INFORMATIONAL; PREPARED BY INNER BALANCE FOR PROVIDERS

Clinical reference: compounded hormone therapy — regulatory framework *and* quality standards

Purpose

Compounding is one of the most common points of skepticism collaborating providers raise about Oestra®. This reference addresses the regulatory framework compounding actually operates under, where it's an appropriate clinical choice, and what quality standards apply, so that the conversation with a skeptical colleague can be about the specific product and patient in front of you, rather than a misconception about compounding as a category.

1 Compounding is not "unregulated." It operates under a distinct regulatory framework

A common misconception is that because compounded drugs don't go through FDA's New Drug Application process, they're unregulated. That's not accurate. Compounding pharmacies operate under a different, but real, regulatory structure:

503A pharmacies (traditional compounding, patient-specific prescriptions) are regulated primarily at the state level, by state boards of pharmacy, under standards set by USP General Chapters <795> (non-sterile compounding) and <797> (sterile compounding).

503B outsourcing facilities (larger-scale compounding, can produce without patient-specific prescriptions) register with and are inspected directly by the FDA, similar to manufacturing facilities.

PCAB accreditation (Pharmacy Compounding Accreditation Board) is a voluntary, rigorous third-party accreditation — not a regulatory requirement — that verifies a pharmacy meets quality standards beyond the state licensing minimum. It's a meaningful signal of quality precisely because it's not mandatory.

OUR PHARMACY PARTNER

Our compounding pharmacy partner is PCAB-accredited, NABP- and LegitScript-certified, licensed and regulated by state pharmacy boards in all 50 states, and sources all active pharmaceutical ingredients (APIs) exclusively from FDA-inspected facilities. Every batch of Oestra® undergoes third-party potency and stability testing, with certificates of analysis available on request.

2 Where compounding is an appropriate clinical choice

Major medical societies, including the conclusions of the 2020 National Academies of Sciences, Engineering, and Medicine review, are correct that FDA-approved products should be the first-line choice for most patients, and compounded hormone therapy is not a universal substitute. The same review identifies a legitimate therapeutic niche for compounding: patients with an allergy or intolerance to an excipient in commercial formulations, a need for a specific hormone ratio or combination not commercially available, or a dose outside what's commercially manufactured.

We agree with this framing. Oestra® is positioned for that population — prescribed after individualized clinical evaluation, not marketed as a categorical replacement for FDA-approved therapy. Patients are counseled on this distinction, including the trade-off in batch-to-batch consistency inherent to compounding relative to industrial manufacturing, as part of informed consent.

3 What compounding does not have, and what we're doing about it

We want to be direct about this rather than talk around it: compounded formulations, including Oestra®, do not have randomized, placebo-controlled trial data that FDA-approved products are required to generate. This is a genuine, structural difference — not a matter of degree.

What we do have: approximately eight years of iterative clinical development and refinement, and internal patient data (dose-response labs, symptom outcomes, side effect profiles and adverse event data) from a patient population of over 60,000 women treated since Inner Balance's founding in 2023. We present this as real-world clinical experience, not as equivalent to controlled trial data, and we are pursuing dedicated clinical studies to build an even stronger evidence base.

Summary for referring providers

1. Compounding operates under a distinct but real regulatory framework (state boards, USP <795>/<797>, and voluntary PCAB accreditation) — it is not unregulated.
2. Our compounding partner holds PCAB accreditation, NABP and LegitScript certification, all-50-state licensure, and sources APIs from FDA-inspected facilities only.
3. FDA-approved products remain the appropriate first choice for most patients; compounding fills a specific niche for patients who can't use commercial formulations as-is.
4. Compounded products, including Oestra, do not have randomized control data — we don't claim otherwise, and we're investing in building that evidence base.