Telehealth founder or operator

Map a remote-care service around responsibilities and evidence. Explore product categories, patient-location questions, compounding distinctions and communication. Use the worked examples to identify issues that require current professional and jurisdiction-specific review.



Priya / fictional visitor

YOUR LEARNING JOURNEY

Build a responsibility map that reveals who owns each patient-facing step and which questions require jurisdiction-specific review. Make unanswered questions visible before treating the service map as complete.

Map service responsibilities, understand the product pathway, then review patient-facing claims.

U.S. cross-state rules vary by state and profession. This worksheet is an educational map, not authorization to operate, prescribe or dispense.

Open the current online guide

Sources and related guides remain accessible on the website. All role paths are open to every reader.

Portrait: fictional illustration, not a real patient, professional reviewer or endorsement. This handbook provides education, not individual medical or legal advice.

Contents

Read in order for a foundation, or use the linked contents to find a specific topic. Page numbers refer to this edition.

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Continue with the reading path and books, then record your findings in the learning worksheet.

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Know which product the evidence describes

A molecule name is a starting point, not a complete product description. Record the active ingredient, chemical form, formulation, route, manufacturer or compounder and the document date. Products using similar names may differ in ways that matter. A result for one preparation does not automatically establish the performance of another.

FDA approval concerns a particular drug product and its authorized labeling. A facility registration, product listing or National Drug Code does not mean FDA has approved the product. A company can have legitimate paperwork for one activity without every product or claim being authorized.

Compounded drugs are prepared under a different framework and are not FDA-approved. They can serve particular patient needs, but FDA does not review each compounded product for safety, effectiveness and quality before marketing in the way it reviews approved medicines. The 503A and 503B pathways have different conditions, explained below.

Investigational means a product or use is being studied; it does not mean success is established. Research-use labeling concerns a claimed purpose and cannot establish suitability for human use. Keep regulatory status, analytical quality and clinical evidence as three separate entries. None can substitute for the other two.

Build a simple comparison: what the paper studied, what the official label describes, and what the current document or service names. Mark missing information rather than filling it with a brand assumption. This comparison is useful for a patient preparing questions and for a professional reviewing a brochure.

Worked learning example

Two documents use the same ingredient name. One describes an approved finished medicine; the other describes bulk powder with a laboratory report. The shared name does not make the powder an approved medicine. Ask what each document actually establishes before carrying claims between them.

READ THE SOURCE

FDA - Is It Really FDA Approved?

FDA - Compounding and FDA: Questions and Answers

Understand the service behind the screen

A telehealth service includes more than the video call. Map assessment, clinical decisions, prescriptions where applicable, dispensing, delivery questions, records and continuing care. Identify which organization and professional are responsible for each step. A convenient interface does not explain those relationships by itself.

For U.S. cross-state care, patient location and the clinician’s profession matter. HHS describes several possible licensure pathways; requirements differ by state. Record where the patient will be during the visit and consult the relevant official licensing source. A platform operating nationally does not demonstrate that every clinician can practice everywhere.

Before a visit, check how to connect, how to obtain accessibility or language assistance, what records to provide and how to reconnect if the technology fails. Ask about privacy and whether a private setting is available. Clarify costs, coverage and ongoing commitments separately from questions about clinical appropriateness.

For an operator, turn the patient journey into a responsibility record: the responsible party, patient-facing contact, handoff information and unresolved question at each stage. Include how a person can obtain records, raise a concern and reach clinical follow-up. This educational map helps reveal omissions; it is not an operating authorization or a substitute for jurisdiction-specific review.

Remote care has limits. A service should be able to explain which situations need examination, testing or urgent in-person assessment. The user-facing explanation should identify a practical contact route and the service’s boundaries, rather than leaving the patient with only an automated purchase or renewal screen.

Worked learning example

A fictional service has a platform support inbox, an independent clinician and a separate pharmacy. A billing question, a new symptom and an unclear product label need different accountable contacts. Mapping those contacts before the visit makes the service easier to understand.

READ THE SOURCE

HHS - Preparing for a Telehealth Visit

HHS - Licensing Across State Lines

503A and 503B: understand the pathway before the product

Compounding means preparing a medicine for particular needs by combining, mixing or altering ingredients. In the United States, sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act establish different conditions for exemptions from certain federal requirements. They are not product-approval programs. A compounded medicine does not become FDA-approved because a pharmacy holds a license or an outsourcing facility appears in a registration database.

Section 503A concerns compounding by a licensed pharmacist in a state-licensed pharmacy or federal facility, or by a licensed physician. Its prescription condition concerns an identified individual patient. Limited anticipatory compounding can occur under specified conditions before a prescription arrives, but that is not unrestricted authority to supply unassigned office stock. When all applicable conditions are met, the product can qualify for exemptions from premarket approval, adequate-directions labeling and federal current good manufacturing practice requirements. Other requirements still apply.

Section 503B concerns outsourcing facilities, where compounding occurs by or under the direct supervision of a licensed pharmacist. These facilities remain subject to current good manufacturing practice, often abbreviated CGMP. They may obtain individual prescriptions or supply healthcare providers with office stock: medicine held before a particular patient needs it. FDA conducts risk-based inspections, and reporting obligations apply. Registration is not a guarantee that every preparation, practice or transaction complies.

Bulk ingredients have separate eligibility gates. Under 503A, FDA describes an applicable USP/NF monograph route; when no applicable monograph exists, a component-of-an-approved-drug route; or, when neither applies, inclusion on the 503A bulks list. Under 503B, a substance generally needs inclusion on the clinical-need bulks list, or the resulting drug must be on the shortage list at compounding, distribution and dispensing. A monograph is a published quality standard, not approval of every preparation made from the ingredient.

A valid certificate of analysis and manufacture by an FDA-registered establishment are additional bulk-substance conditions, not substitutes for eligibility. Interim enforcement policies are also distinct from the statutory lists: nomination or Category 1 status is not final list inclusion. Other limits, including restrictions involving essentially copies of available medicines, still need attention. Review the specific product, pathway and date rather than assuming that a familiar ingredient or a national shortage headline answers everything.

503A status as of October 31, 2026: interim Categories 1, 2 and 3 are not the final 503A bulks list. Category 1 concerns adequately supported nominations under evaluation; Category 2 identifies significant safety concerns; Category 3 concerns inadequate nomination support. Removal from Category 2 does not itself establish eligibility. An advisory-committee recommendation is nonbinding advice, not list inclusion. Addition to the final list requires FDA rulemaking; other 503A conditions still apply. Read the category record, committee record and final rule separately rather than treating one as a substitute for another.

Illustrative case: the clinic refrigerator

A clinic asks for unnamed-patient inventory. “Our supplier is a compounding pharmacy” does not resolve the office-stock question. The useful next questions concern the facility’s actual pathway, the exact preparation, the relevant federal conditions and applicable state rules. This example is a reading exercise, not clearance to obtain or administer stock.

Status-note sources checked October 31, 2026; this is not a claim that every retained source was re-reviewed.

READ THE SOURCE

FDA - Human Drug Compounding Laws

FDA - Provisions Applicable to Human Drug Compounding

FDA - 503A Bulk Drug Substances

FDA - 503B Bulk Drug Substances

FDA - Interim categories (PDF updated May 14, 2026)

FDA - July 23-24, 2026 PCAC meeting page

Federal Register - PCAC meeting notice, April 16, 2026

What “gray market” leaves unexplained

“Gray market” is a loose conversational label, not a quality grade or a legal conclusion. It can blur several different issues: an unapproved product promoted for human use, an authentic product outside a documented supply chain, a counterfeit identity, misleading research labeling, or a preparation that does not meet a compounding pathway’s conditions. Name the actual question before deciding what a document or testimonial proves.

A research-use statement describes a claimed purpose; it does not automatically settle intended use. In a March 31, 2026 warning letter to Gram Peptides, FDA explained that website evidence established intended human use despite research-only and not-for-human-consumption disclaimers. This is an example of FDA’s stated enforcement findings, not a final court judgment or a claim about the company’s later status. The broader lesson is to read the surrounding claims and presentation, not a disclaimer in isolation.

Counterfeit and unapproved are also different concepts. Counterfeit identity concerns a product falsely represented as authentic. Unapproved status concerns the absence of applicable approval. Lawfully compounded medicines are themselves not FDA-approved, so “unapproved” alone does not describe every applicable legal condition. Conversely, calling something compounded does not establish that it meets those conditions. Classification requires the exact product, source, claims and regulatory context.

Chemical names require precision. On its current GLP-1 concerns page, FDA states that retatrutide and cagrilintide cannot be used in compounding under federal law. The same page distinguishes semaglutide sodium and acetate from the active ingredient in approved medicines and says the agency is unaware of a lawful basis for their compounding use. These are product-specific statements, reviewed October 31, 2026; do not generalize them to every peptide, salt or jurisdiction.

A separate FDA clarification dated April 1, 2026 discusses restrictions on preparations that are essentially copies of commercially available drugs. It explains that adding another active ingredient does not automatically avoid those restrictions. That dated statement should remain dated: it is not an independently checked live shortage-database result. An April 30, 2026 announcement proposing exclusion of three GLP-1 substances from the 503B bulks list was a proposal, not a final decision.

For an educational review, record exactly what is known: the named item, original source, date, claimed use and unresolved identity or quality questions. Distinguish a reported adverse event from proven causation and a compelling anecdote from a controlled study. Neither a disclaimer nor a dramatic personal story turns an uncertain product into a verified clinical option.

Illustrative case: “research only” beside human promises

A page says research only while its surrounding language promises personal recovery or weight loss. A reader should record the tension between those messages and examine the applicable rules. The footer alone cannot answer whether the product is being marketed for human use.

READ THE SOURCE

FDA - Gram Peptides Warning Letter, March 31, 2026

FDA - Concerns with Unapproved GLP-1 Drugs

FDA - Compounding Questions and Answers

FDA - Compounding Clarification, April 1, 2026

FDA - Proposed 503B Exclusions, April 30, 2026

Explain a claim with its evidence attached

A reader receives a message from the complete presentation: headline, image, testimonial, spoken words and qualifications. Write down the actual impression before judging the evidence. A document titled “education” can still communicate a product benefit or sales claim.

Keep a claim ledger with the exact wording, intended audience, primary source and relevant limits. Record the population, product, outcome and date. Attach a decision: supported as written, needs narrowing, or unanswered. This makes review repeatable when a sentence moves from a website to a printed handout.

Use plain language without removing uncertainty. Explain an unfamiliar term when it first appears. Put a consequential limitation beside the claim it qualifies. A small disclaimer elsewhere cannot repair an unsupported headline. Separate community reports from controlled evidence and company statements from independently established findings.

Give each document a content owner, version and review date. Preserve sources and consequential limitations when adapting it for another audience. Keep a change record so later readers can identify which claim changed and why.

Worked learning example

An illustrated handout combines a vial photograph with “clinically proven recovery” while its citation is an animal experiment. The evidence does not support that human claim. A useful revision describes the animal study and its limits directly, and removes the unsupported promise.

Changed claims about presentation checked against FTC guidance October 31, 2026.

READ THE SOURCE

FTC - Health Products Compliance Guidance

Where to report a problem and how to check a pharmacy

FDA MedWatch accepts reports of adverse events and product-quality problems. Record the product name, manufacturer or compounder, lot if available, dates, what happened and relevant packaging or photographs; distinguish what you observed from what you suspect caused it. A report communicates a concern and does not itself prove causation.

Use FDA BeSafeRx to learn how to evaluate an online pharmacy, then follow FDA’s state-pharmacy directory to the relevant board’s license lookup. Match the legal name and address, check the current license record and contact the board when an entry is unclear. A license lookup and a product-approval record answer different questions.

Worked learning example - fictional

A package names a dispensing pharmacy different from the website brand. Look up the pharmacy’s legal name and address, not just the platform name. If reporting a damaged container, retain its lot number and describe the damage without assuming which organization caused it.

Sources for this addition checked October 31, 2026.

READ THE SOURCE

FDA - Reporting serious problems

FDA - BeSafeRx

FDA - State pharmacy license lookup directory

Accurate patient-facing claims

On March 3, 2026, FDA announced warning letters to 30 telehealth companies concerning misleading promotion of compounded GLP-1 products. Its examples included implying sameness with approved medicines and branding that obscured who compounded the product. The announcement date is distinct from individual letter dates.

The GoodGirlRX letter, dated February 20 and posted March 3, challenged imagery suggesting the telehealth company was the compounder and statements implying FDA approval of compounded products. Use this record to examine attribution and product status, rather than treating it as a verdict on every telehealth service. Warning letters describe FDA’s concerns at that time; later responses or actions may change the record.

Worked learning example - fictional

Fictional risky page: “Our FDA-approved formula delivers the same results,” above a platform-branded vial. Corrected educational description: “This service coordinates clinical care; a separately identified pharmacy prepares the compounded medication. Compounded medications are not FDA-approved. Evidence for an approved product does not establish identical results for this preparation.” Replace the vague pharmacy reference with the actual documented organization in a real page; changing the wording alone does not establish compliance.

Sources for this addition checked October 31, 2026.

READ THE SOURCE

FDA - March 3, 2026 announcement

FDA - GoodGirlRX warning letter, February 20, 2026

Reading path and books

1. Map clinical and product roles

Separate the platform, clinician and supplying pharmacy rather than presenting them as one anonymous service.

2. Review the evidence language

Compare marketing promises with the actual populations and outcomes studied.

3. Distinguish investigational content

Keep education about emerging compounds separate from the services offered.

Continue in the Church Library

Choose the level that fits your background. Book links lead to the Library, where reading options and any affiliate disclosures are shown.

Testing Treatments - Evans, Thornton, Chalmers and Glasziou

Start with fair comparisons and uncertainty. The library entry includes an official free reading option. Published in 2011; use current official sources for regulatory questions.

The Art of Statistics - David Spiegelhalter

Go deeper into denominators, uncertainty and interpreting data. Read alongside the actual study rather than using a statistical slogan as a verdict.

Bottle of Lies - Katherine Eban

Investigative cases provide context for manufacturing oversight and documentation. The book is not a current supplier assessment or a conclusion about every generic medicine.

Browse all Library rooms

Examples in practice

These examples identify published resources and their uses; they are not evaluated services.

HHS telehealth patient resources

An official example of practical patient education: preparation, access, privacy and follow-up questions.

Questions and explanations

Who is accountable for assessment, prescribing, dispensing and follow-up?

Assign responsibility to named organizations or professional roles at each handoff, then give the patient a usable contact route. Assessment and clinical follow-up belong in the clinical responsibility map; dispensing and product-label questions require the relevant pharmacy contact. For example, when a platform contracts with an independent clinician and pharmacy, neither a support chatbot nor a shared brand makes their responsibilities interchangeable. Record who receives an unresolved concern and who confirms that the handoff was completed.

Are implied claims stronger than the underlying evidence?

Compare the whole presentation with the actual evidence, including visuals, testimonials and implied comparisons. The question is not only whether each sentence is literally true, but whether the resulting impression promises more than the evidence supports. For example, a testimonial about immediate energy beside an animal-study citation can imply established human benefit without stating that claim outright. Narrow the message to the finding that was actually observed and put the important limitation beside it.

Read the source: health products compliance guidance

Could a reader mistake this educational page for an offer of treatment?

A page can read like an offer when educational descriptions are paired with treatment-selection buttons, service availability language or claims about personal outcomes. A disclaimer does not settle that interpretation by itself. For example, an investigational-compound explainer beside a “choose this treatment” control conveys something different from a clearly labeled research article. Review the page’s full context and keep research reporting distinct from the service the platform actually provides.

Read the source: health products compliance guidance

Read the source: gram peptides 721806 03312026

Glossary

Comparator
The reference group or intervention against which an outcome is compared, such as placebo or another treatment.

Endpoint
An outcome defined for a study. A biological measurement and a patient-important outcome are not necessarily the same thing.

Formulation
The composition and presentation of a product, including ingredients beyond the active substance.

Adverse event
An unwanted medical occurrence during observation; occurrence does not itself establish a causal connection to treatment.

Investigational
Under investigation. This describes research status, not proof of safety or benefit.

API
Active pharmaceutical ingredient: the substance intended to provide a medicine’s pharmacological activity. An API is not the same as a finished medicine.

503A / 503B
Different U.S. statutory pathways for qualifying compounded drugs. Neither makes a compounded drug FDA-approved.

CGMP
Current good manufacturing practice: requirements for manufacturing controls and quality. The applicable framework depends on the activity and product.

Gray market
An informal description of uncertain or unauthorized distribution channels, not a regulatory approval category.

Learning worksheet

Service responsibility map

Use these prompts to record what you understand, what remains uncertain and which source could answer the question.

Learning prompt	Filled-in fictional example
Service responsibility map	Fictional example: Handoff: a patient reports a symptom to platform support. Owner: clinical team. Record needed: patient-facing clinical contact and confirmation that the concern reached that team.

List each service step and the responsible professional or organization.

Record where patients are located and which licensure questions need checking.

Map consent, privacy, accessibility, technology backup and escalation responsibilities.

Document follow-up ownership, pharmacy contact, material review dates and how complaints reach a responsible person.

Educational information, not individualized medical or legal advice.

Explore another perspective in the Community Center