COLORADO BIOSCIENCE ASSOCIATION

303.592.4073
info@cobioscience.com
cobioscience.com
600 Grant Street, Suite 306
Denver, CO 80203

April 9, 2026

Re: HB26-1262 Patient Access to Compounded Medical Items

The Honorable Kyle Mullica, Chair
Senate Health & Human Services Committee
State Capitol, 200 E Colfax
Denver, CO 80203

Dear Chair Mullica and Members of the Committee:

The Colorado BioScience Association (CBSA) is monitoring HB26-1262 Patient Access to Compounded Medical Items, but we appreciate the opportunity to provide perspective on policies affecting intellectual property protections, federal regulatory oversight, and pharmaceutical compounding.

CBSA champions Colorado's life sciences ecosystem and the patients it serves. CBSA's members include more than 720 life sciences companies and organizations employing more than 40,000 people in Colorado. Our life sciences community drives global health innovations that improve and save lives, from concept to commercialization. CBSA represents biotechnology and pharmaceutical, medical device and diagnostics, digital health, ag-bio and animal health, academic and research institutions, and the service provider companies that support the work of our ecosystem. CBSA is committed to advancing affordability solutions that correct market failures, increase competition, and lower costs for patients while preserving patient access to high-quality medical products and supporting medical innovation.

A strong and predictable intellectual property framework is essential to sustaining medical innovation in the United States. The development of a new therapy requires years of scientific research, clinical trials, regulatory review, and significant capital investment. Patent protections — including clearly defined exclusivity periods established under federal law — provide a limited but critical window that enables companies to assume this risk and continue investing in future treatments. Weakening, shortening, or creating uncertainty around those protections can have lasting consequences for research pipelines, patient access to next-generation therapies, and the overall competitiveness of our life sciences sector.

Equally important is preserving alignment with the U.S. Food and Drug Administration's comprehensive national regulatory framework. FDA-approved products are subject to rigorous standards for safety, efficacy, labeling, and manufacturing quality. Regulatory predictability and consistent oversight are foundational not only to patient safety, but also to maintaining a stable environment for innovation and investment.

Pharmaceutical compounding plays a legitimate and important role in the healthcare system when conducted within established federal guardrails. Compounding can address individualized patient needs, provide alternative dosage forms, and support access during FDA-recognized shortages. However, federal law does not intend for compounding to replicate commercially available, FDA-approved products — particularly during active patent or exclusivity periods — or to function as a parallel commercial pathway

COLORADO BIOSCIENCE ASSOCIATION

303.592.4073
info@cobioscience.com
cobioscience.com
600 Grant Street, Suite 306
Denver, CO 80203

outside those guardrails. Clear and enforceable boundaries are necessary to protect patient safety, respect intellectual property rights, and preserve the integrity of the FDA-approved marketplace.

As policymakers evaluate proposals in this area, we respectfully encourage an approach that:

- Upholds strong and enforceable patent protections, including established exclusivity periods;
- Maintains alignment with federal regulatory standards and oversight structures; and
- Reinforces the appropriate and limited role of compounding within the pharmaceutical supply chain.

A balanced framework can protect patients, sustain continued innovation, and ensure that Colorado remains a competitive and predictable environment for life sciences research, development, and investment.

We appreciate your thoughtful consideration and stand ready to serve as a resource.

Sincerely,

/s/

Amy B. Goodman
VP and Counsel for Policy + Advocacy
Colorado BioScience Association

Senate Health & Human Services

04/09/2026

HB26-1262 Patient Access to Compounded Medical Items

Typed Text of Testimony Submitted

Name, Position, Representing	**Typed Text of Testimony**
Christine Fallabel Against The American Diabetes Association	My name is Christine Fallabel, and I am the director of state government affairs with the American Diabetes Association. I am writing to respectfully oppose the Colorado Patient Access and Compounding Clarity Act as currently drafted. The ADA is the nationâ€™s largest non-profit organization representing over 40 million Americans affected by diabetes. We strive every day to improve the lives of people living with and at risk of diabetes and help to prevent diabetes for millions more living in our country. While I appreciate the intent to align state law with federal standards and promote clarity, the provision prohibiting the State Board of Pharmacy from adopting more restrictive rules than federal law raises serious patient safety concerns. The U.S. Food and Drug Administration (FDA) primarily oversees 503B outsourcing facilities and exercises limited, episodic oversight of traditional 503A state-licensed compounding pharmacies. Day-to-day regulation of those pharmacies has historically and appropriately been the responsibility of state boards of pharmacy. By tying Coloradoâ€™s regulatory authority to federal baselines and preventing the Board from

	adopting more protective standards, this bill could unintentionally create a regulatory gap. If federal oversight does not fully extend to state-licensed compounding pharmacies, and the state is restricted from strengthening its own rules, a significant number of compounding pharmacies could operate with reduced practical oversight. Compounded medications play a critical role in patient care, particularly for vulnerable populations, like people living with diabetes and obesity, requiring sterile preparations. Given the potential risks associated with compounding, Colorado should preserve, not limit, the Boardâ€™s authority to respond to emerging safety concerns, evolving USP standards, and state-specific needs. Patient access and patient safety are not competing goals. Ensuring strong, flexible state oversight is essential to maintaining public trust and preventing avoidable harm. For these reasons, I respectfully urge you to reconsider or amend the bill to preserve the State Board of Pharmacyâ€™s full regulatory authority over compounding practices in Colorado. We respectfully oppose HB 26-1262 but are happy to work with you to get the bill to a place that would be more protective of the needs of people living with and at risk of diabetes. Thank you for your time and consideration.