

Regulatory Compliance Rule Submission Memorandum

To: Erin Bennett, Regulatory Compliance Division Director

From: Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director, Texas State Board of Pharmacy

Date: December 22, 2020

Subject: 22 TEX. ADMIN. CODE §291.1 concerning Pharmacy License Application

The Texas State Board of Pharmacy (TSBP) has proposed amendments to §291.1, concerning Pharmacy License Application, as published in the October 2, 2020 issue of the *Texas Register* at 45 TexReg 6875.

The amendments add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy license applicant to attend a pharmacy ownership training course. The proposed rule possibly affects market competition and is submitted to the Regulatory Compliance Division for review. The preamble and text of the proposed rule as published in the *Texas Register*, and the language of any amendments to the proposed rule that the TSBP intends to adopt, are attached to this memorandum.

To facilitate the Regulatory Compliance Division's review of the proposed rule, TSBP provides answers to the following questions.

1. Briefly describe the proposed rule.

The amendments to §291.1 add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy license applicant to submit proof of attendance of a pharmacy ownership training course.

2. What is the purpose of the proposed rule?

The purpose of the amendments is to improve awareness and education amongst non-pharmacist individual owners and managing officers with the requirements and responsibilities of pharmacy ownership in order to prevent violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a retail pharmacy or the responsibility and role of pharmacy owners.

3. Describe any relevant factual background to the proposed rule and the impetus for the state agency to consider rulemaking.

The Board has identified a lack of education and training of non-pharmacist individual owners and managing officers of community pharmacies regarding the administrative and operational functions of a pharmacy and the responsibility and role of pharmacy owners in complying with pharmacy laws and protecting patient safety as a contributing factor to

violations that have resulted in disciplinary action. The proposed pharmacist ownership training course is intended to provide education and training prior to ownership in an attempt to prevent violations of law and lapses of proper oversight due to a lack of knowledge or awareness.

4. Describe the legal authority for the proposed rule.

a. Is the proposed rule specifically required or authorized by state statute? If so, list the statute(s).
No.

b. Is the proposed rule within the scope of the state agency's general authority to regulate in a given occupation or industry? If so, describe how the proposed rule is within the scope, and reference the applicable state statute(s).

Yes. The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy, and §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

5. Describe the process that the state agency followed in developing the proposed rule, including any public hearings held, public comments invited, studies conducted, and data collected or analyzed.

Amendments to §291.1 concerning Pharmacy License Application was included on the open meetings notice published on July 21, 2020 for the August 4, 2020 Board meeting, and the meeting agenda along with the suggested amendment language was posted on TSBP's website. The open meetings notice and agenda invited public comment regarding any agenda item at the Board meeting. The suggested amendments were presented at the August 4, 2020 Board meeting and no public comment regarding §291.1 was received. The Board voted to propose the amendments and the amendments were published in the October 2, 2020 edition of the *Texas Register* for public comment. The Board received one comment in favor of the proposed amendments. Amendments to §291.1 concerning Pharmacy License Application was included on the open meetings notice published on October 19, 2020 for the November 3, 2020 Board meeting and public hearing on proposed rules for adoption and other agenda items, and the meeting agenda along with the suggested amendment language was posted on TSBP's website. No comments were provided on the amendments at the public hearing. The Board members discussed the training course amendments at the Board meeting, noting that the course would be free, offered online, a few hours long, and a one-time requirement. The Board members stated that the course was not intended to be a barrier, but a service to educate the individual as they go through the licensure process and operate a pharmacy so that the individuals have a good understanding of the rules and can avoid some of the pitfalls the Board members have observed during informal settlement conferences of disciplinary cases. The Board members discussed the public interest served by the training course outweighing the barrier of requiring a free online course that is a few hours long.

6. Describe the harm that the proposed rule is intended to address and how the proposed rule will address the harm.

The proposed amendments are intended to prevent violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a community pharmacy or the responsibility and role of pharmacy owners that could result in patient or public harm, such as a dispensing error due to a failure to set proper operational procedures or the diversion of controlled substances from the pharmacy due to a failure to establish proper safeguards. The proposed ownership course would provide education on the requirements and responsibilities of pharmacy ownership to fill gaps in knowledge or awareness. The course is intended to be a preventative measure for those who are unfamiliar with the pharmacy landscape and do not have a corporate structure to provide similar education and training.

7. Do any less restrictive alternatives to the proposed rule exist for addressing the same harm? If so, include a comparison of the proposed rule to the alternatives and a justification for not pursuing a less restrictive alternative. If no less restrictive alternatives exist, explain why.

TSBP has not identified any less restrictive alternatives to address the same harm. The intent of the proposed amendments is to be preventative before patient/public harm occurs.

Requiring the course of pharmacy owners after a violation has occurred would not remedy the harm that has already occurred.

8. Indicate how the proposed rule affects market competition (See Section 57.105(d), Texas Occupations Code).

- It creates a barrier to market participation in the state.
- It results in higher prices or reduced competition for a product or service provided by or to a license holder in the state.
- It both creates a barrier to market participation in the state and results in higher prices or reduced competition for a product or service provided by or to a license holder in the state.

The Regulatory Compliance Division notified TSBP that RCD had identified a possible anticompetitive market effect but did not describe the nature of the identified possible effect. The proposed ownership course would be offered online at no cost, so the proposed amendments would not result in higher prices. The only potential effect would be a possible barrier to market participation in the state by requiring one-time attendance of the course.

9. Describe the specific impact that the proposed rule will have on market competition and how that effect is consistent with state policy as established by the Legislature in state statute.

The proposed amendments would require a non-pharmacist individual owner or managing officer to submit proof of attendance of a one-time, free, online pharmacy ownership course prior to the issuance of a license for a community pharmacy. The Board interprets §551.002 of the Texas Pharmacy Act as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy, §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act, and §560.052 as authorizing the agency to adopt rules establishing the standards to qualify for licensing as a pharmacy. The training course would protect the public by preventing violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a retail pharmacy or the responsibility and role of pharmacy owners that could result in patient or public harm, such as a dispensing error due to a failure to set proper

operational procedures or the diversion of controlled substances from the pharmacy due to a failure to establish proper safeguards.

10. Does the proposed rule relate to a question that is the subject of an opinion request pending before the Office of the Attorney General? Does the proposed rule relate to an opinion previously issued by the Office of the Attorney General?

No.

11. Does the proposed rule relate to a matter on which there is pending litigation or a final court order?

No.

12. Is there anything else that the state agency would like the Regulatory Compliance Division to know about the proposed rule?

The Legislature has previously excluded pharmacies operated by publicly traded companies and wholly owned by a retail grocery store chain from certain application requirements, as shown in §560.052(b)(3) of the Texas Pharmacy Act.

Regulatory Compliance Rule Submission Memorandum

To: Erin Bennett, Regulatory Compliance Division Director

From: Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director, Texas State Board of Pharmacy

Date: December 22, 2020

Subject: 22 TEX. ADMIN. CODE §291.3 concerning Required Notifications

The Texas State Board of Pharmacy (TSBP) has proposed amendments to §291.3, concerning Required Notifications, as published in the October 2, 2020 issue of the *Texas Register* at 45 TexReg 6876.

The amendments add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy to attend a pharmacy ownership training course within 90 days of notifying the board of a change of managing officer, clarify the change of ownership notification requirements, and correct grammatical errors. The proposed rule possibly affects market competition and is submitted to the Regulatory Compliance Division for review. The preamble and text of the proposed rule as published in the Texas Register, and the language of any amendments to the proposed rule that the TSBP intends to adopt, are attached to this memorandum.

To facilitate the Regulatory Compliance Division's review of the proposed rule, TSBP provides answers to the following questions.

1. Briefly describe the proposed rule.

The amendments to §291.3 add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy to submit proof of attendance of a pharmacy ownership training course within 90 days of notifying the board of a change of managing officer.

2. What is the purpose of the proposed rule?

The purpose of the amendments is to improve awareness and education amongst non-pharmacist individual owners and managing officers with the requirements and responsibilities of pharmacy ownership in order to prevent violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a retail pharmacy or the responsibility and role of pharmacy owners.

3. Describe any relevant factual background to the proposed rule and the impetus for the state

agency to consider rulemaking.

The Board has identified a lack of education and training of non-pharmacist individual owners and managing officers of retail pharmacies regarding the administrative and operational functions of a pharmacy and the responsibility and role of pharmacy owners in complying with pharmacy laws and protecting patient safety as a contributing factor to violations that have resulted in disciplinary action. The proposed pharmacist ownership training course is intended to provide education and training prior to ownership in an attempt to prevent violations of law and lapses of proper oversight due to a lack of knowledge or awareness.

4. Describe the legal authority for the proposed rule.

a. Is the proposed rule specifically required or authorized by state statute? If so, list the statute(s).
No.

b. Is the proposed rule within the scope of the state agency's general authority to regulate in a given occupation or industry? If so, describe how the proposed rule is within the scope, and reference the applicable state statute(s).

Yes. The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy, §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act, and §560.052 as authorizing the agency to adopt rules establishing the standards to qualify for licensing as a pharmacy.

5. Describe the process that the state agency followed in developing the proposed rule, including any public hearings held, public comments invited, studies conducted, and data collected or analyzed.

Amendments to §291.3 concerning Pharmacy License Application was included on the open meetings notice published on July 21, 2020 for the August 4, 2020 Board meeting, and the meeting agenda along with the suggested amendment language was posted on TSBP's website. The open meetings notice and agenda invited public comment regarding any agenda item at the Board meeting. The suggested amendments were presented at the August 4, 2020 Board meeting and no public comment regarding §291.3 was received. The Board voted to propose the amendments and the amendments were published in the October 2, 2020 edition of the *Texas Register* for public comment. To date, TSBP has not received any public comment regarding the proposed amendments.

6. Describe the harm that the proposed rule is intended to address and how the proposed rule will address the harm.

The proposed amendments are intended to prevent violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a retail pharmacy or the responsibility and role of pharmacy owners that could result in patient or public harm, such as a dispensing error due to a failure to set proper operational procedures or the diversion of controlled substances from the pharmacy due to a failure to establish proper safeguards. The proposed ownership course would provide education on the requirements and responsibilities of pharmacy ownership to fill gaps in knowledge or

awareness. The course is intended to be a preventative measure for those who are unfamiliar with the pharmacy landscape and do not have a corporate structure to provide similar education and training.

7. Do any less restrictive alternatives to the proposed rule exist for addressing the same harm? If so, include a comparison of the proposed rule to the alternatives and a justification for not pursuing a less restrictive alternative. If no less restrictive alternatives exist, explain why.

TSBP has not identified any less restrictive alternatives to address the same harm. The intent of the proposed amendments is to be preventative. Requiring the course of pharmacy owners after a violation has occurred would not remedy the harm that has already occurred.

8. Indicate how the proposed rule affects market competition (See Section 57.105(d), Texas Occupations Code).

- It creates a barrier to market participation in the state.
- It results in higher prices or reduced competition for a product or service provided by or to a license holder in the state.
- It both creates a barrier to market participation in the state and results in higher prices or reduced competition for a product or service provided by or to a license holder in the state.

The Regulatory Compliance Division notified TSBP that RCD had identified a possible anticompetitive market effect but did not describe the nature of the identified possible effect. The proposed ownership course would be offered at no cost, so the only potential effect would be a possible barrier to market participation in the state.

9. Describe the specific impact that the proposed rule will have on market competition and how that effect is consistent with state policy as established by the Legislature in state statute.

The proposed amendments would require a non-pharmacist individual owner or managing office to attend a free pharmacy ownership course prior to the issuance of a license for a retail pharmacy.

10. Does the proposed rule relate to a question that is the subject of an opinion request pending before the Office of the Attorney General? Does the proposed rule relate to an opinion previously issued by the Office of the Attorney General?

No.

11. Does the proposed rule relate to a matter on which there is pending litigation or a final court order?

No.

12. Is there anything else that the state agency would like the Regulatory Compliance Division to know about the proposed rule?

The Legislature has previously excluded pharmacies operated by publicly traded companies and wholly owned by a retail grocery store chain from certain application requirements, as shown in §560.052(b)(3).

Regulatory Compliance Rule Submission Memorandum

To: Erin Bennett, Regulatory Compliance Division Director

From: Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director, Texas State Board of Pharmacy

Date: December 22, 2020

Subject: 22 TEX. ADMIN. CODE §291.14 concerning Pharmacy License Renewal

The Texas State Board of Pharmacy (TSBP) has proposed amendments to §291.14, concerning Pharmacy License Renewal, as published in the December 11, 2020 issue of the *Texas Register* at 45 TexReg 8821.

The amendments add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy to attend a pharmacy ownership training course within 90 days of notifying the board of a change of managing officer. The proposed rule possibly affects market competition and is submitted to the Regulatory Compliance Division for review. The preamble and text of the proposed rule as published in the Texas Register, and the language of any amendments to the proposed rule that the TSBP intends to adopt, are attached to this memorandum.

To facilitate the Regulatory Compliance Division's review of the proposed rule, TSBP provides answers to the following questions.

1. Briefly describe the proposed rule.

The amendments to §291.14 add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy to submit proof of attendance of a pharmacy ownership training course within 90 days of notifying the board of a change of managing officer.

2. What is the purpose of the proposed rule?

The purpose of the amendments is to improve awareness and education amongst non-pharmacist individual owners and managing officers with the requirements and responsibilities of pharmacy ownership in order to prevent violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a retail pharmacy or the responsibility and role of pharmacy owners.

3. Describe any relevant factual background to the proposed rule and the impetus for the state agency to consider rulemaking.

The Board has identified a lack of education and training of non-pharmacist individual owners and managing officers of community pharmacies regarding the administrative and

operational functions of a pharmacy and the responsibility and role of pharmacy owners in complying with pharmacy laws and protecting patient safety as a contributing factor to violations that have resulted in disciplinary action. The proposed pharmacist ownership training course is intended to provide education and training prior to ownership in an attempt to prevent violations of law and lapses of proper oversight due to a lack of knowledge or awareness.

4. Describe the legal authority for the proposed rule.

a. Is the proposed rule specifically required or authorized by state statute? If so, list the statute(s).
No.

b. Is the proposed rule within the scope of the state agency's general authority to regulate in a given occupation or industry? If so, describe how the proposed rule is within the scope, and reference the applicable state statute(s).

Yes. The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy, §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act, and §560.052 as authorizing the agency to adopt rules establishing the standards to qualify for licensing as a pharmacy.

5. Describe the process that the state agency followed in developing the proposed rule, including any public hearings held, public comments invited, studies conducted, and data collected or analyzed.

Amendments to §291.14 concerning Pharmacy License Renewal was included on the open meetings notice published on October 19, 2020 for the November 3, 2020 Board meeting and public hearing on proposed rules for adoption and other agenda items, and the meeting agenda along with the suggested amendment language was posted on TSBP's website. No comments were provided on the amendments at the public hearing. The Board members discussed the training course amendments at the Board meeting, noting that the course would be free, offered online, a few hours long, and a one-time requirement. The Board members stated that the course was not intended to be a barrier, but a service to educate the individual as they go through the licensure process and operate a pharmacy so that the individuals have a good understanding of the rules and can avoid some of the pitfalls the Board members have observed during informal settlement conferences of disciplinary cases. The Board members discussed the public interest served by the training course outweighing the barrier of requiring a free online course that is a few hours long.

6. Describe the harm that the proposed rule is intended to address and how the proposed rule will address the harm.

The proposed amendments are intended to prevent violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a retail pharmacy or the responsibility and role of pharmacy owners that could result in patient or public harm, such as a dispensing error due to a failure to set proper operational procedures or the diversion of controlled substances from the pharmacy due to a failure to establish proper safeguards. The proposed ownership course would provide education on the

requirements and responsibilities of pharmacy ownership to fill gaps in knowledge or awareness. The course is intended to be a preventative measure for those who are unfamiliar with the pharmacy landscape and do not have a corporate structure to provide similar education and training.

7. Do any less restrictive alternatives to the proposed rule exist for addressing the same harm? If so, include a comparison of the proposed rule to the alternatives and a justification for not pursuing a less restrictive alternative. If no less restrictive alternatives exist, explain why.

TSBP has not identified any less restrictive alternatives to address the same harm. The intent of the proposed amendments is to be preventative before patient/public harm occurs.

Requiring the course of pharmacy owners after a violation has occurred would not remedy the harm that has already occurred.

8. Indicate how the proposed rule affects market competition (See Section 57.105(d), Texas Occupations Code).

- It creates a barrier to market participation in the state.
- It results in higher prices or reduced competition for a product or service provided by or to a license holder in the state.
- It both creates a barrier to market participation in the state and results in higher prices or reduced competition for a product or service provided by or to a license holder in the state.

The Regulatory Compliance Division notified TSBP that RCD had identified a possible anticompetitive market effect of the similar proposed amendments to §291.1 and §291.3 but did not describe the nature of the identified possible effect. The proposed ownership course would be offered online at no cost, so the proposed amendments would not result in higher prices. The only potential effect would be a possible barrier to market participation in the state by requiring one-time attendance of the course.

9. Describe the specific impact that the proposed rule will have on market competition and how that effect is consistent with state policy as established by the Legislature in state statute.

The proposed amendments would require a non-pharmacist managing officer to provide proof of attendance of a one-time, free, online pharmacy ownership course within 90 days of the notification of a change of managing officer that designates the individual as a new managing officer. The Board interprets §551.002 of the Texas Pharmacy Act as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy, §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act, and §560.052 as authorizing the agency to adopt rules establishing the standards to qualify for licensing as a pharmacy. The training course would protect the public by preventing violations of law and/or lapses of proper oversight due to a lack of knowledge or awareness regarding the functions of a retail pharmacy or the responsibility and role of pharmacy owners that could result in patient or public harm, such as a dispensing error due to a failure to set proper operational procedures or the diversion of controlled substances from the pharmacy due to a failure to establish proper safeguards.

10. Does the proposed rule relate to a question that is the subject of an opinion request pending before the Office of the Attorney General? Does the proposed rule relate to an opinion previously issued by the Office of the Attorney General?

No.

11. Does the proposed rule relate to a matter on which there is pending litigation or a final court order?

No.

12. Is there anything else that the state agency would like the Regulatory Compliance Division to know about the proposed rule?

The Legislature has previously excluded pharmacies operated by publicly traded companies and wholly owned by a retail grocery store chain from certain application requirements, as shown in §560.052(b)(3) of the Texas Pharmacy Act.

improve awareness and education amongst non-pharmacist individual owners and managing officers with the requirements of pharmacy ownership. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

- (1) The proposed amendments do not create or eliminate a government program;
- (2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;
- (3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;
- (4) The proposed amendments do not require an increase or decrease in fees paid to the agency;
- (5) The proposed amendments do not create a new regulation;
- (6) The proposed amendments do expand an existing regulation by adding a training requirement;
- (7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and
- (8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 31, 2020.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.1. Pharmacy License Application.

(a) To qualify for a pharmacy license, the applicant must submit an application which includes any information requested on the application and, as required by §560.052(b) of the Act, a sworn disclosure statement as specified in §291.4 of this title (relating to Sworn Disclosure Statement).

(b) The applicant may be required to meet all requirements necessary in order for the Board to access the criminal history record information, including submitting fingerprint information and being responsible for all associated costs. The criminal history information may be required for each individual owner, or if the pharmacy is owned by a partnership or a closely held corporation for each managing officer.

(c) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for the issuance of a pharmacy license.

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CHAPTER 291. PHARMACIES
SUBCHAPTER A. ALL CLASSES OF
PHARMACIES

22 TAC §291.1

The Texas State Board of Pharmacy proposes amendments to §291.1 concerning Pharmacy License Application. The amendments, if adopted, add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy license applicant to attend a pharmacy ownership training course.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to

(d) For purpose of this section, managing officers are defined as the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

(e) Prior to the issuance of a license for a pharmacy located in Texas, the board shall conduct an on-site inspection of the pharmacy in the presence of the pharmacist-in-charge and owner or representative of the owner, to ensure that the pharmacist-in-charge and owner can meet the requirements of the Texas Pharmacy Act and Board Rules.

(f) If the applicant holds an active pharmacy license in Texas on the date of application for a new pharmacy license or for other good cause shown as specified by the board, the board may waive the pre-inspection as set forth in subsection (e) of this section.

(g) Effective January 1, 2021, prior to the issuance of a license for a Class A pharmacy, if not licensed as a Texas pharmacist, each individual owner or managing officer must submit proof of attendance for a pharmacy ownership training course approved by the board, unless:

(1) the pharmacy for which the application is made is operated by a publicly traded company; or

(2) the pharmacy for which the application is made is wholly owned by a retail grocery store chain.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on September 14, 2020.

TRD-202003761

Allison Vordenbaumen Benz, R.Ph., M.S.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: November 1, 2020

For further information, please call: (512) 305-8010



22 TAC §291.3

The Texas State Board of Pharmacy proposes amendments to §291.3 concerning Required Notifications. The amendments, if adopted, add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy to attend a pharmacy ownership training course within 90 days of notifying the board of a change of managing officer, clarify the change of ownership notification requirements, and correct grammatical errors.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to improve awareness and education amongst non-pharmacist individual owners and managing officers with the requirements of pharmacy ownership. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an

economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

(1) The proposed amendments do not create or eliminate a government program;

(2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;

(3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;

(4) The proposed amendments do not require an increase or decrease in fees paid to the agency;

(5) The proposed amendments do not create a new regulation;

(6) The proposed amendments do not expand an existing regulation by adding a training requirement;

(7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and

(8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., October 31, 2020.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.3. Required Notifications.

(a) Change of Location.

(1) When a pharmacy changes location, the following is applicable:

(A) A new completed pharmacy application containing the information outlined in §291.1 of this title (relating to Pharmacy License Application), must be filed with the board not later than 30 days before the date of the change of location of the pharmacy.

(B) The previously issued license must be returned to the board office.

(C) An amended license reflecting the new location of the pharmacy will be issued by the board; and

(D) A fee as specified in §291.6 of this title (relating to Pharmacy License Fees) will be charged for issuance of the amended license.

(2) At least 14 days prior to the change of location of a pharmacy that dispenses prescription drug orders, the pharmacist-in-charge shall post a sign in a conspicuous place indicating that the pharmacy is changing locations. Such sign shall be in the front of the pre-

scription department and at all public entrance doors to the pharmacy and shall indicate the date the pharmacy is changing locations.

(3) Disasters, accidents, and emergencies which require the pharmacy to change location shall be immediately reported to the board. If a pharmacy changes location suddenly due to disasters, accidents, or other emergency circumstances and the pharmacist-in-charge cannot provide notification 14 days prior to the change of location, the pharmacist-in-charge shall comply with the provisions of paragraph (2) of this subsection as far in advance of the change of location as allowed by the circumstances.

(4) When a Class A-S, C-S, or E-S pharmacy changes location, the pharmacy's classification will revert to a Class A, Class C, or Class E unless or until the Board or its designee has inspected the new location to ensure the pharmacy meets the requirements as specified in §291.133 of this title (relating to Pharmacies Compounding Sterile Preparations).

(5) When a Class B pharmacy changes location, the Board shall inspect the pharmacy at the new location to ensure the pharmacy meets the requirements as specified in subchapter C of this title (relating to Nuclear Pharmacy (Class B)) prior to the pharmacy becoming operational.

(b) Change of Name. When a pharmacy changes its name, the following is applicable:

(1) A new completed pharmacy application containing the information outlined in §291.1 of this title [~~(relating to Pharmacy License Application)~~] must be filed with the board within 10 days of the change of name of the pharmacy;

(2) The previously issued license must be returned to the board office;

(3) An amended license reflecting the new name of the pharmacy will be issued by the board; and

(4) A fee as specified in §291.6 of this title [~~(relating to Pharmacy License Fees)~~] will be charged for issuance of the amended license.

(c) Change of Managing Officers.

(1) The owner of a pharmacy shall notify the board in writing within 10 days of a change of any managing officer of a partnership or corporation which owns a pharmacy. The written notification shall include the effective date of such change and the following information for all managing officers:

(A) name and title;

(B) home address and telephone number;

(C) date of birth;

(D) a copy of social security card or other official document showing the social security number as approved by the board; and

(E) a copy of current driver's license, state issued photo identification card, or passport.

(2) For purposes of this subsection, managing officers are defined as the top four executive officers, including the corporate officer in charge of pharmacy operations, who are designated by the partnership or corporation to be jointly responsible for the legal operation of the pharmacy.

(3) Effective January 1, 2021, for each Class A pharmacy, if not licensed as a Texas pharmacist, each individual owner or managing officer must submit proof of attendance for a pharmacy ownership

training course approved by the board within 90 days of the notification submitted under paragraph (1) of this subsection, unless:

(A) the pharmacy for which the notification is submitted is operated by a publicly traded company; or

(B) the pharmacy for which the notification is submitted is wholly owned by a retail grocery store chain.

(d) Change of Ownership.

(1) When a pharmacy changes ownership, a new pharmacy application must be filed with the board following the procedures as specified in §291.1 of this title [~~(relating to Pharmacy License Application)~~] within 10 days of the change of ownership. [~~In addition, a copy of the purchase contract or mutual agreement between the buyer and seller must be submitted.~~]

(2) The license issued to the previous owner must be returned to the board.

(3) A fee as specified in §291.6 of this title will be charged for issuance of a new license.

(e) Change of Pharmacist Employment.

(1) Change of pharmacist employed in a pharmacy. When a change in pharmacist employment occurs, the pharmacist shall report such change in writing to the board within 10 days.

(2) Change of pharmacist-in-charge of a pharmacy. The incoming pharmacist-in-charge shall be responsible for notifying the board within 10 days in writing on a form provided by the board that a change of pharmacist-in-charge has occurred. The notification shall include the following:

(A) the name and license number of the departing pharmacist-in-charge;

(B) the name and license number of the incoming pharmacist-in-charge;

(C) the date the incoming pharmacist-in-charge became the pharmacist-in-charge; and

(D) a statement signed by the incoming pharmacist-in-charge attesting that:

(i) an inventory, as specified in §291.17 of this title (relating to Inventory Requirements), has been conducted by the departing and incoming pharmacists-in-charge; if the inventory was not taken by both pharmacists, the statement shall provide an explanation; and

(ii) the incoming pharmacist-in-charge has read and understands the laws and rules relating to this class of pharmacy.

(f) Notification of Theft or Loss of a Controlled Substance or a Dangerous Drug.

(1) Controlled substances. For the purposes of the Act, §562.106, the theft or significant loss of any controlled substance by a pharmacy shall be reported in writing to the board immediately on discovery of such theft or loss. A pharmacy shall be in compliance with this subsection by submitting to the board a copy of the Drug Enforcement Administration (DEA) report of theft or loss of controlled substances, DEA Form 106, or by submitting a list of all controlled substances stolen or lost.

(2) Dangerous drugs. A pharmacy shall report in writing to the board immediately on discovery the theft or significant loss of any dangerous drug by submitting a list of the name and quantity of all dangerous drugs stolen or lost.

(g) Fire or Other Disaster. If a pharmacy experiences a fire or other disaster, the following requirements are applicable.

(1) Responsibilities of the pharmacist-in-charge.

(A) The pharmacist-in-charge shall be responsible for reporting the date of the fire or other disaster which may affect the strength, purity, or labeling of drugs, medications, devices, or other materials used in the diagnosis or the treatment of the injury, illness, and disease; such notification shall be reported to the board, within 10 days from the date of the disaster.

(B) The pharmacist-in-charge or designated agent shall comply with the following procedures.

(i) If controlled substances, dangerous drugs, or Drug Enforcement Administration (DEA) order forms are lost or destroyed in the disaster, the pharmacy shall:

(I) notify the DEA and the board of the loss of the controlled substances or order forms immediately upon discovery; and

(II) notify the board in writing of the loss of the dangerous drugs by submitting a list of the dangerous drugs lost.

(ii) If the extent of the loss of controlled substances or dangerous drugs is not able to be determined, the pharmacy shall:

(I) take a new, complete inventory of all remaining drugs specified in §291.17(c) of this title (relating to Inventory Requirements);

(II) submit to DEA a statement attesting that the loss of controlled substances is indeterminable and that a new, complete inventory of all remaining controlled substances was conducted and state the date of such inventory; and

(III) submit to the board a statement attesting that the loss of controlled substances and dangerous drugs is indeterminable and that a new, complete inventory of the drugs specified in §291.17(c) of this title was conducted and state the date of such inventory.

(C) If the pharmacy changes to a new, permanent location, the pharmacist-in-charge shall comply with subsection (a) of this section.

(D) If the pharmacy moves to a temporary location, the pharmacist shall comply with subsection (a) of this section. If the pharmacy returns to the original location, the pharmacist-in-charge shall again comply with subsection (a) of this section.

(E) If the pharmacy closes due to fire or other disaster, the pharmacy may not be closed for longer than 90 days [as specified in §291.11 of this title (relating to Operation of a Pharmacy)].

(F) If the pharmacy discontinues business (ceases to operate as a pharmacy), the pharmacist-in-charge shall comply with §291.5 of this title (relating to Closing a Pharmacy).

(G) The pharmacist-in-charge shall maintain copies of all inventories, reports, or notifications required by this section for a period of two years.

(2) Drug stock.

(A) Any drug which has been exposed to excessive heat, smoke, or other conditions which may have caused deterioration shall not be dispensed.

(B) Any potentially adulterated or damaged drug shall only be sold, transferred, or otherwise distributed pursuant to the provisions of the Texas Food Drug and Cosmetics Act (Chapter 431, Health

and Safety Code) administered by the Bureau of Food and Drug Safety of the Texas Department of State Health Services.

(h) Notification to Consumers.

(1) Pharmacy.

(A) Every licensed pharmacy shall provide notification to consumers of the name, mailing address, Internet site address, and telephone number of the board for the purpose of directing complaints concerning the practice of pharmacy to the board. Such notification shall be provided as follows.

(i) If the pharmacy serves walk-in customers, the pharmacy shall either:

(I) post in a prominent place that is in clear public view where prescription drugs are dispensed:

(-a-) a sign which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's name, mailing address, Internet site address, telephone number, and a toll-free telephone number for filing complaints; or

(-b-) an electronic messaging system in a type size no smaller than ten-point Times Roman which notifies the consumer that complaints concerning the practice of pharmacy may be filed with the board and list the board's name, mailing address, Internet site address, telephone number, and a toll-free number for filing complaints; or

(II) provide with each dispensed prescription a written notification in a type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, Internet site address, telephone number of the board, and a toll-free telephone number for filing complaints)."

(ii) If the prescription drug order is delivered to patients at their residence or other designated location, the pharmacy shall provide with each dispensed prescription a written notification in type size no smaller than ten-point Times Roman which states the following: "Complaints concerning the practice of pharmacy may be filed with the Texas State Board of Pharmacy at: (list the mailing address, Internet site address, telephone number, and a toll-free telephone number for filing complaints)." If multiple prescriptions are delivered to the same location, only one such notice shall be required.

(iii) The provisions of this subsection do not apply to prescriptions for patients in facilities where drugs are administered to patients by a person required to do so by the laws of the state (i.e., nursing homes).

(B) A pharmacy that maintains a generally accessible site on the Internet that is located in Texas or sells or distributes drugs through this site to residents of this state shall post the following information on the pharmacy's initial home page and on the page where a sale of prescription drugs occurs.

(i) Information on the ownership of the pharmacy, to include at a minimum, the:

(I) owner's name or if the owner is a partnership or corporation, the partnership's or corporation's name and the name of the chief operating officer;

(II) owner's address;

(III) owner's telephone number; and

(IV) year the owner began operating pharmacies in the United States.

(ii) The Internet address and toll free telephone number that a consumer may use to:

(I) report medication/device problems to the pharmacy; and

(II) report business compliance problems.

(iii) Information about each pharmacy that dispenses prescriptions for this site, to include at a minimum, the:

(I) pharmacy's name, address, and telephone number;

(II) name of the pharmacist responsible for operation of the pharmacy;

(III) Texas pharmacy license number for the pharmacy and a link to the Internet site maintained by the Texas State Board of Pharmacy; and

(IV) the names of all other states in which the pharmacy is licensed, the license number in that state, and a link to the Internet site of the entity that regulates pharmacies in that state, if available.

(C) A pharmacy whose Internet site has been verified by the National Association of Boards of Pharmacy to be in compliance with the laws of this state, as well as in all other states in which the pharmacy is licensed shall be in compliance with subparagraph (B) of this paragraph.

(2) Texas State Board of Pharmacy. On or before January 1, 2005, the board shall establish a pharmacy profile system as specified in §2054.2606, Government Code.

(A) The board shall make the pharmacy profiles available to the public on the agency's Internet site.

(B) A pharmacy profile shall contain at least the following information:

(i) name, address, and telephone number of the pharmacy;

(ii) pharmacy license number, licensure status, and expiration date of the license;

(iii) the class and type of the pharmacy;

(iv) ownership information for the pharmacy;

(v) names and license numbers of all pharmacists working at the pharmacy;

(vi) whether the pharmacy has had prior disciplinary action by the board;

(vii) whether the pharmacy's consumer service areas are accessible to disabled persons, as defined by law;

(viii) the type of language translating services, including translating services for persons with impairment of hearing, that the pharmacy provides for consumers; and

(ix) insurance information including whether the pharmacy participates in the state Medicaid program.

(C) The board shall gather this information on initial licensing and update the information in conjunction with the license renewal for the pharmacy.

(i) Notification of Licensees or Registrants Obtaining Controlled Substances or Dangerous Drugs by Forged Prescriptions. If a licensee or registrant obtains controlled substances or dangerous drugs

from a pharmacy by means of a forged prescription, the pharmacy shall report in writing to the board immediately on discovery of such forgery. A pharmacy shall be in compliance with this subsection by submitting to the board the following:

(1) name of licensee or registrant obtaining controlled substances or dangerous drugs by forged prescription;

(2) date(s) of forged prescription(s);

(3) name(s) and amount(s) of drug(s); and

(4) copies of forged prescriptions.

(j) Notification of Disciplinary Action. For the purpose of the Act, §562.106, a pharmacy shall report in writing to the board not later than the 10th day after the date of:

(1) a final order against the pharmacy license holder by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state; or

(2) a final order against a pharmacist who is designated as the pharmacist-in-charge of the pharmacy by the regulatory or licensing agency of the state in which the pharmacy is located if the pharmacy is located in another state.

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on September 14, 2020.

TRD-202003760

Allison Vordenbaumen Benz, R.Ph., M.S.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: November 1, 2020

For further information, please call: (512) 305-8010



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PART 15. TEXAS STATE BOARD OF PHARMACY

CHAPTER 291. PHARMACIES

SUBCHAPTER A. ALL CLASSES OF PHARMACIES

22 TAC §291.14

The Texas State Board of Pharmacy proposes amendments to §291.14, concerning Pharmacy License Renewal. The amendments, if adopted, add a requirement for each non-pharmacist individual owner or managing officer of a Class A pharmacy to attend a pharmacy ownership training course within 90 days of notifying the board of a change of managing officer.

Allison Vordenbaumen Benz, R.Ph., M.S., Executive Director/Secretary, has determined that, for the first five-year period the rules are in effect, there will be no fiscal implications for state or local government as a result of enforcing or administering the rule. Ms. Benz has determined that, for each year of the first five-year period the rule will be in effect, the public benefit anticipated as a result of enforcing the amendments will be to improve awareness and education amongst non-pharmacist individual owners and managing officers with the requirements of pharmacy ownership. There is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies),

rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required.

For each year of the first five years the proposed amendments will be in effect, Ms. Benz has determined the following:

- (1) The proposed amendments do not create or eliminate a government program;
- (2) Implementation of the proposed amendments does not require the creation of new employee positions or the elimination of existing employee positions;
- (3) Implementation of the proposed amendments does not require an increase or decrease in the future legislative appropriations to the agency;
- (4) The proposed amendments do not require an increase or decrease in fees paid to the agency;
- (5) The proposed amendments do not create a new regulation;
- (6) The proposed amendments do expand an existing regulation by adding a training requirement;
- (7) The proposed amendments do not increase or decrease the number of individuals subject to the rule's applicability; and
- (8) The proposed amendments do not positively or adversely affect this state's economy.

Written comments on the amendments may be submitted to Megan G. Holloway, Deputy General Counsel, Texas State Board of Pharmacy, 333 Guadalupe Street, Suite 3-500, Austin, Texas, 78701, FAX (512) 305-8061. Comments must be received by 5:00 p.m., January 26, 2021.

The amendments are proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency to protect the public through the effective control and regulation of the practice of pharmacy. The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper administration and enforcement of the Act.

The statutes affected by these amendments: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.14. Pharmacy License Renewal.

(a) Renewal requirements.

(1) A license to operate a pharmacy expires on the last day of the assigned expiration month.

(2) The provision of the Act, §561.005, shall apply if the completed application and a renewal fee is not received in the board's office on or before the last day of the assigned expiration month.

(3) An expired license may be renewed according to the following schedule:

(A) If the license has been expired for 90 days or less, the license may be renewed by paying to the board a renewal fee that is equal to one and one-half times the required renewal fee as specified in §291.6 of this title (relating to Pharmacy License Fees).

(B) If the license has been expired for 91 days or more, the license may not be renewed. The pharmacy may apply for a new license as specified in §291.1 of this title (relating to Pharmacy License Application), including, as required by §560.052(b) of the Act, the submission of a sworn disclosure statement as specified in §291.4 of this title (relating to Sworn Disclosure Statement).

(4) Effective January 1, 2021, for each Class A pharmacy, if not licensed as a Texas pharmacist, each individual owner or managing officer must submit proof of attendance for a pharmacy ownership training course approved by the board within 90 days of notification of a change of any managing officer of a partnership or corporation which owns a pharmacy, unless:

(A) the pharmacy for which the notification is submitted is operated by a publicly traded company; or

(B) the pharmacy for which the notification is submitted is wholly owned by a retail grocery store chain.

(b) If the board determines on inspection at the pharmacy's address on or after the expiration date of the license that no pharmacy is located or exists at the pharmacy's address (e.g., the building is vacated or for sale or lease, or another business is operating at the location), the board shall not renew the license.

(c) Additional renewal requirements for Class E pharmacies. In addition to the renewal requirements in subsection (a) of this section, a Class E pharmacy shall have on file with the board an inspection report issued:

(1) not more than three years before the date the renewal application is received; and

(2) by the pharmacy licensing board in the state of the pharmacy's physical location except as provided in §291.104 of this title (relating to Operational Standards).

The agency certifies that legal counsel has reviewed the proposal and found it to be within the state agency's legal authority to adopt.

Filed with the Office of the Secretary of State on November 20, 2020.

TRD-202004958

Allison Vordenbaumen Benz, R.Ph., M.S.

Executive Director

Texas State Board of Pharmacy

Earliest possible date of adoption: January 10, 2021

For further information, please call: (512) 305-8010

