

# From Implementation to Investigation: Practical Guidance for Pharmacists in the Telehealth Era

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## ACPE Information

From Implementation to Investigation: Practical Guidance for Pharmacists in the Telehealth Era has been accredited by ACPE for pharmacists and technicians.

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Megan Davis and Derek Davis have no conflicts of interest or financial relationships in regards to this program.



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## Conflict of Interest Disclosure

- I declare that neither I nor any immediate family member have a current affiliation or financial arrangement with any potential sponsor and/or organization(s) that may have a direct interest in the subject matter of this presentation.



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## Learning Objectives

- At the completion of this activity, the participant will be able to:
  - Explain the role of telehealth platforms and risks/benefits of certain business arrangements.
  - Describe the role of telehealth's impact on pharmacists, including the pharmacist's responsibility in ensuring telehealth prescriptions are valid.
  - Provide examples of enforcement actions involving telehealth providers, platforms, and pharmacies.



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## Overview

- Telehealth Defined
- Pharmacy – Telehealth Business Model Example
- Roles and Requirements Among the Participants
- Telehealth Regulatory Trends and Related Affects on Pharmacy
- Impacts of Compliance on Pharmacy Services
- Potential Solutions and Strategies



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## “Telehealth” – What is it?



**Kids during telehealth meetings:**



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## “Telehealth” – What is it?

- “Telehealth service” – A health service delivered by a health professional acting within the scope of the health professional’s license to a client at a different physical location than the health professional using telecommunications or informational technology. 16 Tex. Admin. Code § 100.61(4).



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## “Telehealth” – What is it?

- “Telehealth” means the interactive use of audio, visual, or other electronic media, including asynchronous store-and-forward technologies and remote patient monitoring technologies, for the purpose of diagnosis, consultation, or treatment. Ariz. Rev. Stat. § 20-1057.13(G).

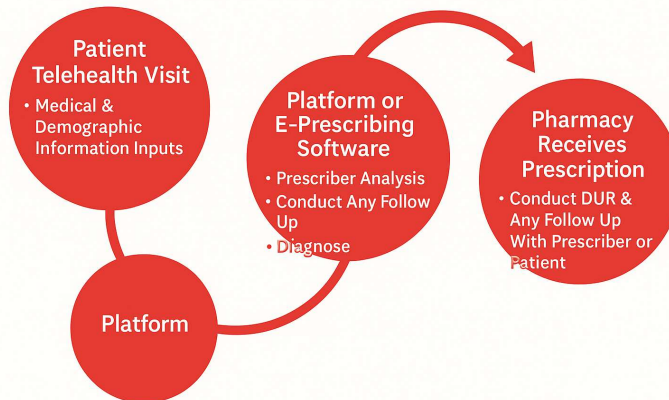


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## How it Works – Telehealth Services Model

### Telehealth Services Model Example



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## The Telehealth Players & Their Responsibilities

- Patient
- Provider
- Platform
- Pharmacy



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## The Telehealth Player: Patient Responsibilities

- The ideal telehealth patient does the following:
  - Provides complete and accurate information
  - Signs consents and required disclosures advising them:
    - Treatment is based on the information provided
    - May be referred for in-person care
    - If seeking something specific, then the healthcare provider may find that a different treatment is more appropriate for the condition diagnosed



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## The Telehealth Player: Provider Requirements

- **Practice Within Scope**  
Ensure all services are delivered within the provider's licensed scope of practice.
- **Licensure Compliance**
  - Verify and meet all applicable licensure requirements.
  - Confirm the patient's physical location at the time of the telehealth encounter, as licensure is often state-dependent.
- **Establish a Valid Provider–Patient Relationship**  
Build a legitimate clinical relationship through appropriate communication and documentation methods.
- **Clinical Evaluation & Standard of Care**
  - Accurately identify the patient's condition using accepted methods.
  - Deliver care that meets or exceeds the standard of care equivalent to in-person visits.



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## Provider Licensure Requirements – State Examples

- When physicians treat patients across state lines through telemedicine, it is usually seen as the physician, not the patient, who is traveling across state borders.
- “Health care services delivered by a physician *licensed in this state* [Texas].” Tex. Occ. Code § 111.001.
- “Physicians, physician assistants and advanced practice registered nurses who use telehealth in the examination, diagnosis, consultation or treatment of a patient located in Maine shall hold an active Maine license or shall hold an active registration in Maine to provide interstate consultative telemedicine services.” Me. Admin. Code 02-373 ch.11 § 3(2).



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## Provider Licensure Requirements - Exceptions

- Some statutory exceptions for **consulting physicians** – A provider must be licensed in Kentucky with the exception of persons who, being nonresidents of Kentucky, and lawfully licensed to practice medicine or osteopathy in their states of actual residence, *infrequently engage in the practice of medicine or osteopathy in this state*, when called to see or attend to *particular patients in consultation or association* with a Kentucky-licensed physician. Ky. Stat. Ann. § 311.560.
- Physician medical licensure laws do not apply to a physician or surgeon residing on the **border of a contiguous state** [if certain requirements are met]. Ohio Rev. Code § 4731.36.



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## Provider: Establishing a Valid Provider-Patient Relationship - Example

- “Proper practitioner-patient relationship” performance of a **history** and in-person (or telehealth) physical examination of the patient adequate to **establish a diagnosis** and to **identify underlying conditions or contraindications** to the treatment recommended or provided. Ark. Code Ann. § 17-92-1003(15).



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## Provider – Validity of a Telehealth Prescription, Example

- Validity of the prescription issued as a result of a telemedicine visit is determined by the same standards that would apply to the issuance of the prescription in an in-person setting. 22 Tex. Admin. Code § 217.24 (Physicians).



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## The Telehealth Platform - Responsibilities

- **Contractual Obligations**

Follow all obligations in provider agreements.

- **Protect Data**

Ensure privacy and security under HIPAA (if applicable) and state laws.

- **Screen Provider Licensure**

Verify providers are licensed where care is delivered.

- **Support Clinical Workflows**

Collect only clinician-approved health information.

- **Transmit Data Accurately**

Deliver records without delay or alteration.

- **Avoid Kickbacks**

Prohibit improper marketing or referral incentives.



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## Roles and Responsibilities for the Telehealth Platform

- The Platform and the contracted Providers have to be on the same page.
- Physicians utilizing telemedicine medical services in their practices shall adopt protocols to prevent fraud and abuse through the use of telemedicine medical services. In order to establish that a physician has made a good faith effort these protocols must be consistent with the standards of ...§ 531.02161 of the Government Code. 22 Tex. Admin. Code § 174.3.



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## Role and Responsibility of the Pharmacy Receiving Prescriptions

### Prescription Processing Responsibilities

- **Verify Completeness**  
Ensure all required prescription elements are present.
- **Follow Policy & Procedure**  
Process according to internal pharmacy protocols.
- **Evaluate for Red Flags**  
Review DUR, PDMP, prescriber credentials, and data accuracy before dispensing.



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## Role and Responsibility of the Pharmacy Receiving Prescriptions

### State Law Compliance Check

- **Verify Legality**  
Confirm the drug and condition are permitted under applicable state law.
- **Common Restrictions:**
  - Controlled substances for pain via telehealth
  - Weight loss medications
  - Abortifacients



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## Assessment: Who Does Each Role?

- Who is responsible for obtaining proper patient consent before the telehealth visit?
- Who must verify that the provider holds an active license in the patient's location?
- Who ensures the telehealth visit complies with the standard of care?
- Who is accountable for establishing a valid provider–patient relationship?
- Who transmits the patient's information to the provider during the telehealth process?



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## Telehealth Regulatory Requirements and Considerations Affecting Pharmacies

- Controlled Substances
- Licensure
- Provider Types
- Technology



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## Regulatory – Controlled Substances

- Increased access to care for conditions that require treatment with controlled substances viewed with a mix of suspicion and relief
- DEA and states not aligned on requirements for telehealth
- Strategies the industry developed in the face of the opioid crisis & subsequent regulatory fallout do not transfer well to telehealth. Geography, for example, is not a measure of the validity of care



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## Controlled Substance Trends – Effect on Pharmacies

- Continued complexity in determining whether the pharmacy can fill the prescription when DEA and state have different requirements
- Risk of filling invalid controlled substance prescriptions that has always existed continues to exist
- Increases importance of checking PDMP as strategy to confirm prescription validity



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## Regulatory – Prescriber Licensure

- States increasingly offering out-of-state providers telehealth-specific licenses in lieu of the full license to practice in their state
- Exceptions to licensure may mean that the prescriber is not licensed in the state where the patient lives or telehealth encounter occurred
- Lawsuits targeting state-specific licensure for healthcare providers



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## Regulatory – Prescriber Licensure

- Unless an exception applies, the prescriber must be licensed in the state where the patient is located at the time of the telehealth visit.
- Exceptions in some states include:
  - Licensure not required if prescriber is located in a bordering state
  - Licensure not required if care is follow up to care provided to that person elsewhere
  - Licensure not required if the patient was in the state temporarily
  - Consultation and collaborating physicians



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## Regulatory Trends

- State associations and licensure compacts – An increasing number of states are joining interstate licensure compacts or associations to simplify the licensing and credentialing process.
- Some licensure compacts focus solely on streamlining the application process, while others allow providers to deliver care in member states without needing additional licenses.



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## Regulatory – Provider Licensure

There are many compacts in existence or in the process of gathering member states, some examples include:

- Interstate Medical Licensure Compact
- Physical Therapy Compact
- Occupational Therapy Compact
- Nurse Licensure Compact
- APRN Compact (pending)



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## Prescriber Licensure Trends – Impact on Pharmacies

- Difficulty in verifying prescriber licensure based on the patient's address, the pharmacy's location, and the prescriber's location.
- Access to reliable tools and resources can assist pharmacies in making timely and accurate licensure assessments.



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## Regulatory – Provider Types

- Increased demand for healthcare providers expands opportunity for different types of providers to practice at the top of their license in the telehealth context, including prescribing by
  - Physicians
  - Nurse Practitioners
  - Physician Assistants
  - Pharmacists



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## Regulatory – Provider Types

- An APRN must obtain a midlevel practitioner controlled substance registration to prescribe CIIICV. The collaborating physician must file with the PMP a notice of delegation of prescriptive authority. 225 ILCS 65/65-40.
- An advanced practice nurse with prescriptive authority must, among other things, maintain geographic proximity to collaborating physician. 848 Ind. Admin. Code 5-1-1.



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## Provider Types – Impact on Pharmacies

- Limits on practice and state-specific collaboration requirements for nurse practitioners or physician assistants can make it impossible for a pharmacy to quickly determine whether that person met all requirements in issuing the prescription.



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## Regulatory - Technology

- Differing state laws on modalities
- Real time audio-visual interactions vs. Asynchronous store-and-forward technology
- Condition-dependent



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## How Are Pharmacies Affected by Telehealth Compliance?



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## Telehealth – Impact on Pharmacy Business

- Investors into the business may be discouraged by noncompliance or murkiness that reduces value
- New transactions may be more difficult, costly, or delayed
- Potential partners could go elsewhere due to reputation or risk profile of related partners
- Enforcement actions detract from patient care, affect individual licenses, may inhibit operating altogether



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## Pharmacy Business – Potential Solutions

- Vendor Vetting and Selection
- Platform Services
- Contracting
- Compliance



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## Strategies

- Policies and practices related to prescription validity must be sound and supportable.
- Vetting business partners and understanding their relevant compliance strategies can be a measure of protection in this interlinked context.
- Monitor legal changes in states served
- Incorporate telehealth into the compliance program
- Document training and processes related to prescription validity confirmation.



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## Contracting Strategies

- Understand relevant insurance coverage, for example ensuring that it covers telehealth-related services
- Indemnification for vendor non-compliance in any respects
- Allocate compliance obligations and risks relevant to the entity's role in the arrangement & what each is actually capable of controlling (hint: what the pharmacy can control may be quite limited)



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## Vendor Selection Strategies

- Ask about their compliance program.
- Ensure that the agreement requires delivery, repair, and maintenance services to facilities smooth operations
- Consider references for the vendor
- Technical capabilities, including data security
- Consider using an RFP process to compare vendors



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## Examples of Ways the Platform Provider Could Help Pharmacies

- Ensure patients are connected only to practitioners licensed in the state where the patient is located
- Have a reliable, documented, secure system for verifying patient identity before they meet with the telehealth practitioner
- Code the software to block therapies and prescriptions from the practitioner for conditions or medications that are prohibited in the patient's state



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# Enforcement Issues



## Regulatory, Criminal, and Litigation Actors

- Drug Manufacturers
- Telehealth Platform
- Pharmacies
- Telehealth Prescribers
- Patients (direct/indirect)
- Health Insurance Companies
- Department of Justice
- Texas Attorney General
- Boards of Pharmacy, Medicine and Nursing



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## Texas v. Carpenter

- Dr. Margaret Daley Carpenter, a New York doctor and founder of the Abortion Coalition for Telemedicine, provided a Collin County, Texas resident with abortion-inducing drugs that ended the life of an unborn child and resulted in serious complications for the mother, who then required medical intervention.
- Drugs Involved were:
  - Mifepristone
  - Misoprostol



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## Texas v. Carpenter – Texas AG Action

### The state sought:

- Injunctive Relief (temporary and permanent) focused on the unlicensed practice of medicine in Texas, the illegal provision of abortion-inducing drugs and violations of Texas's anti-abortion laws.
- Civil penalties (no less than \$100,000 for each violation)
- Legal fees

### Outcome:

- Dr. Carpenter did not respond to the suit in Texas, a state judge issued a default judgment in February 2025 ordering her to pay a civil penalty of at least \$100,000 and permanently barring her from providing abortion pills to women in Texas.



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## Done Health

- Ruthia He and David Brody were the sole incorporators of Done, a self-proclaimed “digital health company” (platform) that operated on a subscription-based health care model for ADHD.
- “Done members” paid a monthly fee to the platform. Done advertised that it provided online diagnosis, treatment, and refills of medication for ADHD. Since the beginning of the COVID-19 pandemic, Done allegedly arranged the prescription of over 40 million pills of Adderall and other stimulants obtaining over \$100 million in revenue.



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Internet Archive: <http://donefirst.com/>

Wayback Machine 379 captures 19 May 2013 - 24 May 2025

ADHD Pricing FAQ Knowledge

Go OCT NOV 22 JAN 2021 2022 2023 About this capture

# ADHD shouldn't be this hard.

Online treatment made just for YOU

[Start a Free Assessment](#)

### It's as easy as this

- 1 minute assessment** – take an online clinical assessment to see if Done can help.
- 30 minute appointment** – available the same day, or as soon as next day, with one of our licensed ADHD clinicians.
- Get ongoing care at ease** – enjoy online visits, worry-free refills, 24/7 care with clinicians and care team.

1	MATTHEW M. YELOVICH (CABN 351330)	<b>FILED</b>  Jun 12 2024  Mark B. Busby CLERK, U.S. DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA SAN FRANCISCO
2	Attorney for the United States	
3	Acting under Authority Conferred by 28 U.S.C. § 515	
4	GLENN S. LEON (NYBN 250785)	
5	Chief	
6	Fraud Section, Criminal Division	
7	Attorneys for United States of America	
8	UNITED STATES DISTRICT COURT	
9	NORTHERN DISTRICT OF CALIFORNIA	
10	SAN FRANCISCO DIVISION	
11	UNITED STATES OF AMERICA,	CASE NO. 3:24-cr-00329 CRB
12	Plaintiff,	<u>VIOLATIONS:</u>
13	v.	21 U.S.C. § 846 – Conspiracy to Distribute
14	RUTHIA HE, A/K/A RUJIA HE, and DAVID	Controlled Substances;
15	BRODY,	21 U.S.C. § 841(a) and (b)(1)(C) – Distribution of
16	Defendants.	Controlled Substances;
17		18 U.S.C. § 1349 – Conspiracy to Commit Health
18		Care Fraud;
19		18 U.S.C. § 1512(k) – Conspiracy to Obstruct Justice;
20		18 U.S.C. § 2 – Aiding and Abetting
21		18 U.S.C. §§ 981(a)(1)(C) and 982(a)(7), 21 U.S.C. §
22		853(a), and 28 U.S.C. § 2461(c) – Forfeiture
23		Allegation
		SAN FRANCISCO VENUE
	<u>INDICTMENT</u>	
	The Grand Jury charges:	
	<u>GENERAL ALLEGATIONS</u>	
	At all times relevant to this Indictment, unless otherwise specified:	



## USA v. He and Brody

- Allegations:
  - Conspiracy to distribute and distribution of controlled substances
  - Conspiracy to commit health care fraud
  - Health care fraud
  - False statements related to health care matters
  - Conspiracy to obstruct justice
  - Tampering with consumer products
  - Intentionally obtaining controlled Substances through deception and subterfuge
- Action Pending: He and Brody each face a maximum penalty of 20 years in prison on the conspiracy to distribute controlled substances and distribution of controlled substances counts



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## Enforcement by Manufacturers



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## Eli Lilly v. Mochi, Fella, and Strive

- Eli Lilly manufactures Mounjaro® and Zepbound®, both GLP-1 products for the treatment of diabetes and weight loss management. They are tizepatide medications.
- The FDA declared a shortage of these medications in 2022
- Eli Lilly holds patents on these medications until at least 2036, although subject to challenges in 2026.
- Lawsuits filed in separate matters against telehealth companies marketing competitive compounded products



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## Eli Lilly v. Mochi, Fella, and Strive

- Telehealth Platform Allegations:
  - Selling unapproved compounded drugs
  - Deceptive and misleading advertising
  - Unlawful Corporate Practice of Medicine (CPOM) violations
- Pharmacy Allegations:
  - Selling Unapproved, Mass-Produced Drugs as “Personalized”
  - False Claims of Superiority to FDA-Approved Medicines
  - Misleading Statements Regarding Regulatory Compliance and Quality



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## Eli Lilly v. Mochi, Fella, and Strive

- Eli Lilly is seeking:
  - Declaratory Judgment
  - Injunctions (preliminary and permanent orders to stop production)
  - Corrective Advertising
  - Monetary Damages
- Cases are pending subject to discovery, motion practice, and trial



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## Have a prescription flu treatment and a COVID-19 test ready in your home.

Hello,

Flu season is coming, and this year we are facing both the influenza and COVID-19 viruses. To better prepare you, you are invited to join a new pilot program called Well At Home offered by UnitedHealth Research and Development. You are eligible because you may be at higher risk for complications if you get sick, and you could benefit from the program.

### Why join?

You will get a doctor-prescribed treatment of oseltamivir (Tamiflu®) to have at home in case you get the flu. Tamiflu is proven to reduce the severity and length of the flu—and the sooner it is taken, the more effectively it treats the flu.<sup>1</sup> Having this medicine already in your home lets you take it sooner if you need it, rather than making trips to a doctor's office and pharmacy.

Since the flu and COVID-19 have similar symptoms, you will also receive a COVID-19 test kit to have at home so you can complete a test from home if needed.

Joining Well At Home is voluntary and costs you nothing. Learn more and sign up at [WellAtHome.com](https://www.WellAtHome.com).

### Here is what you get after joining:



Prescription flu medicine



An easy-to-use thermometer



Immediate doctor access by phone to provide diagnosis and treatment guidance



A COVID-19 test



## TEXAS STATE BOARD OF PHARMACY

Re: [REDACTED]

License #3 [REDACTED]

### STATEMENT OF ALLEGATIONS

#### COUNT

On or about September 22, 2020, through on or about March 22, 2021, [REDACTED] and [REDACTED], while acting as employees (pharmacists-in-charge) of [REDACTED], allowed [REDACTED] to dispense and ship to Texas patients approximately 31,692 prescriptions for 10 oseltamivir 75 mg capsules that were not valid, in that they were not issued for a legitimate medical purpose by a practitioner acting in the usual course of medical practice. Specifically, the prescriptions were issued as part of the "Well At Home" program administered by United Healthcare, in which Medicare Advantage plan beneficiaries were invited to enroll and receive a preventative healthcare kit containing the oseltamivir, a thermometer, and a COVID-19 test. Patients completed an online questionnaire at the time of enrollment, which were reviewed by a practitioner without interaction with the patients to determine whether a prophylactic prescription for oseltamivir was warranted. The prescriptions were received and dispensed by [REDACTED] placed in a sealed container inside the kit, and shipped to patients with instructions not to open the container until directed to do so by a healthcare provider following a telehealth visit should they develop flu-like symptoms.



## Two Primary Questions Presented

- Are the prescriptions necessary for a legitimate medical purpose?
- Did a proper prescriber-patient relationship exist?



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## Legitimate Medical Purpose Defense

### Is oseltamivir effective?

Yes when administered within 48 hours of flu onset, clinical trials show oseltamivir reduces severity of the flu and risk of hospitalization in the general adult population:

Variable	Reduction (Control vs Treatment)	Population	Source
Risk of Hospitalization	<b>59%</b> (1.7% vs 0.7%; $p < 0.02$ )	Placebo Treatment	1,063 1,350 Kaiser et al, 2005 <sup>4</sup>
	<b>38%</b> (95% CI 26% - 48%)	No treatment Treatment	31,674 31,674 Peters et al., 2008 <sup>5</sup>
	<b>26%</b> (95% CI 0.61 – 0.90, $p = 0.004$ )	No treatment Treatment	775/60,427 110/11,632 Nordstrom et al., 2005 <sup>6</sup>
	<b>30%</b> (RR: 0.70, 95% CI: 0.60 to 0.82, $p < 0.0001$ )	No treatment Treatment	264/30,259 375/30,158 Gums et al., 2008 <sup>7</sup>



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## Legitimate Prescriber Defense

- Texas Telemedicine Act –
  - (b) This chapter is promulgated to clarify the requirements in Chapter 111 of the Texas Occupations Code related to the provision of telemedicine medical services. This chapter does not apply to out-of-state telemedicine licenses issued by the Board pursuant to §151.056 of the Act and §172.12 of this title (relating to Out-of-State Telemedicine License), federally qualified health centers (FQHCs), or to consultations provided by health insurance help lines.



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## Med Spa App Platform

- The App is the telemedicine platform
  - Provides no medical or pharmacy services
  - Just “referrals” to a physician/Botox injectors
- MSL – Provided Training and Certification for Injectors
  - No formal health care degree or training required
  - Certificate issued at the end of a one-day training course
- Medical Group
  - Oversight of contracted NP/PA Examiners
  - Responsibility for meds administered to Botox patients



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## Texas Medical Board

Mailing Address: PO Box 2018 • Austin TX 78768-2018  
 Location Address: 1801 Congress Suite 9.200 • Austin TX 78701  
 Phone (512) 305-7100 • Fax (888) 859-5336 • Website: www.tmb.state.tx.us

June 10, 2024

MD

Re: File # [REDACTED] (please refer to this number in future correspondence)

Dear Doctor [REDACTED]

The Texas Medical Board (TMB) has initiated a formal investigation concerning File# [REDACTED] to determine if a violation of the Medical Practice Act has occurred. The general statutory allegation is:

164.052(a)(17) AIDING/ABETTING IN UNLICENSED PRACTICE OF MEDICINE  
 164.053(a)(8) FAILURE TO SUPERVISE DELEGATES  
 164.052(A)(5) UNPROFESSIONAL CONDUCT  
 and more specifically relates to:

It has been alleged that you are the Medical Director for [REDACTED], and that you are the Chief Medical Officer for [REDACTED]. It has been alleged that you are aiding and/or abetting these individuals in the unlicensed practice of medicine in Texas as [REDACTED]. In addition, it has been alleged that the Texas Department of State Health Services inspected API [REDACTED] on 03-11-2024, and found many violations: staff were injecting patients with counterfeit filler (fake Restylane Lyft, fake Botox, and Fake Juvederm), staff were using fillers from foreign countries on patients which are not FDA approved; staff were using unapproved medical devices on patients from foreign countries; staff were providing therapies to patients using unapproved new drugs and/or drugs that staff made at their homes. Your delegates at [REDACTED] also advertise and treat a number of medical conditions with the products that are counterfeit, fake, non-FDA approved, and/or made by staff at their homes. Lastly, it has been alleged that you do not see or evaluate the patients before they receive medical treatments. Please furnish a narrative.

## Medical Spa Treatment

### CERTIFICATION

FOR RECEIVING TREATMENT (GFE)

[REDACTED] PLLC hereby certified that the following treatments have been approved for.

*E. B.*

TREATMENTS: BOTOX & OTHER NEUROTOXINS

Expiration Date: 10/05/2023



*[Signature]*

[REDACTED], PLLC  
 CHIEF MEDICAL OFFICER

[REDACTED]