



OHIO LEGISLATIVE SERVICE COMMISSION

Bill Analysis

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BILL SUMMARY

Compact establishment

- Enacts into law the Solemn Covenant of the States ("Compact"), an interstate compact intended to award prizes for curing diseases.
- Provides that the Compact becomes effective and binding upon enactment into law by two states.
- Provides that upon enactment by six states, the governing Solemn Covenant of States Commission ("Commission") is established and the Compact becomes binding and effective as to any other state that enacts it into law.
- Grants the Commission the power to review treatments for the cure of diseases specified by the Commission, to award prizes for successful cures, and to make treatments widely available for use.

Cure prize process

- Requires the Commission to establish criteria for defining and classifying diseases for which prizes will be awarded, which must include at least ten major diseases, determined by its severity, survival rate, and public health and treatment expenses.
- Requires the Commission to adopt criteria for a successful treatment, which must include a 95% survival rate through at least five years after treatment has ended, and no more than one year of treatment.
- Requires the list of diseases to be updated every three years.

- Requires the five-year public health expenses for each disease in each compacting state to be published and updated every three years.
- Requires the prize amount for each cure to be equal to (1) the most recent estimated total five-year savings in public health expenses for the disease in all compacting states, (2) money donated by others intended for the prize, and (3) any other factors the Commission finds appropriate.
- Requires the Compact to adopt and publish rules that establish a common set of ethical standards that embodies the laws and restrictions in each of the 50 states.
- Requires that in order for an entity to be eligible to claim a prize, the entity must not have violated any of the ethical standards in any one of the 50 states that are in effect at the time that the research is done, regardless of whether the states have joined the Compact.
- Requires the Compact to annually review all state laws to determine if any additional ethical standards have been enacted by any of the 50 states and the federal government.
- Requires the Compact to adopt and publish updated ethics rules to reflect new state laws.
- Provides that updated rules must not take effect in cure criteria for a period of three years, in order to allow researchers to have sufficient notice.
- Requires an opportunity for rejected cure submissions to be appealed not later than 30 days after rejection.
- Requires the Commission to continue to monitor and review a treatment even after it has been accepted.
- Allows the Commission to modify or withdrawal approval of a treatment, or to rescind a prize offer, for not meeting cure criteria.
- Requires a two-thirds favorable vote from all members for a cure approval to be effective.
- Requires the prize winner to transfer the patent and all related intellectual property for a treatment to the Commission in exchange for the prize.
- Requires the Commission, upon acceptance of a cure, to obtain a loan that is equal to the most recently calculated total estimated five-year public health expenses for the disease in all compacting states.



- Requires each compacting state to annually pay its actual one-year savings in public health expenses for the disease for which a cure has been accepted, until it has fulfilled its prize responsibility.
- Allows a state to meet its prize responsibility by any method including the issuance of (1) revenue bonds and obligations or (2) general obligation bonds and other debt.
- Declares that revenue bonds and obligations are not a debt of the issuing state.
- Provides that a state entering into the Compact, except to the extent authorized by the compacting state's laws, does not (1) commit the full faith and credit or taxing power of the compacting state for the payment of prizes or (2) make prize payment responsibilities a debt of the compacting state.
- Grants the Commission the power to make a treatment widely available, including arranging for its manufacture, production, or provision of the treatment.
- Allows the Commission to collect royalty fees on manufacturers, producers, or providers in noncompacting states or foreign countries, as long as the fees are not more than the estimated five-year savings in public health expenses for that state or country.
- Allows the Commission to pay or reimburse expenses related to payment of the prize with royalty fees collected, which include hiring actuaries and making interest payments.

General powers

- Establishes several powers of the Commission, including the ability to adopt bylaws and rules, make hiring decisions, manage property, enforce compliance by compacting states, make amendments to the Compact, and more.

Organization

- Requires the Commission to establish bylaws providing for various administrative procedures, including voting, appointing and electing members, committees, election of officers, personnel policies, and more.

Membership

- Allows any state, district, or territory of the United States and the federal government to become a compacting state.
- Allows foreign countries or its subdivisions to join as nonvoting liaison members.



- Provides that each compacting state is represented by one member, with each state determining its member's qualifications and period of service.
- Requires each compacting state to pay annual dues.
- Provides that compacting states have no claim to property held by the Commission.

Meetings and voting

- Requires the Commission to have meetings and take actions consistent with the Compact, with a majority of members constituting a quorum.
- Provides that each member has the right to cast one vote regarding the Commission's actions or matters, and to participate in the business and affairs of the Commission.
- Allows members to vote in person or by other means, which may include telephone.
- Requires the Commission to meet at least once per year, with additional meetings to be held pursuant to the bylaws.
- Requires the bylaws to provide a list of matters about which the Commission may enter into executive session.

Finances

- Grants the Commission the power to establish a budget and make expenditures, borrow money, establish annual dues, and allocate a portion of these funds towards prize amounts.
- Allows the Commission to accept contributions to fund initial operations, as long as the independence of the Commission's performance is not compromised.
- Grants the Commission the power to accept donations, as long as it avoids the appearance of impropriety.
- Requires donations to be kept in a separate, interest-bearing account.
- Exempts the Commission from taxation in and by the compacting states.
- Provides for the Commission to undergo an annual financial audit and a management and performance audit at least every three years.



Committees

- Grants the Commission the power to appoint committees, including management, legislative, and advisory committees, which may include members, state legislators (or their representatives), medical professionals, and other interested persons.
- Provides that the management committee may consist of no more than 14 members when 26 states enact the Compact, and must consist of members representing states whose total public health expenses of all the established diseases are the highest.
- Requires the management committee to exercise various managerial responsibilities, including managing day-to-day affairs, overseeing the Commission's offices, and coordinating with other governmental entities.
- Requires the Commission to annually elect officers for the management committee, and allows the committee to hire an executive director to administer committee operations and to serve as the Commission's secretary.
- Grants the Commission the ability to appoint advisory committees to monitor all operations related to the Compact's purposes and to make recommendations to the Commission.
- Requires the Commission to consult with an advisory committee before approving cure criteria, changing the bylaws or rules, adopting an annual budget, or addressing any other significant matter.

Compliance and default

- Requires the Commission to notify any compacting state of any noncompliance of Compact bylaws and rules.
- Provides that any state that fails to fix its noncompliance will be deemed in default, which triggers notice and hearing.
- Provides that if the Commission determines that the state is in default, after the hearing, the state would be suspended from the Compact.
- Provides that if a compacting state fails to cure the default within a specified amount of time, the state would be expelled from the Compact.

Withdrawal

- Allows compacting state to withdraw from the Compact by: (1) repealing the enabling law, and (2) notifying the Commission in writing of the intent to withdraw



on a date that is (a) at least three years after the date the notice is sent, and (b) after the repeal takes effect.

- Provides that a withdrawing state remains liable for all responsibilities incurred through the effective date of the withdrawal.
- Allows reinstatement by a withdrawing state by re-enacting legislation for the Compact.

Dissolution

- Provides that the Compact dissolves on the effective date the (1) withdrawal or expulsion of a compacting state, which action reduces Compact membership to one state, or (2) Commission votes to dissolve the Compact.
- Requires the Commission, through its bylaws, to adopt a mechanism for winding up Compact operations and provide for equitable distribution of surplus funds remaining after payment of debts and obligations.

Records

- Requires the Commission to prescribe bylaws and rules regarding records, including public inspection and copying of information, procedures for sharing records otherwise exempt from disclosure, and guidelines for entering into agreements with federal and state agencies to receive or exchange records subject to nondisclosure.
- Requires the Commission to keep, in accordance with its bylaws and rules, complete and accurate accounts of its internal receipts, including grants and donations, and disbursement of all funds.
- Provides that any compacting state's laws regarding confidentiality and nondisclosure do not relieve any member of its duty to disclose records relevant to the Commission (with an exception for privileged records).
- Provides that confidential information that the Commission holds remains confidential after it is provided to any member and that all cure submissions are confidential.

Annual report to governors/legislatures

- Requires the Commission to make an annual report to the governors and legislatures of the compacting states, which report must include a report of the independent audit.



Legal actions and disputes

- Grants the Commission the power to bring and prosecute legal proceedings in its name, and to issue subpoenas.
- Grants the Commission the power to provide for dispute resolution among compacting states or between the Commission and those who submit cures for consideration.
- Requires as part of its dispute resolution proceedings, administrative review by a review panel, judicial review of decisions issued after an administrative review, qualifications to be appointed to a panel, and due process requirements.
- Provides that the venue for any judicial proceedings by or against the Commission must be brought in the court of competent jurisdiction for the geographical area in which the Commission's principle offices are located.
- Provides for the following regarding the Commission's members and staff for claims arising out of actual or alleged actions occurring within the scope of that person's official duties, as long as claims are not caused by intentional or willful and wanton misconduct:
 - They are immune from liability;
 - That the Commission must defend them in any civil action arising out of such actions;
 - That the Commission will indemnify them and hold them harmless for the amount of any settlement or judgment obtained against that person.

Amendments, severability, and construction

- Provides that the Commission may propose any amendment to the Compact and that no amendment will become effective until all compacting states have enacted it into law.
- Provides that the Compact's provisions are severable and that they must be liberally construed to effectuate its purpose.

Compact binding effect and other laws

- Specifies that nothing in the Compact's provisions prevents the enforcement of any other law of a compacting state, provided that all agreements between the



Commission and compacting states and all lawful actions by the Commission are binding.

- Allows the Commission to issue advisory opinions in a dispute over the meaning or interpretation of Commission actions, upon the request of a party and a majority vote of compacting states.
- Provides that if any provision of the Compact is unconstitutional in any compacting state, that provision becomes ineffective for that state.

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CONTENT AND OPERATION

Compact establishment

The bill enacts into law, in section 3799.01 of the Revised Code, the Solemn Covenant of the States to Award Prizes for Curing Diseases ("Compact"), which is an interstate compact intended to award prizes for curing diseases. The Compact becomes effective and binding upon enactment into law by two Compacting states. Once six states enact the Compact, the governing Solemn Covenant of States Commission ("Commission") is established and the Compact becomes binding and effective on any other state that enacts the Compact into law. The Commission is a body corporate and politic and an instrumentality of each of the compacting states. The Commission is also solely responsible for the Compact's liabilities.¹

Generally, the Commission has the power to receive and review in an expeditious manner treatments and therapeutic protocols for the cure of diseases specified by the Commission, and to award prizes for submissions that meet the Commission's standards for a successful cure treatment and therapeutic protocol.² Upon acceptance of a successful cure treatment or therapeutic protocol, the Commission will make the treatment widely available.³ (See "**Cure prize process**," below.)

Cure prize process

Prize creation

The Commission must adopt rules establishing criteria for defining and classifying the diseases for which prizes will be awarded. In doing so, it may consult the most recent edition of the International Classification of Disease, as published by the World Health Organization, or other definitions agreed to by a two-thirds vote of the Commission.⁴

The Commission must adopt rules regarding prizes for curing diseases that establish the following:

¹ Art. I.1.2, II.1 and 2; Art. XIII.1 and 2.

² Art. III.2.

³ Art. III.3.

⁴ Art. VI.2.



- At least ten major diseases for which to create prizes, which must be determined by (1) the severity of the diseases to an individual's overall health and well-being, (2) the survival rate or severity of impact of the disease, and (3) the public health expenses and treatment expenses for the disease.
- The criteria for a treatment or therapeutic protocol to be considered a cure for any of the diseases for which a prize may be awarded, which include: (1) a 95% survival rate through at least five years after the treatment or protocol has ended, and (2) no more than one year of treatment.
- The procedure for determining the diseases for which to award prizes, which includes the option to award prizes for more than ten diseases that meet the above criteria, if agreed to by two-thirds of the Commission;
- A requirement to update the list every three years;
- The submission and evaluation procedures and guidelines, including filing and review procedures, and limitations preventing public access to treatment or protocol submissions;
- The estimated five-year public health expenses for each disease in each compacting state, and a procedure to update these expenses every three years. The expenses must be calculated, estimated, and publicized every three years by actuaries employed or contracted by the Commission.
- The prize amount for cures to each disease, which must be equal to the most recent estimated total five-year savings in public health expenses for the disease in all compacting states, amounts donated by charities, individuals, and any other entities intended for the prize, and any other factors the Commission deems appropriate.⁵

"Public health expenses" is defined as the amount of all costs paid by taxpayers in a specified geographic area relating to a particular disease.⁶

Ethical standards

The Compact, recognizing that its goal is to pool the potential savings of as many states and countries as possible to generate sufficient financial incentive to develop a

⁵ Art. VI.3(a) to (f).

⁶ Art. I.4.

cure for many of the world's most devastating diseases, must also adopt rules that establish a common set of ethical standards that embody the laws and restrictions in each state of the United States. The Compact must publish these common ethical standards along with the specific criteria for a cure for each of the diseases that the Compact has targeted.

In order to be eligible to claim a prize, the entity submitting a cure must not have violated any of the ethical standards in any one of the 50 states, regardless of whether the states have joined the Compact. As long as a researcher follows the common ethical standards in effect at the time that the research is done, an entity presenting a cure will be deemed to have followed the standards.

On or before January 1 of each year, the Compact must review all state laws to determine if any additional ethical standards have been enacted by any of the 50 states and the federal government. Any changes to the common ethical standards rules based on new state laws must be adopted and published by the Compact, but must not take effect in cure criteria for a period of three years, so that researchers have sufficient notice (see **COMMENT 1**).⁷

Review of submissions and selection of winner

The Commission must adopt rules that provide a process for the Commission to review submitted treatments and therapeutic protocols for curing diseases that includes the following:

- An opportunity for appeal, not later than 30 days after a rejection of a treatment or protocol for prize consideration, to a review panel established under the Commission's dispute resolution process (see "**Dispute resolution**," below);
- Commission monitoring and review of treatment and protocol effectiveness consistent with cure criteria established by the Commission for the particular disease;
- Commission reconsideration, modification, or withdrawal of approval of a treatment or protocol for prize consideration for failure to continue to meet the cure criteria established by the Commission for the particular disease.⁸

⁷ Art. VI.5. A corrective amendment may be helpful to clarify that the Commission, rather than the Compact, must adopt, publish, and review rules.

⁸ Art. VI.4(b).



A decision regarding the approval of an award for a successful treatment or therapeutic process will be effective only if two-thirds of all members vote in favor of approval.⁹

The Compact also requires the adoption of rules that require a prize winner to transfer to the Commission the patent and all related intellectual property for a treatment or therapeutic protocol in exchange for the prize. A prize will be awarded only to the first person or entity that submits a successful cure for a particular disease.¹⁰

Awarding the prize

Upon the acceptance of a cure, the Commission must obtain a loan from a financial institution that is equal to the most recently calculated total estimated five-year public health expenses for the disease in all compacting states in order to award the prize amount.¹¹ Each compacting state must then annually pay the compacting state's *actual* one-year savings in public health expenses for the disease for which a cure has been accepted. The compacting state must continue to make annual payments until it has fulfilled its prize responsibility. Each compacting state's payment responsibility begins one year after the date the cure becomes widely available. The Commission must employ or contract with actuaries to calculate each state's actual one-year savings in public health expenses at the end of the year to determine each state's responsibilities for the succeeding year.¹² In addition, the Commission retains the right to continuously evaluate the cure in the interim and rescind a prize offer if the Commission finds the cure no longer meets the Commission's criteria.¹³

Issuing debt to pay prize

A compacting state can meet its prize responsibility by any method, including the issuance of bonds or other obligations.

Revenue debt

If revenue bonds or obligations are issued to pay the prize responsibility, repayment of the principal and interest of those bonds or obligations must be made from revenue derived from the estimated public health expense savings from a cure to

⁹ Art. IV.6.

¹⁰ Art. VI.3(g)(i).

¹¹ Art. VI.3(g)(vi).

¹² Art. VI.3(g)(iii).

¹³ Art. VI.3(g)(vi).

the disease. If the compacting state does not make such revenue available to repay some or all of the revenue bonds or obligations issued, the owners or holders of those bonds or obligations have no right to have excises or taxes levied to pay the principal or interest on them. The revenue bonds and obligations are not a debt of the issuing state.¹⁴

General obligation debt

A compacting state may issue general obligation bonds or other debt that are general obligations, under which the full faith and credit, revenue, and taxing power of the state is pledged to pay the principal and interest under those obligations, only if authorized by the compacting state's constitution or, if constitutional authorization is not required, by other law of the compacting state.¹⁵

Payment limitations

The Compact provides that, except to the extent authorized by the compacting state's constitution or, if constitutional authorization is not required, by other law of the compacting state, the state, by entering into the compact, does not: (1) commit the full faith and credit or taxing power of the compacting state for the payment of prizes or other obligations under the Compact, or (2) make prize payment responsibilities or other obligations under the compact a debt of the compacting state. This provision exists to prevent states from incurring debt in a manner that violates the state's constitution.¹⁶

Licensing, dispensing, and royalty fees

Under the Compact, the Commission has the power to make a cure treatment or therapeutic protocol widely available, including by arranging or contracting for the manufacturing, production, or provision of any drug, serum, or other substance, device, or process.¹⁷ The Commission may also establish and collect royalty fees imposed on manufacturers, producers, and providers in noncompacting states or foreign countries of any drug, serum, or other substance, device, or process used for a cure treatment or therapeutic protocol. However, royalty fees for a particular state or country must cumulatively not be more than the estimated five-year savings in public health expenses

¹⁴ Art. VI.3(g)(iv).

¹⁵ Art. VI.3(g)(v).

¹⁶ Art. XVI.2(c).

¹⁷ Art. III.3.



for that state or country, as calculated by actuaries employed or contracted by the Commission.¹⁸

The Commission may pay or reimburse expenses related to the payment of a prize with collected royalty fees. These expenses include employing or contracting actuaries to calculate annual taxpayer savings amounts in compacting states, and payment of interest and other expenses related to a loan obtained for prize payment. The Commission may also annually disburse any amounts remaining after making payments or reimbursements as refunds to compacting states based on the percent of the state's prize obligation in relation to the total obligation amount of all compacting states.¹⁹

General powers

The Compact establishes several powers of the Commission. Among them includes the ability to adopt bylaws and rules, which have the force and effect of law and would be binding in the compacting states.²⁰ Bylaws must be approved by a majority vote of all Commission members. Notwithstanding any civil service or other similar laws of a compacting state, the Commission's bylaws must exclusively govern the Commission's personnel policies and programs.²¹ Rules must be adopted to effectively and efficiently achieve the purposes of the Compact.²² The Model State Administrative Procedure Act of 1981 by the Uniform Law Commissioners, as amended, governs rulemaking procedures, to the extent the Model Act is appropriate to Commission operations.²³ Rules that exceed the Commission's rule-making authority will be invalid.²⁴ Rules may be amended as the Commission sees necessary.²⁵

The Commission also has the following powers:

- To establish and maintain offices;

¹⁸ Art. III.4.

¹⁹ Art. III.5.

²⁰ Art. III.1.

²¹ Art. V and V.7.

²² Art. VI.1.

²³ Art. VI.7.

²⁴ Art. VI.8.

²⁵ Art. VI.6.



- To borrow, accept, or contract for personnel services, including personnel services from a compacting state's employees;
- To determine qualifications of and hire employees, professionals, or specialists; and elect or appoint officers;
- To fix compensation, define duties, and provide appropriate authority for employees, professionals specialists, and officers to carry out the purposes of the Compact;
- To establish personnel policies and programs relating to conflict of interest, rates of compensation, qualifications of personnel, and other related policies;
- To lease, purchase, or accept appropriate gifts or donations, or hold, own, improve, or use any real or personal property, as long as the Commission strives to avoid any appearance of impropriety;
- To sell, convey, mortgage, pledge, lease, exchange, abandon, or otherwise dispose of any property;
- To monitor compacting states for compliance with the Commission's bylaws and rules;
- To enforce compliance by compacting states with the Commission's bylaws and rules;
- To adopt a corporate seal;
- To perform other functions necessary or appropriate to carry out the Compact's purposes.²⁶

The Commission has the power to propose amendments to the Compact for enactment by the compacting states. An amendment becomes effective only if all of the compacting states enact it into law.²⁷

Organization

The Commission must establish bylaws for the following:

²⁶ Art. III.8-10, 12-15, 21-22.

²⁷ Art. XIII.3.



- Guidelines and voting requirements for decisions, other than award approvals, of the Commission;
- Reasonable procedures for appointing and electing members, as well as holding meetings of the management committee (see "**Committees**," below);
- Reasonable standards and procedures for (1) establishment and meetings of other committees, (2) governing general or specific delegation of any authority or function of the Commission, and (3) voting guidelines and procedures for Commission decisions;
- Titles, duties, authority, and reasonable procedures for the election of the Commission's officers;
- Reasonable standards and procedures for establishing personnel policies and programs of the Commission;
- A code of ethics to address permissible and prohibited activities of members and employees;
- The maintenance of the Commission's books and records.²⁸

Membership

Under the Compact, any state (defined as any state, district, or territory of the United States) is eligible to become a compacting state.²⁹ The bylaws must also establish a mechanism to allow the federal government to join as a compacting state, and for foreign countries or its subdivisions to join as liaison members. Foreign countries or subdivisions, however, have no voting power or the power to bind the Commission in any way.³⁰

Each compacting state is to be represented by one member, as selected by the compacting state. The compacting state must determine its member's qualifications and period of service, and must be responsible for any action to remove or suspend its member or to fill the member's position if it becomes vacant. The Compact provides

²⁸ Art. IV.7 and V.2-3, 6-7, 9-10.

²⁹ Art. I.1 and XIII.1.

³⁰ Art. V.8.



that nothing in the Compact should be construed to affect a compacting state's authority regarding the qualification, selection, or service of its own member.³¹

Each compacting state is responsible for paying annual dues (see "**Financial responsibilities of the Commission**," below).³² No compacting state will have any claim to or ownership (1) of any property held by or vested in the Commission or (2) to any Commission funds held under the Compact's terms.³³

Meetings and voting

The Commission must meet and take actions consistent with the Compact, bylaws, and rules. The Commission must meet at least once per year, with additional meetings to be held as set forth in the bylaws. The bylaws must also provide reasonable procedures for calling and conducting meetings, ensuring reasonable advance notice of each meeting, and providing for the right of citizens to attend each meeting with enumerated exceptions designed to protect the public's interest and the privacy of individuals. A majority of the Commission members constitutes a quorum necessary to conduct business or take actions at meetings. Each member has the right and power to cast one vote regarding matters or actions of the Commission and to participate in the business and affairs of the Commission. Members may vote in person or by other means as provided in the bylaws, which may provide for participation by telephone or other means.³⁴

The bylaws must also provide a list of matters about which the Commission may go into executive session. Entering such a session would require a majority vote of all Commission members. The Commission is required to make public as soon as practicable: (1) a copy of the vote to go into executive session, revealing the vote of each member with no proxy votes allowed, and (2) the matter requiring executive session, without identifying the actual issues or individuals involved.³⁵

³¹ Art. II.3.

³² Art. III.20 and VI.4(d).

³³ Art. VIII.4.

³⁴ Art. IV.1-5 and Art. V.4.

³⁵ Art. V.5.



Finances

Financial responsibilities of the Commission

Under the Compact, the Commission has the power to establish a budget, make expenditures, borrow money, and establish annual membership dues for compacting states.³⁶ The Commission must prescribe bylaws establishing the fiscal year of the Commission, as well as governing the acceptance of and accounting for donations, annual member dues, and other sources of funding. The bylaws must also set the proportion of these funds to be allocated to prize amounts for treatments and therapeutic protocols that cure disease.³⁷ The Commission must also adopt rules that establish and impose annual dues on compacting states, which are to be calculated based on the percentage of each compacting state's population in relation to the population of all compacting states.³⁸

To fund initial operations, the Commission may accept contributions from compacting states and other sources, as long as the independence of the Commission's performance of its duties is not compromised.³⁹

Fundraising

Under the Compact, the Commission has the power to accept, use, and dispose of all appropriate donations and grants of money, equipment, supplies, materials, and services. However, the Commission must, at all times, strive to avoid any appearance of impropriety.⁴⁰ To this end, the Commission may establish bylaws governing any fundraising efforts and in which the Commission wishes to engage.⁴¹ Commission rules must require all donation amounts going towards a prize to be kept in a separate, interest-bearing account maintained by the Commission. This account is the only account in which prize money is to be kept.⁴²

³⁶ Art. III.17, 18, and 20.

³⁷ Art. V.1 and 11.

³⁸ Art. VI.4(d).

³⁹ Art. VIII.1.

⁴⁰ Art. III.11.

⁴¹ Art. V.12.

⁴² Art. VI.3(g)(ii).



Exemption from taxation

The Compact provides that the Commission is to be exempt from taxation in and by the compacting states.⁴³

Financial audits

The financial accounts and reports, including the Commission's system of internal controls and procedures are to be audited annually by an independent certified public accountant. On the Commission's determination, but not less frequently than every three years, the auditor's review shall include a management and performance audit of the Commission.⁴⁴

Sharing Commission account information

The Commission's internal accounts are not confidential and such materials may be shared with any compacting state upon request. But, any work papers related to any internal or independent audit and any information subject to the compacting states' privacy laws, must remain confidential.⁴⁵

Committees

Under the Compact, the Commission has the power to appoint committees, including management, legislative, and advisory committees comprised of members, state legislators or their representatives, medical professionals, and such other interested persons as the Commission chooses to designate.⁴⁶

Management committee

The Commission may establish a management committee comprised of no more than 14 members when 26 states enact the Compact. The committee must consist of members representing compacting states whose total public health expenses of all of the established diseases are the highest. The committee will have authority and duties established in the Commission's rules and bylaws, which include:

- Managing authority over the day-to-day affairs of the Commission, consistent with the bylaws, rules, and purposes of the Compact;

⁴³ Art. VIII.2.

⁴⁴ Art. VIII.3.

⁴⁵ Art. VIII.3.

⁴⁶ Art. III.19.



- Overseeing the offices of the Commission;
- Planning, implementing, and coordinating communications and activities with state, federal, and local government organizations in order to advance the goals of the Compact.

The Commission must annually elect officers for the committee, with each having authority and duties as specified in the bylaws and rules. The committee, subject to Commission approval, may also appoint or retain an executive director for a designated period, with terms, conditions, and compensation determined by the committee. The executive director will serve as the Commission's secretary, but cannot be a member of the Commission. The executive director may hire and supervise other staff as authorized by the committee.⁴⁷

Advisory Committees

The Commission may also appoint advisory committees to monitor all operations related to the purposes of the Compact and make recommendations to the Commission, as long as the manner of selection and term of any committee member is established in the bylaws and rules. The Commission must consult with an advisory committee, pursuant to the bylaws and rules, before doing any of the following:

- Approving cure criteria;
- Amending, enacting, or repealing any bylaw or rule;
- Adopting the Commission's annual budget;
- Addressing any other significant matter or taking any other significant action.⁴⁸

Compliance

If any compacting state is in noncompliance with the Compact's bylaws and rules, the Commission must notify the state in writing. If a compacting state fails to remedy the noncompliance within the time specified in the written notice, the compacting state will be deemed in default.⁴⁹

⁴⁷ Art. VII.1.

⁴⁸ Art. VII.2.

⁴⁹ Art. X.

Default

Grounds for default include failure of a compacting state to perform its obligations or responsibilities, and any other grounds designated in the rules. Once the Commission determines that a state has defaulted in the performance of any obligations or responsibilities, it must provide notice and hearing on the default. If after such notice and hearing it is determined that the compacting state is in default, then all rights, privileges, and benefits conferred by the Compact on the defaulting state will be suspended from the effective date of default, as fixed by the Commission. The Commission must immediately notify the defaulting state in writing of the suspension pending cure of the default, along with the conditions and time period within which the defaulting state must cure the default. If the defaulting state fails to cure the default within the specified time period, the defaulting state will be expelled, and all rights, privileges, and benefits conferred by the Compact will be terminated. An expelled state must reenact the Compact in order to become a compacting state again. Any state that is expelled remains liable for any cure prize for three years after its removal.⁵⁰

Withdrawal

A compacting state may withdraw from the compact by doing both of the following: (1) repealing the law enacting the Compact in that state, and (2) notifying the Commission in writing of the intent to withdraw on a date that is (a) at least three years after the date the notice is sent, and (b) after the repeal takes effect. This date is the effective date of the withdrawal.

The member representing the withdrawing state must immediately notify the management committee (or the Commission, if a management committee has not yet been established) in writing upon introduction of legislation in that state to repeal the Compact. The Commission or management committee must notify the other compacting states of the introduction of legislation within ten days after it receives notice.

The withdrawing state is responsible for all obligations, duties, and liabilities incurred through the effective date of the withdrawal, including any obligations, the performance of which extend beyond the effective date of the withdrawal. The Commission's actions must continue to be effective and be given full force and effect in the withdrawing state. The Commission must take appropriate legal action to ensure that any compacting state that withdraws from the Compact remains liable for its responsibility towards a prize for a cure that was accepted. A state that has withdrawn

⁵⁰ Art. XIV.2.



from the Compact can reinstate its membership on legislative re-enactment of the Compact by that state. Reinstatement is effective on the effective date of re-enactment.⁵¹

Dissolution

The Compact will dissolve effective on the date the (1) withdrawal or expulsion of a compacting state reduces Compact membership to one compacting state, or (2) Commission votes to dissolve the Compact.

On dissolution, the Compact becomes null and void and shall be of no further force or effect. The business and affairs of the Commission must be wound up and any surplus funds distributed under the bylaws. The Commission must pay, however, all outstanding prizes awarded before dissolution, as well as any other outstanding debts and obligations incurred during the Compact's existence. Any unawarded funds donated to be a part of a prize must be returned to the donor, along with any interest earned on the amount.⁵²

Under its bylaws, the Commission must provide a mechanism for winding up its operations. The bylaws must also provide for the equitable distribution of any surplus funds after the payment and reserving of all Commission debts and obligations.⁵³

Records

Under the bill, the Commission must prescribe bylaws providing for the maintenance of the Commission's books and records.⁵⁴ The Commission is also required to adopt the following rules regarding records:

- Conditions and procedures for public inspection and copying information and official records (however, records and information involving the privacy of individuals or that would otherwise violate federal and compacting states' privacy laws are exempt);
- Procedures for sharing records and information otherwise exempt from disclosure with federal and state agencies, including law enforcement;

⁵¹ Art. XIV.1. and Art. XIV.2(a).

⁵² Art. XIV.3.

⁵³ Art. V.12.

⁵⁴ Art. V.10.



- Guidelines for entering into agreements with federal and state agencies to receive or exchange information or records subject to nondisclosure and confidentiality provisions.⁵⁵

Financial records

The Commission must keep complete and accurate accounts of all of its internal receipts, including grants and donations, and disbursements of all funds under its control. The Commission's internal financial accounts are to be subject to the accounting procedures established under the Commission's bylaws or rules.⁵⁶

Confidentiality

The Compact also provides that, with the exception of privileged records, data, and information, any compacting state's laws regarding confidentiality or nondisclosure do not relieve any member of its duty to disclose any relevant records, data, or information to the Commission. However, disclosure to the Commission is not to be deemed to waive or affect any confidentiality requirement. Additionally, the Commission is not subject to the compacting state's laws regarding confidentiality and nondisclosure with respect to records, data, and information in its possession, except as otherwise provided in the Compact. Confidential information that the Commission holds must remain confidential after such information is provided to any member. The Compact also provides that all cure submissions that the Commission receives are confidential.⁵⁷

Annual report to governors/legislatures

The Commission must also make an annual report to the governors and legislatures of the compacting states, which report must include a report of the independent audit.⁵⁸

Legal actions and disputes

The Compact provides that the Commission has the power to bring and prosecute legal proceedings or actions in its name as the Commission and to issue subpoenas requiring the attendance and testimony of witnesses and the production of

⁵⁵ Art. VI.4(a)(i-iii).

⁵⁶ Art. VIII.3.

⁵⁷ Art. IX.

⁵⁸ Art. VIII.3.

evidence.⁵⁹ It also provides procedures for dispute resolution, venue, immunity, defenses, and indemnification.

Dispute resolution

The Commission has the power to provide for dispute resolution among compacting states or between the Commission and those who submit treatments and therapeutic protocols for the cure of disease for consideration. The Commission must establish in its rules, as part of this process, the following:

- Administrative review by a review panel appointed by the Commission;
- Judicial review of decisions issued after an administrative review;
- Qualifications to be appointed to a panel;
- Due process requirements, including notice and hearing procedures, and other procedures, requirements, or standards necessary to provide adequate dispute resolution.⁶⁰

Venue

The Compact provides that venue for any judicial proceedings by or against the Commission must be brought in the court of competent jurisdiction for the geographical area in which the Commission's principle office is located.⁶¹

Qualified immunity, defense, and indemnification

The Compact provides for the following regarding the Commission's members, officers, executive director, employees and representatives, for claims arising out of actual or alleged actions occurring within the scope of that person's official duties, provided that the claims are not caused by intentional or willful and wanton misconduct:

- They are immune from liability, either personally or in their official capacity;

⁵⁹ Art. III.6.

⁶⁰ Art. III.16; Art. VI.4(c)(i) to (iii).

⁶¹ Art. XI.

- That the Commission must defend them in any civil action arising out of such actions (although that person may also retain his or her own counsel);
- That the Commission will indemnify them and hold them harmless for the amount of any settlement or judgment obtained against that person.⁶²

Amendments to Compact

The Commission is authorized to propose amendments to the Compact. No amendment becomes effective, however, until all compacting states enact the amendment into law.⁶³

Severability and construction

The Compact provides that its provisions are severable. Therefore, if any phrase, clause, sentence, or provision is deemed unenforceable, the remaining provisions will remain enforceable. The Compact also provides that it must be liberally construed to effectuate its purposes.⁶⁴

Binding effect of Compact and other laws

The Compact provides that nothing in its provisions prevents the enforcement of any other law of a compacting state. However, all agreements between the Commission and the compacting states are binding in accordance with their terms. Moreover, all of the Commission's lawful actions, including its rules, are binding upon the compacting states.⁶⁵

Under the Compact, the Commission may issue advisory opinions in a dispute over the meaning or interpretation of Commission actions, upon request of a party and a majority vote of the compacting states.⁶⁶

Finally, if any provision of the Compact violates the constitution of any compacting state, the obligations, duties, powers, or jurisdiction sought to be conferred by that provision will be ineffective as to that compacting state. But, those obligations,

⁶² Art. XII.

⁶³ Art. XIII.3.

⁶⁴ Art. XV.

⁶⁵ Art. XV.1 and 2(a) and (b).

⁶⁶ Art. XV.2(d).



duties, powers, or jurisdiction must remain in the compacting state and be exercised by the agency to which they are delegated by law in effect at the time the Compact becomes effective (see **COMMENT 2**).⁶⁷

COMMENT

1. The Compact must adopt rules requiring all prize submissions to comply with each of the 50 states' laws regarding ethical standards for research. The Compact is also required to annually "review all state laws to determine if additional ethical standards have been enacted by any of the 50 states and the federal government." Any changes in state laws must be adopted and published by the Compact. But, while the Compact must review federal laws, there is no requirement that federal laws must be adopted in the Compact's rules. Additionally, it is not clear how the rules will establish common ethical standards if, for example, one state's medical research ethics laws conflict with those of another state.

2. Any provision of the Compact that exceeds the constitutional limits of a compacting state is declared to be ineffective to that state. But, the Compact provides that the obligations, duties, powers, or jurisdiction imposed by the ineffective provision are to "remain" in the state, and requires the agency to which these obligations are delegated by law in effect at the time the Compact becomes effective, to exercise those obligations. There appears to be a conflict in that a compacting state is required to recognize law that is unconstitutional and ineffective within that state.

HISTORY

ACTION	DATE
Introduced	09-12-17
Reported, H. Health	02-14-18
Re-referred by H. Rules & Reference	03-13-18
Rereported, H. Government Accountability & Oversight	03-20-18

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⁶⁷ Art. XVI.

