

RULE ANALYSIS

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

Short Title: Prescription Pick Up Locations.

Rule Number: §291.9

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 amendments, if adopted, allow a pharmacist or pharmacy to deliver prescription drugs by means of a contract carrier and certain prescription drugs by use of unmanned aircraft systems.

The Board reviewed and voted to propose the amendments during the February 4, 2025, meeting. The proposed amendments were published in the March 21, 2025, issue of the *Texas Register* (50 TexReg 2028).

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 **§291.9. Delivery of Prescription Drugs.**

6 The Texas State Board of Pharmacy proposes amendments to §291.9, concerning Prescription
7 Pick Up Locations. The amendments, if adopted, allow a pharmacist or pharmacy to deliver
8 prescription drugs by means of a contract carrier and certain prescription drugs by use of
9 unmanned aircraft systems.

10 Daniel Carroll, Pharm.D., Executive Director/Secretary, has determined that, for the first five-
11 year period the rules are in effect, there will be no fiscal implications for state or local
12 government as a result of enforcing or administering the rule. Dr. Carroll has determined that,
13 for each year of the first five-year period the rule will be in effect, the public benefit anticipated
14 as a result of enforcing the amendments will be to improve medication access, delivery choice,
15 and health outcomes for Texas citizens. There is no anticipated adverse economic impact on
16 large, 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 amendments will be in effect, Dr. Carroll has
19 determined the following:

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

32 Written comments on the amendments 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., April 29, 2025.

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

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

42 *§291.9. Prescription Pick Up Locations.*

43 (a) No person, firm, or business establishment may have, participate in, or permit an
44 arrangement, branch, connection or affiliation whereby prescriptions are solicited, collected,
45 picked up, or advertised to be picked up, from or at any location other than a pharmacy which is
46 licensed and in good standing with the board.

47 (b) A pharmacist or pharmacy by means of its employee or by use of a common **or**
48 **contract** carrier [(e.g., U.S. Mail)], at the request of the patient, may:

49 (1) pick up prescription orders at the:

50 (A) office or home of the prescriber;

51 (B) residence or place of employment of the person for whom the prescription was issued; or

52 (C) hospital or medical care facility in which the patient is receiving treatment; and

53 (2) deliver prescription drugs to the:

54 (A) office of the prescriber if the prescription is:

55 (i) for a dangerous drug; or

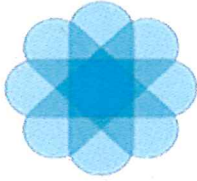
56 (ii) for a single dose of a controlled substance that is for administration to the patient in the
57 prescriber's office;

58 (B) residence of the person for whom the prescription was issued;

59 (C) place of employment of the person for whom the prescription was issued, if the person is
60 present to accept delivery; or

61 (D) hospital or medical care facility in which the patient is receiving treatment.

62 **(c) A pharmacist or pharmacy by use of unmanned aircraft systems (i.e., "drones"), at the**
63 **request of a patient or patient's agent, may deliver prescription drugs, excluding**
64 **controlled substances, sterile compounded preparations, or drugs requiring storage**
65 **below a "cool" temperature as defined by §291.15 of this title (relating to Storage of**
66 **Drugs), to the residence of the person for whom the prescription was issued.**



**SMALL UAV
COALITION**
*A Partnership for
Safety & Innovation*

April 22, 2025

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

**Re: Comments on March 21, 2025 Proposed Amendments to 22 TAC §§ 291.9 and 291.12
Regarding UAS Prescription Drug Delivery**

Dear Mr. Briggs:

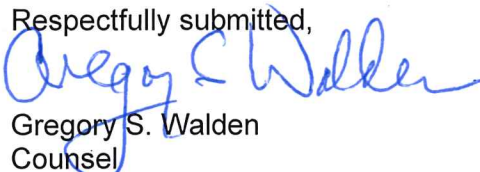
On behalf of the Small UAV Coalition, thank you for the opportunity to submit comments on the Texas State Board of Pharmacy's proposed amendments to its rules governing prescription drug delivery. We applaud the Board for its leadership in proposing regulatory changes that expressly permit prescription medication delivery by unmanned aircraft systems (UAS or drones). This is a significant and commendable step forward in modernizing pharmacy regulations to reflect the capabilities and benefits of advanced delivery technologies.

The Small UAV Coalition is a partnership of leading consumer and technology companies who believe that U.S. leadership in the research, development, production, and operation of drones will benefit consumers in all walks of life. We support policies that facilitate the responsible deployment of drones across a range of use cases — including health care and pharmaceutical delivery — where these technologies can improve public access, reduce environmental impact, and support improved patient outcomes.

The proposed amendment reflects a forward-thinking approach by recognizing that drone delivery can expand patient access to timely and secure prescription drug delivery, particularly in areas underserved by traditional ground transportation. We appreciate the Board's careful work to build a framework that enables innovation while maintaining core safeguards for patient safety, drug integrity, and pharmacist accountability. We recognize that the proposed amendment reflects a thoughtful initial framework and would welcome the opportunity to work with the Board and staff on future refinements.

We commend the Board for initiating this rulemaking and share its goal of supporting safe, efficient, and equitable access to prescription medications for all Texans. We look forward to continued collaboration as these policies evolve and would be pleased to serve as a resource in future discussions.

Respectfully submitted,



Gregory S. Walden
Counsel

Small UAV Coalition

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Rob Geddes, PharmD, MBA
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April 21, 2025

Danny Carroll
Executive Director
Texas Board of Pharmacy
1801 Congress Avenue Suite 13100
Austin, TX 78701

Re: Proposed Rules 22 TAC Sections 291.9, 291.12, 291.32, and 291.120

Dear Executive Director Carroll,

CVS Health is the largest pharmacy provider in the country with over 9,000 pharmacies in operation. In Texas we proudly operate 787 pharmacies. Our pharmacists and technicians working in Texas play a pivotal role in supporting the health of the citizens of the state. CVS pharmacies provide a critical access point for patients in the healthcare ecosystem. I am writing to you in my capacity as Executive Director of Pharmacy Advocacy and Regulatory Affairs for CVS Health as part of our efforts to continue to drive quality in healthcare – including by supporting patient access – through community pharmacy.

22 TAC Sections 291.9 and 291.12 – Unmanned Aircraft Delivery

During the COVID-19 pandemic, the need for additional access points for patients to receive life-saving medications became increasingly important, and highlighted an area of need that remains post-pandemic. Home delivery is an important means of access to care for patients who are homebound or experience limited access to transportation. We applaud the Texas Board of Pharmacy for allowing innovation to grow within this important area of healthcare by authorizing a pilot using unmanned aircraft to deliver prescriptions to patients. While we support the proposed regulations recently discussed in the February 7, 2025, Board meeting, we have some minor amendments we suggest the Board consider to support greater patient access to pharmacy services.

First, the final provision of Section 291.9 introduces limitations on the use of unmanned aircraft when delivering prescriptions and also the location where the delivery can be made. The exclusion list, which is repeated in Section 291.12, includes “drugs requiring storage below a ‘cool’ temperature as defined by section 291.15 of this title.” This would exclude delivery via this method for drugs that have to be stored at less than 46 degrees Fahrenheit, such as drugs required to be kept frozen or refrigerated.

There are methods used currently to deliver prescriptions with these cold chain temperature requirements that may include insulated packaging, gel ice packs, or a combination of solutions. These have been proven to be a safe and effective way to maintain temperatures. Given the demonstrated reliability of packaging that can maintain the recommended temperatures during a longer duration delivery via common carriers, such as UPS, Fedex, or USPS, we believe the shorter duration delivery using an unmanned aircraft can also maintain recommended temperatures for a patient's prescription.

Secondly, Sections 291.12 and 291.32 both limit the delivery location to a patient's place of residence. Considering the technology and a requirement for the patient to be present for delivery, we believe the use of the word "residence" to be overly restrictive. We recommend a minor change to use "selected delivery location" instead, to permit the patient to have their prescriptions delivered to them when and where needed.

Based on the context outlined above we suggest the following minor amendments to the proposed language for each section:

22 TAC Section 291.9

(c) A pharmacist or pharmacy by use of unmanned aircraft systems (i.e., "drones"), at the request of a patient or patient's agent, may deliver prescription drugs, excluding controlled substances, and sterile compounded preparations, ~~or drugs requiring storage below a "cool" temperature as defined by §291.15 of this title (relating to Storage of Drugs),~~ to the ~~residence~~ selected delivery location of the person for whom the prescription was issued.

22 TAC Section 291.12

e) Delivery by unmanned aircraft systems (i.e., "drones"). A pharmacy may deliver prescription drugs, excluding controlled substances, and sterile compounded preparations, ~~or drugs requiring storage below a "cool" temperature as defined by §291.15 of this title (relating to Storage of Drugs),~~ by use of a common or contract carrier providing an unmanned aircraft system delivery service as provided in §291.9 of this title on request of the patient or patient's agent.

(1) Standards. Unmanned aircraft systems shall maintain appropriate federal registration and comply with all state and federal laws and rules. 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.

(2) The pharmacist-in-charge is responsible for developing written policies and procedures regarding prescription drug delivery in accordance with this subsection to be used by pharmacy personnel to include, but not be limited to, the following:

(A) training pharmacy personnel engaged in preparing and packaging prescription drugs for delivery;

(B) packaging prescription drugs for delivery;

(C) verification of the correct recipient and delivery address;

(D) maintaining the confidentiality of prescription records;

(E) secure transfer of prescription drugs from the pharmacy;

(F) provision of patient counseling;

(G) remediation of errors in delivery or adverse events; and

(H) recordkeeping.

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

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

(5) Records. The pharmacy shall document each change in the chain of custody of a prescription drug, including departure of the prescription drug from the pharmacy, transfer to the person or entity fulfilling delivery, and delivery to the patient.

(6) Confirmation of presence at residence. The pharmacy shall receive confirmation from the patient or patient's agent that the patient or patient's agent is present at the ~~selected delivery location residence~~ before unmanned aircraft system delivery is initiated.

(7) Security. The pharmacy must ensure that delivery is made to a reasonably secure location at the patient's ~~selected delivery location residence~~ that minimizes the opportunity for unauthorized access to prescription drugs and confidential prescription records.

22 TAC Section 291.32 – Pharmacist to Technician Ratio

We appreciate the Board responding to requests for rulemaking to improve how a central fill pharmacy can be staffed. We support the change to make the technician to pharmacist ratio not applicable in a central fill pharmacy when there is no direct interaction between patients and the pharmacy. As has been outlined and discussed during the most recent Board meeting, these facilities operate very differently than a traditional Class A pharmacy. This change will be beneficial to allow a central fill facility to operate safely and efficiently.

22 TAC Section 291.120 – Ownership Definitions

The term “common ownership” is used throughout the Texas Administrative code, which permits flexibility to pharmacies under common ownership in certain situations. Generally,



pharmacies owned in a corporate structure may have the same name but have a different legal entity that directly owns it, sharing common ownership at a different level within the corporate structure. The new definitions for “common ownership” and “owner of record” that are used in 22 TAC Section 291.120 narrow the scope of common ownership as it has been recognized in the past to only be between two or more pharmacies who have the same “owner of record.” These definitions exclude pharmacies who share common ownership at a different level. Based on this we suggest the following modifications to the definitions to avoid unintended consequences.

(3) Common ownership--Two or more pharmacies with an identical owner of record with the Board and/or **each with an owner that is a legal parent, subsidiary, or affiliate of the other's**.

(4) Owner of record--The direct owner of the pharmacy provided on the pharmacy's application for a pharmacy license or most recent approved change of ownership form.

Thank you for the opportunity to comment on these proposed rules. Please direct any questions to Rob.Geddes@CVSHealth.com or 208-860-5342.

Sincerely,

Rob Geddes, PharmD, MBA
Executive Director,
Pharmacy Advocacy and Regulatory Affairs



April 25, 2025

**Mr. Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy
George H. W. Bush State Office Building
1801 Congress Avenue, Suite 13.100
Austin, Texas 78701**

**RE: Proposed amendments to 22 TAC § 291.9 (Prescription Drug Pickup);
and § 291.12, (Delivery of Prescription Drugs) - (March 21, 2025 Texas
Register)**

Dear Mr. Briggs:

**Memorial Hermann Health System (Memorial Hermann) welcomes the
opportunity to comment on proposed amendments to 22 TAC § 291.9
(Prescription Drug Pickup); and § 291.12, (Delivery of Prescription
Drugs), as published in the March 21, 2025, Texas Register.**

**Memorial Hermann is the teaching hospital system for the McGovern
Medical School at UTHealth Houston, the largest health system serving
a 150-mile radius of Houston, and the largest safety net hospital serving
Southeast Texas, comprising 17 hospitals and approximately 300 health
care delivery sites, supported by a workforce of more than 35,000 full-
time employees and 7,000 physician partners. Memorial Hermann
supports the busiest air ambulance service in the country (*Life Flight*);
the nation's busiest Level I trauma center (located within our Texas
Medical Center hospital); and one of five congressionally-designated**

“rehabilitation innovation centers,” The Institute for Rehabilitation and Research (TIRR-Memorial Hermann), the only such facility located in the Southern United States. The Memorial Hermann Community Benefits Corporation (CBC) perennially contributes more in direct community investment to improving the health of our community than any other health system in our region. Memorial Hermann also maintains a robust innovation hub, through which our system engages strategic partners, such as Zipline International, Inc., allowing our system to pursue its strategic goals of expanding access to, and bringing down the cost of care for our community.

While Memorial Hermann, and its approximately 1500-member pharmacy service line, appreciates the considerable generosity of time the Texas Board of Pharmacy board members and staff have afforded us over the course of the last year, as the board has considered proposals contemplating drone delivery of prescription drugs, and supports adoption of the board’s proposed draft rules, we would respectfully suggest a number of modifications to the draft rules as recently published in the Texas Register:

- 1. Memorial Hermann respectfully request removal of the exclusion for “drugs requiring storage below a ‘cool’ temperature,” in Subsection 291.12(e).**

We believe this exclusion restricts a significant number of products our system feels can be safely and reliably delivered by our transportation partner, Zipline. Zipline has an 8-year track record of successful deliveries of drugs requiring storage below a “cool” temperature, having made nearly a quarter million such deliveries. As is currently the case for Memorial Hermann’s pharmacy service line’s ground transportation service providers, our pharmacies will ensure that our drone deliveries will utilize safe, temperature-controlled packaging, which is validated through industry-standard, third-party testing labs. Our system believes the exclusion, as proposed, would preclude us from providing some of our most vulnerable patients with prescription drugs that are critical to

their management of chronic illness. One of the reasons Memorial Hermann has enthusiastically pursued its relationship with Zipline is our commitment to improving the health of our community, and belief that drone deliveries will significantly reduce the time it takes for us to deliver critical prescriptions to our patients, as contrasted with delivery times we experience with our current ground delivery service providers.

2. Memorial Hermann respectfully request removal of Subsection 291.9(c), restricting drone deliveries to residential homes only.

We believe this provision, if adopted, will limit the ability of health systems and their patients to receive prescription drugs, via drone, within hospitals, outpatient healthcare facilities, pharmacies, or an emergency or crash site. In contemplating our engagement with Zipline, Memorial Hermann has planned on the ability to utilize drone deliveries within our health system, as another strategy designed to provide quicker access to critical medications for our patients. We also assert that our system facilities, within which we would propose delivering prescriptions via drone, are more secure than many of our patients' homes.

3. Memorial Hermann respectfully requests modification to Subsection 291.12(e)(6), relating to a patient's "confirmation of presence at residence."

We agree with Zipline's assertion that the rules applicable to ground transportation service providers are sufficient for drone deliveries, which offer comparable confirmation and security features than for ground deliveries. As we have observed throughout our engagement with Zipline, and our visits to its facilities, in order to receive a drone delivery, our patients will have to affirmatively opt in through our pharmacies. Patients will be able to track their deliveries, as is not the case for many ground delivery services. Our patients will be notified at the time their delivery has been dispatched and is en route, and patients will be able to monitor their deliveries in real time, to ensure accurate and timely delivery. Upon receipt of a delivery, our patients will be able to verify receipt with Zipline and with our dispensing pharmacy.

Memorial Hermann appreciates this opportunity to provide written comments relating to the Texas Board of Pharmacy's proposed draft rules published in the March 21, 2025, Texas Register, and also plans to provide public comment during the May 6 board meeting. I and my team would be happy to respond to any questions or comments board members or staff may have in advance of the May 6 meeting.

Respectfully,

A handwritten signature in cursive script that reads "Binita Patel".

**Binita Patel, PharmD, MS, CPEL
Vice President, Pharmacy Service Line
Memorial Hermann Health System
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Houston TX 77024
Binita.patel@memorialhermann.org
(262)391-9415**



April 25, 2025

Via mail and email

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy
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1801 Congress Avenue, Suite 13.100
Austin, Texas 78701
Email: eamon.briggs@pharmacy.texas.gov
Fax: (512) 305-8061

Dear Mr. Briggs:

Zipline International Inc. thanks the Texas State Board of Pharmacy for the opportunity to comment on the proposed amendments to 22 TAC § 291.9, Prescription Pick Up Locations, and § 291.12, Delivery of Prescription Drugs (Tex. Reg. Mar. 21, 2025) (together, the “Draft Rule”). We commend the Board and the State of Texas for expanding Texans’ access to prescriptions by incorporating delivery via unmanned aircraft systems (“UAS”) operators.

We fully support passage of the Draft Rule and share the Board’s commitment to patient safety and drug integrity. UAS technology is capable today of transporting a broad array of medical products to improve the lives of patients and overall health of communities. Our letter highlights some of Zipline’s specific capabilities and the benefits they can bring to prescription drug delivery.

For the Board’s consideration, further below, we respectfully offer refinements to three provisions that align with that commitment while making the rule more durable and administrable.

I. With a proven track record of successful healthcare deliveries via UAS, Zipline has designed its services in Texas to support safe, compliant transport of prescription drugs.

Zipline operates the largest drone delivery service in the world. We design, manufacture, and operate unmanned aircraft systems that deliver medical supplies, healthcare goods, and consumer products. We started by delivering blood to health systems in Rwanda in 2016 and have grown to operate in eight countries, including operations in the United States since 2020 in support of COVID-19 responses. Zipline’s aircraft, flight paths, maintenance, and training are all regulated by and accountable to the Federal Aviation Administration. Zipline has flown more than 100 million autonomous miles and made more than 1.5 million deliveries to customers to date.

In 2025, Zipline launched commercial UAS delivery services in the Dallas/Fort Worth area and is ready to begin safely delivering prescription drugs to Texans *today*—as soon as the rules allow. We and our healthcare partners are confident that Texans will choose Zipline because they love our fast, safe, and sustainable UAS.

We understand and share the Board’s focus on ensuring that innovative technologies satisfy high standards of safety, security, and integrity. Helping pharmacies meet these standards in their deliveries is foundational to our service model, and our safeguards are specifically designed to address them.

Our operations and technical offerings include:

- A. Demonstrated success delivering hundreds of thousands of medical commodities requiring storage below a “cool” temperature.** Zipline has eight years of experience with cold chain delivery. We have made over 240,000 deliveries of medical products requiring storage below a “cool” temperature, including in the United States, and make an average of 240 cold chain deliveries every day. Examples of the medical products we deliver include the Oral Polio Vaccine and Measles and Rubella, Pentavalent, and Pneumococcal Conjugate Vaccine—as well as cold or frozen whole blood, fresh frozen plasma, and platelets, and cold anti-venom treatments.¹

Moreover, Zipline’s cold chain experience includes delivery of the mRNA COVID-19 vaccine with ultra-cold chain requirements. As part of this effort, Zipline worked with Pfizer and BioNTech to test and validate an end-to-end model vaccine delivery solution, pioneering new solutions to expand vaccine access.
- B. Integration with pharmacy-provided packaging solutions that are validated to meet safety standards.** Zipline’s UAS services are designed to integrate with pharmacies’ existing, temperature-controlled packaging. This packaging is validated through industry-standard third-party testing labs and is often the same packaging already used for ground transport.
- C. Dedicated direct delivery without stops—one package, one aircraft, one patient.** To address limitations of traditional delivery, Zipline’s UAS delivers prescriptions directly from the pharmacy to the patient. Each autonomous flight carries a single delivery, for a single recipient—eliminating unnecessary hand-offs, avoiding package mix-ups, and reducing exposure to delays or extended routes.
- D. Advantages of speed.** Designed to avoid traffic congestion and similar delays, Zipline’s UAS can make a ten-mile delivery in about ten minutes, even during rush hour. See Appendix A: Example of Estimated Transportation Time Efficiencies from UAS Delivery. Data from Zipline’s operations in Dallas so far show that the average one-way flight time of a delivery is under 3.5 minutes.
- E. Pre-scheduled, effective delivery windows.** To receive Zipline delivery, patients affirmatively opt in through their pharmacies and coordinate a delivery window during which they will be home to receive the delivery. That window is typically far narrower than the eight- or 24-hour windows often provided by traditional ground methods.
- F. Patient-designated delivery location for enhanced security and reliability.** Instead of relying on couriers to leave packages in unsecured, publicly accessible areas, patients may choose—and expect—an exact delivery location, such as a secure location in a fenced backyard. The patient also confirms that the delivery location will be accessible and safe during the delivery window. This reduces risk of loss and improves reliability. See Appendix B: Selection of Delivery Location.

¹ As a relevant aside, we also regularly make deliveries in the United States of refrigerated and frozen perishable foods, including ice cream, eggs, and meat.

G. Real-time tracking and transparency for precision and predictability. Unlike many ground delivery systems, Zipline offers notifications when delivery is dispatched, an updated window, and real-time tracking, giving patients visibility and control so they can be in the right place at the right time to receive their delivery. See Appendix C: Real-Time Tracking.

H. Timely, verification-enabled pharmacy follow-up. Zipline’s system enables patients to verify receipt of their deliveries, with data shared directly with the pharmacy for documentation and follow-up. See Appendix D: Delivery Notification & Verification.

II. Zipline respectfully offers three narrowly-tailored and operationally-informed refinements to the Draft Rule.

A. To reflect operational realities while maintaining accountability, revise Subsection 291.12(e)(6) to shift responsibility to the delivery provider to confirm that the patient will be present at the time of delivery.

We support the Board’s intent to ensure medications are not dispatched without a patient available to receive them.² As drafted, however, the rule requires pharmacies to confirm patient presence at the home prior to dispatch, even when it is a third-party UAS operator that is conducting the delivery. While this mandate may be workable in the limited situations where the pharmacy is *also* the UAS operator, it creates operational friction for most cases, where the UAS operator will be a third party—not the pharmacy itself. In the lion’s share of cases, the rule would add layers of communication and handoffs between the pharmacy, the patient, and the delivery provider, increasing the likelihood of delays. By contrast, UAS operators directly manage dispatch and are best positioned to confirm patient presence before initiating delivery. Without relaxing safety standards, Zipline’s proposed amendment would more closely reflect operational realities while still holding pharmacies responsible for selecting compliant providers.

We also recommend clarifying that the patient must confirm they *will be* present at the time of delivery to reduce ambiguity. This better aligns with the rule’s apparent intent to ensure timely receipt. For example, a patient who confirms they are returning home in two minutes should still be eligible for delivery, while one who confirms presence but immediately leaves may not meet the spirit of the requirement.

B. Amend Subsection 291.12(e) to empower pharmacies to exercise their professional judgment to choose UAS delivery for cold chain drugs and sterile compounds when it is a safe, appropriate option based on individualized patient needs.

We respectfully recommend removing the categorical exclusion for “drugs requiring storage below a ‘cool’ temperature” and instead allowing pharmacies to choose cold chain delivery when they are satisfied that validated controls are in place. The exclusion’s sweep restricts a wide range of medications that can be safely and reliably delivered by UAS. In fact, many of the excluded products would be among the most critical, such as insulin for diabetic patients, and include precisely the use cases our healthcare partners are most eager to support with UAS delivery.

² Because UAS delivery providers can provide comparable—if not better—tracking and security than ground transport, Zipline believes that omission of this provision in its entirety would be appropriate and better promote tailored adherence to relevant safety standards. To the extent the Board wishes to retain the provision, however, we submit for consideration the following revision to Subsection 291.12(e): (6) Confirmation of presence at residence. The pharmacy is responsible for ensuring that an unmanned aircraft system delivery service shall receive confirmation from the patient or patient’s agent that the patient or patient’s agent will be present at the delivery location~~residence~~ before unmanned aircraft system delivery is initiated.

An outcome-based standard—focused on whether the medication arrives within the required temperature range—would better serve patients than a categorically prescriptive standard focused on mode of delivery. We are confident about our ability to meet or exceed relevant quality-controlled standards. Zipline’s systems, for example, use validated packaging provided by the pharmacy to maintain compliance across delivery windows, just like ground transport options. In fact, UAS delivery can offer *better* cold chain performance than traditional logistics models: it is faster, more direct, and avoids the extended custody times and multiple stops common with ground transportation.

Importantly, our proposed revision would not impact pharmacy accountability: just as with ground transport, Texas pharmacies retain responsibility for upholding standards and ensuring thoughtful, compliant selection of delivery providers. The revision would empower pharmacies to use their judgment and expertise to tailor care to individualized patient circumstances and needs while preserving the Board’s standards for patient safety.

C. Enable access to delivery to secure, patient- and pharmacy-authorized locations by removing Subsection 291.9(c), which restricts UAS deliveries only to residential homes.

Similar principles of pharmacy autonomy and patient choice support allowing UAS delivery to secure, pharmacy-authorized locations that are available for ground delivery. In particular, excluding sites such as secure clinics, medical campuses, and doctors’ offices limits critical use cases, including interfacility delivery and access for patients who receive care in infusion centers and outpatient or long-term care settings. In many cases, these secure locations offer better control and clinical oversight than a doorstep. And as noted above, with Zipline, pharmacies already take steps to determine an appropriate delivery window with the patient, and we provide additional safeguards like real-time tracking and recipient verification to support authorized receipt.

Pharmacies are well-positioned to assess the appropriateness and security of currently excluded locations based on patient consent and professional standards, as they already do when assessing ground transport. In deciding whether to use UAS delivery where it meets those standards, pharmacists should be able to weigh the security- and integrity-enhancing features of a given UAS service, patient needs, and other individualized factors. By holding UAS providers to the same safety expectations as traditional couriers, with pharmacy oversight, this approach would support better access without compromising integrity.

III. There are strong policy rationales for adopting a future-ready rule that incentivizes innovation and empowers pharmacists to use their professional judgment.

Zipline appreciates the Board’s thoughtful approach to modernizing pharmacy rules and sees this Draft Rule as a key opportunity to adopt a durable, forward-looking framework that supports innovation and improves patient access. The revisions Zipline proposes are grounded in core related policy principles:

A. Preserving pharmacist autonomy, professional judgment, and individualized care determinations alongside patient choice. Pharmacists are already accountable for the safe and appropriate delivery of medications. Maintaining this discretion supports individualized care, aligns with existing practice standards, and ensures pharmacists remain responsible for delivery decisions, whether by air or ground. A pharmacist would not authorize UAS delivery if it cannot be performed safely or if a patient does not want it. Conversely, if UAS delivery is the safest option for a given situation where ground delivery is permitted, the pharmacist should be empowered to select it.

B. Incentivizing innovation to improve safety features. The Draft Rule’s categorical limits on UAS delivery—especially where ground couriers are permitted—risk discouraging innovation.

Rules should incentivize all delivery providers, regardless of mode, to develop the safest and most effective methods for transporting medications, whether for cold chain use cases or non-residential deliveries. Blanket bans risk deterring investment in better models of care.

- C. Avoiding disproportionate burdens on independent and locally-owned pharmacies.** Operational mandates that lack a clear safety rationale, including rigid confirmation steps or delivery location restrictions, could unintentionally exclude smaller providers from participating in innovative delivery models, undermining both competition and patient access.
- D. Building a future-proofed, consistent framework that supports efficient regulatory processes.** By adopting a Draft Rule that uses a consistent, mode-neutral standard—anchored in safety outcomes and enforced through pharmacy oversight—the Board can reduce the need for frequent updates and comment periods while supporting high-quality care as evolving technologies continue to meet and exceed safety and traceability benchmarks used in traditional modes.

IV. Conclusion

We thank the Board for its thoughtful work on these important regulatory updates and the opportunity to contribute our perspective. We strongly support the Board's efforts to modernize its rules to reflect evolving technologies and care models, and we view the successful adoption of the Draft Rule as a top priority. While we respectfully recommend targeted revisions to ensure the rule is durable, practical, and inclusive, our goal is to strengthen—not delay—this important step forward. We welcome continued collaboration as the Draft Rule moves toward implementation. Please let us know of any questions or additional information we can provide.

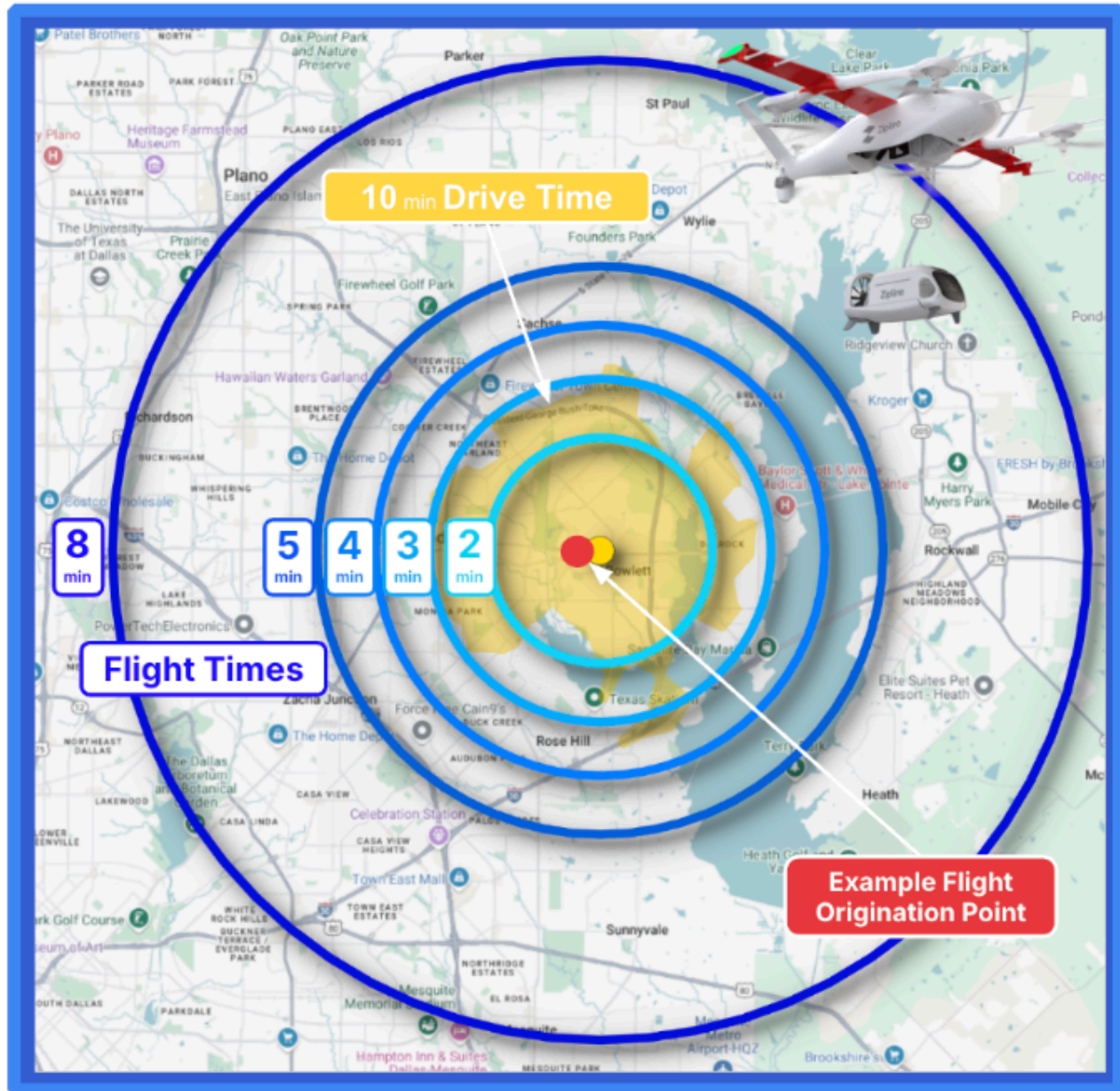
Respectfully,

Keval Patel

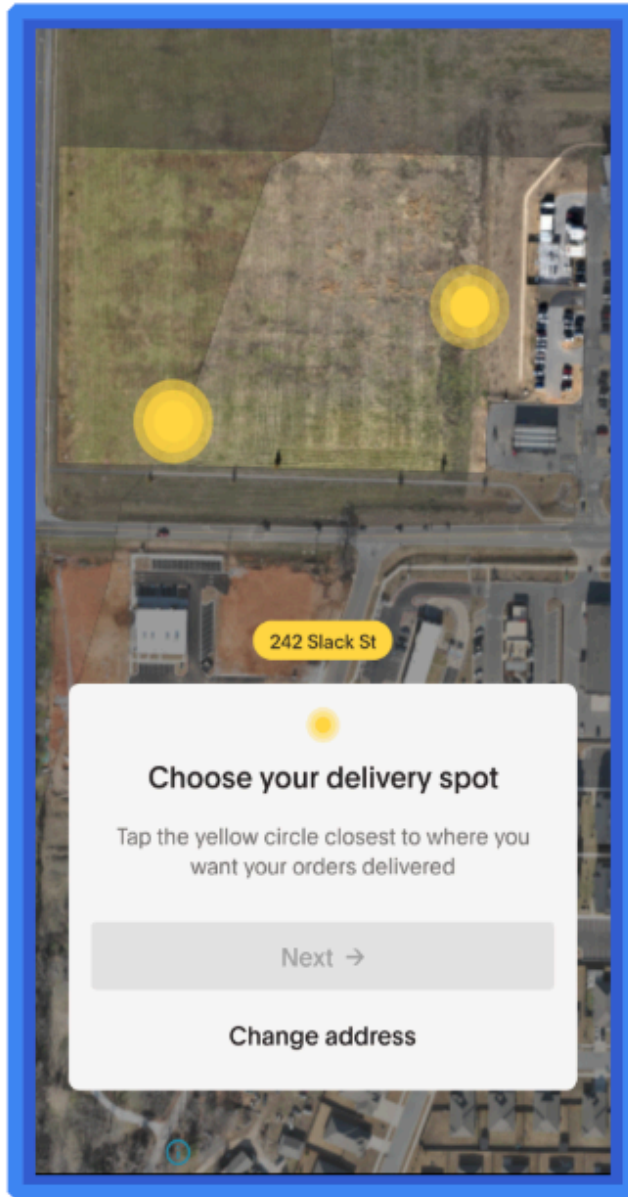
Keval M. Patel
General Counsel
Zipline International Inc.
333 Corey Way
South San Francisco, CA 94080

Illustrative Examples of Zipline's Capabilities

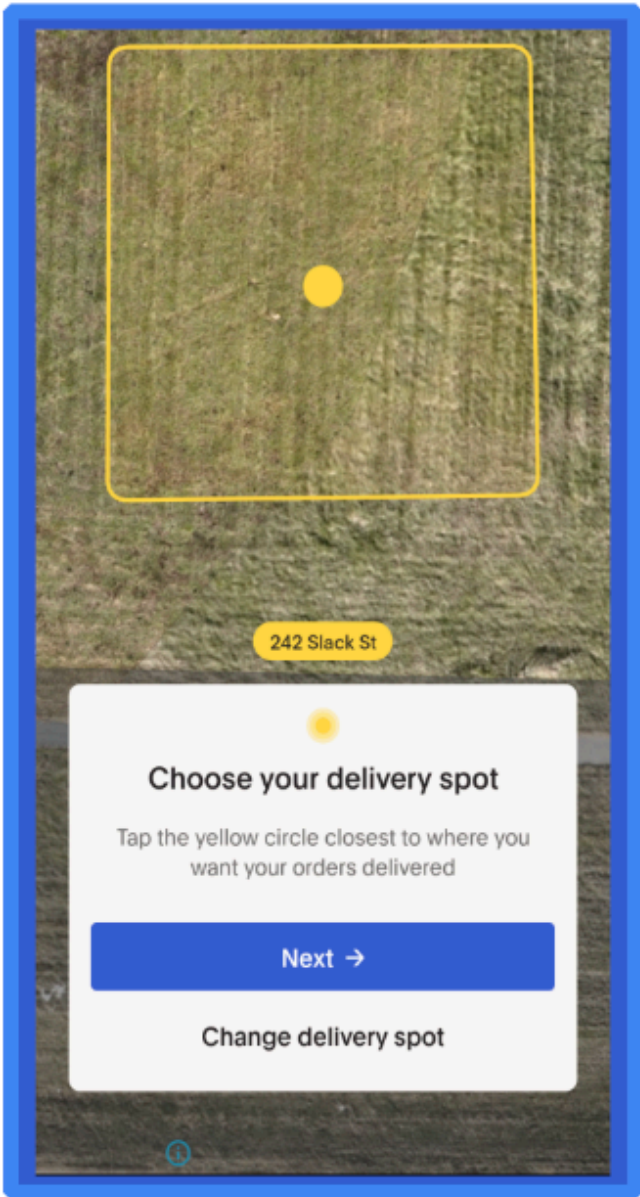
Appendix A: Example of Estimated Transportation Time Efficiencies from UAS Delivery



Appendix B: Selection of Delivery Location

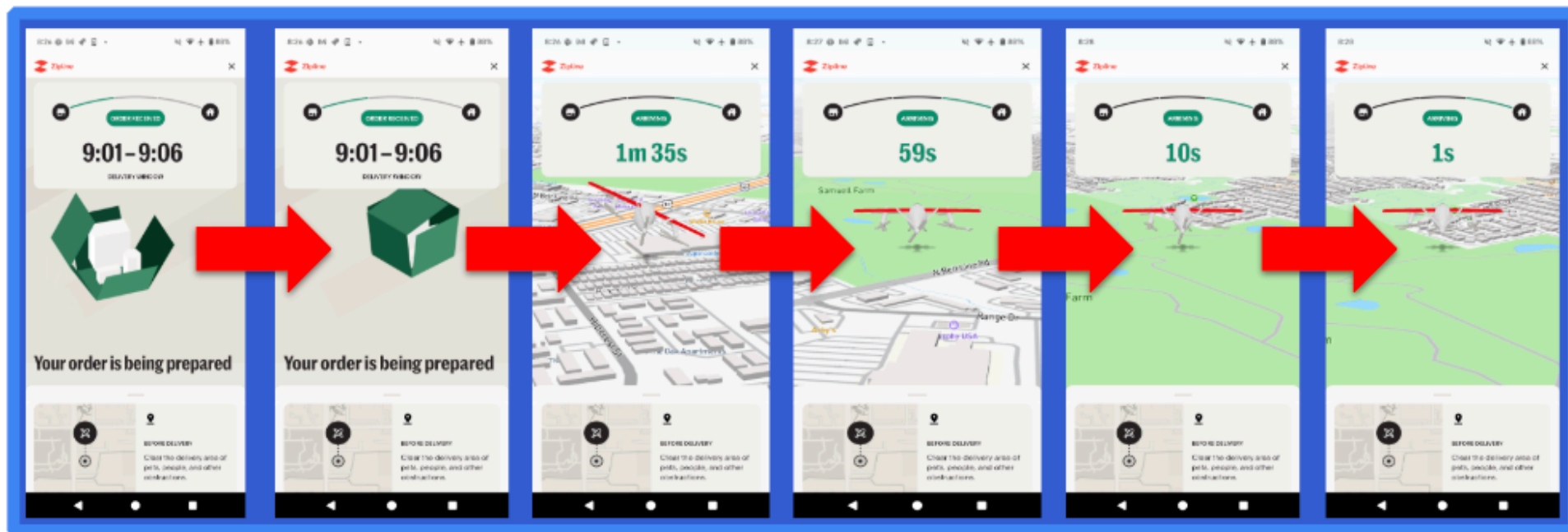


With Zipline, the patient—not the courier—chooses the delivery spot.



Our UAS will deliver to that selected location, so patients know where to be to receive their package.

Appendix C: Real-Time Tracking



Appendix D: Delivery Notification & Verification

