

Navigating the Regulatory Maze: Telemedicine Compliance and Its Impact on Pharmacies and the Public Health



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Presenter

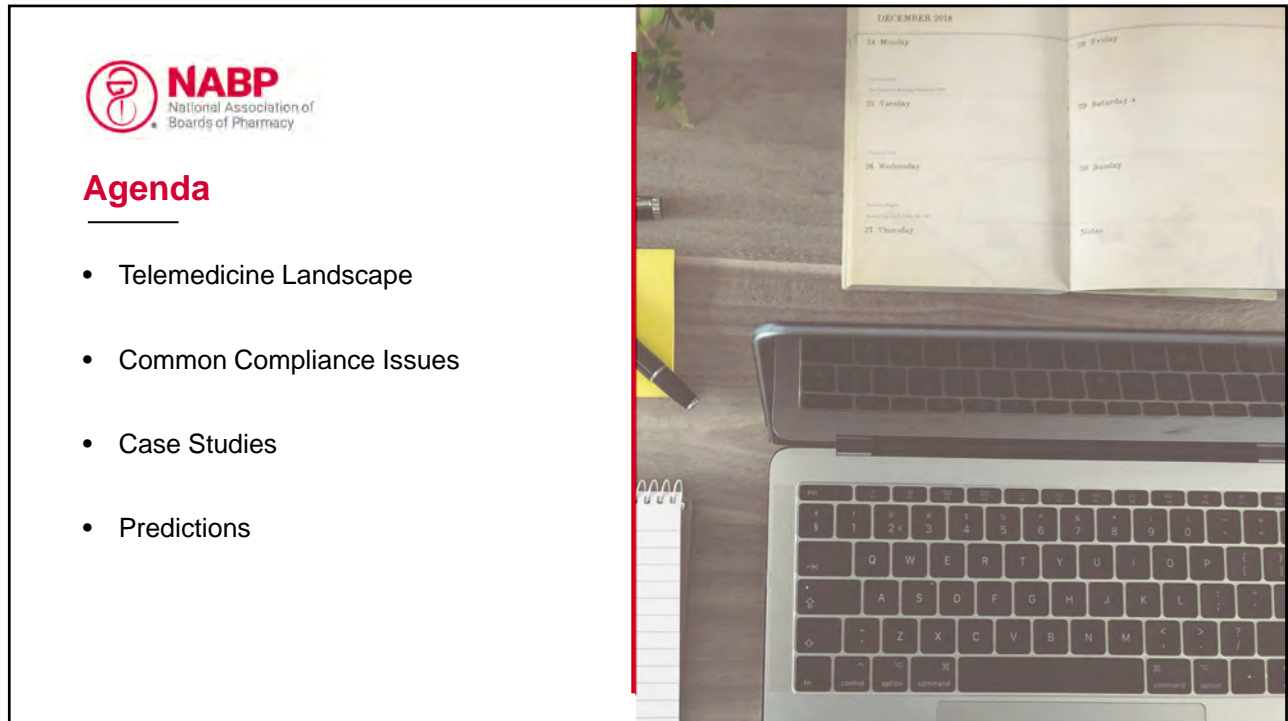


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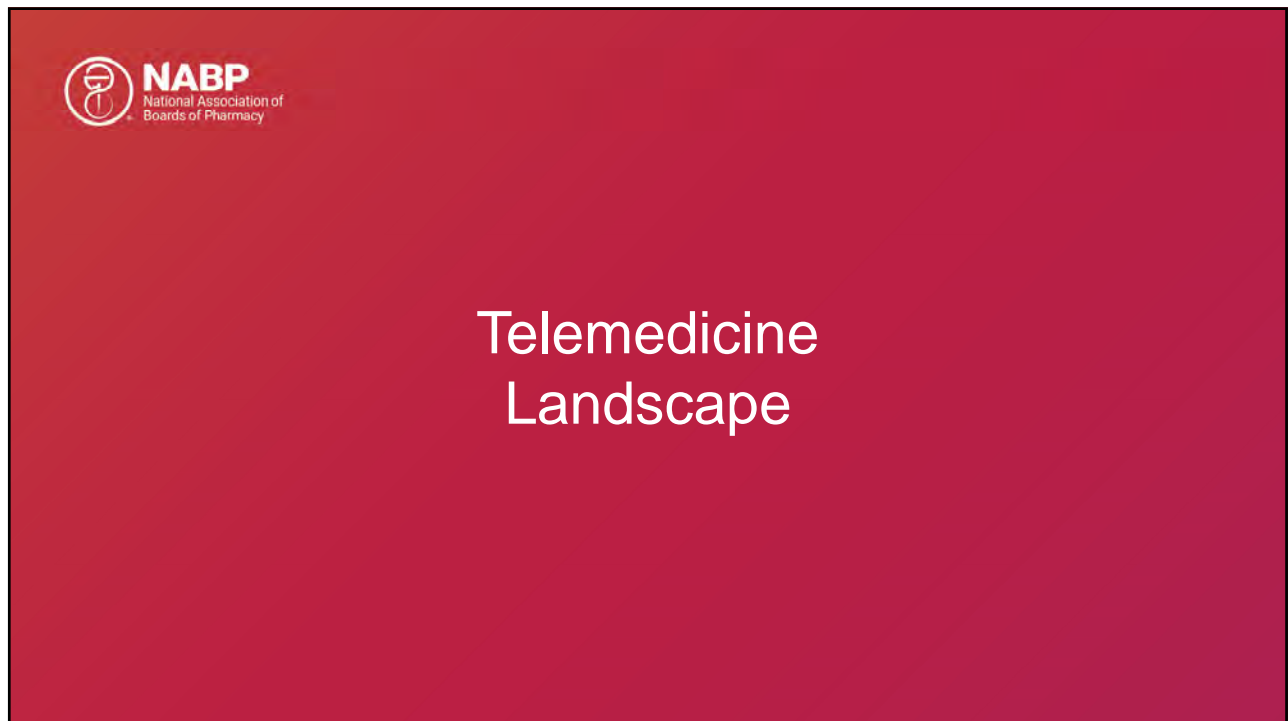
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The image is a composite. On the left is a white presentation slide with the NABP logo at the top left. The logo consists of a red circle containing a white caduceus symbol, followed by the text "NABP National Association of Boards of Pharmacy". Below the logo, the word "Agenda" is written in red and underlined. A bulleted list follows: "Telemedicine Landscape", "Common Compliance Issues", "Case Studies", and "Predictions". On the right side of the composite image is a photograph of a desk. A silver laptop is open, showing its keyboard. Behind the laptop is a calendar for December 2014, with dates from Monday the 21st to Sunday the 28th visible. A yellow sticky note is attached to the desk surface.

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The slide has a solid red background with a slight gradient. In the top left corner is the NABP logo, which includes a white caduceus symbol inside a red circle, followed by the text "NABP National Association of Boards of Pharmacy". Centered on the slide in a large, white, sans-serif font is the text "Telemedicine Landscape".

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Direct-to-Consumer Telemedicine Expansion

From Viagra to COVID to ADHD to GLP-1 agonists

The timeline shows four stages: 1998 with blue pills labeled 'VGR 100'; 2020 with a red and white coronavirus particle; 2020-2022 with a colorful brain diagram; and 2023 with two figures labeled 'Before' and 'After' showing a weight loss transformation.

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Business Model Risk Factors

The diagram features a balance scale where the left pan is lower, indicating lower risk, and the right pan is higher, indicating higher risk.

Lower risk

- Two-way, real-time audio-video
- Visits limited to preexisting patients
- Website has an affiliated brick-and-mortar medical clinic
- Treats many disease states
- Website does not promote individual drugs
- Offers services to a limited number of states

Higher risk

- Online questionnaire
- Subscription service model
- Offers services in all 50 states
- Offers to prescribe controlled substances
- Treats limited number of disease states
- Bundles telemedicine visit and shipment of prescription drugs
- Relationship between telemedicine platform and pharmacy
- Refunds consulting fee if patient does not get prescription

DOES THE TELEMEDICINE COMPANY ACCEPT INSURANCE?

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Common Compliance Issues

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Telemedicine Modality Requirements

- **“Telemedicine modality”** describes the mechanism(s) by which a patient has an encounter with a provider.
- Some states use modality to determine whether there is a **valid patient-practitioner relationship**.
- Telemedicine modality requirements are **state specific**.

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Examples of State-Specific Modality Requirements

Alaska

- **State Medical Board Rule:** “Unprofessional conduct” includes “providing treatment, rendering a diagnosis, or prescribing medications based solely on a patient-supplied history that a physician licensed in this state received by telephone, facsimile, or electronic format[.]”
- In Alaska, the key issue is that the **patient history cannot be patient supplied.**

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Examples of State-Specific Modality Requirements

Missouri

- **Pharmacy Rule:** “A pharmacist shall not dispense a prescription drug if the pharmacist has knowledge, or reasonably should know under the circumstances, that the prescription order for such drug was issued on the basis of an [i]nternet-based questionnaire [...]”
- **Telemedicine Statute:** “No health care provider shall prescribe any drug, controlled substance, or other treatment to a patient based solely on an internet request or an internet questionnaire.”
- **Statute Regarding How to Establish a Physician-Patient Relationship:** “A questionnaire completed by the patient, whether via the internet or telephone, does not constitute an acceptable medical interview and examination for the provision of treatment by telehealth.”

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Examples of State-Specific Modality Requirements

North Dakota

- **North Dakota Food, Drug, and Cosmetic Act:** “A controlled substance **or specified drug may not be** delivered, distributed, or **dispensed without a valid prescription**. It is also unlawful for a person to knowingly or intentionally aid or abet in these activities.”
- **“Valid prescription’** means a prescription that is issued for a **legitimate medical purpose** in the usual course of professional practice **by a practitioner who has conducted an in-person medical evaluation** of the patient.”
- **“Specified drugs’** mean [...] Phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.”

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Examples of State-Specific Modality Requirements

Wisconsin

- **Medical Examining Board Rule:** “Providing treatment recommendations, including issuing a prescription, based only on a **static electronic questionnaire** does not meet the standard of minimally competent medical practice.”
- Some states specifically call out “static” questionnaires.

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DEA Requirements are in Flux

- Under the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, a prescribing practitioner—subject to certain exceptions—**may prescribe controlled medications** to a patient **only after conducting an in-person evaluation** of that patient.
- In response to the COVID-19 Public Health Emergency, DEA granted **temporary exceptions** to the Ryan Haight Act. These “COVID telemedicine flexibilities” **expire on December 31, 2025**.
- Will DEA's updated requirements be stricter than what has been allowed for the past 4 years?

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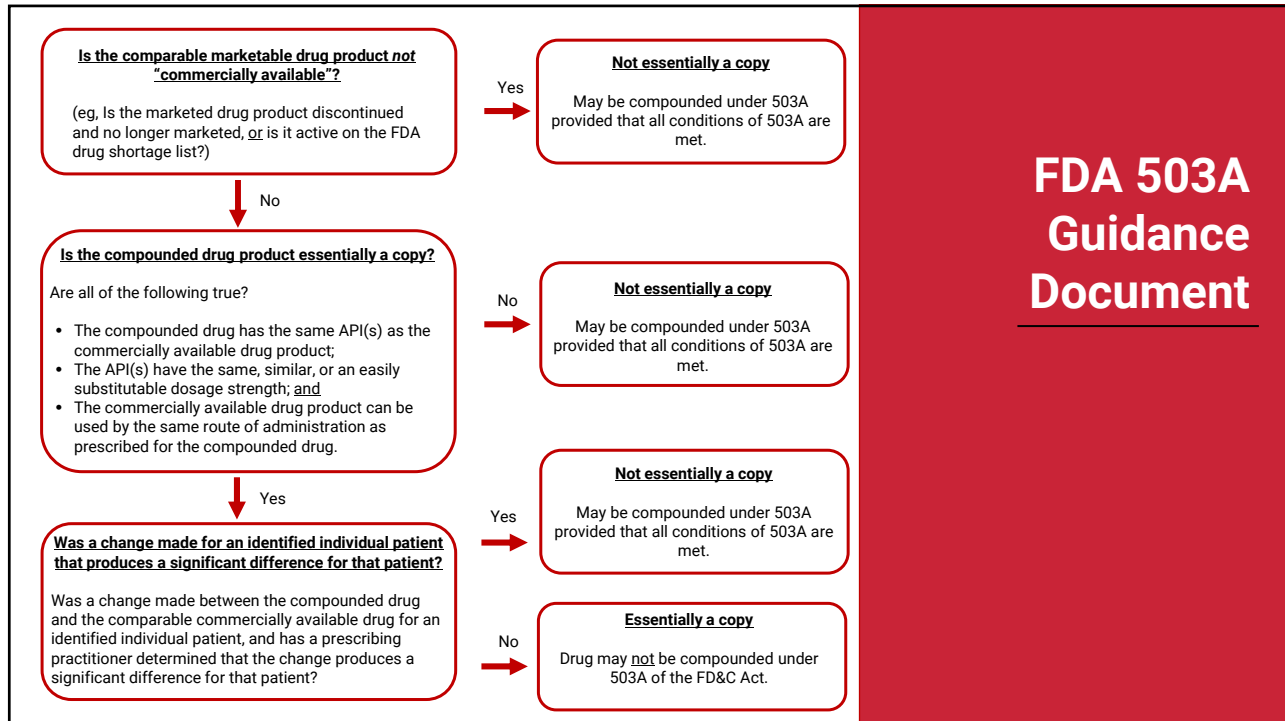
Compounding Commercially Available Products

- FDCA 503A: A drug product may be compounded by a licensed pharmacist or physician, so long as the compounder “**does not compound regularly or in inordinate amounts** (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.”
- Similar language for 503B in FDCA, and under state law.
- Many telemedicine platforms deal in compounded products (especially GLP-1s and PDE-5), sometimes with minimal if any change to the commercial drug product.
- These products are often marketed irrespective of a patient-specific need to achieve a cheaper sale price or to create a faux market niche.

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FDA 503A Guidance Document

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Case Studies

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Pharmacy Held Accountable for Rx Issued Solely on the Basis of an Internet-based Questionnaire

- Iowa Board of Pharmacy performed an undercover test order from a telemedicine platform. The Board ordered tretinoin and submitted an online questionnaire and a photo of a baby doll as part of the online questionnaire. The medication was dispensed.
- **657 Iowa Admin. Code r. 8.19(5):** “The pharmacy and professional pharmacy staff shall ensure that the prescription drug or medication order, regardless of the means of transmission, has been issued for a legitimate medical purpose by a prescriber acting in the usual course of the prescriber’s professional practice. A pharmacist shall not dispense a prescription drug if the pharmacist **knows or should have known that the prescription was issued solely on the basis of an Internet-based questionnaire.**”



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Pharmacy Held Accountable for Rx Issued Solely on the Basis of an Internet-based Questionnaire

- The nonresident pharmacy’s license was placed on probation indefinitely and the company paid a civil penalty of \$10,000.
- The pharmacy agreed to not ship prescriptions into Iowa until it receives written confirmation from the Board that it has demonstrated, through an on-site inspection performed by a board representative, full compliance with Iowa statutes and rules.



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Feds Arrest Telemedicine CEO Under CSA

- “The founder and CEO of a California-based digital health company and its clinical president were arrested [...] in connection with their alleged participation in a scheme to distribute Adderall over the internet[.]”
- The firm allegedly arranged for the prescription of over 40 million pills of Adderall and other stimulants and obtained over \$100 million in revenue.
- Allegedly:
 - Mandated 30-minute time limits on initial encounters.
 - Utilized short intake forms with limited or no patient a/v communication.
 - Implemented an auto-refill policy.
 - Compensated prescribers based on number of patients receiving prescriptions, not consultations.



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Magnitude of Impact

“The [CDC] is issuing this Health Alert Network [...] Health Advisory to inform public health officials, clinicians, and affected patients, their families, and caregivers about potential disrupted access to care among individuals taking prescription stimulant medications and possible increased risks for injury and overdose. On June 13, 2024, the U.S. Department of Justice announced a federal health care fraud indictment against a large subscription-based telehealth company that provides [ADHD] treatment to patients ages 18 years and older across the United States. Patients who rely on prescription stimulant medications to treat their ADHD and have been using this or other similar subscription-based telehealth platforms could experience a disruption to their treatment and disrupted access to care. A disruption involving this large telehealth company could impact as many as 30,000 to 50,000 patients ages 18 years and older across all 50 U.S. states.”



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Nonresident Compounding Pharmacy's License Is Restricted

- Compounding pharmacy receives Form 483 Notification.
- Oklahoma Board of Pharmacy files disciplinary action.
- Iowa Board of Pharmacy conducts its own investigation.
- Compounding pharmacy sues the Iowa Board of Pharmacy.
- Compounding pharmacy loses—and loses again on appeal.



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Predictions

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Ketamine Telemedicine Platforms

Once-taboo ketamine booms for US at-home mental care



MEDPAGETODAY

Special Reports - Exclusives

Ketamine via Telehealth: Psychiatrists Urge Caution

— One company markets at-home doses, but the science isn't settled and safety concerns remain

by Sophie Fuchs, Enterprise & Investigative Writer, MedPage Today
July 28, 2022

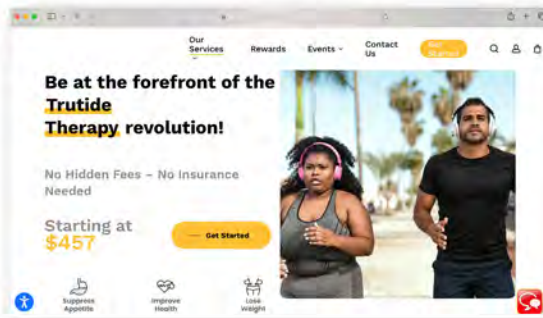


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Telemedicine Platforms Offering Compounded GLP-1 Agonists

- Legitimate drug shortage—but what comes next/now?
- Pop-up telemedicine platforms are offering investigational new drugs (eg, retatrutide).
- Civil litigation?



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Self-Assessment Question

Relevant telemedicine prescribing regulations may be governed by:

1. State Boards of Medicine
2. State Boards of Pharmacy
3. DEA
4. All of the above

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Self-Assessment Question

An asynchronous patient engagement tool is permitted to create a valid patient-practitioner relationship _____.

1. Everywhere
2. Nowhere
3. Sometimes, it depends on the drug
4. Sometimes, it depends on the drug and state

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Self-Assessment Question

Due to emergency COVID-19 exceptions, DEA temporarily permits the prescribing of controlled substances via audio-visual, real-time, two-way interactive communication systems:

1. True
2. False

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Questions?

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Q&A

You may use the Q&A tool on your screen to submit questions to the presenter.

Our host will read the questions out loud in the order they are received.

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3. Select the webinar from the Live Meetings and Conferences list
4. Enter the session code provided at the end of the webinar
5. Complete the course and speaker evaluations
6. Select the appropriate credit (pharmacist or pharmacy technician)
7. Enter your NABP e-Profile ID and date of birth and certify that the information is correct
8. Click the claim button

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The handout for today's presentation can be found at:
www.nabp.pharmacy/webinar

Questions about submitting your claim? Please contact CPE@nabp.pharmacy.

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