

# Ohio Legislative Service Commission

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S.B. 95\* 135<sup>th</sup> General Assembly

# **Bill Analysis**

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Version: As Reported by House Health Provider Services

**Primary Sponsor**: Sen. Reynolds

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#### **SUMMARY**

# Remote dispensing pharmacies

- Authorizes the operation of remote dispensing pharmacies and requires the State Board of Pharmacy to regulate them.
- Requires a remote dispensing pharmacy to be staffed by two or more pharmacy interns or certified pharmacy technicians and overseen and operated by both a supervising pharmacy and pharmacist through the use of a telepharmacy system.
- Requires the Board to adopt rules governing the operation of remote dispensing pharmacies within 18 months of the bill's effective date and, if the Board fails to do so, authorizes the Ohio Attorney General or a county prosecuting attorney to apply for a court order requiring their adoption.

# Mailing drugs to patients

 Prohibits health plan issuers, pharmacy benefit managers, and other administrators from prohibiting a pharmacy from mailing or delivering drugs to patients as an ancillary service.

## Pharmacist administration of injectable drugs

 Authorizes a pharmacist to administer by injection the following drugs if prescribed by a physician and if other conditions specified in current law are met: HIV treatment drugs in long-acting or extended-release forms and any other drug specified in Board rules.

\* This analysis was prepared before the report of the Health Provider Services Committee appeared in the House Journal. Note that the legislative history may be incomplete.

## Pharmacy technician trainees

Authorizes the Board to register as a pharmacy technician trainee an applicant who is age
17 and possesses a high school diploma or certificate of high school equivalence.

#### Certified mental health assistants

- Establishes licensure by the State Medical Board for certified mental health assistants (CMHAs).
- Authorizes CMHAs to provide mental health care under the supervision, control, and direction of a physician with whom the CMHA has entered into a supervision agreement.
- Authorizes CMHAs to prescribe and personally furnish drugs and therapeutic devices in the exercise of physician-delegated prescriptive authority, including certain identified controlled substances.
- Specifies application procedures including education requirements, renewal procedures, and continuing education requirements for CMHAs.
- Establishes within the Medical Board an advisory committee to advise the Board and the Department of Higher Education regarding CMHA education programs.
- Authorizes the Medical Board to discipline CMHAs in a manner similar to that of other Board licensees.
- Prohibits an individual from claiming to be able to function as a CMHA if that individual does not hold a CMHA license, and imposes criminal penalties for violations of that and other related prohibitions.

# **Uniform Duties to Incapacitated Persons Act**

- Modifies the law governing the use of medical identifying devices, including by recognizing devices containing bar or quick response codes that may be scanned to obtain medical information in an emergency.
- Names these provisions of the act "Paige's Law."

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#### **DETAILED ANALYSIS**

#### **Pharmacies**

## Remote dispensing pharmacies

The bill requires the State Board of Pharmacy to regulate remote dispensing pharmacies.<sup>1</sup> The bill defines "remote dispensing pharmacy" as one where the dispensing of drugs, counseling of patients, and other pharmacist care is provided through a telepharmacy system. Dispensing of drugs at the pharmacy may include the dispensing of drug therapy related devices.<sup>2</sup> A telepharmacy system is one that monitors the dispensing of drugs and provides for related drug utilization review and patient counseling services by an electronic method.<sup>3</sup>

#### **Eligibility conditions**

To operate as a remote dispensing pharmacy, the pharmacy must satisfy all of the following:

- Be licensed by the Board as a terminal distributor of dangerous drugs;
- Use only a telepharmacy system that meets standards established by the Board in rules;
- Be staffed by two or more pharmacy interns or certified pharmacy technicians;
- Have a supervising pharmacy and supervising pharmacist;
- Be located in Ohio, in a building that is zoned for commercial use;

<sup>2</sup> R.C. 4729.554(A)(1).

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<sup>&</sup>lt;sup>1</sup> R.C. 4729.554(B).

<sup>&</sup>lt;sup>3</sup> R.C. 4729.554(A)(2).

In general, not be located within a ten-mile radius of an outpatient pharmacy.<sup>4</sup>

# Exceptions to the exclusion area surrounding an outpatient pharmacy

The bill establishes circumstances when a remote dispensing pharmacy's proximity to an outpatient pharmacy may be closer than ten miles. Specifically, the ten-mile radius around an outpatient pharmacy that otherwise constitutes an area of exclusion does not apply in relation to (1) federally qualified health centers (FQHCs) and (2) locations approved by the Board based on a demonstration of need.<sup>5</sup>

Regarding FQHCs, the bill permits a remote dispensing pharmacy to be within the ten-mile radius of an outpatient pharmacy if the remote pharmacy is part of an FQHC or an FQHC lookalike, which is a facility that meets the eligibility requirements for federal FQHC funding but does not receive it. The remote pharmacy must be located on the same property as, or a campus contiguous to, the FQHC or look-alike.

Regarding location approvals based on a demonstration of need, the bill requires a remote dispensing pharmacy to meet standards established by the Board in rules for demonstrating the need. Further, as part of the Board's approval process, the bill requires the Board to establish a method by which persons may register to receive notice from the Board of requests for location approvals. The Board also must establish a system for accepting public comments regarding the requests. When the Board receives a request, it must electronically notify persons who register to be notified, and post notice on its website regarding a public comment period of 60 days. During that 60-day period, the Board must permit other pharmacies to submit requests for location approvals. After that period ends, the Board, in determining whether any of the location requests should be approved, must consider public comments, supervising pharmacy location in relation to the proposed remote dispensing pharmacy, and any other standards specified in rules. The determination must be made at the Board's next regularly scheduled meeting that occurs on or after the date that is 90 days after the electronic notices described above were sent.<sup>6</sup>

#### **Operational conditions**

The bill establishes conditions on the operation of each remote dispensing pharmacy. These include all of the following:

The pharmacy must not fill prescriptions at a rate that exceeds an average of 150 prescriptions per day during a 90-day period, unless otherwise approved by the Board.

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<sup>&</sup>lt;sup>4</sup> R.C. 4729.554(B) and (C).

<sup>&</sup>lt;sup>5</sup> R.C. 4729.554(C)(2)(b).

<sup>&</sup>lt;sup>6</sup> R.C. 4729.554(C)(2)(c).

- The pharmacy must implement a quality assurance plan to ensure that there is a planned and systematic process for (1) monitoring and evaluating the quality and appropriateness of the pharmacy services and (2) identifying and resolving problems.
- If the pharmacy holds a category III terminal distributor of dangerous drugs license, it must maintain a perpetual controlled substance inventory, as specified in Board rules.

#### Pharmacy interns and technicians

The bill sets limits on the practice of pharmacy interns and certified pharmacy technicians when assisting in the process of dispensing drugs.<sup>8</sup> When staffing a remote dispensing pharmacy, these practitioners are prohibited from doing any of the following:

- Counseling an individual regarding drugs that are dispensed, recommending drugs and drug therapy related devices or otherwise providing advice, or assisting with the selection of drugs and drug therapy related devices for treatment of common diseases and injuries or with providing instruction on their use;
- Performing sterile or nonsterile drug compounding, except for the reconstitution of prepackaged dangerous drugs;
- Engaging in the repackaging of dangerous drugs;
- Administering immunizations or performing diagnostic testing, unless a pharmacist is onsite to provide direct supervision;
- Performing any other activities prohibited in Board rules.

#### **Supervising pharmacies**

The bill establishes requirements to be met by the pharmacies that supervise remote dispensing pharmacies. First, it requires a supervising pharmacy to be both licensed by the Board as a terminal distributor of dangerous drugs and located in Ohio. Second, the supervising pharmacy must either (1) be under common ownership and control with the remote dispensing pharmacy or (2) operate under a contract that meets requirements specified in Board rules. Third, it requires the supervising pharmacy to control the telepharmacy system used by the remote dispensing pharmacy and to employ or contract with the supervising pharmacist of the remote dispensing pharmacy.

## **Supervising pharmacists**

The bill sets a number of conditions and limitations on the pharmacist who serves as the supervising pharmacist of a remote dispensing pharmacy.<sup>10</sup> The supervising pharmacist must be licensed by the Board, physically located in Ohio, and employed by or under contract with the

<sup>8</sup> R.C. 4729.554(G).

<sup>9</sup> R.C. 4729.554(D).

<sup>10</sup> R.C. 4729.554(E).

<sup>&</sup>lt;sup>7</sup> R.C. 4729.554(F).

supervising pharmacy. In serving in this position, the supervising pharmacist must be in full and actual charge of the pharmacy by using its telepharmacy system and surveillance system. The pharmacist is prohibited from simultaneously overseeing the activities of more than one remote dispensing pharmacy, unless otherwise approved by the Board.

The supervising pharmacist must oversee the pharmacy interns and certified pharmacy technicians who are assisting in the dispensing process at the remote dispensing pharmacy and must provide that oversight through the pharmacy's telepharmacy system and surveillance system. Next, the supervising pharmacist must verify each prescription and dispensed drug before the drug leaves the remote dispensing pharmacy. Such verification includes a visual review and the use of barcoding and any other technology required in Board rules. Finally, the supervising pharmacist must offer to provide patient counseling for each drug dispensed under a new prescription.

#### **Rulemaking**

The bill requires the Board to adopt rules governing the regulation of remote dispensing pharmacies. <sup>11</sup> The Board must do so in accordance with Ohio's Administrative Procedure Act and not later than 18 months after the bill's effective date. If the Board fails to meet this deadline, the bill authorizes the Ohio Attorney General or a county prosecuting attorney to apply to a court of common pleas for a court order requiring the rules to be adopted. <sup>12</sup>

The Board must include all of the following in the required rules:

- Standards for a system of continuous video surveillance and recording of each remote dispensing pharmacy, including establishing an adequate number of views of the entire pharmacy and requiring the retention of each recording for at least 60 days;
- Standards for telepharmacy systems and surveillance systems, including standards to ensure that the systems are capable of (a) facilitating a safe and secured method for appropriate pharmacist supervision, (b) allowing an appropriate exchange of visual, verbal, and written communications for patient counseling and other pharmacy services, and (c) being secure and compliant with the federal Health Insurance Portability and Accountability Act (HIPAA);
- Requirements for any contract between a supervising pharmacy and remote dispensing pharmacy;
- Standards for making a demonstration of need in the case of a remote dispensing pharmacy seeking to locate within ten miles of an outpatient pharmacy;
- Requirements for implementing a remote dispensing pharmacy's quality assurance plan;

<sup>&</sup>lt;sup>11</sup> R.C. 4729.554(H).

<sup>&</sup>lt;sup>12</sup> Section 3.

- The qualifications and training necessary for pharmacy interns and certified pharmacy technicians who staff remote dispensing pharmacies, including the number of experiential hours required;
- Any additional activities that pharmacy interns and certified pharmacy technicians are prohibited from performing;
- The number of pharmacy interns and certified pharmacy technicians that a supervising pharmacist may supervise at any given time;
- The maximum distance that a supervising pharmacist may be physically located from the remote dispensing pharmacy;
- Standards for remote patient counseling by a supervising pharmacist, including the counseling required to be offered for each drug dispensed under a new prescription;
- Standards for and frequency of remote dispensing pharmacy inspections by the supervising pharmacist;
- Requirements for the closure of a remote dispensing pharmacy if its telepharmacy system or surveillance system, or any related security system used by the pharmacy, is malfunctioning;
- Requirements related to perpetual controlled substance inventories;
- Security requirements for remote dispensing pharmacies that include methods for supervising pharmacists to determine who has accessed the pharmacy;
- Standards by which a supervising pharmacist may be approved to oversee more than one remote dispensing pharmacy simultaneously;
- Requirements for a remote dispensing pharmacy's responsible person;
- Any other standards or procedures the Board considers necessary to implement the bill's provisions on remote dispensing pharmacies.

#### **Telehealth**

Regarding existing law that generally authorizes health care professionals to provide telehealth services, the bill makes adjustments to account for the authority being granted to pharmacists to practice through remote dispensing pharmacies. Currently, a pharmacist may use telehealth to perform an action involved in dispensing a prescription drug only if the action is authorized through Board rules. The bill specifies that a pharmacist's telehealth authority also applies to drug dispensing actions performed through remote dispensing pharmacies. <sup>14</sup>

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<sup>&</sup>lt;sup>13</sup> R.C. 4743.09, not in the bill.

<sup>&</sup>lt;sup>14</sup> R.C. 4729.285.

#### Mailing drugs to patients

The bill prohibits health plan issuers, pharmacy benefit managers, and other administrators from prohibiting a pharmacy from mailing or delivering drugs to patients as an ancillary service.<sup>15</sup>

# Pharmacist administration of injectable drugs

The bill adds drugs to existing law that authorizes pharmacists to administer by injection certain drugs prescribed by a physician. The additional drugs are (1) HIV treatment drugs in longacting or extended-release forms and (2) any other drugs specified in rules adopted by the Board.

The bill maintains the pharmacist training, protocol, and other requirements of current law that apply to pharmacist administration of injectable drugs. Currently authorized injectable drugs include addiction treatment and antipsychotic drugs administered in long-acting or extended-release forms.<sup>16</sup>

#### Pharmacy technician trainees

The bill authorizes the Board to register as a pharmacy technician trainee an applicant who is age 17 and possesses a high school diploma or certificate of high school equivalence. Current law provides a pathway for a 17-year-old to be registered, but only if the individual is enrolled in certain career-technical school programs that are approved by the Board. By permitting the Board to accept the completion of high school education, the bill creates an additional pathway for a 17-year-old to be registered as a pharmacy technician trainee.<sup>17</sup>

#### Certified mental health assistant licensure

The bill establishes licensure for a new type of mental health professional. Under the bill, a certified mental health assistant (CMHA) is an individual who provides mental health care under the supervision, control, and direction of a physician with whom the CMHA has entered into a supervision agreement. A CMHA may practice in any setting within which a supervising physician has supervision, control, and direction of the CMHA.<sup>18</sup> A supervising physician may be a physician authorized to practice medicine and surgery or osteopathic medicine and surgery.<sup>19</sup>

## Services that may be performed by a CMHA

The bill authorizes a CMHA to perform the following services authorized by the supervising physician that are part of the supervising physician's normal course of practice and expertise:<sup>20</sup>

<sup>16</sup> R.C. 4729.45.

<sup>&</sup>lt;sup>15</sup> R.C. 3959.22.

<sup>&</sup>lt;sup>17</sup> R.C. 4729.921(B).

<sup>&</sup>lt;sup>18</sup> R.C. 4772.01(A), 4772.09(A) and (B), 4772.11(A).

<sup>&</sup>lt;sup>19</sup> R.C. 4772.01(E).

<sup>&</sup>lt;sup>20</sup> R.C. 4772.09(C).

- 1. Ordering diagnostic, therapeutic, and other medical services as appropriate based on the patient's diagnosis that has been made by the supervising physician;
- 2. Ordering, prescribing, personally furnishing, and administering drugs and medical devices as provided in the bill and discussed below;
- 3. Ordering occupational therapy or referring a patient to occupational therapy, if related to the patient's diagnosis; and
- 4. Referring a patient to emergency medical services for acute safety concerns, so long as the CMHA consults with the supervising physician as soon as practicable thereafter.

Additionally, a CMHA may provide telehealth services in accordance with existing law that establishes standards for telehealth services for various health care professionals.<sup>21</sup>

#### **Delegation of tasks**

The bill authorizes CMHAs to delegate the performance of a task to implement a patient's care plan and, if certain conditions are met, delegate administration of a drug. The CMHA must be physically present at the location where the task is performed or the drug is administered. Before making such a delegation, the CMHA must determine that the task or drug is appropriate for the patient and the person to whom the delegation is made may safely perform the task or administer the drug. Generally, the delegation may be to any person.<sup>22</sup>

There are certain conditions that must be met for a CMHA to delegate administration of a drug, as follows:<sup>23</sup>

- The CMHA is granted physician-delegated prescriptive authority by the supervising physician and be authorized to prescribe the drug to be administered;
- The drug is not a controlled substance;
- The drug is not administered intravenously; and
- The drug is not administered in a hospital inpatient care unit, hospital emergency department, freestanding emergency department, or ambulatory surgical facility.

#### **Prohibited services**

A CMHA is prohibited from doing any of the following:24

- 1. Making an initial diagnosis;
- 2. Treating a patient for any diagnosis or condition not found in the most recent version of the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the

<sup>24</sup> R.C. 4772.09(D); see also R.C. 4772.11(A)(2).

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<sup>&</sup>lt;sup>21</sup> R.C. 4772.091 and 4743.09; see also R.C. 5164.95.

<sup>&</sup>lt;sup>22</sup> R.C. 4772.092(A), (B), and (D).

<sup>&</sup>lt;sup>23</sup> R.C. 4772.092(C).

American Psychiatric Association, or a similar publication if designated by the Medical Board; and

3. Engaging in electroconvulsive therapy, transcranial magnetic stimulation, or any other intervention designated as invasive by Medical Board rules.

#### **Supervision agreements**

The bill requires a physician to enter into a supervision agreement with each CMHA who will be supervised by the physician. A supervision agreement can apply to one or more CMHAs, but generally may not apply to more than one physician, unless the physician chooses to designate in the supervision agreement other physicians to act as alternate supervising physicians. The supervision agreement must clearly state that the supervising physician is legally responsible and assumes legal liability for the services provided by the CMHA. It must be signed by the supervising physician and the CMHA. A supervision agreement may be amended.<sup>25</sup>

A supervision agreement must include the following terms:<sup>26</sup>

- 1. The responsibilities to be fulfilled by the supervising physician and the CMHA;
- 2. Any limitations on the responsibilities to be fulfilled by the CMHA; and
- 3. The circumstances under which the CMHA is required to refer a patient to the supervising physician.

The Medical Board, pursuant to an adjudication conducted in accordance with the Administrative Procedure Act, may take disciplinary action and impose a civil penalty against a CMHA that practices, or a supervising physician that supervises, in a manner that departs from, or fails to conform to, the terms of a supervision agreement, or otherwise fails to comply with the requirements for supervision agreements discussed above. If the Board finds that a CMHA or supervising physician has failed to keep a copy of the supervision agreement in their records, the Board may take disciplinary action and impose a civil penalty or may permit the individual to agree in writing to update the records and pay a civil penalty. Any civil penalty cannot be more than \$5,000 and must be deposited into the State Treasury to the credit of the State Medical Board operating fund.<sup>27</sup>

# **Supervision requirements**

#### Communication

Generally, the bill requires that a supervising physician must be continuously available for direct communication with a CMHA, either by being physically present where the CMHA is practicing or being readily available through telecommunication and being located within a distance of where a CMHA is practicing such that the physician can reasonably assure proper care of patients. During the first 1,000 hours of practice, however, the supervising physician must be

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<sup>&</sup>lt;sup>25</sup> R.C. 4772.10(A) and (B)(5) and (C); see also R.C. 4772.11(E).

<sup>&</sup>lt;sup>26</sup> R.C. 4772.10(B).

<sup>&</sup>lt;sup>27</sup> R.C. 4772.10(D) and (E) and 4731.24.

physically present at the location where the CMHA is practicing. This does not require the physician to be in the same room as the CMHA.<sup>28</sup>

#### Diagnosis and reevaluation

As discussed above, the supervising physician must initially diagnose a patient with a diagnosis or condition found in the DSM prior to a CMHA providing services to a patient. After the initial diagnosis, the supervising physician must personally and actively review the CMHA's professional activities at least weekly.<sup>29</sup> A patient must be reevaluated by the supervising physician at least every two years, or sooner if there is a significant change in the patient's condition or possible change in diagnosis. Additionally, annual reevaluation is required if the CMHA prescribes a controlled substance to the patient.<sup>30</sup>

#### Quality assurance and review

The supervising physician must comply with the quality assurance standards established by the Medical Board in rules, which are discussed in greater detail below. The supervising physician may perform other quality assurance activities that the physician considers appropriate. Additionally, the supervising physician must regularly perform other reviews of the CMHA that the supervising physician considers necessary.<sup>31</sup>

A supervising physician can authorize a CMHA to perform a service only if the physician is satisfied that the CMHA is capable of competently performing the service. A supervising physician is prohibited from authorizing performance of any service that is beyond the physician's or CMHA's normal course of practice and expertise.<sup>32</sup>

The bill requires the Medical Board to adopt rules establishing quality assurance standards, including a process for all of the following:<sup>33</sup>

- Routine review by the supervising physician of selected patient record entries and medical orders made by the CMHA;
- Discussion of complex cases;
- Discussion of new medical developments relevant to the practice of the supervising physician and CMHA; and
- Performance of any other quality assurance activities the Medical Board considers necessary.

<sup>&</sup>lt;sup>28</sup> R.C. 4772.11(A)(1).

<sup>&</sup>lt;sup>29</sup> R.C. 4772.11(A)(2) and (3)(a).

<sup>&</sup>lt;sup>30</sup> R.C. 4772.11(A)(3)(b).

<sup>&</sup>lt;sup>31</sup> R.C. 4772.11(A)(4) and (5).

<sup>&</sup>lt;sup>32</sup> R.C. 4772.11(C).

<sup>33</sup> R.C. 4772.19(B)(4).

#### Limit on the number of CMHAs that may be supervised at one time

While a physician may enter into supervision agreements with unlimited CMHAs, a physician can only supervise up to five CMHAs at one time.<sup>34</sup>

### **Liability – termination of agreement**

The bill states that a supervising physician assumes liability for the services provided by a CMHA while the supervision agreement is pending. A supervising physician is not liable for any services provided by a CMHA after the supervision agreement expires or is terminated.<sup>35</sup>

#### Physician-delegated prescriptive authority

A licensed CMHA is authorized to prescribe and personally furnish drugs and therapeutic devices in the exercise of physician-delegated prescriptive authority. The prescriptive authority may be exercised only to the extent that that it is granted by the supervising physician. A CMHA must comply with all conditions placed on the prescriptive authority by the supervising physician. Examples of conditions that may be placed on the prescriptive authority include (1) identifying drugs and therapeutic devices that the physician chooses not to permit the CMHA to prescribe, (2) limits on dosage units and refills that may be prescribed, (3) circumstances for required physician referral, and (4) any other responsibilities a supervising physician must fulfill.<sup>36</sup>

#### **Controlled substances**

#### Controlled substances that may be prescribed

If a CMHA has physician-delegated prescriptive authority for controlled substances, the CMHA must register with the federal Drug Enforcement Administration. Only the following controlled substances may be prescribed by a CMHA:<sup>37</sup>

- 1. Buprenorphine, but only for patients actively engaged in opioid use disorder treatment;
- 2. Benzodiazepines, but only for patients diagnosed with chronic anxiety disorders or acute anxiety or agitation (in the latter case, only in an amount indicated for a period of seven or less days); and
- 3. FDA-approved stimulants for the treatment of attention deficit hyperactivity disorder (ADHD), but only if the supervising physician has diagnosed the patient with or confirmed the diagnosis of ADHD.

If a CMHA has physician-delegated prescriptive authority to prescribe a minor an opioid analgesic, the CMHA must comply with existing law that requires a discussion of risks and guardian consent.<sup>38</sup>

<sup>35</sup> R.C. 4772.11(E).

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<sup>&</sup>lt;sup>34</sup> R.C. 4772.11(B).

<sup>&</sup>lt;sup>36</sup> R.C. 4772.12(A) and (B).

<sup>&</sup>lt;sup>37</sup> R.C. 4772.12(B)(3) and 4772.13(A); see also R.C. 3719.06(A)(4).

<sup>&</sup>lt;sup>38</sup> R.C. 4772.12(B)(4), citing R.C. 3719.061, not in the bill.

Regarding buprenorphine for use in medication-assisted treatment, the Medical Board is required to adopt rules establishing standards and procedures a CMHA must follow, including related to detoxification, relapse prevention, patient assessment, individual treatment planning, counseling and recovery supports, diversion control, and other related topics. The rules may apply to all circumstances, or only to prescribing in office-based practices or other specified practice locations. The rules must be consistent with rules previously adopted for advanced practice registered nurses, physician assistants, and physicians.<sup>39</sup>

## Compliance with OARRS

Similar to other prescribers, a CMHA must comply with the following before prescribing a controlled substance:<sup>40</sup>

- Before the initial prescription, request from the Pharmacy Board's drug database, known as OARRS, a report related to the patient covering the past 12 months;
- If the patient's course of treatment continues for more than 90-days after the initial report, make periodic requests for OARRS reports until the treatment has ended, at least every 90 days; and
- Assess the requested reports and document it in the patient's record.

The above provisions do not apply in various enumerated circumstances, such as when a drug is prescribed for less than seven days, to a hospice patient in a hospice care program, or for administration in a hospital, nursing home, or assisted living facility.<sup>41</sup>

The Medical Board is required to adopt rules related to OARRS requirements.<sup>42</sup>

## Other provisions related to prescribing

Similar to other prescribers, such as physician assistants, the bill includes provisions related to:

- CMHAs personally furnishing to patients samples of drugs and therapeutic devices that are included in the CMHA's physician-delegated prescriptive authority;<sup>43</sup>
- CMHAs personally furnishing to patients complete or partial supplies of drugs and therapeutic devices that are included in the CMHA's physician-delegated prescriptive authority;<sup>44</sup>

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<sup>&</sup>lt;sup>39</sup> R.C. 4772.13(D)(2).

<sup>&</sup>lt;sup>40</sup> R.C. 4772.13(B).

<sup>&</sup>lt;sup>41</sup> R.C. 4772.13(C).

<sup>&</sup>lt;sup>42</sup> R.C. 4772.13(D)(1).

<sup>&</sup>lt;sup>43</sup> R.C. 4772.14(A); see also R.C. 3719.81.

<sup>&</sup>lt;sup>44</sup> R.C. 4772.14(B).

- CMHAs treating patients with medication-assisted treatment, and prerequisites in existing law that must be met;<sup>45</sup>
- CMHAs personally furnishing supplies of naloxone and prescriptions for naloxone, and authorizing it to be furnished or administered in accordance with protocols.<sup>46</sup>

The bill includes corresponding changes to Ohio's criminal drug laws and pharmacy laws related to CMHA authority to possess, prescribe, furnish, administer, and sell drugs under the bill.<sup>47</sup>

#### License issuance and renewal

#### **Application and education requirements**

An individual who seeks a CMHA license must file a written application with the Medical Board. The application must include an application fee to be specified by the Board in rules.<sup>48</sup>

To be eligible for a CMHA license, an applicant must be 18 years old or older, hold a bachelor's degree in any field of study, and meet one of the following additional education requirements:<sup>49</sup>

- 1. Hold a master's degree or higher from a CMHA program (see "CMHA education programs," below); or
- 2. Hold a diploma from an accredited medical school or osteopathic medical school and have completed 12 months of coursework from a CMHA program.

A CMHA applicant also must comply with existing law regarding criminal records checks for professional licenses.<sup>50</sup>

#### Renewal

A CMHA license is valid for two years, unless earlier revoked or suspended.<sup>51</sup> A license may be renewed for additional two-year periods. The Medical Board must provide licensees with renewal notices at least one month before expiration. The biennial renewal fee is to be specified by the Board in rules. Self-reporting of any criminal offense that is grounds for refusing to issue

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<sup>&</sup>lt;sup>45</sup> R.C. 4772.15 and 3719.064.

<sup>&</sup>lt;sup>46</sup> R.C. 3715.50 to 3715.503.

<sup>&</sup>lt;sup>47</sup> R.C. 2925.01, 2925.02, 2925.03, 2925.11, 2925.12, 2925.14, 2925.23, 2925.36, 2925.55, 2925.56, 4729.01, and 4729.51.

<sup>&</sup>lt;sup>48</sup> R.C. 4772.04(A) and 4772.19(B)(2); see also R.C. 4772.26, regarding fees.

<sup>&</sup>lt;sup>49</sup> R.C. 4772.04(B).

<sup>&</sup>lt;sup>50</sup> R.C. 4772.041 and 4776.01; R.C. 4776.02 to 4776.04, not in the bill.

<sup>&</sup>lt;sup>51</sup> R.C. 4772.06.

a license under the bill is required as part of the renewal application. A renewal applicant must comply with continuing education requirements, discussed below.<sup>52</sup>

Similar to other licensees the Medical Board regulates, the bill includes provisions related to the automatic suspension of licenses not renewed, and reinstatement and restoration of those licenses.<sup>53</sup>

#### **Continuing education**

#### Requirements

To be eligible for license renewal, a CMHA that has been granted physician-delegated prescriptive authority must (1) complete every two years at least 12 hours of continuing education in pharmacology through a Medical Board-approved program or course and (2) if the CMHA prescribes opioid analgesics or benzodiazepines, certify that the CMHA has been granted access to the OARRS drug database, unless the Pharmacy Board has notified the Medical Board that the CMHA has been restricted from obtaining information from OARRS, the Pharmacy Board no longer maintains the drug database, or the CMHA does not practice in Ohio.<sup>54</sup>

The Medical Board may establish additional continuing education requirements in rules. 55

#### Reductions and extensions

The Medical Board must provide for pro rata reductions for continuing education in pharmacology for CMHAs who have been disabled or absent from the country. It also must grant reporting extensions for CMHA serving on active duty during a reporting period. <sup>56</sup>

#### Investigating compliance

The Medical Board may investigate continuing education compliance though random sampling and other means. If the Board finds a violation, it may take disciplinary action in accordance with the Administrative Procedure Act or permit the individual to agree to complete the continuing education and pay a civil penalty. A civil penalty cannot exceed \$5,000.<sup>57</sup>

#### **Duplicate license**

The bill requires the Medical Board, if requested by a CMHA, to issue a duplicate license to replace one that is missing or damaged, to reflect a name change, or for other reasonable cause. The duplicate license fee is \$35.<sup>58</sup>

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<sup>&</sup>lt;sup>52</sup> R.C. 4772.08(A) to (C).

<sup>&</sup>lt;sup>53</sup> R.C. 4772.08(E); See also R.C. 4772.082, regarding restoration of licenses.

<sup>&</sup>lt;sup>54</sup> R.C. 4772.081(A).

<sup>&</sup>lt;sup>55</sup> R.C. 4772.081(C).

<sup>&</sup>lt;sup>56</sup> R.C. 4772.081(A)(1) and (B) and 5903.12.

<sup>&</sup>lt;sup>57</sup> R.C. 4772.08(D) and (F).

<sup>&</sup>lt;sup>58</sup> R.C. 4772.07.

#### **CMHA education programs**

To constitute a CMHA program under the bill, the program shall be at least 30 credit hours of graduate coursework and include courses in the following areas:59

- Psychiatric diagnoses included in the DSM;
- Laboratory studies used in diagnosing or managing psychiatric conditions;
- Medical conditions that mimic or present as psychiatric conditions;
- Medical conditions associated with psychiatric conditions or treatment;
- Psychopharmacology;
- Psychosocial interventions;
- Conducting suicide and homicide risk assessments;
- Forensic issues in psychiatry, including involuntary hospitalization and mandated treatment;
- Basic behavioral health counseling; and
- Clinical experiences in inpatient psychiatric units, outpatient mental health clinics, psychiatric consultation and liaison services, and addiction services.

Related to approval of CMHA programs by the Chancellor of Higher Education, the bill creates an advisory committee within the Medical Board. The committee is required to advise the Board and the Department of Higher Education regarding CMHA programs until there is a national accrediting body for CMHAs. Until then, the committee is required to reference the physician assistant accrediting standards from the Accrediting Review Commission on Education for the Physician Assistant in providing feedback and recommendations. Once there is a national accrediting body, the committee will cease to exist.

The bill authorizes the Ohio State Medical Association, Northeast Ohio Medical University, and the Ohio Psychiatric Physicians Association to recommend appointments for the advisory committee to the Executive Director of the Medical Board. After considering the recommendations, the Executive Director must make initial appointments within 60 days of the bill's effective date. The bill includes other details concerning the advisory committee, such as terms of membership, filling vacancies, committee organization, and the authority to conduct meetings virtually.60

<sup>60</sup> R.C. 4772.05(B) and (C).

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<sup>&</sup>lt;sup>59</sup> R.C. 4772.05(A).

#### **Discipline**

#### **Against CMHAs**

The Medical Board, by an affirmative vote of at least six members, may take various disciplinary actions against CMHAs, including limiting, revoking, and suspending licenses, refusing to issue, renew, or reinstate them, and reprimanding license holders. The reasons discipline may be imposed are similar to reasons for discipline for other health care professionals regulated by the Board. Generally, disciplinary actions must be taken pursuant to an adjudication under the Administrative Procedure Act.<sup>61</sup>

Also pursuant to an adjudication under the Administrative Procedure Act, in addition to the discipline described above, the Medical Board may impose civil penalties against CMHAs for violations of the bill's provisions. The amount of a civil penalty is to be determined by the Board in accordance with guidelines adopted by the Board, but cannot exceed \$20,000. Generally, the civil penalties are to be deposited into the Board's operating fund, except that civil penalties related to impairment of practice due to habitual or excessive use or abuse of drugs or alcohol are to be used solely for investigations, enforcement, and compliance monitoring.<sup>62</sup>

The bill addresses numerous other matters related to professional discipline in the standard manner that current law addresses those matters for other Medical Board licensees, such as physicians and physician assistants. These matters include:

- Consent agreements, Board-ordered mental and physical examinations of CMHAs, summary license suspensions in the case of a danger of immediate and serious harm to the public, and automatic license suspensions due to certain criminal convictions;<sup>63</sup>
- The handling of CMHAs in default of child support orders;<sup>64</sup>
- Probate court adjudications of mental illness or mental incompetence of a CMHA;<sup>65</sup>
- Board investigations of evidence related to violations of the bill's provisions, including subpoena powers, confidentiality of investigatory information, and quarterly Board reports concerning cases being investigated;<sup>66</sup>
- Prosecutor reporting of CMHA convictions related to sex offenses, drug offenses, or controlled substances violations, as well as prosecutor reporting of CMHA (1) convictions

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<sup>&</sup>lt;sup>61</sup> R.C. 4772.20(A) to (F).

<sup>&</sup>lt;sup>62</sup> R.C. 4772.203.

<sup>&</sup>lt;sup>63</sup> R.C. 4772.20(D) and (G) to (N); See also R.C. 3719.121.

<sup>&</sup>lt;sup>64</sup> R.C. 4772.201; R.C. 3123.41 to 3123.50, not in the bill.

<sup>&</sup>lt;sup>65</sup> R.C. 4772.202.

<sup>&</sup>lt;sup>66</sup> R.C. 4772.21; See also R.C. 3719.13.

or procedural dismissals for other felonies and (2) misdemeanors committed in the course of practice or involving moral turpitude;<sup>67</sup>

- Reporting by health care facilities that take formal disciplinary actions against a CMHA;<sup>68</sup>
- Reporting by CMHAs, physicians, or professional associations or societies of CMHAs or physicians that believe a violation of the bill's provisions has occurred;<sup>69</sup>
- Reporting by CMHA professional associations or societies that suspend or revoke a CMHA's membership for violations of professional ethics, or reasons of professional incompetence or malpractice;<sup>70</sup>
- Reporting by insurers providing professional liability insurance to CMHAs for final dispositions resulting in damages over \$25,000;<sup>71</sup>
- Enforcement of the bill's provisions by the secretary of the Medical Board;<sup>72</sup> and
- Injunctions against unlicensed CMHA practice.<sup>73</sup>

#### **Against supervising physicians**

The bill authorizes the Medical Board to take any of the disciplinary action authorized under current law against a supervising physician who fails to maintain supervision of a CMHA in accordance with the bill's requirements.<sup>74</sup>

## **Criminal penalties**

#### **Prohibited conduct**

The bill prohibits a nonlicensed CMHA from holding that person's self out as being able to function as a CMHA, or using words or letters indicating or implying that the person is a CMHA. It prohibits any person from practicing as a CMHA without the supervision, control, and direction of a physician, and without entering into a supervision agreement. It also prohibits the advertising of CMHA services, except when seeking employment, and prohibits a CMHA from failing to wear identification as a CMHA while practicing.<sup>75</sup>

<sup>&</sup>lt;sup>67</sup> R.C. 4772.22 and 2929.42.

<sup>&</sup>lt;sup>68</sup> R.C. 4772.23(A).

<sup>&</sup>lt;sup>69</sup> R.C. 4772.23(B).

<sup>&</sup>lt;sup>70</sup> R.C. 4772.23(C).

<sup>&</sup>lt;sup>71</sup> R.C. 4772.23(D).

<sup>&</sup>lt;sup>72</sup> R.C. 4772.24.

<sup>&</sup>lt;sup>73</sup> R.C. 4772.25.

<sup>&</sup>lt;sup>74</sup> R.C. 4731.22(B)(52).

<sup>&</sup>lt;sup>75</sup> R.C. 4772.02(A) through (C) and (E) and (F).

Regarding physicians, the bill prohibits a supervising physician from authorizing a CMHA to perform services that are not within the physician's normal course of practice and expertise or that are inconsistent with the supervision agreement.<sup>76</sup>

#### **Penalties**

The bill specifies that a violation of any of the above "**Prohibited conduct**" is a first degree misdemeanor on the first offense, and a fourth degree felony for each subsequent offense.<sup>77</sup>

Additionally, the bill criminalizes violations of reporting duties, as described above, by health care facilities that take formal disciplinary actions against a CMHA; by CMHAs, physicians, or professional associations or societies of CMHAs or physicians that believe a violation of the bill's provisions has occurred; by CMHA professional associations or societies that suspend or revoke a CMHA's membership; and by insurers providing professional liability insurance to CMHAs. Those violations are a minor misdemeanor on the first offense, and a fourth degree misdemeanor on subsequent offenses, except that an individual guilty of a subsequent offense is not subject to imprisonment, but rather, only a fine of up to \$1,000 for each offense.<sup>78</sup>

## Rulemaking

As discussed in greater detail above, the bill requires the Medical Board to adopt rules related to the licensure of CMHAs. The rules must be adopted in accordance with the Administrative Procedure Act.<sup>79</sup>

#### Miscellaneous provisions applicable to the Medical Board

Consistent with existing Medical Board laws, the bill generally provides to the Medical Board and its agents immunity from damages related to performing official duties.<sup>80</sup>

The bill requires the Medical Board to comply with existing law regarding human trafficking convictions of CMHAs.<sup>81</sup>

# Bill interpretation

The bill provides that it should not be construed to affect or interfere with the practice of medical personnel in the military or U.S. Veterans Administration employees. The bill does not prevent other individuals from performing services a CMHA is authorized to perform, if those services are within the individual's scope of practice under other Ohio laws. The bill does not prevent a physician from delegating to nurses and other qualified persons, so long as the physician does not hold the delegate out to be a CMHA. The bill should not be construed as

<sup>77</sup> R.C. 4772.99(A).

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<sup>&</sup>lt;sup>76</sup> R.C. 4772.02(D).

<sup>&</sup>lt;sup>78</sup> R.C. 4772.99(B), citing R.C. 4772.23(A) through (D).

<sup>&</sup>lt;sup>79</sup> R.C. 4772.19.

<sup>&</sup>lt;sup>80</sup> R.C. 4772.27.

<sup>&</sup>lt;sup>81</sup> R.C. 4772.28

authorizing a CMHA to independently order or direct the execution of procedures to a registered nurse or licensed practical nurse, except to the extent the CMHA is authorized to do so by a physician who is responsible for supervising the CMHA.<sup>82</sup>

#### **Medicaid coverage**

The bill requires the Medicaid Director to submit a request to the federal Centers for Medicare and Medicaid Services for a Medicaid waiver to allow services provided by a CMHA to be paid by the Medicaid program.<sup>83</sup>

#### **Miscellaneous provisions**

The bill adds CMHAs to various other provisions of Ohio law that apply to other types of health care providers. The provisions include:

- 1. Providing immunity to volunteer health care providers rendering care to indigent uninsured individuals;<sup>84</sup>
- 2. Liability of mental health professionals for failing to warn of violent behaviors of clients under certain circumstances;<sup>85</sup>
- 3. Administration and distribution of drugs under a Director of Health-developed protocol during a declared public health emergency;<sup>86</sup>
- 4. Patient requests for copies of medical records;87
- 5. Board of health purchased liability insurance for health care professionals with whom the board contracts;<sup>88</sup>
- 6. Providing immunity for health care providers donating, accepting, or dispensing drugs under the drug repository program;<sup>89</sup>
- 7. Universal blood and bodily fluid precautions developed by Medical Board rules;90
- 8. Medical Board records of applicants and licensees;<sup>91</sup>

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<sup>&</sup>lt;sup>82</sup> R.C. 4772.03.

<sup>83</sup> Section 4.

<sup>84</sup> R.C. 2305.234.

<sup>&</sup>lt;sup>85</sup> R.C. 2305.51.

<sup>86</sup> R.C. 3701.048.

<sup>&</sup>lt;sup>87</sup> R.C. 3701.74.

<sup>88</sup> R.C. 3709.161.

<sup>89</sup> R.C. 3715.872.

<sup>&</sup>lt;sup>90</sup> R.C. 4731.051.

<sup>&</sup>lt;sup>91</sup> R.C. 4731.07.

- 9. Reporting to the Medical Board violation of certain health care professional licensing laws;<sup>92</sup>
- 10. Medical Board programs for practitioners suffering impairment of practice due to habitual or excessive use or abuse of drugs or alcohol;<sup>93</sup>
- 11. Penalty enhancements for violations of the chiropractor licensing law;<sup>94</sup>
- 12. Specifying that Ohio's emergency medical professionals law does not restrict the practice of CMHAs;<sup>95</sup>
- 13. The definition of health care professional for purposes of balance billing of Medicare beneficiaries;<sup>96</sup>
- 14. Unlicensed in-home health care provided to individuals with developmental disabilities when prescribed or otherwise directed by a licensed health care professional;<sup>97</sup> and Continuing education extensions for active duty military.<sup>98</sup>

## **Uniform Duties to Incapacitated Persons Act – Paige's Law**

In 1976, the General Assembly enacted the Uniform Duties to Disabled Persons Act, which authorizes and encourages those with certain medical conditions to wear medical identifying devices and carry identification cards. <sup>99</sup> The law also allows or requires law enforcement officers, paramedics, medical practitioners (defined to include only physicians), and other persons to search for these devices and cards under certain circumstances.

The bill maintains this law, renamed the Uniform Duties to Incapacitated Persons Act, but makes several revisions to it, including by (1) recognizing identifying devices that contain bar or quick response codes and (2) authorizing these devices to be scanned in certain circumstances to determine the wearer's medical information.

## Identifying device and identification card

Current law defines an identifying device as an identifying bracelet, necklace, metal tag, or other similar device bearing the emergency symbol and information needed in an emergency. The bill expands this definition in two ways. First, it adds chains or other pieces of jewelry to the definition. And second, it specifies that an identifying device may contain – on its front or back –

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<sup>&</sup>lt;sup>92</sup> R.C. 4731.224.

<sup>&</sup>lt;sup>93</sup> R.C. 4731.25 and 4731.251.

<sup>&</sup>lt;sup>94</sup> R.C. 4734.99.

<sup>&</sup>lt;sup>95</sup> R.C. 4765.51.

<sup>&</sup>lt;sup>96</sup> R.C. 4769.01.

<sup>&</sup>lt;sup>97</sup> R.C. 5123.47.

<sup>&</sup>lt;sup>98</sup> R.C. 5903.12.

<sup>&</sup>lt;sup>99</sup> R.C. 2305.41 to 2305.49.

a bar code or quick response code that may be scanned to determine medical information needed in an emergency. 100

Existing law maintained by the bill specifies that, by wearing an identifying device, a person gives his or her consent for any law enforcement officer or medical practitioner who finds the person in a disabled condition to make a reasonable search of the person's clothing or other effects for an identification card. <sup>101</sup> It defines a card as one containing the holder's name, type of medical condition, physician's name, and other medical information. <sup>102</sup> Current law does not, however, extend this consent to paramedics.

Existing law also authorizes a law enforcement officer and a person other than a law enforcement officer or medical practitioner to search for a disabled person's identifying device and if found, make a reasonable search for an identification card. It further requires a trained paramedic and medical practitioner, when examining or treating a disabled person, to (1) search for a device and if found, make a reasonable search for an identification card and (2) examine the device or card for emergency information.<sup>103</sup>

## Authority to scan an identifying device

The bill specifically authorizes both of the following to scan an identifying device containing a bar or quick response code:

- A law enforcement officer when he or she finds an incapacitated person;
- A person other than an emergency medical service provider, health care practitioner, or law enforcement officer when that person finds an incapacitated person and an emergency medical service provider, health care practitioner, or law enforcement officer is not present.<sup>104</sup>

The bill also authorizes, rather than requires as under current law, an emergency medical service provider or health care practitioner, when examining or treating an incapacitated person, to make a prompt and reasonable search for an identifying device or identification card and scan or examine the person's identifying device or card if one is found.<sup>105</sup>

Additionally, the bill extends to emergency medical service providers as well as registered nurses, certified nurse practitioners, clinical nurse specialists, and physician assistants the consent to search for a device or identification card and scan a device that a person gives by wearing such a device. <sup>106</sup>

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<sup>100</sup> R.C. 2305.41(C).
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<sup>&</sup>lt;sup>101</sup> R.C. 2305.42(C).

<sup>&</sup>lt;sup>102</sup> R.C. 2305.41(D).

<sup>&</sup>lt;sup>103</sup> R.C. 2305.43, 2305.44, and 2305.45.

<sup>&</sup>lt;sup>104</sup> R.C. 2305.43(B) and 2305.45(A).

<sup>&</sup>lt;sup>105</sup> R.C. 2305.44(A).

<sup>&</sup>lt;sup>106</sup> R.C. 2305.42(C).

Lastly, if an identifying device or card is found, the bill authorizes the law enforcement officer, emergency medical service provider, health care practitioner, or other person to inspect both sides of the device or card. 107

## Prompt and reasonable search

Wherever current law refers to a reasonable search for an identifying device or identification card made by a law enforcement officer, medical practitioner, or paramedic, the bill instead refers to a prompt and reasonable search. 108

## **Incapacitated condition and person**

The law regarding the use of and search for a person's medical identifying device refers to a *disabled condition*, defined to mean the condition of being unconscious, semiconscious, incoherent, or otherwise incapacitated to communicate, and a *disabled person*, or a person in a disabled condition. While the bill eliminates these terms and replaces them with *incapacitated condition* and *incapacitated person*, the meanings remain the same.<sup>109</sup>

#### **Emergency medical service provider**

The bill eliminates references to *paramedics* and replaces them with references to *emergency medical service providers*. Current Ohio law recognizes three types of emergency medical service technicians (EMTs), one of which is a paramedic (EMT-paramedic), as well as first responders. By replacing the reference, the bill's provisions apply to EMTs-basic, EMTs-intermediate, EMTs-paramedic, and first responders. 110

## Health care practitioner

The bill replaces the definition of a *medical practitioner*, defined under existing law to mean only a medical or osteopathic physician, with *health care practitioner*, which means a medical or osteopathic physician, physician assistant, registered nurse, certified nurse practitioner, and clinical nurse specialist. The bill then replaces references to a medical practitioner found throughout the Uniform Duties to Incapacitated Persons Act with references to a health care practitioner.<sup>111</sup>

# Physical and mental illness

Where current law refers to a medical illness that may result in an individual becoming unconscious, semiconscious, incoherent, or otherwise incapacitated, the bill specifies that the illness may be either physical or mental.<sup>112</sup>

<sup>&</sup>lt;sup>107</sup> R.C. 2305.43(B), 2305.44(A), and 2305.45(A).

<sup>&</sup>lt;sup>108</sup> R.C. 2305.43 and 2305.44.

<sup>&</sup>lt;sup>109</sup> R.C. 2305.41(A), (B), (E), and (F).

<sup>&</sup>lt;sup>110</sup> R.C. 2304.44.

<sup>&</sup>lt;sup>111</sup> R.C. 2305.41.

<sup>&</sup>lt;sup>112</sup> R.C. 2305.42(A) and 2305.43(A).

# **HISTORY**

Action	Date
Introduced	03-23-23
Reported, S. Health	05-08-24
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