Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*

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Comments on the proposed rules will be accepted until close of business on March 29, 2024. Please send all comments to the following email address:
RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

Agency, Board, or Commission Name: State of Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Summer Corson
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Regulation/Package Title (a general description of the rules' substantive content):

Terminal Distributors and Drug Distributors Spring 2024

Rule Number(s): 4729:5-3-23, 4729:5-5-18, 4729:5-2-03, 4729:5-2-04, 4729:6-2-05

Date of Submission for CSI Review: 3/7/2024

Public Comment Period End Date: 3/29/2024

Rule Type/Number of Rules:

New/ 3 rules

No Change/____ rules (FYR? ___)

Amended/ 2 rules (FYR? Y)

Rescinded/ 2 rules (FYR? Y)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**
   Please include the key provisions of the regulation as well as any proposed amendments.

New

- 4729:5-3-23 – Outlines the rules for operating and registering a mobile clinic.
- 4729:5-2-03 – Outlines the requirements when there is a change in ownership, business name, category, or address of a terminal distributor of dangerous drugs. (Rescinds existing rule 4729:5-2-03)

- 4729:6-2-05 – Outlines the requirements when there is a change in ownership, business name, category, or address of a drug distributor. (Rescinds existing rule 4729:6-2-05)

Amend

- 4729:5-5-18 – Permits the packaging of multiple drugs in the same container under certain conditions. The rule is being amended to allow for up to a 90-day supply.
- 4729:5-2-04 – Specifies the procedure for discontinuing as a terminal distributor which requires a licensee to file a notice with the Board. The terminal distributor will need to complete an inventory of all controlled substances being transferred or disposed of. The rule is being amended to require notice within 30 days of closure rather than 30 days prior.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

   The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
   If yes, please briefly explain the source and substance of the federal requirement.

   These rules do not implement a federal requirement.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

   N/a

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

   Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and distribution of dangerous drugs.

   Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules establishing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

   No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
If applicable, please include the date and medium by which the stakeholders were initially contacted.

   The rules in this package were distributed for public comment to all licensees and registrants of the Board.

   Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

10. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?**

    The Board received 10 comments from stakeholders for rule 4729:5-5-18 regarding changing the quantity of the patient medication packages dispensed at once to be a 90-day supply instead of a 31-day supply because outpatient pharmacies generally dispense 90 days at a time. The Board updated the days' supply to 90 to reflect this.

    Additionally, the Board received one comment on rule 4729:5-5-23 asking for an exception to the non-profit requirement of the rule for entities providing treatment for substance use disorder and mental health. This was added to the rule prior to filing with CSI.

11. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

    Scientific data was not used to develop or review this rule.

12. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**
Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the practice of pharmacy and distribution of dangerous drugs, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. **What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

    The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

14. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.**

    The rules will be posted on the Board of Pharmacy's web site, information concerning the rules will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

    Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. **Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:**
    a. **Identify the scope of the impacted business community, and**

       Terminal distributors of dangerous drugs and drug distributors.

    b. **Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).**
       The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a

representative business. Please include the source for your information/estimated impact.

In general, violation of these rules may result in administrative licensure discipline for a licensee. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

New

- 4729:5-3-23 – Licensees who opt to operate a mobile clinic will experience increased administrative costs to ensure proper oversight and recordkeeping.
- 4729:5-2-03 – Requires any change in ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application fee, required fee, and license. Licensure as a terminal distributor of dangerous drugs costs between $160 and $220 annually. The application takes between 30-60 minutes to complete.
- 4729:6-2-05 – This requires the submission of a new application if there is a change in ownership, business name, category, or address of a drug distributor. The overall cost of this regulation is the biennial licensure fee ($1,900 – $2,000) and it takes 1-2 hours to complete the new application.

Amend

- 4729:5-5-18 – Pharmacies that dispense customized patient medication packages will experience compliance cost to meet the labeling requirements and to ensure the medications are placed in a tamper-evident packaging.
- 4729:5-2-04 – Requires a terminal distributor of dangerous drugs to notify the board of discontinuation of business. A discontinuation of business form is two pages and takes approximately 10 minutes to complete. The licensee must also submit a complete inventory of all controlled substances being transferred or disposed of and keep records of purchase and dispensing for three years. The inventory may take several hours to complete depending on the size of the controlled substance stock. The terminal distributor is also required to notify their patients who have been dispensed a prescription in the last six months that the location is shutting down, contacting them either by email, direct mail, or text message. The time to complete this requirement depends on the number of patients were receiving their medications at that location.

16. **Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify.** ***(Reductions in regulatory***

burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).

New

- 4729:5-3-23 – Mobile clinics can register for a satellite license at no cost, reducing fees.

Amend

- 4729:5-5-18 - The Board updated the quantity of the patient medication packages dispensed at once to be a 90-day supply instead of a 31-one day supply to simplify the dispensing process, because outpatient pharmacies generally dispense 90 days at a time.
- 4729:5-2-04 – The updated rule allows terminal distributors more time to notify the Board of its closure. The terminal distributor must notify the Board within 30 days of closure instead of at least 30 days in advance of closure.

17. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

    The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform standards for the operation of terminal distributor of dangerous drugs, including mobile dispensing units.

Regulatory Flexibility

18. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

    These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

    The State of Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the practice of pharmacy or the preparation/distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

20. **What resources are available to assist small businesses with compliance of the regulation?**

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations and host regional meetings to discuss changes to Ohio laws and rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Furthermore, the Board also developed external inspection guides available to all licensees to ensure compliance with our regulations.

Rule 4729:5-3-23 | Mobile clinics or medication units. (NEW)

(A) The following may operate a mobile unit to dispense, personally furnish, or otherwise distribute or administer prescription medications and devices to individuals in this state without a fixed address or who would otherwise not have access to medication services:

(1) A nonprofit organization, corporation, or association as defined in the Ohio Revised Code; or

(2) A for-profit entity for the purpose of providing services to an individual needing treatment for a substance use disorder, a mental health condition, and any related medical issue.

(B) A mobile clinic or medication unit shall register for a no-cost, satellite license affiliated with an existing terminal distributor of dangerous drugs as specified by the board.

(C) A mobile clinic or medication unit shall comply with the following:

(1) Except as provided in paragraph (C)(2) of this rule, if distributing dangerous drugs that have already been dispensed or personally furnished in accordance with this division of the Administrative Code, the drugs must be in the full and actual charge of a licensed or registered health care professional authorized under Chapter 4715., 4723., 4729., 4730., 4731., or 4741. of the Revised Code.

(2) If transporting drugs for distribution and there is no healthcare professional present on the mobile unit, as described in paragraph (C)(1) of this rule, all dangerous drugs shall be secured using physical locks to prevent unauthorized access.

(3) If engaged in the following:

(a) Dispensing dangerous drugs: a licensed pharmacist shall be on the premises and the mobile unit shall be under the control and management of the pharmacist. All dispensing activities shall comply with the requirements of Chapter 4729:5-5 of the Administrative Code.

(b) Personally furnishing dangerous drugs: a licensed healthcare professional authorized to prescribe drugs shall be on the premises and the mobile unit shall be under the control and management of the licensed healthcare provider. All personally furnishing activities shall comply with the requirements of Chapter 4729:5-19 of the Administrative Code.

(4) Implement a record keeping system that will provide accountability for proper receipt, delivery, disposal, and return of all prescription medications in accordance with applicable record keeping provisions in division 4729:5 of the Administrative Code.

(5) Except for mobile units that are stored in a locked garage with access control, dangerous drugs shall not be left in the mobile unit during the hours that the mobile unit is not in operation. Without exception, a terminal distributor shall not maintain controlled substances in the mobile unit when the unit is not in use.

(6) All mobile units shall be dry, well lit, well ventilated, and maintained in a clean, sanitary, and orderly condition. Storage areas for dangerous drugs shall be maintained at temperatures and conditions which will ensure the integrity of the drugs as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling.

(7) All mobile units shall be secured with suitable locks capable of preventing unauthorized access.

Rule 4729:5-5-18 | Dispensing customized patient medication packages by an outpatient pharmacy. (AMEND)

In lieu of dispensing two or more dangerous drugs in separate containers, a pharmacist practicing at an outpatient pharmacy may dispense a customized patient medication package. A customized patient medication package is a package for a specific patient comprising a series of containers and containing two or more prescribed solid oral dosage forms that complies with the following requirements:

(A) The package is designed, or each container is labeled, to indicate the day and time or period of time when the contents within each container are to be taken by the patient.

(B) The number of drugs placed in each container cannot exceed the capability of the container to prevent damage to the dosage forms.

(C) The quantity of the package dispensed may not be more than a ~~**thirty-one-day**~~ **ninety-day** supply.

(D) The labels must be of sufficient size to properly and clearly label a thirty-one-day or less supply with all information required in accordance with this chapter of the Administrative Code, including the use of accessory labels.

(E) The package must include an expiration date or beyond-use date, which shall not exceed the expiration date on the manufacturer's container or six months from the date the drug was originally packaged, whichever date is earlier. If multiple manufacturer containers are used, the expiration date shall not exceed the expiration date on the manufacturer's container that will expire first or six months from the date the drug was originally repackaged, whichever date is earlier.

(F) Dangerous drugs which have been dispensed in a customized patient medication package may only be returned to stock or re-dispensed in accordance with all the following:

(1) The drugs have not been in the possession of the ultimate user; and

(2) The drugs have not been placed in the same container with another dangerous drug (i.e. did not come into direct contact with a different drug within the same container).

(G) The containers of a package are sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

(H) Any pharmacy dispensing customized patient medication packages in accordance with this rule must implement policies and procedures that will exclude drugs having any of the following characteristics from such packaging:

(1) The U.S.P. monograph or official labeling requires dispensing in the original container, unless there is documentation from the manufacturer stating otherwise;

(2) The drugs or dosage forms are incompatible with packaging components or each other;

(3) The drugs are therapeutically incompatible when administered simultaneously;

(4) The drugs require special packaging.

Rule 4729:5-2-03 | Change in description of a terminal distributor of dangerous drugs. (RESCIND/NEW)

(A) Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires an application and required fee. The 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) For all terminal distributors of dangerous drugs:

(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 currently licensed terminal distributor 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) A 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 application and fee is required.

(D) A change of ownership in accordance with this rule may result in the issuance of a new license.

(E) A change of ownership, as described in paragraph (B) of this rule, of a licensee's parent or holding company which does not exercise direct control of the licensed entity, shall not require an application, fee, or new license number.

(F) A change of address includes the physical relocation of the licensee's operations and location of the drug stock. 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 the licensee's operations shall not require an application and fee. The licensee shall submit written notification to the board, in a manner determined by the board, indicating the change of address.

Rule 4729:5-2-04 | Procedure for discontinuing business as a terminal distributor of dangerous drugs. (AMEND)

(A) A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the board of pharmacy. The notice shall be submitted, in a manner determined by the board**, within thirty days of discontinuation of business as a terminal distributor of dangerous drugs**. ~~**at least 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 licensee's control.**~~ This notice shall include the following information:

(1) The name, address, and license number of the terminal distributor discontinuing business.

(2) The name, address, and license number of the terminal distributor or other authorized entity where the dangerous drugs will be transferred.

(3) The name and address of the secured location where the records of purchase and sale will be kept in accordance with this division of the Administrative Code.

(4) The proposed date of discontinuing business.

(B) Unless the licensee is informed by the executive director before the proposed date of discontinuing business that the transfer of dangerous drugs and records may not occur, the licensee discontinuing business may transfer the dangerous drugs and **patient** records**.** ~~**in accordance with the following:**~~

~~**(1)**~~ **(C)** On the date of discontinuing business, a complete **inventory of** all controlled substances being transferred, or disposed of, in accordance with rule 4729:5-3-01 of the Administrative Code, shall be made. The inventory shall list the name, strength, dosage form, and quantity of all controlled substances transferred or disposed.

~~**(2)**~~ This inventory shall serve as the final inventory of the licensee discontinuing business and the initial inventory of the licensee to whom the controlled substances are being transferred. A copy of the inventory shall be included in the records of each licensee involved in the transfer.

(D) A terminal distributor of dangerous drugs licensed as a pharmacy that is permanently closing shall:

(1) Provide notification, using the information on file with the pharmacy, to each patient who has filled a prescription within the previous six months. This notification must be made a minimum of fifteen calendar days prior to closing and must include:

(a) The last day the pharmacy will be open;

(b) Name, address, and telephone number of the pharmacy that will take possession of the pharmacy records or the person who will serve as the custodian of records;

(c) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(d) The last day a transfer may be initiated.

(2) The notification shall be made via:

(a) Direct mail, e-mail, or text message; and

(b) Posting a closing notice on each pharmacy entrance, on each telephone greeting, and pharmacy-operated internet (e.g., website, social media, mobile applications).

(3) Provide any new patients filling prescriptions during the fifteen-calendar day period prior to the pharmacy closing with written notification that includes:

(a) The last day the pharmacy will be open;

(b) Name, address and telephone number of the pharmacy to which pharmacy records will be transferred or the person who will serve as the custodian of pharmacy records;

(c) Instructions on how patients can arrange for transfer of their pharmacy records to a pharmacy of their choice; and

(d) The last day a transfer may be initiated.

Rule 4729:6-2-05 | Change in description of a distributor of dangerous drugs. (RESCIND/NEW)

(A) Any change in the ownership, business or trade name, category, or address of a distributor of dangerous drugs requires an application and required fee. The 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) For all distributors of dangerous drugs:

(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 currently licensed drug distributor 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) A 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 application and fee is required.

(D) A change of ownership in accordance with this rule may result in the issuance of a new license.

(E) A change of ownership, as described in paragraph (B) of this rule, of a licensee's parent or holding company which does not exercise direct control of the licensed entity, shall not require an application, fee, or new license number.

(F) A change of address includes the physical relocation of the licensee's operations and location of the drug stock. 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 the licensee's operations shall not require an application and fee. The licensee shall submit written notification to the board, in a manner determined by the board, indicating the change of address.