Rules and Resolutions – December 2024

Resolutions

Indicates resolutions was authorized by the Board President in accordance with a Board resolution adopted on May 5, 2020.

1) Appointment to the Controlled Substance Advisory Committee

The Board hereby appoints D. Rich Miller III as chair of the Controlled Substance Advisory Committee.

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Rules

For Filing with JCARR

4729:9-3-01 - Sale of Distribution of Ephedrine-Containing Products. (NEW)

Amended paragraph (C):

(C) Except for products listed in paragraph (B) of this rule or products excepted in accordance with paragraph (D) of this rule, any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall:

(1) Submit an application for the appropriate category III license in accordance with section 4729.52 of the Revised Code or 4729.54.

(2) Comply with all applicable security and storage requirements in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(3) Conduct an inventory of all products containing ephedrine pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(4) Maintain all records required in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(5) The requirements listed in this paragraph does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(1) of section 3719.44 of the Revised Code or paragraph (B) of this rule.

Previous Paragraphs consolidated into new paragraph (C):

(C) Except as provided in paragraph (H) of this rule, any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall submit an application for the appropriate category III license in accordance with section 4729.52 of the Revised Code or 4729.54 of the Revised Code to conduct such activities in accordance with Chapters 3719. and 4729. of the Revised Code.

(D) Except as provided in paragraph (H) of this rule, schedule V products containing ephedrine may be sold at wholesale or retail, and must be maintained in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(E) Except as provided in paragraph (H) of this rule, a licensee who possesses any quantity of ephedrine or schedule V dangerous drug products containing ephedrine shall take an inventory pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(F) Except as provided in paragraph (H) of this rule, all licensees are required to keep records pursuant to Chapter 3719. of the Revised Code and agency 4729 of the Administrative Code shall maintain such records for ephedrine and schedule V drug products containing ephedrine.

(G) This requirements listed in paragraphs (C), (D), (E), and (F) do not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(1) of section 3719.44 of the Revised Code or paragraph (B) of this rule.

4729:9-3-01 **Sale of Distribution of Ephedrine-Containing Products.**

(A) As used in this rule, "ephedrine" is alpha-[-(Methylamino)ethyl]benzene-methanol; alpha-[1-(methylamino) ethyl]benzyl alcohol; 2-methylamino-1-phenyl-1-propanol; 1-phenyl-1-hydroxy-2-methylaminopropane; 1-phenyl-2- methylaminopropanol; alpha- hydroxy-beta-methylaminopropylbenzene; a product which occurs in the Chinese herb Ma Huang (Ephedra vulgaris, Ephedra sinica Stapf., Ephedra equisetina Bunge, Gnetaceae) and in several other Ephedra spp. Isomeric forms include d- and l-ephedrine as well as d-and l-pseudoephedrine with l-ephedrine and d-pseudoephedrine as the naturally occurring isomers.

(B) Each of the following products containing ephedrine, its salts, its isomers, or the salts of its isomers is excepted from classification as a schedule V controlled substance:

(1) All products that contain the isomer known as pseudoephedrine or its salts, but do not also contain any of the isomer known as ephedrine or its salts.

(2) "Breathe Easy" herb tea.

(3) "Bronkaid Dual Action" caplets.

(4) "Hydrosal" hemorrhoidal ointment.

(5) "Primatene Dual Action Formula" tablets.

(6) "Primatene" tablets.

(7) "SnoreStop" tablets.

(8) Drug products listed in division (K)(1) of section 3719.44 of the Revised Code.

(C) Except for products listed in paragraph (B) of this rule or products excepted in accordance with paragraph (D) of this rule, any person who manufactures, sells at wholesale or retail, dispenses, imports or exports products containing ephedrine, its salts or isomers, or who proposes to engage in such activities, shall:

(1) Submit an application for the appropriate category III license in accordance with section 4729.52 of the Revised Code or 4729.54.

(2) Comply with all applicable security and storage requirements in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(3) Conduct an inventory of all products containing ephedrine pursuant to rule 4729:5-3-07 or 4729:6-3-06 of the Administrative Code.

(4) Maintain all records required in accordance with Chapters 3719. and 4729. of the Revised Code and agency 4729 of the Administrative Code.

(5) The requirements listed in this paragraph does not apply if the ephedrine product is a food product or a dietary supplement that is specifically excepted in division (K)(1) of section 3719.44 of the Revised Code or paragraph (B) of this rule.

(D) A petition requesting that a drug product containing ephedrine be excepted by the board of pharmacy from being legally classified as a schedule V controlled substance stimulant may be submitted by any person engaged in the legitimate manufacture or wholesale sale of such products in the United States. The petition shall include the following information:

(1) Full name, address, and telephone number of the manufacturer.

(a) If incorporated, the petition must include copies of the incorporation papers and the names, dates of birth, addresses, and social security numbers of the officers of the corporation and all stockholders holding more than ten percent of the corporation's stock.

(b) If a proprietorship, the petition must include the name, address, date of birth, and social security number of the owner(s).

(c) If a partnership, the petition must include the names, addresses, dates of birth, and social security numbers of the partners.

(2) A description of the package sizes and the manner of packaging of the drug product.

(3) A limited number of samples of each dosage form marketed in the final marketed packages.

(4) The manner of distribution, advertising, and promotion of the product including the following:

(a) The full name and address of all accounts located in Ohio to which the products have been or will be distributed at wholesale based on other products marketed by the petitioner.

(b) Copies of all advertisements used to promote the product within the last twelve months shall be included with the petition. A list of the publications in which the advertisements appeared or will appear if not presently marketed. If the product has not yet been marketed, copies of other products marketed by the petitioner shall be submitted with the petition.

(5) A listing of all ingredients in the product, indicating the quantity of each ingredient, whether or not it has any therapeutic value, and its purpose for

being included in the product. Documentation of the therapeutic value of all active ingredients in the product shall be included with the petition.

(6) A list of all names the product is marketed or will be marketed under in the United States or any other country.

(7) Any information regarding the product's abuse or potential for abuse in the United States or other countries where the product is marketed or will be marketed under any of the names listed in paragraph (D)(6) of this rule.

(E) The board shall consider the following factors in determining whether a particular over-the-counter (OTC) drug product containing the schedule V controlled substance ephedrine is manufactured and distributed for legitimate use in a manner consistent with the pertinent OTC tentative or final monograph issued by the United States food and drug administration and in a manner that reduces the likelihood of inappropriate use and/or abuse:

(1) The package size and the manner of packaging;

(2) Distribution, advertising, and promotion of the product;

(3) Labeling and the name of the product;

(4) The potential, duration, scope, and significance of inappropriate use and/or abuse;

(5) Other facts as may be relevant to and consistent with public health and safety.

(F) The board shall remove a drug product exception for a particular drug product if it determines that the drug product is not manufactured and distributed for legitimate use and in a manner that reduces the likelihood of abuse.

For Filing with CSI and JCARR

4729:5-2-06 - Zoning. (NEW)

Propose rescission from CSI to consider additional feedback.

4729:8-3-02 - Information required for submission.

Commenter	Comment	Draft Board Comment Response
Nationwide Children's Hospital	(A)(14) – (A)(19) We would appreciate clarification on the difference between the Species Code and Veterinary Species Code. If there's truly only one code, we recommend removing (A)(14). Based on our assessment, there is only one specified code in ASAP 5.0 called Veterinary Species Code: 01 = Cat/Feline 02 = Dog/Canine 03 = Small Animal (Hamster, Rabbit, Other Rodent) 04 = Reptile 05 = Bird 06 = Livestock, Large Animal 99 = Other	The species code identifies if the patient is a human or animal. If an animal is selected, the pharmacy will also have to indicate whether it is a large animal (such as cattle) or a small animal (such as a dog or cat). Therefore, both the species code and the vet species code are necessary to collect. This will make it easier for the Board to better identify sources of controlled substance diversion because we can filter out large quantities associated with heard animals and other large species. The commenter exclusively treats humans and therefore will never be required to utilize a veterinary species code and can default that code to human for all OARRS submissions.

4729:8-3-02.1 - Supplemental information required for submission.

Propose rescission from CSI to consider additional feedback.

Comments
I am writing to submit feedback on proposed rule 4729:8-3-02.1, specifically regarding the requirement for the last four digits of a patient's social security number within the Ohio Automated Rx Reporting System (OARRS). As the Director of Pharmacy at a Federally Qualified Health Center (FQHC), I am deeply concerned about the potential barriers this requirement could create for patients in underserved communities.

Many individuals receiving care in Ohio, particularly those in marginalized or vulnerable populations, do not possess a social security number. For these patients, the requirement to provide even the last four digits of a social security number may result in unintended obstacles to accessing essential healthcare. This is especially concerning given the mission of FQHCs to provide comprehensive, accessible care to all, regardless of their background or documentation status.

If this rule is implemented, I strongly urge that clear guidance be provided for healthcare providers and pharmacists to ensure these patients can still access necessary medications. Specifically, guidance on alternative identifiers or processes for patients without social security numbers would be essential to prevent delays or denials of care.

It is critical to balance the objectives of regulatory compliance with the imperative to maintain equitable access. I look forward to continued dialogue on this issue to help ensure that all Ohio residents can receive the care they need.

I am writing to submit feedback on proposed rule 4729:8-3-02.1, specifically regarding the requirement for the last four digits of a patient's social security number within the Ohio Automated Rx Reporting System (OARRS). As a Clinical Pharmacist at a Federally Qualified Health Center (FQHC), I am concerned about the potential barriers this requirement could create for patients in underserved communities.

Many individuals receiving care in Ohio, particularly those in marginalized or vulnerable populations, do not possess a social security number. For these patients, the requirement to provide the last four digits of a social security number may result in unintended obstacles to accessing essential healthcare. This is concerning given the mission of FQHCs to provide comprehensive, accessible care to all.

If this rule is implemented, I strongly urge that clear guidance and/or alternatives be provided for healthcare providers and pharmacists to ensure these patients can still access necessary medications without the use of the last four digits of a social security number.

4729:8-3-02.1

- (B)(3)
    - Social Security number (SSN) is reportable in our retail pharmacy system. However, this information is not documented in many patient’s charts. We request revising the language to account for the following scenarios: 1) information is not on file, 2) if a patient refuses to disclose, or 3) information is not obtainable. Such revision could state: “Last four digits of patient social security number, if available.”

This letter is in response to the solicitation for stakeholder comment on the proposed rule(s) dated November 4, 2024 (reissued November 15, 2024).

The Ohio Pharmacists Association (OPA) was formed September 2, 1879 in Columbus, Ohio under the name Ohio State Pharmaceutical Association (OSPA). The purpose of the Association was to elevate the character of the pharmaceutical profession, by uniting the reputable druggists of the state in order to foster the education of those learning the art and thereby stimulate the talent of those engaged in pharmacy. In cooperation with its members and leaders, the present-day OPA continues to function by this purpose and act to positively impact the profession as these past extraordinary individuals did.

The Ohio Pharmacists Association appreciates the opportunity to provide comments on the proposed rule set related to the Ohio Automated Rx Reporting System (OARRS). Anytime OPA can improve public safety and the pharmacy work environment, we will partner towards that improvement. We submit the following comment for your consideration.

Rule 4729:8-3-02.1 | Supplemental information required for submission. (NEW)

Since its inception, OARRS has given pharmacists and prescribers access to critical information to improve patient care related to controlled substances. Unfortunately, there have been isolated cases of intentional deception by individuals who have exposed the limits of any medical records system to their advantage. In this case, name, birthdate, and other patient driven information have been willfully altered by the patient to avoid detection by the OARRS system and obtain additional controlled substances. This often includes the patient using multiple prescribers, multiple pharmacies, and in some cases, multiple surrounding states. This activity puts the patient at risk for overdose, adds to the risk of sale of controlled substances by individuals and/or fosters addiction that leads to illicit drug use and possible death. Finding a way to eliminate this patient deception is key to the core mission of OARRS.

In order to properly obtain the required data under the proposed rule, existing computer systems must be able to comply. Today, most systems do not have the ability to collect the data required under the rule. As you know, pharmacies are not the author of this software, and we are at the mercy of outside developers to accommodate the rule. I might suggest delaying the effective date of the rule beyond the standard timeframe to allow meaningful compliance. Additionally, the data being requested has a subjective nature to which we fear accuracy could be in question. For example, patient race and ethnicity can be

subjective to both the pharmacist/prescriber and the patient. This creates an unreliable data set as it is not universally measured by an outside source. The proposed collection of the last four digits of a social security number would also seem to have its limits given it no longer appears on public documents outside of the Social Security card itself. This would seem to lead to a similar conundrum as orally given dates of birth.

As we both share a desire to build a stronger OARRS system, OPA would like to suggest that the Ohio Board of Pharmacy extend its rule drafting process. This could include additional input from various sources about how to secure more objective data and severely limit the ability for patients to abuse the existing loopholes within the OARRS system. Such input could also include functionality such that patients, pharmacies and prescribers who are currently compliant are not hindered in their practice abilities, burdened with additional workload, and assist the Board of Pharmacy in the outcome we both desire. OPA stands at the ready to assist the Board of Pharmacy in a solution that better identifies patients through available data and leads to better patient care. We appreciate your time in allowing this comment period on the proposed rules.

Rule 4729:11-1-01 | Definitions - home medical equipment. (AMEND)

As used in this division:

(A) "24/7 coverage" means that facilities that provide HME services must have a telephone number that is operational twenty-four hours a day, seven days a week that clients can call to seek assistance. The telephone line may be an answering service that is monitored on a regular basis by the HME provider and should also alert clients to contact 911 in an emergency.

(B) "Abandoned application" means an application submitted for licensure or registration where an applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If an application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the licensure or registration requirements in effect at the time of reapplication.

An application shall not be deemed abandoned if the application is subject to any of the following:

(1) An administrative proceeding; or

(2) If there is discipline pending against the applicant.

(C) "Accrediting body" means an agency recognized by the board under rule 4729:11-2-04 of the Administrative Code.

~~**(D) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.**~~

(**D**) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section 3719.011 of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or

drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

(**E**) "Board" means the state board of pharmacy.

(**F**) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(**G**) "Certificate of registration" or "registration" means a person holding a valid certificate of registration issued under Chapter 4752. of the Revised Code.

(H) “Client” or “patient” means a person who receives HME services from an HME services provider.

(I) "CMS" means the centers for medicare and medicaid services.

(J) "Contact hour" means a period of sixty minutes with a minimum of fifty minutes of instruction. For credit hours earned on an academic quarter system, one credit hour is equivalent to ten contact hours. For credit hours earned on an academic trimester system, one credit hour is equivalent to twelve contact hours. For credit hours earned on an academic semester system, one credit hour is equivalent to fifteen contact hours.

(K) "Disciplinary action" means any of the following by a federal agency or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:

(1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration or certification;

(2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;

(3) An administrative fine or monetary penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand, or probation;

(4) An action to reprimand or place the license, registration, or certification holder on probation;

(5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation, or surrender;

(6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;

(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;

(8) The surrender of a license or other relinquishment, registration or certification in lieu of a formal sanction against a person's license, registration or certificate, whether permanent or temporary;

(9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license in the future.

(10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.

(L) "Expired certificate of registration" means the holder of a certificate of a registration under Chapter 4752. of the Revised Code has failed to fulfill all requirements of certificate renewal and has failed to request that the board place the certificate into inactive status.

(M) "Expired license" means the holder of a license under Chapter 4752. of the Revised Code has failed to fulfill all requirements of licensure renewal, and who has failed to request that the board place the certificate on inactive status.

(N) "Home medical equipment" or "HME" has the same meaning as defined in section 4752.01 of the Revised Code. Pursuant to division (B)(3) of that section, HME shall also include the following equipment:

(1) Hospital grade pulse oximeters pursuant to a prescription issued by a prescriber;

(2) Home photo therapy (bili lights or blankets);

(3) Individually sized or customized accessories that are an integral part of equipment defined in this paragraph and paragraphs (T) and (DD) of this rule;

(4) Transcutaneous electronic nerve stimulators (TENS), excluding devices labeled by the federal food and drug administration for over-the-counter use and are identified with the federal food and drug administration product code "NUH.OTC TENS";

(5) Drop foot stimulators;

(6) Bone growth stimulators;

(7) Vision restoration therapy devices;

(8) In-home patient lifts;

(9) Life-sustaining equipment as defined in paragraph (T) of this rule; and

(10) Technologically sophisticated medical equipment as defined in paragraph (DD) of this rule.

(O) "Home medical equipment services" or "HME services" has the same meaning as defined in section 4752.01 of the Revised Code.

(P) "Home medical equipment services provider" or "HME services provider" has the same meaning as defined in section 4752.01 of the Revised Code.

(Q) "Inactive status" means the status of a license or registration issued under Chapter 4752. of the Revised Code of a facility that has made a request, in a manner determined by the board, that the board place the license or registration into inactive status. A facility with an inactive license does not hold a current, valid license or certificate of registration under Chapter 4752. of the Revised Code.

(R) "In-service education" means that a continuing education program is offered by a HME service provider organization and not an approved peer review organization.

(S) "Joint commission on accreditation of healthcare organizations," as used in section 4752.12 of the Revised Code, means "the joint commission" or its predecessor organization.

(T) "Life sustaining equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

(1) Ventilators;

(2) Oxygen concentrators;

(3) Oxygen liquid systems;

(4) Oxygen compressed gas systems;

(5) Non-invasive ventilator system (e.g. bi-level, iron lungs, rocking beds, diaphragmatic pacers, etc.);

(6) Any other life sustaining equipment as determined by the board.

(U) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions. It also includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

(V) "Place on probation" means to take action against a license or registration for a period of time determined by the board which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee or registrant may engage.

(W) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the board.

(X) "Refuse to grant or renew" means to deny original or continued licensure or registration for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed or registered by the board or a person seeking to attain such status by licensure or registration, and whose license or registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure or registration, whose license the state board of pharmacy has refused to grant or renew must meet all requirements established by the board in rule and as may be set forth in the person's board order.

(Y) "Registered" and "licensed" mean that a person has met the initial qualifications for a certificate of registration (registered) or license (licensed) with the state board of pharmacy

under Chapter 4752. of the Revised Code and rules adopted thereunder and have complied with renewal procedures, including payment of applicable fees.

(Z) "Revoke" means to take action against a license or registration rendering such license or registration void and such license or registration shall not be reissued. Revoke is an action that is permanent against the licensee or registrant.

(AA) "Staff" means employees or their representatives of a licensee or registrant.

(BB) "Suspend" means to take action against a license or certificate of registration rendering such license or registration without force and effect for a period of time as determined by the state board of pharmacy.

(CC) "Summary suspension" means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section 4752.09 of the Revised Code. The board may suspend a license or registration issued pursuant to Chapter 4752. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(DD) "Technologically sophisticated medical equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

(1) Oxygen conservation devices;

(2) CPAP (continuous positive airway pressure) devices;

(3) High frequency chest wall oscillators (vests);

(4) Intrapulmonary percussive ventilation (IPV) devices;

(5) Intermittent positive pressure breathing (IPPB) devices;

(6) Cough-assist mechanical in-exsuffaltor;

(7) Apnea monitors;

(8) Percussors for chest physiotherapy;

(9) Suction machines;

(10) Feeding pumps;

(11) Infusion pumps;

(12) Continuous passive motion (CPM) devices;

(13) Custom seating or positioning systems;

(14) Custom rehab equipment (e.g. standers & gait trainers);

(15) Vacuum assisted wound closure devices;

(16) Electric wheelchairs and custom scooters;

(17) Auto-titrating airway devices; and

(18) Any other technologically sophisticated medical equipment as determined by the board.

Rule 4729:11-2-02 | Designated representative. (AMEND)

(A) A location licensed or registered as a HME provider shall have a designated representative at all times.

(B) When there is a change of designated representative, the state board of pharmacy shall be notified by the new designated representative within ten days of the effective date of the appointment of the new designated representative in a manner determined by the board.

(C) The designated representative shall be responsible for compliance with all applicable state and federal laws, regulations, and rules governing the provision of HME services.

(D) The designated representative shall be physically present at the licensed or registered location for a sufficient amount of time to provide supervision of the activities conducted by a HME services provider.

(E) Unless otherwise approved by the board, a HME services provider shall not have a designated representative who:

(1) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(2) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(3) Has committed an act that constitutes a ~~**misdemeanor theft**~~ **disqualifying** offense, regardless of the jurisdiction in which the act was committed.

~~**(4) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.**~~

(**4**) Is addicted to or abusing alcohol or drugs.

~~**(6) Has committed an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed.**~~

(**5**) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

(**6**) Has been excluded from participation in medicare or a state health care program.

(**7**) Has been the subject of any of the following by an accrediting agency or a licensing or certification agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license, registration, certification, or accreditation; or

(b) A disciplinary action that was based, in whole or in part, on the person's provision of home medical equipment services.

~~**(7) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee's professional practice.**~~

~~**(11) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.**~~

Rule 4729:11-2-03 | Applications. (AMEND)

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making an application for a HME services provider license or certificate of registration:

(1) The name, full physical business address (not a post office box), and telephone number of the applicant.

(2) All trade, fictitious, or business names used by the applicant (e.g. "doing business as" or "formerly known as").

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of HME.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, **limited liability company,** corporation, ~~**or**~~ government agency**, or nonprofit organization**).

(5) The following information for the owner(s) and/or operator(s) of the applicant:

(a) For a partnership:

(i) The full name, business address, social security number, and date of birth of each partner. If the partner is not a natural person, each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(ii) The name of the partnership.

(iii) The partnership's federal employer identification number.

(b) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.

(c) For a limited lability company: the full name, business address, social security number, and date of birth of each member. If the member(s) is not a natural person, each business entity that is a member having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(d) For a corporation:

(i) The full name, business address, social security number, and date of birth of the corporation's president, vice-president, secretary, treasurer, and chief executive officer, or any equivalent position. For a publicly traded corporation that obtains a criminal records check waiver pursuant to paragraph (A)(3) of rule 4729:6-2-03 of the Administrative Code, the full name, business address, social security number, and date of birth of the corporate officers subject to a criminal records check as determined by the board's executive director or director's designee.

(ii) The name or names of the corporation.

(iii) The state of incorporation.

(iv) The corporation's federal employer identification number.

(v) The name of the parent company, if applicable.

(vi) If the corporation is not publicly traded on a major stock exchange, the full name, business address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation.

(e) For a government agency: the full name, business address, social security number, and date of birth of the agency director.

(f) For a nonprofit organization: the full name, business address, social security number, and date of birth of the executive director or any equivalent position.

~~**(5) The following information for the owner(s) and/or operator(s) of the applicant:**~~

~~**(a) For a partnership:**~~

~~**(i) The full name, business address, social security number, and date of birth of each partner; if the partner is not a natural person each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person;**~~

~~**(ii) The name of the partnership; and**~~

~~**(iii) The partnership's federal employer identification number.**~~

~~**(b) For a corporation:**~~

~~**(i) The full name, business address, social security number and date of birth of the corporation's president, vice-president, secretary, treasurer and chief executive officer, or any equivalent position;**~~

~~**(ii) The name or names of the corporation;**~~

~~**(iii) The state of incorporation;**~~

~~**(iv) The corporation's federal employer identification number;**~~

~~**(v) The name of the parent company, if applicable;**~~

~~**(vi) If the corporation is not publicly traded on a major stock exchange, the full name, business address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation.**~~

~~**(c) For a sole proprietorship:**~~

~~**(i) The full name, business address, social security number, and date of birth of the sole proprietor; and**~~

~~**(ii) If applicable, the federal employer identification number of the business entity.**~~

(6) If the person making application for a certificate of registration, information necessary to verify accreditation authorized pursuant to rule 4729:11-2-04 of the Administrative Code.

(7) If applicable, the Ohio medicaid number, federal medicare number, and federal tax identification number for the applicant.

(8) A copy of the applicant's certificate of product and professional liability insurance from an insurer showing a minimum one million dollars per occurrence, three million dollars aggregate of coverage.

(9) A list of the HME to be stored, repaired, leased or sold by the applicant.

(10) A brief description of the HME services provided, including square footage of the facility.

(11) A list of the personnel currently employed by the applicant who are engaged in the delivery of HME services, including job titles.

(12) List of other licenses, registrations, or certifications held by the applicant.

(13) Any additional information required on the application as determined by the board.

(14) Any follow-up information as deemed necessary upon the receipt of the application materials.

Rule 4729:11-2-04 | Recognized accrediting bodies. (NO CHANGE)

(A) The board recognizes the joint commission as a national body that accredits HME services providers.

(B) The board, at its discretion, may recognize other national accrediting bodies if an agency submits a written request to the board for recognition. The board shall consider the following criteria in determining whether to recognize an agency:

(1) The agency is recognized by CMS or other nationally recognized independent quality review organization;

(2) The agency operates under the control of a multi-disciplinary governing body or board;

(3) The agency operates within the continental United States;

(4) The agency currently accredits and maintains accreditation of at least fifty HME, respiratory, or rehab organizations;

(5) The agency has a measurable process with outcome standards for determining whether to accredit a HME services provider;

(6) The agency performs on site evaluations of organizations using quantitative performance criteria;

(7) The agency awards accreditation for a finite period of time;

(8) The agency develops and publishes surveyor/site visitor qualifications and competencies;

(9) The agency provides written reports of survey visits, observations, violations, citations, and requirements for improvement; and

(10) The agency signs a cooperative agreement with the board, for mutual reporting of legal or accrediting violations.

(C) National accrediting bodies recognized by the board shall be posted to the board's website (www.pharmacy.ohio.gov).

(D) National accrediting bodies recognized by the former respiratory care board prior to January 21, 2018 shall be deemed recognized by the state board of pharmacy.

(E) If the board determines that the agency applying to be recognized does not meet the requirements of paragraph (B) of this rule, the board may deny recognition of the agency. An agency denied by the board may not resubmit a request for recognition for twenty-four months from the date of denial.

Rule 4729:11-2-05 | Change in description of a HME services provider or discontinuation of business. (AMEND)

(A) Any change in the ownership, business or trade name, category, or address of a HME services provider requires a new application~~, and~~ required fee~~, and license or certificate of registration~~. The ~~new~~ application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.

~~(B) A change of ownership includes any of the following:~~

~~(1) A change of controlling interest of ten percent or more of a licensed or registered corporation's outstanding shares of voting stock.~~

~~(2) Any business entity change from its original form, as licensed or registered, to a sole proprietor ownership, partnership, limited liability company, corporation or any other business entity.~~

~~(3) An existing corporation ceases and a new corporation or other business entity is formed.~~

~~(4) An existing corporation continues and there is a one hundred percent stock purchase by another corporation or other business entity.~~

~~(5) Two wholly-owned subsidiaries of a parent company are merged.~~

~~(6) A currently licensed or registered HME services provider is purchased or operated by a different business entity than what is listed on the original application, even if the location maintains the original "doing business as" (DBA) and/or designated representative.~~

~~(7) Any partnership change other than that which was originally licensed.~~

~~(a) A partnership change is deemed to have occurred when:~~

~~(i) There is an addition or removal of one or more partners in a partnership to which a license is issued.~~

~~(ii) The entity is sold and the sale becomes final.~~

~~(b) For partnerships, a transfer of a proportion of ownership among existing partners is not a change of ownership, if there is no addition or removal of a partner.~~

~~(8) Any other business model change as determined by the board to be a change of ownership.~~

~~(C) For publicly traded corporations, a routine sale of stock is not a change of ownership.~~

~~A publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.~~

(B) A change of ownership includes any of the following:

(1) For all HME services providers:

(a) Any business entity change from its original form, as licensed, to a sole proprietorship, partnership, limited liability company, corporation, or any other business entity.

(b) Two wholly owned subsidiaries of a parent company are merged.

(c) A HME services provider is purchased or operated by a different business entity than what is listed on the original application, even if the location maintains the original "doing business as" (DBA) and/or responsible person.

(2) For corporations:

(a) Except as provided in paragraph (B)(2)(d) of this rule, a change of controlling interest of ten per cent or more of a licensed corporation's outstanding shares of voting stock.

(b) An existing corporation ceases, and a new corporation or other business entity is formed.

(c) An existing corporation continues and there is a one hundred per cent stock purchase by another corporation or other business entity.

(d) For publicly traded corporations, a routine sale of stock is not a change of ownership.

A publicly traded corporation is a company that has listed itself on at least one public stock exchange or has issued securities and is subject to public reporting requirements.

(3) For partnerships, any partnership change, other than that which was originally licensed.

(a) A partnership change is deemed to have occurred when:

(i) There is an addition of one or more partners in a partnership to which a license is issued.

(ii) The entity is sold, and the sale becomes final.

(b) Transfer of a portion of ownership among existing partners is not a change of ownership, if there is no addition of a partner.

(4) For a limited liability company, any membership change of a limited liability company, other than that which was originally licensed.

(a) A membership change is deemed to have occurred when:

(i) There is an addition of one or more members in a company to which a license is issued.

(ii) The entity is sold, and the sale becomes final.

(b) For limited liability companies, a transfer of a portion of ownership among existing members is not a change of ownership, if there is no addition of a member.

(5) Any other business model change, as determined by the board to be a change of ownership.

(**C**) If any change of ownership in accordance with paragraph (B) of this rule results in a new or different DBA, or a new or different employer identification number (EIN), **an** ~~**a new**~~ application fee is required.

(**D**) A change of ownership set forth in this rule or as otherwise determined by the board's executive director or the director's designee, may require the board to issue a new license or registration number.

(**E**) A change of ownership**,** as described in paragraph (B) of this rule**,** of a licensee's parent or holding company shall not require a new application, required fee, or license/registration.

(F) A change of address includes the physical relocation of a HME services provider's operations and location of home medical equipment. This shall include a change of suites within an existing building or campus.

(G) A change of address that results from a change within a local government entity or United States postal service (U.S.P.S.) that does not include any physical relocation of a HME service provider's operations shall not require an application and fee. The HME services provider shall submit written notification to the board, in a manner determined by the board, indicating the change of address.

(**H**) A HME services provider who plans to discontinue business activities shall file a notice with the **state** board **of pharmacy**. The notice shall be submitted, in a manner determined by the board, ~~**at least**~~ **within** thirty days in advance of the proposed date of discontinuing business~~**, unless waived by the board's executive director or the director's designee due to extraordinary circumstances beyond the provider's control**~~. This notice shall include the following information:

(1) The name, address, and license or registration number of the HME services provider discontinuing business.

(2) The name and address of the location where the records will be maintained in accordance with rule 4729:11-3-02 of the Administrative Code.

(3) The proposed date of discontinuing business.

Rule 4729:11-3-01 | Minimum standards for licensed home medical equipment services providers ~~licensees~~.

(A) This rule sets forth the minimum acceptable standards for licensure as a HME services provider under Chapter 4752. of the Revised Code.

(B) A licensee shall maintain knowledge of the duties and responsibilities of a HME services provider and shall practice in accordance with the following:

(1) Chapter 4752. of the Revised Code;

(2) Division 4729:11 of the Administrative Code;

(3) Any other applicable federal and state laws, rules and regulations; and

(4) Position statements, standards of care or guidelines for providing HME services from nationally recognized organizations. ~~, including medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier standards, joint commission, or other accrediting bodies recognized by the board pursuant to rule 4729:11-2-04 of the Administrative Code.~~

(C) A licensee and the licensee's staff shall demonstrate competence and accountability in all areas of HME services in which they are engaged, including, but not limited to, the following:

(1) HME storage, leasing, sales, delivery, billing services, maintenance, cleaning, infection control, and repair;

(2) Appropriate recognition, referral, or consultation and intervention when a complication arises in conjunction with the function of HME or when a change in patient or client compliance occurs; and

(3) Referral to another HME services provider if the client's needs are beyond the scope of the license holder.

(D) A licensee is responsible for maintaining a facility that meets all the following requirements:

(1) The facility must have appropriate physical space to safely store, maintain and service on site equipment;

(2) The facility must have separation of business office, patient records, equipment cleaning, maintenance, and storage functions, as applicable;

(3) The facility must be able to demonstrate appropriate equipment flows through various stages to ensure that the equipment is properly disinfected, repaired, stored, and maintained;

(4) The facility must maintain inventory on site or by arrangement with a supplier to meet the needs of the licensee's current client base; ~~**and**~~

(5) The facility must meet all federal, state and local laws, rules, and regulations, including those pertaining to the storage, maintenance, **rental,** and sale of upholstery or bedding, if applicable.

(E) Only employees and authorized contractors of a HME services provider shall be permitted to have unsupervised access to client records and HME maintained by the provider. When no HME employees are on-site to provide supervision, all patient records and HME equipment shall be secured by either:

(i) A physical barrier with suitable locks to prevent unauthorized access; or

(ii) An alarm system that is monitored by a central station for control and can detect unauthorized access. The alarm system shall be tested on a biannual basis. The HME services provider or the entity that manages security for the provider shall maintain testing records for three years from the date of testing and shall make such records readily retrievable.

(**F**) In maintaining equipment, a licensee shall:

(1) Maintain and document equipment in accordance with the manufacturer's guidelines;

(2) Clean, disinfect, repair, store, segregate and identify all equipment in a manner that ensures the equipment is safe for use by the public;

(3) Ensure that all equipment is used within the manufacturer's recommended guidelines and expirations dates, if applicable.

(**G**) A licensed HME services provider shall:

(1) Maintain appropriate staffing to handle the scope of equipment sold, rented and maintained and to appropriately meet the demands of the business.

(2) Ensure that all staff members are trained and supervised by qualified persons.

(3) Maintain personnel records for each employee, which shall include all of the following:

(a) Job description for the position held by the employee.

(b) Application qualifications.

(c) For any employee that provides HME services, supervises an employee who provides HME services, or has access to records maintained in accordance with rule 4729:11-3-02 of the Administrative Code who is working within the state of Ohio, a criminal background check shall be performed only upon initial hire by the Ohio bureau of criminal identification and investigation (BCI&I) and shall consist of both a BCI&I ~~**and FBI**~~ criminal records check.

(d) Orientation and training records.

(e) Verification of competence.

(f) Performance plan to be completed annually by the licensee.

(**H**) A licensed HME services provider shall possess product and professional liability insurance coverage in the amount of one million dollars per occurrence, three million dollars aggregate. The certificate of insurance must show that the product and professional liability insurance coverage is contained in the total aggregate amount.

Rule 4729:11-3-02 | Record keeping. (AMEND)

(A) A **licensed or registered** HME services provider shall maintain records for each client that has been sold or leased equipment.

(1) All records maintained in accordance with this rule shall be uniformly maintained and readily retrievable for inspection and copying by properly identified agents, inspectors or employees of the state board of pharmacy.

(2) All client records must contain a prescriber order, if required, and documentation of settings and other data relevant to the equipment that has been sold or leased, and other documentation regarding service checks of the equipment sold or rented to the client.

(3) All client records must be maintained for three years from the date of sale or in the case of a minor client, records must be maintained for seven years after the client turns eighteen years of age.

(B) A HME services provider located in this state intending to maintain records at a location other than the location licensed or registered by the state board of pharmacy shall notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the licensee or registrant.

(C) A HME services provider maintaining records at location other than the location licensed or registered by the state board of pharmacy or via a computerized record keeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this rule within three business days.

Rule 4729:11-3-03 | Inspections and corrective actions.

(A) An entity licensed or registered by the state board of pharmacy pursuant to Chapter 4752. of the Revised Code is subject to an on-site inspection by the board. An authorized board ~~**agent**~~ **employee** may, without notice, carry out an on-site inspection or investigation of an entity licensed or registered by the board. Upon verification of the board ~~**agent's**~~ **employee's** credentials, the ~~**agent**~~ **employee** shall be permitted to enter the licensed or registered entity.

(B) Submission of an application for a license or registration as a HME services provider with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board agent.

(C) If an agent of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the agent may provide written notice, in a manner determined by the board, of the nature of the observed violations to the designated representative on the license, registration or application. The licensee, registrant or applicant may also be subject to disciplinary actions pursuant to Chapter 4752. of the Revised Code and this division of the Administrative Code.

(D) Violations may include any of the following:

(1) Violating any rule of the board;

(2) Violating any provision of Chapter 4752. of the Revised Code;

(3) Violating any federal, state and local law, rule, or regulation regarding the provision of HME services.

(E) The licensee, registrant or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:

(1) The action(s) the licensee, registrant or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or

(2) An explanation disputing the observed violations.

(F) The designated representative of a HME services provider shall comply with investigations and inspections conducted by the board or accrediting body recognized in accordance with

rule 4729:11-2-04 of the Administrative Code and shall instruct their staff members to comply with all requests made by the board or accrediting body.

Rule 4729:11-3-04 | Continuing education. (NO CHANGE)

(A) Licensed HME services providers shall provide ten contact hours of continuing education per renewal cycle for staff rendering home medical equipment services.

(B) Of the number of continuing education contact hours required, one contact hour shall include subject content on infection control, equipment cleaning standards and cleaning agents, rotation of inventory, or equipment separation requirements. The remaining contact hours must be relevant to the HME services rendered. The following are acceptable sources of continuing education:

(1) In-service education developed and taught by the licensed HME services provider.

(2) In-service education developed and taught by a HME manufacturer.

(3) Continuing education approved by any organization recognized by the board that offers continuing education relevant to HME services rendered.

(C) Any organization that provides HME continuing education may apply to the board to be recognized as an authorized continuing education provider. Request for recognition must be made in writing to the board and must include an overview of the organization and an outline of the continuing education courses provided by the organization, including course content.

(D) Documentation of all completed continuing education courses taken by each staff member must be maintained in the employee's personnel file for three years from the date of completion and shall made readily retrievable.

In-service continuing education credits shall be documented for employed staff involved in HME service delivery to the public. Records of attendance and completion shall include any of the following:

(1) Sign in logs;

(2) Agendas and training manuals;

(3) Certificates of completion; or

(4) Online completion logs/rosters.

Rule 4729:11-3-05 | Advertising and solicitation. (AMEND)

(A) No **licensed or registered** HME services provider shall advertise or solicit for patronage in connection with the licensee or registrant's business if any communication contained therein is false, fraudulent, deceptive, or misleading.

(B) Excluding a free consultation, any advertisement or solicitation which offers HME services on a gratuitous basis shall include a disclaimer. If the advertisement is visual, the disclaimer shall be contained therein. If the advertisement is audio-based, the disclaimer shall be read. A written copy of the disclaimer shall be provided to every patient who responds to an offer, prior to the rendering of patient care.

(1) The disclaimer shall clearly and conspicuously state the following:

(a) Any exclusions, prohibitions, restrictions, limitations, conditions, or eligibility requirements which apply to the offer; and

(b) Any additional services, which are associated with the offer, that are rendered on the same day but are not provided free of charge.

(C) All advertisements and solicitations shall include therein the name of the licensee or registration holder pursuant to Chapter 4752. of the Revised Code who has reviewed and approved the content of the advertisement or solicitation.

(D) Any trade or fictitious names utilized in connection with HME services or sales shall be duly registered with the Ohio secretary of state.

(E) Each of the following shall constitute an abusive telemarketing act and shall be considered a violation of this rule:

(1) Use of threats, intimidation, or profane or obscene language.

(2) Calling a person repeatedly or continuously with intent to annoy, abuse or harass any person at the number called.

(3) Calling a person when that person has previously stated that they do not wish to receive an outbound telephone call made by or on behalf of the seller whose goods or services are being offered or a person who is listed on federal government's national do not call registry. Every seller of goods or services shall maintain a "do not call" list.

(4) Calling a person's residence at any time other than between eight a.m. and eight p.m. local time at the person's location.

(5) Requiring an immediate response from the prospect to any offer made during the solicitation.

(6) Failure to disclose within the first sixty seconds of the telephone call the solicitors identity and the practice on whose behalf the solicitation is being made; the purpose of the telephone call; a statement of the goods or services being sold; and that no purchase or payment is necessary to participate in a promotion if a promotion is offered.

(7) The solicitors are prohibited from misrepresenting their affiliation with, or endorsement by, any government or third-party organization.

(8) Communicating with prospective patients in a way that invades privacy of the prospect**ive patient**~~,~~ or interferes with an existing prescriber/patient relationship.

(F) A licensee or registrant may utilize testimonials in advertising if the patient giving the testimonial has given written consent as to the exact wording and proposed use of the testimonial. A copy of such consent and testimonial shall be retained by the HME service provider for two years from the last date of publication. Testimonials shall be true and shall not be false, fraudulent, deceptive or misleading.

(G) A HME services provider may not utilize signs which include any false, fraudulent, deceptive or misleading information.

Rule 4729:11-3-06 | Minimum standards for registered home medical equipment services providers (NEW)

(A) This rule sets forth the minimum acceptable standards for registration as a HME services provider under Chapter 4752. of the Revised Code.

(B) For any employee that provides HME services, supervises an employee who provides HME services, or has access to records maintained in accordance with rule 4729:11-3-02 of the Administrative Code who is working within the state of Ohio, a criminal background check shall be performed only upon initial hire by the Ohio bureau of criminal identification and investigation (BCI&I) and shall consist of both a BCI&I criminal records check.

(C) All registered HME services providers shall comply with:

(1) All applicable federal and state laws, rules, and regulations;

(2) The Centers for Medicare and Medicaid Services “Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS) Quality Standards” (8/12/2024);

(3) Position statements, standards of care or guidelines for providing HME services from nationally recognized organizations;

(4) Pursuant to section 4752.09, federal rules issued pursuant to the medicare program established under Title XVIII of the "Social Security Act," 49 Stat. 620(1935), 42 U.S.C. 1395, as amended, relating to operations, financial transactions, and general business practices of home medical services providers.

(D) In maintaining equipment, a registrant shall:

(1) Maintain and document equipment in accordance with the manufacturer's guidelines;

(2) Clean, disinfect, repair, store, segregate and identify all equipment in a manner that ensures the equipment is safe for use by the public;

(3) Ensure that all equipment is used within the manufacturer's recommended guidelines and expirations dates, if applicable.

Rule 4729:11-4-01 | Disciplinary Actions.

(A) The state board of pharmacy may, in accordance with Chapter 119. of the Revised Code, impose any one or more of the following sanctions on an applicant for a license or certificate of registration issued under Chapter 4752. of the Revised Code or a license or certificate of registration holder for any of the causes set forth in paragraph (B) of this rule:

(1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license or certificate of registration;

(2) Reprimand or place the license or certificate holder on probation;

(3) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or not more than five thousand dollars if the acts committed are not classified as an offense by the Revised Code.

(B) The board may impose the sanctions listed in paragraph (A) of this rule for any of the following:

(1) Violation of any provision of this chapter or an order or rule of the board, as those provisions, orders, or rules are applicable to persons licensed or registered under this chapter.

~~**(2) A plea of guilty to or a judicial finding of guilt of a felony or a misdemeanor that involves dishonesty or is directly related to the provision of home medical equipment services.**~~

(2) Has a conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense.

(3) Making a material misstatement in furnishing information to the board.

(4) Professional incompetence.

(5) Being guilty of negligence or gross misconduct in providing home medical equipment services.

(6) Aiding, assisting, or willfully permitting another person to violate any provision of this chapter or an order or rule of the board, as those provisions, orders, or rules are applicable to persons licensed or registered under this chapter.

(7) Failing to provide information in response to a written request by the board.

(8) Engaging in conduct likely to deceive, defraud, or harm the public.

(9) Denial, revocation, suspension, or restriction of a license or certificate of registration to provide home medical equipment services, for any reason other than failure to renew, in another state or jurisdiction.

(10) Directly or indirectly giving to or receiving from any person a fee, commission, rebate, or other form of compensation for services not rendered.

(11) Knowingly making or filing false records, reports, or billings in the course of providing home medical equipment services, including false records, reports, or billings prepared for or submitted to state and federal agencies or departments.

(12) Failing to comply with federal rules issued pursuant to the medicare program established under Title XVIII of the "Social Security Act," 49 Stat. 620(1935), 42 U.S.C. 1395, as amended, relating to operations, financial transactions, and general business practices of home medical services providers if applicable.

(13) Failing to satisfy the qualifications for licensure or registration under Chapter 4752. of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the license or registration is granted or renewed.

(14) Commission of an act that constitutes a ~~**felony**~~ **disqualifying offense** in this state, regardless of the jurisdiction in which the act was committed.

~~**(15) Commission of an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.**~~

(**15**) Commission of a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(**16**) Violation of any restrictions placed by the state board of pharmacy on a license or registration or violating any terms of a board order issued against the licensee or registrant.

(**17**) Exclusion from participation in medicare or a state health care program.

~~**(19) Commission of an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.**~~

~~**(20) Commission of an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed.**~~

(**18**) Employs a designated representative that does not meet the requirements set forth in rule 4729:11-2-02 of the Administrative Code.

(**19**) Retaliating against or disciplining an employee for filing a complaint with a state board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this paragraph, retaliation or discipline of an employee includes, but is not limited to, the following:

(a) Removing or suspending the employee from employment;

(b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;

(c) Transferring or reassigning the employee;

(d) Denying the employee a promotion that otherwise would have been received;

(e) Reducing the employee in pay or position.

(**20**) The ownership of such entity has been transferred from a person whose license or registration issued in accordance with Chapter 4752. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to the spouse or other family member.

(**21**) The ownership of such facility has been transferred from a licensee or registrant whose license or registration has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed or registered.

(**22**) If applicable, failing to comply with the accreditation standards of a national accrediting body recognized pursuant to rule 4729:11-2-04 of the Administrative Code upon which a registration by the board has been granted.

(**23**) Unless otherwise approved by the board, a HME services provider knowingly employs a person who provides HME services to the public who:

(a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(c) Has committed an act that constitutes a ~~**misdemeanor theft**~~ **disqualifying** offense, regardless of the jurisdiction in which the act was committed.

~~**(d) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.**~~

(**d**) Is addicted to or abusing alcohol or drugs.

~~**(f) Has committed an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed**~~

(**e**) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

(**f**) Has been excluded from participation in medicare or a state health care program.

(**g**) Has been the subject of any of the following by an accrediting agency or a licensing or certification agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license, registration, certification, or accreditation; or

(ii) A disciplinary action that was based, in whole or in part, on the person's provision of home medical equipment services.

~~**(h) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee's professional practice.**~~

~~**(k) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.**~~

(C) On receiving notification, the board shall suspend or revoke any registration found to have the accreditation upon which the certificate of registration was issued revoked, suspended, or otherwise no longer valid.

Proposal to Classify 2-Benzylbenzimidazole "Nitazene" Opioid Pharmacophores as Schedule I Controlled Substances

Section 1: Summary

The Ohio Board of Pharmacy, pursuant to section 3719.44 of the Ohio Revised Code, proposes the placement of the following into Schedule I:

- All compounds that meet the structural requirements of the 2-benzylbenzimidazole opioids pharmacophores. *For the purposes of this report, these substances will be referred to as 2-benzylbenzimidazole "Nitazene" opioid pharmacophores*

Section 2: Background

Pursuant to section 3719.44 the Board may add or transfer a compound, mixture, preparation, or substance to schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.

In making a determination to add an unscheduled compound, the Board is required to consider the following eight criteria:

(1) The actual or relative potential for abuse;
(2) The scientific evidence of the pharmacological effect of the substance;
(3) The state of current scientific knowledge regarding the substance;
(4) The history and current pattern of abuse;
(5) The scope, duration, and significance of abuse;
(6) The risk to the public health;
(7) The potential of the substance to produce psychic or physiological dependence liability; and
(8) Whether the substance is an immediate precursor.

Section 3: Evaluating 2-benzylbenzimidazole "Nitazene" Opioid Pharmacophores Under the Eight Criteria

(1) The actual or relative potential for abuse.

The 2-benzylbenzimidazole opioids are not structurally related to the traditional phenanthrene (morphine) or fentanyl opioids (Vandeputte et al., 2021). The 2-benzylbenzimidazole opioids were first synthesized in the 1950's and 1960's by the Swiss pharmaceutical company CIBA and one agent, etonitazene, was shown to have an antinociceptive potency 1000-fold greater than that of morphine (Vandeputte et al., 2021). To date, these substances are not approved for medical use anywhere in the world (DEA, 2021). Recent in vitro studies have demonstrated that when compared to fentanyl binding to the μ_1 opioid receptor (MOR), the potency of the 2-benzylbenzimidazole opioids pharmacophores ranged from 20 to 50 times more potent than fentanyl (Vandeputte et al., 2021).

For decades, the regulation of dopamine release in the nucleus accumbens (NAc) has been demonstrated to be central to the euphoria associated with drug reinforcement (Nestler, 2005). The activation of the MOR within the ventral tegmental area results in dopamine release in the NAc (Jalabert et al., 2011; Mori et al., 2016). Therefore, the 2-benzylbenzimidazole opioids pharmacophores have a high potential for abuse (Federal Register, 2021). Recently, nitazenes have been shown to increase dopamine release in the shell of the nucleus accumbens (DeLuca et al., 2022).

(2) The scientific evidence of the pharmacological effect of the substance.

As noted above (Evaluation Criterion 1), the 2-benzylbenzimidazole opioids pharmacophores have been shown to have antinociceptive activity and MOR binding potency greater than that of fentanyl.

(3) The state of current scientific knowledge regarding the substance.

The structure-activity relationship of the 2-benzylbenzimidazole opioids pharmacophores dates back to their discovery in the 1950s (DEA, 2021). Vandeputte et al., (2021) thoroughly characterized the binding potency of the 2-benzylbenzimidazole opioids pharmacophores to the MOR and compared this binding to fentanyl and hydromorphone. The findings from this study clearly demonstrate that these agents activate the MOR with a potency that is much greater than that of fentanyl and hydromorphone.

(4) The history and current pattern of abuse.

The trafficking of counterfeit tablets containing novel opioid agonist is contributing to the drug overdose issue in the United States. In March 2019, isotonitazene first appeared on the drug scene in Canada and Europe (EMCDDA, 2020 and Mueller et al., 2021). Since 2019, over 14 different forms of 2-benzylbenzimidazole opioids pharmacophores have been identified and characterized pharmacologically (Vandeputte et al., 2021). To date, at the federal and state level, 20 of these 2-benzylbenzimidazole opioids pharmacophores have been scheduled (EO-2024-06D and Federal Register, 2024).

(5) The scope, duration, and significance of abuse.

Please see evaluation criterion 3 and 4.

(6) The risk to the public health.

In April 2022, the DEA emergency scheduled seven benzimidazole-opioids: Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-Pyrrolidino Etonitazene, and Protonitazene. Between November 2020 and July 2021, these seven benzimidazoles were identified in 44 toxicology and postmortem cases in the United States (DEA, 2021). To date, isotonitazene has been identified in over 250 deaths in the United States (Vandeputte et al., 2021) Since January 2021, Ohio BCI has identified 16 different benzimidazole opioid compounds in 1062 items (Ohio BCI Laboratory Statistics). Because 2-benzylbenzimidazole opioids pharmacophores activate the MOR leading to their rewarding potential, this also contributes to their ability to induce respiratory depression (Horsfall and Sprague, 2017).

(7) The potential of the substance to produce psychic or physiological dependence liability; and

The regulation of dopamine release in the nucleus accumbens (NAc) has been demonstrated to be central to the euphoria associated with drug abuse (Nestler, 2005). The activation of the MOR by the 2-benzylbenzimidazole opioids pharmacophores within the ventral tegmental area would result in dopamine release in the NAc (Jalabert et al., 2011; Mori et al., 2016). Therefore, the 2-benzylbenzimidazole opioids pharmacophores have a high potential for abuse (DEA, 2021). DeLuca et al., (2022) demonstrated that nitazenes do indeed increase the release of dopamine in the nucleus accumbens.

(8) Whether the substance is an immediate precursor.

2-benzylbenzimidazole opioids pharmacophores are not considered immediate precursors.

Section 4: Finding of the Board

Section 3719.44 of the Ohio Revised Codes authorizes the Ohio Board of Pharmacy may add or transfer a compound, mixture, preparation, or substance to schedule I when it appears that there is a high potential for abuse, that it has no accepted medical use in treatment in this state, or that it lacks accepted safety for use in treatment under medical supervision.

After a thorough review of all available data, the Ohio Board of Pharmacy finds that all compounds that meet the structural requirements of the 2-benzylbenzimidazole opioids pharmacophores that have not been previous scheduled by the Drug Enforcement Agency (DEA). For the purposes of this report, these substances will be referred to as 2-benzyl-benzimidazole "Nitazene" opioid pharmacophores:

1. Have a high potential for abuse;
2. Have no accepted medical use in treatment in this state;
3. Lack accepted safety for use in treatment under medical supervision; and
4. Pose a risk to the public health of the citizens in this state.

Based on these findings, the Board hereby concludes that compounds meeting the definition of 2-benzylbenzimidazole opioids pharmacophores warrant control in Schedule I and authorizes the filing of amended rule 4729:9-1-01 of the Administrative Code as found in Section 5 of this document.

Section 5: Proposed Rule

4729:9-1-01 – Schedule I Controlled Substances

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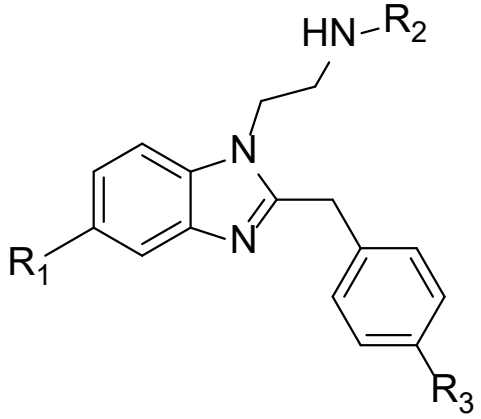
(B) Narcotics-opiates

Any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, unless specifically excepted under federal drug abuse control laws, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation (for purposes of 3-methylthiofentanyl only, the term isomer includes the optical and geometric isomers):

(88) Except as otherwise provided in section 3719.41 of the Revised Code, any compound that meets the following 2-benzylbenzimidazole opioids pharmacophore requirements to bind at the μ receptor, as identified by a report from an established forensic laboratory, is a schedule I controlled substance:

(a) A chemical scaffold consisting of a 2-(benzyl)-1H-benzimidazole-1-ethanamine, whether or not further substituted:

(b) Polar functional group or alkyl or aryl or a halogen substitutions in the R1 or R2 or R3 positions below.



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References:

De Luca MA, Tocco G, Mostallino R, Laus A et al. Pharmacological characterization of novel synthetic opioids: isotonitazene, metonitazene, and piperidylthiambutene as potent μ-opioid receptor agonists. Neuropharmacol. 2021;221:109263.

Drug Enforcement Administration, Department of Justice. (2021, December). Schedules of Controlled Substances: Temporary Placement of Butonitazene, Etodesnitazene, Flunitazene, Metodesnitazene, Metonitazene, N-pyrrolidino etonitazene, and Protonitazene in Schedule I. Retrieved from federalregister.gov

EMCDDA. (2020) Report on the Risk Assessment of N,N-Diethyl-2-[[4-(1-Methylethoxy)Phenyl]Methyl]-5-Nitro-1Hbenzimidazole- 1-Ethanamine (Isotonitazene) in Accordance with Article 5c of Regulation (EC) No 1920/2006 (as Amended), EMCDDA Publications Office, Luxembourg.

EO-2024-06D. https://content.govdelivery.com/attachments/OHIOGOVERNOR/2024/06/04/file_attachments/2898004/Signed-EO-2024-06D.pdf

Federal Register. Schedules of controlled substances: temporary placement of N-Desethyl Isotonitazene and N-Piperidinyl Etonitazene in Schedule I. DEA. July 29, 2024. https://www.federalregister.gov/documents/2024/07/29/2024-16391/schedules-of-controlled-substances-temporary-placement-of-n-desethyl-isotonitazene-and-n-piperidinyl

Jalabert M, Bourdy R, Courtin J, Veinante P, Manzoni OJ, Barrot M et al. Neuronal circuits underlying acute morphine action on dopamine neurons. PNAS 2011;108:16446–50.
Horsfall JT, Sprague JE. The pharmacology and toxicology of the "Holy Trinity." Basic Clin Pharmacol Toxicol 2017;120:115-119.

Mori T, Iwase Y, Saeki T, Iwata N, Murata A, Masukawa D et al. Differential activation of dopaminergic systems in rat brain basal ganglia by morphine and methamphetamine. Neuroscience 2016;322:164–70.

Mueller, F., Bogdal, C., Pfeiffer, B., Andrello, L., Ceschi, A., Thomas, A., and Grata, E. (2021) Isotonitazene: Fatal Intoxication in Three Cases Involving This Unreported Novel Psychoactive Substance in Switzerland. Forensic Sci. Int. 320, 110686.

Nestler EJ. Is there a common molecular pathway for addiction? Nat Neurosci 2005;8:1445–9.

Vandeputte MM, Uytfanghe k, Layle NK, St. Germaine DM, Iula DM, Stove CP. Synthesis, chemical characterization, and μ-opioid receptor activity assessment of the emerging group of "nitazene" 2-benzylbenzimidazole synthetic opioids. ACS Chem Neuro. 2021; 12:1241-1251.