

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 May 2, 2023, meeting. The proposed rule was published in the June 16, 2023, issue of the *Texas Register* (48 TexReg 3037).

1 **TITLE 22. EXAMINING BOARDS**
2 **PART 15. TEXAS STATE BOARD OF PHARMACY**
3 **CHAPTER 291. PHARMACIES**
4 **SUBCHAPTER A. ALL CLASSES OF PHARMACIES**

5 **§291.12. Delivery of Prescription Drugs.**

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

9 Julie Spier, R.Ph., President, has determined that, for the first five-year period the rules are in
10 effect, there will be no fiscal implications for state or local government as a result of enforcing or
11 administering the rule. Ms. Spier has determined that, for each year of the first five-year period
12 the rule will be in effect, the public benefit anticipated as a result of enforcing the proposed rule
13 will be to improve the health, safety, and welfare of patients by ensuring the safety and efficacy
14 of prescription drugs that are delivered to a patient or patient's agent by Class A, Class A-S,
15 Class E, and Class E-S pharmacies. There is no anticipated adverse economic impact on large,
16 small or micro-businesses (pharmacies), rural communities, or local or state employment.
17 Therefore, an economic impact statement and regulatory flexibility analysis are not required.

18 For each year of the first five years the proposed rule will be in effect, Ms. Spier has determined
19 the following:

- 20 (1) The proposed rule does not create or eliminate a government program;
- 21 (2) Implementation of the proposed rule does not require the creation of new employee
22 positions or the elimination of existing employee positions;
- 23 (3) Implementation of the proposed rule does not require an increase or decrease in the future
24 legislative appropriations to the agency;
- 25 (4) The proposed rule does not require an increase or decrease in fees paid to the agency;
- 26 (5) The proposed rule does create a new regulation concerning the delivery of prescription
27 drugs;
- 28 (6) The proposed rule does not limit or expand an existing regulation;
- 29 (7) The proposed rule does not increase or decrease the number of individuals subject to the
30 rule's applicability; and
- 31 (8) The proposed rule does not positively or adversely affect this state's economy.

32 Written comments on the proposed rule may be submitted to Eamon D. Briggs, Deputy General
33 Counsel, Texas State Board of Pharmacy, 1801 Congress Avenue, Suite 13.100, Austin, Texas
34 78701-1319, FAX (512) 305-8061. Comments must be received by 5:00 p.m., July 24, 2023.

35 The new rule is proposed under §§551.002 and 554.051 of the Texas Pharmacy Act (Chapters
36 551 - 569, Texas Occupations Code). The Board interprets §551.002 as authorizing the agency
37 to protect the public through the effective control and regulation of the practice of pharmacy.
38 The Board interprets §554.051(a) as authorizing the agency to adopt rules for the proper
39 administration and enforcement of the Act.

40 The statutes affected by the proposed rule: Texas Pharmacy Act, Chapters 551 - 569, Texas
41 Occupations Code.

42 **§291.12.Delivery of Prescription Drugs.**

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

45 **(b) Delivery by mail. A pharmacy may deliver prescription drugs by use of a common**
46 **carrier or the U.S. Mail as provided in §291.9 of this title (relating to Prescription Pick Up**
47 **Locations) on request of the patient or patient's agent.**

48 **(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the**
49 **patient or patient's agent in accordance with standards of the manufacturer or the United**
50 **States Pharmacopeia.**

51 **(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in**
52 **tamper proof and tamper evident mailers that are resistant to tearing and moisture.**

53 **(3) Temperature. The pharmacy shall ensure the integrity of any prescription drug**
54 **requiring temperature control other than "room temperature" storage as defined in**
55 **§291.15 of this title (relating to Storage of Drugs) that is delivered by mail. The pharmacy**
56 **shall use temperature tags, time temperature strips, insulated packaging, gel ice packs,**
57 **or a combination of these as necessary.**

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

61 **(A) timeliness of delivery;**

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

63 **(C) failure to receive the proper prescription drug.**

64 **(5) Replacement. If a prescription drug is in any way compromised during delivery, the**
65 **pharmacy shall replace the drug or arrange for the drug to be replaced, either by**
66 **promptly delivering a replacement to the patient or by promptly contacting the prescriber**
67 **to arrange for the drug to be dispensed to the patient by a pharmacy of the patient's or**
68 **patient's agent's choice.**

69 **(6) Refusal to deliver. The pharmacy shall refuse to deliver by mail a prescription drug**
70 **which in the professional opinion of a pharmacist may be clinically compromised by**
71 **delivery by mail.**

72 **(c) Delivery by pharmacy employee. A pharmacy may deliver prescription drugs by**
73 **means of its employee as provided in §291.9 of this title on request of the patient or**
74 **patient's agent.**

75 **(1) Standards. The pharmacy is responsible for any problems in the delivery of the**
76 **prescription drug. The delivery shall be on a continuous route from the pharmacy to the**
77 **patient or patient's agent.**

78 **(2) Temperature. The prescription drug shall be maintained within the temperature range**
79 **recommended by the manufacturer until the delivery has been completed.**

80 **(d) All deliveries. A pharmacy that delivers prescription drugs by mail or by pharmacy**
81 **employee shall also comply with the following:**

82 **(1) Counseling information. The pharmacy shall comply with the requirements of**
83 **§291.33(c)(1)(F) of this title (relating to Operational Standards).**

84 **(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the**
85 **delivery of a prescription drug. The notification shall provide information to the patient or**
86 **patient's agent about the timeliness in addressing the proper storage of the prescription**
87 **drug. The pharmacy shall document and maintain a record of the notification.**

88 **(3) Required signature. The pharmacy shall require the patient or patient's agent to sign**
89 **for delivery if the prescription drug is reasonably likely to be compromised if left**
90 **unattended. If the drug cannot be delivered with a signature, the package may not be left**
91 **unattended and shall be returned to be held for pickup or redelivered on the request of**
92 **the patient or patient's agent.**

93 **(4) Compromised delivery. The pharmacy shall include with the delivery the procedures**
94 **for the patient or patient's agent to follow if the prescription drug does not arrive in a**
95 **timely manner or if the integrity of the packaging or prescription drug has been**
96 **compromised during delivery.**

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

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

99 **(B) patient complaints and audits regarding the timeliness of deliveries;**

100 **(C) prescription drugs that were compromised in delivery; and**

101 **(D) the failure of a patient to receive a prescription drug delivery.**

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

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11 administering the rule. Ms. Spier has determined that, for each year of the first five-year period
12 the rule will be in effect, the public benefit anticipated as a result of enforcing the proposed rule
13 will be to improve the health, safety, and welfare of patients by ensuring the safety and efficacy
14 of prescription drugs that are delivered to a patient or patient's agent by Class A, Class A-S,
15 Class E, and Class E-S pharmacies. There is no anticipated adverse economic impact on large,
16 small or micro-businesses (pharmacies), rural communities, or local or state employment.
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- 26 (5) The proposed rule does create a new regulation concerning the delivery of prescription
27 drugs;
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37 to protect the public through the effective control and regulation of the practice of pharmacy.
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39 administration and enforcement of the Act.

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47 **Locations) on request of the patient or patient's agent.**

48 **(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the**
49 **patient or patient's agent in accordance with standards of the manufacturer or the United**
50 **States Pharmacopeia.**

51 **(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in**
52 **tamper proof and tamper evident mailers that are resistant to tearing and moisture.**

53 **(3) Temperature. The pharmacy shall ensure the integrity of any prescription drug**
54 **requiring temperature control other than "room temperature" storage as defined in**
55 **§291.15 of this title (relating to Storage of Drugs) that is delivered by mail. The pharmacy**
56 **shall use temperature tags, time temperature strips, insulated packaging, gel ice packs,**
57 **or a combination of these as necessary.**

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

61 **(A) timeliness of delivery;**

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

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64 **(5) Replacement. If a prescription drug is in any way compromised during delivery, the**
65 **pharmacy shall replace the drug or arrange for the drug to be replaced, either by**
66 **promptly delivering a replacement to the patient or by promptly contacting the prescriber**
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68 **patient's agent's choice.**

69 **(6) Refusal to deliver. The pharmacy shall refuse to deliver by mail a prescription drug**
70 **which in the professional opinion of a pharmacist may be clinically compromised by**
71 **delivery by mail.**

72 **(c) Delivery by pharmacy employee. A pharmacy may deliver prescription drugs by**
73 **means of its employee as provided in §291.9 of this title on request of the patient or**
74 **patient's agent.**

75 **(1) Standards. The pharmacy is responsible for any problems in the delivery of the**
76 **prescription drug. [The delivery shall be on a continuous route from the pharmacy to the**
77 **patient or patient's agent.]**

78 **(2) Temperature. The prescription drug shall be maintained within the temperature range**
79 **recommended by the manufacturer until the delivery has been received by the patient or**
80 **patient's agent[completed].**

81 **(d) All deliveries. A pharmacy that delivers prescription drugs by mail or by pharmacy**
82 **employee shall also comply with the following:**

83 **(1) Counseling information. The pharmacy shall comply with the requirements of**
84 **§291.33(c)(1)(F) of this title (relating to Operational Standards).**

85 **(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the**
86 **delivery of a prescription drug. The notification shall provide information to the patient or**
87 **patient's agent about the timeliness in addressing the proper storage of the prescription**
88 **drug. The pharmacy shall document and maintain a record of the notification.**

89 **(3) Required signature. The pharmacy shall require the patient or patient's agent to sign**
90 **for delivery if the prescription drug is required to be maintained at a cold temperature as**
91 **defined by §291.15 of this title and in the professional opinion of a pharmacist is**
92 **reasonably likely to be compromised if left unattended. If the drug cannot be delivered**
93 **with a signature, the package may not be left unattended and shall be returned to be held**
94 **for pickup or redelivered on the request of the patient or patient's agent.**

95 **(4) Compromised delivery. The pharmacy shall include with the delivery the procedures**
96 **for the patient or patient's agent to follow if the prescription drug does not arrive in a**
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105 **rules relating to the delivery of controlled substances.**



July 21, 2023

Eamon D. Biggs
Deputy General Counsel
Texas State Board of Pharmacy
1801 Congress Avenue
Austin, TX 78701-1319

Re: 22 TAC Sections 291.12 - Delivery of Prescription Drugs

Dear Deputy General Counsel Biggs,

Albertsons Companies operates 192 pharmacies in Texas under six different banners (Albertsons, Amigos, Market Street, Randalls, Tom Thumb, and United). Our company has worked diligently to keep our sites open to serve our patients' needs during the COVID-19 public health emergency. Patient access to pharmacy care is paramount and has been a lesson we have had reinforced with each step during the pandemic.

Albertsons Companies appreciates the opportunity to provide comments on the recent proposed regulations related to delivery of prescription drugs that were recently filed in the Texas Register. It is from the perspective of patient access to pharmacy care that we would like to deliver these comments.

Home delivery in the pharmacy setting became more prominent during the pandemic as patients were isolated and adhering to social distancing recommendations. This also opened opportunities for home delivery to patients who are home bound for reasons other than the pandemic. Home delivery supports health equity and can improve patient access for individuals who are challenged with transportation in underserved areas. ACI has concerns with language in section 291.12 (c) (1) that requires a continuous route from the pharmacy to the patient. This could be interpreted to mean that a pharmacy employee could only deliver to one patient home at a time and then be required to return to the pharmacy to obtain the next patient's prescription queued for delivery. This would present a very cost ineffective method of delivery and would likely result in pharmacies ceasing to offer home delivery. This would also likely reverse the gains in health equity the pharmacy industry has delivered over the last three years. If this is not the intention of the Board, we would ask for clarification in the language to avoid similar misinterpretation. Alternatively, ACI suggests the following amendment to the language:



(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug. ~~The delivery shall be on continuous route from the pharmacy to the patient or patient's agent.~~

Removing this language would remove the concern with potential patient access issues in preserving the reasonable ability of a pharmacy employee to deliver prescriptions to a patient's home. Additionally, ACI believes that (c) (2) related to maintaining appropriate temperatures during the delivery process will prohibit leaving patient prescriptions in an unattended delivery vehicle and negate the potential for temperature excursions in the last mile fulfillment.

Additionally, ACI has concerns with section 291.12 (d) (3) related to requiring signature on any prescription drug delivery that is reasonably likely to be compromised if left unattended. This seems to be a redundant requirement that only adds administrative burden to the process and will potentially create patient access issues when redelivery by the carrier is required. Section 291.12 (b) (3) delivery by mail requires the pharmacy ensure integrity of any prescriptions requiring temperature control and section 291.12 (c) (2) requires the manufacturer recommended temperature range is maintained until the delivery is completed. ACI suggests striking section 291.12 (d) (3) and moving the requirement for replacement found in section 291.12 (b) (5) to section 291.12 (d) as it should be applicable to all deliveries and would negate the need for signatures being required.

Thank you for this opportunity to provide feedback on these important regulations. If you have questions, please reach out to me at Rob.Geddes@albertsons.com or 208-513-3470.

Sincerely,

A handwritten signature in blue ink, appearing to read "Rob Geddes", written in a cursive style.

Rob Geddes, PharmD, MBA
Director, Pharmacy Legislative and Regulatory Affairs

Richard Gutoski, R.Ph.
Manager, Professional Practices
Alliance Rx Walgreens Pharmacy
P: 480-752-5269
Richard.gutoski@alliancerxwp.com

January 24, 2023

Via Email

Texas Board of Pharmacy
Attention: Eamon D. Briggs, Deputy General Counsel
1801 Congress Avenue, Ste 13.100
Austin, TX 78701
Email: eamon.briggs@pharmacy.texas.gov

Re: Comments to Amendments Concerning Delivery of Prescription Drugs

Dear Mr. Briggs and respected members of the Texas Board of Pharmacy:

On behalf of AllianceRx Walgreens Pharmacy, we thank you for the opportunity to comment on the proposed rules §291.12 Delivery of Prescription Drugs. Here are some items for your consideration:

- “(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with standards of the manufacturer or the United States Pharmacopeia.”
 - Recommendation: This topic is already addressed in the Central Fill rule (§291.125), we would recommend aligning with the standards discussed in that language.
- “(6) Refusal to deliver. The pharmacy shall refuse to deliver by mail a prescription drug which in the professional opinion of a pharmacist may be clinically compromised by delivery by mail.”
 - Recommendation: To clarify the intention of the rule, we recommend amending the language to indicate “dispensing” pharmacist.
- “(3) Required signature. The pharmacy shall require the patient or patient's agent to sign for delivery if the prescription drug is reasonably likely to be compromised if left unattended. If the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.”
 - The addition of a signature requirement introduces a complicated step in the process. There will be times when a patient, or agent, is unavailable to sign for the delivery. This is the case if the patient happens to be bed-bound, or if the patient is

- at work. This would present the possibility of a delay in therapy because the package will not be delivered as intended by the pharmacy.
- Signature requirements will create unnecessary complications for patients in terms of figuring out how to pick these up from the carrier if they are not home during delivery times.
 - Another aspect of this relates to the requirement under “Notification of delivery”. Is the need for a signature warranted if the pharmacy is going to notify the patient of a pending delivery? If, after delivery, the patient has any concerns regarding the integrity of the medication, the pharmacist may offer, at their professional discretion, a local fill or replacement of the medication at our cost.
 - Finally, the statement in the introduction “There is no anticipated adverse economic impact on large, small, or micro-businesses (pharmacies), rural communities, or local or state employment.” is not accurate. A signature requirement for a delivery is an added service from the carrier that incurs an additional cost for the delivery.
 - Recommendation: remove the language entirely since this is also addressed in §291.125.

AllianceRx Walgreens Pharmacy appreciates the opportunity to comment on the proposed regulations. If the board would like additional information, please feel free to contact me.

Sincerely,



Richard Gutoski R.Ph.



July 24, 2023

Deputy General Counsel Eamon D. Briggs
Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319

Submitted via email to eamon.briggs@pharmacy.texas.gov

RE: Proposed Rulemaking – §291.12, Concerning Delivery of Prescription Drugs

Dear Mr. Briggs:

This letter is in response to the solicitation for stakeholder feedback on proposed rulemaking that appeared in the Texas Register on June 16, 2023.

CenterWell Pharmacy, Inc. (CenterWell Pharmacy) is a full-service home delivery pharmacy serving patients across all 50 states. CenterWell Pharmacy provides holistic care that is personalized and coordinated with easy-to-use options so our patients can receive the care and prescriptions they need exactly when they need them. This includes home delivery services, as well as retail and specialty pharmacy services. Our pharmacies employ many pharmacists and pharmacy technicians who are critical to ensuring that patients across the country, including those in Texas, have access to the medication that they need.

CenterWell Pharmacy appreciates the opportunity to provide comments on the proposed rule.

CenterWell Pharmacy recognizes the Board of Pharmacy's efforts to protect the public through the effective control and regulation of the practice of pharmacy. However, ***the Board's proposal could create delays in the delivery of care for Texans.***

- ***Changes to signature requirements will potentially limit patient access to needed medications and create unnecessary burdens for Texans.***

Requiring a patient signature could create an access-to-care issue. Some patients may not be able to physically sign for their medications due to an ailment or physical limitation. If a patient is unable to sign for a medication when delivery is first attempted, the patient may receive the medication late or not at all if the medication is routed to a pick up location. Patients choose home delivery due to a variety of reasons including home-bound status, convenience, and affordability. This is particularly true for seniors as one in six Medicare beneficiaries currently depend on home delivery for at least one of their prescription drugs.¹ Timely delivery of medications is critical for patients, and this proposal's broad requirements for patient signatures could create unnecessary burdens for Texans by limiting at-home delivery.

¹ <https://www.kff.org/coronavirus-covid-19/issue-brief/mail-delays-could-affect-mail-order-prescriptions-for-millions-of-medicare-part-d-and-large-employer-plan-enrollees/>

Recommendation

As previously stated, the proposed rule could create delays in the delivery of care for Texans. With that in mind, **CenterWell Pharmacy strongly recommends that the Board reconsider the draft rule's changes and not require broad signature requirements related to the delivery of prescription drugs.** To do so, we recommend striking the following language:

~~(3) Required signature. The pharmacy shall require the patient or patient's agent to sign for delivery if the prescription drug is reasonably likely to be compromised if left unattended. If the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.~~

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

Sincerely,



Scott Clark
Market Vice President
Pharmacy Professional Practice
sclark8@humana.com

July 24, 2023

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 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.

Proposed Rule Modeling

It is recognized that much of the language was modeled after Georgia Board of Pharmacy Rule 480-48 Delivery by Mail, which was promulgated in 2015.¹ CVS Health participated in the rulemaking and would like to offer suggested amendments to the proposed rule, which provide clear requirements to licensees as well as flexibility to ensure safety of medications shipped or delivered to patients.

Delivery by Mail

CVS Health supports the proposed language to address delivery by mail of prescription medications in or into Texas, however we do have one suggested amendment to this section of the rules. In section (b)(1) Standards, we ask the Board to add other standards which are recognized nationally, such as Utilization Review Accreditation Commission, also known more commonly as "URAC" or NABP's Digital Pharmacy Accreditation. A pharmacy which has URAC accreditation "qualifies all medication distribution processes for appropriate temperature ranges."² A pharmacy that holds NABP Digital Pharmacy Accreditation "proudly displays your ongoing commitment to providing quality healthcare and safe pharmacy practices over the internet."³ Additionally, there may be other and evolving standards or proprietary studies/data that ensure patient safety and prescription shipping integrity; therefore, we would request the Board consider amending proposed rule to allow for other standards for a pharmacy to follow for delivery by mail.

§291.12. Delivery of Prescription Drugs.

(b) Delivery by mail. A pharmacy may deliver prescription drugs by use of a common carrier or the 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.

(1) Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with ~~written or practice~~ standards of the manufacturer, ~~or~~ the United States Pharmacopeia, nationally recognized accreditation entities or similar standards.

Delivery by Pharmacy Employee

To supply consistent guidelines for a pharmacy who may deliver either by mail or by pharmacy employee, as well as not require different standards dependent on method of delivery, we request the Board consider amending language in this section to mirror the language in the delivery by mail section.

As currently proposed in §291.12 (c)(1), requiring a continuous route from the pharmacy to the patient or patient's agents implies that only one delivery by a pharmacy employee is completed at a time, with the employee required to return to the pharmacy prior to completing the next delivery. We feel this is an onerous requirement on the pharmacy employee and would hinder the increased patient demand on the convenience of delivery that has erupted with COVID and into the post-COVID era. Therefore, we ask for an amendment to be made for the standards, like what we suggested for (b)(1) of this rule.

(c) Delivery by pharmacy employee. A pharmacy may deliver prescription drugs by means of its employee 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. ~~The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with standards of the manufacturer, the United States Pharmacopeia, nationally recognized accreditation entities or similar standards. The delivery shall be on a continuous route from the pharmacy to the patient or patient's agent.~~

For added consistency throughout the rule, CVS Health requests that section (c)(2) be amended to reference section (b)(3) of this rule so that a separate temperature requirement is not needed when delivering by a pharmacy employee vs delivery by mail or common courier, again providing consistency across the different delivery modalities.

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

(2) Temperature. ~~The pharmacy shall ensure the integrity of any prescription drug delivered to a patient or patient's agent by using appropriate packaging provided in §291.12 (b)(3). The prescription drug shall be maintained within the temperature range recommended by the manufacturer until the delivery has been completed.~~

All Deliveries

CVS Health appreciates the added language providing conformity of delivery, despite the method used. In review of subsection (d)(2) referencing notification, we do not see a specific method that must be used for notification and appreciate the broadness of this language. As you may know, the way in which patients or patient's agents wish to receive notifications is evolving from telephone calls to text messages, emails, or other electronic notifications. CVS commends the Board on flexibility in notification method. We do request the Board consider amending the notification and signature sections to allow a patient to request the requirement of a signature upon delivery, instead of requiring the signature. We have concern that the current proposed rule requiring signature in subsection (d)(3) may delay patient's receiving maintenance therapy if there is not a location to hold for pick up or redelivery cannot occur due to a timing issue and cause the unintended consequence of a delay in care. We have supplied proposed amendments to the language below.

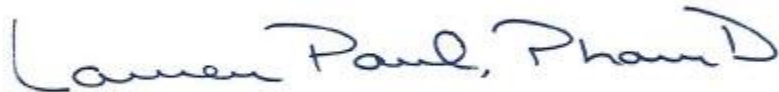
(d) All deliveries. A pharmacy that delivers prescription drugs by mail or by pharmacy employee shall also comply with the following:

(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. The notification shall provide information to the patient or patient's agent about the timeliness in addressing the proper storage of the prescription drug ~~and the ability to request a signature upon delivery.~~ The pharmacy shall document and maintain a record of the notification.

(3) Required signature. The pharmacy shall require the patient or patient's agent to sign for delivery ~~if the patient requests a signature upon delivery as noticed in (d)(2). the prescription drug is reasonably likely to be compromised if left unattended.~~ If the drug cannot be delivered with a ~~requested~~ signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.

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. CVS respectfully requests the Board consider our suggested amendments, due to experience in distributing medications safely to our patients and our science based, evidence backed methods.

Sincerely,



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

References

1. Board of Pharmacy Rules and Regulations of the State of Georgia. Chapter 480-48 Delivery by Mail. Available from <https://rules.sos.ga.gov/gac/480-48> (Accessed June 27, 2023)
2. Mail Service Pharmacy Accreditation. Available from <https://www.urac.org/accreditation-cert/mail-service-pharmacy-accreditation/> (Accessed June 27, 2023)
3. National Association Boards of Pharmacy Digital Pharmacy. Available from <https://nabp.pharmacy/programs/accreditations-inspections/digital-pharmacy/> (Accessed July 15, 2023)



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July 24, 2023

VIA EMAIL: eamon.briggs@pharmacy.texas.gov

Texas State Board of Pharmacy
Attn: Eamon D. Briggs, Deputy General Counsel
1801 Congress Avenue, Suite 13.100
Austin, Texas 78701

RE: Comments in Opposition to Proposed Rule 22 TAC §291.12 – Delivery of Prescription Drugs

Dear Texas State Board of Pharmacy:

We are writing on behalf of Express Scripts Pharmacy, Inc., and ESI Mail Pharmacy Service Inc. (collectively “Express Scripts”), and Accredo Health Group, Inc. (“Accredo”) (referred to collectively in this letter as “Express Scripts/Accredo”) to provide comments on the Texas State Board of Pharmacy’s (“Board”) proposed rule 22 TAC §291.12. As you know, the proposed rule seeks to regulate acceptable temperature ranges of prescription drugs shipped or delivered to patients in Texas by resident and non-resident pharmacies.

Express Scripts/Accredo appreciates the Board’s role in protecting the health and welfare of Texas residents and agrees that temperature standards are necessary. However, Express Scripts/Accredo disagrees with the Board’s approach of establishing rigid temperature standards via state administrative regulation, which are not easily revised to respond to industry changes, and do not allow pharmacies to adapt operations based on prevailing scientific data. As written, the proposed rule’s inflexible standards do not encompass all widely accepted scientific data and industry best practices related to temperature during shipment. Mail-order (and resident) pharmacies must have the ability to continue following science-based industry standards. Such standards include those set by accreditation bodies, shipment methods and excursion data employed by manufacturers and wholesalers, as well as independent test outcomes and data metrics used by entities in the supply chain. These organizations and entities are in the best position to adapt industry standards based on the latest data regarding impact of temperature on drug stability and potency.

As discussed further below, the proposed rule would impose standards that are intended to address conditions during the storage of a drug, as opposed to the temperatures required during the shipping and delivery of a drug. The proposed rule also does not account for information such as excursion, extended stability data, and quality assay data outcomes relied upon by manufacturers and wholesalers when shipping and delivering prescription drugs to pharmacies. The proposed rule

would create a double standard whereby a drug shipped to the pharmacy would not require any additional packaging or temperature controls, but when delivered by the pharmacy to a patient, would require stringent packaging and temperature controls that will add costs without any demonstrable benefit to patient safety.

Express Scripts/Accredo supports reasonable regulations designed to protect the integrity of drug products throughout the supply chain, from manufacturer, to wholesaler, to pharmacy, to the patient. Accordingly, we respectfully ask the Board to consider these comments and further revise the proposed rule to comport with current safe, reliable, and nationally accepted evidence-based standards set by the Utilization Review Accreditation Commission, the United States Pharmacopeia, manufacturer excursion and stability data, and other reliable data sources. Doing so will promote patient safety and help maintain temperature standardization across all partners in the supply chain.

I. Background:

February 3, 2023 marked the 36th anniversary of the first mail-service prescriptions delivered by Express Scripts. During that time, Express Scripts has pioneered and employed innovative technology to ensure the integrity of the medications they ship to patients' homes. For any medication shipped in insulated packaging, Express Scripts uses advanced technology that takes into account the acceptable temperature range for each medication, as well as all the forecasted weather patterns the medication will pass through on its journey from an Express Scripts/Accredo pharmacy to the patient's hands. Using a forecasting temperature program with a patented algorithm, shipping and destination temperatures are identified and then matched to the medication's temperature profile. Express Scripts uses this information to determine the appropriate shipping time frame and the packaging that should be used in transit. That technology is used to determine the optimal packaging and delivery methods for temperature sensitive medications delivered by the Express Scripts and Accredo pharmacies.

For all medications, including those stored at controlled room temperature, Express Scripts/Accredo relies on definitions, standards, and guidelines published in the United States Pharmacopeia (USP), but also relies on manufacturer excursion data and their shipping methodologies, stability data, quality assay outcomes, and patient feedback. Express Scripts/Accredo also relies on other metrics to determine the type of temperature-controlled packaging needed, if any, based on the range of safe temperatures the medication can endure in its specific form and the current temperature and weather patterns on the delivery route.

A. Utilization Review Accreditation Commission

In keeping with its commitment to patient safety, the Express Scripts and Accredo pharmacies maintain Accreditation with the Utilization Review Accreditation Commission (URAC). Express Scripts holds Mail Service Pharmacy Accreditation and Accredo holds Specialty Pharmacy Accreditation. Among other rigorous standards, an organization that receives URAC

Accreditation has met the highest standards of temperature management in the United States. As discussed on URAC's website¹:

URAC's first set of standards addressed prescription drug stability and integrity at the pharmacy level and during shipping. In 2015, URAC implemented specific validation requirements for transporting cold chain medications. In 2019, URAC expanded those requirements to address medication delivery and internal storage procedures at all temperature levels. To obtain accreditation, URAC now requires organizations to qualify their product storage and delivery programs through continuous monitoring and testing.

Express Scripts/Accredo urges the Board to recognize this industry standard as it seeks to establish uniform delivery standards for Texas licensed pharmacies. We also ask that the Board be mindful that standards it sets may be subject to legal challenges if they are vague, impose undue burdens on pharmacies that deliver medications across state lines, or conflict with standards in place in other states.

II. Proposed Rule Section 291.12(b) – Delivery by Mail

A. Paragraph (b)(1) – Standards.

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

While we understand the Board's intent is to ensure drug stability and potency, the standards sought to be imposed by the Board do not take into account evidence-based data and standards that actually focus on drug efficacy as opposed to lifetime environmental conditions in which a drug is stored. Initially we note that "standards of the manufacturer" is not defined. If the intent is for the reference to manufacturer standards to include a manufacturer's stability, excursion, and other data to determine the appropriate measures to take when delivering a medication to a patient, we would agree with that approach. However, if the intent is to incorporate standards recommended by a manufacturer that are applicable to storage, and to apply those standards to shipping and delivery, we disagree with the approach.

Likewise, despite the general reference to the USP, the proposed rule does not identify which section of USP should be followed. Again, USP standards applicable to storage should not be relied upon to set standards applicable to shipping and delivery. Further, reliance on USP standards without recognizing the results of independent assay test outcomes and other metrics is misplaced. We again urge the Board to recognize URAC accreditation standards approach which requires pharmacies to qualify their product storage and delivery programs through continuous monitoring and testing, and allows pharmacies to rely on those results to ensure that the stability

¹ <https://www.urac.org/blog/cold-chain-medication-management/>; <https://www.urac.org/accreditation-cert/mail-service-pharmacy-accreditation/>; <https://www.urac.org/accreditation-cert/specialty-pharmacy/> (last visited 7/10/2023).

and potency of dispensed drug products are maintained during shipment and delivery. It is imperative that the Board recognize the distinction between storage, during which medications are exposed to environmental conditions for a prolonged period of time, versus environmental conditions during shipping. We further request that the Board recognize that shipping a drug to a patient consistent with the way in which a manufacturer ships the same drug to the pharmacy is consistent with the “*standards of the manufacturer*” referenced in (b)(1).

We would also point out that, despite the Board’s focus on storage temperature (discussed in section “B” below), the Board does not seek to impose the same requirements on drugs shipped into Texas by wholesalers and manufacturers. Medications delivered to a pharmacy by a manufacturer or wholesaler are subjected to the same environmental conditions as a medication that is delivered to a patient by a pharmacy, and to impose requirements on one segment of the supply chain without regard to the tried and true packaging and delivery methods relied upon by the supply chain as a whole is arbitrary, and could form the basis of a legal challenge.

Second, the reference in (b)(1) to “*all prescription drugs*” is inconsistent with subparagraph (b)(3), which applies to “*any prescription drug requiring temperature control other than ‘room temperature’ storage as defined in §291.15[.]*” We request that the Board clarify its intent on how (b)(1) and (3) are intended to work together.

Third, (b)(1) creates a different standard for mail-order deliveries by non-resident pharmacies versus the standard for delivery by pharmacy employees found in subsection (c)(1), which is: “*The pharmacy is responsible for any problems in the delivery of the prescription drug. The delivery shall be on a continuous route from the pharmacy to the patient or patient’s agent.*”

To address these concerns, we ask that the Board consider the following revision to its proposed rule:

(1) The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient’s agent in a manner that protects the stability and potency of the drug during transit by adhering to delivery ~~accordance with~~ standards of the manufacturer, ~~or~~ the United States Pharmacopeia, or any other applicable standards, and to qualify their product storage and delivery programs through continuous monitoring and testing.

B. Paragraph (b)(3) – Temperature.

(b)(3) The pharmacy shall ensure the integrity of any prescription drug requiring temperature control other than “room temperature” storage as defined in §291.15 of this title (relating to Storage of Drugs) that is delivered by mail. The pharmacy shall use temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.

The first issue with proposed paragraph (b)(3) is that the definitions in §291.15 deal with recommended *storage* temperatures that are not intended to set absolute temperature limits during shipping. See 22 TAC §291.15 (“All drugs shall be stored at the proper temperature and conditions

as defined by the following terms[.]” Likewise, these “storage” temperatures are not intended to account for the full range of temperature at which drug stability and potency is maintained. Rather, the referenced storage temperature focuses on the environment in which a drug is stored for the life of the drug.

In fact, USP recognizes that temperature excursions outside of respective labeled storage conditions may be acceptable provided that stability data and scientific/technical justification exist, demonstrating that product safety, quality, and efficacy is not affected. However, the language in (b)(3) would not allow use of this evidence-based information, nor would it even allow a pharmacy to use a manufacturer’s transit excursion information (assuming the manufacturer even provides such information). As such, because it is not possible to prevent all environmental storage temperature excursions during shipping, and because maintaining storage temperatures does not directly equate with drug potency and efficacy, the references to standards of “storage” temperature should be replaced.

Second, proposed (b)(3) appears to impose a more restrictive standard than what is referenced in (b)(1) and used across the industry. As written, (b)(3) could be interpreted as not allowing for any temperature excursions, which would be inconsistent with USP and generally accepted standards.

Third, it is not clear whether the Board intends paragraph (b)(3) to only apply to cold chain products versus all products, including drugs that are required to be stored (again, not shipped and delivered) at “controlled” room temperature. We note that by incorporating the definition of “room temperature” found in §291.15, the proposed language appears to apply to all drugs other than drugs intended to be stored at “the temperature prevailing in a working area.” See 22 TX ADC §291.15(4). We are not aware of any drugs that are intended to be stored at “room temperature.” Likewise, there are conflicting standards between (b)(3) and paragraph (b)(1), which applies to “all prescription drugs.”

We request that the Board revise the language in paragraph (b)(3) to remove any ambiguity as to its scope. Also, while it appears paragraph (b)(3) is written in a way that does not require all packages be shipped with the types of monitoring or control devices referenced, and only requires such monitoring and controls “as necessary” to ensure the integrity of the product, clarification is needed to ensure that the regulation is not misinterpreted in the future. We propose the following revision:

*(b)(3) The pharmacy shall **take measures to ensure the integrity of any prescription drug determined to require**ing temperature control **during delivery.** ~~other than "room temperature" storage as defined in §291.15 of this title (relating to Storage of Drugs) that is delivered by mail.~~ **This may include, without limitation, the pharmacy shall use of temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these, as necessary.***

C. Paragraph (b)(5) – Replacement.

(b)(5) If 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.

Express Scripts/Accredo have a system in place for replacement of products, as needed, which may have been compromised. Pharmacists are available to patients 24/7 to discuss any perceived drug compromise. If, after being provided with pharmacist counseling, stability data, and other information, the patient still believes their medication is compromised, a replacement will be issued as appropriate. However, the portion of proposed (b)(5) requiring a pharmacy to contact the prescriber to arrange for a replacement to be dispensed by possibly another pharmacy seems misplaced.

Requiring outreach to a prescriber to address a problem that can be easily addressed by the dispensing pharmacy is unnecessary, unrealistic, and unduly burdensome. First, prescribers are not easy to reach and imposing the responsibility on the prescriber to arrange for another pharmacy to dispense a drug would almost certainly add unnecessary delay to the process. Second, if the patient does not have an insurance benefit that allows for dispensing from the second pharmacy, neither the prescriber nor the original dispensing pharmacy would be in a position to address that issue. Third, the dispensing pharmacy cannot be put in the position of dictating to a prescriber when and where to send a prescription on behalf of a patient.

We agree that patient care requires the prompt replacement of a drug that has been compromised during delivery. However, the process followed by most pharmacies, that would include direct replacement by expedited delivery, if needed to address the patient need, is sufficient. If the patient or the original pharmacy has concerns about the timing of delivery of a replacement drug, rather than contacting the prescriber for a new prescription, the original pharmacy can simply transfer the prescription to the pharmacy of the patient's choice. Prescriber outreach to obtain a new prescription to be filled at another pharmacy would be necessary only as a last resort, reserved for situations where replacement or transfer is not possible.

We request that paragraph (b)(5) be revised as follows:

(5) If 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, if the drug cannot be replaced within the time needed to ensure that the patient does not experience an interruption in therapy, by promptly arranging for transfer of the prescription, to the extent allowed under state and federal law and regulation, to the pharmacy of the patient's or patient's agent's choice. ~~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.~~

III. Proposed Rule Section 291.12(d) – All Deliveries

A. Paragraph (d)(2) – Notification of delivery.

(d)(2) The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. The notification shall provide information to the patient or patient's agent about the timeliness in addressing the proper storage of the prescription drug. The pharmacy shall document and maintain a record of the notification.

Express Scripts/Accredo maintains a system whereby patient notification is provided consistent with their pre-selected communication preferences (e.g., phone, email, text, or fax). Based on what appears to be the Board's indication that paragraph (b)(3) applies only to cold chain products, we would request that paragraph (b)(2) similarly reflect its application to only cold chain products, as follows:

*(d)(2) The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. **For any prescription drug determined to require temperature control during delivery,** ~~The~~ notification shall provide information to the patient or patient's agent about the timeliness in addressing the proper storage of the prescription drug. The pharmacy shall document and maintain a record of the notification.*

B. Paragraph (d)(3) – Required signature.

(d)(3) Required signature. The pharmacy shall require the patient or patient's agent to sign for delivery if the prescription drug is reasonably likely to be compromised if left unattended. If the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.

The undefined language, “reasonably likely to be compromised”, is problematically vague. To begin with, the temperature standards in proposed (b)(3) (seen earlier above) are drawn from sources dealing with *storage* of finished drug products, not transient shipping. Thus, under proposed (d)(3), any storage temperature excursion whatsoever could render a drug “compromised” regardless of whether such excursions have been shown by manufacturer data, or other reliable data sources, to not result in a compromised product. Further, Express Scripts/Accredo have developed a system whereby, if it is determined based on environmental conditions in the delivery area, industry standards, and other metrics mentioned earlier above that a drug could be compromised at any point during shipment, the drug will be held until it can be shipped without compromise. Patients receive proper notification throughout this process and have

the ability to request a transfer of their prescription. Further, Express Scripts/Accredo has a process in place whereby it determines whether a drug is suitable for mail delivery, and if concerns that the potency, stability, or efficacy of the drug could be adversely impacted during delivery, those drugs are removed from the formulary of drugs that can be delivered by mail. For example, drugs that are required to be shipped frozen are excluded from standard mail delivery.

Additionally, the potential benefit of a signature requirement is outweighed by the risk of delaying patient access to their medications if they are not available at the time of delivery. Express Scripts/Accredo has a system in place to notify patients of the status of their delivery, enabling them to receive or retrieve their medications on a timely basis. Patients also have the ability to request that a signature be provided on delivery. However, an outright requirement for all patients to provide a signature would place a heavy burden on patients to ensure they are physically available to receive the delivery. As such, we respectfully request that the Board delete paragraph (d)(3) from the proposed rule or revise it as follows:

(d)(3) Required signature. The pharmacy shall ~~may~~ require the patient or patient's agent to sign for delivery if the ~~of a~~ prescription drug is reasonably likely to be compromised if left unattended. If ~~required and if~~ the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.

C. Paragraph (d)(5) – Records.

(d)(5) Records. The pharmacy shall maintain records for two years on the following events:

- (A) when a prescription drug was sent to the patient or patient's agent;*
- (B) patient complaints and audits regarding the timeliness of deliveries;*
- (C) prescription drugs that were compromised in delivery; and*
- (D) the failure of a patient to receive a prescription drug delivery.*

As written, subsections (c) and (d) would require pharmacy recordkeeping without ever having received notification from a patient/agent regarding compromised delivery or failure of receipt. Thus, we would request adding a knowledge/notification element by rolling (c) and (d) into subparagraph (b), as follows:

(d)(5) Records. The pharmacy shall maintain records for two years on the following events:

- (A) when a prescription drug was sent to the patient or patient's agent;*
- (B) patient complaints ~~and audits~~ regarding ~~delivery of the drug or other concerns in which the pharmacy provided a replacement of the drug.~~ the timeliness of deliveries, ~~including, but not limited to, patient complaints of~~;*
- ~~(C)~~ prescription drugs that were compromised in delivery; ~~and~~*
- ~~(D)~~ the failure of a patient to receive a prescription drug delivery.*

IV. Fiscal Impact

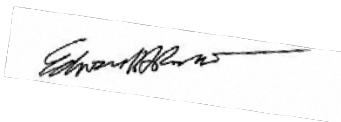
Per the Board's notice of rulemaking published in the June 16, 2023 edition of the Texas Register, "[t]here is no anticipated adverse economic impact on large, small or micro-businesses (pharmacies), rural communities, or local or state employment. Therefore, an economic impact statement and regulatory flexibility analysis are not required." Contrary to the Board's assertion, for many entities there would certainly be substantial cost of compliance based on the volume of prescriptions mailed and otherwise delivered in the state, changes to packaging, building out new processes, including electronic systems, and more.²

After the Board has provided clarification and input on the matters address earlier above, pharmacies will be in a better position to assess the potential costs of compliance. Without that information, the Board cannot satisfy its obligation to provide an economic impact analysis. As such, we respectfully request the Board perform a complete economic impact analysis.

V. Conclusion

Based on the foregoing, we respectfully request that the Board consider these comments and revise the proposed rule consistent with the comments above. We likewise request that these comments be considered during the Board's August 1, 2023, meeting. Should you have any questions or require additional information, we would be happy to assist. Thank you for your consideration.

Sincerely,

A handwritten signature in black ink, appearing to read "Edward D. Rickert", is written over a white rectangular background that is slightly tilted.

Edward D. Rickert, Esq.
Michael S. Elkins, Esq.

² We note that if the Board interprets its proposed rule in a way that would impose these extra costs, pharmacies that dispense medications from outside Texas would likely be disparately impacted. Since the Board has not provided any data to show how its proposed rule would benefit the public (i.e., that the rule would have a positive impact on the stability and potency of medication during transit, as opposed to simply impacting environmental conditions in which a drug is stored during transit), the rule would be susceptible to legal challenge under the Commerce Clause of the U.S. Constitution. *See, e.g., Pike v. Bruce Church, Inc.*, 397 U.S. 137 (1970) (laws that impose burdens on interstate commerce that exceed any putative local benefit are invalid.)



July 24, 2023

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy
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Austin, TX 78701-1319
EMAIL: eamon.briggs@pharmacy.texas.gov

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 comment on the Texas State Board of Pharmacy (“Board”) Proposed Rule for Chapter 291, Subchapter A (“Proposed Rule”) within the Texas Administrative Code (“TAC”). The language of the Proposed Rule would establish new law via § 291.12 and concerns the “Delivery of Prescription Drugs.” If adopted, it would impose specific requirements on pharmacies using mail service, 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 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.

§ 291.12 Delivery of Prescription Drugs

(b) Delivery by mail.

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

PCMA respectfully requests that changes be made to this provision. Patients should not be required to request delivery of their prescriptions via mail.

Pharmaceutical Care Management Association
325 7th Street, NW, 9th Floor
Washington, DC 20004
www.pcmnet.org



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? And would the fact that a health plan member/patient or their provider has previously sent a prescription 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: (6) Refusal to deliver. This provision allows a pharmacy 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 mail. A pharmacy may deliver prescription drugs by use of a common carrier or the U.S. Mail as provided in 291.9 of this title (relation 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.”

(1) Standards.

This provision requires that a pharmacy ensure all prescription drugs delivered to a patient or patient agent be in accordance with the standards of the manufacturer or the United States Pharmacopeia (“USP”).

PCMA respectfully requests that this provision be changed to allow the inclusion of nationally recognized standards beyond just drug manufacturers and the USP. We believe there are other standards, like the Utilization Review Accreditation Commission (“URAC”) or the National Association of Boards of Pharmacy (“NABP”) Digital Pharmacy Accreditation, which can be added to this language to allow for other standards that are nationally recognized to be used as standards for delivery to a patient.

At present, this language would impose requirements that are for storage of product over time and do not consider the transit and excursion fluctuations when drugs are moved from the manufactures to distributors to pharmacies and to patient. The manufacturers publish excursion data in many cases for short periods that does not impact potency. The reference to the USP guidelines and USP 659 relates to the appropriate storage of products and their definitions. The accrediting organizations have been reviewing this and have specific quality control measures in place for all accredited organizations based on cold chain requirements. Lastly, these requirements would isolate one step in a four-part logistics channel and place all product liability on the dispensing pharmacy.

PCMA recommends the following:

(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.

This provision requires a pharmacy to ensure that prescription drugs are packaged in tamper proof and tamper evident mailers that are “resistant to tearing and moisture.”

PCMA respectfully requests that this provision be changed to reflect the fact that there is no packaging that is 100% resistant to moisture.

PCMA recommends the following:

(2) Packaging. The pharmacy shall ensure that prescription drugs are packaged in generally and commercially available tamper proof and tamper evident mailers that are resistant to tearing and moisture.

(3) Temperature.

This provision imposes requirements on a pharmacy to ensure the proper temperature of any prescription drug requiring temperature control. It specifies that a pharmacy shall use temperature tags, time temperature strips, insulated packaging, gel ice packs, “or a combination of these as necessary.”

PCMA respectfully request that this provision change. The language “or a combination of these” implies that not all are required. Temperature tags and time temperature strips in packages have false positive and failures that can add significant costs. Thus, an alternative may be a pack out testing type of requirement that has specific testing temperature of pack outs at certain seasons and geographic locations similar to accreditation requirements. Then those results are used to support the transport of the medications in certain pack outs daily.

PCMA recommends the following:

(3) Temperature. The pharmacy shall ensure the integrity of any prescription drug requiring temperature control other than “room temperature” storage as defined in §291.15 of this title (relating to Storage of Drugs) that is delivered by mail. The pharmacy shall use items such as temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.

(5) Replacement.

This provision states that a prescription drug shall be replaced if the drug is in any way compromised during delivery. It would be prudent for the Board to recognize the various scenarios that may play out and to rely upon the professional judgment of a pharmacist to determine if a replacement of a prescription drug is required.

PCMA respectfully requests that this provision change. Sometimes, the professional judgment of the pharmacist may be that the drug was not actually “compromised.” Further, it would be prudent



to have members of the health plan obtain replacements from a local in-network pharmacy, to determine whether the member's prescription drug has indeed been "compromised."

PCMA recommends the following:

(5) Replacement. If in the professional judgment of a pharmacist, 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 an in-network pharmacy of the patient's or patient's agent's choice.

(c) Delivery by pharmacy employee.

This section establishes when the manner and methods for a pharmacy employee to delivery prescription drugs at the patient or patient's agent request.

(1) Standards.

The standards in both this provision and the entirety of this section regarding deliveries by pharmacy employees do not match those for delivery by mail.

PCMA respectfully requests that at the very least, the standards provisions in these sections align. One way to align these sections would be the removal of the "continuous route" language. It is entirely impractical and overly broad to require a pharmacy employee to complete one delivery at a time. Once the package leaves a pharmacy, its destination is the patient's home. However, the package may travel through numerous cities and carrier hubs (e.g. – U.S. Postal Service, FedEx, and UPS).

PCMA recommends the following:

(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. The pharmacy is responsible for any problems in the delivery of the prescription drug. ~~The delivery shall be on a continuous route from the pharmacy to the patient or patient's agent.~~

(2) Temperature.

This provision states that in the context of a prescription drug delivery by a pharmacy employee, temperature shall be maintained until the delivery has been completed. Specifically, it says that the recommended temperature range shall be maintained "until the delivery has been completed."

PCMA respectfully requests that this provision change. As is, it is unclear. Especially for those drugs shipped without a signature required upon delivery.



PCMA recommends the following:

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

(d) All deliveries.

This section establishes additional requirements for pharmacies involved in the delivery of prescription drugs via pharmacy employee 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 F pharmacies § 291.104(b)(3). What is the intent of the Board regarding this language?

PCMA respectfully requests that this provision be stricken. Patients are not forced to speak to a pharmacist before a prescription drug order is released. How is a pharmacy to notify a patient or patient's agent if there is an election to not be counseled?

PCMA recommends 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.

This provision states that a pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. It also states that the notification shall provide information to the patient or patient's agent about the timeliness in addressing the proper storage of the prescription drug. And that the pharmacy shall document and maintain a record of the notification.

PCMA respectfully requests changes be made to this provision. Patients can schedule when to receive their drugs. However, is this for all deliveries? Alternatively, what about programs that health plan members may opt-into? Patients play a key role regarding *when* drugs are delivered to them.

Also, 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. Summarily, how the package is received and stored should be under the discretion of the patient or patient's agent.

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 notification shall provide information to the patient or patient's agent about the timeliness in addressing the proper storage of the prescription drug.~~ The pharmacy shall document and maintain a record of the notification. The patient or the patient's agent shall have the option to opt out of such notifications.

(3) Required signature.

This provision states that a pharmacy shall require the patient or patient's agent to sign for delivery if the prescription drug is "reasonably likely to be compromised" if left unattended. Also, it says that if the drug cannot be delivered with a signature, the package may not be left unattended and must be returned to be held for pickup or redelivered on the request of the patient or patient's agent.

PCMA respectfully requests that this provision change. Currently, the language is both overbroad and vague. For example, what does it mean to be "reasonably likely to be compromised?" Requiring a signature on such deliveries is burdensome because a patient plays a key role in when drugs are delivered. If the drug is a specialty drug, there are communications from the pharmacy to the patient to ensure timely delivery and proper storage, such as temperature requirements.

Often, pharmacies ship "signature-required" and "carrier obtains" deliveries. The deliveries may also have an eSignature function that allows a package to be left at a delivery location with a patient electronically signing that they have received the delivery. Other considerations include delivery of prescription drugs to a multi-family housing complex, the opportunity for package tampering may be high. The determination of whether a signature should be required upon the delivery of a prescription drug should be the decision of the receiver and the shipping pharmacy.

Noteworthy is that requiring a signature may lead to lapses in therapy if there is no one available for signature. This is especially true when deliveries are made to a patient that is elderly and/or disabled. Our member companies have found that when Medicaid and/or Medicare plans include a signature requirement for the delivery of prescription drug deliveries, a patient's continuity of care is often disrupted.

PCMA recommends the following:

(3) Required signature. The pharmacy ~~shall~~ may require a signature for deliveries under the professional judgment of a pharmacist, or if requested by the patient or patient's agent to sign for delivery if the prescription drug is reasonably likely to be compromised if left unattended. If the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.



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.

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 myself or my colleague, Melodie Shrader (mshrader@pcmanet.org), PCMA's Vice President of State Affairs, with any questions or for further discussion.

Sincerely,

Peter Fjelstad
Director, State Regulatory & Legal Affairs

CC: Julie Spier, R.Ph., President, Texas State Board of Pharmacy

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Jeenu Philip, R.Ph.
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July 24th, 2023

Via Email

Texas Board of Pharmacy
Attention: Julie Spier, RPh, President, Texas Board of Pharmacy
Eamon Briggs, Deputy General Counsel
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
Email: eamon.briggs@pharmacy.texas.gov
Cc: megan.holloway@pharmacy.texas.gov

Re: **Comments to new proposed rule §291.12.Delivery of Prescription Drugs**

Dear Mr. Briggs, Ms. Spier and respected members of the Texas Board of Pharmacy,

On behalf of all pharmacies owned and operated by Walgreen Co. in the state of Texas, Walgreens appreciates the opportunity to submit comments on the proposed new rule §291.12 Delivery of Prescription Drugs.

Walgreens recognizes the Board's intent in providing additional protection for patients for delivery of prescription drugs to patients. In our review of the new rule, we found some areas that we believe should be re-evaluated and amended or stricken. During the Board's previous discussions of this topic, the Board's conversation revolved around patient notification. We believe the rules as drafted have gone far beyond this discussion and create heavy burdens on pharmacies both in-state and out-of-state.

Within the preamble to the rules, the Board has indicated that "there is no anticipated adverse economic impact on large, small or micro-businesses".... We believe this would be inaccurate if shipping costs are impacted for EACH prescription mailed or delivered. Considering the millions of prescriptions being mailed and delivered, the Board has not addressed in-state patient complaints to assist in justifying the immense cost and added compliance risk associated with these rules.

§291.12.Delivery of Prescription Drugs.

Delivery by Mail:

(b) Delivery by mail. *A pharmacy may deliver prescription drugs by use of a common carrier or the 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.*

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

(2) Packaging. *The pharmacy shall ensure that prescription drugs are packaged in tamper proof and tamper evident mailers that are resistant to tearing and moisture.*

(3) Temperature. *The pharmacy shall ensure the integrity of any prescription drug requiring temperature control other than "room temperature" storage as defined in §291.15 of this title (relating to Storage of Drugs) that is delivered by mail. The pharmacy shall use temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.*



Walgreens agrees that standards should be required when shipping medications. We believe the proposed language can be streamlined and less prescriptive, provide greater flexibility while still capturing the intent of the Board. The added amended language below is captured from §22-291.125 Texas Centralized Prescription Dispensing rules with a slight modification to include a reference to USP standards.

As such,

Walgreens recommends the below changes to section (b):

***(b) Delivery by mail.** A pharmacy may deliver prescription drugs by use of a common carrier or the 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.*

***(1) Standards for Packaging and shipping.** Pharmacies shall utilize adequate storage or shipment materials, containers and shipping processes to ensure drug stability and potency. Such shipping processes shall include the use of appropriate packaging material and/or devices to ensure that the drug is maintained at an appropriate temperature range as allowed by USP standards to maintain the integrity of the medication throughout the delivery process.*

The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with standards of the manufacturer or the United States Pharmacopeia.

~~***(2) Packaging.** The pharmacy shall ensure that prescription drugs are packaged in tamper proof and tamper evident mailers that are resistant to tearing and moisture.*~~

~~***(3) Temperature.** The pharmacy shall ensure the integrity of any prescription drug requiring temperature control other than "room temperature" storage as defined in §291.15 of this title (relating to Storage of Drugs) that is delivered by mail. The pharmacy shall use temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these as necessary.*~~

Delivery by Pharmacy Employee:

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

Walgreens believes this section should be amended to include common carriers as mentioned within §291.9 since there are common carriers that may not fall within the previous category of delivery by mail. We also recommend a slight technical amendment to change "on" to "at" in referencing the "request of the patient...".

(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug. The delivery shall be on a continuous route from the pharmacy to the patient or patient's agent.

Walgreens agrees that the pharmacy is responsible in the delivery of the prescription drug. However, the need to have a continuous route should not be determined by the Board, but rather based on how many prescriptions are to be delivered and the most efficient route determined. We believe determining delivery routes goes above and beyond the Board's purview and therefore should be stricken.

(2) Temperature. The prescription drug shall be maintained within the temperature range recommended by the manufacturer until the delivery has been completed.

We agree that medications should stay within the appropriate temperature range to ensure the integrity of the medication throughout the delivery process. As in the previous section, Walgreens believes that the same standards that apply to manufacturer and wholesale distributor shipping should apply to pharmacies delivering medications. Since USP determines these standards, we believe it makes sense to reference USP within the rule.



Walgreens recommends the below change to section (c):

(c) Delivery by pharmacy employee or common carrier. A pharmacy may deliver prescription drugs by means of its employee or common carrier as provided in §291.9 of this title ~~or~~ at request of the patient or patient's agent.

(1) Standards. The pharmacy is responsible for any problems in the delivery of the prescription drug. ~~The delivery shall be on a continuous route from the pharmacy to the patient or patient's agent.~~

(2) Temperature. The prescription drug shall be maintained within the temperature range as allowed by USP to maintain the integrity of the medication ~~recommended by the manufacturer~~ until the delivery has been completed.

Signature Requirements:

(d) All deliveries. A pharmacy that delivers prescription drugs by mail or by pharmacy employee shall also comply with the following:

(2) Notification of delivery. The pharmacy shall notify the patient or patient's agent of the delivery of a prescription drug. The notification shall provide information to the patient or patient's agent about the timeliness in addressing the proper storage of the prescription drug. The pharmacy shall document and maintain a record of the notification.

(3) Required signature.

The pharmacy shall require the patient or patient's agent to sign for delivery if the prescription drug is reasonably likely to be compromised if left unattended. If the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.

Requiring signature requires is by far the most burdensome requirements within these rules and we believe has extreme *unintended consequences*. Since the Board discussed notification requirements and not signature requirements, we believe the signature requirements should be stricken.

Below are the primary reasons we believe that signature requirements are unnecessary and should be stricken:

- The basis for requiring a signature within the rule is vague and subjective. Since there is a notification requirement already, how is one to know how long medications may be left unattended and therefore compromised? We believe that as long as the proper notification requirements are met, the responsibility should transfer to the patient for ensuring medications are brought into a temperature-controlled environment after delivery vs. requiring a signature.
- Requiring a signature requires the patient or agent to be available for the delivery. This creates unnecessary complications for patients in terms of figuring out how to pick these up from the carrier or risk having them returned to the pharmacy with the pharmacy refusing to offer another delivery.
- Signature requirements will result in unintended adherence-related issues. Any barrier to patients receiving medications will decrease adherence. Signature requirements will be a significant barrier for many who may work or are unable to answer a doorbell in a timely fashion.
- If prescriptions are not delivered, where are they then stored? If delivered using a common carrier like FedEx or UPS, these are then most likely a FedEx warehouse or truck. This creates just as much, if not more likelihood for the delivery to get compromised.
- Signature requirements add significant costs to a pharmacy which then would most likely be passed onto the patients. Either way, we believe this would create an economic burden that the Board has not properly addressed.



Walgreens recommends the below changes to section (d):

~~–(3) Required signature.~~

~~The pharmacy shall require the patient or patient's agent to sign for delivery if the prescription drug is reasonably likely to be compromised if left unattended. If the drug cannot be delivered with a signature, the package may not be left unattended and shall be returned to be held for pickup or redelivered on the request of the patient or patient's agent.~~

Walgreens thanks the Board for considering our feedback on this rulemaking. If the Board would like additional information, please feel free to contact me.

Sincerely,

A handwritten signature in blue ink, appearing to read "Jeenu Philip R.Ph.", is written over a horizontal line.

Jeenu Philip R.Ph.



Unite For Safe
Medications

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Board of Pharmacy Members

Texas State Board of Pharmacy

1917 S. Interstate 35

Austin, Texas 78741

24 July 2023

Dear Board of Pharmacy Members,

First, I appreciate the Board of Pharmacy's willingness to update the current Texas regulations relating to the temperature storage of medications by mail. This comment is related to proposed regulation in §291.12.

Although most mail order pharmacies at least try to protect medications that are required to be refrigerated, they mostly ignore the importance of storing critical room temperature medications in safe temperatures and sometimes, the system fails for refrigerated medications. This is true for critical room temperature children's liquid oral transplant medications, eye drops, migraine medications, thyroid medications, and many others.

Patients have stated that Boards of Pharmacies have denied them the right to complain unless they could show evidence of harm, leaving patients no choice but to take medications that they are aware could be less effective or harmful in other ways as it is well-known that medications can increase in impurities when stored in unsafe temperatures as those experienced during shipping. This is unethical and unacceptable. When chronic conditions worsen, doctors and patients don't know if it's from the unsafe storage in a hot Texas mailbox and truck or due to normal progression of the disease.

For patients like my son who is a transplant survivor, taking a less potent or adulterated medication may not show the effects overnight but the effects can occur over a long slow decline in his condition.

Patients are not warned that medications exposed to such high-temperature extremes can reduce the shelf life of medication, lower potency, or create harmful by-products. Many patients and physicians have learned about this issue the hard way.

Recently, a mother shared a video of her daughters' medication left on their front porch, and a temperature sensor showed that the medication was 95 degrees. Although the front porch was hot, the hot trucks were much hotter, hotter than 110-115 degrees. A pharmacist outreached to the drug manufacturer. The drug manufacturer states that stability testing hasn't been performed on the drug to show the medication would be safe beyond 104 degrees. Many news outlets have reported readings of UPS trucks in Texas over 150 degrees. This mother asked for a cooling pack. Due to the medication not being labeled a

drug that required "cooling" per the mail order pharmacy's policy, the mother was denied any cooling packs or a cooler for her child's room temperature medication. Additionally, the pharmacist from one of the large three PBMs mail order pharmacy confirmed that he couldn't tell the parent the exact temperature that the medication was exposed to in the truck as they were not tracking the temperature of the inside of the truck.

Pharmacists and Boards of Pharmacy have known about the issue of improper storage of medications to pharmacies from wholesalers and that medications have been stored improperly from mail order pharmacies for quite some time as parents of children with chronic conditions and patients are not warned that lives are at risk. This is one of the worst unethical injustices in our nation today.

Air conditioning and temperature control are not new. It has been existent since the 1940s. Yet many wholesalers and mail order pharmacies refuse to use such technology or ship medications in safe packaging. Without regulation, innovation and protection in this area has been slow-moving.

Although wholesalers generally ship medications quickly, medications are still arriving to pharmacies in non-temperature-controlled vehicles and could be arriving at pharmacies adulterated. Pharmacists that work at these pharmacies are aware of this issue, but feel muted and fearful to speak due to risks of retaliation. For patients forced to a mail order pharmacies, medications are shipped and exposed to extreme temperatures for 2-5 days.

For the Board's current proposed regulation, I am concerned that the regulation may be vague.

1. "Standards. The pharmacy shall ensure that all prescription drugs are delivered to the patient or patient's agent in accordance with standards of the manufacturer or the United States Pharmacopeia."

Without defining what the standards of the manufacturer or USP are, I am concerned a loophole will be left for the mail order pharmacies not to comply. Many states that have adopted similar regulations and medications continue to be shipped in only bags and left in hot trucks and mailboxes. Most of these pharmacies are not meeting USP's or drug manufacturers' guidelines. For the drug manufacturer most drug manufacturers will not allow for medications to exceed temperatures to the point of 120 to 150 degrees. I urge the Texas Board of Pharmacy to Be more definitive in their direction of using USP or drug manufacturers guidelines.

- **What chapter of USP should the mail order pharmacies adhere to, and how will pharmacies and the Board of Pharmacy know that medications are stored outside of these temperatures?**
- **How will mail order pharmacies determine if they adhere to the drug manufacturer's standards?** Will they adhere to the drug manufacturers' excursion data on the label or additional stability data that will most likely not allow for medications to be shipped in the 120-150 degrees that medications are commonly stored in during shipping? Manufacturers and drug testing facilities have stated that medications that are tested at higher temperature for an accelerated stability test such as 120 degrees only performs this testing to ensure that medications will remain stable at room temperature up to the time of the expiration date.

2. "The pharmacy shall use temperature tags, time temperature strips, insulated packaging, gel ice packs, or a combination of these **as necessary.**"

I encourage the Board to define as necessary as this can be another loophole for mail order pharmacies. Currently, the mail order pharmacies do not feel that the combination of any of these are necessary for room temperature medications. For patients, a temperature sensor should be required on every package, especially for those patients who are forced to mail order pharmacies as the only option of affordable coverage. A temperature sensor is the only way that patients can be alerted that their medication has been exposed to such high temperature extremes that may render them harmful or useless.

3. "Replacement. If 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."

If possible, defining of "promptly" would be helpful to patients. If possible, it is critical to ensure that patients nor their pharmacies that are assisting the patients that have received adulterated drugs should not be penalized. For example, patients shouldn't be forced to pay a higher copay due to the issue that is no fault of their own. Pharmacists rescuing the patients shouldn't lose money filling the prescription in a safe way.

The Board of Pharmacy should include their contact information on packaging. Most patients that I speak to are not aware of the existence of the Board of Pharmacy. Filing complaints with the mail order pharmacies themselves isn't working well for patients as the usual response is "it should be okay" as the mail order pharmacies refuse to tell the patients the truth that it's really anyone's best guess.

Again, I sincerely appreciate the Boards critical discussion and attention on this issue.

Sincerely,

Loretta Boesing, Founder of Unite for Safe Medications

From: [Dorothy Edwards](#)
To: [Eamon Briggs](#)
Subject: Comment on June 16, 2023 Texas Register Proposed Rule Changes
Date: Monday, July 17, 2023 4:19:04 PM

Dear Deputy Briggs,

Hello, my name is Dorothy Edwards and I am commenting to express approval for the upcoming proposed rule changes concerning the delivery of prescription drugs 22 TAC §291.12. Though I am not a Texas resident, I think that prescription drugs should be sent in such a way that the integrity of the medication is preserved and I urge that temperature sensors be required when transporting temperature sensitive medications. Other states may follow in adopting these important safety regulations if Texas successfully approves this rule.

Thank you for your consideration,

Dorothy Edwards

Comment on proposed rule §291.12.Delivery of Prescription Drugs

Hello Mr. Briggs,

My name is Elizabeth Kroger. I am a resident in Cibolo, Texas. I receive a medication every month in the mail that is a lozenge that I do not have the option to pick up at a nearby pharmacy. The temperatures are in the nineties currently where I live and the medication itself says it is to be stored in a dark, cool place. It is important to me that the medication that I receive is safe and effective. If carriers are agreeing to transport medication then they should have the responsibility to deliver it in proper storage conditions and unaltered by heat. Anyone who receives a package expects it to be delivered without being damaged and medication should be no different, especially when the consequences of it being damaged are much more severe.

Thank you for reading my comment,
Elizabeth Kroger

Comment on proposed rule §291.12.Delivery of Prescription Drugs

Attn: Eamon D. Briggs

I strongly support regulating the temperature of medications stored while being shipped from mail order pharmacies. I am dependent on receiving two of my prescriptions from mail order pharmacies, and if they were spoiled upon arrival, that would deteriorate my health until I could obtain more. Please implement policies to ensure medications are stored according to their temperature requirements.

Thank you,

MJ Kubala

Comment on proposed rule §291.12.Delivery of Prescription Drugs

I support proper temperature storage of medications by mail. If medicine is not properly stored while in transit, it will go bad and people may die from it.

Sincerely,

Elena Rumiantseva