May 14, 2026

Scott Partika, Director
Ohio Department of Medicaid
50 West Town Street, Suite 400
Columbus, OH 43215

Re: Medical Necessity Policy and Application to Compounded Medications

Dear Director Partika:

On behalf of the Alliance for Pharmacy Compounding, the National Community Pharmacists Association, the American Pharmacists Association's Compounding Community, and the Ohio Pharmacists Association, we appreciate the opportunity to provide input on the Ohio Department of Medicaid's Medical Necessity Policy as it relates to compounded medications. APC is a national trade association representing more than 600 compounding pharmacies and approximately 7,400 compounding professionals, including both 503A pharmacies and FDA-registered 503B outsourcing facilities. NCPA represents America's community pharmacists, including 18,900 independent community pharmacies, and approximately 45 percent of NCPA's members provide compounding. APhA's Compounding Community, with over 3,400 compounding pharmacists, is to provide a professional network for compounding professionals. The Compounding Community focuses on education, communication, collaboration, advocacy, and the sharing of ideas in compounding pharmacy practice. Together, we work to ensure patients maintain access to prescribed compounded medications when Food and Drug Administration (FDA)-approved options are not available or not clinically appropriate.

We are writing to provide clarification regarding compounded medications and their role in patient care, particularly in the context of medical necessity determinations.

Compounded drugs, by definition, have not undergone the federal approval process required by the FDA. They are not evaluated through the rigorous clinical trial framework used to establish safety and effectiveness, nor are they approved for specific indications, dosing, and populations as commercially manufactured drugs are.

Because of this, compounded medications could never meet the evidentiary bar set forth in the Ohio Department of Medicaid's Medical Necessity Policy. That policy prioritizes FDA-approved indications, requires alignment with established clinical criteria, and relies on randomized controlled trials and systematic reviews to support coverage determinations. Compounded drugs, which are prescribed patient-specific preparations and not subject to FDA approval, are not designed or intended to generate that level of evidence and therefore cannot satisfy those criteria.

This is not a flaw in prescribed compounded medications; it reflects their distinct and limited role. Compounded medications are not intended to compete with or replace FDA-approved therapies. Rather, they serve patients when prescribed as approved options are not clinically appropriate, such as when a patient cannot tolerate a commercially available formulation, require a different dosage form, or have a documented allergy to an ingredient.

Maintaining this distinction is essential. Policies that apply FDA approval standards to compounded medications could inadvertently restrict access for patients who are prescribed these medications and rely on them when no suitable FDA-approved alternative exists.

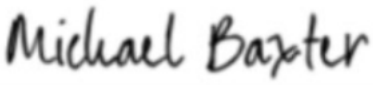
We also encourage ODM to recognize that these ingredients are commonly utilized in compounded topical preparations to address individualized patient needs that may not be met by commercially available FDA-approved products. While some ingredients may not be specifically FDA-approved for topical administration, that does not necessarily mean they lack a legitimate medical purpose when prescribed and compounded for a specific patient pursuant to a practitioner's clinical judgment.

Thank you for your attention to this issue. We would be happy to provide additional context if helpful.

Sincerely,

Scott Brunner, CAE
Chief Executive Officer
Alliance for Pharmacy Compounding

Steve Postal, JD
Senior Director, Policy & Regulatory Affairs
National Community Pharmacists Association



Michael Baxter
Vice President, Government Affairs
American Pharmacists Association

Sara Kilpatrick
Chief Executive Officer
Ohio Pharmacists Association

cc:
Pharmacy Policy Team
Ohio Department of Medicaid
Pharmacy & Therapeutics (P&T) Committee
Ohio Department of Medicaid
Clinical and Utilization Management Leadership
Gainwell Technologies