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Jordan Fisher Blotter, Director
Office of Regulation and Policy Coordination
Maryland Department of Health
201 West Preston Street, Room 534
Baltimore, Maryland 21201

mailto:mdh.regs@maryland.gov

Re: Comments Related to Proposed Amendments to COMAR 10.34.19 Sterile Pharmaceutical Compounding

Director Blotter, Executive Director Speights-Napata and Members of the Maryland Board of Pharmacy:

The Alliance for Pharmacy Compounding and its members thank you for the opportunity to comment on the proposed revisions to COMAR 10.34.19. We appreciate the Board's ongoing work to modernize Maryland's compounding regulatory framework, but several elements of your draft create uncertainty for pharmacists and leave important regulatory areas undefined. APC shares other commenters' interest in clarity around incorporation by reference and inspection expectations, but believes clarity alone is insufficient where entire regulatory frameworks have been removed.

1. The proposed chapter addresses only sterile compounding, leaving nonsterile compounding without regulatory framework

The Board proposes to retitle this chapter "Sterile Pharmaceutical Compounding" and remove incorporation of USP 795 (nonsterile compounding standards). While Maryland's pharmacy practice act defines "compounded nonsterile preparations" as products "compounded in accordance with USP 795," the removal of USP 795 from regulation creates significant operational uncertainty.

Without regulatory incorporation, Maryland pharmacies lack clarity on:

- how USP 795 will be enforced
- what documentation, QA, or recordkeeping inspectors will expect
- how pharmacies should demonstrate compliance
- what constitutes non-compliance

This differs from national practice. Most states that rely on statutory authority for compounding still include both sterile and nonsterile requirements in regulation, providing pharmacies with clear operational expectations. Without such framework, Maryland inspectors may interpret compliance inconsistently, and pharmacists lack the regulatory guidance needed to ensure full compliance.

Recommendation: Create a separate COMAR chapter for nonsterile compounding that incorporates USP 795 and establishes parallel documentation, training, and quality assurance requirements. Alternatively, maintain comprehensive coverage of both sterile and nonsterile compounding in a single chapter.

2. Limited standards for ingredient selection and verification

While the proposed rules appropriately require certificates of analysis and safety data sheets for active pharmaceutical ingredients, neither the statute nor COMAR 10.34.19 establishes requirements for: Neither the statute nor COMAR 10.34.19 includes provisions addressing:

- API supplier qualification
- COA verification
- Identity/purity acceptance criteria
- Handling and documentation of excipients
- Component suitability for compounding

USP 795 and USP 797 both treat ingredient selection as foundational to quality. Most states explicitly regulate it to ensure consistency between pharmacies and inspectors. The limited API guidance in Maryland's rule is a meaningful divergence from USP and national best practices.

Recommendation: Add provisions requiring written procedures for API supplier qualification, component verification against certificates of analysis, and acceptance criteria for ingredients used in compounding.

3. No "essentially a copy" framework and no guidance on 503B-to-503A compounding

Federal law (21 U.S.C. §353a) requires 503A pharmacies to avoid compounding "essentially a copy" of a commercially available product unless the prescriber documents a clinical difference. Many state boards mirror this requirement so inspectors and licensees are aligned with federal expectations.

Maryland's proposed rule contains no such provision. It also does not address:

- whether 503A pharmacies may obtain compounded preparations from 503B outsourcing facilities
- how the state intends to align with FDA's 2023 draft GFI confirming that 503B-to-503A patient-specific supply is not considered wholesaling

Leaving these issues unaddressed creates avoidable uncertainty and may lead to inconsistent enforcement.
Recommendation: Include an "essentially a copy" provision consistent with federal law, and clarify the Board's position on 503B-to-503A supply arrangements in accordance with evolving FDA guidance.

4. New FDA-guidance clause creates broad and unpredictable enforcement authority

The proposed §.17F states: "The Board may reference FDA guidance documents when inspecting or reviewing compounding practices not specifically outlined in this chapter or a chapter of USP." This proposal poses several challenges:

- FDA guidance is nonbinding, but this provision could allow it to be treated as de facto Maryland law.

- Because the proposed chapter omits nonsterile compounding, FDA guidance could become the fallback standard for areas where Maryland has intentionally chosen not to regulate.
- FDA guidance often addresses manufacturers and outsourcing facilities, not traditional 503A pharmacies.
- Pharmacies cannot reliably know which FDA documents an inspector may rely on.

State regulation should give pharmacies clear expectations. A broad, undefined reference to any FDA guidance introduces uncertainty rather than clarity. Pharmacies cannot meaningfully comply with standards that are not codified, enumerated, or subject to notice-and-comment rulemaking.

Recommendation: Narrow this provision to specify which FDA guidance documents may be referenced or eliminate it in favor of comprehensive state regulations that give pharmacies clear, enforceable standards.

Request

APC respectfully asks the Board to:

1. Create a parallel regulatory chapter for nonsterile compounding that incorporates USP 795 and establishes clear documentation, training, and quality assurance requirements, or maintain comprehensive coverage in a single chapter.
2. Add clear requirements for API selection consistent with USP and federal law.
3. Include an "essentially a copy" provision and clarify expectations for 503B-to-503A supply.
4. Narrow or clarify the FDA-guidance clause so it does not substitute for missing standards.
5. Ensure Maryland's regulations align with the nationally recognized minimum standards in USP 795 and 797.

Thank you for your consideration and for the Board's ongoing work to protect Maryland patients while supporting a clear, practical regulatory environment for compounding pharmacists. I would welcome the opportunity to provide additional input or participate in future stakeholder discussions.

Respectfully,

Scott Brunner, CAE
Chief Executive Officer

The Alliance for Pharmacy Compounding is the voice for pharmacy compounding, representing more than 600 compounding small businesses, including 7,500+ compounding pharmacists and technicians in both 503A and 503B settings, as well as prescribers, educators, researchers, and suppliers.