RULE ANALYSIS

Introduction: **THE AMENDMENTS ARE SUBMITTED TO THE BOARD FOR CONSIDERATION AS AN ADOPTED RULE**

Short Title: Delivery of Prescription Drugs.

Rule Number: §291.12

Statutory Authority: Texas Pharmacy Act, Chapter 551-569, Occupations Code:

(1) Section 551.002 specifies that the purpose of the Act is to protect the public through the effective control and regulation of the practice of pharmacy; and
(2) Section 554.051 gives the Board the authority to adopt rules for the proper administration and enforcement of the Act.

Purpose: The new rule, if adopted, specifies requirements for the delivery of prescription drugs to a patient or patient's agent.

The Board reviewed and voted to propose the new rule during the February 6, 2024, meeting. The proposed rule was published in the March 22, 2024, issue of the *Texas Register* (49 TexReg 1852).

TITLE 22. EXAMINING BOARDS
PART 15. TEXAS STATE BOARD OF PHARMACY
CHAPTER 291. PHARMACIES
SUBCHAPTER A. ALL CLASSES OF PHARMACIES

§291.12. Delivery of Prescription Drugs.

The Texas State Board of Pharmacy proposes a new rule §291.12, concerning Delivery of Prescription Drugs. The new rule, if adopted, specifies requirements for the delivery of prescription drugs to a patient or patient's agent.

Daniel Carroll, Pharm.D., 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. Dr. Carroll 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 proposed rule will be to improve the health, safety, and welfare of patients by ensuring the safety and efficacy of prescription drugs that are delivered to a patient or patient's agent by Class A, Class A-S, Class E, and Class E-S pharmacies. For each year of the first five-year period the proposed rule §291.12 will be in effect, the probable economic cost to persons required to comply with the rule is $0.28 to $13.87 per package.

Economic Impact Statement

The Texas State Board of Pharmacy (Board) anticipates a possible adverse economic impact on some small or micro-businesses (pharmacies) or rural communities by the adoption of proposed rule §291.12. The economic cost to an individual will be the same as the economic cost to a business, if the individual chooses to pay the delivery-related expenses for the business. As of January 19, 2024, there are 3,936 Class A, Class A-S, Class E, and Class E-S pharmacies that offer home delivery services, as indicated by the pharmacies on Board licensing forms. The Board estimates that 381 rural communities in Texas have a Class A, Class A-S, Class E, or Class E-S pharmacy that offers home delivery services.

The economic impact of the proposed new rule on a particular pharmacy would be dependent on the volume of prescription dispensations the pharmacy delivers by common carrier or by pharmacy employee or same-day courier service. Additionally, the economic impact would be dependent on the types of drugs dispensed by the pharmacy as certain types of drugs are more likely to require strict temperature control. In total, the estimated cost would be $0.28 to $13.87 per package. The estimated cost of tamper evident packaging is $0.07 to $0.25 per package. The estimated cost of a temperature tag is $1.82 per package. The estimated cost of a time temperature strip is $1.20 per package. The estimated cost of insulated packaging is $2.04 to $5.60 per package. The estimated cost of an ice gel pack is $0.21 to $2.00 per package. The estimated cost of notification of delivery is $0.00 to $3.00 per package.

Alternative methods of achieved the purpose of proposed rule §291.12 were considered by the Board based on public comments received concerning two prior drafts of the proposed rule. The Board previously published for public comment proposed new rule §291.12 during its May 2, 2023, meeting. The proposed rule was published in the June 16, 2023, issue of the *Texas Register* (48 TexReg 3037). The Board received 12 written public comments concerning the proposed rule. Additionally, the Board received five oral public comments at the August 1, 2023, Board meeting. After reviewing and considering the comments, the Board directed Board staff to

redraft the rule to address the concerns expressed in the comments. The amended rule draft was presented at the November 7, 2023, Board meeting and an additional oral comment was made concerning the potential rule proposal. After discussing the amended rule draft, the Board directed Board staff to redraft the rule to address the additional concerns expressed by Board members and the public. The amended rule draft was then presented at the February 6, 2024, Board meeting and two oral comments were made concerning the potential rule. The Board made additional changes to the rule proposal to address concerns expressed by Board members and the public. The updated rule proposal reflects the least restrictive methods of ensuring the safety and efficacy of prescription drugs delivered by common carrier or by pharmacy employee or same-day courier service.

Regulatory Flexibility Analysis

The Texas State Board of Pharmacy (Board) anticipates a possible adverse economic impact on some small or micro-businesses (pharmacies) or rural communities as a result of proposed rule §291.12. Alternative methods of achieved the purpose of proposed rule §291.12 were considered by the Board based on public comments received following a previous proposal of the rule. The Board previously published for public comment proposed new rule §291.12 during its May 2, 2023, meeting. The proposed rule was published in the June 16, 2023, issue of the *Texas Register* (48 TexReg 3037). The Board received 12 written public comments concerning the proposed rule. Additionally, the Board received five oral public comments at the August 1, 2023, Board meeting. After reviewing and considering the comments, the Board directed Board staff to redraft the rule to address the concerns expressed in the comments. The amended rule draft was presented at the November 7, 2023, Board meeting and an additional oral comment was made concerning the potential rule proposal. After discussing the amended rule draft, the Board again directed Board staff to redraft the rule to address the concerns expressed by Board members and the public. The amended rule draft was then presented at the February 6, 2024, Board meeting and two oral comments were made concerning the potential rule. The Board made additional changes to the rule proposal to address concerns expressed by Board members and the public. The updated rule proposal reflects the least restrictive methods of ensuring the safety and efficacy of prescription drugs delivered by common carrier or by pharmacy employee or same-day courier service. The Board finds that alternative regulatory methods would not be consistent with the health, safety, and environmental and economic welfare of the state.

For each year of the first five years the proposed rule will be in effect, Dr. Carroll has determined the following:

(1) The proposed rule does not create or eliminate a government program;

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

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

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

(5) The proposed rule does create a new regulation concerning the delivery of prescription drugs;

(6) The proposed rule does not limit or expand an existing regulation;

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

(8) The proposed rule would have a de minimis impact on this state's economy.

Written comments on the proposed rule may be submitted to Eamon D. Briggs, Deputy General Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., April 30, 2024.

The new rule is 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 the proposed rule: Texas Pharmacy Act, Chapters 551 - 569, Texas Occupations Code.

§291.12. Delivery of Prescription Drugs.

(a) Applicability. This section applies to the delivery of prescription drugs by a pharmacy licensed by the board as a Class A, Class A-S, Class E, or Class E-S pharmacy.

(b) Delivery by common carrier. A pharmacy may deliver prescription drugs by use of a common carrier (e.g., U.S. Mail) as provided in §291.9 of this title (relating to Prescription Pick Up Locations) on request of the patient or patient's agent. For purposes of this section, common carrier means a person or entity who holds out to the general public a willingness to provide transportation of property from place to place for compensation in the normal course of business, with the exception of a same-day courier service.

(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with nationally recognized standards, such as those of the manufacturer or the United States Pharmacopeia.

(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in commercially available tamper evident packaging.

(3) Temperature. The pharmacy shall ensure that any prescription drug delivered by common carrier is packaged in a manner that maintains a temperature range appropriate for the drug. This may include, without limitation, use of temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.

(4) Irregularity in delivery. The pharmacy shall provide a method by which a patient or patient's agent can notify the pharmacy as to any irregularity in the delivery of the patient's prescription, to include but not be limited to:

(A) timeliness of delivery;

(B) condition of the prescription drug upon delivery; and

(C) failure to receive the proper prescription drug.

(5) Refusal to deliver. The pharmacy shall refuse to deliver by common carrier a prescription drug which in the professional opinion of the dispensing pharmacist may be clinically compromised by delivery by common carrier.

(c) Delivery by pharmacy employee or same-day courier service. A pharmacy may deliver prescription drugs by means of its employee or a same-day courier service as provided in §291.9 of this title on request of the patient or patient's agent.

(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug.

(2) Temperature. The prescription drug shall be maintained within the temperature range allowed by the United States Pharmacopeia or recommended by the manufacturer until the delivery has been received by the patient or patient's agent.

(d) All deliveries. A pharmacy that delivers prescription drugs by common carrier or by pharmacy employee or same-day courier service shall also comply with the following:

(1) Counseling information. The pharmacy shall comply with the requirements of §291.33(c)(1)(F) of this title (relating to Operational Standards).

(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug.

(3) Compromised delivery. If a pharmacist determines a prescription drug is in any compromised during delivery, the pharmacy shall replace the drug or arrange for the drug to be replaced, either by promptly delivering a replacement to the patient or by promptly contacting the prescriber to arrange for the drug to be dispensed to the patient by a pharmacy of the patient's or patient's agent's choice.

(4) Records. The pharmacy shall maintain records for two years on the following events:

(A) when a prescription drug was sent and delivered to the patient or patient's agent; and

(B) patient complaints regarding compromised deliveries.

(5) Controlled substances. A pharmacy shall comply with all state and federal laws and rules relating to the delivery of controlled substances.

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(b) Delivery by common carrier. A pharmacy may deliver prescription drugs by use of a common carrier (e.g., U.S. Mail) as provided in §291.9 of this title (relating to Prescription Pick Up Locations) on request of the patient or patient's agent. Common[~~For purposes of this section, common~~] carrier means a person or entity who holds out to the general public a willingness to provide transportation of property from place to place for compensation in the normal course of business. A pharmacy that delivers prescription drugs by use of a common carrier providing a same-day courier service is not subject to subsection (b) of this section and shall comply with subsection (c) of this section[~~, with the exception of a same-day courier service~~].

(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with nationally recognized standards, such as those of the manufacturer or the United States Pharmacopeia.

(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in commercially available tamper evident packaging.

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(c) Delivery by pharmacy employee or common carrier providing a same-day courier service. A pharmacy may deliver prescription drugs by means of its employee or a common carrier providing a same-day courier service as provided in §291.9 of this title on request of the patient or patient's agent.

(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug.

(2) Temperature. The prescription drug shall be maintained within the temperature range allowed by the United States Pharmacopeia or recommended by the manufacturer until the delivery has been received by the patient or patient's agent.

(d) All deliveries. A pharmacy that delivers prescription drugs by common carrier or by pharmacy employee or by a common carrier providing a same-day courier service shall also comply with the following:

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(A) when a prescription drug was sent and delivered to the patient or patient's agent; and

(B) patient complaints regarding compromised deliveries.

(5) Controlled substances. A pharmacy shall comply with all state and federal laws and rules relating to the delivery of controlled substances.

TEXAS FEDERATION OF DRUG STORES

April 30, 2024

Via Email

Texas State Board of Pharmacy
Attention: Eamon Briggs, Deputy General Counsel and Daniel R. Carroll, Executive Director/Secretary
1801 Congress Avenue
Austin, TX 78701-1319
Email: eamon.briggs@pharmacy.texas.gov
Daniel.carroll@pharmacy.texas.gov

Re: Proposed amendment to Rule *§22-291.12 Delivery of Prescription Drugs*

Dear Mr. Briggs, Mr. Carroll and Board members,

I am commenting today on behalf of the members of the Texas Federation of Drug Stores (TFDS), an association representing member company chain pharmacies doing business in Texas. Several of our members have commented on Rule *§22-291.12 Delivery of Prescription* during this process. I would like to begin by saying thank you to you and the Board members for your tireless effort to develop a rule that is both enforceable and fair. We agree with the purpose of the rule to ensure that procedures are in place for consumer requested delivery of medications from a pharmacy to assure safe delivery of drugs that include protection of the integrity of the medication.

TFDS recognizes the Board has produced many redrafts that have led to clarifying and improving the rule so that the economics of home delivery from a Class A pharmacy continue to make this service available to a broad set of our customers and does not treat one form of delivery more onerously than another substantially similar service. We appreciate the efforts of the Board and, again, thank you.

However, TFDScontinues to have concerns with the requirement to maintain records for a period of two years on patient complaints on compromised deliveries. This language is part of *§291.12. Delivery of Prescription Drugs*. We recommend the proposed rule be amended to strike the language pertaining to retention of complaint records as follows:

(4) Records. The pharmacy shall maintain records for two years on the following events:
(A) when a prescription drug was sent and delivered to the patient or patient's agent; ***~~and~~***
~~(B) patient complaints regarding compromised deliveries.~~

TFDS respectfully requests the Board to strike the highlighted language. Pharmacies would need to create a procedure for recording and being able to recall complaints that are specific to delivery. This is a burdensome undertaking. TFDS is unaware of any other recordkeeping requirements for complaints received by a pharmacy for any other process and would ask that delivery of medications not be treated differently. Companies work diligently to resolve complaints and are customer service oriented. Each company has internal processes for the escalation of any concern a patient reports until resolution. Delivery complaints should be treated the same as all forms of consumer complaints.

We appreciate the opportunity to comment on the proposed rule as filed in the Texas Register and thank you for your attention to our remaining concern. If you have any questions, please do not hesitate to contact me.

Sincerely

Doug Read
H-E-B, Director of Pharmacy Compliance and Regulatory Affairs
President, Texas Federation of Drug Stores
1005 Congress Avenue, Suite 900
Austin, TX 78701

cc: TFDS Board Members

Jeenu Philip, R.Ph.
Director, Pharmacy Affairs
Walgreen Co.
200 Wilmot Rd.
Deerfield, IL. 60015
p: 904-386-6776
jeenu.philip@walgreens.com

April 25th, 2024

Via Email

Texas Board of Pharmacy
Attention: Eamon Briggs, Deputy General Counsel and Daniel R. Carroll, Executive Director/Secretary
1801 Congress Avenue
Austin, TX 78701-1319
Email: eamon.briggs@pharmacy.texas.gov
Daniel.carroll@pharmacy.texas.gov

Re: Proposed amendment to §*22-291.12 Delivery of Prescription Drugs*

Dear Mr. Briggs, Mr. Carroll and respective Board members,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Texas, we would like to thank the Board for the opportunity to comment on its proposed rulemaking regarding §*22-291.12 Delivery of Prescription Drugs.*

Background:

Walgreens fully supports the Board's mission to ensure safe delivery of prescription drugs to any patient or their authorized agent who elects to choose this service offering. We also support that all patients should expect to receive their delivered prescription drugs with the same level of safety and efficacy as they would from visiting their traditional pharmacy in person.

However, there is one section within the proposed rule which we believe will create an unintended hardship for most pharmacies to comply with. We respectfully ask the Board to strike the following language from *§291.12. Delivery of Prescription Drugs*:

§291.12. Delivery of Prescription Drugs.
(4) Records. The pharmacy shall maintain records for two years on the following events:
(A) when a prescription drug was sent and delivered to the patient or patient's agent; ~~and~~
~~(B) patient complaints regarding compromised deliveries.~~

Rationale:

Walgreens believes that requiring pharmacies to maintain records of patient complaints regarding any compromised deliveries are unnecessary and onerous for the following reasons:

1. A complaint is an ambiguous term and not defined in these rules. Patients may provide constructive feedback while not necessarily issuing a complaint. We do not believe that complaints and constructive feedback are the same thing.

Walgreens

2. The majority of patient complaints that pharmacies typically receive are provided verbally either by telephone or in person from the patient or their authorized agent. We believe that most pharmacies do not have an established form for tracking complaints issued verbally, especially when minor.

3. Complaints submitted via written or electronic means may be easily documented, however, verbal complaints would be difficult for a pharmacy to document accurately in the absence of a standardized complaint form. In addition, many pharmacies have mechanisms already in place to track written complaints submitted centrally or to a general phone number but do not parse out feedback regarding delivery separately.

4. There is an established escalation process for complaints patients have, whereas patients may leverage escalation internally within a pharmacy company or externally through the Board of Pharmacy if the pharmacy fails to properly address a delivery concern. This process goes for any concern the patient may have, so requiring the lodging of delivery complaints is unnecessary.

5. To our knowledge, the Board does not require patient complaints to be maintained by any pharmacy within its recordkeeping requirements. Why should the delivery of prescription drugs be held to a different standard?

6. We are unaware of the requirement to log complaints as a requirement in any state. We believe that states have recognized the onerous nature of this type of requirement and determined that it is not in the best interest of public safety to create burdensome requirements.

Walgreens thanks the Board for the opportunity to provide comment to its proposed rule *§291.12. Delivery of Prescription Drugs*. If the Board would like additional information, please feel free to contact me.

Sincerely,

Jeenu Philip R.Ph.

CVSHealth

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

April 29, 2024
Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy 1801 Congress Avenue
Suite 13.100
Austin, TX 78701-1319
EMAIL: eamon.briggs@pharmacy.texas.gov

Re: CVS Health's Comments on Proposed New Rule §291.12 Delivery of Prescription Drugs

Dear Deputy General Counsel Briggs and members of the Texas State Board of Pharmacy:

I am writing to you in my role as Executive Director of Pharmacy Advocacy & Regulatory Affairs for CVS Health ("CVS") and its family of pharmacies. CVS Health, the largest pharmacy health care provider in the United States, is uniquely positioned to provide diverse access points of care to patients in the state of Texas through our integrated offerings across the spectrum of pharmacy care which includes community, long term care, specialty infusion, mail order and specialty mail. Through our pharmacy offerings in community, mail, and specialty pharmacies, we deliver approximately 3.5 million prescriptions annually in Texas and appreciate the opportunity to submit comments on proposed new rule §291.12, concerning Delivery of Prescription Drugs. CVS Health is supportive and committed to the safe shipping and delivery of prescription medications to patients not only in Texas, but across the United States, our territories and to our armed services members deployed across the world. CVS has over forty years' experience in safely distributing medications through the mail and has shipped over one billion medications safely to its patients.

CVS appreciates the professional judgement language that exists in rule. However, we would be remiss to not acknowledge that the rules as proposed focus only on one portion of the drug distribution cycle, failing to address drug distribution from the drug manufacturers and wholesalers. Dispensers ship, mail and deliver medications to patients in the same manner and in consideration of the same factors as those medications are shipped to them from manufacturers and wholesalers. It is the manufacturers that have performed stability studies on their drug products and would be best positioned to provide the example for the rest of the distribution supply chain on how their drugs should be shipped. Yet, the proposed rules only address pharmacy delivery to the patient, typically the briefest portion of the distribution cycle and typically modeled after delivery methods by manufacturers, which calls into question the necessity of the regulation.

Delivery by Common Carrier

Despite our concerns with the proposed rules addressing only a portion of the drug distribution cycle, we welcome the inclusion of nationally recognized standards as suggested by our previous letter dated July 24, 2023. With this change, the Board recognizes that there may be other and evolving standards or proprietary studies/data that ensure patient safety and prescription shipping integrity, allowing flexibility in safe shipping and delivery of prescription medications.

Delivery by Pharmacy Employee or Same-Day Courier Service

For added consistency throughout the rule, CVS Health requests that section (c)(2) be amended to language like what is found in (b)(3) of this rule, so that a separate temperature requirement is not needed when delivering by a pharmacy employee or same-day courier vs delivery by common carrier.

> (c) Delivery by pharmacy employee or same-day courier service. A pharmacy may deliver prescription drugs by means of its employee or a same-day courier service as provided in §291.9 of this title on request of the patient or patient's agent.

CVSHealth

Lauren Paul, PharmD, MS | 200 Highland Corporate Drive | Woonsocket, RI 02895 | T: 540-604-3661

(2) Temperature. ~~The prescription drug shall be maintained within the temperature range allowed by the United States Pharmacopeia or recommended by the manufacturer until the delivery has been received by the patient or patient's agent.~~ The pharmacy shall ensure that any prescription drug delivered by pharmacy employee, or same-day courier service is packaged in a manner that maintains a temperature range appropriate for the drug.

We appreciate the opportunity to submit comments on the proposed new rule. CVS is a staunch advocate for the safe dispensing of medications and has adopted multiple packaging systems for the safe delivery of drugs when called for and supported by science and data.

Sincerely,

Lauren Paul, PharmD, MS
Executive Director, Pharmacy Advocacy & Regulatory Affairs
CVS Health

Zipline International Inc.
333 Corey Way, South San Francisco, CA 94080

Anne Titus Hilby
Deputy General Counsel
Zipline International Inc.
333 Corey Way
South San Francisco, CA 94080

April 29, 2024

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy
George H. W. Bush State Office Building
1801 Congress Avenue
Suite 13.100
Austin, Texas 78701
Via email: eamon.briggs@pharmacy.texas.gov

Dear Mr. Briggs:

Zipline International Inc. ("Zipline") respectfully submits these comments to the Texas State Board of Pharmacy supporting the proposed new rule considering the Delivery of Prescription Drugs, 22 TAC § 291.12 (Tex. Reg. Mar. 22, 2024) ("Draft Rule"). As the world's leading autonomous logistics service, Zipline has seen firsthand the power of instant delivery to expand access to medicine in rural communities, strengthen medical supply chains, and improve the lives of patients.

Zipline is a U.S. common carrier whose mission is to transform logistics and delivery systems so that everyone on the planet can receive the goods they need, right when they need them, regardless of where they live. Zipline designs, manufactures, and operates the world's largest autonomous on-demand delivery system. We have used our electric, lightweight, autonomous aircraft to fly over 70 million miles and have completed over 1 million commercial deliveries. We currently make a delivery to a paying customer every 70 seconds and operate on four continents.

Zipline received our Part 135 air carrier certificate for commercial package delivery operations from the FAA in June 2022, one of the first in the nation to receive this approval. We currently operate our drone delivery service in multiple states, providing daily home prescription delivery on behalf of retail and health system pharmacies. We are planning to expand into Texas later this year to provide Texas communities with access to safe, fast, and quiet home delivery of prescription and over-the-counter medicines, as well as grocery, restaurant, retail and e-commerce items.

Zipline applauds the Board for providing patients with access to home prescription delivery, both under current Board rules,* see *22 TAC § 291.9, and the Draft Rule.

Home prescription delivery provides substantial benefits to patients. Allowing patients to select where and when they want their prescriptions—on their schedule, not someone else's. This puts time back in their day and allows them to stay focused on work, school, and family. It is particularly helpful for patients who live in rural areas and must travel long distances to pick up prescriptions, as well as seniors and others with mobility limitations for whom leaving the home can be challenging and time consuming.

Home prescription delivery also benefits pharmacies. Specifically, Zipline and our existing partners have identified operational and financial efficiencies related to drone prescription delivery. Rising labor costs and fluctuations in fuel prices are major financial challenges for health systems.[1] Zipline's U.S. healthcare partners have found that using Zipline's services resulted in a 50 percent reduction in delivery costs and $5,226 in savings per patient associated with improvements in drug adherence. This means that by using Zipline for delivery, health systems can save more money to reinvest in the healthcare provided to patients.

Zipline applauds the Board for recognizing the importance of uniform standards for prescription delivery.

Zipline applauds the Board for setting consistent quality standards for home prescription delivery in the Draft Rule, including for temperature maintenance, notice, and recordkeeping.

Patients must be able to trust that their prescriptions will always be transported with the same high level of care. This should be true regardless of whether the prescriptions are delivered by a pharmacy employee, delivery service provider, plane, train, automobile, drone, bike, or scooter – or another delivery technology that may not even exist today. Similarly, pharmacy employees should be confident that the same quality standards will apply in all cases and not have to worry which set of administrative rules will apply when switching from one delivery type or provider to another. And, establishing uniform delivery quality standards, regardless of delivery provider or method, creates consistency with home pharmacy delivery rules in other states.

Zipline appreciates the opportunity to comment in this proceeding. Thank you for your time and consideration.

Respectfully,

Anne Titus Hilby
Deputy General Counsel
Zipline International Inc.

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[1] American Hospital Association, "Massive Growth in Expenses and Rising Inflation Fuel Continued Financial Challenges for America's Hospitals and Health Systems," April 2022, *available at* https://www.aha.org/guidesreports/2023-04-20-2022-costs-caring.

April 30, 2024

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy
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SENT VIA EMAIL

Re: Texas State Board of Pharmacy – Proposed Rule – Chapter 291. Pharmacies. Subchapter A. All Classes of Pharmacies (22 TAC § 291.12)

Dear Mr. Briggs:

The Pharmaceutical Care Management Association ("PCMA") appreciates the opportunity to again comment on the Texas State Board of Pharmacy ("Board") Proposed Rule for Chapter 291, Subchapter A ("Proposed Rule") within the Texas Administrative Code ("TAC"). We submitted written comments on previous language related to the same issues addressed in this letter, dated July 24, 2023, and we appreciate the work that has been done by the Board since last summer to implement some necessary changes. However, we still have concerns with the current Proposed Rule. Although TAC 44 §291.33(c)(1)(F)(iv) and 22 § 291.104(b)(1)(b) already include delivery requirements, the language of the Proposed Rule would establish a new rule via § 291.12 addressing the "Delivery of Prescription Drugs." If adopted, it would impose specific requirements on pharmacies using common carriers or delivery services to dispense of prescription drugs to a patient or a patient's agent.

Currently, the language of the Proposed Rule would isolate the last entity in the pharmaceutical supply chain – pharmacies – in the distribution channel. Moreover, the language makes no distinction between storage and permitted excursions during transit of the entire logistics channel.

PCMA is the national trade association representing pharmacy benefit managers ("PBMs"). PCMA's member companies administer drug benefits for more than 266 million Americans, including most Texans who have health insurance through employer-sponsored health plans, commercial health plans, union plans, Medicare Part D plans, managed Medicaid plans, the state employee health plan, and others.

Below are PCMA's general concerns with the Proposed Rule. Also included are requests and recommendations regarding specific provisions in the Proposed Rule.

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Missing Details – Economic Impact Statement

PCMA and its member companies again acknowledge the work done by the Board over the past

year bringing the language of the Proposed Rule to a place that is more palatable to all stakeholders. We have concerns that the Economic Impact Statement accompanying the Proposed Rule neglects to include an increase in costs related to shipping as well as labor cost for packaging requirements. PCMA and its member companies believe this omission is a cause of concern for all stakeholders as the potential increase(s) in costs may have a ripple effect that is ultimately borne by Texans seeking to fill their prescriptions.

The Board should consider potential increases in shipping and labor costs to all classes of pharmacies that offer delivery service. Such costs may be large added expenses to the health care system, mainly pharmacies, throughout the State of Texas, especially considering the limited number of complaints the Board received over a two-year timeframe related to concerns with delivery of prescriptions.

Finally, PCMA was able to obtain information from one of our member companies showing that the increased cost of freight, shipping and labor would come out to around $76 per prescription. This huge increase in costs is not good for Texans.

Language of Proposed Rule

§ 291.12 Delivery of Prescription Drugs

(b) Delivery by common carrier.

This section allows a pharmacy to deliver prescription drugs by use of a common carrier, such as the U.S. Mail.

PCMA respectfully requests that changes be made to this provision requiring the request of patient or patient's agent. Presently, the language in this section raises questions. Does the fact that it is referencing "Prescription Pick Up Locations" mean that patient consent is only required when pick up locations are used? Would a prescription sent by a health plan member/patient or their provider to the mail service pharmacy be sufficient to meet the "on request" standard?

Congruent with the beginning of this section is the language in a later provision: (5) Refusal to deliver. This provision allows a pharmacist to refuse delivery by mail if, in the professional opinion of the pharmacist, it may be "compromised by delivery by mail." Similar language should be included at the beginning of this section that would allow a pharmacist's professional opinion to determine which prescription drugs may be delivered by mail.

PCMA recommends the following:

> *(b) Delivery by common carrier. A pharmacy may deliver prescription drugs by use of a common carrier (e.g. U.S. Mai)l a~~s provided in 291.9 of this title (relating to Prescription Pick Up Locations) on request of the patient or patient's agent~~ if, in the professional opinion of a pharmacist the prescription drug will likely not be compromised by delivery by mail.*

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(d) All deliveries.

This section establishes additional requirements for pharmacies involved in the delivery of prescription drugs via pharmacy employees or mail.

(1) Counseling information.

This provision states that a pharmacy must comply with existing law regarding patient counseling under § 291.33(c)(1)(F), relating to operational standards – specifically, prescription dispensing and delivery, as well as the communication by a pharmacy regarding a prescription drug.

It should be noted that § 291.33(c)(1)(F) applies to Class A pharmacies. There is a separate counseling section for Class E pharmacies § 291.104(b)(3). Does the Board intend that all pharmacies delivering via common carrier, pharmacy employee or same-day courier service following counseling requirements outlined for Class A pharmacies as referenced?

(2) Notification of delivery.

This provision states that a pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug.

Patients should be allowed to opt-out of notifications. In the digital age, individuals often receive a plethora of notification each day. Whether via email, text message, or otherwise, individuals should be allowed to choose what notifications they want to receive, and the frequency received.

PCMA recommends the following:

> (2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. The patient or the patient's agent shall have the option to opt out of such notifications.

(3) Compromised delivery.

This provision states that in the event a pharmacist determines that the delivery of a prescription drug has been compromised, the pharmacy shall promptly correct the compromise, including having the burden to contact the prescriber to arrange for the drug to be dispensed to the patient "by a pharmacy of the patient's or patient's agent's choice."

Allowing the patient's or patient's agent's choice of any pharmacy, without limitation, will lead to increased costs. Moreover, if the delivery of a prescription drug is compromised, there may be a plethora of reasons resulting in such a compromise. And the compromise may not be the result of any error on the part of the pharmacy. Therefore, it would be prudent to include some sort of guardrail(s) for cost and quality control regarding which pharmacy may correct the compromised delivery. One such guardrail would be to add language to the provision limiting the correction of the compromised delivery to an "in-network" pharmacy. This "in-network" pharmacy could be the pharmacy that was party to the compromised delivery, or a different retail "in-network" pharmacy.

PCMA recommends the following:

> (3) Compromised delivery. If a pharmacist determines a prescription drug is in any way compromised during delivery, the pharmacy shall replace the drug or arrange for the drug to be replaced, either by prompt delivery of a replacement to the patient or arrange for the drug to be dispensed to the patient by an in-network pharmacy of the patient's or patient's agent's choice.

General Thoughts on Temperature

The Proposed Rule refers to "temperature range" in two places, but that term is undefined. Further, the Proposed Rule does not clearly delineate the intent for shipping prescription drugs that, according to the relevant pharmaceutical manufacturers, require conditions other than refrigerated or freezer conditions.

PCMA and its member companies respectfully request that the Board work with all stakeholders on language that would rectify this issue, while keeping patient safety and costs at the forefront of any discussion.

PCMA's Overall Request

PCMA respectfully requests that the Board make the changes outlined in this letter. Proceeding with the current language in the Proposed Rule would result in overburdening pharmacies (i.e., private businesses) – thus increasing costs for delivery and access to prescription drugs.

Contrary to the preamble of the Proposed Rule, if enacted as is, this language *would* have an adverse impact on private businesses, i.e., pharmacies. The current language fails to consider various scenarios. Therefore, we also respectfully request that an economic impact statement and regulatory flexibility analysis be conducted by the Board.

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Again, we appreciate the opportunity to comment on the Board's Proposed Rule. We look forward to a continued dialogue with the Board regarding the Proposed Rule. Please feel free to contact either of us, as well as our colleague, Melodie Shrader (mshrader@pcmanet.org), PCMA's Senior Vice President of State Affairs, with any questions or for further discussion.

Sincerely,

Dr. Johnny Garcia, PharmD, RPh
Senior Director, Policy
PCMA

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Peter Fjelstad
Assistant Vice President, State Regulatory & Legal Affairs
PCMA

CC: Julie Spier, R.Ph., President, Texas State Board of Pharmacy
Daniel Carroll, Pharm.D., Executive Director, Texas State Board of Pharmacy

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From: A. J. Day
To: Megan Holloway; Eamon Briggs
Subject: TSBP proposed rules
Date: Tuesday, April 30, 2024 11:34:44 AM

Good morning Megan and Eamon,

Below are my comments for proposed changes to 291.12 *Delivery of Prescription Drugs*, and below that are comments for proposed changes to 291.131 *Pharmacies Compounding Non-Sterile Preparations*.

Thank you for the opportunity to comment, and I look forward to the meeting on May 7.
Best wishes,
-A.J.

291.12
Line 112, (2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in commercially available tamper evident packaging.

- Does this mean that the drug packaging itself such as the prescription bottle is tamper evident or that the shipping package has to have tamper evidence? Assume the prescription itself, though the language in the proposal is unclear

Line 133, (2) Temperature. The prescription drug shall be maintained within the temperature range allowed by the United States Pharmacopeia or recommended by the manufacturer until the delivery has been received by the patient or patient's agent.

- What is the expectation for this? Should the pharmacy have data on their shipping practices? Will this be applied to mail order pharmacies?

Line 142, (3) Compromised delivery. If a pharmacist determines a prescription drug is in any compromised during delivery

- Typo, missing word. Should this read “is in any **way** compromised during delivery”?

291.131
Line 123, (1) Active pharmaceutical ingredient--Any substance intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body.

- Phrase “thereby becoming” is an unusual phrase. Does this mean that intermediates or precursors are considered API? Suggest utilizing the language from federal code 21CFR207.1
    - Active pharmaceutical ingredient means any substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body. Active pharmaceutical ingredient does not include intermediates used in the synthesis of the substance.

Line 136, (5) [(~~4~~)] Compounding--The preparation, mixing, assembling, packaging, or

labeling of a drug or device:

- This definition is not consistent with other federal standards or definitions, which could result in a lack of clarity over what activities are compounding. Part D (line 144) includes research as the definition of compounding, but Federal law places research outside the scope of compounding as defined in the FDCA. Would the Board consider the USP definition:
    - "combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation:"

Line 146, (6) Containment primary engineering control

- Worker and environmental exposures risks are not limited to hazardous drugs, and CVE's are effective for drugs not listed as hazardous. CVE's are not just about minimizing exposure, they are also instrumental in preventing cross-contamination of compounded preparations. Would the Board consider the USP definition here:
    - A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.

Line 171, that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

- This line is carried over from the existing 291.131 language. However, as written it could be taken to suggest compliance with all USP chapters. Suggested re-phrasing:
    - for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drugs as set forth in TAC §291.131

Line 191, (B) determining that all personnel involved in non-sterile compounding obtain continuing education appropriate for the type of compounding done by the personnel;

- How much CE is "appropriate"?

Line 207, (ii) obtain continuing education appropriate for the type of compounding undertaken or supervised [done] by the pharmacist.

- How much CE is "appropriate"?

Line 220, (B) obtain continuing education appropriate for the type of compounding done by the pharmacy technician or pharmacy technician trainee; and

- How much CE is "appropriate"?

Line 229, (C) Training shall include instruction, experience, and demonstrated proficiency in the following areas:

- What is expected to be documented for "experience"?

Line 239, (d) Operational Standards.

- This bullet seems incomplete. Below is additional detail on this point from USP 795, for the Board's consideration (modified to reference TAC instead of USP)
    - Understand the requirements of TAC 291.131
    - Understand and interpret safety data sheets (SDSs) and, if applicable, certificates of analysis (COA)
    - Read and understand procedures related to their compounding duties

Line 257, (I) name and strength of the compounded preparation or list of the active ingredients and strengths;

- As written it seems like tradenames would be allowable on prescription labels (ex. Dr. Smith's magic mouthwash). This makes it difficult for patients or poison control to identify the ingredients if they have an adverse reaction. Best practices are to identify the API in the compound on the label, not to allow "trade names" or proprietary

names

Line 263, (C) Commercially available products may be compounded for dispensing to individual patients provided the following conditions are met:

- Suggest rephrasing to “(C) Essential copies of commercially available products may be compounded…”

Line 272, (e.g., the preparation is dispensed in a strength that is only slightly different from a commercially available product)

- How will the Board determine “only slightly different”? FDA guidance document defines an acceptable strength that is greater than 10% different from the commercial product. If TSBP holds the same or a different expectation, could we specify the number here?

Line 292, (H) A pharmacist may add flavoring to a prescription at the request of a patient, the patient's agent, or the prescriber. The pharmacist shall label the flavored prescription with a beyond-use-date that shall be no longer than fourteen days if stored in a refrigerator unless otherwise documented. Documentation of beyond-use-dates longer than fourteen days shall be maintained by the pharmacy electronically or manually and made available to agents of the board on request.

- Some commercial suspension products are not to be refrigerated. What happens if a flavor is added to one of those products and this regulation requires refrigeration due to the addition of a flavor?
- What are the requirements to provide longer than 14 days BUD, apart from just documentation? Does the pharmacy need to have any data to support the longer BUD? What kind of data is acceptable? What about the documentation and data to support the amount of a specific flavor used in a specific product?

Line 304, (A) Pharmacies engaging in compounding shall have a designated and adequate area for the safe and orderly compounding of non-sterile preparations, including the placement of equipment and materials.

- More direction on what is considered to be an adequate area for safe and orderly compounding would serve both the Board and the pharmacies well. Examples: Separate the CVE from the sink by at least 3 feet due to likely microbial content of the sink. Locate CVE away from doors due to causing airflow fluctuations when another person enters or exist the compounding area.

Line 307, (B) Only personnel authorized by the responsible pharmacist shall be in the immediate vicinity of a drug compounding operation.

- Suggest changing “immediate vicinity of a drug compounding operation” to “designated compounding area”

Line 314, (D) Appropriate measures shall be used to prevent cross-contamination between compounding non-sterile preparations with different components

- Suggest removing the phrase “with different components”. Prevention of cross contamination between compounded non-sterile preparations is sufficient language. As written, this could suggest that it is acceptable for a new batch of Compound X to be contaminated with residues of the previous batch of Compound X.

Line 318, or the meticulous cleaning of contaminated equipment prior to its use for the preparation of other drug products

- Suggest removing “other drug products” and replacing with “subsequent compounds”. Whether those next compounds use the same MFR or different is irrelevant.

Line 323, (A) If [if] the pharmacy engages in compounding non-sterile preparations that require weighing a component of the preparation, the pharmacy shall have a Class A prescription balance, or analytical balance and weights which shall be calibrated and have

the accuracy of the balance verified by the pharmacy at least every 12 months as specified in the pharmacy's SOPs. The pharmacy shall document the calibration and verification

- Recommend requiring calibration of balance every day compounding is performed
- Recommend requiring a standardized weight set such as NIST

Line 392, (I) The beyond-use date of the compounded non-sterile preparation shall not exceed the shortest remaining expiration date of any of the commercially available starting components.

- Suggest removing “commercially available”. That phrase only adds confusion and suggests that pure API do not need to be considered for this statement.

Line 418, (III) If the beyond-use date of the compounded non-sterile preparation is extended beyond the beyond-use date specified in subclauses (I) and (II) of clause (ii), an aqueous compounded non-sterile preparation must pass antimicrobial effectiveness testing.

- Suggest adding “as described in USP <51>”, to avoid questions/debates over what constitutes a valid antimicrobial effectiveness test

Line 435, (6) Written drug information. Written information about the compounded preparation or its major active ingredient(s) shall be given to the patient at the time of dispensing. A statement which indicates that the preparation was compounded by the pharmacy must be included in this written information. If there is no written information available, the patient should be advised that the drug has been compounded and how to contact a pharmacist, and if appropriate the prescriber, concerning the drug.

- The first sentence says SHALL be given to the patient, which is a requirement. The final sentence gives instructions on a workaround. Suggest changing “shall” to “should”, OR keeping as “shall” and removing the alternative provided in the last sentence.

Line 442, (A) Drugs used in non-sterile compounding shall be USP/NF grade substances manufactured in an FDA-registered facility.

- Not all drugs have a USP/NF monograph. Ketotifen is an example of this. It is in commercially available drug products and is available as an API, but does not have a USP/NF monograph. Suggest rephrasing to state that the drugs will be USP/NF grade if a monograph exists.

Line 444, (B) If USP/NF grade substances are not available…

- Why not acknowledge other pharmaceutical compendial grades, like EP, JP, and BP, before going for conventionally lab-grade or food-grade materials?

Line 451, (C) If a drug, component, or material is not purchased from an FDA-registered facility, the pharmacist shall establish purity and stability by obtaining a Certificate of Analysis from the supplier and the pharmacist shall compare the monograph of drugs in a similar class to the Certificate of Analysis.

- A food or cosmetic will not have a COA
- COAs for non-drug substances should not be compared to COAs of drug substances. In addition to the data provided on the COA, the overall manufacturing process quality may vary greatly.
- What does comparing a drug COA to a monograph of a similar drug tell us? How does one decide that the comparison means the chemical is unacceptable or not?

Line 460, (E) All components shall be stored in properly labeled containers in a clean, dry area, under proper temperatures.

- “dry area” is not defined in TAC 291.131. Does this mean no standing water? Humidity of a certain level?

Line 470, (I) A pharmacy may not compound a preparation that contains ingredients appearing on a federal Food and Drug Administration list of drug products withdrawn or removed from the market for safety reasons.

This Federal list often places limitations on certain ingredients without outright banning all compounded iterations. Prohibiting everything that just appears on the list will restrict patient care.

- Cisapride and diethylstilbestrol are on the FDA's list because they were withdrawn from the human market. Both medications are standards of care in veterinary medicine.
- Potassium chloride is on the list, but only for specific high doses and dosage forms:
    - Potassium chloride: All solid oral dosage form drug products containing potassium chloride that supply 100 milligrams or more of potassium per dosage unit (except for controlled-release dosage forms and those products formulated for preparation of solution prior to ingestion).

Line 512, (B) Finished preparation checks. The prescription drug and medication orders, written compounding procedure, preparation records, and expended materials used to make compounded non-sterile preparations shall be inspected for accuracy of correct identities and amounts of ingredients, packaging, labeling, and expected physical appearance and properties before the non-sterile preparations are dispensed.

- No documentation of the inspection is required. Suggest adding a documentation (initials/signature) requirement.

Line 520, When developing these procedures, pharmacy personnel shall consider the provisions of Chapter 795, concerning Pharmacy Compounding Non-Sterile Preparations, Chapter 1075, concerning Good Compounding Practices, and Chapter 1160, concerning Pharmaceutical Calculations in Prescription Compounding contained in the current USP/NF. Such procedures shall be documented and be available for inspection.

- USP Chapters 1075 and 1160 no longer exist. Suggest referencing USP 1163 concerning Quality Assurance

Line 545, (C) Documentation of the performance of quality control procedures is not required if the compounding process is done pursuant to a patient specific order and involves the mixing of two or more commercially available oral liquids or commercially available preparations when the final product is intended for external use.

- What is the reason for not needing documentation of QC for mixing commercial products for external use? How does this serve patients?
- This section, e.1.C., allows for the mixing of unlimited creams and mouthwashes using commercial products with no QC documentation. And section d.1.h. allows for the addition of flavors and extending the BUD to anything you want if you just document something (no specific requirements, just "document"). Both sections present safety concerns as written.

Line 646, (i) verify the source of the raw materials to be used in a compounded drug;

- If a Class C pharmacy wants to dispense a compound obtained from a Class A pharmacy, what does the Class C pharmacy need to do to verify the source of the raw materials that Class A used in the preparation? Does the Class A pharmacy need to provide a list of the vendor for each ingredient for each formulation, with each order?

Line 647, (ii) comply with applicable United States Pharmacopoeia guidelines, including the testing requirements,

- This states compliance with USP is required. Is that the intent, rather than TAC rules?

Line 736, (1) The pharmacy shall have written procedures for the recall of any compounded non-sterile preparations provided to a patient, to a practitioner for office use, or a pharmacy for administration. Written procedures shall include, but not be limited to, the requirements as specified in paragraph (3) of this subsection.

This states “or a pharmacy for administration”, but pharmacies don’t administer drugs. Should this read “practitioner for administration”?

A.J. Day, PharmD | Vice President of Clinical Services

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AUSTIN
COMPOUNDING PHARMACY

Part of the Revelation Network of Compounding Pharmacies

April 30, 2024

Eamon D. Briggs, Deputy General Counsel
Texas State Board of Pharmacy
1801 Congress Avenue
Suite 13.100
Austin, TX 78701
RE: Proposed Rules §291.12 and §291.131

Dear Members of the Texas State Board of Pharmacy,

Revelation Pharma is a national network of 503A and 503B facilities that provide compounded pharmaceuticals to patients and providers throughout the U.S. We currently own and operate 14 pharmacies located in 13 states and are licensed in all 50 states. One of these stores is Austin Compounding Pharmacy, where I am the Pharmacist-in-Charge. As the compounding pharmacy industry continues to grow, it is our mission to lead the industry in quality and safety by utilizing best practices to provide innovative care to patients with unique medication needs.

We appreciate the opportunity to provide comments on proposed rule *291.12 concerning delivery of prescription drugs*, and changes to rule *291.131 regarding non-sterile compounding*. With our Austin pharmacy solely doing non-sterile preparations, these updates mean a great deal to our business. Overall, we support the rule changes as they ensure quality and safety for patients and our staff. Many of these practices are already utilized amongst our stores, and thus most of our concern is around clarification.

Please see the following comments outlined by our regulatory team:

§291.12. Delivery of Prescription Drugs.
General comment on this section: Rules developed with vague terms; Lacks well defined procedures and standards.

(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug. What does this responsibility entail? This language is broad and lacks definition. Does this mean that the pharmacy is responsible for replacement costs?

(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. What notification suffices this requirement? If a patient does not have an email or phone that can receive SMS, this presents an undue burden or expectation. Recommend language indicating "through reasonable means."

(4) Records. The pharmacy shall maintain records for two years on the following events:

(A) when a prescription drug was sent and delivered to the patient or patient's agent; and – What proof of delivery meets this requirement? Current carriers only maintain POD electronic records for up to 90 days. Pharmacy systems do not all capture delivery details, just fill date and validation metrics.

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(3) Compromised delivery. If a pharmacist determines a prescription drug is in any [way] compromised during delivery, the pharmacy shall replace the drug or arrange for the drug to be replaced, either by promptly delivering a replacement to the patient or by promptly contacting the prescriber to arrange for the drug to be dispensed to the patient by a pharmacy of the patient's or patient's agent's choice. Grammer suggestion - word omitted. We would like to see "compromised" defined.

§291.131. Pharmacies Compounding Non-sterile Preparations.

(A) Master Formulation Record. A master formulation record shall be developed and approved by a pharmacist for all compounded preparations. Once approved, a duplicate of the master formulation record shall be used as the compound record each time the compound is prepared and on which all documentation for that compound occurs. The master formulation record shall contain at a minimum; We have some concern with this standard, as qualified and experienced non-pharmacist staff can (and do) support formulation development. A pharmacist may maintain the responsibility for final approval.

Once again, we thank the board for their consideration of feedback and your initiative to adopt standards that outline best practices in our industry. Please let us know of any questions or the need for additional information.

Thank you,

Halister Joseph Drummond

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