforcement actions, but shall not affect the availability, scope, or enforceability of any liability protection, immunity, defense, procedural safeguard, substitution right, indemnification obligation, or limitation on damages provided under this Act.

(vi) The licensing authority may incorporate the assessment authorized under this subsection into license issuance or renewal fees or collect the assessment through a separate billing mechanism, as determined by rule.

(e) **Private Insurance Assessment.**

(i) Every health insurance carrier or health maintenance organization providing private health insurance coverage to residents of [State] shall pay a per-member-per-month assessment to the Vaccine Injury Compensation Fund established under Section 8.

(ii) The assessment shall be set initially at [$XX] per covered life per month, subject to adjustment pursuant to subsection (5).

(iii) The assessment shall be collected quarterly and remitted to the [State Treasurer] for deposit in the Vaccine Injury Compensation Fund.

(iv) This subsection shall apply only to private insurance coverage and shall not apply to Medicaid, Medicare, CHIP, or other government-funded insurance programs.

(v) Insurers may include the assessment in premium rates subject to approval by the [Insurance Commissioner].

(vi) This subsection shall not apply to self-funded employee welfare benefit plans governed by the Employee Retirement Income Security Act of 1974 (ERISA), 29 U.S.C. § 1001 et seq., and shall not be construed to require any such plan to pay assessments, fees, or contributions under this Act.

(2) **Reserve Requirement.**

(a) Before any compensation fund established under this Act begins accepting claims, the fund must have a reserve equal to at least [twenty-four (24) months] of projected claims based on actuarial analysis.

(b) The initial reserve shall be funded through:

(i) A one-time General Fund appropriation;

(ii) Accelerated collection of assessments or fees; or

(iii) A combination thereof.

(c) The reserve requirement ensures the fund can meet immediate obligations and prevents first-year budget crises.

(3) **Investment of Fund Assets.**

(a) All funds shall be invested by the [State Treasurer] in accordance with applicable state investment laws and policies.

(b) Investment earnings shall be credited to the respective fund and used only for the purposes of that fund.

(c) The [State Treasurer] shall provide periodic financial reports, including quarterly internal reports, on fund balances and investment performance to the [State Department of Health] and administering agency, and shall provide an annual public report to the [Governor] and [State Legislature].

(4) **Annual Actuarial Review.**

(a) The [State Department of Health] shall retain an independent actuarial firm to conduct an annual review of all compensation funds established under this Act.

(b) The review shall assess:

(i) Fund adequacy to meet projected claims;

(ii) Recommended adjustments to assessment rates or fees;

(iii) Trends in vaccine and immunizing agent injury claims and costs;

(iv) Comparison to actuarial projections from prior years; and

(v) Recommendations for any statutory or regulatory changes.

(c) The actuarial review shall be submitted to the [Governor] and [State Legislature] by [November 1] of each year.

(d) The actuarial review required under this subsection shall serve as the exclusive basis for adjustments made under subsection (5).

(5) **Actuarial Adjustment Authority.**

(a) Except where a rate, fee, or assessment is expressly fixed by statute, all assessments, fees, contribution amounts, and reserve levels established under this Section shall be adjusted annually based on actuarial analysis.

(b) Adjustments under this subsection shall be made by the [State Department of Health], [Insurance Commissioner], or other designated administering authority, by rule, and shall be based on the independent actuarial review required under subsection (4).

(c) Any adjustment under this subsection shall:

(i) Be reasonably related to projected claims experience and fund adequacy;

(ii) Preserve required reserve levels under subsection (2); and

(iii) Remain within any maximum limits established by statute unless modified by legislative enactment.

(d) The administering authority shall publish all actuarial assumptions and rate adjustments annually.

(6) **Treatment of Funding Shortfalls.**

(a) Except as expressly provided in subsection (1) or by legislative appropriation, the General Fund shall have no obligation to cover deficits in any compensation fund established under this Act.

(b) If, based on actuarial review, a fund is projected to become insolvent within the next fiscal year, the administering authority shall:

(i) Propose actuarially justified adjustments under subsection (5);

(ii) Notify the [Governor] and [State Legislature]; and

(iii) Identify whether existing statutory funding mechanisms are sufficient to restore solvency.

(c) The Legislature may, but is not required to, appropriate General Fund revenues to address any projected shortfall.

(d) Continue processing and paying existing claims to the extent funds are available, using actuarially appropriate pro rata adjustments if necessary.

(e) No provision of this Act shall be construed to create a legally enforceable obligation of the State to appropriate General Fund revenues.

SECTION 12. FUND ADMINISTRATION TRANSPARENCY AND PUBLIC REPORTING

(1) **Compensation Fund Reporting**.

(a) The administering agency shall publish an annual public report for each fund established under this Act, which shall include:

(i) The number and types of claims filed;

(ii) The number of claims approved and denied;

(iii) The amounts paid for medical expenses, lost wages, and other compensation;

(iv) Administrative costs;

(v) Fund balance, reserves, and actuarial projections.

(b) All aggregate data required to be published under this Section shall also be made available in a machine-readable, non-proprietary format, including but not limited to CSV, JSON, or other open

data standards used by the State. Such data shall be published through the State's official open data portal or equivalent public access mechanism, where available.

(c) Data published under this subsection shall be de-identified and aggregated in a manner consistent with applicable state and federal privacy laws and shall not permit re-identification of individual claimants or providers.

(2) **Public Availability of Governing Materials.**

(a) The [State Department of Health] shall make publicly available, in a consolidated and accessible format:

(i) Any guidance, advisories, or clinical materials issued by the State that relate to vaccine or immunizing agent administration under this Act;

(ii) The [State] Vaccine Injury Table, if applicable;

(iii) Procedures for filing claims under Sections 8 or 9; and

(iv) A plain-language explanation of provider protections and claimant options.

(3) **Deference to Existing Reporting Requirements.**

(a) Nothing in this Act shall be construed to modify, expand, or limit:

(i) Existing state or federal requirements governing immunization documentation, reporting to immunization information systems, or adverse event reporting; or

(ii) The authority of the [State Department of Health] to administer or enforce such requirements under other provisions of law.

(4) **Confidentiality.**

(a) All information created exclusively for purposes of evaluating or administering a claim under this Act, and submitted solely in connection with such evaluation or administration, shall remain confidential and protected in accordance with applicable state and federal privacy laws.

(b) Such information shall not be used by a State agency, based solely on such information, for disciplinary, licensing, or enforcement purposes with respect to covered vaccine administration, except as expressly authorized by this Act.

(c) The filing, existence, or outcome of one or more claims under this Act shall not be admissible as evidence of negligence, professional misconduct, or standard-of-care violations in any civil action or disciplinary proceeding.

(d) Nothing in this subsection shall be construed to:

(i) Restrict the use of information in proceedings arising from conduct determined not to constitute covered vaccine administration; or

(ii) Limit the authority of a court or licensing board to obtain or consider evidence independently obtained outside the claims process under this Act.

(e) Information otherwise required to be created, maintained, or disclosed under applicable law shall not become confidential or privileged solely because it is also submitted in connection with a claim under this Act.

SECTION 13. ATTORNEY'S FEES AND COSTS

(1) **Presumptive Fee Shifting.**

(a) In any civil action arising under this Act, the prevailing party shall be entitled to recover reasonable attorney's fees and costs from the non-prevailing party, unless the court finds that the non-prevailing party's position was substantially justified or that special circumstances make an award unjust; provided, however, that in any action against the State, attorney's fees may be awarded only to the extent expressly permitted under the [State Tort Claims Act] or this Act.

(2) **Substantial Justification.**
   (a) For purposes of this Section, a position is "substantially justified" if it had a reasonable basis in law and fact at the time it was asserted.
(3) **Application.**
   (a) This Section applies to:
      (i) Actions against healthcare providers or healthcare facilities;
      (ii) Actions involving the assertion or denial of immunity or safe harbor under this Act;
      (iii) Appeals from determinations under this Act; and
      (iv) Proceedings related to certificates of merit or threshold eligibility determinations.
   (b) This Section governs the award of attorney's fees and costs in all civil actions arising under this Act, except where another provision expressly provides otherwise.
(4) **Partial Prevailing.**
   (a) If the court determines that neither party wholly prevailed, or that each party prevailed on significant issues, the court may apportion fees and costs in a manner it deems equitable.
(5) **No Expansion of Liability.**
   (a) Nothing in this Section shall be construed to create liability for attorney's fees beyond the scope of this Act.

SECTION 14. ANTI-CIRCUMVENTION AND SCOPE PROVISIONS

(1) **No Derivative Claims.**
   (a) No civil action may be brought against an employer, hospital, clinic, professional corporation, or other entity based on theories of:
      (i) Negligent hiring, supervision, training, or credentialing of a healthcare provider regarding vaccine or immunizing agent administration that constitutes covered vaccine administration;
      (ii) Ostensible or apparent agency related to covered vaccine administration;
      (iii) Vicarious liability for acts of healthcare providers in administering vaccines or immunizing agents that constitute covered vaccine administration; or
      (iv) Corporate negligence related to vaccine or immunizing agent administration policies or protocols that comply with Recognized Medical Guidelines.
   (b) This subsection does not preclude claims based on:
      (i) Defective medical equipment or vaccine or immunizing agent storage failures;
      (ii) Violations of informed consent laws unrelated to the decision to administer the vaccine or immunizing agent; or
      (iii) Negligent acts unrelated to the clinical decision to administer or the method of administering the vaccine or immunizing agent.
(2) **Informed Consent Safe Harbor.**
   (a) For the purposes of the Act, a healthcare provider or healthcare facility shall be deemed to have obtained legally adequate informed consent for vaccine or immunizing agent administration if the provider:

(i) furnished to the patient, or to the patient's parent or guardian, a current Vaccine Information Statement (VIS) published by the Centers for Disease Control and Prevention, or equivalent information approved by the State Board of Health, where such disclosure is required by applicable law; and

(ii) afforded a reasonable opportunity to ask questions and responded to any material questions actually posed.

(b) Compliance with subsection (a) shall conclusively establish that legally required informed consent was obtained for purposes of this Act.

(c) The failure to document informed consent in the medical record, or to satisfy any element of subsection (a), shall not, standing alone, give rise to liability or defeat the protections of this Act, unless the healthcare provider or healthcare facility acted unreasonably under applicable state law.

(d) This Act does not create any independent cause of action for failure to obtain informed consent. Whether legally required informed consent was obtained shall be evaluated solely under applicable state law, based on the totality of the circumstances and the reasonableness of the healthcare provider's conduct, including reasonable reliance on the apparent authority of a parent, guardian, or other individual presenting the patient for care.

(e) Nothing in this subsection shall be construed to require written consent, documentation of consent, or verification of legal decision-making authority, except where expressly required by applicable state law.

(3) **No Liability for Guideline Development.**

(a) The [State Board of Health], the [State Department of Health], and any advisory body or individual involved in developing, reviewing, or approving Recognized Medical Guidelines shall be immune from civil liability for any injury allegedly arising from the adoption or content of such guidelines.

(b) This immunity applies regardless of whether the guidelines are challenged as negligent, arbitrary, or otherwise deficient.

(4) **Off-Label Use Protection.**

(a) The fact that a vaccine or immunizing agent is administered for an off-label use shall not, by itself, constitute evidence of negligence, deviation from the standard of care, or grounds for professional discipline, if:

(i) The off-label use is supported by Recognized Medical Guidelines; and

(ii) The provider reasonably believed the off-label use was medically appropriate for the specific patient.

(b) Healthcare providers shall not be subject to discipline by professional licensing boards solely based on off-label vaccine or immunizing agent administration that complies with subsection (a).

(5) The absence of a vaccine or immunizing agent from the ACIP Immunization Schedule shall be inadmissible as evidence that the administration of said vaccine or immunizing agent deviated from the standard of care.

SECTION 15. REGULATORY HARMONIZATION AND SCOPE OF PRACTICE CLARITY

(1) **Temporary Expansion of Protected Vaccines.**

(a) Any vaccine or immunizing agent administration lawfully authorized under an emergency order or temporary authorization shall be deemed covered vaccine administration for purposes of this Act.

(2) **Regulatory Cleanup.**

(a) The [State Board of Health], [State Board of Pharmacy], [State Medical Board], [State Board of Nursing], and other relevant regulatory bodies shall:

(i) Review all existing rules and regulations relating to vaccines and immunization;
(ii) Identify and repeal or amend duplicate, inconsistent, or outdated provisions;
(iii) Harmonize requirements for recordkeeping, reporting, storage, and administration of vaccines and immunizing agents across regulatory bodies; and
(iv) Adopt regulations implementing this Act.

(b) Such review and rulemaking shall be completed no later than [twelve (12) months] after the effective date of this Act.

SECTION 16. ADMINISTRATIVE AUTHORITY AND AGENCY DESIGNATION

(1.) **Governor Designation.**

(a) To the extent not expressly designated by statute, the Governor shall, no later than the effective date of this Act, designate one or more state agencies to administer the provisions of this Act that the State has adopted.

(b) Such designation may assign different functions to different agencies based on administrative expertise, existing infrastructure, and operational capacity.

(c) Functions that may be separately assigned include, but are not limited to:
(i) Claims intake and administration;
(ii) Medical review panel coordination;
(iii) Compensation fund management;
(iv) Actuarial oversight and reserve management;
(v) Provider certification and compliance monitoring;
(vi) Data collection and reporting;
(vii) Legal defense and litigation management; and
(viii) Interstate compact participation.

(d) The Governor shall notify the General Assembly and publish in the [State Register] the name of each designated agency and the specific functions assigned to each.

(e) The Governor may redesignate administrative authority as necessary, provided that pending claims are not disrupted and at least [60] days written notice is provided to the General Assembly.

(2.) **Default Designation in Absence of Gubernatorial Action.**

(a) If the Governor has not made a designation pursuant to paragraph (1) by the applicable deadline, administrative authority shall vest as follows:
(i) For purposes of medical expertise and administrative matters, the [State Department of Health/State Health and Human Services Agency];
(ii) For purposes of actuarial oversight, the [State Comptroller/State Auditor];
(iii) For purposes of legal defense and litigation management, the Attorney General;

(b) Default designations under this subsection remain in effect until the Governor makes an express designation pursuant to paragraph (1), which may be made at any time.

(c) No claim, action, or administrative proceeding shall be dismissed, delayed, or invalidated solely because the Governor has not made a formal designation, provided that the claim is filed with or defended by the agency holding authority under this subsection.

(d) Designated state agencies shall coordinate with relevant professional licensing boards and other state entities as necessary to implement the provisions of this Act adopted by the State.

SECTION 17. RELATIONSHIP TO EXISTING LAW AND FEDERAL PROGRAMS

(1) **Federal Program Primacy and No Overlapping State Remedy.**

(a) This Act supplements, and does not replace, diminish, or provide an alternative to, the federal VICP or CICP.

(b) If a vaccine-related injury is within the scope of coverage of the VICP or CICP, the applicable federal program shall provide the exclusive forum for adjudication of such claim, and no provision of this Act shall apply, regardless of whether compensation is awarded, denied, or rejected under federal law.

(c) No compensation shall be paid, and no immunity, defense, substitution, or other protection under this Act shall apply, with respect to any injury that is compensable or adjudicable under the VICP or CICP.

(d) The Legislature finds and declares that this Act applies exclusively to vaccine or immunizing agent injuries for which no federal compensation remedy is available, and is intended solely to address gaps in federal coverage through the exercise of the State's traditional police powers to regulate public health, professional liability, and sovereign responsibility.

(e) Nothing in this Act shall be construed to create a overlapping, alternative, or supplemental remedy for any injury for which Congress has provided an exclusive federal compensation scheme.

(f) Nothing in this Act shall be construed to reduce, limit, delay, or otherwise affect any right, remedy, protection, presumption, or procedural benefit available to claimants or vaccine administrators under the federal Vaccine Injury Compensation Program.

(g) For purposes of this Act, a claim shall be deemed to fall outside the scope of an exclusive federal compensation program solely where federal law affirmatively excludes the claim from coverage, including where the VICP or CICP determines that it lacks statutory jurisdiction because the vaccine, immunizing agent, or alleged injury is not covered by the applicable federal program.

(i) Nothing in this subsection shall be construed to permit a claim to proceed under this Act where the claim was within the scope of a federal compensation program but was dismissed, denied, or barred due to the claimant's failure to comply with federal procedural or timing requirements.

(2) **Preliminary Federal Program Applicability Screening.**

(a) If a vaccine-related injury potentially falls within the scope of the VICP or CICP, the claimant shall, before proceeding under this Act, either:

(i) File a petition with the applicable federal program (VICP or CICP) and receive a determination that the claim is not within the scope of such federal program; or

(ii) Request a preliminary, non-binding determination from the [State Department of Health] as to whether, based on the information submitted, the claim appears to fall outside the scope of the VICP or CICP.

(b) Any determination issued by the [State Department of Health] under subparagraph (a)(ii):

(i) Shall be solely for purposes of administering this Act;

(ii) Shall not be binding on any court, administrative tribunal, or adjudicatory body, including but not limited to any federal court, the United States Court of Federal Claims, the VICP, or the CICP;

(iii) Shall not expand, limit, or alter the scope of the VICP or CICP as a matter of federal law; and

(iv) Shall not create estoppel, reliance, or waiver against the State, any healthcare provider, or any other party.

(c) If it is later determined by a court of competent jurisdiction that a claim proceeded under this Act was in fact within the scope of the VICP or CICP, any action under this Act shall be dismissed without prejudice, and no liability or obligation shall arise under this Act by reason of a prior state determination.

(d) The [State Department of Health] shall establish an expedited administrative procedure for issuing preliminary determinations under this subsection, and shall issue such determinations within thirty (30) days of receipt of a complete request.

(e) The running of any applicable statute of limitations for claims under this Act or under State law shall be tolled during:

(i) The pendency of any VICP or CICP petition; and

(ii) The period between submission of a request for a preliminary determination under this subsection and issuance of the determination, plus thirty (30) days thereafter.

(3) **Federal Preemption Savings Clause.**

(a) Nothing in this Act shall be construed to conflict with or be preempted by federal law, including but not limited to:

(i) The National Childhood Vaccine Injury Act, 42 U.S.C. §§ 300aa-1 et seq.;

(ii) The Public Readiness and Emergency Preparedness (PREP) Act, 42 U.S.C. § 247d-6d;

(iii) The Federal Tort Claims Act, 28 U.S.C. §§ 1346(b), 2671–2680; or

(iv) The Vaccines for Children (VFC) Program, 42 U.S.C. § 1396s; or

(v) Implementing regulations.

(b) If any provision of this Act is found to conflict with federal law, such provision shall be severed and the remainder of the Act shall remain in full force and effect.

(4) **State Law Savings Clause.**

(a) Nothing in this Act shall be construed to:

(i) Require any action, expenditure, delegation of authority, or funding mechanism in violation of the Constitution or laws of this State; or

(ii) Impair the powers or duties of the Legislature with respect to appropriations or taxation.

(b) If any provision of this Act could reasonably be construed in more than one manner, it shall be construed in a manner that preserves its validity under the Constitution and laws of this State.

(5) **No Interference with VFC Program.**

(a) Nothing in this Act shall:

(i) Impose any fee, tax, or assessment on vaccines purchased through the federal Vaccines for Children (VFC) program;

(ii) Alter the terms or conditions under which healthcare providers participate in the VFC program;

(iii) Create any liability for the federal government or VFC program administrators; or

(iv) Otherwise conflict with VFC program regulations.

(b) Any fees or assessments imposed under this Act shall apply only to vaccines purchased outside the VFC program and administered to privately insured individuals.

(6) **No Abrogation of Existing Protections.**

(a) Nothing in this Act shall be construed to abrogate, diminish, or limit any immunity, limitation of liability, or protection afforded to healthcare providers, healthcare facilities, or vaccine or immunizing agent manufacturers under:

(i) [State] law, including but not limited to [list relevant state immunity statutes];

(ii) The [State Tort Claims Act];

(iii) Professional liability statutes or regulations;

(iv) The [State] Emergency Management Act;

(v) The [State] Good Samaritan Act; or
(vi) Any other [State] or federal law.

(b) The protections provided by this Act are in addition to, and cumulative with, all other protections available under law.

(7) **Relationship to Existing Vaccine Liability Provisions.**

(a) To the extent any existing statutory provision addressing vaccine or immunizing agent liability conflicts with this Act, the provisions of this Act shall control.

(8) **Workers Compensation.**

(a) Nothing in this Act shall be construed to modify, limit, or expand the scope, exclusivity, or application of the [State] Workers' Compensation Act. Where an alleged injury arising from covered vaccine administration constitutes an injury arising out of and in the course of employment and is compensable under the Workers' Compensation Act, workers' compensation shall remain the primary remedy, and no duplicative recovery shall be permitted under this Act for the same elements of loss. Compensation paid or payable under the Workers' Compensation Act shall be credited against any compensation available under this Act to the extent necessary to prevent double recovery. If a claim for workers' compensation benefits is denied on grounds that the injury is not compensable under the Workers' Compensation Act, the claimant may pursue relief under this Act, subject to all applicable eligibility requirements.

SECTION 18. SEVERABILITY

If any provision of this Act, or the application of any provision to any person or circumstance, is held invalid, the invalidity shall not affect other provisions or applications of this Act that can be given effect without the invalid provision or application, and to this end the provisions of this Act are severable.

SECTION 19. SUNSET REVIEW

(1) **Mandatory Legislative Review.**

(a) The [State Legislature] shall conduct a comprehensive review of this Act no later than [five (5) years] after its effective date.

(b) The review shall assess:

(i) The number and types of vaccine and immunizing agent injury claims filed under this Act;
(ii) The effectiveness of the liability protections in maintaining provider confidence and patient access to vaccines and immunizing agents;
(iii) The financial status and sustainability of any compensation funds established under this Act;
(iv) The interaction between this Act and the federal VICP and CICP;
(v) Changes in vaccine and immunizing agent recommendations or federal law that may warrant amendments to this Act;
(vi) Public health outcomes related to vaccine and immunizing agent coverage rates; and
(vii) Recommendations for any necessary statutory changes.

(c) The [State Department of Health] shall prepare a comprehensive report for the [Legislature] containing data and analysis on all matters listed in subsection (b).

(2) **No Automatic Repeal.**

(a) This Act shall remain in effect unless specifically repealed by the [Legislature], but shall be subject to periodic review as provided in this Section.

SECTION 20. RULES AND IMPLEMENTATION

(1) **Rulemaking Authority.**

(a) The [State Board of Health], the [State Department of Health], the [Insurance Commissioner], the [Attorney General], and other agencies, as appropriate, shall adopt rules necessary to implement this Act, including but not limited to rules governing:

(i) The establishment and maintenance of the [State] Vaccine Injury Table;

(ii) Procedures for filing and processing claims under any compensation funds established by this Act;

(iii) Standards for determining causation and calculating compensation;

(iv) Recordkeeping, reporting, and data sharing requirements;

(v) Assessment rates and fee structures for funding mechanisms;

(vi) Certification and qualification requirements for expert witnesses under Section 8; and

(vii) Any other matters necessary to effectuate the purposes of this Act.

(b) All rules shall be adopted in accordance with the [State Administrative Procedure Act].

(c) Proposed rules shall be subject to public comment and shall be reviewed by relevant stakeholder groups, including healthcare providers, patient advocates, insurance industry representatives, and public health officials.

(d) To the extent that this Act assigns administrative, procedural, or operational functions to an interstate commission or compact entity established pursuant to this Act, State agencies shall not be required to adopt duplicative rules addressing the same subject matter and may rely on rules, procedures, or standards duly adopted by such commission or compact entity, unless State-specific rules are necessary to implement or enforce provisions of this Act applicable solely within this State.

(2) **Initial Implementation Timeline.**

(a) Within [ninety (90) days] of the effective date of this Act, the [State Department of Health] shall:

(i) Begin development of the [State] Vaccine Injury Table required under Section 9, if applicable;

(ii) Issue interim guidance to healthcare providers regarding the protections afforded by this Act;

(iii) Establish forms and procedures for filing claims; and

(iv) Initiate the rulemaking process.

(b) Within [one hundred eighty (180) days] of the effective date, all state agencies with rulemaking authority under this Act shall publish proposed rules for public comment.

(c) Within [twelve (12) months] of the effective date, all final rules shall be adopted and the Act shall be fully operational.

SECTION 21. APPROPRIATIONS

(1) **Initial Funding.**
  (a) There is hereby appropriated from the [State] General Fund to the [State Department of Health] the sum of [amount to be determined based on actuarial analysis] for the fiscal year beginning [date] for the purpose of:
    (i) Establishing the initial reserve for any compensation fund created under this Act;
    (ii) Administrative costs of implementing this Act, including staffing, technology systems, and actuarial services; and
    (iii) At least [$X] for public education regarding the protections and procedures under this Act.
  (b) This appropriation shall remain available until expended and shall not revert to the General Fund.
(2) **Ongoing Funding.**
  (a) Beginning in the fiscal year in which revenue mechanisms contemplated in Section 11 are established, funding for administration and operation of this Act shall be provided through such mechanisms and any additional appropriations as the [Legislature] may authorize.

SECTION 22. EFFECTIVE DATE

(1) This Act shall take effect on [date - recommend at least 12 months after passage to allow for rulemaking and initial fund capitalization], and shall apply exclusively to covered vaccine administrations occurring on or after such date, except that:
  (a) Sections 3 (Definitions), 19 (Rules and Implementation), and 20 (Appropriations) shall take effect immediately upon enactment to allow for preparatory activities; and
  (b) The rulemaking provisions of Section 20 shall take effect immediately to allow agencies to begin the rulemaking process.

SECTION 23. MULTI-STATE VACCINE INJURY COMPACT

[Drafting Note to States: This Section establishes an interstate compact that becomes effective when adopted by two or more states in identical form. The first state to enact this language is the "Founder State," and each subsequent state enacting identical language becomes a "Member State" upon the effective date of its enactment. ANY DEVIATION in the Compact language between states may render the Compact legally void as between those states. States should adopt this Section verbatim to ensure legal effectiveness.]

(1) **Authorization and Formation.**
  (a) The [Governor], with the advice and consent of the [State Legislature], is authorized to cause [State] to enter into the Multi-State Vaccine Injury Compact ("MSVI Compact" or "Compact") established by this Section with other states that enact substantially identical legislation for the purposes of:
    (i) Coordinating administrative services for vaccine injury compensation;
    (ii) Establishing a centralized medical review process;
    (iii) Optionally participating in shared risk pools for actuarial stability; and

(iv) Preserving provider immunity and protections established in this Act.

(b) This Compact shall become effective upon its adoption by at least two (2) states. The Compact shall bind each Member State from the effective date of that state's enactment of this Section.

(c) Entry into this Compact shall not modify, limit, or diminish any immunity, safe harbor, defense, or protection afforded to healthcare providers or facilities under Sections 4 through 8 of this Act. The provider protections in this Act remain in full force and effect regardless of [State]'s participation status in any Compact component.

(d) Entry into this Compact shall not supersede the definitions established in Section 3 of this Act, including "Covered Vaccine Administration" and "Recognized Medical Guidelines," which shall remain determined by [State] law as applied to vaccine administrations occurring within [State].

(2) **Compact Governance Structure.**

(a) The Member States hereby create the Multi-State Vaccine Injury Compact Commission ("MSVI Commission" or "Commission"), which shall function as the governing body for the Compact.

(b) The Commission shall consist of one Commissioner appointed by the Governor of each Member State, who shall serve at the pleasure of the appointing Governor and shall continue to serve until a successor is appointed and qualified.

(c) Each Member State shall have one vote on the Commission. For purposes of this Section, each Commissioner shall cast the vote of the Member State that appointed the Commissioner. Unless otherwise specified in this Section, decisions shall require approval by a majority of Member States.

(d) A majority of the Commissioners in office shall constitute a quorum for the transaction of business. Vacancies or failure of a Member State to appoint or maintain a Commissioner shall not impair the authority of the Commission to act. An abstention shall not be counted as a vote cast for or against a matter but shall not affect the existence of a quorum.

(e) The Commission shall meet at least quarterly and shall make all meeting agendas, minutes, financial reports, actuarial analyses, and policy documents publicly available on a website maintained by the Commission.

(f) The Commission may hire an Executive Director and such staff as necessary to administer the Compact's administrative services and any pooled funds established hereunder.

(3) **Public Records, Confidentiality, and Privacy.**

(a) Except as expressly provided in this Section, the Commission shall not be subject to the public records, open records, or freedom of information laws of any Member State.

(b) The Commission shall make publicly available meeting agendas and minutes, adopted rules and policies, annual budgets, and final audited financial and actuarial reports, in a manner determined by the Commission.

(c) Individually identifiable health information, claim files, medical records, actuarial working papers, deliberative materials, and any information designated confidential by a Member State shall be confidential, exempt from public disclosure, and used solely for purposes of administering this Compact.

(d) The Commission and all Review Panel activities shall comply with the Health Insurance Portability and Accountability Act (HIPAA) and applicable state privacy laws. The Commission is authorized to enter into business associate or equivalent data-protection agreements as necessary.

(e) Disclosure of information pursuant to this Compact shall not constitute a waiver of any privilege or confidentiality protection under state or federal law.

(4) **Modular Participation Framework**

(a) Member States may elect their level of participation in the Compact by selecting one or more of the following tiers:

(i) **Tier 1: Administrative Services Only (mandatory for Compact participation).** All Member States shall participate in shared administrative services as set forth in subsection (4).

(ii) **Tier 2: Multi-State Table Injury Compensation Pool (optional).** Member States may elect to participate in the Multi-State Table Injury Compensation Pool for "Table Injuries" as defined in the Uniform Vaccine Injury Table, as set forth in subsection (6).

(iii) **Tier 3: Excess Coverage Pool (optional).** Member States may elect to participate in the Multi-State Excess Coverage Pool for claims exceeding primary compensation thresholds, as set forth in subsection (7).

(b) By enacting this Section, [State] hereby elects to participate in the following tiers of the Multi-State Vaccine Injury Compact:

(i) ☐ Tier 1 — Administrative Services (mandatory for Compact participation);

(ii) ☐ Tier 2 — Multi-State Table Injury Compensation Pool;

(iii) ☐ Tier 3 — Multi-State Excess Coverage Pool.

(c) The elections indicated above constitute [State]'s binding participation choices for purposes of this Compact. Any subsequent modification of these elections shall be made only in accordance with the procedures set forth in this Section.

(d) Each Member State shall, at the time of enacting this Section or by subsequent legislation or regulatory action, designate which optional tiers (Tier 2 and/or Tier 3) it elects to join. A Member State may elect to participate in:

(i) Tier 1 only (administrative services);

(ii) Tiers 1 and 2 (administrative services plus Table Injury pool);

(iii) Tiers 1 and 3 (administrative services plus Excess Coverage pool); or

(iv) Tiers 1, 2, and 3 (full participation).

(e) Within thirty (30) days of enacting this Section, each Member State shall notify the Commission in writing of its participation tier election(s). A Member State may change its participation tier election prospectively by providing written notice to the Commission at least one hundred eighty (180) days prior to the beginning of the next fiscal year, subject to approval by two-thirds vote of the Commission.

(f) Member States shall have financial obligations and entitlements only with respect to the tier(s) they have elected to join:

(i) A Member State participating in Tier 1 only shall pay administrative assessments under subsection (4) but shall have no obligation to contribute to or draw from pooled funds under subsections (6) or (7).

(ii) A Member State participating in Tier 2 shall contribute to and may draw from the Multi-State Table Injury Compensation Pool, but shall have no obligation to contribute to or draw from the Multi-State Excess Coverage Pool, unless it has also elected Tier 3 participation.

(iii) A Member State participating in Tier 3 shall contribute to and may draw from the Multi-State Excess Coverage Pool, but shall have no obligation to contribute to or draw from the Multi-State Table Injury Compensation Pool, unless it has also elected Tier 2 participation.

(iv) No Member State shall have any joint, several, or contingent liability for the obligations of pooled funds it has not elected to join.

(g) The Commission shall establish, by two-thirds vote, equitable contribution formulas applicable to all funds administered by the Commission under this Compact, including administrative services assessments and pooled compensation or excess coverage funds.

(i) In establishing contribution formulas, the Commission may consider, as appropriate to the fund at issue:

(A) Population of the Member State;
(B) Number of vaccine doses administered within the Member State;
(C) Historical claims experience of the participating Member State relevant to the applicable fund;
(D) Projected claims exposure of the participating Member State based on actuarial analysis;
(E) Equal allocation among participating Member States; or
(F) A combination of the foregoing or other equitable factors.

(h) All assessments, fees, taxes, appropriations, and other funding mechanisms governing funds contributed by Member States to the Commission are governed exclusively by Section 11.

(i) The Commission shall obtain an independent actuarial analysis of each pool managed by the Commission at least annually and:

(i) Shall adjust Member State contribution formulas as necessary to maintain actuarial soundness. Adjustments to contribution formulas shall require two-thirds vote of the Commission; and

(ii) May purchase commercial reinsurance or establish risk-sharing arrangements to ensure adequate coverage, as it determines appropriate.

(iii) Based on the actuarial analysis and applicable contribution formulas, the Commission shall annually determine and notify each participating Member State of the amount required to be contributed by that Member State for the upcoming fiscal year with respect to each tier in which the Member State participates.

(iv) Each Member State shall be solely responsible for raising and remitting its assessed contributions using any lawful funding mechanisms available under its own laws. The Commission shall have no authority to levy taxes, fees, or assessments directly on providers, facilities, insurers, or individuals.

(v) Failure of a Member State to remit its assessed contribution shall not invalidate the assessment and may result in prospective suspension of that Member State's participation in the affected pool or tier, after notice and an opportunity to cure, without relieving the Member State of responsibility for obligations incurred prior to suspension. Suspension under this subsection shall not affect the processing or adjudication of claims arising from covered vaccine administrations occurring prior to the effective date of suspension.

(5) Shared Administrative Services.

(a) All Member States shall participate in the following shared administrative services provided by the Commission on a cost-sharing basis:

(i) The Commission shall establish and maintain the Multi-State Vaccine Injury Review Panel ("Review Panel") as set forth in subsection (5).

(ii) The Commission shall recruit, credential, and maintain a roster of qualified medical experts with expertise in immunization, vaccine safety, pediatrics, infectious diseases, neurology, immunology, and related specialties.

(iii) The Commission shall retain independent actuarial consultants to provide annual actuarial reviews of pooled funds (for Member States participating in Tiers 2 and/or 3) and individual state funds (upon request).

(iv) The Commission shall develop and maintain:

(A) Standardized claim filing forms and secure online portals;
(B) Secure case management systems for tracking claims across Member States;
(C) Data analytics tools for identifying vaccine safety trends;
(D) Public-facing websites for claimant education and transparency; and
(E) Secure data-sharing infrastructure necessary to administer this Compact.

(v) The Commission shall maintain a secure database containing:
(A) De-identified aggregate data on vaccine injury claims across Member States;
(B) Provider disciplinary actions related to vaccine administration (to the extent permitted by Member State law and subject to due process protections);
(C) Information received from Member States or federal authorities relating to vaccine safety, product recalls, or manufacturing defects, solely to the extent necessary to administer claims, identify duplicative filings, or transmit such information to appropriate authorities already possessing jurisdiction; and
(D) Statistical trend analyses to inform policy development.
(vi) The Commission shall facilitate regular meetings of Member State officials to share best practices regarding claims processing, fraud prevention, claimant outreach, and legislative developments.

(b) The Commission shall prepare an annual budget for Tier 1 administrative services, which shall be funded through administrative assessments on all Member States calculated according to a formula adopted by majority vote of the Commission, which may be based on:
(i) Equal allocation among Member States;
(ii) Proportional allocation based on Member State population;
(iii) Proportional allocation based on number of vaccines administered within each Member State;
(iv) Proportional allocation based on number of claims processed through the Review Panel; or
(v) A combination of the foregoing factors.

(c) The Commission shall operate Tier 1 administrative services on a cost-recovery basis without generating profits. Administrative assessments may include amounts reasonably necessary to fund current operations, planned capital expenditures, reserves, and multi-year system development costs, including the development, dissemination, and maintenance of materials and mechanisms reasonably necessary to provide notice to healthcare providers and potential claimants of the existence, purpose, scope, and procedures of compensation and coverage programs administered under this Act and the Compact. Any surplus revenues not allocated to planned or reserved costs shall be applied to reduce Member State assessments in the following fiscal year or transferred to a reserve fund for capital improvements.

(d) All assessments, fees, and processes established under this subsection shall apply equally and neutrally to all entities conducting business within a Member State, without regard to the state of incorporation, principal place of business, or domicile of such entity, and shall be based solely on the entity's business activity within that Member State. This requirement applies to assessments under subsections (6) and (7) as well.

(e) A Member State may satisfy any reporting, data submission, actuarial, audit, or administrative reporting requirement imposed under this Act by designating the Commission to perform such reporting on the State's behalf, to the extent the report relates to matters administered through the Compact.
(i) Any report, analysis, or filing prepared by the Commission pursuant to a delegation under this subsection shall be deemed a report of the Member State for purposes of compliance with this Act.
(ii) Delegation under this subsection shall not relieve a Member State of responsibility for the accuracy, completeness, or timeliness of any report required by its law.

(6) **Centralized Vaccine Injury Review Panel.**

(a) The Commission shall establish the Multi-State Vaccine Injury Review Panel (the "Review Panel"), which shall consist of:

(i) Not nine (9) members;
(A) At least six (6) shall be physicians or other licensed clinicians with expertise in pediatrics, infectious diseases, neurology, immunology, epidemiology, vaccine safety, or related specialties;
(B) At least three (3) shall be attorneys with expertise in vaccine injury law, medical malpractice, or administrative law; and
(ii) Additional members as determined necessary by the Commission, provided that the Review Panel shall not exceed fifteen (15) members and that in the ordinary course no more than two (2) members may be residents of any single Member State.
(iii) During any interim period in which fewer than five (5) Member States have appointed Commissioners, the Commission may:
(A) Constitute the Review Panel with not fewer than seven (7) members, provided that at least five (5) members are clinicians and at least two (2) members are attorneys, and provided further that the Commission shall appoint additional members to bring the Review Panel to nine (9) members as soon as practicable; and
(B) Temporarily waive the per-state residency limitation applicable to Review Panel members, solely to ensure the operational capacity of the Review Panel. Any such waiver shall be time-limited and shall expire automatically upon the appointment of Commissioners by five (5) or more Member States.

(b) Panel members shall be appointed by majority vote of the Commission for staggered terms of four (4) years and may be reappointed. The Commission shall ensure geographic and specialty diversity among Panel members.
(c) The Review Panel shall perform the following functions for claims arising from vaccine administrations in Member States:
(i) Review claims and issue binding determinations as to whether an injury qualifies as a "Table Injury" under the Uniform Vaccine Injury Table established in subsection (5)(e).
(ii) For injuries not listed in the Uniform Vaccine Injury Table ("Non-Table Injuries"), evaluate medical evidence and issue findings regarding whether the injury was caused by vaccine administration according to standards established by the Commission.
(iii) Issue "Certifications of Coverage" that are binding upon Member States' respective Departments of Health, certifying that:
(A) The vaccine administration constituted "covered vaccine administration" under the law of the Member State where the vaccine was administered;
(B) The injury qualifies as a Table Injury or causally related Non-Table Injury; and
(C) The claimant is eligible for compensation from the applicable Member State fund or pooled fund.
(iv) Issue advisory recommendations regarding appropriate compensation amounts, taking into account the compensation schedules and standards of the Member State where the injury occurred.
(d) Determinations and Certifications issued by the Review Panel regarding Table Injury status, causation, and coverage eligibility shall be binding upon Member States' respective Departments of Health, subject to the appeal rights set forth in subsection (5)(f).
(e) The Commission shall adopt and maintain a Uniform Vaccine Injury Table based on current medical and scientific consensus.
(i) The Uniform Vaccine Injury Table shall identify:
(A) Specific vaccines and immunizing agents;

(B) Injuries, disabilities, illnesses, and conditions for which medical and scientific evidence demonstrates a causal relationship with such vaccines; and

(C) Time periods within which the first symptom or manifestation of onset of each injury must occur after vaccine administration to qualify as a Table Injury.

(ii) The Uniform Vaccine Injury Table shall be based on authoritative medical evidence and shall be reviewed and updated at least annually. Amendments to the Table shall require approval by two-thirds vote of the Commission.

(f) The Commission shall establish uniform standards for determining causation of Non-Table Injuries, which shall be based on current medical and scientific evidence. These standards shall govern the Review Panel's causation determinations but shall not supersede Member State law regarding standards of care or provider liability.

(g) The Uniform Vaccine Injury Table and causation standards established under this subsection relate solely to medical facts regarding vaccine-related injuries and compensation eligibility.

(i) Nothing in this subsection shall be construed to:

(A) Establish, modify, or interpret the "Recognized Medical Guidelines" or clinical standard of care applicable in any Member State;

(B) Determine whether a healthcare provider complied with the applicable standard of care;

(C) Create admissible evidence of negligence, deviation from medical guidelines, or breach of the standard of care in any civil action or professional discipline proceeding; or

(D) Supersede any Member State's authority to define "Recognized Medical Guidelines" under Section 3 of this Act.

(ii) Determinations regarding whether a healthcare provider complied with "Recognized Medical Guidelines" for purposes of immunity under Section 5 and safe harbor under Section 6 shall be made solely under the law of the Member State where the vaccine was administered.

(h) The Commission shall adopt uniform procedures for:

(i) Filing of claims on standardized forms;

(ii) Submission of medical records and expert reports;

(iii) Conduct of Review Panel hearings (which may be conducted remotely);

(iv) Issuance of written determinations with findings of fact and conclusions;

(v) Timelines for Review Panel action (target of ninety (90) days from receipt of complete claim); and

(vi) Protection of confidentiality in accordance with applicable federal and state privacy laws.

(i) Member States participating in the Compact hereby authorize and direct their respective Departments of Health to share patient-specific medical information, vaccination records, and claim-related documentation with the Review Panel and Commission staff as necessary to adjudicate claims, in accordance with subsection (3) (Public Records, Confidentiality, and Privacy).

(7) **[Multi-State Table Injury Compensation Pool.]**

(a) Member States that elect Tier 2 participation hereby establish the Multi-State Table Injury Compensation Pool ("Table Injury Pool"), which shall function as a shared risk pool for compensating Table Injuries as defined in the Uniform Vaccine Injury Table.

(b) The Table Injury Pool shall provide compensation for Table Injuries arising from covered vaccine administration occurring within the territory of a Member State participating in Tier 2.

(c) The Commission shall establish and maintain the Table Injury Pool as a separate trust fund, segregated from general funds of any Member State and from other Compact funds. The Table Injury Pool shall be used solely for:
    (i) Payment of compensation for Table Injuries to eligible claimants;
    (ii) Administrative costs directly attributable to Table Injury claims processing;
    (iii) Actuarial services and medical expert review for Table Injury determinations; and
    (iv) Maintenance of required reserves as determined by independent actuarial analysis.

(d) All funding sources collected within a Member State for purposes of funding Table Injury Pool contributions shall apply equally and neutrally to all entities conducting business within that Member State, without regard to the state of incorporation, principal place of business, or domicile of such entity, and shall be assessed solely based on the entity's business activity within that Member State.

(e) After a claim has satisfied the preliminary federal program applicability requirements set forth in Section 17, upon issuance of a Certification of Coverage by the Review Panel for a Table Injury, the Commission shall authorize payment of compensation from the Table Injury Pool according to:
    (i) Uniform compensation schedules adopted by two-thirds vote of the Commission, with adjustments for state-specific cost-of-living differences; or
    (ii) If the Member State where the injury occurred maintains supplemental compensation standards more generous than the uniform schedule, the Certification of Coverage shall also authorize payment of such supplemental amounts, which shall be paid from that Member State's standalone fund established under Section 9 (if any), in accordance with that Member State's law and procedures.

(f) The Review Panel shall adjudicate only claims that have satisfied the preliminary federal program applicability requirements set forth in Section 17 and shall have no authority to determine the scope or applicability of the applicable federal program.

(g) Compensation from the Table Injury Pool shall be available for the categories of damages authorized under Section 9(5) of this Act, as applicable, subject to caps and schedules adopted by the Commission.

(h) For all purposes under Section 9 of this Act, including exclusive remedy, offsets, subrogation, caps, and finality, an award paid pursuant to a Certification of Coverage from the Table Injury Pool shall be deemed an award paid by that Member State under Section 9, regardless of whether the payment is made from a State Fund or a Pooled Fund.

(i) Acceptance of compensation from the Table Injury Pool shall have the same legal effect as acceptance of compensation from a Member State fund under Section 9, including exclusive remedy, offsets, and subrogation.

(j) A Member State participating in Tier 2 may, but is not required to (as determined by that Member State's legislature):
    (i) Merge its standalone State Vaccine Injury Compensation Fund (if any) into the Table Injury Pool, with assets and liabilities transferred;
    (ii) Maintain its standalone State Vaccine Injury Compensation Fund as a supplemental fund for injuries not covered by the Uniform Vaccine Injury Table or for supplemental compensation amounts exceeding the uniform schedule; or
    (iii) Dissolve its standalone State Vaccine Injury Compensation Fund and rely exclusively on the Table Injury Pool.

(8) **Tier 3: Multi-State Excess Coverage Pool**

(a) Member States that elect Tier 3 participation hereby establish the Multi-State Excess Coverage Pool (the "Excess Pool"), which shall function solely as a catastrophic, multi-state reinsurance mechanism for liability arising from covered vaccine administration. The Excess Pool is intended

to supplement, and not replace, excess liability coverage provided under Member State law, including coverage provided pursuant to Section 10 of this Act or equivalent state law.

(b) The Excess Pool shall attach only with respect to amounts of liability exceeding the Uniform Attachment Threshold of One Million Dollars ($1,000,000) per claim arising from covered vaccine administration.

(c) As a condition of Tier 3 participation, each Member State shall retain responsibility, under its own law, for excess liability coverage up to the Uniform Attachment Threshold specified in subsection (b).

(d) Nothing in this Compact shall be construed to relieve any Member State of responsibility for liability amounts below the Uniform Attachment Threshold, including amounts covered pursuant to Section 10 of this Act or equivalent state law.

(e) Amounts of liability below the Uniform Attachment Threshold shall not be the personal responsibility of any healthcare provider or healthcare facility solely by reason of Tier 3 participation or a Member State's election to participate in the Excess Pool.

(f) The Excess Pool shall provide coverage for amounts exceeding the Uniform Attachment Threshold up to a Maximum Multi-State Excess Coverage Limit, initially set at Five Million Dollars ($5,000,000) per claim.

(g) The Commission may, by a two-thirds vote and based on independent actuarial analysis, adjust the Maximum Multi-State Excess Coverage Limit prospectively, provided that no such adjustment shall apply to claims arising from vaccine administrations occurring before the effective date of the adjustment.

(h) Nothing in this subsection shall be construed to prohibit a Member State from:

  (i) Maintaining or establishing an excess liability threshold under state law that is lower than the Uniform Attachment Threshold;

  (ii) Providing excess liability coverage under state law that exceeds the Uniform Attachment Threshold or the Maximum Multi-State Excess Coverage Limit; or

  (iii) Providing supplemental coverage using state funds or other lawful mechanisms.

(i) Payments from the Excess Pool shall be made solely for the purpose of indemnifying Member States, healthcare providers, or healthcare facilities for excess liability amounts and shall not create any direct right of payment to claimants.

(j) For claims by providers having provided covered vaccine administration within Tier 3 Member States:

  (i) Coverage up to the Uniform Attachment Threshold shall be paid from the Member State's standalone Excess Vaccine Liability Fund, if maintained.

  (ii) Coverage exceeding the Uniform Attachment Threshold shall be paid from the Excess Pool, up to the Maximum Multi-State Excess Coverage Limit.

(k) The Commission shall establish and maintain the Excess Pool as a separate trust fund, segregated from all other Compact funds and Member State funds. The Excess Pool shall be used solely for:

  (i) Payment of excess liability above the Uniform Attachment Threshold;

  (ii) Administrative costs directly attributable to excess claims processing;

  (iii) Reinsurance premiums or risk transfer arrangements (if any); and

  (iv) Maintenance of required reserves as determined by independent actuarial analysis.

(9) **Withdrawal from the Compact.**

(a) Any Member State may withdraw from the Compact, in whole or from specific participation tiers, by enacting legislation expressing the state's intent to withdraw and providing written notice to the Commission and all other Member States.

(i) Withdrawal from any tier of the Compact requires two (2) years written notice. The withdrawal shall be effective on the last day of the fiscal year following the expiration of the notice period.

(ii) A notice of withdrawal may be rescinded at any time prior to its effective date by written notice to the Commission and all other Member States, and upon rescission the withdrawal shall be deemed null and void as if no notice had been given.

(b) A withdrawing Member State shall remain liable for:

(i) All administrative assessments and pool contributions owed through the effective date of withdrawal;

(ii) Its proportionate share of all claims filed before the effective date of withdrawal that are approved for payment after withdrawal, calculated according to the contribution formula in effect at the time the claims were filed; and

(iii) Its proportionate share of any unfunded actuarial liabilities in pooled funds from which it is withdrawing, to be paid over a period not exceeding five (5) years as determined by independent actuarial analysis.

(c) If a Member State withdraws from a pooled fund (Tier 2 or Tier 3) that has surplus reserves at the time of withdrawal, the withdrawing Member State shall receive its proportionate share of such surplus, as determined by an independent actuarial valuation conducted as of the effective date of withdrawal, net of incurred-but-not-reported claims and appropriate contingency reserves.

(i) Such surplus shall be paid in equal annual installments over a period of five (5) years, unless the Commission determines, based on actuarial analysis, that an accelerated payment schedule will not materially impair the actuarial soundness of the pooled fund.

(d) Claims filed for covered vaccine administrations within a withdrawing Member State:

(i) Before the effective date of withdrawal shall continue to be processed by the Review Panel;

(ii) On or after the effective date of withdrawal shall be processed according to the administrative procedures of the withdrawing Member State.

(e) For purposes of this Section, a claim shall be deemed “filed” on the date it is formally submitted to the Review Panel or other designated adjudicatory authority in accordance with applicable procedures, and not on the date of injury or accrual.

(f) Any determinations or Certifications of Coverage issued by the Review Panel prior to the effective date of withdrawal shall remain valid and binding upon the withdrawing Member State for purposes of payment and administration of claims.

(g) Withdrawing Member States shall continue to provide the Commission with access to necessary medical records and documentation for claims filed before withdrawal.

(h) A Member State that has withdrawn from the Compact may re-enter by enacting new legislation adopting this Section, subject to:

(i) Approval by two-thirds vote of the Commission;

(ii) (ii) Payment of any outstanding financial obligations from prior membership;

(iii) Satisfaction of actuarial and financial stability requirements established by the Commission; and

(iv) Such other conditions as the Commission may reasonably impose.

(i) Withdrawal from the Compact shall not affect the provider protections under Sections 4 through 8 of this Act, which shall remain in full force and effect. The withdrawing Member State shall continue to administer its standalone funds (if any) under Sections 9 and 10 using internal resources or third-party contractors.

(j) Notwithstanding the foregoing, a Member State may not withdraw from Tier 3 participation during any period in which the Commission has formally determined, based on independent actuarial analysis, that the Multi-State Excess Coverage Pool is subject to

heightened catastrophic risk or reserve insufficiency. Any such restriction shall apply only for the duration specified in the actuarial determination and shall not exceed one (1) year unless renewed by a subsequent actuarial determination.

(10) **Dissolution of the Compact.**

(a) The Compact shall automatically dissolve if fewer than two (2) Member States remain, effective on the date the second-to-last Member State's withdrawal becomes effective.

(b) The Member States may voluntarily dissolve the Compact by unanimous vote of the Commission, provided that at least two (2) years written notice is provided to all Member States.

(c) Upon dissolution of the Compact:

(i) The Commission shall immediately cease accepting new claims and shall establish a wind-down plan for processing all pending claims;

(ii) All pending claims shall be transferred to the Member State of the claimant's residence (or, if the claimant is not a resident of a Member State, the Member State where the injury occurred) for processing under that Member State's administrative procedures within ninety (90) days of dissolution;

(iii) Pooled funds shall be distributed to Member States in proportion to their contributions, after payment of all approved claims, administrative costs, and wind-down expenses;

(iv) Any unfunded liabilities shall be allocated to Member States in proportion to their contributions, to be paid within one (1) year of dissolution;

(v) All records shall be transferred to Member States and maintained in accordance with applicable state records retention laws;

(vi) The Commission shall prepare a final accounting and report to all Member States within one hundred eighty (180) days of dissolution; and

(vii) The Commission shall be dissolved, and all employees shall be terminated with appropriate severance.

(d) If the Compact dissolves while claims are pending before the Review Panel:

(i) All pending claims shall revert to the administrative process of the Member State where the injury occurred;

(ii) Any determinations or Certifications of Coverage issued by the Review Panel before dissolution shall remain valid and binding upon all former Member States for purposes of payment and administration of claims.

(e) After dissolution, all claims arising from vaccine administrations occurring before dissolution shall be processed according to the administrative procedures of the Member State where the injury occurred, without reference to the Compact.

(11) **Preservation of State Sovereignty.**

(a) Entry into this Compact does not constitute a cession of sovereign authority, and each Member State retains complete and final authority over:

(i) Definitions of "Recognized Medical Guidelines" and medical standards of care applicable within its jurisdiction;

(ii) Determinations regarding whether healthcare providers complied with applicable medical standards for purposes of provider immunity and safe harbor;

(iii) Professional licensing and discipline of healthcare providers;

(iv) Enactment, amendment, or repeal of laws governing vaccine injury compensation;

(v) Supplemental compensation standards more generous than uniform schedules;

(vi) Tort law and civil procedure applicable within its jurisdiction; and

(vii) Authority to withdraw from the Compact as provided in subsection (9).

(b) Any Member State may, by statute or rule, provide supplemental compensation, extended time periods, or broader coverage for covered vaccine administrations in its state beyond the Uniform

Vaccine Injury Table or uniform compensation schedules, provided that such supplemental benefits are funded through:

(i) Additional contributions from that Member State to pooled funds; or

(ii) A separate supplemental state fund maintained by that Member State.

(c) No Member State shall have joint or several liability for the obligations of any other Member State or for pooled funds it has not elected to join. Each Member State's liability is limited to:

(i) Its proportionate contributions to pooled funds it has elected to join;

(ii) Its share of administrative assessments under Tier 1; and

(iii) Wind-down obligations in the event of withdrawal or dissolution as specified in subsections (9) and (10).

(d) The Commission is an interstate governmental entity created by this Compact and is not an agency, instrumentality, or political subdivision of any Member State.