Submitted Electronically

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Department of Labor and Industry
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Re: Notice of Proposed Rulemaking; MAR Notice No. 2026-131.1

Dear Dr. Tinsen:

The Collaborative for Evidence-Based Medicines ("CEBM") is a national provider-led organization advancing evidence-backed medicines, safe compounding, and stronger oversight and accountability to protect patients. CEBM brings together providers, patient advocates, academics, consumer groups, manufacturers, and other stakeholders to advance our patient safety mission. The signatories to this letter are pharmacists, physicians, and regulatory professionals who sit on the CEBM Board or who are otherwise closely involved in CEBM's work to advance patient safety. CEBM's members bring decades of clinical, scientific, and policy experience to bear on the critical questions presented by these proposed rules.

CEBM respectfully submits these comments in response to the Montana Board of Pharmacy's (the "Board") proposed amendments to its compounding regulations, as published under MAR Notice No. 2026-131.1. We commend the Board for undertaking this effort to modernize Montana's compounding regulations and to bring them into closer alignment with federal law and nationally recognized standards. CEBM supports many of the Board's proposed provisions and writes to offer targeted recommendations that we believe would further strengthen protections for Montana patients.

I. The Patient Safety Imperative: Why This Rulemaking Matters Now

To start, we urge the Board to consider the growing body of evidence documenting patient harm from compounded drugs which motivates CEBM's comments. For example, a recent pharmacovigilance study by researchers at Binghamton University found that patients taking compounded GLP-1/GIP receptor agonist drugs were nearly 2.5 times more likely to experience an adverse event requiring hospitalization and over 8.5 times more likely to have an adverse event involving product quality issues compared to patients taking FDA-approved medicines.[1] As of May 31, 2026, the Food and Drug Administration ("FDA") has received 1,720 reports of adverse events associated with compounded GLP-1/GIP drugs alone.[2] Given that compounding pharmacies have no

[1] Kenneth L. McCall et al., *Safety Analysis of Compounded GLP-1 Receptor Agonists: A Pharmacovigilance Study Using the FDA Adverse Event Reporting System* (2025), https://www.tandfonline.com/doi/full/10.1080/14740338.2025.2499670.
[2] Food and Drug Administration, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss" current as of June 15, 2026, *available at*: https://www.fda.gov/drugs/drug-alerts-and-statements/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss (last accessed Aug. 19, 2026).

obligation to monitor or report adverse events, this figure captures only a fraction of actual patient harm. From the perspective of the clinicians and patient advocates in our collaborative, these numbers represent real patients who sought treatment and instead received products that put their health at risk.

Montana is not insulated from these risks. As just one example, in April 2025, FDA issued a warning letter to OSRX, Inc., a registered outsourcing facility located in Missoula, documenting insanitary conditions in the preparation of sterile drug products.[3] This is not an abstract, out-of-state problem. It is happening here, and Montana's patients deserve the protections that this rulemaking can provide.

II. Strengthening Oversight of Compounding Pharmacies

CEBM strongly supports proposed ARM 24.174.841(1)-(2) and New Rule 1 that requires pharmacies engaged in sterile and nonsterile compounding to comply with relevant USP general chapters relevant to the scope of practice, which would include chapters <795>, <797>, <800>, and <825>. The principle is straightforward: USP standards should be mandatory, not aspirational. These chapters represent the scientific consensus on minimum quality requirements for compounded preparations. They are developed through a transparent, expert-driven process with extensive public participation.[4] They exist precisely to be enforceable and to establish a floor below which no pharmacy should operate. When states treat USP compliance as optional, the result is a patchwork of quality practices that puts patients at unacceptable risk.

Adopting the USP standards would bring Montana in line with a strong majority of other states and help better address widespread interstate movement of compounded drugs. According to the National Association of Boards of Pharmacy ("NABP") 2025 Annual Survey, over forty-two states have incorporated current USP Chapter <797> sterile compounding standards into their regulations or otherwise require compounding pharmacies to adhere to USP Chapter <797>. Montana's adoption of these same requirements joins a growing national consensus and facilitates the coordinated oversight that compounding demands. This interstate coordination matters because state Boards of Pharmacy are the primary safety gatekeepers for compounded drugs. Despite Congress' intent that 503A compounding remain small-scale and patient-specific, most compounders distribute across state lines, making shared USP-NF standards essential for coordinated interstate oversight. When states apply the same baseline standards, patients receive consistent protections regardless of where their medications originate.

We further support the requirement of a sterile compounding endorsement for non-resident and resident pharmacies and the requirement for pharmacies to comply with Section 503A of the Food, Drug, and Cosmetic Act ("FDCA"). However, we recommend one enhancement to these provisions: the Board should condition the issuance of a compounding endorsement on successful inspection by the

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[3] *See, e.g.*, FDA Warning Letter to OSRX, Inc. (Apr. 25, 2025), https://tinyurl.com/4jktue76 (observing that at a registered outsourcing facility located in Missoula, Montana, "drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health").

[4] All comments received and responses from the USP Compounding Expert Committee are published online. *See, e.g.*, USP, Commentary for <797>, USP-NF 2023 Issue 1 (Nov. 1, 2022), https://tinyurl.com/3fpkd24k.

Board itself or by a qualified entity the Board recognizes, such as the NABP. On-site inspection remains the most reliable mechanism for confirming that actual conditions match documented procedures.

III. Preventing Compounding of Copies of Commercially Available Drugs

Federal law has long prohibited 503A pharmacies from compounding drugs that are essentially copies of commercially available products.[5] This prohibition exists for a fundamental reason: when an FDA-approved medicine is available, patients should receive that medicine rather than an untested, unregulated copy. Compounding fills a vital role when patients have genuine needs that no approved product can meet. But compounding was never intended to become a pathway for mass-producing cheaper versions of approved drugs without regulatory safeguards that protect patients.

In practice, however, compounding has increasingly been used for precisely this purpose. The compounding pharmacy market is a five-billion-dollar industry and is projected to grow to a nearly nine-billion-dollar industry by 2035.[6] Growth of this magnitude reflects a market increasingly driven by consumer demand and commercial promotion rather than by the patient-specific clinical needs the framework was built to address. As the NABP recently observed, "the compounded GLP-1 period already showed that demand of this kind blows past the small-scale, patient-specific compounding Congress had in mind when it built the 503A framework."[7] The explosion of the compounded drug market, along with documented adverse events as a result of these products, demonstrates the consequences of failing to enforce the copy prohibition at the state level.

The Board's proposed rules align with FDCA section 503A, but we recommend that the Board take the additional step of amending ARM 24.174.301 to define what it means for a compounded product to be "essentially a copy" of a commercially available drug. Such a definition should require that any drug that contains the same active ingredient as FDA-approved, available drug be considered a "essentially a copy," unless the compounded preparation includes a change that produces a clinically significant difference for the identified individual patient as determined by the prescribing practitioner and verified by the dispensing pharmacist. Moreover, the combination of multiple active ingredients that could be administered separately should not be allowed to create the pretext to compound copies of approved drugs, and should not constitute a "clinically significant difference."

Finally, we recommend that the Board revise ARM 24.174.2301 to designate compounding product that is an "essentially a copy of a commercially available drug product" as unprofessional conduct and grounds for discipline from the Board. This creates a clear enforcement mechanism and signals to the profession that mass manufacturing under the guise of patient-specific compounding will not be tolerated in Montana.

IV. Supply Chain Integrity and Ingredient Accountability

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[5] 21 U.S.C. § 353a(b)(1)(D).

[6] Towards Healthcare, "503A U.S. Compounding Pharmacies Market Size, Growth and Geographical Insights" last updated Jan. 5, 2026, *available at*: https://www.towardshealthcare.com/insights/503a-us-compounding-pharmacies-market (last accessed June 26, 2026).

[7] NABP, Comment to Docket No. FDA-2025-N-6895; Pharmacy Compounding Advisory Committee Meeting — Consideration of Seven Peptide Substances for the Section 503A Bulk Drug Substances List (Jul. 9, 2026), https://tinyurl.com/32prycjc.

CEBM supports the Board's enhanced recordkeeping requirements for active pharmaceutical ingredients ("APIs") and bulk drug substances. We urge the Board to go further by specifying minimum content requirements for certificates of analysis ("CoAs") and requiring that pharmacies compounding sterile drugs maintain copies of all CoAs for the APIs they use.

Ingredient sourcing for compounded drugs presents a growing problem, with FDA documenting repeated instances of fraud in the API supply chain. FDA has identified patterns in which intermediaries obscure the true origin of ingredients—for instance, by removing labeling from the original manufacturer and replacing it with their own, making it impossible for downstream pharmacies to verify the identity and country of location for the original manufacturer or manufacturing conditions.[8] In the most alarming cases, industrial chemicals that were never manufactured under pharmaceutical controls, and never intended for human use, have been falsely represented as suitable for drug compounding, including for injectable products.[9]

This matters to Montana's compounding pharmacies as much as it matters to patients. Pharmacies that act in good faith deserve the regulatory tools to verify that the ingredients they purchase are what they claim to be. A CoA requirement with specified minimum content serves this purpose.

We recommend that the Board amend ARM 24.174.841(2) and New Rule 1 to require that COAs, in order to be valid, include certain minimum information, such as:

- The identity of the ingredient or substance;
- The name address of the original manufacturer of the ingredient or substance;
- Results from all applicable quality testing (e.g., identity, potency, etc.), so that Montana pharmacies can have confidence in the quality of the ingredients they receive; and
- A clear representation from the source that the ingredient or substance is of pharmaceutical grade and otherwise suitable for use in compounded preparations.

V. Transparency Through Labeling and Adverse Event Reporting

Patients receiving compounded medications are often unaware that their products have not undergone FDA review for safety and efficacy.[10] They may also lack any mechanism to report problems

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[8] *See* FDA Warning Letter to Darmerica LLC (Dec. 8, 2025), https://tinyurl.com/yc2fxmfx (citing failures with qualifying API suppliers, including "given FDA's documented compliance concerns related to API manufacturers" in the distributor's supply chain); FDA Warning Letter to Harbin Jixianglong Biotech Co., Ltd. (May 1, 2026), https://tinyurl.com/bdd763m7. *See also id.* at 22 ("Sichuan Friendly API may be repackaged and/or relabeled before it is further distributed, and not all of the repackaged/relabeled API identifies Sichuan Friendly as the original API manufacturer.")

[9] *See, e.g.,* FDA, API Sourcing, or Buyer Beware !!!, https://www.fda.gov/media/164526/download ("Entities down the line were taking the site's industrial chemicals and relabeling it … for Pharmacy compounding"); *id.* at 32 ("Entities down the line were taking the site's oral grade API and relabeling as injectable grade.").

[10] ASOP Global Foundation "ASOP Global Foundation, 2025 U.S. Consumer Behavior Survey, Snapshot: GLP-1 Medications are Reshaping Demand" Dec. 2025, *available at*: https://asopfoundation.pharmacy/wp-content/uploads/2025/12/ASOP-Foundation-Survey-Snapshot-GLP1s.pdf ("86% of online GLP-1 purchasers incorrectly believe that compounded medications are evaluated by the FDA for safety and efficacy.")

they experience. CEBM believes that basic transparency, including information about what patients are receiving and accountability is a foundational element of patient-centered care.

Aligning with the direction of both federal and state policy, we recommend that the Board consider two additions to the proposed rules:

1. Mandatory adverse event reporting. Pharmacies compounding sterile and nonsterile preparations should be required to report serious adverse events to the Board. The current absence of any reporting obligation means that the Board lacks the safety signal data it needs to identify problematic facilities or products before widespread harm occurs.[11]
2. Minimum labeling requirements. All compounded preparations should bear a label that clearly states the product has not been reviewed or approved by FDA, and that provides information on how to report serious adverse events. Patients and their providers deserve to make informed decisions, and clear labeling supports that goal.[12]

VI. Regulatory Oversight of Outsourcing Facilities

CEBM supports proposed New Rule 3 establishing an endorsement framework for 503B outsourcing facilities. These entities occupy a unique position in the drug supply chain because they compound drugs without patient-specific prescriptions and generally distribute at larger scale. As such, they require oversight commensurate with the risks their operations present.

The proposed rule appropriately requires outsourcing facilities to register with FDA, comply with section 503B of the FDCA and federal cGMP regulations, compound under the direct supervision of a licensed pharmacist, and maintain pharmacist-in-charge oversight of all policies, procedures, and training. This framework establishes the minimum conditions necessary for meaningful state-level accountability.

The need for this oversight is demonstrated by recent experience. FDA has documented that multiple outsourcing facilities continued to compound with bulk tirzepatide products long after that drug left FDA's shortage list on October 2, 2024, in clear violation of the conditions on which the federal exemptions for outsourcing facilities depend.[13] New Rule 3 will give the Board authority to hold such

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[11] For adverse event reporting: 1) Texas ("A pharmacy that compounds sterile preparations shall notify the board immediately of any adverse effects reported to the pharmacy or that are known by the pharmacy to be potentially attributable to a sterile preparation compounded by the pharmacy")(22 Tex. Admin. Code § 291.133(g)(5)), 2) Maryland ("A pharmacy shall:… B. Report to the Board within 5 calendar days: (1) Adverse events that have been discovered including corrective actions taken or proposed")(COMAR 10.34.19). Moreover, the version of the SAFE Drugs Act that the Senate Health, Education, Labor, and Pensions Committee advanced in July 2026 included new adverse event reporting requirements.

[12] For labeling requirements: California ("Any compounded drug preparation dispensed to a patient or readied for dispensing to a patient shall also include, on the container label or on a receipt provided to the patient, a statement that the drug has been compounded by the pharmacy.")(16 CCR § 1735.4).; Ohio ("Labels for a compounded drug that is prepared in anticipation of a patient-specific prescription shall also contain the following:…(5) The statement "Compounded Drug" or other similar statement shall also be displayed prominently on the label.") (OAC Rule 4729:7-2-03(J)(2)).

[13] *See, e.g.*, FDA, Form FDA 483 to BPI Labs, LLC (Apr. 17, 2026), https://tinyurl.com/mvtxsxhk; FDA, Warning Letter to ProRx LLC (Apr. 7, 2026), https://tinyurl.com/2k7dwjzm; FDA, Warning Letter to GenoGenix LLC (Jan. 20, 2026), https://tinyurl.com/8mndzwyk

facilities accountable and, where necessary, to revoke endorsements to protect patients from receiving products compounded under inadequate conditions.

VII. Documentation to Facilitate Accountability

Finally, we support the proposed documentation framework in ARM 24.174.841(3) and New Rule 1 requiring the designated person to maintain comprehensive, inspection-ready records. Effective oversight is impossible without organized documentation. The proposed categories—personnel qualifications, certification reports, environmental monitoring, equipment records, standard operating procedures, compounding and release records, and adverse event documentation—equips the Board with the baseline information it needs to conduct meaningful inspections and hold facilities accountable.

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For the foregoing reasons, CEBM respectfully urges the Board to adopt the proposed rules with the additional recommendations described above.

As physicians, pharmacists, and regulatory professionals committed to ensuring that patients receive treatments that are safe, effective, and supported by evidence, CEBM stands ready to support the Board in any way that advances that shared goal.

Respectfully submitted,

By the Board of the Collaborative for Evidence-Based Medicines (CEBM):

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