Ohio Legislative Service Commission

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Sens. Eklund, Manning, Beagle, Tavares, Brown, Coley, Faber, Hackett, Hite, Jones, Obhof, Skindell, Thomas, Uecker, Williams

Reps. Green, Sprague, Amstutz, Anielski, Antonio, Arndt, Baker, Bishoff, Boggs, Boose, Boyce, Boyd, Celebrezze, Clyde, Conditt, Craig, Driehaus, Fedor, Gavarone, Ginter, Hall, Huffman, Kuhns, LaTourette, Leland, Manning, M. O'Brien, S. O'Brien, Patterson, Pelanda, Phillips, Reineke, Rezabek, Rogers, Ryan, Sheehy, R. Smith, Sweeney, Sykes, Terhar, Young

Effective date: April 6, 2017; certain provisions effective on other dates

ACT SUMMARY

PHARMACY AND DRUG LAWS

Pharmacy technician registration

- Establishes a system of registration through the State Board of Pharmacy for registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees that replaces law governing employment as a qualified pharmacy technician.

- Establishes requirements for registration, including age, education and experience, character, criminal records check, and certification requirements.

- Specifies the activities a pharmacy technician or trainee may engage in, but excludes any that require the exercise of professional judgment.

- Specifies conduct for which the Board may impose disciplinary sanctions on a pharmacy technician or trainee.

Pharmacist and pharmacy intern discipline

- Authorizes the Board to restrict a pharmacist or pharmacy intern's license or reprimand the license holder.

- Modifies the conduct for which the Board can impose sanctions, including specifying additional actions that constitute "unprofessional conduct in the practice of pharmacy."

Dangerous drug sales and possession

- Modifies provisions regarding the occasional sale of drugs at wholesale.

- Prohibits the unauthorized distribution of dangerous drugs at retail, which is in addition to the continuing prohibition on the unauthorized retail sale and possession of dangerous drugs for sale at retail.

- Specifies that business entities whose members are authorized to provide the professional services being offered by the entity are exempt from the prohibition on possession of dangerous drugs.

- Requires prescribers and certain business entities through which prescribers provide professional services to be licensed as terminal distributors of dangerous drugs to possess, have custody or control of, or distribute schedule I, II, III, IV, or V controlled substances.

- Establishes a reduced fee of $60 for certain business entities and other persons required by the act to obtain licenses as terminal distributors of dangerous drugs.

- Reorganizes, with modifications, other laws governing the authority to sell, purchase, distribute, deliver, or possess dangerous drugs.

Pharmacy Board powers, duties, and procedures

- Authorizes the Board to maintain its books and records in electronic format.

- Authorizes the Board to adopt rules requiring a licensee or registrant to report to the Board a violation of state or federal law, including any rule adopted under the authority of the Pharmacy Law.

- Requires pharmacy interns, pharmacy technicians, pharmacy technician trainees, terminal distributors of dangerous drugs, and wholesale distributors of dangerous drugs to cooperate with federal, state, and local government investigations and to divulge all relevant information when requested by a government agency.

- Authorizes the Board to designate certain attorneys as hearing examiners to conduct any administrative hearing the Board is empowered to hold or undertake.

Disciplinary action – controlled substances and dangerous drugs

- Expands the circumstances under which a licensing board may suspend a license, certificate, or evidence of registration without a hearing for actions related to controlled substances.

NALOXONE

Access and administration

- Permits naloxone to be available at locations serving individuals who may be at risk of opioid-related overdoses.

- Permits a board of health to authorize one or more individuals to personally furnish naloxone to certain individuals.

- Modifies a board of health's authority to authorize a pharmacist or pharmacy intern to dispense naloxone without a prescription.

- Modifies the qualified immunity that peace officers are entitled to in circumstances involving naloxone.

Project DAWN grants

- Authorizes a county health department to use grant funding to provide naloxone through a Project DAWN program within the county if the funds available for naloxone grants are not being used by local law enforcement and emergency personnel.

OPIOID ANALGESICS

Outpatient prescription limits

- Limits the authority of a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs to dispense or sell an opioid analgesic pursuant to an outpatient prescription.

- Specifies that not more than a 90-day supply may be dispensed or sold and that a prescription cannot be filled if more than 14 days have elapsed since it was issued or, if the prescription specifies the earliest date on which it may be filled and other conditions are satisfied, 14 days since that date.

Prior authorization and utilization review

- Requires certain health insurers and the Medicaid program to apply prior authorization requirements or utilization review measures as conditions of covering opioid analgesics prescribed for chronic pain, except in specified circumstances.

OFFICE-BASED OPIOID TREATMENT

- Requires the State Board of Pharmacy to establish a licensing process to regulate facilities, clinics, and other locations at which office-based opioid treatment is provided to more than 30 patients, or that meet criteria specified in Board rules.

- Provides for the facilities, clinics, or other locations to be licensed as category III terminal distributors of dangerous drugs with an office-based opioid treatment classification.

- Authorizes sanctions against a person who fails to obtain the required license or fails to comply with the act's requirements for office-based opioid treatment.

METHADONE TREATMENT FACILITIES

- Eliminates requirements that an applicant for a methadone treatment facility license (1) be operated by a nonprofit or government entity and (2) have been a fully certified services provider for at least two years immediately preceding the application date.

- Requires the Department of Mental Health and Addiction Services to adopt rules specifying any additional licensing requirements.

- Requires the Department to conduct an analysis of unmet needs for methadone treatment and the impact of the licensing requirement changes on the overall treatment capacity in Ohio.

DRUG COURT PROGRAMS

- Authorizes a community addiction services provider to provide access to time-limited recovery supports as part of providing medication-assisted treatment services for certain addicted offenders.

- Specifies that recovery support is a form of assistance intended to help initiate and sustain recovery from alcoholism, drug addiction, or mental illness, but it does not include treatment or prevention services.

DRUG TREATMENT FOR PREGNANT WOMEN

Encouraging treatment

- Requires certain health care professionals to encourage drug treatment for pregnant patients under certain circumstances.

- With respect to that requirement, grants those health care professionals limited immunity from civil or criminal liability.

- Requires the Department of Mental Health and Addiction Services, as part of a continuing program, to give priority to treating addicted pregnant women.

- Prohibits a community addiction services provider that receives public funds from refusing to treat a pregnant woman solely because she is pregnant if the provider offers appropriate treatment.

Child welfare proceedings

- Prohibits a public children services agency from filing a child welfare complaint solely because the mother used a controlled substance while pregnant if the mother (1) enrolled in drug treatment before the end of her 20th week of pregnancy, (2) completed treatment or is in the process of completing treatment, and (3) maintained her regularly scheduled appointments and prenatal care.

- Permits a court to hold in abeyance or dismiss a child welfare complaint when the mother enrolled in drug treatment after the end of her 20th week of pregnancy if the mother meets other conditions regarding treatment and prenatal care.

Prenatal screening and tests in criminal proceedings

- Provides that evidence obtained through a screening or test to determine pregnancy or provide prenatal care is not admissible in a criminal proceeding against the woman who was screened or tested.

PHARMACY BENEFIT MANAGERS

Maximum allowable cost pricing information

- Specifies that the pricing updates pharmacy benefit managers must provide pharmacies be maximum allowable cost pricing updates and be in a secure, easily searched, electronic format.

- Requires pharmacy benefit managers to use the most up-to-date pricing data within one business day of the update when calculating reimbursements.

- Requires a pharmacy benefit manager to make available to a pharmacy the manager's written procedure for withdrawing a drug from maximum allowable cost reimbursement.

Drug reimbursement appeals

- Clarifies that the process for appealing drug reimbursements must be electronic.

- Eliminates the requirement that the drug be available for purchase in Ohio from the requirement that, when denying a drug reimbursement appeal, the pharmacy benefit manager identify a drug that can be purchased at or below the drug's benchmark price from a national or regional wholesaler.

- Explicitly requires that, if an appeal is upheld or granted, the pharmacy benefit manager must adjust the drug reimbursement to the appeal price.

Multiple maximum allowable cost lists – disclosures

- Limits to the aggregate difference the requirement that a pharmacy benefit manager using multiple maximum allowable cost lists disclose the differences between the amount paid to a pharmacy and the amount charged to a plan sponsor.

- Revises the time within which the price difference disclosure must be made to require that it be made within ten days of signing a contract with a pharmacy (continuing law) or on a quarterly basis (instead of within ten days of any update to a maximum allowable cost list).

- Exempts Medicare pharmacy benefit plans and plans subject to ERISA from this disclosure requirement.

COMMUNITY ADDICTION AND MENTAL HEALTH SERVICES

- Requires boards of alcohol, drug addiction, and mental health services (ADAMHS boards) to make recovery supports available along with addiction services and mental health services.

- Requires the Department of Mental Health and Addiction Services to adopt rules specifying the types of recovery supports for which certification must be obtained, and prohibits an ADAMHS board from contracting for recovery supports that are required to meet quality criteria or core competencies unless the supports meet those standards.

- Revises the list of services and supports that must be included in an ADAMHS board's continuum of care.

- Permits the Department to waive for a limited time the requirement that an ADAMHS board's continuum of care include all of the otherwise required essential elements if the Department determines that the board has made reasonable efforts to include those elements.

- Permits the Department to waive a requirement that addiction services and recovery supports for opioid and co-occurring drug addiction include ambulatory detoxification and medication-assisted treatment if the Department makes certain determinations.

- Extends medication-assisted treatment to services accompanied by medication approved for the treatment or prevention of alcoholism.

- Prohibits denying a service or support for opioid and co-occurring drug addiction on the basis of an individual's prior experience with the service or support, rather than the individual's failure.

- Revises the waiting list duties of community addiction services providers, ADAMHS boards, and the Department.

- Permits the Department to withhold part, rather than all, of the funds to be allocated to an ADAMHS board for failure to comply with the board's approved budget.

- Maintains a requirement that the Department provide assistance to *any* county for certain ADAMHS board-related activities by eliminating a requirement that the Department provide assistance to *each* county for the activities, and specifies that the Department is to provide the assistance for one or more of the activities, instead of all of the activities.

OTHER MENTAL HEALTH AND ADDICTION SERVICES PROVISIONS

- Includes services for prevention of mental illness in services for which ADAMHS boards and the Department are responsible.

- Exempts the Department's contracts for addiction services or recovery supports from laws governing purchases of services by the Department of Administrative Services.

- Eliminates a provision prohibiting the Department of Mental Health and Addiction Services from disclosing mental health treatment information about certain persons who are incarcerated unless the person is notified and does not object.

- Removes creed from, and adds ancestry and military status to, the classes that are protected against discrimination by ADAMHS boards and community services providers.

- Restricts to certain types the residential facilities to which an ADAMHS board may make referrals and that may serve as permissible living arrangements under the Residential State Supplement program.

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CONTENT AND OPERATION

PHARMACY AND DRUG LAWS

Pharmacy technician registration

The act establishes a system of registration through the State Board of Pharmacy for two kinds of pharmacy technicians, registered pharmacy technicians and certified

pharmacy technicians, as well as pharmacy technician trainees. Under law repealed by the act, pharmacy technicians were not licensed or registered. Instead, persons who met certain age, education, examination, and criminal background check requirements were designated as "qualified pharmacy technicians" and could then be used by pharmacists, pharmacy owners, and managers.[1]

Registration

Registered pharmacy technicians – eligibility

The act requires an applicant for registration as a registered pharmacy technician to meet all of the following conditions:

(1) Be at least 18 years old;

(2) Possess a high school diploma or certificate of high school equivalence (often referred to as a general equivalence diploma or GED), or have been employed continuously since before April 8, 2009, as a pharmacy technician without a high school diploma or GED;

(3) Be of good moral character, as defined in rules adopted by the Board;

(4) Comply with certain criminal records check requirements in continuing law or, if the applicant met the requirements to be a qualified pharmacy technician under the repealed law and had a criminal records check conducted within 24 months of the application date, authorize release of those results;

(5) Obtain from a pharmacy's responsible person an attestation that the applicant has successfully completed education and training that meets requirements to be established by the Board in rules. However, until April 6, 2019, an applicant who met the requirements of the repealed law may instead demonstrate that the applicant has completed a pharmacy training and education program that was appropriate for a qualified pharmacy technician under prior rules.[2] ("Responsible person" has the meaning given in rules adopted by the Board.[3])

The law repealed by the act required qualified pharmacy technicians to meet all of the above requirements, comply with criminal records check requirements, and pass a competency examination approved by the Board.

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[1] R.C. 4729.90, 4729.901, 4729.92, and 4729.921; R.C. 4729.42, repealed.

[2] R.C. 4729.90, 4776.02, and 4776.04; R.C. 4729.42, repealed.

[3] R.C. 4729.90(A).

Certified pharmacy technicians – eligibility

The act requires an applicant for registration as a certified pharmacy technician to comply with the same age, moral character, and criminal records check requirements as an applicant for registration as a registered pharmacy technician. The applicant must also meet all of the following requirements:

(1) Possess a high school diploma or GED;

(2) Obtain from a pharmacy's responsible person an attestation that the applicant has successfully completed education and training that meets the requirements to be established by the Board in rules. However, until April 6, 2019, an applicant who met the requirements in the repealed law to be a qualified pharmacy technician may demonstrate that the applicant completed a pharmacy training and education program that was appropriate under the prior rules, plus instruction on sterile drug compounding and preparing and mixing intravenous drugs that are to be injected into a human being.

(3) Have a current pharmacy technician certification from an organization that has been recognized by the Board.[4]

Application process

The act requires an applicant for registration as a pharmacy technician to file an application with the Board in accordance with rules to be adopted by the Board. The application must be accompanied by a nonrefundable $50 application fee.

If an applicant qualifies, the Board must register the applicant as a registered pharmacy technician or certified pharmacy technician, as applicable. A pharmacist or pharmacy intern whose license has been denied, revoked, suspended, or otherwise restricted by the Board cannot be registered as a pharmacy technician.

Registration is valid for a period specified by the Board in rules to be adopted under the act. The period cannot exceed 24 months unless the Board extends the period to adjust license renewal schedules.[5]

Registration renewal

A registered pharmacy technician or certified pharmacy technician who wishes to renew must file an application for registration renewal in accordance with rules to be

[4] R.C. 4729.90; R.C. 4729.42, repealed.

[5] R.C. 4729.90(C) and 4729.901.

adopted by the Board. Registration must be renewed in accordance with the Board's rules and standard renewal procedures established under continuing law. The renewal fee is $25 per year.

A registered pharmacy technician or certified pharmacy technician who fails to renew registration in accordance with the act is prohibited from engaging in authorized activities, which are discussed below.

If a registration has not been renewed by the date specified in the rules but has not lapsed for more than 90 days, it may be reinstated. An applicant seeking reinstatement must submit a renewal application, the renewal fee, and a late fee of $50. Registration that has lapsed for more than 90 days cannot be renewed, but the registration holder may reapply for registration.[6]

Authorized activities

The act authorizes registered pharmacy technicians and certified pharmacy technicians to engage in certain activities at locations licensed as terminal distributors of dangerous drugs. The activities must be under the direct supervision of a pharmacist and cannot require the exercise of professional judgment.

For registered pharmacy technicians, the authorized activities are:

(1) Accepting new prescription orders from a prescriber or a prescriber's agent;

(2) Entering information into and retrieving information from a database or patient profile;

(3) Preparing and affixing labels;

(4) Stocking dangerous drugs and retrieving those drugs from inventory;

(5) Counting and pouring dangerous drugs into containers;

(6) Placing dangerous drugs into patient storage containers;

(7) Nonsterile drug compounding as authorized in rules the Board is required to adopt under the act;

(8) Other activities specified by the Board in rules to be adopted under the act.[7]

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[6] R.C. 4729.902.

[7] R.C. 4729.91(A).

Certified pharmacy technicians are authorized to engage in all of the activities registered pharmacy technicians are authorized to engage in plus the following:

(1) Accepting or requesting refill authorizations for dangerous drugs that are not controlled substances from a prescriber or the prescriber's agent, so long as there is no change from the original prescription;

(2) Sterile drug compounding as authorized in rules the Board is required to adopt under the act;

(3) Other activities specified by the Board in rules to be adopted under the act.[8]

Pharmacy technician trainee registration

Eligibility

The act requires an applicant for registration as a pharmacy technician trainee to comply with the same age, high school diploma (or GED or continuous employment since before April 8, 2009), and moral character requirements as an applicant for registration as a registered pharmacy technician, as discussed above. The applicant must be enrolled in or plan to enroll in education and training that will allow the applicant to meet the requirements to be established by the Board in rules. The applicant also must comply with criminal records check requirements.[9]

Application process

A pharmacy technician trainee applicant is required by the act to file an application with the Board in accordance with rules to be adopted by the Board. The application must include a nonrefundable $25 application fee.

If an applicant qualifies, the Board is required to register the applicant as a pharmacy technician trainee. A pharmacist or pharmacy intern whose license has been denied, revoked, suspended, or otherwise restricted by the Board cannot be registered as a pharmacy technician trainee.

Registration is valid for one year from the date of registration and is not renewable. However, an individual may reapply if the individual's previous registration has lapsed for more than five years or with Board approval.[10]

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[8] R.C. 4729.91(B).

[9] R.C. 4729.92.

[10] R.C. 4729.92(B) and 4729.921.

Authorized activities

A pharmacy technician trainee may, under the direct supervision of a pharmacist, engage in the same activities as a registered pharmacy technician, as described above.[11]

Sanctions for registered pharmacy technicians and trainees

The act specifies that the Board, after notice and a hearing in accordance with the Administrative Procedure Act (R.C. Chapter 119.), may impose sanctions if a registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee is found to:

(1) Have been convicted of a felony, or a crime of moral turpitude;

(2) Have engaged in dishonesty or unprofessional conduct, as prescribed in rules the Board is required to adopt under the act;

(3) Be addicted to or abusing alcohol or drugs, or impaired physically or mentally to such a degree as to render the individual unable to perform the individual's duties;

(4) Have violated, conspired to violate, attempted to violate, or aided and abetted the violation of any provisions of the Pharmacy Law, Drug Offenses Law, Controlled Substances Law, certain provisions of the Pure Food and Drug Law, or any rules adopted by the Board under any of those laws;

(5) Have committed fraud, misrepresentation, or deception in applying for or securing a registration issued by the Board;

(6) Have failed to comply with an order of the Board or a settlement agreement;

(7) Have engaged in any other conduct for which the Board may impose discipline as set forth in rules that the Board is required to adopt under the act.

The sanctions the Board may impose are:

(1) Revoking, suspending, restricting, limiting, or refusing to grant or renew a registration;

(2) Reprimanding or placing the registration holder on probation;

[11] R.C. 4729.93.

(3) Imposing a fine or forfeiture not to exceed in severity any fine designated under continuing law for a similar offense, or if continuing law does not have a penalty, a fine or forfeiture not to exceed $500.[12]

Timely requests for hearings

Under the act, if notice of an opportunity for a hearing is required but the applicant or registrant does not make a timely request for it, the Board is not required to hold a hearing. The Board may adopt a final order containing the Board's findings and impose any of the sanctions listed above.[13]

Sealing of records

The act also specifies that continuing law regarding the sealing of the following criminal records does not have an effect on the Board's action or any sanction imposed: records of any conviction, guilty plea, judicial finding of guilt resulting from a plea of no contest, or a judicial finding of eligibility for a pretrial diversion program or intervention in lieu of conviction. The Board is not required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.[14]

Board-ordered physical and mental examinations

The act provides that an individual authorized to practice as a pharmacy technician or trainee accepts the privilege of practicing in Ohio subject to supervision by the Board. Filing an application for or holding registration constitutes consent to submitting to a mental or physical examination when ordered by the Board, as well as a waiver of all objections to the admissibility of testimony or examination reports.

The act authorizes the Board to require an individual who is a pharmacy technician or trainee to submit to a physical or mental examination, or both, if the Board has reasonable cause to believe that the individual is physically or mentally impaired. The act specifies that the expense of the examination is the responsibility of the individual.

If the individual fails to submit to the ordered examination, absent circumstances beyond the individual's control, the allegations are to be deemed admitted and a suspension order must be entered without taking testimony or presenting evidence. Any subsequent administrative hearing concerning the failure to submit to an

[12] R.C. 4729.96(A).

[13] R.C. 4729.96(D).

[14] R.C. 4729.96(E).

examination is limited to consideration of whether the failure was beyond the individual's control.

If, based on the results of an examination, the Board determines that the individual's ability to practice is impaired, the Board is required to suspend the individual's registration or deny the individual's application. The Board must require submission to a physical or mental examination and treatment as a condition of initial, continued, reinstated, or renewed registration to practice.

An order of suspension issued by the Board cannot be suspended by a court while an administrative appeal is pending.[15]

Criminal acts

The act prohibits a registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee from knowingly engaging in any of the following:

(1) Dishonesty or unprofessional conduct, as prescribed in rules the Board is required to adopt under the act;

(2) Violation, or conspiracy, attempting, or aiding in the violation of, any provisions of the Pharmacy Law, Drug Offenses Law, Controlled Substances Law, certain provisions of the Pure Food and Drug Law, or any rules adopted by the Board under any of those laws;

(3) Fraud, misrepresentation, or deception in applying for or securing a registration issued by the Board;

(4) Failure to comply with an order of the Board or a settlement agreement;

(5) Any other conduct for which the Board may impose discipline as set forth in rules that the Board is required to adopt under the act.

Under the act, a violation of the prohibition described above is a minor misdemeanor, unless a different penalty is specified in the Revised Code.[16]

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[15] R.C. 4729.96(C).

[16] R.C. 4729.96(F) and 4729.99(A).

Registration suspension for controlled substance addiction

The act adds individuals who are registered pharmacy technicians, certified pharmacy technicians, or pharmacy technician trainees to the licensed health professionals whose license, certificate, or registration must be suspended by the board that issued it if the person is or becomes addicted to the use of controlled substances. The State Board of Pharmacy may suspend a technician or trainee's registration under that provision by telephone conference call. The suspension lasts until the individual offers satisfactory proof of no longer being addicted.[17]

Prohibitions and penalties

The act prohibits a person who is not a pharmacist, pharmacy intern, registered pharmacy technician, certified pharmacy technician, or pharmacy technician trainee from knowingly engaging in any of the activities that a registered pharmacy technician or certified pharmacy technician is authorized to engage in at a location licensed as a terminal distributor of dangerous drugs. However, the act provides that it does not prevent a licensed health professional from engaging in activities that are authorized as part of the health professional's practice. An individual who violates this prohibition is guilty of unauthorized pharmacy-related drug conduct, a second degree misdemeanor unless the offender previously has been convicted of or pleaded guilty to a violation of that prohibition or the prohibitions discussed below.[18]

Law repealed by the act contained a similar prohibition and penalty for pharmacists, pharmacy interns, and qualified pharmacy technicians. However, it only prohibited engaging in the compounding of any drug, packaging or labeling any drug, and preparing or mixing any intravenous drug to be injected.

Similar to the repealed law, the act also prohibits (1) a pharmacist from knowingly allowing any person employed by or otherwise under the control of the pharmacist to violate the prohibition described above, and (2) a terminal distributor of dangerous drugs from knowingly allowing any person employed by or otherwise under the control of the person who owns, manages, or conducts the terminal distributor to violate the prohibition described above. An individual who violates this prohibition is guilty of permitting unauthorized pharmacy-related drug conduct, a second degree misdemeanor unless the person is a repeat offender.

The act does not maintain a provision that prohibited a qualified pharmacy technician from modifying or altering information contained in a criminal records check

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[17] R.C. 3719.121(A) and 4729.96(B).

[18] R.C. 3719.21, 4729.95 and 4729.99; R.C. 4729.42, repealed.

report or using it in any manner that would constitute the crime of falsification. Under the repealed law, an individual who violated the provision was guilty of falsification and forever disqualified from performing services as a qualified pharmacy technician, health care professional, or health care worker. The act does, however, permit the Board to discipline for committing fraud, misrepresentation, or deception in applying for or securing a registration issued by the Board.

Rules on continuing education and other registration provisions

In addition to the rules described above, the act requires the Board to adopt rules establishing continuing education requirements. The Board may also adopt other rules that it considers appropriate to implement the provisions regarding registered pharmacy technicians, certified pharmacy technicians, and pharmacy technician trainees.[19]

Discipline of pharmacists and pharmacy interns

Restrictions and reprimands

Regarding the Board's authority to sanction pharmacists and pharmacy interns, the act authorizes the Board to restrict licenses and reprimand license holders.[20] This is in addition to continuing law authorizing the Board to impose a fine or to revoke, suspend, limit, place on probation, or refuse to grant or renew an identification card.

Grounds for discipline

The act makes several changes concerning the conduct for which a licensee may be disciplined.[21] The act replaces a sanction for gross immorality or being convicted of a felony with a sanction for being convicted of a felony or a crime of moral turpitude. The Board may also impose sanctions if a pharmacist or pharmacy intern has done either of the following:

(1) Failed to comply with an order of the Board or a settlement agreement;

(2) Engaged in any other conduct for which the Board may impose discipline as set forth in rules the Board may adopt under the act.

Another continuing circumstance in which the Board may impose sanctions is if the person has engaged in unprofessional conduct in the practice of pharmacy. The act

[19] R.C. 4729.94.

[20] R.C. 4729.16(A)(1).

[21] R.C. 4729.16(A)(2).

adds the following as actions that constitute "unprofessional conduct in the practice of pharmacy":

(1) Failing to conform to prevailing standards of care of similar pharmacists or pharmacy interns under the same or similar circumstances, whether or not actual injury to the patient is established;

(2) Engaging in any other conduct that the Board specifies as unprofessional conduct in the practice of pharmacy in rules that the act authorizes the Board to adopt.[22]

Board-ordered physical or mental examinations

Continuing law authorizes the Board to require a pharmacist or pharmacy intern to submit to a physical or mental examination, or both, if the Board has reasonable cause to believe that the individual is physically or mentally impaired. The act eliminates a requirement that the Board's belief be based on an administrative adjudication.

Instead, the act provides that an individual authorized to practice as a pharmacist or pharmacy intern accepts the privilege of practicing in Ohio subject to Board supervision. By filing an application or holding a license to practice, an individual gives consent to submit to a physical or mental examination when ordered to do so by the Board. The individual also waives all objections to the admissibility of testimony or examination reports.

The act adds that if the individual fails to submit to the ordered examination, absent circumstances beyond the individual's control, the allegations will be deemed admitted and a suspension order must be entered without taking testimony or presenting evidence. Any subsequent administrative hearing concerning failure to submit to an examination is limited to consideration of whether the failure was beyond the individual's control.

If the Board determines, based on the results of an ordered physical or mental examination, that the individual's ability to practice is impaired, the Board is required to suspend the individual's license or deny the individual's application. The Board must require submission to a physical or mental examination and treatment as a condition of an initial, continued, reinstated, or renewed license to practice. The act specifies that the expense of the examination is the responsibility of the individual to be examined.

[22] R.C. 4729.16(C).

An order of suspension issued under the act's provisions cannot be suspended by a court while an administrative appeal is pending.[23]

Timely requests for hearings

The act adds a provision regarding hearings conducted by the Board. It provides that if notice of an opportunity for a hearing is required, but an applicant or licensee does not make a timely request for a hearing, the Board is not required to hold a hearing. The Board may adopt a final order that contains the Board's findings and may impose any of the sanctions listed above.[24]

Sealing of records

The act provides that, notwithstanding continuing law, the sealing of the following criminal records does not have an effect on the Board's action or any sanction imposed: records of any conviction, guilty plea, judicial finding of guilt resulting from a plea of no contest, or a judicial finding of eligibility for a pretrial diversion program or intervention in lieu of conviction. The act provides that the Board is not required to seal, destroy, redact, or otherwise modify its records to reflect the court's sealing of conviction records.[25]

Criminal penalties

The act clarifies the conduct for which the Board may impose a criminal penalty. Prior to the act, engaging in *any* conduct for which the Board could impose sanctions constituted a minor misdemeanor. Instead, the act specifies that it is a minor misdemeanor only when a person *knowingly* engages in any of the following forms of sanctionable conduct:[26]

(1) Dishonesty or unprofessional conduct in the practice of pharmacy;

(2) Having violated, conspired to violate, attempted to violate, or aided and abetted the violation of any provisions of the Pharmacy Law, Drug Offenses Law, Controlled Substances Law, certain provisions of the Pure Food and Drug Law, or any rules adopted by the Board under any of those laws;

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[23] R.C. 4729.16(E) (primary) and 4729.18.

[24] R.C. 4729.16(F).

[25] R.C. 4729.16(G).

[26] R.C. 4729.16(A) and (H) and 4729.99(A).

(3) Permitting someone other than a pharmacist or pharmacy intern to engage in the practice of pharmacy;

(4) Lending the pharmacist or pharmacy intern's name to an illegal practitioner of pharmacy, or having a professional connection with an illegal practitioner;

(5) Dividing or agreeing to divide remuneration made in the practice of pharmacy with another individual;

(6) Violating the terms of a pharmacist consult agreement;

(7) Committing fraud, misrepresentation, or deception in applying for or securing a license or identification card issued under the Pharmacy Law, the Pure Food and Drug Law, or the Controlled Substances Law;

(8) Failing to comply with a Board order or settlement agreement;

(9) Engaging in any other conduct for which the Board may impose discipline as set forth in rules adopted by the Board.

Selling, purchasing, distributing, or delivering dangerous drugs

The act makes both substantive and organizational changes to provisions governing selling, purchasing, distributing, and delivering dangerous drugs, including changes to exemptions from licensure as a terminal distributor of dangerous drugs.

Who may make wholesale sales of dangerous drugs

The act generally continues to prohibit any person other than a registered wholesale distributor of dangerous drugs from possessing for sale, selling, distributing, or delivering, at wholesale, dangerous drugs. Prior law provided for several exceptions to that prohibition, and the act makes both substantive and organizational changes to those exceptions. The act provides the following exceptions to the prohibition:

(1) A licensed terminal distributor of dangerous drugs that is a pharmacy may make occasional sales of dangerous drugs at wholesale. This replaces prior law, which provided that a pharmacist who was a licensed terminal distributor, or employed by a licensed terminal distributor, could make occasional sales of dangerous drugs at wholesale.

(2) A licensed terminal distributor of dangerous drugs having more than one licensed location may transfer or deliver dangerous drugs from one of its licensed locations to another if the license issued for each location is in effect at the time of the

transfer or delivery. This replaces prior law, which referred to a licensed terminal distributor having more than one "establishment or place" instead of "licensed location."

(3) A licensed terminal distributor of dangerous drugs that is not a pharmacy may make occasional sales of naloxone at wholesale. This replaces prior law, which specified that a board of health or health department could make occasional sales of naloxone at wholesale to state or local law enforcement.[27]

The act moves one other exception to a new section of the Revised Code. Under this relocated exception, a manufacturer of dangerous drugs is permitted to donate asthma inhalers and epinephrine autoinjectors to boards of education, community schools, STEM schools, college-preparatory boarding schools, and chartered or nonchartered nonpublic schools.[28]

Who a wholesale distributor may sell dangerous drugs to

The act continues to prohibit a registered wholesale distributor of dangerous drugs from possessing for sale, or selling, at wholesale, dangerous drugs, except to specified persons. The act adds that the distributor also may not distribute dangerous drugs, except to specified persons. Although the act largely maintains the persons to whom a wholesaler may sell dangerous drugs to, instead of listing each person, the act classifies many of those persons as persons exempt from licensure as a terminal distributor of dangerous drugs in a separate section of the Revised Code. The act then authorizes a wholesaler to sell dangerous drugs to those exempted persons.

Accordingly, the specified persons to whom a wholesale distributor may sell dangerous drugs to under the act are the following:

(1) A licensed terminal distributor of dangerous drugs, subject to continuing limitations based on the category of the terminal distributor's license;

(2) Any person exempt from licensure as a terminal distributor of dangerous drugs as described in the act, subject to limitations for pain management clinics and office-based opioid treatment locations and prescribers employed by those clinics and locations (described below);

(3) A registered wholesale distributor of dangerous drugs;

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[27] R.C. 4729.51(A).

[28] R.C. 4729.513.

(4) Terminal or wholesale distributors of dangerous drugs that are located in another state, not engaged in the sale of dangerous drugs within Ohio, and actively licensed to engage in the sale of dangerous drugs by the state in which the distributor conducts business.

The act does not maintain provisions designating the following persons as persons to whom a wholesale distributor may sell dangerous drugs:

(1) A licensed optometrist who holds a topical ocular pharmaceutical agents certificate;

(2) A manufacturer of dangerous drugs;

(3) Carriers or warehouses for the purpose of carriage or storage.[29]

Limitation on a wholesaler selling dangerous drugs to certain prescribers

The act continues to prohibit a registered wholesale distributor of dangerous drugs from possessing for sale, selling, or distributing, at wholesale, dangerous drugs to (1) a prescriber who is employed by a pain management clinic that is not licensed as a terminal distributor of dangerous drugs with a pain management clinic classification and (2) certain business entities that are, or are operating, a pain management clinic without a license with that classification. The act extends this prohibition to business entities that provide office-based opioid treatment without the licensure required by the act (discussed below), as well as to prescribers employed by those entities.[30]

Limitation on a wholesaler selling dangerous drugs to a terminal distributor

The act maintains provisions that restrict the category of dangerous drugs a wholesaler may sell at wholesale to a licensed terminal distributor of dangerous drugs. The act also applies that restriction to wholesaler distribution of such drugs.[31]

Prohibition on the retail sale and possession of dangerous drugs

The act clarifies that the unauthorized distribution of dangerous drugs at retail is prohibited. This is in addition to law maintained by the act that generally prohibits the following:

(1) Selling dangerous drugs at retail;

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[29] R.C. 4729.51(B) and 4729.541 (primary) and 2947.231.

[30] R.C. 4729.51(C).

[31] R.C. 4729.51(D).

(2) Possessing dangerous drugs for sale at retail;

(3) Possessing dangerous drugs.[32]

Exemptions to all three prohibitions

The following persons and entities continue to be exempt from the prohibitions listed above:

(1) A licensed terminal distributor of dangerous drugs;

(2) A person who possesses, or possesses for sale or sells, at retail, a dangerous drug in accordance with the Controlled Substances Law, Pharmacy Law, and laws governing the following licensed health professionals: dentists, nurses, optometrists, pharmacists, physician assistants, physicians, and veterinarians;

(3) A licensed, certified, or registered individual who has been certified to conduct diabetes education by a national certifying body if diabetes education is within the individual's scope of practice;

(4) An individual who holds a valid certificate issued by a nationally recognized S.C.U.B.A. diving certifying organization with respect to medical oxygen that will be used for the purpose of emergency care or treatment at the scene of a diving emergency.

Additionally, the act adds that the following are exempt from all three prohibitions:

(1) A business entity that under Ohio law is a corporation, limited liability company, or professional association if the entity has a sole shareholder who is a prescriber and is authorized to provide the professional services being offered by the entity;

(2) A business entity that under Ohio law is a corporation, limited liability company, partnership or limited liability partnership, or professional association if, to be a shareholder, member, or partner, an individual must be legally authorized under Ohio law to perform the professional service provided by the entity and each such individual is a prescriber;

(3) A facility that is owned and operated by the U.S. Departments of Defense or Veterans Affairs.[33]

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[32] R.C. 4729.51(E) (primary) and 2929.14.

[33] R.C. 4729.51(E)(2)(a).

Exemptions to the prohibition on possession only

Under the act, a registered wholesale distributor of dangerous drugs is exempt only from the prohibition on possession of dangerous drugs. Under prior law, a wholesaler was also exempt from selling, and possessing for sale, dangerous drugs at retail. Additionally, the following continue to be exempt from the prohibition on possession of dangerous drugs:

(1) Schools and camps possessing epinephrine autoinjectors and asthma inhalers in accordance with continuing law;

(2) Qualified entities possessing epinephrine autoinjectors in accordance with continuing law;

(3) With respect to the possession of naloxone, a law enforcement agency and its peace officers. As opposed to prior law, the purpose of possessing the naloxone is no longer specified.

The act also adds to the list of persons exempted from the possession prohibition a service entity that may possess naloxone under the act (see "**Service entities**," below).[34]

Purchase of dangerous drugs

The act generally prohibits persons exempt from terminal distributor licensure under the act's reorganized provisions[35] from purchasing dangerous drugs from any person other than a registered wholesale distributor. This adds to law maintained by the act that prohibits a licensed terminal distributor from purchasing dangerous drugs from any person other than a registered wholesale distributor, subject to numerous exceptions that the act also applies to the additional persons exempted.[36]

Exception for occasional purchases

The act provides that a licensed terminal distributor or person exempt from licensure under the act's reorganized provisions may make occasional purchases of dangerous drugs from an entity other than a wholesale distributor, if either of the following applies:

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[34] R.C. 4729.51(E)(2)(b).

[35] See R.C. 4729.541.

[36] R.C. 4729.51.

(1) The person is making an occasional purchase of dangerous drugs from a pharmacy that is making an occasional sale of dangerous drugs at wholesale;

(2) The person is making an occasional purchase of naloxone from a terminal distributor that is not a pharmacy and is making an occasional sale of naloxone at wholesale.

This is instead of prior law that provided that a licensed terminal distributor could make occasional purchases of dangerous drugs from a pharmacist who was a licensed terminal distributor or employed by a licensed terminal distributor.[37]

Exception for more than one establishment or place of business

Prior law provided that a licensed terminal distributor having more than one establishment or place of business could transfer or receive dangerous drugs from one licensed establishment or place of business to another. The act refers to a licensed terminal distributor having more than one licensed location, instead of an establishment or place of business. This reflects terminology changes elsewhere in the act. The act also refers to delivering dangerous drugs from one licensed location to another, instead of receiving dangerous drugs between locations.[38]

Distribution of epinephrine autoinjectors and inhalers in schools

Regarding the authorization for schools to deliver epinephrine autoinjectors and asthma inhalers, the act instead provides that the schools may *distribute* the autoinjectors and inhalers in accordance with provisions in continuing law.[39]

Exemption from licensure as a terminal distributor of dangerous drugs

As part of its reorganization, the act classifies certain persons to whom a wholesaler continues to be authorized to sell dangerous drugs to, and certain persons who continue to be authorized to engage in the retail sale and possession of dangerous drugs, as exempt from licensure as a terminal distributor of dangerous drugs. Prior to the act, only certain business entities were explicitly afforded that exception to licensure. While the act's changes are largely organizational, one substantive change requires previously exempt business entities to be licensed if they possess, have custody or control of, or distribute controlled substances.

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[37] R.C. 4729.51(F)(1).

[38] R.C. 4729.51(F)(2).

[39] R.C. 4729.51(I).

The act generally provides that the following are exempt from licensure as a terminal distributor of dangerous drugs:

(1) A licensed health professional authorized to prescribe drugs;

(2) A business entity that is a corporation, limited liability company, or professional association formed under Ohio law if the entity has a sole shareholder who is a prescriber and is authorized to provide the professional services being offered by the entity;

(3) A business entity that is a corporation, limited liability company, partnership, limited liability partnership, or professional association formed under Ohio law, if, to be a shareholder, member, or partner, an individual must be legally authorized under Ohio law to perform the professional service provided by the entity and each such individual is a prescriber;

(4) A licensed, certified, or registered individual who has been certified to conduct diabetes education by a national certifying body, but only with respect to insulin for diabetes education and only if diabetes education is within the individual's scope of practice;

(5) An individual who holds a valid certificate issued by a nationally recognized S.C.U.B.A. diving certifying organization approved by the State Board of Pharmacy, but only with respect to medical oxygen for emergency care or treatment at the scene of a diving emergency;

(6) With respect to epinephrine autoinjectors that may be possessed under continuing law, any of the following: the board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school; a STEM school; a college-preparatory boarding school; a residential camp; a child day camp; a child day camp operated by any county, township, municipal corporation, township park district, park district, or joint recreation district; or a qualified entity;

(7) With respect to asthma inhalers that may be possessed under continuing law, any of the following: the board of education of a city, local, exempted village, or joint vocational school district; a chartered or nonchartered nonpublic school; a community school; a STEM school; a college-preparatory boarding school; a residential camp; a child day camp; or a child day camp operated by any county, township, municipal corporation, township park district, park district; or joint recreation district;

(8) With respect to naloxone that may be possessed under continuing law,[40] a law enforcement agency and its peace officers;

(9) With respect to naloxone that may be possessed under the act, a service entity;

(10) A facility that is owned and operated by the U.S. Department of Defense, U.S. Department of Veterans Affairs, or any other federal agency.[41]

Exceptions to the exemption from licensure

Pain management clinics and office-based opioid treatment providers

The act continues to require specified business entities to obtain licensure as a terminal distributor of dangerous drugs if the entity is a pain management clinic or operates a pain management clinic. The act extends that requirement to all persons otherwise exempt from licensure as a terminal distributor under the act's provisions. Therefore, any pain management clinic or person operating a pain management clinic continues to be required to be licensed as a terminal distributor of dangerous drugs with a pain management clinic classification.

Similar to pain management clinics, the act adds that licensure is required for otherwise exempt persons operating a facility, clinic, or other location described in the office-based opioid treatment provisions of the act if those provisions require the person to hold a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification.[42] This replaces the prior law that required a business entity to hold a terminal distributor license in order to possess, have custody or control of, or distribute controlled substances containing buprenorphine used to treat drug dependence or addiction.

Compounded drugs and controlled substances

The act also requires licensure for an otherwise exempt person or entity when compounded drugs or controlled substances are involved.[43]

Regarding compounded drugs, the act continues to require licensure for a business entity owned by a health professional to provide professional services if the

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[40] See R.C. 2925.61.

[41] R.C. 4729.541(A) (primary) and 4729.68.

[42] R.C. 4729.541(B) and (C).

[43] R.C. 4729.541(D).

entity possesses, has custody or control of, or distributes dangerous drugs that are compounded or used for the purpose of compounding. The act applies that requirement to all persons it otherwise generally classifies as exempted from licensure.

Regarding controlled substances, the act provides that the exemption from terminal distributor licensure for a business entity does not apply in the case of possession, custody or control of, or distribution of any of those drugs. Because many of the act's exemptions relate to drugs that are not controlled substances (such as insulin, medical oxygen, epinephrine, medication in asthma inhalers, and naloxone), the primary effect of the act's provision is to require prescribers and the business entities that they provide professional services through to be licensed as terminal distributors in order to possess, have custody or control of, or distribute controlled substances.

Terminal distributor fees

Under continuing law, the fee for a terminal distributor license ranges from $45 to $150 depending on which drugs the license holder is authorized to possess. Under the act, the fee is $60 for a person who would otherwise be exempt from licensure but must obtain a license because the person possesses, has custody or control of, or distributes compounded drugs or controlled substances. The act maintains a $40 fee for business entities organized for the purpose of practicing veterinary medicine.[44]

Conditions a wholesale distributor must meet before selling dangerous drugs

Under law largely continued by the act, before a registered wholesale distributor of dangerous drugs may sell dangerous drugs at wholesale to any person, the wholesaler generally must obtain a certificate indicating that the purchaser is a licensed terminal distributor of dangerous drugs. As under prior law, the act specifies under its reorganized provisions that a wholesale distributor does not have to obtain the certificate from any person exempted from terminal distributor licensure.[45]

Board powers, duties, and procedures

Books and registers

The act authorizes the books and registers of the Board to be in electronic format, and also makes changes related to the act's provisions for registering pharmacy technicians and trainees. Continuing law requires the Board to keep a record of its proceedings and a record of all identification cards and licenses granted to pharmacists

[44] R.C. 4729.54(G).

[45] R.C. 4729.60 and 4729.541(A).

and pharmacy interns, as well as each renewal, suspension, or revocation. The act requires the Board to keep those same records for registrations.

The act adds a provision that an official statement from the Board that a person has been subjected to disciplinary action is prima-facie evidence of the record of the Board in any court or before an officer of the state. Continuing law contains the same provision with regard to whether an identification card or license has been issued, revoked, or suspended. The act applies those provisions to registrations as well.[46]

Duty to report violations to the Board

The act authorizes the Board to adopt rules requiring a licensee or registrant to report to the Board a violation of state or federal law, including any rule adopted by the Board. In the absence of fraud or bad faith, a person who makes such a report or testifies in an adjudication will not be liable to any person for damages in a civil action as a result of the report or testimony.[47]

Cooperation with investigations

The act requires pharmacy interns, pharmacy technician trainees, registered pharmacy technicians, certified pharmacy technicians, licensed terminal distributors of dangerous drugs, and registered wholesale distributors of dangerous drugs to cooperate with federal, state, and local government investigations and to divulge all relevant information when requested by a government agency. Continuing law requires pharmacists to comply as well.[48]

Generic drug substitution

The act adds a culpable mental state specification to continuing prohibitions related to generic drug substitution and labeling requirements. Under the act, a pharmacist is prohibited from *knowingly* failing to comply with (1) conditions on a pharmacist's substitution of a generic drug when filling a prescription for a drug prescribed by its brand name, and (2) labeling requirements for dispensed drugs. Under the act, any violation of those provisions continues to be a minor misdemeanor.[49]

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[46] R.C. 4729.06.

[47] R.C. 4729.10.

[48] R.C. 4729.19.

[49] R.C. 4729.38(E) and 4729.99(A).

Hearing examiners

The act permits the Board to designate one or more attorneys as hearing examiners, subject to the Administrative Procedure Act. The attorneys must either be classified as administrative law attorney examiners or as administrative law attorney examiner administrators under the State Job Classification Plan, or the Board may enter into a personal service contract with an attorney admitted to the practice of law in Ohio.[50]

Hearing examiners are permitted to conduct any hearing the Board is empowered to hold pursuant to the Administrative Procedure Act. Hearing examiners must hear and consider introduced evidence and issue in writing proposed findings of fact and conclusions of law to the Board for its consideration within 30 days after the hearing.

The act requires that the Board be given a hearing transcript and all exhibits and documents presented at the hearing. The Board must make a decision and take action within 90 days following the receipt of the hearing examiner's proposed findings of fact and conclusions of law.

The act requires the Board's final decision in any hearing to be in writing and contain findings of fact and conclusions of law. Copies of the decision must be delivered to the parties personally or by certified mail. The decision is final on delivery or mailing, but it may be appealed as provided by the Administrative Procedure Act.

Disciplinary action regarding controlled substances and dangerous drugs

The act expands the circumstances under which a board that licenses professionals may suspend a license, certificate, or evidence of registration without a hearing for actions related to drugs. Under continuing law, if a licensing board determines there is clear and convincing evidence that continuation of a professional's practice or method of administering, prescribing, dispensing, or personally furnishing controlled substances presents a danger of immediate and serious harm to others, the agency may suspend the license, certificate, or registration without a hearing. The act permits a board to also take this action based on the professional's method of preparing or dispensing controlled substances. This makes the provision applicable to professionals such as pharmacists who prepare and dispense controlled substances.[51]

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[50] R.C. 4729.171.

[51] R.C. 3719.121(B).

Service entities

Procuring naloxone

The act permits an entity that serves individuals who may be at risk of opioid-related overdose to procure naloxone for use in emergency situations.[52] A "service entity" is a public or private entity that provides services to individuals who there is reason to believe may be at risk of experiencing an opioid-related overdose. The following are specifically included as service entities: a college or university, school, local health department, community addiction services provider, court, probation department, halfway house, prison, jail, community residential center, homeless shelter, or similar entity.

The act permits a service entity to purchase and possess naloxone without obtaining a license from the State Board of Pharmacy.[53]

Authority to administer naloxone

The act permits a service entity employee, volunteer, or contractor who is authorized to do so by a physician or board of health to administer naloxone to an individual who is apparently experiencing an opioid-related overdose. Before authorizing naloxone administration, a physician or board of health must establish a written protocol, which in the case of a board of health, must be established through a physician acting as the board's health commissioner or medical director. A protocol must include all of the following:[54]

(1) A description of the clinical pharmacology of naloxone;

(2) Precautions and contraindications concerning administration;

(3) Any limitations concerning the individuals to whom naloxone may be administered;

(4) The dosage that may be administered and any variation in the dosage based on circumstances specified in the protocol;

(5) Labeling, storage, record-keeping, and administrative requirements;

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[52] R.C. 4729.514(B).

[53] R.C. 4729.51 and 4729.541(A).

[54] R.C. 3707.562(D) and 4731.943(D).

(6) Training requirements that must be met before an individual can be authorized to administer naloxone.

An authorized service entity employee, volunteer, or contractor must obtain the naloxone from the service entity, comply with the protocol, and summon emergency services as soon as practicable. An employee, volunteer, or contractor, acting in good faith, who administers naloxone in accordance with the act is immune from criminal prosecution for unauthorized practice of medicine or violation of Ohio drug laws.[55] Although this criminal immunity does not apply to peace officers or emergency medical technicians, other immunity provision in continuing law apply.

Qualified civil immunity

The act provides qualified civil immunity for acts related to procuring and administering naloxone by service entities and their employees, volunteers, and contractors.

Under the act, a board of health is immune from liability for damages in any civil action for an act or omission of a service entity employee, volunteer, or contractor who the board, in good faith, authorizes to administer naloxone. A physician, including a physician serving as a board's health commissioner or medical director, is immune from liability and is not subject to damages in any civil action, prosecution in any criminal proceeding, or professional disciplinary action for an act or omission of a service entity employee, volunteer, or contractor who the physician in good faith authorizes to administer naloxone.[56]

The act provides further that a service entity or service entity employee, volunteer, or contractor is not liable for damages in any civil action or subject to prosecution in any criminal proceeding or professional disciplinary action for any act or omission associated with procuring, maintaining, accessing, or using naloxone under the act, unless the act or omission constitutes willful or wanton misconduct. The act provides that this immunity does not eliminate, limit, or reduce any other immunity or defense to which a service entity or employee, volunteer, or contractor may be entitled under the Revised Code or Ohio's common law.[57]

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[55] R.C. 2925.61(C).

[56] R.C. 3707.562(E) and 4731.943(E).

[57] R.C. 3707.562(E), 4729.514(C), and 4731.943(E).

Boards of health

Authority to personally furnish naloxone

The act permits a board of health that establishes a protocol to authorize one or more individuals to personally furnish a supply of naloxone to either of the following:[58]

(1) An individual who there is reason to believe is experiencing or at risk of experiencing an opioid-related overdose;

(2) A family member, friend, or other person in a position to assist such an individual.

The authorized individual must comply with the board's protocol and must instruct the individual to whom the naloxone is furnished to summon emergency services as soon as practicable.[59]

A board of health's protocol must be established through a physician serving as the board's health commissioner or medical director, be in writing and include all of the following:[60]

(1) A description of the clinical pharmacology of naloxone;

(2) Precautions and contraindications;

(3) Any limitations the board specifies concerning the individuals to whom naloxone may be furnished;

(4) The naloxone dosage that may be furnished and any variation in the dosage based on circumstances specified in the protocol;

(5) Labeling, storage, record-keeping, and administrative requirements;

(6) Training requirements that must be met before an individual can be authorized to furnish naloxone;

(7) Any instructions or training the authorized individual must provide to an individual to whom naloxone is furnished.

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[58] R.C. 3707.561(A).

[59] R.C. 3707.561(B).

[60] R.C. 3707.561(C).

When these actions are done in good faith, the authorizing board of health, the physician serving as the board's health commission or medical director, and the individual authorized to furnish the naloxone are not liable for damages in any civil action or subject to prosecution in any criminal proceeding or professional disciplinary action for any act or omission of the individual to whom the naloxone is ultimately furnished.[61]

Dispensing naloxone by pharmacists and pharmacy interns

The act permits a board of health to grant the authority to dispense naloxone without a prescription pursuant to a protocol established by the State Board of Pharmacy to any pharmacist or pharmacy intern who practices pharmacy in a county that includes all or part of the health district represented by the board.[62] Under prior law, a board of health could grant that authority only to pharmacists and pharmacy interns who worked within the board's jurisdiction.

Immunity for peace officers

Under prior law, a peace officer's immunity from administrative action and criminal prosecution for administering naloxone to an individual apparently experiencing an opioid-related overdose was conditioned on the peace officer obtaining the naloxone from the law enforcement agency that employed the officer. The act removes this condition. It provides, in addition, immunity from civil liability for peace officers for any injury, death, or loss to person or property that allegedly arises from obtaining, maintaining, accessing, or administering the naloxone.

The act states that the provisions providing civil immunity to peace officers do not eliminate, limit, or reduce any other immunity or defense an entity or person may be entitled to under any provision of the Revised Code or state common law.[63]

Grants for Project DAWN

Continuing law appropriates up to $500,000 in each fiscal year of the 2016-2017 biennium for use by county health departments in enhancing access to naloxone across Ohio through a grant program to local law enforcement, emergency personnel, and first responders. The act provides that if these entities are not making use of the naloxone grant, the county health department is permitted to use grant funding to provide

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[61] R.C. 3707.561(D).

[62] R.C. 3707.56.

[63] R.C. 2925.61(E)(2).

naloxone through a Project DAWN (Deaths Avoided with Naloxone) program within the county.[64]

A Project DAWN program is a community-based overdose education and naloxone distribution program. Participants receive training that includes recognizing the signs and symptoms of overdose and administering intranasal naloxone.[65]

OPIOID ANALGESICS

Limits on dispensing or selling

90-day supply

The act limits the authority of a pharmacist, pharmacy intern, or terminal distributor of dangerous drugs to dispense or sell an opioid analgesic pursuant to a prescription for a drug to be used on an outpatient basis. It prohibits dispensing or selling more than a 90-day supply of the drug, as determined according to the prescription's instructions for use of the drug, regardless of whether the prescription was issued for a greater amount. The act permits the Board to adopt rules that further decrease the 90-day supply limit. The rules must be adopted in accordance with the Administrative Procedure Act.[66]

14-day prescription deadline

The act generally prohibits a pharmacist, pharmacy intern, or terminal distributor from dispensing or selling an opioid analgesic pursuant to a prescription if the drug is to be used on an outpatient basis and more than 14 days have elapsed since the prescription was issued. The act permits the Board to adopt rules that further decrease the 14-day deadline.[67]

The act exempts an opioid analgesic prescription from the 14-day deadline if all of the following apply:

(1) The prescriber has provided written instructions indicating the earliest date on which the prescription may be filled;

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[64] Sections 3 and 4, amending Section 331.120 of H.B. 64 of the 131st General Assembly, the main operating budget act for fiscal years 2016 and 2017.

[65] Ohio Department of Health, *Project DAWN*, available at www.healthy.ohio.gov/vipp/drug/ProjectDAWN.aspx.

[66] R.C. 4729.46(B)(1) and (D).

[67] R.C. 4729.46(B)(2) and 4729.46(D).

(2) The prescription is one of multiple prescriptions for the opioid analgesic issued by the prescriber to the patient on a single day;

(3) When combined, the prescriptions do not authorize the patient to receive more than a 90-day supply of the opioid analgesic.

A prescription that satisfies these conditions may be filled until 14 days have elapsed since the date indicated on the prescription as the earliest date on which it may be filled.[68]

Out-of-state delivery

The act specifies that these prohibitions do not apply when the pharmacist, pharmacy intern, or terminal distributor dispenses or sells an opioid analgesic that is to be delivered by mail, parcel post, or common carrier to a patient who resides outside of Ohio.[69]

Limitations on prescribing

The act permits a state board that licenses prescribers to adopt rules limiting the amount of an opioid analgesic that may be prescribed under a single prescription. The rules must be adopted in accordance with the Administrative Procedure Act. The prescribers included in this provision are physicians, dentists, and veterinarians and certain optometrists, physician assistants, and advanced practice registered nurses.[70]

Prior authorization or utilization review for opioid analgesics

The act requires certain health insurers and the Medicaid program to apply prior authorization requirements or utilization review measures as conditions of providing coverage of opioid analgesics prescribed for chronic pain, except in specified circumstances.[71] Chronic pain is pain that has persisted after reasonable medical efforts have been made to relieve it or cure its cause and has continued for longer than three continuous months.[72]

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[68] R.C. 4729.46(B)(3).

[69] R.C. 4729.46(C).

[70] R.C. 3719.062.

[71] R.C. 1739.05, 1751.691, 3923.851, 5164.091, and 5167.12.

[72] R.C. 1751.691(A), 3923.851(A), and 5164.091(A). See also 4731.052, not in the act.

When implementing the required prior authorization or utilization review, the health insurer or Medicaid program must consider all of the following:[73]

(1) If the course of treatment with the drug continues for more than 90 days, the requirements of continuing law regarding physician management of chronic pain;[74]

(2) If the morphine equivalent daily dose[75] for the drug exceeds 80 milligrams or the patient is being treated with a benzodiazepine at the same time the opioid analgesic is prescribed, the opioid prescribing guidelines established by the Governor's Cabinet Opiate Action Team.

Exceptions

A health insurer or the Medicaid program is not required to apply prior authorization requirements or utilization review measures when the opioid analgesic is prescribed under any of the following circumstances:

(1) To a hospice patient in a hospice care program;

(2) To an individual who has been diagnosed with a terminal condition but is not a hospice patient in a hospice care program;

(3) To an individual who has been diagnosed with cancer or another condition associated with the individual's cancer or history of cancer.[76]

Types of health care coverage affected

Health insurers

The following types of health insurers are subject to the act: (1) health insuring corporations, (2) sickness and accident insurers, (3) multiple employer welfare arrangements, and (4) public employee benefit plans.[77]

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[73] R.C. 1739.05(B), 1751.691(B)(2), 3923.851(B)(2), 5164.091(B)(2), and 5167.12(E).

[74] R.C. 4731.052, not in the act.

[75] A morphine equivalent daily dose is a numerical standard against which the potency of most opioids can be compared. See Brandeis University, Prescription Drug Monitoring Program Training and Technical Assistance Center, *Daily Morphine Milligrams Equivalents Calculator and Guide*, available at http://www.pdmpassist.org/content/guidelines.

[76] R.C. 1739.05(B), 1751.691(B)(1), 3923.851(B)(1), 5164.091(B)(1), and 5167.12(E).

[77] R.C. 1739.05, 1751.691, 3923.851, and 5164.091.

Medicaid

The act also applies to the coverage of prescribed drugs under Medicaid. Regarding Medicaid managed care, it applies to health insuring corporations that serve as Medicaid managed care organizations.[78]

ERISA

The act does not affect health care coverage that is part of employee benefits offered by private employers that self-insure their benefit programs. These programs are generally precluded from state regulation by the federal Employee Retirement Income Security Act (ERISA), a comprehensive federal statute governing administration of employee benefit plans. Larger employers frequently choose to establish their own health insurance plans for their employees in lieu of purchasing coverage from a sickness and accident insurer or health insuring corporation.

Implementation date

In the case of health insurers, the act governs policies, contracts, agreements, or plans issued, delivered, renewed, established, or modified in Ohio on or after January 1, 2018. For Medicaid in general, it applies beginning January 1, 2018; for Medicaid managed care organizations, it applies to contracts entered into on or after that date.[79]

OFFICE-BASED OPIOID TREATMENT

Licensing

The act establishes licensing requirements for facilities, clinics, and other locations where office-based opioid treatment is provided. Effective August 4, 2017, the act prohibits knowingly operating a location without the required licensed if a prescriber provides the treatment to more than 30 patients or the location meets other identifying criteria in rules the State Board of Pharmacy must adopt under the act. The required license is referred to as a category III terminal distributor of dangerous drugs license with an office-based opioid treatment classification. A category III license authorizes the holder to possess, have custody or control of, or distribute any controlled substance.[80]

"Office-based opioid treatment" is defined by the act as the treatment of opioid dependence or addiction using a controlled substance. A prescriber who provides

[78] R.C. 5164.091 and 5167.12.

[79] Section 7.

[80] R.C. 4729.533 and 4729.54; Section 9(C).

treatment subject to the act must apply for a license in the same way as other terminal distributors and meet both the requirements that apply to terminal distributors and the act's additional requirements for such prescribers.[81]

Exemptions

The following are excluded from the act's licensing requirements: (1) hospitals, (2) facilities for treatment of opioid dependence or addiction that are operated by a hospital, (3) physician practices owned or controlled, in whole or in part, by a hospital or an entity that owns or controls, in whole or in part, one or more hospitals, (4) facilities that conduct only clinical research and use controlled substances in studies approved by a hospital-based institutional review board or an institutional review board that is accredited by the Association for the Accreditation of Human Research Protections Programs, Inc., (5) facilities that hold a category III terminal distributor of dangerous drugs license for the purpose of treating drug dependence or addiction as part of an opioid treatment program and are already subject to certification by the U.S. Substance Abuse and Mental Health Services Administration, and (6) programs or facilities licensed or certified by the Ohio Department of Mental Health and Addiction Services.[82]

Operation requirements

An applicant for licensure as a terminal distributor with an office-based opioid treatment classification must submit evidence satisfactory to the Board that the treatment will be operated in accordance with the act's requirements. Under those requirements, the license holder must do all of the following:

(1) Be in control of a facility owned and operated solely by one or more physicians, unless the Board has exempted the applicant from this requirement;

(2) Comply with requirements for conducting office-based opioid treatment established by the State Medical Board in rules adopted under continuing law;[83]

(3) Require any person with ownership of the facility to submit to a criminal records check and send the result directly to the Pharmacy Board for review;

(4) Require all employees of the facility to submit to a criminal records check and ensure that no person is employed who has previously been convicted of or pleaded

[81] R.C. 4729.552, not in the act.

[82] R.C. 4729.553(B)(2).

[83] R.C. 4731.056, not in the act.

guilty to any federal felony theft or drug offense or a felony theft or drug offense in Ohio or another state;

(5) Maintain a list of each person with ownership of the facility and notify the Pharmacy Board of any changes.

The act prohibits a person from knowingly failing to remain in compliance with these requirements.[84]

Criminal records check

Results of criminal records checks must be sent directly to the Pharmacy Board for review. Information in the results is to be made available only to the person who requested the records check and the employer or potential employer.[85]

Sanctions for illegal or improper operation

Pharmacy Board sanctions

The act authorizes the Pharmacy Board to impose a fine of not more than $5,000 for failure to comply with the requirements for operation of a location subject to licensure as a terminal distributor with an office-based opioid treatment classification. A separate fine may be imposed for each day of violation. The sanction must be imposed in accordance with the Administrative Procedure Act (R.C. Chapter 119.), which requires the Board to give notice and an opportunity for a hearing.

In addition, the act authorizes the Pharmacy Board to suspend, without a prior hearing, the license of a terminal distributor with an office-based opioid treatment classification if the Board determines by clear and convincing evidence that there is danger of immediate and serious harm to others. If the license holder is a physician, the Board must consult with the secretary of the Medical Board or, if the secretary is unavailable, another physician member of the Board before suspending the license.[86]

Medical Board sanctions

Continuing law authorizes the Medical Board to take professional disciplinary action against a physician for any of a number of reasons specified in statute. The act authorizes the Board to take any of the permitted forms of discipline against a physician for either of the following:

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[84] R.C. 4729.553(C) to (E).

[85] R.C. 4729.071(B), 4776.02(A) and (B)(2), and 4776.04(B).

[86] R.C. 4729.571.

--Practicing at a location subject to licensure as a terminal distributor of dangerous drugs with an office-based opioid treatment classification unless the person operating that location has obtained and maintains the license with the classification;

--Owning a location subject to licensure as a terminal distributor of dangerous drugs with an office-based opioid treatment classification unless that location is licensed with the classification.[87]

Criminal sanctions

Failure to obtain the required license or comply with the act's office-based opioid treatment requirements is a felony of the fifth degree. If the offender has previously been convicted of or pleaded guilty to the same offense or a violation of pharmacy or drug laws, the offense is a felony of the fourth degree.[88]

Rules

The act requires the Pharmacy Board to adopt rules as it considers necessary to implement and administer its licensing requirements. The rules must be adopted in accordance with the Administrative Procedure Act.[89]

METHADONE TREATMENT FACILITIES

License requirements

Effective June 1, 2017,[90] the act eliminates two requirements that must be met to receive a license for a methadone treatment facility. With this change, a license applicant is no longer required to (1) be operated by a private, nonprofit organization or by a government entity and (2) have been fully certified as a community addiction services provider for at least two years.[91]

The act provides instead that an applicant must meet any additional requirements established by the Ohio Department of Mental Health and Addiction Services in rules.

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[87] R.C. 4731.22(B).

[88] R.C. 4729.99(E).

[89] R.C. 4729.553(G).

[90] Section 9(A).

[91] R.C. 5119.391(C)(1) and (2) (primary) and 5119.392.

The act requires the Department to adopt rules that revise the requirements governing licensure of methadone treatment providers. The rules must include the following requirements:

(1) Be in good standing with the Medicaid program, Medicare program, and the U.S. Drug Enforcement Administration;

(2) Be in good standing in any other jurisdiction in which the community addiction services provider provides services that are comparable to the methadone treatment services authorized by Ohio law;

(3) Be able to meet, and have a plan to provide treatment in accordance with, treatment standards established by federal regulations[92] and accepted standards of medical care for opioid treatment services established by a nationally recognized standards organization selected by the Department's Director.

The act provides that if the Department has not adopted the rules, or if the rules are not in effect, on June 1, 2017, it cannot issue any licenses to maintain methadone treatment under continuing law until the rules are adopted and in effect.

The act also requires the Department, not later than April 6, 2019, to conduct an analysis of unmet needs for methadone treatment in Ohio and the impact of the elimination of the licensure requirements discussed above on the overall treatment capacity in Ohio. The report must be completed within 180 days after beginning the analysis. The Department must publish the report on its website.[93]

DRUG COURT PROGRAMS

Recovery supports

Under a continuing program conducted by the Department of Mental Health and Addiction Services and certain courts with specialized docket programs for drugs, community addiction services providers are used to provide medication-assisted treatment and other services to certain offenders in the criminal justice system who have alcohol or opioid addictions. The act authorizes these providers to provide access to time-limited recovery supports. The act specifies that a recovery support is a form of assistance intended to help an individual with addiction or mental health needs, or a member of such an individual's family, to initiate and sustain the individual's recovery

[92] 42 Code of Federal Regulations 8.12.

[93] Section 5.

from alcoholism, drug addiction, or mental illness. It specifies that a recovery support does not include an addiction or mental health treatment or prevention service.[94]

DRUG TREATMENT FOR PREGNANT WOMEN

Encouraging pregnant women to enroll in drug treatment

The act requires certain health care professionals who care for pregnant women to encourage enrollment in drug treatment programs. The health care professionals to whom the act applies are physicians, registered nurses, licensed practical nurses, and physician assistants. These health professionals must encourage enrollment in treatment when providing prenatal care before the end of the 20th week of pregnancy if they have reason to believe that the woman is using or has used a controlled substance in a manner harmful to the fetus.

The encouraged treatment must be provided by a provider of addiction services or alcohol and drug addiction services. The act defines "addiction services" as services (including intervention) for the treatment of persons with alcohol, drug, or gambling addictions, and for the prevention of such addictions. It defines "alcohol and drug addiction services" as services (including intervention) for the treatment of alcoholics or persons who abuse drugs of abuse and for the prevention of alcoholism and drug addiction.

The health care professionals subject to the act are immune from civil liability and are not subject to criminal prosecution for (1) failing to recognize a pregnant woman's use of a controlled substance in a manner that is harmful to her fetus or (2) any action taken in good faith compliance with the act's requirements.[95]

Treatment priority

The act requires the Department of Mental Health and Addiction Services to give priority to treating drug-addicted pregnant women as part of a continuing program developed by the Department to identify addicted pregnant women and provide intervention and continued monitoring.

The act also requires a community addiction services provider that receives public funds to give priority to pregnant women referred to treatment. The act prohibits

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[94] Sections 3 and 4, amending Section 331.90 of H.B. 64 of the 131st General Assembly.

[95] R.C. 3701.59; R.C. 5119.01(A)(2) and (3).

the provider from refusing to treat a pregnant woman solely because she is pregnant, so long as appropriate treatment is offered by the provider.[96]

Child welfare proceedings

The act places restrictions on the filing of a child welfare complaint by a public children services agency (PCSA) when such a complaint is filed solely due to a mother's use of a controlled substance while pregnant. Under continuing law, PCSAs are required to assess and investigate reports of abuse, neglect, or dependency to determine whether a child is safe or at risk. In appropriate circumstances, a PCSA may file a complaint with the juvenile court alleging that a child is an abused, neglected, or dependent child.[97] The court must then determine whether the child is an abused, neglected, or dependent child and, if so, whether the child should be removed from the parent's custody.

The act prohibits a PCSA from filing such a complaint regarding a child who is less than 30 days old solely because the child's mother used a controlled substance while pregnant, so long as the mother did all of the following:

(1) Before the end of the 20th week of pregnancy, enrolled in a drug treatment program provided by a provider of addiction services or alcohol and drug addiction services;

(2) Successfully completed the program or is in the process of completing the program and is in compliance with the program's terms and conditions as determined by the program;

(3) Maintained her regularly scheduled appointments and prenatal care recommended by her health care provider for the remaining duration of the pregnancy.

If a pregnant woman enrolled in a drug treatment program after the end of her 20th week of pregnancy, the act permits a court to do either of the following instead of considering the complaint:

(1) Hold it in abeyance if the court finds the woman is in the process of completing the program and has maintained her regularly scheduled appointments and prenatal care;

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[96] R.C. 5119.17.

[97] R.C. 2151.27, not in the act.

(2) Dismiss it if the court finds that the woman successfully completed the program and maintained her regularly scheduled appointments and prenatal care.

The act specifies that it does not prevent a PCSA from filing a complaint regarding a newborn if the PCSA determines that the mother, or any other adult caring for the newborn, is unable to provide adequate parental care.[98]

Prenatal screening and tests in criminal proceedings

The act provides that evidence of the use of a controlled substance obtained through a screening or test regarding pregnancy or prenatal care is not admissible in a criminal proceeding against the woman who was screened or tested. However, the act specifies that it does not prohibit criminal prosecution based on evidence obtained through other methods.[99]

Maiden's Law

The act specifies that its provisions regarding drug treatment for pregnant women are to be known as "Maiden's Law."[100]

PHARMACY BENEFIT MANAGERS

Maximum allowable cost pricing information

The act amends the law related to pharmacy benefit managers and maximum allowable cost drug reimbursement.

Continuing law requires pharmacy benefit managers to provide pharmacies with the pricing information used to determine maximum allowable cost pricing, to update and implement this pricing information at least every seven days, and to provide a means by which a pharmacy may review these updates. The act specifies that these pricing updates are to be maximum allowable cost pricing updates, that they are to be in an electronic format, and that they must be in a format that is secure and easily searched. Additionally, the act requires a pharmacy benefit manager to use the most up-to-date pricing data within one business day of the update when calculating drug product reimbursements.

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[98] R.C. 2151.26.

[99] R.C. 2945.65.

[100] Section 8.

The act requires a pharmacy benefit manager to make available to a pharmacy, upon request, the manager's written procedure for withdrawing a drug from being subject to maximum allowable cost reimbursement.[101]

Drug reimbursement appeals

The act amends the process by which a pharmacy may appeal a drug product reimbursement. Continuing law requires a pharmacy benefit manager to maintain a process for appealing drug reimbursements and resolving related disputes. The act clarifies that this process must be electronic. When denying a drug reimbursement appeal, former law required the pharmacy benefit manager provide a reason for the denial and identify a drug that could be purchased *in Ohio* from a national or regional wholesaler at a price at or below the benchmark price determined by the pharmacy benefit manager; the act eliminates the requirement that the drug be available for purchase in Ohio. Additionally, the act explicitly requires that if an appeal is upheld, then the pharmacy benefit manager must adjust the drug product reimbursement to the pharmacy's appeal price.[102]

Multiple maximum allowable cost lists – disclosures

Continuing law requires a pharmacy benefit manager that uses multiple maximum allowable cost lists to disclose this fact to a plan sponsor, as well as any differences between the amount paid to a pharmacy and the amount charged to a plan sponsor. The act requires this disclosure to be made in the aggregate.[103]

Additionally, under former law, this disclosure was to be made within ten days of either of the following:

- The signing of a contract between a pharmacy benefit manager and a plan sponsor;
- Any update to a maximum allowable cost list.

The act instead requires the disclosure to be made on a quarterly basis or within ten days of the signing of a contract.[104]

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[101] R.C. 3959.111(A)(1).

[102] R.C. 3959.111(A)(3).

[103] R.C. 3959.111(B)(1)(b).

[104] R.C. 3959.111(B)(2).

Finally, the act exempts Medicare pharmacy benefit plans and pharmacy benefit plans that are subject to the Employee Retirement Income Security Act of 1974, i.e., self-insured, large employer plans, from this disclosure requirement.[105]

Rules

The act specifically authorizes the Superintendent of Insurance to adopt rules as necessary to implement requirements related to pharmacy benefit managers and maximum allowable cost.[106]

COMMUNITY ADDICTION AND MENTAL HEALTH SERVICES

The act revises the system for making addiction and mental health services available in communities. The system involves three main entities: boards of alcohol, drug addiction, and mental health services (ADAMHS boards), providers of the services, and the Department of Mental Health and Addiction Services.

Under the system, ADAMHS boards are responsible for making certain addiction and mental health services available to residents of their service districts. This is accomplished in large part by planning, budgeting, and contracting with providers. In general, the Department has a supervisory role under which it approves the boards' plans and budgets, allocates state and federal funds, and certifies many of the providers.

Many of the statutes governing community addiction and mental health services were revised by H.B. 483 of the 130th General Assembly to take effect September 15, 2016. The effective date of the revision was delayed until July 1, 2017, by H.B. 483 of the 131st General Assembly and S.B. 129 of the 131st General Assembly. The act provides for its revisions to also take effect July 1, 2017.[107]

Recovery supports

The act requires ADAMHS boards to make recovery supports available and perform related functions as part of the process of making addiction services and mental health services available. It requires the Department to perform the same types of oversight functions for recovery supports that it performs for addiction services and mental health services. Recovery supports are forms of assistance intended to help an individual who is addicted to alcohol or drugs or has a mental illness, or a member of

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[105] R.C. 3959.111(B)(3).

[106] R.C. 3959.111(D).

[107] Section 9(B).

such an individual's family, initiate and sustain the individual's recovery. Alcohol and drug addiction services and mental health services are not themselves recovery supports.[108]

The act requires the Director of Mental Health and Addiction Services to adopt rules specifying the types of recovery supports for which certification must be obtained from the Director for the provider to be eligible to receive funding for the supports.

Recovery housing that is required to be part of the array of services and supports for opioid and co-occurring drug addiction is not to be subject to certification as a recovery support.[109] (See "**Array of services for opioid and co-occurring drug addiction**," below.)

The act requires ADAMHS boards to do all of the following regarding recovery supports:

(1) Evaluate the need for recovery supports and set priorities;[110]

(2) Address the Department's priorities for recovery supports in the boards' annual community addiction and mental health plans;[111]

(3) Investigate, or request that another agency investigate, any complaint alleging abuse or neglect of any person receiving recovery supports;[112]

(4) Conduct program audits that review and evaluate the quality, effectiveness, and efficiency of recovery supports.[113]

(5) Provide for all contracted recovery supports to be audited at least annually;[114]

(6) Recruit and promote local financial support for recovery supports from private and public sources;[115]

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[108] R.C. 5119.01(A)(16) (primary) and 340.01(A)(1).

[109] R.C. 5119.36(E)(1) (primary), 340.034(B), and 5119.01(A)(6)(c).

[110] R.C. 340.03(A)(1)(a) and (b).

[111] R.C. 340.03(A)(1)(c).

[112] R.C. 340.03(A)(2).

[113] R.C. 340.03(A)(4) and 5119.22(D).

[114] R.C. 340.03(A)(6).

[115] R.C. 340.03(A)(7).

(7) Approve fee schedules and related charges for contracted recovery supports or adopt a unit cost schedule or other methods of payment;[116]

(8) Submit to the Director of Mental Health and Addiction Services and county commissioners, and make available to the public, annual reports that address recovery supports, as well as addiction and mental health services;[117]

(9) Assure that the list of services (including recovery supports) they submit for approval to the Department are available to severely mentally disabled persons residing in their service districts;[118]

(10) Establish a mechanism for obtaining advice and involvement of persons receiving recovery supports on matters pertaining to the supports in their districts;[119]

(11) Include as essential elements in the board's community based continuum of care (a) outreach and engagement activities to locate persons in need of addiction services and mental health services to inform them of available recovery supports, (b) specified recovery supports, and (c) an array of recovery supports for all levels of opioid and co-occurring drug addiction (see "**Continuum of care**," below);[120]

(12) Contract with community addiction services providers and community mental health services providers for recovery supports, but a board may not contract for recovery supports that are required by the Director to meet quality criteria or core competencies unless the supports meet the criteria or competencies;[121]

(13) Include in a list to be submitted to the Department for approval the recovery supports it intends to make available;[122]

(14) Contract with community mental health services providers to ensure, through ongoing monitoring, that recovery supports included in the board's approved

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[116] R.C. 340.03(A)(8).

[117] R.C. 340.03(A)(9).

[118] R.C. 340.03(A)(11).

[119] R.C. 340.03(A)(13).

[120] R.C. 340.032(A)(2)(a) and (9), 340.033, and 2929.13.

[121] R.C. 340.036 (primary), 307.86, 340.03, 340.091, 340.13, 3313.65, 5119.01(A)(7) and (8), 5119.36, and 5119.366.

[122] R.C. 340.08(B) and (C), 340.011, 340.09(A)(2), and 5119.22(G).

list of services are available to Residential State Supplement recipients referred to the providers;[123]

(15) Include complaints concerning the rights of persons seeking or receiving recovery supports within the report a board must submit to the Department summarizing other complaints concerning the rights of persons seeking or receiving services.[124]

The act requires that an ADAMHS board's executive director (1) supervise recovery supports for which the board contracts or supports to determine whether the supports are being administered in accordance with state statutes and rules, (2) recommend to the board changes necessary to increase the effectiveness of recovery supports, (3) encourage the development and expansion of recovery supports, and (4) include information about recovery supports in an annual report to the board.[125]

Regarding county government, the act provides that county treasurers are to be custodians of funds for recovery supports. It also requires that the monthly reports county auditors must submit to boards regarding receipts, disbursements, and ending balances for funds for services also include that information for funds for recovery supports.[126]

The act requires the Department to do all of the following regarding recovery supports:

(1) Provide training, consultation, and technical assistance regarding recovery supports to the Department's employees, community services providers, and ADAMHS boards;[127]

(2) To the extent it has available resources, promote and support a full range of recovery supports that are available and accessible to all Ohio residents, especially severely emotionally disturbed children and adolescents; severely mentally disabled adults; pregnant women; parents, guardians, or custodians of children at risk of abuse

[123] R.C. 340.091.

[124] R.C. 340.08(E).

[125] R.C. 340.041.

[126] R.C. 340.10.

[127] R.C. 5119.21(A)(2).

or neglect; and other special target populations, including racial and ethnic minorities, as determined by the Department;[128]

(3) Develop standards and measures for evaluating the effectiveness of recovery supports and promote, direct, conduct, and coordinate scientific research, taking ethnic and racial differences into consideration, concerning methods of providing effective recovery supports;[129]

(4) Establish a program to protect and promote the rights of persons receiving recovery supports, including the issuance of guidelines on informed consent and other rights;[130]

(5) Promote the involvement of persons who are receiving or have received recovery supports and their families and other persons with a close relationship to them in the planning, evaluation, delivery, and operation of recovery supports;[131]

(6) Notify and consult with recovery supports consumers and their families who are affected by rules, standards, and guidelines issued by the Department;[132]

(7) Consult with persons receiving recovery supports when establishing guidelines for the use of funds the Department allocates to ADAMHS boards;[133]

(8) Assess an ADAMHS board's evaluation of recovery supports;[134]

(9) Include in the annual report the Department submits to the Governor the number and types of recovery supports provided to severely mentally disabled persons through state-operated services and community services providers;[135]

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[128] R.C. 5119.21(A)(3).

[129] R.C. 5119.21(A)(4) and (6).

[130] R.C. 5119.21(A)(8).

[131] R.C. 5119.21(A)(9).

[132] R.C. 5119.21(A)(10).

[133] R.C. 5119.23(C).

[134] R.C. 5119.22.

[135] R.C. 5119.60.

(10) Collect information about recovery supports delivered and persons served for reports and evaluations relating to state and federal funds expended for recovery supports.[136]

The act authorizes the Department to require boards to report under a community behavioral health system information on recovery supports provided.[137] No community services provider may fail to supply statistics and other information within its knowledge and with respect to its recovery supports that the Department requests.[138]

With certain exceptions, all records and reports identifying a person and pertaining to the person's provision of, or payment for, recovery supports are confidential under the act when maintained in connection with a service certified by the Department or recovery supports paid for with funds administered by the Department or an ADAMHS board. The records and reports may be disclosed to staff members of a board or staff members designated by the Director for the purpose of evaluating the quality, effectiveness, and efficiency of recovery supports and determining whether recovery supports meet minimum standards. A community mental health services provider that ceases to operate may transfer the records and reports to another community mental health services provider that assumes its caseload or to a board.[139]

The Department's hospitals, institutions, and other facilities are permitted by the act to exchange psychiatric records and other pertinent information with payers and providers of recovery supports as needed to facilitate a patient's continuity of care or for an individual's emergency treatment.[140]

Continuum of care

The act revises the continuum of care that each ADAMHS board must establish to the extent resources are available as part of the duty to make addiction services and mental health services available to the residents of its service district. The act refers to this as a "community-based continuum of care."[141]

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[136] R.C. 5119.61(A).

[137] R.C. 5119.22(E).

[138] R.C. 5119.61(B).

[139] R.C. 5119.28.

[140] R.C. 5122.31(A)(7).

[141] R.C. 340.032 (primary), 340.01, 340.03, 340.033, 340.034, 340.08, 340.09, 2929.13, 4731.62, 5119.01, 5119.21, 5119.22, and 5119.23.

Essential elements

The act also revises the essential elements that must be included in a community-based continuum of care. Under the act, the following are the essential elements:

(1) Prevention and wellness management services;

(2) At least both of the following outreach and engagement activities: (a) locating persons in need of addiction services and persons in need of mental health services to inform them of available addiction services, mental health services, and recovery supports and (b) helping recipients of those services obtain services necessary to meet basic human needs for food, clothing, shelter, medical care, personal safety, and income;

(3) Assessment services;

(4) Care coordination;

(5) Residential services;

(6) At least the following outpatient services: nonintensive, intensive (such as partial hospitalization and assertive community treatment), withdrawal management, and emergency crisis;

(7) At least the following inpatient services (where appropriate): psychiatric care and medically managed alcohol or drug treatment;

(8) At least all of the following recovery supports: peer support; a wide range of housing and support services (including recovery housing); employment, vocational, and educational opportunities; assistance with social, personal, and living skills; multiple paths to recovery such as 12-step approaches and parent advocacy connection; and support, assistance, consultation, and education for families, friends, and persons receiving addiction services, mental health services, and recovery supports;

(9) An array of addiction services and recovery supports for all levels of opioid and co-occurring drug addiction;

(10) Any additional elements the Department determines are necessary to establish the community-based continuum of care.[142]

The act permits the Director to issue to an ADAMHS board a time-limited waiver of the requirement that the board's community-based continuum of care include all of

[142] R.C. 340.032 and 5119.01(A)(13).

the essential elements. The waiver may be issued if the Director determines that the board has made reasonable efforts to include in the continuum the elements being waived. The waiver must specify the amount of time for which it is issued and which of the essential elements are waived. The Director must establish procedures for issuing these waivers. In establishing the procedures, the Director must consult with board representatives and consider recommendations made by the Department's medical director.[143]

Law that was to go into effect July 1, 2017, would have required that the essential elements include grievance procedures and protection of the rights of persons receiving addiction or mental health services. The act requires instead that each ADAMHS board ensure that (1) the rights of persons receiving any elements of the community-based continuum of care are protected and (2) persons receiving any of the elements are able to use grievance procedures that apply to the elements.[144]

Array of services for opioid and co-occurring drug addiction

Law that was to go into effect July 1, 2017, would have required an ADAMHS board's continuum of care to include an array of treatment and support services for all levels of opioid and co-occurring drug addiction. As discussed above, the act instead requires a board's community-based continuum of care to include an array of addiction services and recovery supports for all levels of opioid and co-occurring drug addiction. The act also makes the following changes related to this issue:

(1) The array must include (a) peer support instead of peer mentoring, (b) residential services instead of residential treatment services, and (c) multiple paths to recovery such as 12-step approaches, instead of just 12-step approaches.[145]

(2) The Director is permitted to issue to a board a waiver of a requirement that the array include ambulatory detoxification and medication-assisted treatment if the Director determines (a) ambulatory detoxification and medication-assisted treatment can be made available through one or more contracts between the board and community addiction services providers that are located not more than 30 miles beyond the borders of the board's service district and (b) the amount of time it takes for residents of the district to travel to a community addiction services provider that provides ambulatory detoxification and medication-assisted treatment does not impose

[143] R.C. 5119.221 (primary), 340.032(A), 340.08(B), 5119.01(A)(13), and 5119.22(F)(5) and (G).

[144] R.C. 340.03(A) and 340.032.

[145] R.C. 340.033.

a significant barrier to successful treatment.[146] The Director must establish procedures for issuing the waivers. In establishing the procedures, the Director must consult with board representatives and consider recommendations made by the Department's medical director.[147]

(3) Medication-assisted treatment is to include services that are accompanied by medication approved by the U.S. Food and Drug Administration for the treatment of alcoholism, prevention of alcoholism, or both.[148]

(4) The addiction services and recovery supports included in the array must be made available in a way that ensures that recipients are able to access the services and supports they need for opioid and co-occurring drug addiction in an integrated manner and in accordance with their assessed needs, rather than without delay, when changing or obtaining additional services or supports for the addiction.[149]

(5) An individual seeking an addiction service or recovery support for opioid and co-occurring drug addiction included in a community-based continuum of care is not to be denied the service or support on the basis of the individual's prior experience with the service or support, rather than on the basis that it previously failed.[150]

Waiting list and reporting duties

The act revises the duties of community addiction services providers, ADAMHS boards, and the Department regarding waiting lists and reports.

Providers' duties

Under the act, a community addiction services provider must maintain a waiting list for the provider's addiction services and recovery supports included in the array of services and supports for all levels of opioid and co-occurring drug addiction required to be included in an ADAMHS board's community-based continuum of care. Law that was to go into effect July 1, 2017, would have required a community addiction services provider to maintain, in an aggregate form, a waiting list of each individual who has (1) been documented as having a clinical need for alcohol and drug addiction services due to an opioid or co-occurring drug addiction, (2) applied to the provider for a

[146] R.C. 5119.221 (primary) and 340.033.

[147] R.C. 5119.22(F)(5).

[148] R.C. 340.01(A)(2) and 340.033.

[149] R.C. 340.033.

[150] R.C. 340.033.

clinically necessary treatment or support service, and (3) not begun to receive the treatment or support service within five days of the individual's application because the provider lacks an available slot for the individual.[151] The act eliminates these requirements.

A provider is required by the act to do all of the following:

(1) Remove an individual from the waiting list if (a) the individual withdraws the request for the addiction services and recovery supports or (b) the individual, after being notified about an available slot, does not contact the provider within a period of time to be specified in the Director's rules or otherwise vacates the slot before beginning to receive the services and supports;

(2) As part of the process of maintaining the waiting list, determine (a) for each individual who seeks the addiction services and recovery supports from the provider, the number of days that starts with the day the individual first contacts the provider about accessing the services and supports and ends on the day of an assessment of the individual's clinical need for the services and supports or, if no assessment is required, the first day the individual accesses the services and supports and (b) for each individual who is required to be assessed for the individual's clinical need for the services and supports, the number of days that starts with the day of the assessment and ends with the first day that the individual accesses the services and supports;

(3) Using information the provider acquires from maintaining the waiting list, determine whether the addiction services and recovery supports are insufficient to meet the needs of individuals on the waiting list.[152]

The act also revises community addiction services providers' reporting duties regarding the waiting lists. Under the act, a provider must report to the Department all of the following information not later than the last day of each month:

(1) An unduplicated count of all individuals who were included on the provider's waiting list during the immediately preceding month and each type of addiction service and recovery support for which they were waiting;

(2) The total number of days each individual had been on the provider's waiting list during the immediately preceding month;

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[151] R.C. 5119.362(A)(1).

[152] R.C. 5119.362(A)(1) to (5).

(3) The last known type of residential setting (identified at least as either institutional or noninstitutional) in which each individual resided during the immediately preceding month;

(4) The total number of individuals who did not contact the provider after receiving, during the immediately preceding month, notice about the provider having slots available for them and, if known, the reasons the contacts were not made;

(5) The total number of individuals who withdrew, in the immediately preceding month, their requests for the addiction services and recovery supports, each type of service and support that those individuals had requested or been assessed as having a clinical need for, and, if known, the reasons those individuals withdrew their requests;

(6) An unduplicated count of all individuals who were referred to another community addiction services provider because the referring provider does not provide the type of addiction service or recovery support that those individuals had requested or been assessed as having a clinical need for and each type of service and support for which those individuals were referred;

(7) All other information specified in rules the Director is to adopt.[153]

The act requires that the reports specify the counties of residence of the individuals in the unduplicated counts and include identifying information required by rules the Director is to adopt so that the Department is able to identify any individuals who are inadvertently duplicated in the counts.[154]

Duties of the ADAMHS boards and Department

The act eliminates ADAMHS boards' compilation, determination, and report duties regarding the waiting lists. Instead, it requires the Department to do both of the following with the reports it is to receive from community addiction services providers: (1) make the reports available on its website and (2) make the reports available in an electronic format to boards in a manner that provides the information about an individual contained in a report to the board that serves the individual's county. The information on the website is to be presented on both a statewide aggregate basis and a county-level aggregate basis.[155] Each board is required to acknowledge to the Department that it has received and reviewed the information made available. Using

[153] R.C. 5119.362(A)(6) and (B)(2).

[154] R.C. 5119.362(B)(1).

[155] R.C. 5119.364.

the information, a board is to determine whether any addiction services and recovery supports included in the array of services and supports for all levels of opioid and co-occurring drug addiction are not meeting the needs for addiction services and recovery supports in the board's service district. A board must inform the Department of its determination. The notice may include any commentary the board determines necessary.[156]

Planning duties

Continuing law requires each ADAMHS board to develop an annual plan regarding services that includes priorities for services. The act specifies that the priorities are the Department's priorities and requires the Department to inform all boards of its priorities in a timely manner so the boards are able to know the Department's priorities before they develop and submit their plans.[157]

Withholding funds

The act requires the Director to withhold, *in whole or in part*, funds otherwise to be allocated to an ADAMHS board if the board's use of state and federal funds fails to comply with the board's budget that has been approved by the Department. Under prior law, the Director's only option was to withhold *all* of the funds.[158]

Assistance to counties

The Department is required to provide assistance to counties for various purposes using funds the General Assembly appropriates. Prior to H.B. 483 of the 131st General Assembly, the Department was required to assist *any* county. In contrast, H.B. 483 requires the Department to assist *each* county. The act restores the prior law so that the Department is required to assist *any* county and to provide the assistance for *one or more*, instead of *all*, of the various purposes. Additionally, instead of authorizing assistance for services within an ADAMHS board's continuum of care, the act authorizes assistance for the provision of addiction services, mental health services, and recovery supports included in a list that boards are required to submit to the Department for approval.[159]

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[156] R.C. 340.20.

[157] R.C. 340.03(A)(1)(c).

[158] R.C. 340.08 and 5119.25.

[159] R.C. 340.09.

Procedures for offering technical assistance

The act requires the Director to establish procedures to be followed when offering technical assistance to help an ADAMHS board meet criteria for approval of a proposed community addiction and mental health plan, budget, list of services, or amendment to an approved plan, budget, or list. In establishing the procedures, the Director must consult with board representatives and consider recommendations made by the Department's medical director.[160]

Collection of personal information

The act prohibits the Department from collecting under its community behavioral health information system any personal information from community services providers, except as required or permitted by state or federal law for purposes related to payment, health care operations, program and service evaluation, reporting activities, research, system administration, and oversight.[161] The Department continues to be prohibited from collecting such information from ADAMHS boards.

Executive directors consulting with providers

The act permits an ADAMHS board's executive director to consult with a community services provider regardless of whether the provider is providing services supported by the board.[162]

OTHER MENTAL HEALTH AND ADDICTION SERVICES PROVISIONS

The act includes various other provisions regarding mental health and addiction services. These provisions take effect July 1, 2017.[163]

Prevention of mental illness

The act provides that "mental health services" provided or made available through ADAMHS boards and the Department include services for the prevention of mental illness, as well as services for the assessment, care, or treatment of persons who have a mental illness.[164]

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[160] R.C. 5119.22(F)(4).

[161] R.C. 5119.22(E).

[162] R.C. 340.041(C).

[163] Section 9(B).

[164] R.C. 5119.01(A)(15).

Contracts for services

The act provides that state law governing the Department of Administrative Services' purchases of services and supplies, including competitive bidding requirements, does not apply to contracts the Director of Mental Health and Addiction Services enters into for addiction services, mental health services, or recovery supports provided to individuals who are alcoholics or addicted to drugs or gambling or to individuals who have a mental illness.[165] Prior law exempted only contracts that the Director entered into for services provided to individuals with mental illness.

Annual report to the Governor

Continuing law requires the Department to submit an annual report to the Governor describing the services the Department offers and how appropriated funds have been spent. Prior law required the report to include the number and types of services provided to severely mentally disabled persons through state-operated services and community mental health services providers. The act modifies the requirement so that the report must also include the number and types of addiction services and recovery supports provided.[166]

Collection of gambling addiction information

Continuing law requires the Department to collect and compile statistics and other information on the care and treatment of mentally disabled persons and the care, treatment, and rehabilitation of alcoholics, drug dependent persons, and persons in danger of drug dependence in Ohio. The act requires that the Department also compile statistics and other information on the care, treatment, and rehabilitation of persons with, or in danger of developing, a gambling addiction.[167]

Disclosing mental health records

The act eliminates a prohibition against the Department disclosing psychiatric hospitalization records, other mental health treatment records, and other pertinent information about certain persons unless they are notified, receive the information, and do not object.[168] The persons are inmates and offenders receiving mental health services

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[165] R.C. 5119.10(B)(8).

[166] R.C. 5119.60.

[167] R.C. 5119.61.

[168] R.C. 5122.31(A)(13).

in an institution of the Department of Rehabilitation and Correction or the Department of Youth Services.

Encouraging rehabilitative services

The act eliminates a requirement that the executive director of an ADAMHS board encourage the development and expansion of rehabilitative services in the fields of addiction and mental health services.[169]

Discrimination prohibition

ADAMHS boards and community services providers under contract with boards are prohibited from discriminating on certain bases when providing services, employing, or contracting. Under the act, the bases include ancestry and military status but no longer include creed.[170] The bases continue to include race, color, religion, sex, age, national origin, and disability.

Residential facilities

The Department licenses residential facilities and has established three licensing categories: class one, class two, and class three. A class two residential facility is a publicly or privately operated home or facility that provides accommodations, supervision, and personal care services to any of the following: one or two unrelated persons with mental illness, one or two unrelated adults receiving Residential State Supplement payments, or three to 16 unrelated adults.[171]

An ADAMHS board is required to perform duties established in the Department's rules regarding referrals of individuals with mental illness or severe mental disability to residential facilities licensed by the Department. The act specifies that the referrals are to be to class two facilities.[172]

The Department administers the Residential State Supplement program, which helps pay for accommodations, supervision, and personal care services provided to recipients of Social Security, Social Security Disability Insurance, or Supplemental Security Income who the Department determines are at risk of needing institutional care. An individual must reside in certain types of living arrangements to qualify for the

[169] R.C. 340.041(F).

[170] R.C. 340.12 and 5119.25(A)(2).

[171] R.C. 5119.34, not in the act.

[172] R.C. 340.03(A)(14).

program, one of which is a residential facility licensed by the Department. The act requires that the residential facility be a class two facility.[173]

HISTORY

ACTION	DATE
Introduced	04-25-16
Reported, S. Health & Human Services	05-25-16
Passed Senate (33-0)	05-25-16
Reported, H. Finance	12-07-16
Passed House (92-3)	12-07-16
Senate concurred in House amendments (32-0)	12-07-16

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[173] R.C. 5119.41(D)(1)(b).