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## DEPARTMENT OF HEALTH

### Fetal-infant mortality review boards

- Authorizes local boards of health to establish fetal-infant mortality review boards to review fetal and infant deaths within the board's jurisdiction.
- Specifies a review board's membership, purposes, and responsibilities.
- Specifies that investigatory materials that a review board possesses are confidential and not public records, and that board meetings are not subject to Ohio's Open Meetings Law.
- Specifies that entities that submit investigatory materials to a review board, as well as board members, are immune from civil liability in connection with their responsibilities.
- Requires the Director of Health (ODH Director) to adopt rules for the establishment and operation of fetal-infant mortality review boards.

### Pregnancy-associated Mortality Review (PAMR) Board

- Establishes in the Ohio Department of Health (ODH) a Pregnancy-associated Mortality Review (PAMR) Board to identify and review all pregnancy-associated deaths for the purpose of reducing their incidence.
- Prohibits the Board from reviewing deaths under investigation or prosecution unless the prosecuting attorney agrees.
- Describes Board membership and operations, and requires the ODH Director to adopt rules concerning how the Board conducts reviews.
- Specifies that information the Board possesses is confidential and not a public record and that Board meetings are exempt from the Open Meetings Law.
- Specifies that those who submit information to the Board, as well as Board members, are immune from civil liability in connection with their responsibilities.

### Home visiting services

- Authorizes the central intake and referral system to include referrals to home visiting programs that use home visiting contractors who provide services within a community HUB that fully or substantially complies with the certification standards developed by the Pathways Community HUB Institute.
- Includes as members of the Ohio Home Visiting Consortium (1) a home visiting contractor who provides services within one or more community HUBs through a contract, grant, or agreement with the Commission on Minority Health and (2) an individual who receives home visiting services through such a contractor.

## **Substance use disorder professionals**

- Authorizes ODH to establish a loan repayment program for professionals who provide treatment and other related services to individuals with substance use disorders.
- Authorizes ODH to establish a program in which a physician who provides medication-assisted treatment in a health resource shortage area may be eligible for financial assistance.

## **Dental Hygiene Resource Shortage Area Fund**

- Eliminates the Dental Hygiene Resource Shortage Area Fund and specifies that donations for the benefit of the Dental Hygienist Loan Repayment Program instead be paid to the Dental Hygienist Loan Repayment Fund.

## **Radiation technology professionals**

- Authorizes nuclear medicine technologists and radiation therapy technologists who are certified in computed tomography (CT) to perform CT procedures.
- Makes other changes to the law governing the regulation of radiation technology professionals.

## **Examination fees**

- Requires ODH to post on its website the fee amounts for examinations administered by other entities on the Department's behalf.

## **Child Lead Poisoning Advisory Council**

- Adds four new members to and updates two member association names represented on the Child Lead Poisoning Advisory Council.

## **Lead abatement: order to vacate**

- If an owner or manager of a residential unit, child-care facility, or school is out of compliance with a lead hazard control order, requires the ODH Director or a board of health to issue an order to vacate, which prohibits the owner or manager from using that property for any purpose.
- Authorizes the Director or a board of health to request a prosecuting attorney, city director of law, village solicitor, or similar chief legal officer to commence a civil action for injunctive and other equitable relief against any person who violates an order to vacate.

## **Lead-Safe Home Fund Pilot Program**

- Requires the ODH Director to establish a Lead-Safe Home Fund Pilot Program to improve housing conditions for children by providing grants to eligible property owners for lead-safe remediation actions.
- Requires the Director to coordinate the program with the Lead Safe Cleveland Coalition.

- Requires the Director to submit a report of the program’s findings and outcomes to the Governor and the General Assembly by June 30, 2021.
- Requires the Coalition to provide ODH with documentation of the amount of private sector dollars collected, and requires ODH to distribute an equal amount, but not exceeding \$1 million in each fiscal year.

### **Ambulatory surgical facilities**

- Modifies the criteria for determining whether a facility must be licensed as an ambulatory surgical facility.
- Extends the licensing requirement to any facility located within an inpatient care building if the facility is operated by a separate entity.

### **Health care facility payments**

- Expresses the General Assembly’s intent to not have licensure requirements or exemptions affect any third-party payments that may be available for certain health care facilities.

### **Newborn screening for Krabbe disease**

- Repeals the law that limits newborn screening for Krabbe disease to a process known as “first tier testing.”

### **Newborn safety incubators (VETOED)**

- Would have exempted a law enforcement agency, hospital, or emergency medical service organization that installs a newborn safety incubator from the requirement to have staff on site under specified circumstances.

### **Occupational disease reporting**

- Eliminates the requirement that physicians report suspected occupational diseases and ailments to the ODH Director.

### **Diabetes action plan reporting cycle**

- Lengthens to three years (from two) the reporting cycle for the ODH Director to submit to the General Assembly a report detailing the prevalence of diabetes.

### **ODM access to Social Security numbers accompanying vital statistics records**

- Requires ODH’s Office of Vital Statistics to make available to the Department of Medicaid, for the purpose of medical assistance eligibility determinations, Social Security numbers that accompany birth certificates or death certificates.

## **Area training centers for nursing home employees**

- Repeals the law requiring the ODH Director to establish and supervise centers for the training of nursing home employees and to contract with other entities to operate the centers.

## **Breast and Cervical Cancer Project**

- Adds certain providers to those eligible to receive payments for services from the Breast and Cervical Cancer Project Income Tax Contribution Fund.
- Expands eligibility for screening and diagnostic services provided through ODH's Ohio Breast and Cervical Cancer Project.

## **Public Health Priorities Fund**

- Renames Ohio's Public Health Priorities Trust Fund as Ohio's Public Health Priorities Fund, eliminates the purposes for money in the fund, and instead requires the ODH Director to use the money for pressing public health needs and innovative programs and prevention strategies.
- Eliminates the prohibition on transferring money from GRF to the fund.

## **Utility Radiological Safety Board**

- Specifies that the Utility Radiological Safety Board (URSB), based on the utilities' decommissioning budgets, may make assessments for URSB operations against Ohio nuclear electric utilities that have stopped producing electricity.
- Expands the definition of "nuclear electric utility" under URSB law to include persons within Ohio engaged in the storage of spent nuclear fuel arising from the production of electricity using nuclear energy.

## **Cancer surveillance advisory board**

- Abolishes the Ohio Cancer Incidence Surveillance System Advisory Board.

## **Certificates of need**

- Requires the ODH Director to determine within 180 days whether a certificate of need (CON) application is complete.
- Modifies the time periods used by the Director in determining each county's bed need and in reviewing CON applications.
- Eliminates the second phase of the four-year CON review period during which certain beds resulting from a reduction could have been made available for redistribution.
- Establishes specific conditions for accepting CON applications in January 2020, with particular criteria to be used in granting an increase in beds in Delaware, Greene, Lake, Licking, and Medina counties.

- Creates an interim period for review of CON applications that begins October 17, 2019, and ends July 1, 2021.
- Eliminates the authority to appeal a decision by the ODH Director regarding a CON, unless the person is the CON applicant or the person who requested a reviewability ruling.
- Eliminates provisions regarding the award of attorney's fees relative to CON appeals.

### **Transfer of nursing home ownership**

- Imposes disclosure requirements on an individual who is assigned or transferred operation of a nursing home.
- Requires that before the ODH Director can issue a license authorizing the person to operate the nursing home, the person must submit documentation including the individual's financial solvency, experience, insurance coverage, and prior nursing home ownership interest.

### **Freestanding emergency departments**

- Requires a freestanding emergency department that is separate and distinct from a hospital to provide notice that identifies the facility as a freestanding emergency department.
- Requires a freestanding emergency department to use its national provider identifier on all claims for payment for health care services or goods.

### **Commission on Infant Mortality**

- Requires the Governor or the Governor's designee to serve on the Commission on Infant Mortality instead of the Executive Director of the Office of Health Transformation or the Executive Director's designee.
- Requires the Speaker of the House and the Senate President to each appoint an individual who represents children's interests to the Commission.

### **Radon mitigation specialists**

- Prohibits the ODH Director from requiring a licensed radon mitigation specialist to be physically present when radon mitigation is performed, but allows the Director to require such a specialist to be physically present immediately before and after radon mitigation is performed.

### **Resident's right to choose hospice care program**

- Adds to the bill of rights for a resident of a nursing home or residential care facility the right to choose a licensed hospice care program that best meets the resident's needs.

## **Solemn Covenant of the States to Award Prizes for Curing Diseases**

- Enacts into law the Solemn Covenant of the States to Award Prizes for Curing Diseases (“Compact”), an interstate compact.
- 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 various powers, including 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.
- Specifies how the Commission is organized, its membership, and administrative, recordkeeping, financial, and reporting requirements.
- Specifies how the Compact is to be enforced.
- 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.
- Allows a compacting state to withdraw from the Compact by: (1) repealing the Compact 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 the Compact dissolves when the Compact membership is reduced to one state or the Commission votes to dissolve it.

### **Fetal-infant mortality review boards**

(R.C. 121.22, 149.43, 3701.049, 3707.70, 3707.71, 3707.72, 3707.73, 3707.74, 3707.75, 3707.76, and 3707.77)

The act authorizes a local board of health to establish and operate a fetal-infant mortality review board, in accordance with rules the ODH Director must adopt, to review:

--Each fetal death experienced by a woman who was, at the time of the fetal death, a resident of the health district in which the board exercises authority; and

--Each death of an infant who was, at the time of death, a resident of the health district in which the local board exercises authority.

## **No reviews during criminal investigation**

The act prohibits a fetal-infant mortality review board from conducting a review of a death while an investigation of the death or prosecution of a person for causing the death is pending, unless the prosecuting attorney agrees to allow it. The law enforcement agency conducting the criminal investigation, on the investigation's conclusion, and the prosecuting attorney prosecuting the case, on the prosecution's conclusion, must notify the review board chairperson of the conclusion.

## **Membership**

If a local board of health establishes a fetal-infant mortality review board, the local board, by a majority vote of a quorum of its members, must select the review board's members. Members may include the following professionals or individuals representing the following constituencies:

- Fetal-infant mortality review coordinators;
- Board-certified obstetricians and gynecologists;
- Key community leaders from the board of health's jurisdiction;
- Health care providers;
- Human services providers;
- Consumer and advocacy groups; and
- Community action teams.

A majority of the review board members may invite additional individuals to serve on the board. The additional members must serve for a period of time determined by a majority of the members and have the same authority, duties, and responsibilities as the members. In addition, the review board, by a majority vote of a quorum of its members, must designate a chairperson.

A vacancy is to be filled in the same manner as the original appointment. A board member is prohibited from receiving any compensation or reimbursement for expenses associated with membership. A review board may work in conjunction with, or be a component of, a child fatality review board or regional child fatality review board.

A review board must convene at least once a year at the call of its chairperson.

## **Purpose**

The act specifies that a review board's purpose is to decrease the incidence of preventable fetal and infant deaths by doing all of the following:

- Assessing, planning, improving, and monitoring the service systems and broad community resources that support and promote the health and well-being of women, infants, and families;

--Recommending and developing plans for implementing local service and program changes, as well as changes to the groups, professions, agencies, and entities that serve families, children, and pregnant women; and

--Providing the Department of Health (ODH) with aggregate data, trends, and patterns regarding fetal and infant deaths.

### **Submission of information; family member participation**

Notwithstanding state confidentiality laws, the act requires an individual, public children services agency, private child placing agency, agency that provides services specifically to individuals or families, a law enforcement agency, or another public or private entity that provided services to a pregnant woman whose fetus died or an infant who died to submit to the review board copies of any record it possesses that the board requests. These records may include maternal health records. In addition, the individual or entity may make available to the board other information, documents, or reports that could be useful to the board's investigation. An exception to this requirement exists when a person is under investigation, or being prosecuted, for causing the death (unless the prosecuting attorney agrees to allow the death review).

The act permits a family member of the deceased to decline to participate in an interview as part of the review process. In that case, the review must continue without that individual's participation.

### **Confidentiality**

Except for information from a public children services agency about a child who is the subject of a child abuse, neglect, or other criminal conduct investigation under limited circumstances in continuing law, the following are confidential and exempt from the Publics Records Law: any record, document, report, or other information presented to a fetal-infant mortality review board or a person abstracting such materials on the board's behalf; statements made by board members during board meetings; all board work products, and data submitted by the board to ODH or a national infant death review database (other than the annual report required by the act, discussed below). These materials must be used by the review board and the Ohio Department of Health (ODH) only in the exercise of their proper functions. In addition, board meetings are not public meetings subject to Ohio's Open Meetings Law.<sup>57</sup>

If the materials are presented in paper form, they must be stored in a locked file cabinet. If a database is used to store the materials electronically, the database must be stored in a secure manner. All information accessible to each board member and used during a review, including information provided by the deceased's mother, must be de-identified.

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<sup>57</sup> R.C. 121.22.

The act prohibits the unauthorized dissemination of this confidential information. A violation of this prohibition is a second degree misdemeanor.

### **Immunity**

The act grants civil immunity to both:

--An individual or public or private entity providing records, documents, reports, or other information to a fetal-infant mortality review board, for injury, death, or loss to person or property that otherwise might be incurred or imposed as a result of providing these materials to a board; and

--Each review board member for injury, death, or loss to person or property that otherwise might be incurred or imposed as a result of the member's participation on the board.

### **Data reporting and annual report**

The act requires a fetal-infant mortality review board, not later than April 1 each year, to both:

--Submit to the fetal-infant mortality database maintained by ODH or a national infant death review database individual data pertaining to each fetal or infant death reviewed in that board's jurisdiction within the 12 months preceding the submission; and

--Submit to ODH a report that summarizes any trends or patterns the review board identifies.

The specific data that must be submitted, and other information the board considers relevant to a review, must be specified by the ODH Director in rules. The report, a public record, may include recommendations on how to decrease the incidence of preventable fetal and infant deaths in the board's jurisdiction and Ohio, as well as any other information the board determines should be included.

### **Rules**

The ODH Director must adopt rules to establish a procedure for fetal-infant mortality review boards to follow in reviewing a fetal or infant death. The rules must be adopted in accordance with the Administrative Procedure Act<sup>58</sup> and do the following:

--Specify the procedures that a local board of health must use to establish and operate a review board;

--Specify the data and other relevant information a review board must use when reviewing a fetal or infant death;

--Establish guidelines for a review board to follow so that information presented to it does not include anything that would permit any person's identity from being ascertained; and

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<sup>58</sup> R.C. Chapter 119.

--Specify the standards and procedures a review board must use when reporting fetal-infant mortality data to ODH's fetal-infant mortality database or a national infant death review database.

## **Pregnancy-associated Mortality Review (PAMR) Board**

(R.C. 121.22, 149.43, 3738.01, 3738.02, 3738.03, 3738.04, 3738.05, 3738.06, 3738.07, 3738.08, and 3738.09)

The act establishes in ODH a Pregnancy-associated Mortality Review (PAMR) Board. The Board is to identify and review all pregnancy-associated deaths statewide for the purpose of reducing the incidence of those deaths.

"Pregnancy-associated death" is defined as the death of a woman while pregnant or within one year of pregnancy regardless of cause.

### **No reviews during criminal investigation**

The act prohibits the PAMR Board from conducting a review of a pregnancy-associated death while an investigation of a death or prosecution of a person for causing the death is pending, unless the prosecuting attorney agrees to allow the review. The law enforcement agency conducting the criminal investigation, on the investigation's conclusion, and the prosecuting attorney prosecuting the case, on the prosecution's conclusion, must notify the Board's chairperson of the conclusion.

### **Membership; technical assistance**

All of the following apply to the PAMR Board:

Members: The ODH Director must appoint the Board's members and make a good faith effort to select members who represent all regions of Ohio and multiple areas of expertise and constituencies concerned with the care of pregnant and postpartum women.

Chairperson: The Board, by a majority vote, must select a chairperson. It may replace a chairperson.

Terms: An appointed member holds office until a successor is appointed, and the ODH Director must fill a vacancy as soon as practicable.

Compensation: Board members are to receive no compensation or reimbursement for any expenses associated with their service.

Meeting times: The Board must meet at the call of its chairperson as often as that individual considers necessary for timely completion of pregnancy-associated death reviews. The reviews must be conducted in accordance with rules the act requires the ODH Director to adopt.

Technical assistance: ODH must provide meeting space, staff services, and other technical assistance required by the Board.

## **Purpose**

The PAMR Board must seek to reduce the incidence of pregnancy-associated deaths in Ohio by:

--Promoting cooperation, collaboration, and communication between all groups, professions, agencies, and entities that serve pregnant and postpartum women and families;

--Recommending and developing plans for implementing service and program changes, as well as changes to the groups, professions, agencies, and entities that serve pregnant and postpartum women and families;

--Providing ODH with aggregate data, trends, and patterns regarding pregnancy-associated deaths using data and other relevant information specified in rules; and

--Developing effective interventions to reduce the mortality of pregnant and postpartum women.

## **Submission of information; family member participation**

Notwithstanding state confidentiality laws, the act requires an individual, government entity, agency that provides services specifically to individuals or families, law enforcement agency, health care provider, or other public or private entity that provided services to a woman whose death is being reviewed by the PAMR Board to submit to the Board a copy of any record it possesses that the Board requests. In addition, the individual or entity may make available to the Board other information, documents, or reports that could be useful to the Board's investigation. An exception to this requirement applies when a person is under investigation or being prosecuted for causing the death unless the prosecuting attorney agrees to allow the death review.

The act permits a family member of the deceased to decline to participate in an interview as part of the review process. In that case, the review must continue without that individual's participation.

## **Confidentiality**

The act specifies that any record, document, report, or other information presented to the PAMR Board, as well as all statements made by Board members during Board meetings, all Board work products, and data submitted to ODH by the Board (other than the biennial reports described below), are confidential and not public records. These materials must be used by the Board and ODH only in the exercise of their proper functions. In addition, Board meetings are not public meetings subject to Ohio's Open Meetings Law.

The act prohibits the unauthorized dissemination of this confidential information. A violation of this prohibition is a second degree misdemeanor.

## **Immunity**

The act grants immunity from civil liability, as follows:

--An individual or public or private entity providing records, documents, reports, or other information to the PAMR Board is not liable for injury, death, or loss to person or

property that might otherwise be incurred or imposed as a result of providing these materials to the Board; and

--Each Board member is not liable for injury, death, or loss to person or property that otherwise might be incurred or imposed as a result of the member's participation on the Board.

## **Report**

The PAMR Board must submit to the Governor, General Assembly, and ODH Director a biennial report that:

--Summarizes its findings from the reviews completed in the preceding three calendar years, including any trends or patterns identified by the Board;

--Makes recommendations on how pregnancy-associated deaths may be prevented, including changes that should be made to policies and laws; and

--Includes any other information related to pregnancy-associated mortality the Board considers useful.

The initial report must be submitted by March 1, 2020, and subsequent reports must be submitted by March 1 every two years. The reports are public records, and the ODH Director must make each report available on ODH's website.

## **Rules**

The ODH Director must adopt rules in accordance with the Administrative Procedure Act<sup>59</sup> that are necessary for the PAMR Board's operations, including rules that:

--Establish a procedure for the Board to follow in conducting pregnancy-associated death reviews;

--Specify the data and other relevant information the Board must use when conducting pregnancy-associated death reviews; and

--Establish guidelines to prevent unauthorized dissemination of confidential information.

## **Central intake/referral system for home visiting services**

(R.C. 3701.611)

Continuing law requires ODH to create a central intake and referral system to serve as a single point of entry for access, assessment, and referral of families to appropriate home visiting services. The act authorizes the system to include referrals to home visiting programs that use home visiting contractors who provide services within a community HUB that fully or substantially complies with the Pathways Community HUB certification standards developed by the Pathways Community HUB Institute. According to the Institute, the Pathways Community

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<sup>59</sup> R.C. Chapter 119.

HUB model focuses on the comprehensive identification and reduction of risk in a culturally connected pay-for-performance approach.<sup>60</sup>

## **Ohio Home Visiting Consortium**

(R.C. 3701.612)

The Ohio Home Visiting Consortium exists to ensure that home visiting services are high-quality and delivered through evidenced-based or innovative, promising home visiting models. The act adds as members of the Consortium (1) a home visiting contractor who provides services within one or more community HUBs described above through a contract, grant, or other agreement with the Commission on Minority Health and (2) an individual who receives home visiting services through such a contractor.

## **Substance use disorder professionals**

(Sections 737.10 and 737.11)

The act authorizes ODH to establish a loan repayment program for professionals who provide treatment and related services to individuals with substance use disorders. Under the program, ODH may agree to repay all or part of the principal or interest of an educational loan taken by a substance use disorder professional. In return, the participating professional must commit to serving in an area of the state with limited access to addiction treatment and related services.

The act also authorizes the Department to establish a program in which a physician who provides medication-assisted treatment to patients with substance use disorders in a health resource shortage area may be eligible for financial assistance. Eligible physicians are those participating in the Department's existing Physician Loan Repayment Program.

## **Dental Hygiene Resource Shortage Area Fund**

(R.C. 3702.967)

Under continuing law, ODH operates a Dental Hygienist Loan Repayment Program in cooperation with the Dentist Loan Repayment Advisory Board. The program is to provide student loan repayment for dental hygienists who agree to serve in areas designated as dental health resource shortage areas.

Law unchanged by the act authorizes the ODH Director to accept donations for the program's operations. Formerly, the Director was required to deposit donations into the state treasury to the credit of the Dental Hygiene Resource Shortage Area Fund. According to ODH staff, however, no donations were received in nearly four years. The act therefore eliminates this fund and requires that any donations be deposited to the credit of the Dental Hygienist Loan Repayment Fund, a preexisting fund.

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<sup>60</sup> Pathways Community HUB Institute, Pathways Community HUB Model Overview, available at <https://pchi-hub.com/hubmodeloverview>.

## Radiation technology professionals

(R.C. 4773.01, 4773.061, 4773.07, and 4773.08)

The act revises the law governing ODH's regulation of radiation technology professionals. First, it authorizes nuclear medicine technologists and radiation therapy technologists who are certified in computed tomography, or CT, to perform CT procedures. It also requires the ODH Director to adopt rules establishing standards for the performance of CT procedures and for the approval of national organizations that certify nuclear medicine and radiation therapy technologists in CT.

Second, it modifies the definitions of radiation technology professionals as follows:

- By adding to the definitions of general x-ray machine operator, radiation therapy technologist, and radiographer references to radiation-generating equipment;
- By specifying that radiation therapy technologists are the same as radiation therapists;
- By removing from the definitions of general x-ray machine operator and radiographer references to determining the site of radiation and replacing them with references to determining procedure positioning.

The act also clarifies that a general x-ray machine operator does not determine procedure positioning, while a radiographer does, and changes references from "radiography" to "radiology."

## Examination fees

(R.C. 3701.044)

When an entity administers an examination or evaluation on behalf of ODH, for the purpose of issuing a license, certificate, or registration or determining competency, and the entity collects and retains an examination or evaluation fee, the act requires ODH to post on its website the dollar amount of the fee. If the entity changes the fee amount, ODH must post the change to its website at least 30 days before the change becomes effective.

## Child Lead Poisoning Advisory Council

(R.C. 3742.32)

The act adds the following members to the Child Lead Poisoning Advisory Council appointed by the ODH Director to assist in developing and implementing the Child Lead Poisoning Prevention Program:

- A representative from Ohio Realtors;
- A representative of the Ohio Housing Finance Agency;
- A physician knowledgeable in lead poisoning prevention; and
- A representative of the public.

It also updates the names of two associations represented on the Council, as follows:

- The reference to Ohio Help End Lead Poisoning Coalition is changed to the Ohio Healthy Homes Network; and
- The reference to the National Paint and Coatings Association is changed to the American Coatings Association.

## **Lead abatement: order to vacate**

(R.C. 3742.18 and 3742.40)

The act requires the ODH Director or a board of health to issue an order to vacate, which prohibits the owner or manager of a residential unit, child-care facility, or school from using the property for *any purpose*, if:

- The owner or manager has failed to comply with a lead hazard control order; and
- The residential unit, child-care facility, or school has not passed a lead hazard clearance examination.

Under prior law, the Director or board could only issue an order to vacate that prohibited the owner or manager from using the property as a residential unit, child-care facility, or school.

The act also authorizes the Director or board to request a prosecuting attorney, city director of law, village solicitor, or similar chief legal officer to commence a civil action for injunctive and other equitable relief against any person who violates or is about to violate the order. The court must grant injunctive relief on a showing that the person has violated or is about to violate the order.

Under prior law, the Director could only request the Attorney General to bring a civil action for civil penalties and injunctive and other equitable relief against any person who violated any provision of the Lead Abatement Law and rules adopted under it. Prior law did not specifically provide for injunctive relief for violations of a lead hazard control order.

## **Lead-Safe Home Fund Pilot Program**

(Section 737.15)

The act requires the ODH Director to establish a two-year Lead-Safe Home Fund Pilot Program (for FY 2020 and 2021) to improve housing conditions for children by providing grants to eligible property owners for lead-safe remediation actions. The Director must enter into a cooperative agreement with the Lead Safe Cleveland Coalition. The Coalition may make certain decisions and determinations regarding the program in accordance with the program requirements specified below.

The act appropriates money in FY 2020 and FY 2021 for the pilot program, to make quarterly distributions to the Coalition. The Coalition must provide ODH with documentation that shows the amount of private sector dollars that have been collected. ODH must distribute an amount that equals the documentation but does not exceed \$1 million in each fiscal year.

The ODH Director must establish the following for the program:

- A means to solicit applicants;
- An application process;
- A process for distributing and administering the grants;
- A methodology for evaluating the eligibility of the applicants; and
- Any other procedures and requirements necessary to administer the program.

By June 30, 2021, the Director, in consultation with the Coalition, must issue a report of the program's findings and outcomes to the Governor and the General Assembly.

## **Ambulatory surgical facilities**

(R.C. 3702.30; conforming changes in R.C. 111.15, 2317.54, 3702.12, 3702.13, and 3711.12)

The act modifies the criteria to determine whether a facility must be licensed as an ambulatory surgical facility. It eliminates standards that were based on the provision of anesthesia services, application for Medicare certification, and receipt of facility fees. Instead, it bases the licensing requirement on the provision of surgical services to patients who do not require hospitalization for inpatient care and who do not receive services for more than 24 hours after admission.

With respect to the location of a facility subject to licensure, the act retains provisions that require licensure when the facility is separate from an inpatient care facility. In addition, it extends the licensure requirement to any facility operated by a separate entity within an inpatient care facility. Accordingly, the licensing requirement applies under the act as follows:

- To a facility that is separate from an inpatient care building, regardless of whether the separate building is part of the same organization as the inpatient care building;
- To a facility located within an inpatient care building, if the facility is not operated by the entity that operates the remainder of the building.

Similar to prior law, the act specifies that the licensing requirement does not extend to the offices of physicians, podiatrists, or dentists. Law unchanged by the act, however, specifies that the licensing requirement does apply to any facility that is held out to any person or government entity as an ambulatory surgical facility or similar facility by signage, advertising, or other promotional efforts.

## **Health care facility payments**

(R.C. 3702.30(E))

In addition to ambulatory surgical facilities, continuing law requires ODH to license freestanding dialysis centers, freestanding inpatient rehabilitation facilities, freestanding birthing centers, freestanding radiation therapy centers, and freestanding or mobile diagnostic imaging centers. The act expresses the General Assembly's intent to not have licensure requirements or exemptions from such requirements affect any third-party payments that may be available for these facilities.

## **Process for screening newborns for Krabbe disease**

(R.C. 3701.501)

Continuing law requires newborns to be screened for Krabbe disease. The act repeals the law that limits the screening process to “first tier testing,” or testing accomplished by measuring galactocerebrosidase activity using mass spectrometry. The act neither requires nor specifies a particular screening process for Krabbe disease.

## **Newborn safety incubators (VETOED)**

(R.C. 2151.3516 and 2151.3532)

Under continuing law, a parent may deliver to a newborn safety incubator his or her newborn who is not older than 30 days without intent to return for the child. A law enforcement agency, hospital, or emergency medical service organization may install a newborn safety incubator that meets certain standards, including that the incubator notify the agency, hospital, or organization within 30 seconds of a newborn being placed inside.

Continuing law requires the agency, hospital, or organization to have one or more officers or employees present at all times at the location where the incubator has been installed. The Governor vetoed a provision that would have exempted an agency, hospital, or organization from this requirement if the following conditions were met:

- An officer or employee could arrive at the location within seven minutes of a newborn being placed inside the incubator;
- The agency, hospital, or organization submitted to ODH a written statement confirming that an officer or employee could arrive at the location within the seven-minute period.

## **Occupational disease reporting**

(R.C. 3701.25, 3701.26, and 3701.27, repealed, with conforming changes in R.C. 3701.571, 3701.99, 3742.03, and 3742.04)

The act eliminates the requirement that a physician who suspects that a patient is suffering from poisoning from lead, cadmium, phosphorus, arsenic, brass, wood alcohol, mercury, or another occupational disease or ailment submit a report to ODH. ODH no longer manages data related to occupational diseases or ailments.

## **Diabetes action plan reporting cycle**

(R.C. 3701.139)

The act modifies the reporting cycle for the ODH Director to submit to the General Assembly a report detailing the prevalence of diabetes in the state. Formerly, the Director was required to submit the report by January 31 of each even numbered year. The act instead requires that this report be submitted to the General Assembly every third year beginning in 2021.

## **ODM access to Social Security numbers accompanying vital statistics records**

(R.C. 3705.07, 3705.09, and 3705.10; R.C. 3705.16, not in the act)

The act requires ODH's Office of Vital Statistics to make Social Security numbers accompanying birth and death certificates available to the Department of Medicaid for medical assistance eligibility determinations in the same manner that the Office makes available the numbers to the Department of Job and Family Services' Division of Child Support for child support enforcement under continuing law.

Under law unchanged by the act, every birth certificate filed in Ohio generally must be accompanied by the Social Security numbers of the child's parents. (The numbers are not, however, recorded on the birth certificate.) Similarly, every death certificate filed in Ohio must contain the decedent's Social Security number.

## **Area training centers for nursing home employees**

(R.C. 3721.41 and 3721.42)

The act repeals the law requiring the ODH Director to establish centers throughout the state for training nursing home employees and to contract with local public or nonprofit entities for their operation.

## **Breast and Cervical Cancer Project**

### **Providers**

(R.C. 3701.601)

The act adds the following providers as eligible to receive payments for services from the Breast and Cervical Cancer Project Income Tax Contribution Fund: free clinics, mammography services providers, radiology services providers, and rural health centers. Under continuing law, the ODH Director must distribute money from the fund to pay for breast and cervical cancer screening, diagnostic, and outreach services for uninsured and under-insured women as part of the Ohio Breast and Cervical Cancer Project. Prior law limited the providers eligible for payments to federally qualified health centers, other community health centers, and health departments operated by local boards of health.

### **Eligibility**

(R.C. 3701.144)

The act expands eligibility for screening and diagnostic services provided through the Breast and Cervical Cancer Project, as follows:

- Increases maximum income eligibility from 250% to 300% of the federal poverty line;
- In the case of women seeking breast cancer screening and diagnostic services generally, eliminates the requirement that they be younger than 65;

- In the case of women seeking breast cancer screening and diagnostic services because of family history, clinical examination results, or other factors, lowers to 21 (from 25) the age at which they become eligible for services.

## **Public Health Priorities Fund**

(R.C. 183.18 and 183.33)

The act renames Ohio's Public Health Priorities Trust Fund as Ohio's Public Health Priorities Fund. It eliminates the purposes for which money in the fund must be used, and instead requires the ODH Director to use the money to:

- Conduct public health awareness and educational campaigns;
- Address any pressing public health issue identified by the Director or described in the State Health Improvement Plan or a successor document prepared for ODH;
- Implement and administer innovative public health programs and prevention strategies;
- Improve the population health of Ohio.

It also authorizes the Director to collaborate with one or more nonprofit entities, including a public health foundation, to meet the act's requirements.

Continuing law requires that all investment earnings of the fund be credited to the fund. The act authorizes the Director of Budget and Management to credit to the fund any money received by the state, ODH Director, or ODH as part of a settlement agreement relating to a pressing public health issue. It also eliminates the prohibition on transferring or appropriating money from GRF to the fund.

## **Utility Radiological Safety Board**

(R.C. 4937.01 and 4937.05)

For purposes of funding Utility Radiological Safety Board (URSB) operations after the only nuclear facilities in Ohio (Davis-Besse Nuclear Power Station and Perry Nuclear Power Plant<sup>61</sup>) cease operation, the act does the following regarding the current URSB operating assessment on those facilities:

- Expands the definition of "nuclear electric utility" to include every person, their agents, assignees, or trustees, within Ohio engaged in the storage of spent nuclear fuel arising from the production of electricity using nuclear energy, instead of just including those persons engaged in the business of producing electricity using nuclear energy.

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<sup>61</sup> U.S. NRC, "Facilities (by NRC Region or State)," available at: <https://www.nrc.gov/info-finder/region-state/>, <https://www.nrc.gov/info-finder/reactors/davi.html>, and <https://www.nrc.gov/info-finder/reactors/perr1.html>.

- Provides that the assessment may be made based on the nuclear electric utility's decommissioning budget for the year of the assessment, if the utility is not engaged in the business of producing electricity using nuclear energy. This is in addition to the continuing law requirement that the URSB assessment be made in proportion to the intrastate gross receipts of the utility, excluding receipts from sales to other public utilities for resale, for the calendar year next preceding the year in which the assessments are made.

The act's changes do not, however, alter the limitation in continuing law that the URSB assessment may only be made against nuclear electric utilities that are subject to the Public Utilities Commission (PUCO) operating assessment law. Under that law, the public utilities that may be assessed include electric utilities and electric services companies (such as a nuclear electric utility), electric cooperatives, and governmental aggregators to the extent that they are certified and supply or arrange to supply retail electric service.<sup>62</sup> If a nuclear electric utility is only in the business of the *storage of spent nuclear fuel* arising from nuclear electricity production and no longer in the business of *producing electricity using nuclear energy*, it is not clear that the utility would continue to be an electric services company against which assessments may be made for URSB.

The act is unclear as to how the assessment is to be paid if the nuclear electric utility is no longer producing electricity. It provides that the assessment is to be made *based on* the decommissioning budget. Under Nuclear Regulatory Commission (NRC) regulations, a nuclear plant decommissioning trust fund may not be used for, or diverted to, any purpose other than to fund the costs of decommissioning the nuclear power plant to which the fund relates, and to pay administrative costs and other incidental expenses, including taxes, of the fund.<sup>63</sup>

H.B. 6, recently enacted by the 133<sup>rd</sup> General Assembly with the effective date of October 22, 2019, provides for rate-payer-funded subsidies to the two nuclear facilities in Ohio to keep them producing electricity. As a result, these facilities may not be shutting down soon.

## **Cancer surveillance advisory board**

(R.C. 3701.264, repealed)

The act abolishes the Ohio Cancer Incidence Surveillance System Advisory Board, but maintains the Ohio Cancer Incidence Surveillance System in ODH. Under prior law, the Board oversaw the collection and analysis of data by the surveillance system and advised the ODH Director and Ohio State University in the system's implementation.

## **Certificates of need**

The act modifies a number of procedures used in conducting the Certificate of Need (CON) Program. Under the program, activities involving long-term care facilities, including an

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<sup>62</sup> See R.C. 4905.10, not in the act.

<sup>63</sup> 18 Code of Federal Regulations (C.F.R.) 35.32(a)(6) and 35.33(b).

increase in the number of beds, may be conducted only if a CON has been granted by the ODH Director.

### **Determining application completeness**

(R.C. 3702.51 and 3702.57; Section 737.50)

The act requires the ODH Director to make a final determination of whether an application for a CON is complete not later than 180 days after the Director receives the application. The Director must adopt rules specifying procedures for making the determination and issuing notice within the 180-day time frame. Until the rules are adopted, however, the time frames specified in ODH's preexisting rules are to continue governing the Director when making the determinations.<sup>64</sup>

### **Bed need determinations**

(R.C. 3702.593(B))

Every four years, continuing law requires the ODH Director to determine the following for purposes of considering CON applications: (1) the long-term care bed supply for each county, (2) the long-term care bed occupancy rate for the state, and (3) each county's bed need in order for the statewide occupancy rate to be 90%. The act revises the dates by which the Director must make the determinations, as well as the four-year periods that are used, as follows:

--The April 1 deadline for making the determinations is changed to October 1;

--The four-year periods that began in 2012 are replaced with four-year periods beginning in 2023.

### **Review periods**

(R.C. 3702.593(D), (I), (J), and (K))

Under continuing law, the process for reviewing CON applications occurs during four-year review periods. The act changes the date that each review period begins from July 1 to January 1. It eliminates all previously scheduled review periods and requires the ODH Director to establish one that begins January 1, 2020, and ends December 31, 2023, with subsequent periods every four years thereafter. Applications can be accepted during the first January of the review period and reviewed through September 30 of that year.

The act eliminates the ODH Director's authority to implement a second phase of acceptance and review of CON applications during the third year of a four-year review period. The second phase was limited to the review of applications to redistribute beds that were made available by facilities that relocated their beds and, in turn, were required to reduce their bed capacity by at least 10% as a condition of the CON authorizing the relocation.

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<sup>64</sup> O.A.C. 3701-12-08 and 3701-12-09.

## January 2020 review

(Section 737.60)

When reviewing CON applications in January 2020, the act generally requires the ODH Director to use the long-term care bed supply and bed need determinations made in calendar year 2016. However, in the case of Delaware, Greene, Lake, Licking, and Medina counties, the Director must:

1. Redetermine the bed supply and bed need determinations made in calendar year 2016 using the same data that was used in those determinations, but without applying laws that permit variations from a county's bed need determination when the Director considers a CON application;

2. Refuse to accept a CON application for any of the specified counties, other than Greene County, unless the applicant is an owner of, or is the operator of, a skilled nursing facility in the county to which the CON application proposes to relocate beds;

3. Refuse to accept a CON application for any of the specified counties if the source of the beds to be relocated is a facility that has a four- or five-star rating under the nursing home quality rating system established by the U.S. Centers for Medicare and Medicaid Services on the date the beds are under contract for purchase or transfer, unless the facility is voluntarily closing; and

4. Use either (a) the standard CON application review process set forth in continuing law, excluding a provision under which the relocation of beds may be approved only if, after the relocation, the number of beds in the facility's service area will be at least equal to the state bed need rate, or (b) the comparative CON application review process set forth in continuing law, excluding a provision under which a comparative review is required if two or more applications propose to relocate beds from the same service area and the number of beds remaining would be less than the state bed need rate. The comparative review process is to be used in order to limit the increase in beds in the specified counties as follows:

- Delaware County – 200 total beds;
- Greene County – 99 total beds;
- Lake County – 200 total beds;
- Licking County – 185 total beds;
- Medina County – 200 total beds.

## Conditions for reviewing applications until July 2021

(Section 737.70)

The act establishes an interim period during which the ODH Director may accept CON applications for review only under specific circumstances. The interim period begins October 17, 2019, and ends July 1, 2021.

To be accepted for review during the interim period, a CON application must meet one of the following conditions:

1. Be submitted under the general provisions governing the CON review process or under a specific provision authorizing the relocation of beds between contiguous counties, and, if relevant, in accordance with the act's provisions governing review of CON applications in January 2020;

2. Propose either:

--The replacement of an existing long-term care facility, if the replacement facility will have the same owner and operator and the replacement will occur in a county with an identified bed need according to the Director's determination made in 2016; or

--The renovation of or an addition to an existing long-term care facility, if the facility is in a county with an identified bed need according to the Director's 2016 determination.

The Director is prohibited from accepting an application during the interim period unless it otherwise complies with the CON statutes and, if relevant, the act's provisions governing review of CON applications in January 2020. The interim period and its conditions for review of CON applications do not apply to pending CON applications.

## Appeals of CON decisions

(R.C. 3702.60)

The act eliminates the authority of certain persons to appeal decisions made by the ODH Director in determining whether a proposed activity is subject to CON review (a reviewability ruling) and whether a CON application is granted or denied. The persons no longer permitted to appeal the decisions include:<sup>65</sup>

1. Any person that resides or regularly uses long-term care facilities within the service area served or to be served by the long-term care services that would be provided under the CON or reviewability ruling in question;

2. Any long-term care facility that is located in the service area where the long-term care services would be provided under the CON or reviewability ruling;

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<sup>65</sup> See the definition of "affected person" in R.C. 3702.51(M), not in the act.

3. Third-party payers that reimburse long-term care facilities for services in the service area where the long-term care services would be provided under the CON or reviewability ruling; and

4. Any CON applicant whose application was reviewed comparatively with the application.

The act retains the authority of the CON applicant to appeal the ODH Director's decision to grant<sup>66</sup> or deny a CON. It also retains the authority of the person who requested a reviewability ruling to appeal the Director's resulting decision. The appeals continue to be subject to the Administrative Procedure Act (R.C. Chapter 119). Further appeals may continue to be made to the 10<sup>th</sup> District Court of Appeals. However, the act eliminates provisions regarding the award of attorney's fees.

## **Transfer of nursing home ownership**

(R.C. 3721.026)

The act imposes disclosure requirements on an individual who is assigned or transferred operation of a nursing home. In that situation, before the ODH Director can issue a license authorizing the person to operate the nursing home, the person must submit documentation showing:

- If the assignment or transfer is done by means other than a lease, the person has financial resources that the Director determines are sufficient to cover any reasonable anticipated revenue shortfall for at least 12 months after the assignment or transfer.
- If the assignment or transfer is done by a lease, (1) the person has obtained a bond for a term of at least 12 months, subject to annual renewal, for not less than \$1 million or (2) if the person cannot obtain a bond at a reasonable cost or the person operates other nursing homes in Ohio, the person has financial resources that the Director determines are sufficient to cover any anticipated revenue shortfall for at least 12 months after the assignment or transfer.
- The person has at least five years' experience as a nursing home operator, manager, or administrator.
- The person has plans for quality assurance and risk management for the nursing home.
- The person has general and professional insurance coverage of at least \$1 million per occurrence and \$3 million aggregate.

The documentation must include (1) projected financial statements for the nursing home for the 12-month period after the assignment or transfer and (2) a list of each currently or previously licensed nursing home in which the person has or had any percentage of

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<sup>66</sup> Under R.C. 3702.52(C)(1), the ODH Director may grant a CON for only part of a project. This may be an example of when a CON applicant would appeal a decision to grant a CON.

ownership. These requirements are in addition to any other nursing home operation requirements.

## **Freestanding emergency departments**

(R.C. 3727.49)

The act requires a freestanding emergency department, which is a facility that provides emergency care and is structurally separate and distinct from a hospital, to provide notice identifying itself as a freestanding emergency department. The notice must be posted either:

- In a conspicuous place in an area of the facility accessible to the public; or
- On the facility's website.

Under the act, a freestanding emergency department must use its national provider identifier on all claims for payment for health care services or goods. A national provider identifier is a unique identification number assigned to a health care provider by the National Provider System pursuant to federal regulations.

Finally, the act authorizes the ODH Director to apply to a court of common pleas for a temporary or permanent injunction restraining a freestanding emergency department from failure to comply with the provisions described above.

## **Commission on Infant Mortality**

(R.C. 3701.68)

The act requires the Governor or the Governor's designee to serve on the Commission on Infant Mortality, instead of the Executive Director of the Office of Health Transformation or the Executive Director's designee. Additionally, the act requires the Speaker of the House and the Senate President to each appoint an individual who represents children's interests. The other 16 members of the Commission are from various government agencies, medical associations, and community-based programs.

The Commission's purpose is to conduct a complete inventory of services provided or administered by the state that are available to address the infant mortality rate, and to track and analyze, with the assistance from academic medical centers, infant mortality rates by county to determine the impact of state and local initiatives to reduce those rates.

## **Radon mitigation specialist**

(R.C. 3723.081)

The act prohibits the ODH Director from requiring a licensed radon mitigation specialist to be physically present to supervise when radon mitigation is performed. However, it allows the Director to require a specialist to be physically present immediately before and after radon mitigation is performed. Under former rules adopted by the Director, a licensed radon mitigation specialist had to be physically present during radon mitigation.

## **Resident's right to choose hospice care program**

(R.C. 3721.13)

The act adds to Ohio's bill of rights for residents of nursing homes and residential care facilities (commonly referred to as assisted living facilities) the right, if a resident has requested the care and services of a hospice care program, to choose a licensed program that best meets the resident's needs.

## **Solemn Covenant of the States to Award Prizes for Curing Diseases**

(R.C. 3799.01)

### **Compact establishment**

The act enacts into law 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.

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. Upon acceptance of a successful cure treatment or therapeutic protocol, the Commission will make the treatment widely available.

### **Cure prize process**

#### **Prize creation**

The Commission must adopt rules establishing criteria to define and classify the diseases for which prizes will be awarded. In doing so, the Commission may define and classify subsets of diseases, such as tubular carcinoma of the breast. A subset of a disease is to be considered as one disease when determining the diseases for which to create prizes. In defining and classifying diseases, the Commission 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.

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

- 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 must include all of the following requirements:
  - It has been approved by the federal Food and Drug Administration or has otherwise obtained legal status for the Compact to immediately contract to manufacture and distribute in the United States.
  - It yields a significant increase in survival with respect to the disease if early death is the usual outcome. However, the commission may award a prize for a treatment or therapeutic protocol that yields a survival rate that is less than what is established in the cure criteria through at least five years after the treatment or protocol has ended. In this case, the prize amount awarded for that treatment or protocol must be reduced from the amount originally determined for that disease. The reduction must be proportionate to the survival rate yielded by that treatment or protocol as compared to the survival rate established in the cure criteria.
  - It requires less than one year of the treatment or protocol to completely cure the disease.
- 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, a requirement that the person or entity submitting the cure bears the burden of proof in demonstrating that the treatment or therapeutic protocol meets the Commission's criteria, and limitations preventing public access to treatment or protocol submissions;
- The estimated five-year public health savings that would result from a cure, which must be equal to the five-year public health expenses for each disease in each compacting state, and a procedure to update these expenses every three years. The savings 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.

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

### **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 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.

The ethical standards requirement is unclear in two ways: (1) while the Compact must review federal laws, there is no requirement that federal laws must be adopted in the Compact's rules, and (2) 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.

### **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.

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.

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 the manufacture and distribution of the 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.

### **Awarding the prize**

The rules also must provide that, 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. 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. 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.

### **Issuing debt to pay prize**

The rules must also provide that a compacting state can meet its prize responsibility by any method, including the issuance of bonds or other obligations (described below).

#### ***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 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.

#### ***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.

### **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.

### **Licensing, dispensing, and royalty fees**

Once a prize winner claims a prize and transfers any intellectual property necessary for the manufacture and distribution of the cure in accordance with 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. However, the Commission may not market the cure or conduct any other activity regarding the cure that is not specifically authorized in the Compact.

With regard to noncompacting states and foreign countries, the Commission also may establish and collect royalty fees imposed on manufacturers, producers, and providers of any drug, serum, or other substance, device, or process used for a cure treatment or therapeutic protocol. However, royalty fees must cumulatively not be more than the estimated five-year savings in public health expenses for that state or country, as calculated by actuaries employed or contracted by the Commission.

The Commission may establish a selling price for the cure, which must not be more than the expenses for the cure's manufacture and distribution, licensing, and any other necessary governmental requirements for compacting states, or those expenses plus any royalty fees, for noncompacting states. The price cannot include the expenses of any other activities.

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 also may 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.

### **General powers**

The Compact establishes several powers of the Commission. Among them is the ability to adopt bylaws and rules, which have the force and effect of law and would be binding in the compacting states. 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.

Rules must be adopted to: (1) effectively and efficiently achieve the purposes of the Compact, and (2) govern the methods, processes, and any other aspect of the research, creation, and testing of a treatment or therapeutic protocol for each disease for which a prize may be awarded. 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. Rules that exceed the Commission's rule-making authority will be invalid. Rules may be amended as the Commission sees necessary.

The Commission also has the following powers:

- To establish and maintain offices;
- 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.

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.

## Organization

The Commission must establish organization bylaws for the following:

- 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.

## Membership

Under the Compact, any state (defined as any state, district, or territory of the United States) is eligible to become a compacting state. 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.

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 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.

Each compacting state is responsible for paying annual dues established under Commission rules (see "**Financial responsibilities of the Commission,**" below). 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.

## 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.

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.

## Finances

### Financial responsibilities of the Commission

Under the Compact, the Commission must annually establish a budget to pay its reasonable expenses. The Commission also has the power to make expenditures, borrow money, and establish annual membership dues for compacting states, which dues must be used for daily expenses of the Commission and not for interest or prize payments. 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. 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.

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.

### **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. To this end, the Commission may establish bylaws governing any fundraising efforts in which the Commission wishes to engage. 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.

### **Exemption from taxation**

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

### **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.

### **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.

### **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.

## **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 the 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;
- 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.

## **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.

## **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.

## **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.

## **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 from the Compact can reinstate its membership by reenacting the Compact. Reinstatement is effective on the effective date of re-enactment.

## **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.

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.

## **Records**

Under the act, the Commission must prescribe bylaws providing for the maintenance of the Commission's books and records. 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;
- Guidelines for entering into agreements with federal and state agencies to receive or exchange information or records subject to nondisclosure and confidentiality provisions.

## **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.

## **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 the information is provided to any member. The Compact also provides that all cure submissions that the Commission receives are confidential.

## **Annual report to governors/legislatures**

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

## **Legal actions and disputes**

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

## **Venue**

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

## **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;
- 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.

## **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.

## **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.

## **Appropriations**

The legislative authority of each compacting state is responsible for making appropriations it determines necessary to pay for Compact costs, if funding is requested or required. These costs may include annual member dues and prize distributions.

## **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.

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.

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, 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. Requiring the ineffective provision to "remain" appears, however, to create a conflict: the compacting state is required to recognize law that is unconstitutional and ineffective within that state.