DEPARTMENT OF HEALTH

Summary orders at nursing homes and assisted living facilities

- Permits the Director of Health to issue orders, take corrective action, and impose fines without providing a nursing home, residential care (assisted living) facility, or other home with notice and an opportunity for a hearing if the Director determines immediate action is necessary to protect resident health or safety.
- Permits a home to request a hearing under the Administrative Procedure Act after a summary order is issued.

Inspections of assisted living facilities

- Authorizes the Director to inspect an assisted living facility every 30 (instead of 15) months, once the facility has had two consecutive 15-month inspections without any substantiated violations and other related conditions are met.

Hospital licensure

- By September 30, 2024, requires a hospital operating in Ohio to be licensed by the Director rather than registered as under current law.
- Specifies that any existing law reference to a hospital that is not included in the act is to be construed as a reference to a hospital licensed under the act's licensure requirements.

Variances from written transfer agreements

- Regarding variances from the written transfer agreement requirement that applies to ambulatory surgical facilities (ASFs), requires:
  - The local hospital at which a consulting physician has admitting privileges to be within a 25-mile radius of the ASF;
  - The consulting physician to actively practice clinical medicine within a 25-mile radius of the ASF;
  - An ASF with an existing variance to demonstrate compliance with the act's requirements within 90 days or the variance must be rescinded.

Home health service provider licensing

- Requires home health agencies and independent (nonagency) providers of skilled home health services and nonmedical home health services to be licensed by the Department of Health (ODH).

Expedited licensing inspections

- Specifies that an existing home, such as a nursing home or assisted living facility may request an expedited licensing inspection from the Director when seeking approval to

increase or decrease its licensed capacity or make any other change for which the Director requires a licensing inspection to be conducted.

Frontline Health Care Worker Pilot Program

- Requires ODH to establish and operate, during FYs 2022 and 2023, a Frontline Health Care Worker Education, Training, and Certification Pilot Program to reimburse adult education institutions for the cost of education-related expenses and wraparound services provided to students enrolled in certain health care training programs.

Technological resources

- Removes a requirement that providers conducting home visits under the Help Me Grow Program, WIC clinics, and Medicaid managed care organizations promote the use of technological resources that provide information on having a healthy pregnancy and healthy baby.

Newborn screening

- Requires newborns to be screened for X-linked adrenoleukodystrophy and spinal muscular atrophy, with the screenings to begin May 28, 2022.
- Requires the state's Newborn Screening Advisory Council, not later than six months after a disorder has been added to the federal Recommended Uniform Screening Panel, to determine whether or not to recommend to the Director that Ohio newborns be screened for the same disorder.
- Requires the Director, not later than six months after receiving the recommendation, to specify the disorder for screening in rule, with screening to begin within one year.
- Provides that screening for any disorder is not required if appropriate laboratory equipment is not available.

Smoking and tobacco

Dispensing nicotine replacement therapy without a prescription

- Authorizes pharmacists to dispense nicotine replacement therapy without a prescription in accordance with physician-established protocols.

Moms Quit for Two grant program

- Continues the Moms Quit for Two grant program for the delivery of tobacco cessation interventions to women who are pregnant or living with children and reside in communities with the highest incidence of infant mortality.

Smoke-Free Workplace Law

- Expands the Smoke-Free Workplace Law to include electronic smoking devices and vapor products.
- Exempts retail vapor establishments from the smoking ban with regard to smoking via vapor products and electronic smoking devices.

- Specifies that the smoking ban applies to retail vapor establishments with regard to all other forms of smoking.
- Requires entities to certify that they are eligible for the retail vapor store smoking ban exemption.
- Defines "retail vapor store" as being a retail establishment that derives more than 80% of its gross revenue from the sale of vapor products, electronic smoking devices, or other electronic smoking product accessories and for which the sale of other products is merely incidental.

Retail tobacco store definition

- Revises the definition of "retail to tobacco store" to apply to stores that sell "lighted or heated tobacco products," conforming the definition to the act's revised definition of "smoking."

Certificate of need capital expenditure threshold

- Increases to $4 million the maximum amount of a capital expenditure that may be made in renovating or adding to a long-term care facility without being subject to review under the Certificate of Need Law.

Children with Medical Handicaps Program eligibility

- Extends the Children with Medical Handicaps Program age limit from 21 to 23 by July 1, 2022, by increasing the age limit by one year in 2021 and 2022.

Home visiting services

- Allows families with children up to age five (instead of age three) to receive home visits through the Help Me Grow Program.
- Changes the frequency of the ODH summit on home visiting services to once every two years, instead of twice a year.

Help Me Grow report

- Requires the Director to submit a report regarding the Help Me Grow program that includes recommendations for using funds associated with Medicaid and TANF to provide services through Help Me Grow.

Rare Disease Advisory Council membership

- Increases to 31 (from 25) the number of members on the Rare Disease Advisory Council by permitting the appointment of public members by the President of the Senate and the Speaker of the House.

Drug overdose fatality review committees

- Authorizes the establishment of county or regional drug overdose fatality review committees.

- Requires each committee to submit to ODH an annual report containing specified information related to the drug overdose or opioid-involved deaths reviewed by the committee.

Suicide fatality review committees

- Authorizes the establishment of county or regional suicide fatality review committees.
- Requires each committee to submit to ODH an annual report containing specified information related to the suicide deaths reviewed by the committee.

Ohio breast and cervical cancer project

- Requires the Director, as part of the Ohio Breast and Cervical Cancer Project (BCCP), to ensure that a woman who was screened for breast or cervical cancer by a provider outside of the BCCP receives cancer treatment.

Summary orders at nursing homes and assisted living facilities

(R.C. 3721.081)

Orders and action

In circumstances where the Director of Health determines immediate action is necessary to protect resident health or safety, because a nursing home, residential care (assisted living) facility, or other home is not acting with sufficient promptness or efficiency to protect resident health or safety, the act authorizes the Director to do either or both of the following without providing notice and an opportunity for a hearing:

1. Issue orders, including specifying actions that a home must immediately take;

2. Take direct action to protect resident health and safety if the home fails to act on an order issued.

The orders may be issued or action taken as necessary to protect the health or safety of residents of a home, including removing a threat to resident health or safety, transferring residents until a threat is resolved, and appointing a temporary administrator for the home for the duration of the order.

The authority is subject to the following limits:

1. The Director cannot enter a home unless the Director provides the operator with 24-hours advance notice;

2. The Director's transfer authority is subject to limitations based on whether the reason for the transfer is an environmental or clinical condition. For environmental conditions affecting a home, the Director may transfer only residents directly affected by the condition. For clinical conditions that affect an entire home, the Director may transfer all residents for the lesser of 30 calendar days or until the condition no longer affects the home. If the condition persists longer than 30 calendar days, the Director must provide notice to the home specifying the reason for

determining that the condition is still affecting the home. The home may request a hearing regarding the notice.

Expenses and fines

A home is responsible for any expenses incurred to comply with an order. If a hearing is conducted and the Director is found to have acted in violation of the act's provisions, all reasonable expenses incurred by the home as a result of the Director's action must be reimbursed to the home within 90 days of the final adjudication order.

The act authorizes the Director to impose a fine of up to $100,000 for each instance of noncompliance with a summary order. All fines must be reasonably commensurate to the harm caused by the home. Fines must be credited to the General Operations Fund in the state treasury.

Requests for hearings

A home that is subject to a summary order or action under the act, including a fine, may request a hearing under the Administrative Procedure Act. The request must be received by the Director within 15 days after the notice of the order was mailed. The hearing must be held within ten days after the request, unless the parties agree otherwise. The Director must issue a final adjudication order no later than 30 days after the hearing is complete. A summary order remains in effect, unless reversed by the Director, until a final adjudication order is issued.

A final adjudication order may be appealed in accordance with the Administrative Procedure Act.

Inspections of assisted living facilities

(R.C. 3721.02)

Under continuing law, before a nursing home or assisted living facility may be licensed, it must be inspected by the Director and the State Fire Marshal, or a fire department approved by the Fire Marshal. A home must be inspected every 15 months thereafter.

The act extends the period for inspections by the Director from 15 months to 30 months if all of the following apply:

- The facility has had at least two consecutive 15-month inspections with no substantiated violations;
- During that same time period, there were no substantiated violations from any other inspections or from any investigations of complaints;
- There are no outstanding violations from any previous inspections or investigations during any other time period.

An assisted living facility still must be inspected by the State Fire Marshal or an approved fire department once every 15 months.

Hospital licensure

(R.C. 3722.02 (primary), 3722.01 to 3722.14, and 3722.99; conforming changes in numerous other R.C. sections)

Beginning September 30, 2024, the act requires each hospital operating within Ohio to hold a license from the Director, rather than be registered, as under current law. Should a hospital fail to obtain the license by the required date, it will be subject to civil and criminal penalties.

Because the act does not amend all of the references to registered hospitals in the Revised Code, it also specifies that, beginning September 30, 2024, any reference to a hospital is to be construed as a reference to a hospital licensed under the act's licensure requirements.

Effective date of mandatory licensure and interim period

Until September 30, 2024, existing law requirements are maintained, and the act's new requirements apply only to hospitals that have obtained licenses. As described in more detail below, ODH may begin to consider applications for licensure September 30, 2022. Hospitals will then have two years to become licensed. During that period, some facilities may be both licensed under the new hospital licensing plan and subject to continuing law requirements. Once the act's license mandate becomes effective on September 30, 2024, each hospital within the state must be licensed by the Director in order to operate.

Definitions

The act defines "**hospital**" to mean an institution or facility that provides inpatient medical or surgical services for a continuous period longer than 24 hours. Note that a **hospital** includes a "**children's hospital**," defined to mean either of the following:

- A hospital that provides general pediatric medical and surgical care in which at least 75% of annual inpatient discharges for the preceding two calendar years were individuals younger than 18; or
- A distinct portion of a hospital that provides general pediatric medical and surgical care, has a total of at least 150 pediatric special care and pediatric acute care beds, and in which at least 75% of annual inpatient discharges for the preceding two calendar years were individuals younger than 18.

Entities not subject to hospital licensure

The act specifies that its licensure requirements do not apply to the following:

- A hospital operated by the federal government;
- An ambulatory surgical facility or other health care facility licensed by the Director;
- A nursing home or residential care (assisted living) facility licensed by the Director;
- A hospital or inpatient unit licensed by the Department of Mental Health and Addiction Services (OhioMHAS);

- A residential facility licensed by OhioMHAS or the Department of Developmental Disabilities;
- A community addiction services provider certified by OhioMHAS;
- A facility providing services under a contract with the Department of Developmental Disabilities;
- A facility operated by a licensed hospice care program and that is used exclusively for the care of hospice patients;
- A facility operated by a licensed pediatric respite care program and that is used exclusively for the care of pediatric respite care patients;
- The site where a health care practice is operated, regardless of whether the practice is organized as an individual or group practice;
- A clinic providing ambulatory patient services where patients are not regularly admitted as inpatients;
- An institution for the sick that is operated exclusively for patients who use spiritual means for healing and for whom the acceptance of medical care is inconsistent with their religious beliefs, accredited by a national accrediting organization, exempt from federal income taxation, and providing 24-hour nursing care pursuant to an exemption from certain Ohio Board of Nursing licensing requirements.

Note on maternity units, newborn care nurseries, and ambulatory surgical facilities

Ohio law requires hospital maternity units and newborn care nurseries to be licensed by the Director. The act maintains this licensure – but only for the period during which a hospital is not required to be licensed. After hospital licensure is mandatory, the act repeals the law governing maternity unit and newborn care nursery licensure because they will be covered by the hospital's license.

The act also specifies that an ambulatory surgical facility does not include a hospital provider-based department that is otherwise licensed under the act's provisions.

Penalties for operating without a license

Should a hospital operate without a license, the act requires the Director to do the following:

- Notify the hospital that it is operating without a license and provide it with an opportunity to apply for licensure;
- Direct the hospital to cease operations;
- Impose a civil penalty of not more than $250,000 as well as a penalty of not less than $1,000 and not more than $10,000 for each day the hospital operates without a license.

The act also authorizes the Director to petition the court of common pleas of the county in which the hospital is located for an order enjoining the hospital from operating.

Moreover, a hospital can be subject to criminal penalties for operating without a license. Violations are first degree misdemeanors, punishable by a fine of not more than $1,000 and a jail term of not more than 180 days.[66] In addition, the act imposes an additional penalty of $1,000 for each day the hospital operates without a license.

Applications for licensure

Each private or public entity, including a state university, seeking to operate a hospital must apply to the Director for a license. The Director cannot consider any application until September 30, 2022. Applications must be submitted in the form and manner prescribed by the Director in rules.

Eligibility

To be eligible for licensure, an applicant must satisfy the following:

- Have submitted a complete application, which includes identifying the main hospital location and any location operated by the hospital and paying the fee specified in rules adopted by the Director;
- Be certified under Title XVIII of the Social Security Act (Medicare), accredited by a national accrediting organization approved by the federal Centers for Medicare and Medicaid Services, or, in the case of a new hospital, eligible under rules adopted by the Director;
- Demonstrate the ability to comply with standards established in rules adopted by the Director;
- Specify the number of beds for the hospital, including skilled nursing beds, long-term care beds, and special skilled nursing beds.

License issuance, validity, and renewals

If an applicant meets the eligibility requirements, the Director must issue to the applicant a license to operate a hospital. The act does not prohibit the Director from issuing a license to a hospital that either (1) occupies space in a building that is also used by another hospital or hospitals or (2) occupies one or more buildings located on the same campus as buildings used by another hospital or hospitals.

The act further provides that a license is valid only for the hospital identified in the application. It also requires the license holder to post a copy of the license in a conspicuous place in the hospital.

[66] R.C. 2929.24 and 2929.28, not in the act.

License transfer

If a hospital is assigned, sold, or transferred to a new owner, the new owner must apply for a license transfer within 30 days of the assignment, sale, or transfer.

The new owner is responsible for complying with any action taken or proposed by the Director (see "**Violations**" and "**Imminent threat of harm**" below). If a notice has been issued under the Administrative Procedure Act, the new owner becomes party to the notice.

Hospital inspections

On the filing of a license application, the Director may inspect the hospital prior to issuing or denying the license. The act also appears to allow for inspections as part of the license renewal process.

Process to avoid inspections

An applicant may avoid an inspection by submitting to the Director a copy of the hospital's most recent final on-site survey report from the federal Centers for Medicare and Medicaid Services or an accrediting organization demonstrating that the hospital is certified or accredited.

Confidentiality of on-site survey reports

The act specifies that a final on-site survey report from the federal Centers for Medicare and Medicaid Services or an accrediting organization that is submitted in accordance with the act's provisions is confidential and not a public record.

Unit inspections

At least once every 36 months, the act requires the Director to inspect each licensed hospital's maternity unit, newborn care nursery, and any unit providing health care services, defined under the act to include the following:

- Pediatric intensive care;
- Solid organ and bone marrow transplantation;
- Stem cell harvesting and reinfusion;
- Cardiac catheterization;
- Open heart surgery;
- Operation of linear accelerators;
- Operation of cobalt radiation therapy units;
- Operation of gamma knives.

Other inspections

The Director may at any time inspect a licensed hospital in order to address an incident that may impact public health, respond to a complaint submitted to the Director, or otherwise ensure the safety of patients cared for by the hospital.

Inspection fees

Any inspection conducted under the act's provisions is subject to a fee. Upon conducting the inspection, the Director must provide the applicant or license holder with a fee statement. Not later than 15 days after receiving the fee statement, the applicant or license holder must submit the total amount of the fee.

Rulemaking

Health, safety, welfare, and quality standards

Not later than September 30, 2022, the Director must adopt rules establishing health, safety, welfare, and quality standards for licensed hospitals, including standards for the following:

- Maternity units;
- Newborn care nurseries;
- Health care services, including pediatric intensive care, solid organ and bone marrow transplantation, stem cell harvesting and reinfusion, cardiac catheterization, open heart surgery, operation of linear accelerators, operation of cobalt radiation therapy units, and operation of gamma knives.

Standards and procedures for licensure

Not later than September 30, 2022, the Director must adopt rules establishing standards and procedures for the licensure of hospitals, including all of the following:

- Procedures for applying and renewing licenses;
- Procedures for transferring licenses;
- Procedures for inspections following complaints;
- Fees for initial applications, license renewals, and license transfers, as well as inspections;
- Standards and procedures for imposing civil penalties;
- Standards and procedures for correcting violations, including through the submission of correction plans;
- Standards and procedures for identifying, monitoring, managing, reporting, and reducing exposures to risk conditions, such as Legionella, including through the use of environmental facility assessments, the development of water management plans, and the use of disinfection measures;
- Standards and procedures for data reporting;
- Standards and procedures for emergency preparedness;
- Standards and procedures for the provision of technical assistance;
- Standards and procedures for new hospitals to demonstrate eligibility for licensure;

- Standards and procedures to address changes to a hospital's license, including adding or removing a location of the hospital.

Corrective action plans, penalties, and fees

In the case of rules regarding the correction of violations, the Director must accept a corrective action plan that also was accepted by the federal Centers for Medicare and Medicaid Services or an accrediting organization, provided that the plan was submitted in response to the same deficiencies identified by the Director.

With respect to the rules governing the imposition of civil penalties, the Director must establish a scale for determining the amount of a civil penalty that may be imposed. The scale must include per day amounts for ongoing violations. The total amount of a civil penalty must not exceed $250,000 for each violation.

In the case of inspection fees, the Director must establish an amount to cover only the costs of inspections. All other fees established in rule are limited to the amount necessary to support the hospital licensure program.

Other rules

The act authorizes the Director to adopt any other rules as necessary to implement the act's provisions.

Administrative Procedure Act

Rules adopted under the act's provisions must be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).

Collaboration with hospital industry

When adopting rules, the Director must collaborate with representatives of Ohio's hospital industry to maximize their public health utility and to limit the administrative burden and costs of compliance.

Federal law

The act prohibits the Director from adopting rules that conflict with requirements under federal statutory or administrative law.

Violations

The act specifically requires each licensed hospital to comply with its provisions and the rules adopted under it. If the Director finds that a license holder has violated any of the act's requirement or the rules adopted under it, the act authorizes the Director to take any of the following actions:

- Impose a civil penalty of not less than $1,000 and not more than $250,000;
- Require the license holder to submit a plan to correct or mitigate the violation;
- Suspend a health care service or revoke a license if the Director determines the license holder is not in substantial compliance with the act or rules adopted under it.

Any decision or determination to take any of the foregoing actions is subject to the Administrative Procedure Act.

Notice of proposed action

If the Director seeks to suspend a health care service or revoke a license, the Director must give the hospital written notice of the proposed action. The notice is required to specify all of the following:

- The nature of the conditions giving rise to the Director's judgment;
- The measures that the Director determines the hospital must take to respond to the conditions; and
- The date, which must not be later than 30 days after the notice is delivered, on which the Director intends to suspend the health care service or revoke the license if the conditions are not corrected and the Director determines that the license holder has not come into substantial compliance with the act or rules adopted under it.

Inspections

After receiving the notice of proposed action, if the hospital notifies the Director, by the time specified in the notice, that the conditions giving rise to the Director's determination have been corrected and that the hospital is in substantial compliance, the act requires the Director to inspect the hospital. If, on the basis of the inspection, the Director determines that the conditions have not been corrected or the hospital has not come into substantial compliance, the Director may suspend the service or revoke the license.

The act also authorizes the Director to suspend a health care service or revoke a license if a hospital fails to notify the Director.

Order of suspension or revocation

When suspending a service or revoking a license, the Director must issue a written order of suspension or revocation and cause it to be delivered to the hospital.

Adjudications and final orders

The act grants a hospital subject to suspension or revocation the opportunity to request an adjudication. If requested, it must be held within seven days after making the request, unless another date is agreed to by the hospital and Director. The suspension or revocation remains in effect, unless reversed by the Director, until a final adjudication order becomes effective.

The act requires the Director to issue a final adjudication order not later than 14 days after the adjudication's completion. If the Director does not issue a final order within the 14-day period, the suspension or revocation is void, but any final adjudication order issued after the 14-day period is not to be affected.

Injunctive relief

If the Director issues a final adjudication order suspending a health care service or revoking a license and the license holder continues to operate a hospital, the Director may ask

the Attorney General to apply to the common pleas court of the county where the hospital is located for an order enjoining the license holder from continuing to operate the hospital.

Imminent threat of harm

The act authorizes the Director to take certain actions if the Director determines that an imminent threat of harm exists at a hospital. "Imminent threat of harm" is defined to mean imminent danger or serious physical or life-threatening harm to one or more occupants of a hospital.

The actions that the Director may take include:

- Petitioning a court for injunctive relief, which may include closing the hospital, suspending a service within the hospital, or transferring its occupants to other hospitals or appropriate settings;
- If the Director opts not to pursue injunctive relief, providing written notice of proposed action;
- If the hospital notifies the Director that it has corrected the conditions giving rise to an imminent threat of harm, conducting inspections to determine if the imminent threat of harm remains.

Notice of proposed action

When providing notice of proposed action, the Director must deliver that notice to the hospital's administrator, governing board, and statutory agent. This may be done either by hand or certified mail.

Technical assistance

The act authorizes the Director to provide each hospital with technical assistance in all of the following areas:

- Infectious diseases, including measures to prevent and control their spread;
- Quality improvement projects, including health equity and disparities;
- Population health initiatives;
- Data analytics;
- Workforce recruitment and development.

The act also allows the Director to engage with one or more quality improvement organizations to assist in providing technical assistance. The Director may terminate the assistance of a quality improvement organization at any time.

The Director may use any fees or civil penalties collected in accordance with the act's provisions to fund the provision of technical assistance to licensed hospitals, including contracting with entities to provide training or technical assistance determined necessary by the Director.

Hospital governing board

Each licensed hospital is required by the act to have a governing board to oversee its management, operation, and control. The governing board is specifically responsible for overseeing the appointment, reappointment, and assignment of privileges to medical staff.

Admitting privileges

The act repeals the law governing the admission and medical supervision of hospital patients, including admissions initiated by advanced practice registered nurses and physician assistants.[67]

Opioid reporting

The act revises the law governing reports of the number of babies diagnosed as opioid dependent at birth. Each licensed maternity unit, newborn care nursery, and maternity home must report those numbers to the Director quarterly. Beginning September 30, 2024, the duty to report will fall instead on hospitals operating maternity units or newborn care nurseries. However, until that date, maternity units, newborn care nurseries, and maternity homes must continue to report to the Director. Note that after September 30, 2024, maternity homes will continue to be required to report.

The act permits a third-party organization to report opioid dependent births on a hospital's behalf. It also requires the Director to adopt rules establishing standards and procedures for the required reporting, including when submitted by third-party organizations.

Disease reporting

Beginning September 30, 2024, each hospital, or a third-party organization on the hospital's behalf, must report to the Director the contagious, environmental, or infectious diseases, illnesses, or health conditions or unusual infectious agents or biological toxins for which it provides treatment to patients.

The act requires the Director to adopt rules that:

- Specify the diseases, illnesses, conditions, infectious agents, and biological toxins to be reported;
- Specify the frequency with which a hospital must report; and
- Prescribe the manner in which reports are to be made, including by third-party organizations.

Any information reported is protected health information as described under continuing law and may be released only in accordance with that law. Under the act, information that does not identify an individual may be released in summary, statistical, or aggregate form.

[67] R.C. 3727.06.

Under continuing law not amended by the act, hospitals are among a list of health care providers required to report to local boards of health the existence of certain diseases.[68] Health providers may do this by submitting an electronic report to the Ohio Disease Reporting System.

General operations fund

The act specifies that any fees and civil penalties collected under it must be deposited in the state treasury and used solely for purposes of administering and enforcing the act's provisions.

Variances from written transfer agreements

(R.C. 3702.304; Section 291.80)

The act adds several new restrictions regarding variances from the written transfer agreement requirement for ambulatory surgical facilities (ASFs). Under Ohio law, an ASF is required to have a written transfer agreement with a local hospital specifying a transfer procedure for patients when additional medical care is necessary. An ASF may, however, apply to the Director of Health for a variance if the transfer agreement requirement will cause the facility undue hardship. A variance application must include a letter, contract, or memorandum of understanding signed by the ASF and one or more consulting physicians who have admitting privileges at a local hospital, and who agree to provide back-up coverage when medical care beyond the level the ASF can provide is necessary.

The act makes the following changes regarding variances:

- Requires that the local hospital where the consulting physician has admitting privileges must be within a 25-mile radius of the ASF.
- Requires a consulting physician to actively practice clinical medicine within a 25-mile radius of the ASF.

An ASF with an existing variance must demonstrate compliance with the act's provisions within 90 days, or the Director must rescind the variance.

Home health service provider licensing

(R.C. 3740.01, 3740.02, 3740.03, 3740.04, 3740.05, 3740.07, 3740.10, 3740.11, and 3740.99; conforming changes in other R.C. sections)

License required

Starting September 30, 2022, the act requires a license for any home health agency or nonagency (independent) provider offering skilled home health services or nonmedical home health services. Skilled home health services include skilled nursing care, physical therapy, occupational therapy, speech-language pathology, medical social services, home health aide services, and any other services the Director specifies by rule. Nonmedical home health services

[68] R.C. 3701.17 and 3701.23, not in the act, and O.A.C. 3701-3-03 and 3701-3-05.

include bathing or bathing assistance; assistance with dressing, walking, and toileting; catheter care (but not insertion), meal preparation and feeding; personal care services, such as assistance with activities of daily living and other services identified in the act; and any other services the Director specifies by rule.

A home health agency is any business or government entity, other than a nursing home, residential care facility, hospice care program, pediatric respite care program, informal respite care provider, Department of Developmental Disabilities-certified provider, residential facility, shared living provider, or immediate family member, that provides skilled home health services or nonmedical home health services at a patient's place of residence. The licensure requirement is for the agency and not individual employees of an agency. Continuing law specifies criminal records check and database review requirements for employees of home health agencies.

Nonagency providers are people who provide care to individuals on a self-employed basis and do not directly or contractually employ other people to provide services. Nonagency provider does not include:

- A caregiver who is an immediate family member of the individual receiving care;
- A person who provides direct care to no more than two individuals who are not immediate family members of the care provider;
- A volunteer;
- A person certified to provide publicly funded child care as an in-home aide;
- A person who provides privately funded child care;
- A caregiver certified by the Department of Developmental Disabilities, such as a supported living provider.

Skilled home health services licenses and nonmedical home health services licenses are valid for three years.

Skilled home health services license requirements

An applicant for a skilled home health services license must submit an application including evidence that the agency or nonagency provider is one of the following: (1) certified for participation in the Medicare program, (2) accredited by an approved national accreditation agency, (3) certified by the Department of Aging to provide community-based long-term care, or (4) otherwise meets Medicare conditions of participation but is not certified for participation in the Medicare program.

The application fee and renewal fee for a skilled home health services license is $250. An applicant for a new license who was not providing direct care immediately prior to September 30, 2021, must provide evidence of a $50,000 surety bond issued by a company licensed to do business in Ohio.

Skilled home health services licenses are inclusive of nonmedical home health services. A home health agency or nonagency provider who holds a skilled home health services license

may provide nonmedical home health services without obtaining a nonmedical home health services license.

Nonmedical home health services license requirements

An application for a nonmedical home health services license must include: (1) fingerprints from the primary owner of the home health agency or of the nonagency provider, (2) copies of any documents filed and recorded with the Secretary of State, (3) a notarized affidavit verifying the identity of the applicant, (4) a copy of the home health agency's criminal records check policy (not applicable to nonagency providers), (5) a statement identifying the applicant's days and hours of operation, (6) a description of the nonmedical home health services to be provided and any relevant policies or procedures, and (7) identification of the applicant's primary place of business and geographic area served. However, the Director is required to waive the requirements if the home health agency or nonagency provider is certified by the Department of Aging to provide community-based long-term care.

The application fee and renewal fee for a nonmedical home health services license is $250. An applicant for a new license who was not providing direct care immediately prior to September 30, 2021, must provide evidence of a $20,000 surety bond issued by a company licensed to do business in Ohio.

ODH duties

Licensing

Under the act, ODH is responsible for reviewing all applications for skilled home health services licenses and nonmedical home health services licenses. For skilled home health services applicants, if the applicant has not had a site visit in the five years prior to submitting an application, the review must include a site visit to verify that Medicare conditions of participation are met.

ODH must issue a license if the applicant has paid the application fee and meets other licensing requirements. ODH has the power to refuse to issue a license or refuse to renew or reinstate a license for reasons it establishes by rule. It may also impose limitations on a license, revoke or suspend a license, place a license holder on probation, or otherwise reprimand the license holder.

The act allows ODH to adjust an initial license renewal date to align renewal of a license with the renewal of a certification or accreditation that is a condition of licensure.

Rulemaking

The Director is responsible for adopting rules to implement the new licensing requirements. These rules must address the following:

- Initial license application forms and procedures;
- License renewal application forms and procedures;

- The documentation that must be provided to demonstrate that Medicare conditions of participation are met if the applicant is not certified for participation in the Medicare program;
- Reasons ODH may take disciplinary action on a license;
- Processes for dispute resolution and appeals related to licensing disputes.

When adopting rules, the Director must consult with the Director of Aging and the Medicaid Director.

Criminal penalties

The act establishes that if a person or agency provides skilled home health services or nonmedical home health services without a license issued by ODH, that person or agency is guilty of a misdemeanor of the second degree on the first offense. For each subsequent offense, the penalty increases to a misdemeanor of the first degree.

Expedited licensing inspections

(R.C. 3721.02)

Nursing homes, residential care (assisted living) facilities, homes for the aging, and veterans' homes (collectively referred to as homes) must be inspected at least once by the Director before the Director issues the home a license. Law maintained by the act permits an applicant for licensure to request an expedited licensing inspection from the Director. The act extends the ability to request an expedited licensing inspection to existing homes when seeking approval to increase or decrease licensed capacity or to make any other change for which the Director requires a licensing inspection. Under preexisting administrative rules, the expedited licensing inspection process was not available to existing homes requiring an inspection for these types of changes.

The act also clarifies, for both new and existing homes, that the obligation to commence an expedited licensing inspection within ten days applies so long as the request for an expedited inspection is complete.

The act provides that any rules adopted by the Director to implement a process for expedited licensing inspections are not subject to the law that requires a state agency to remove two or more existing rules when simultaneously adopting a new rule.

Obsolete procedures and terms

The act eliminates provisions of law describing (1) a process by which a home may request that the Director review plans for a building that is to be used as a home to determine compliance with applicable state and local building and safety codes and (2) authority to collect fees for reviewing the plans. According to representatives of ODH, this process for reviewing plans is not currently used by the Department.

The act also replaces the following terms that are no longer used to refer to certain types of long-term care facilities: rest home and adult care facility.

Frontline Health Care Worker Pilot Program

(Section 291.60)

In FY 2022 and 2023, the act requires ODH to establish and operate a Frontline Health Care Worker Education, Training, and Certification Pilot Program. Its purpose is to reimburse adult education institutions for the cost of education and wraparound services provided to students of health care training programs. The reimbursement is for costs incurred for students 18 or older who (1) are enrolled in programs to prepare them for employment as a health care virtual assistant, medical assistant, medical coder, nurse aide, patient care assistant, or phlebotomist, and (2) reside in a county with a population of 500,000 or more, that has experienced more than 15,000 confirmed cases of COVID-19, and is a severely distressed area, distressed area, or underserved area as defined by the U.S. Department of Housing and Urban Development.

The act defines adult education institution as a private, nonprofit provider of career education and training for adults that is licensed, accredited, or credentialed, or otherwise recognized in a manner approved by ODH. To be eligible under the pilot program, an adult education institution must not receive other higher education funding from the state.

The act identifies two types of expenses that are reimbursable under the pilot program:

1. Education-related expenses, including tuition, course fees, laboratory fees, enrollment application fees, books, and supplies; and

2. Wraparound services costs, including smoking cessation, drug and alcohol counseling, college and career access advising, financial aid counseling and scholarship retention services, workability and employability skills training, employment placement and retention services, financial literacy, or any other similar or related service approved by ODH.

ODH may adopt rules in accordance with the Administrative Procedure Act (R.C. Chapter 119) to implement the pilot program.

Technological resources

(R.C. 3701.132 and 3701.61; repealed R.C. 5167.172)

The act repeals the law that requires the Help Me Grow Program, WIC clinics, and Medicaid managed care organizations to promote the use of technological resources, such as text messaging applications, that provide information on having a healthy pregnancy and healthy baby.

Newborn screening

(R.C. 3701.501)

The act revises the law governing the screening of newborns for genetic, endocrine, and metabolic disorders. Under continuing law, each newborn is to be screened for the disorders specified in rules adopted by the Director. Continuing law also requires the rules to specify Krabbe disease for screening. The act adds X-linked adrenoleukodystrophy and spinal muscular atrophy, with the screenings to begin May 28, 2022.

To assist the Director in determining other disorders for which a newborn must be screened, Ohio law has established the Newborn Screening Advisory Council (NSAC). As part of this law, the NSAC is to evaluate disorders and make recommendations to the Director. In doing so, it must consider certain factors, including a disorder's incidence and the potential for successful treatment. To this list of factors, the act adds whether the U.S. Secretary of Health and Human Services has included the disorder in the federal Recommended Uniform Screening Panel (RUSP).

In the case of a disorder included within the RUSP, the act requires the NSAC to do the following:

- Not later than six months after the disorder's inclusion, determine whether or not to recommend to the Director that each newborn be screened for the disorder;
- If the screening is recommended, submit the recommendation as soon as practicable to the Director.

The act further requires the Director, not later than six months after receiving NSAC's recommendation, to specify the disorder for screening in rules. The screening must begin no later than one year after the rule becomes effective.

With respect to any disorder specified for screening in ODH rules, the act provides that screening is not required if appropriate laboratory equipment is not available.

Smoking and tobacco

Dispensing nicotine replacement therapy without a prescription

(R.C. 4729.284 and 4731.90)

Provider and protocol requirements

The act authorizes a pharmacist to dispense nicotine replacement therapy without a prescription in accordance with a physician-developed protocol to individuals who are 18 years old or older and seeking to quit using tobacco-containing products. The following requirements must be met in order for the authorization to apply:

- The pharmacist must successfully complete an accredited or approved course on nicotine replacement therapy, which is a type of medication that delivers small doses of nicotine;
- The pharmacist must practice in accordance with a physician-established protocol that specifies a definitive set of treatment guidelines and the locations where the nicotine replacement therapy may be dispensed.

The act requires the protocol to include provisions to implement the following requirements:

- Use by the pharmacist of a screening procedure to determine if an individual is a good candidate to receive nicotine replacement therapy dispensed by a pharmacist;

- Referral by the pharmacist of high-risk individuals or individuals with contraindications to a primary care or other provider;
- Development and implementation of a follow-up care plan in accordance with guidelines adopted in rules.

Documentation and notice

The act requires documentation related to screening, dispensing, and follow-up care plans to be maintained in the pharmacy's records for three years. Not later than 72 hours after a screening is conducted, the pharmacist must provide notice to the individual's primary care provider, or to the individual if the primary care provider is unknown.

Prohibition

The act prohibits a pharmacist from dispensing nicotine replacement therapy without a prescription unless the act's requirements are met. It also prohibits a pharmacist from delegating the pharmacist's authority to dispense or supervise the dispensing of nicotine replacement therapy.

Rules

The act requires the Pharmacy Board to adopt rules in accordance with the Administrative Procedure Act to implement its provisions. The rules must specify which nicotine replacement therapies may be included in a protocol. Regarding rules related to requirements for protocols, the Pharmacy Board must consult with the State Medical Board and ODH.

Qualified immunity

The act provides that a physician who in good faith authorizes a pharmacist to dispense nicotine replacement therapy under the act is not liable for or subject to damages in a civil action, criminal prosecution, or professional disciplinary action related to an act or omission of the individual to whom nicotine replacement therapy is dispensed.

Moms Quit for Two grant program

(Section 291.30)

The act continues Moms Quit for Two. Authorized in each biennium since 2015, it is a grant program administered by ODH that awards funds to government or private, nonprofit entities demonstrating the ability to deliver evidence-based tobacco cessation interventions to women who are pregnant or living with children and reside in communities that have the highest incidence of infant mortality, as determined by the Director.

Program funds cannot be used to provide tobacco cessation interventions to Medicaid-eligible women.

Smoke-Free Workplace Law

(R.C. 3794.01)

The act expands the Smoke-Free Workplace Law to include electronic smoking devices and vapor products. Continuing law prohibits smoking in a public place or a place of

employment. For a first violation of this prohibition, ODH issues a warning letter to the offending individual or proprietor. Subsequent fines are set in accordance with the following:

Violation #	Proprietor Violation	Individual Violation
2nd	$100	$100
3rd	$500	$100
4th	$1,000	$100
5th and subsequent	$2,500	$100

ODH also may sue repeat offenders seeking a court requiring the offender to stop the offending behavior.[69]

The act also revises the definition of "retail tobacco store" to apply to stores that sell "lighted or heated tobacco products" as opposed to "cigars, cigarettes, pipes, or other smoking devices for burning tobacco," conforming it to the act's revised definition of "smoking."

Retail vapor store

(R.C. 3794.01 and 3794.03)

The act exempts retail vapor stores from the Smoke-Free Workplace Law, in so far as it applies to vapor products and electronic smoking devices. Retail vapor stores would still be prohibited from allowing all other forms of smoking. A retail vapor store must annually certify its status as such with ODH to qualify for the exemption. The act defines a retail vapor store as being a store that derives more than 80% of its gross revenue from the sale of vapor products, electronic smoking devices, or other electronic smoking accessories.

Certificate of need capital expenditure threshold

(R.C. 3702.511)

Under Ohio's Certificate of Need (CON) Program, certain activities involving long-term care facilities can be conducted only if a CON has been issued by the Director. One activity that requires a review under the CON Program is the renovation of, or addition to, a long-term care facility involving capital expenditures over a set amount. The act increases to $4 million the capital expenditure threshold that results in a CON review and the requirement that a CON be obtained to conduct the activity.

[69] R.C. 3794.02 and 3794.09, not in the act; O.A.C. 3701-52-09.

Children with Medical Handicaps Program eligibility

(R.C. 3701.021 and 3701.022; Section 291.10)

Ohio's Children with Medical Handicaps Program (CMH) is administered by the Department and serves families of children and young adults with special health care needs. The CMH Program has three core components:

- Diagnostic – An individual under age 21 who meets medical criteria, regardless of income, may receive services from CMH-approved providers for up to six months to diagnose or rule out a special health care need or establish a plan of care;
- Treatment – An individual under age 21 who meets both medical and financial criteria may receive treatment from CMH-approved providers for an eligible condition;
- Service coordination – The family of an individual under age 21 who meets medical criteria, regardless of income, may receive assistance locating and coordinating services for the individual with the medical diagnosis.

The act requires the Director to increase the maximum age of CMH participants by establishing eligibility requirements that progressively increase the maximum age of an individual who can be served by the program. In 2021 and 2022 on July 1, the Director's rules must increase the age limit by one year. The final increase, on July 1, 2022, allows individuals under 23 to participate. This annual increase does not apply to the diagnostic component of the CMH Program. The act appropriates an additional $500,000 to the CMH Program in each fiscal year.

Home visiting services

(R.C. 3701.61 and 3701.613 with conforming changes in R.C. 5167.16)

The act expands eligibility to receive home visiting services through the Help Me Grow Program to include families with pregnant women or children under age five. Former law limited home visits to families with pregnant women or children under age three.

Moreover, the act reduces, from twice a year to every two years, the frequency with which ODH must facilitate a summit to share the latest research on home visiting programs and to discuss how to make home visiting programs more effective.

Help Me Grow report

(Section 291.70)

The Director is required to submit a report by January 15, 2022, to the chairperson and ranking minority member of the standing health committee and finance committee of each house of the General Assembly. The report must include the number of families being served by the program who are eligible for Medicaid and the number of families who are eligible for programs funded by the TANF block grant. The report also must include recommendations for incorporating a Medicaid component funded in part with state matching funds, and recommendations for using TANF dollars to provide services for TANF eligible families in the Help Me Grow program.

Rare Disease Advisory Council membership

(R.C. 103.60)

The act adds three public members appointed by the President of the Senate and three appointed by the Speaker of the House to serve on the Rare Disease Advisory Council. Of those members, the act requires that one from each chamber be recommended to the President and the Speaker by the minority leaders of the Senate and House, respectively.

Drug overdose fatality review committees

(R.C. 121.22, 307.631, 307.632, 307.633, 307.634, 307.635, 307.636, 307.637, 307.638, 307.639, 3701.0410, 4729.80, 4729.86, and 4731.22)

The act authorizes the board of county of commissioners of a single county or the boards of two or more counties jointly to establish a county or regional committee to review drug overdose and opioid-involved deaths occurring in that county or region. To formally establish a drug overdose fatality review committee, the board or boards must appoint a health commissioner of a board of health located in the county or counties to do so.

The act also recognizes a body acting as a drug overdose fatality review committee on September 30, 2021, and requires the body to continue to function as the county's review committee, with the same duties, obligations, and protections as a review committee established under the act.

Purpose

The purpose of a drug overdose fatality review committee is to decrease the incidence of preventable overdose deaths by doing all of the following:

- Promoting cooperation, collaboration, and communication between all groups, professions, agencies, or entities engaged in drug abuse prevention, education, or treatment efforts;
- Maintaining a comprehensive database of all overdose deaths occurring in the county or region to develop an understanding of the causes and incidence of those deaths;
- Recommending and developing plans for implementing local service and program changes that might prevent overdose deaths; and
- Providing the ODH with aggregate data, trends, and patterns concerning overdose deaths.

Membership, chairperson, and meetings

If established, a review committee must consist of the health commissioner and the following four members:

1. The chief of police or sheriff or designee of the chief or sheriff;

2. A public health official or designee;

3. The executive director of the county's ADAMHS board or designee; and

4. An Ohio-licensed physician.

In the case of a review committee serving two or more counties, the members must be representatives from the most populous county.

The review committee is required by the act to invite the county coroner or, in the case of a review committee serving two or more counties, the county coroner from the most populous county, to serve on the committee.

The health commissioner convenes committee meetings and serves as the committee's chairperson. Committee meetings are not subject to Ohio's Open Meetings Law. Any vacancy on the committee must be filled in the same manner as original appointments. Members are neither compensated for serving on the committee nor reimbursed for expenses incurred, unless compensation or reimbursement is received as part of the member's regular employment. A majority of the members may invite additional members to serve on the committee. Each additional member serves for the period of time determined by the majority and has the same authority, duties, and responsibilities as an original member.

Information to be collected

For each drug overdose or opioid-involved death reviewed by a committee, the committee must collect all of the following:

1. Demographic information of the deceased, including age, sex, race, and ethnicity;

2. The year in which the death occurred;

3. The geographic location of the death;

4. The cause of death;

5. Any factors contributing to the death; and

6. Any other information the committee considers relevant.

On the request of a review committee, any individual, law enforcement agency, or other public or private entity that provided services to a person whose death is reviewed by the committee must submit to the committee a summary sheet of information. In the case of a request made to a health care entity, the summary sheet must contain only information available and reasonably drawn from a medical record created by the entity. With respect to a request made to any other individual or entity, the sheet must contain only information available and reasonably drawn from any record involving the person to which the individual or entity has access.

Also on the request of a review committee, a county coroner must make available to the committee the coroner's full and complete record that relates to the person whose death is being reviewed.

Confidentiality

Any information, document, or report presented to a review committee, all statements made by committee members during meetings, all work products of the committee, and data submitted to ODH, other than the annual report, are confidential and may be used by the

review committee, its members, and ODH only in the exercise of proper committee or departmental functions.

Security of information collected

Each review committee must establish a system for collecting and maintaining information necessary for the review of drug overdose or opioid-involved deaths in the county or region. In an effort to ensure confidentiality, each committee must maintain all records in a secure location; develop security measures to prevent unauthorized access to records containing information that could reasonably identify any person; and develop a system for storing, processing, indexing, retrieving, and destroying information obtained in the course of reviewing a drug overdose or opioid-involved death.

Annual reports

By April 1 of each year, a committee must prepare and submit to ODH a report that includes the following information for the previous calendar year:

1. The total number of drug overdose or opioid-involved deaths in the county or region;

2. The total number of drug overdose or opioid-involved deaths reviewed by the committee along with the total number not reviewed by the committee;

3. A summary of demographic information for the deaths reviewed, including age, sex, race, and ethnicity; and

4. A summary of any trends or patterns identified by the committee.

The report also must include recommendations for actions that might prevent other deaths and may include any other information the review committee determines should be included. The report is a public record for the purposes of Ohio's Public Records Law.

Pending investigations or prosecutions

A review committee may not conduct 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 the review. On the conclusion of an investigation or prosecution, the law enforcement agency conducting the criminal investigation or prosecuting attorney prosecuting the case must notify the committee's chairperson of the conclusion.

In addition, an individual, law enforcement agency, prosecuting attorney, or entity cannot provide to a review committee any information regarding the death of a person while an investigation or prosecution is pending, unless the prosecuting attorney has agreed to allow the review.

Immunity

Any individual or entity providing information to a review committee is immune from civil liability for injury, death, or loss to person or property that otherwise might be incurred or imposed as a result of providing the information. Each member of a review committee is also immune from civil liability as a result of the member's participation on the committee.

Suicide fatality review committees

(R.C. 121.22, 307.641, 307.642, 307.643, 307.644, 307.645, 307.646, 307.647, 307.648, 307.649, 307.6410, 2151.421, 3701.0411, 4729.80, 4729.86, and 4731.22)

Similar to the provisions described above with regard to drug overdose fatality review committees, the act authorizes the establishment of suicide fatality review committees. Except as provided below, the process for establishing and conducting suicide fatality review committees and their powers and duties regarding suicide deaths are the same as those described above that apply to drug overdose fatality review committees with regard to drug overdose deaths.

Purpose

The purpose of a suicide fatality review committee is to decrease the incidence of preventable suicide deaths by doing all of the following:

- Promoting cooperation, collaboration, and communication between all groups, professions, agencies, or entities engaged in suicide prevention, education, or mental health treatment efforts;
- Maintaining a comprehensive database of all suicide deaths occurring in the county or region to develop an understanding of the causes and incidence of those deaths;
- Recommending and developing plans for implementing local service and program changes and changes to the groups, professions, agencies, or entities that serve local residents that might prevent suicide deaths; and
- Advising ODH of aggregate data, trends, and patterns concerning suicide deaths.

Hybrid committee

The act authorizes a board of county commissioners to establish a hybrid drug overdose fatality and suicide fatality review committee to review drug overdose, opioid-involved, and suicide deaths occurring in the county. A hybrid committee must follow the same procedures as a drug overdose fatality and suicide fatality review committee.

Ohio Breast and Cervical Cancer Project

(R.C. 3701.145)

The act requires the Director to ensure that, as part of the ODH's Ohio Breast and Cervical Cancer Project (BCCP), a woman who meets all of the following conditions receives treatment for breast or cervical cancer:

1. The woman was screened for breast or cervical cancer by a health care provider who either does not participate in BCCP or was not paid by BCCP for the screening;

2. The woman is in need of treatment for breast or cervical cancer;

3. The woman has a countable income not exceeding 300% of the federal poverty line;

4. The woman is not covered by health insurance;

5. The woman is less than 65 years of age.

The act authorizes the Director to adopt rules as necessary to implement this requirement and directs that the rules be adopted in accordance with the Administrative Procedure Act (R.C. Chapter 119).

Under continuing law, BCCP provides breast or cervical cancer screening and diagnostic services to women meeting certain eligibility criteria.[70]

Federal law allows states the option of providing full Medicaid coverage to certain women diagnosed with breast or cervical cancer, including pre-cancerous conditions. In Ohio, this Medicaid option is available only to women who are diagnosed through BCCP. Rather than expand Medicaid coverage to women who satisfy many of the same eligibility requirements but were screened for breast or cervical cancer outside BCCP, sometimes referred to as the "wrong door," the act instead requires the Director of Health to ensure treatment for these women as part of BCCP. Women meeting eligibility requirements who are diagnosed through BCCP will continue to be treated for breast or cervical cancer through Medicaid.

[70] R.C. 3701.144.