March 2025 – Rules and Resolutions

Resolutions

NOTE: *All resolutions that are starred (*) were initially authorized by the Board President pursuant to resolution R-2022-0128.*

Exception for Mobile Clinics Provided by the Ohio Department of Health*

A terminal distributor of dangerous drugs (TDDD) may operate a mobile clinic or medication unit temporarily provided by the Ohio Department of Health without needing to register for a no-cost, satellite license pursuant to OAC 4729:5-3-23 if all the following conditions are met:

1. The TDDD operates the mobile clinic or medication unit in accordance with all other requirements of OAC 4729:5-3-23 (specifically the requirements of paragraph C);

2. The TDDD operates the mobile clinic or medication unit provided by the Department for no longer than 60 calendar days.

3. If the TDDD wishes to utilize the mobile clinic or medication unit provided by the Department longer than 60 calendar days, they must submit for a no-cost, satellite license in accordance with OAC 4729:5-3-23 (B)

The Ohio State University College of Pharmacy - Proposal for Waiver of Student to Preceptor Ratio

Pursuant to OAC 4729:2-1-01 (M)(3), the Board hereby grants the following intern-to-pharmacist ratio for The Ohio State University College of Pharmacy (OSUCOP) under the following circumstances:

1. Events that have been reviewed and approved by College of Pharmacy staff as Community Engagement Activities – a maximum of 4 interns per one pharmacist.

2. Medication Reconciliation Introductory Pharmacy Practice Experiences (IPPE) precepted by OSUCOP pharmacists at The Ohio State University Wexner Medical Center – a maximum of 3 interns per one pharmacist.

Supporting documentation can be found in Appendix I of this document.

January 29, 2025

Ohio Board of Pharmacy
77 South High Street, 17th Floor
Columbus, Ohio 43215-6126

Re: Proposal to the Ohio Board of Pharmacy regarding pharmacy intern to supervising pharmacist ratios

The Ohio State University College of Pharmacy (OSUCOP) proposes to expand the intern-to-pharmacist ratio for two specific cases

1. Events that have been reviewed and approved by College of Pharmacy staff as Community Engagement Activities **(requesting 4:1 ratio)**
2. Medication Reconciliation Introductory Pharmacy Practice Experiences (IPPE) precepted by OSUCOP pharmacists at The Ohio State University Wexner Medical Center **(requesting 3:1 ratio)**

Request #1: Community Engagement Activities

Pharmacy students at OSUCOP serving in free clinics, conducting brown bag medication reviews, and conducting point-of-care screenings in the community aid in providing high quality healthcare to the underserved communities in and around central Ohio. They address significant public health needs through access to safe and effective medications and screening for common chronic diseases. By expanding the ratio of interns to pharmacists in these community engagement settings, students would be able to reach more patients. One of the major limitations for student run free clinics and community engagement activities is the availability of pharmacist preceptors.

The free clinics associated with OSUCOP have physicians onsite to oversee general clinic operations including physician-log medication dispensing, but it can be challenging to identify pharmacists able to precept enough students to allow dispensing services as well as other tasks, such as taking medication histories, to efficiently occur. With this expanded ratio, pharmacist preceptors could be utilized more effectively to precept students in practice of pharmacy tasks to dispense medications and provide care to patients more efficiently and effectively.

Community point-of-care testing events involve students seated at a table together at a public event conducting blood glucose finger sticks and blood pressure measurement and counseling patients on their results. These screenings involve many technical tasks around conducting the actual screening that do not require pharmacist expertise. Often, preceptors are standing around waiting until the tests are complete to engage with the students and patients around

the interpretation and counseling on results. Allowing a 4:1 ratio would provide greater access to screenings for chronic disease at these events with assured pharmacist oversight on all activities that involve the practice of pharmacy.

Other community engagement activities hosted by students at The Ohio State University College of Pharmacy involve brown bag medication reviews and public-facing educational activities. For these as well as the free clinics and point-of-care testing events described above, the pharmacists are present at the events solely to precept students in community engagement. They do not have additional dispensing, staffing, or patient care expectations, so their entire focus is upon the student-patient interaction.

Furthermore, the PharmD program at Ohio State has class sizes of approximately 130 students per class per year. The Ohio State University College of Pharmacy is dedicated to student pharmacists having community engagement experience to reinforce their civic responsibility and their role as pharmacists in community, beyond traditional practice sites. With these high enrollments in the program, it has become harder for students to find opportunities that are available. Expansion of these ratios will allow students to gain more experience in the field and make for civically and community-engaged professionals in the future.

The College of Pharmacy will provide oversight in the application of this ratio expansion to ensure that the activities taking place in the community have the appropriate number of preceptors to student volunteers and involve a setup for the event that is reasonable to accommodate, with adequate precepting, a safe environment for patients. Any event proposal will be reviewed by the Office of Outreach and Engagement at the college and deemed approved or disapproved for the ratio of 4:1. This expansion ultimately would give Ohio State more flexibility to oversee student activities and improve access to healthcare which is an integral part of pharmacy student training and pharmacy as a profession in Ohio.

Request #2: Medication Reconciliation Introductory Pharmacy Practice Experiences (IPPE) precepted by OSUCOP pharmacists

All OSU College of Pharmacy (OSUCOP) student pharmacists gain essential experience completing medication reconciliation for patients admitted to the OSU Wexner Medical Center (OSUWMC) as a part of their required introductory pharmacy practice experiences (IPPEs). Medication reconciliation is critical to ensuring patient safety and optimizing therapeutic outcomes. Teaching students this process develops important foundational practice skills such as communication, development of an accurate home medication list, and documentation in the electronic medical record. Currently, The OSUCOP employs pharmacists whose primary responsibility is to precept student pharmacists completing IPPE medication reconciliation at the OSUWMC. In many other precepting situations, pharmacist preceptors have diverse job

responsibilities. For example, pharmacist preceptors in hospital settings commonly precept students completing medication histories while also verifying orders and attending to other patient care responsibilities. In contrast, the OSUCOP pharmacists who precept IPPE students completing medication reconciliation focus solely on training the student pharmacists and verifying the accuracy of the student activities. The OSUCOP pharmacists have no staffing/coverage requirement while they are at OSUWMC. For this reason, we would like to request the student intern:pharmacist ratio be expanded to 3:1.

By increasing the student intern:pharmacist ratio for medication reconciliation activities precepted by OSUCOP pharmacists, we can ensure that all IPPE student pharmacists have the opportunity to be precepted by pharmacists whose sole focus is on their instruction. This would provide a more cohesive, focused, and effective learning environment where preceptors can dedicate their time exclusively to mentoring students without competing patient care demands. We believe this adjustment would enhance the quality of education for our students, ultimately benefiting patient care and the pharmacy profession.

In summary, we request:

- An expansion of 2:1 to 4:1 for Ohio State College of Pharmacy students at community events and/or free clinics where these students serve, including:
    - Any free clinic where College of Pharmacy Students serve
    - Community point-of-care testing events
    - Brown bag medication reviews
    - All events covered by this change would be reviewed and approved by staff of College of Pharmacy
- An expansion of 2:1 to 3:1 for OSUCOP IPPE medication reconciliation activities completed at OSUWMC and precepted by OSUCOP pharmacists.

We thank you very much for your consideration in this matter and are happy to answer any questions from the Ohio Board of Pharmacy.

Jennifer L. Rodis, PharmD, FAPhA, rodis.2@osu.edu
Julie Legg, PharmD, FNAP legg.31@osu.edu

Rules – For Filing with CSI and JCARR

Rule 4729:8-3-02 | Information required for submission. (AMEND)

(A) Pharmacies pursuant to paragraphs (A) and (B) of rule 4729:8-3-01 of the Administrative Code that dispense drugs listed in Chapter 4729:8-2 of the Administrative Code to outpatients shall report the following dispensing information to the board of pharmacy in accordance with rule 4729:8-3-03 of the Administrative Code:

(1) Pharmacy drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(2) Pharmacy name;

(3) Pharmacy address;

(4) Pharmacy telephone number;

(5) Pharmacy dispensing software vendor or proprietary software;

(6) Pharmacy license number, if both the drug enforcement administration registration and national provider identifier are not provided;

(7) Type of pharmacy or dispenser;

(8) Indication if entity is a mail order pharmacy;

(~~5~~ **9**) Patient full name;

(~~6~~ **10**) Patient residential address;

(~~7~~ **11**) Patient telephone number;

(~~8~~ **12**) Patient date of birth;

(~~9~~ **13**) Patient gender;

(14) Species code;

(15) Owner's name for veterinary patients;

(16) Owner's date of birth for veterinary patients;

(17) Owner's gender for veterinary patients;

(18) Name of animal;

~~**(19) Veterinary species code for veterinary patients that is either:**~~

~~**(a) For small animals: 03;**~~

~~**(b) For large animals, including livestock: 06.**~~

(~~10~~ **19**) Prescriber's full name (first name and last name);

(20) Transmission form of prescription (e.g., written, verbal, electronic, etc.);

(~~11~~ **21**) Prescriber's drug enforcement administration registration number. If not applicable, another mutually acceptable identifier;

(~~12~~ **22**) Date prescription was issued by the prescriber;

(~~13~~ **23**) Date the prescription was **filled** ~~**dispensed or sold by the pharmacy**~~;

(24) Date the prescription was sold, if available;

(~~14~~ **25**) Indication of whether the prescription dispensed is new or a refill;

(~~15~~ **26**) Number of the refill being dispensed;

(~~16~~ **29**) National drug code of the drug dispensed;

(30) Indication if the product is compounded in accordance with division 4729:7 of the Administrative Code;

(~~17~~ **31**) Quantity of the drug prescribed;

(~~18~~ **32**) Quantity of drug dispensed;

(~~19~~ **33**) Number of days' supply of the drug dispensed as indicated by the prescriber pursuant to agency 4729 of the Administrative Code, except as follows:

(a) If a days' supply is not indicated by the prescriber, the pharmacy shall calculate and report the number of days' supply of the drug dispensed;

(b) If the quantity of drug dispensed is different from the quantity indicated on the prescription, the pharmacy shall calculate and report the number of days' supply of the drug dispensed.

(~~20~~ **34**) Serial or prescription number assigned to the prescription order;

(~~21~~ **35**) Source of payment for the prescription that indicates one of the following: private pay (cash), medicaid, medicare, commercial insurance, or workers' compensation. Use of discount cards shall be reported as private pay;

(~~22~~ **36**) Pharmacy national provider identification (NPI) number;

(~~23~~ **37**) Prescriber's national provider identification (NPI) number, if prescriber does not have an NPI**, then the prescriber's state license number or** another mutually acceptable identifier;

(~~24~~ **38**) Any of the following as indicated by the prescriber pursuant to agency 4729 of the Administrative Code:

(a) The ICD-10-CM medical diagnosis code of the primary disease or condition that the controlled substance drug is being used to treat. The code shall, at a minimum, include the first four alpha-numeric characters of the ICD-10-CM medical diagnosis code, sometimes referred to as the category and the etiology (ex. M 16.5);

(b) For dentists licensed pursuant to Chapter 4715. of the Revised Code, the "Code on Dental Procedures and Nomenclature" (CDT code), as published by the American dental association, of the dental treatment requiring the controlled substance prescription;

(c) If no such code is indicated on the prescription, the pharmacy shall indicate "NC" in the diagnosis data field.

…

Rule 4729:8-3-03 | Electronic format required for the transmission of drug sales. (RESCIND CURRENT / NEW)

(A) All prescription dispensing information or prescriber personally furnishing information required to be submitted to the board pursuant to rule 4729-8-3-02 of the Administrative Code must be transmitted in the following format specified by the "American Society for Automation in Pharmacy" (ASAP) for prescription monitoring programs:

(1) ASAP Version 5.0 Standard for Prescription Drug Monitoring Programs (1/1/2024); or

(2) Until **December** 1, 2025, ASAP Version 4.2A Standard for Prescription Drug Monitoring Programs (3/15/2017).

(B) The board's executive director or the director's designee may authorize up to a six-month extension to the implementation of ASAP Version 5.0 beyond **December** 1, 2025. Such extensions may only be considered if the pharmacy or prescriber has made all reasonable and prudent attempts to meet the deadline.

(C) In the event that a pharmacy or a prescriber cannot electronically transmit the required information pursuant to paragraph (A) of this rule, the pharmacy or prescriber may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

(D) All wholesale data required to be submitted to the board of pharmacy pursuant to rule 4729-8-3-02 of the Administrative Code shall be transmitted in the report format used when transmitting controlled substance data to the federal drug enforcement administration via the "Automation of Reports and Consolidated Orders System" (ARCOS)" or other mutually acceptable format.

(E) In the event that a drug distributor or terminal distributor cannot electronically transmit the required information pursuant to paragraph (D) of this rule, the drug distributor or terminal distributor may request a variance from the board's executive director or the director's designee to submit drug sales information in a mutually acceptable format.

CenterWell Pharmacy

February 17, 2025

Summer Corson
Policy & Public Affairs Liaison
State of Ohio Board of Pharmacy
77 South High Street, 17th Floor
Columbus, OH 43215-6126

Submitted electronically via email to summer.corson@pharmacy.ohio.gov

Dear Ms. Corson:

This letter is in response to the solicitation for stakeholder feedback on the State of Ohio Board of Pharmacy's (Board) new proposed rule 4729:5-5-26 related to outpatient pharmacy delivery services. CenterWell Pharmacy, Inc. (CenterWell Pharmacy) appreciates the opportunity to provide comments to the Board.

Our comments are specific to a portion of Proposed Rule 4729:5-5-26. The revised rule, dated January 17, 2025, states:

> (B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following:
>
> (1) Contact the patient or patient's caregiver for consent prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services. Consent may be provided in writing, electronically, or verbally.

CenterWell Pharmacy previously submitted comments on this rule in September 2024. We appreciate the Board's consideration of those comments and the changes that were made to the proposal as a result.

In response to our previous comments, the Board indicated, "Consent is required prior to delivery and not required prior to the shipment of each refill. Therefore, the Board does not believe such a consent requirement would be burdensome to the pharmacy. For example, a pharmacy needs to contact a patient for billing information prior to shipping the drug anyway. Therefore, there are a number of avenues to capture patient consent for such services." Additionally, the word "approval" was changed to "consent" in the revised version.

While we recognize the Board's response to our previous comments, we have additional concerns and clarifying questions that were not addressed by the Board's previous response in November.

We would appreciate clarification about what qualifies as a patient's general consent for delivery services. How does that come into play when a pharmacy receives a new prescription from a provider or a patient requests that a prescription be transferred to a specific pharmacy? If, at the request of a patient, a provider sends a prescription to the

pharmacy or a prescription is transferred to a pharmacy, does that meet the threshold for a patient's general consent?

Our patients rely on us to deliver their medications in a safe and seamless manner. Within our internal systems, we build custom patient profiles that contain information including, but not limited to, other drugs the patient may be taking and any allergies, as well as shipping and billing information. Once the necessary profile elements are recorded, we can safely, quickly, and efficiently process routine fulfillments for that patient without needing to contact him or her.

To reiterate our previous comments, our concern with (1) above is that it could potentially lead to delays in therapy while we work to obtain a patient's consent or wait to receive a return phone call. We also encounter patients who are reluctant to answer or return phone calls due to concerns about sharing sensitive information with scammers or as part of a phishing attempt. If the requirement is finalized as currently written, we anticipate the outreach required to obtain patient consent will result in some prescriptions not being filled because a pharmacy will be unable to reach a patient.

Several years ago, the Centers for Medicare & Medicaid Services (CMS) required Part D sponsors and their network retail and mail-order pharmacies to obtain enrollee consent to deliver a new or refill prescription prior to each delivery. Due to consumer complaints about increased delivery delays, CMS modified its policy to no longer require consent prior to shipping.

For additional information on the history of this change at CMS and the associated requirements, the Calendar Year 2020 Final Call Letter[1] is linked below. The relevant portion of the letter begins at the bottom of page 230.

One of the conditions of the revamped CMS policy requires pharmacies to provide a refund for any unwanted fills, and this applies to both new prescriptions ordered by the prescriber and refills that have been shipped as part of a pharmacy's automatic refill program. CenterWell Pharmacy's processes are compliant with this today.

Furthermore, if we receive a new prescription directly from a provider's office, the patient will receive a notification from us (according to their communication preferences) to make sure they are aware of the requested medication before it ships. This notification provides an opportunity for the patient to contact us and cancel the order if necessary.

We believe the existing processes for refunds and notifications enable patients to receive their medications in an efficient manner while also providing a layer of protection in the event they receive an unwanted prescription.

Recommendation

To provide additional protection for patients and greater clarity to pharmacies, we suggest

[1] *See, Announcement of Calendar Year (CY) 2020 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter.* April 1, 2019. Available at: https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2020.pdf

modifying the language in the following way:

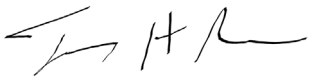
(B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following:

(1) Contact the patient or patient's caregiver for consent prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services. Consent may be provided in writing, electronically, or verbally. In lieu of contacting the patient or patient's caregiver to obtain consent for prescriptions delivered via mail, the pharmacy shall provide a refund if the patient or patient's caregiver notifies the pharmacy that a dispensed prescription was unneeded or unwanted.

Conclusion

Thank you for the opportunity to provide feedback to the Board on the proposed rule. Please feel free to contact me if you have any questions related to the comments.

Sincerely,



Travis Garrison
Associate Vice President, State Affairs
tgarrison2@humana.com

CenterWell Pharmacy, Inc. is a full-service home delivery pharmacy serving patients across all 50 states. CenterWell Pharmacy provides holistic care that is personalized and coordinated with easy-to-use options so our patients can receive the care and prescriptions they need when they need them. These services include prescription home delivery, as well as retail and specialty pharmacy services. CenterWell Pharmacy's largest pharmacy, which opened in 2008, is located in West Chester Township, Ohio.

CenterWell Pharmacy is fully owned and operated by Humana. Humana employs approximately 2,900 associates and contractors who work in Ohio.

4729:5-5-26 Outpatient pharmacy delivery services (NEW) (Current Rule Text)

(B) An outpatient pharmacy licensed as a terminal distributor of dangerous drugs providing delivery services of dispensed drugs and devices in this state shall comply with the following:

(1) Contact the patient or patient's caregiver for consent prior to any billing or delivery of a drug or device, except if the patient has provided general consent for delivery services. Consent may be provided in writing, electronically, or verbally. **In lieu of contacting the patient or patient's caregiver to obtain consent for prescriptions delivered via mail, the pharmacy shall provide a refund if the patient or patient's caregiver notifies the pharmacy that a dispensed prescription was unneeded or unwanted.**

4729:11-1-01 **Definitions - home medical equipment.**

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.~~

~~(E)~~(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.

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

~~(G)~~(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.

~~(H)~~(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 a 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) "Disqualifying offense" has the same meaning as defined in rule 4729-3-01 of the Administrative Code.

~~(L)~~(M) "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)~~(N) "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~~ license ~~on~~ into inactive status.

~~(N)~~(O) "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~~U) and (~~DD~~EE) 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~~U) of this rule; and

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

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

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

~~(Q)~~(R) "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)~~(S) "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)~~(T) "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)~~(U) "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)~~(V) "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)~~(W) "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)~~(X) "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)~~(Y) "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)~~(Z) "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)~~(AA) "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)~~(BB) "Staff" means employees or their representatives of a licensee or registrant.

~~(BB)~~(CC) "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)~~(DD) "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)~~(EE) "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.

4729:11-2-01 **Licensure, registration and renewal.**

(A) An applicant applying for licensure as a HME services provider shall:

(1) File an application with the board pursuant to rule 4729:11-2-03 of the Administrative Code; and

(2) Submit the required fee as established in paragraph (F) of this rule.

(3) To be licensed as a HME services provider, the applicant shall comply with the following:

(a) The applicant shall be physically located in Ohio. A HME services provider located outside the boundaries of the state of Ohio may only apply for a certificate of registration pursuant to paragraph (B) of this rule.

(b) Meet the minimum standards set forth in rule 4729:11-3-01 of the Administrative Code.

(c) Comply with all recordkeeping requirements in accordance with rule 4729:11-3-02 of the Administrative Code.

(d) Submit to an on-site inspection pursuant to rule 4729:11-3-03 of the Administrative Code.

(B) An applicant applying for a certificate of registration as a HME services provider shall:

(1) File an application with the board pursuant to rule 4729:11-2-03 of the Administrative Code.

(2) Submit the required fee as established in paragraph (F) of this rule.

(3) The applicant shall be accredited by the joint commission on accreditation of healthcare organizations or another national accrediting body recognized by the board in accordance with rule 4729:11-2-04 of the Administrative Code. Part of the registration process shall be an inquiry to the accrediting agency with which the entity is accredited. This information will be used as a part of the consideration in granting a registration.

(C) The persons listed in paragraphs (A) and (B) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure or registration. In the event the applicant is not owned by a natural person, each business entity with an

ownership interest in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person.

(D) A license or registration expires at the end of the period for which it is issued and may be renewed. For purposes of issuing and renewing licenses, the board shall use a biennial licensing period that begins on the first day of July of each even-numbered year and ends on the thirtieth day of June of the next succeeding even-numbered year.

(E) A person who seeks to renew a license or registration shall submit an application for renewal, containing information as required by the board, and pay the required fee in accordance with paragraph (F) of this rule on or before the thirtieth day of June each even-numbered year.

(F) The board establishes the following non-refundable fees:

(1) Applications for an initial certificate of registration shall include a fee of one hundred and fifty dollars.

~~(1)~~(2) ~~All applications~~ Applications for an initial ~~and biennial renewal of a~~ license shall include a fee ~~no greater than one thousand two~~ of three hundred dollars~~;~~.

(3) Applications for biennial renewal of a certificate of registration shall include a fee of three hundred dollars.

~~(2)~~(4) ~~All applications~~ Applications for ~~initial and~~ biennial renewal of a ~~certificate of registration~~license shall include a fee ~~no greater than~~of ~~five~~four hundred dollars.

~~(3)~~(5) If an application for renewal of a license or certificate of registration is filed with the board after the renewal date, the applicant will be charged an additional late fee of two hundred dollars.

~~(4)~~(6) If a complete application for renewal has not been submitted by the sixty-first day after the renewal date specified in this rule, the license or certificate of registration is considered void and cannot be renewed, but the holder may reinstate the licensure or registration in accordance with procedures specified by the board.

(G) A person that fails to renew a license or certificate or registration in accordance with this rule is prohibited from engaging in the provision of HME services.

(H) ~~On or before June 30, 2022, a~~ A HME services provider located outside the boundaries of the state of Ohio currently licensed under Chapter 4752. of the Revised Code shall obtain a registration as a HME services provider.

(I) Except as provided in division (B) of section 4752.02 of the Revised Code, no person shall provide home medical equipment services or claim to the public to be a HME services provider unless either of the following is the case:

(1) The person holds a valid license issued under this division of the Administrative Code;

(2) The person holds a valid certificate of registration issued under this division of the Administrative Code.

4729:11-2-02 **Designated representative.**

(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.~~

~~(5)~~(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.~~

~~(7)~~(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.

~~(8)~~(6) Has been excluded from participation in medicare or a state health care program.

~~(9)~~(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.

~~(10) 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.~~

4729:11-2-03 **Applications.**

(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 operators(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 liability 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.

(ii) The name or names of the coporation.

(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.

4729:11-2-05 **Change in description of a HME services provider or discontinuation of business.**

(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 in ownership includes any of the following:

(1) For all HME services providers:

(a) Any business entity change from its original form, as licensed or registered, 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 in 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.

~~(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.~~

~~(D)~~(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), ~~a new~~an application fee is required.

~~(E)~~(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.

~~(F)~~(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 services 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.

~~(G)~~(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.

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

(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~~,~~ and 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:

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

(2) 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.

~~(E)~~(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.

~~(F)~~(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.

~~(G)~~(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.

4729:11-3-02 **Record keeping.**

(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.

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.

4729:11-3-05 **Advertising and solicitation.**

(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 prospective 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.

4729:11-3-06 **Minimum standards for registered home medical equipment services providers.**

(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 investigation (BCI) and shall consist of a BCI 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 expiration dates, if applicable.

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

~~(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.~~

(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.~~

~~(16)~~(15) Commission of a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

~~(17)~~(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.

~~(18)~~(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.~~

~~(21)~~(18) Employs a designated representative that does not meet the requirements set forth in rule 4729:11-2-02 of the Administrative Code.

~~(22)~~(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.

~~(23)~~(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.

~~(24)~~(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.

~~(25)~~(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.

~~(26)~~(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~~diaqualifying 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.~~

~~(e)~~(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~~

~~(g)~~(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.

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

~~(i)~~(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.

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