RETAIL ASSOCIATION OF MAINE
Voice of Maine Retail

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March 19, 2025

Senator Donna Bailey, Chair
Representative Kristi Mathieson, Chair
Members of the Health Coverage, Insurance and Financial Services Committee

RE: Testimony IN OPPOSITION to LD 538, An Act to Amend Maine's Prescription Drug Labeling Law by Allowing the Removal of the Name of a Prescriber of Mifepristone, Misoprostol and Their Generic Alternatives

Dear Senator Bailey, Representative Mathieson and members of the HCIFS Committee:

My name is Curtis Picard, and I serve as the President and CEO of the Retail Association of Maine. Our association represents retailers of all sizes including a number of independent and chain retail pharmacies. I am submitting testimony to respectfully oppose LD 538.

First, let me say that I truly appreciate the proponents of this bill reaching out to us to solicit our feedback. I sent my impacted members additional information about the bill, and I am relying on the feedback that I've received in crafting this testimony.

We take no issue with the intent of the bill, and understand the genesis behind the proposal. However, our opposition to LD 538 centers on two principal reasons:

1. Conflict with Federal Law and Risk of Misbranding
LD 538 proposes to allow the substitution of a health care facility's name in place of the prescriber's name on prescription labels for specific drugs. While the intent of this bill may be to safeguard provider privacy, my members believe it may directly conflict with federal law.

Under **21 U.S.C. § 353(b)(2)**[1], a drug dispensed by prescription is exempt from certain federal labeling requirements only if the label includes specific elements, including:
"...the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber, and...the directions for use..."

[1] https://www.law.cornell.edu/uscode/text/21/353

Failure to include the prescriber's name, even at the request of the practitioner, renders the drug misbranded under **21 U.S.C. § 352**[2]. Misbranding is a prohibited act under **21 U.S.C. § 331**[3], which exposes pharmacies to significant FDA enforcement risk.

My members believe the federal law is clear: **the prescriber's name must be on the label**. Pharmacies cannot lawfully comply with LD 538 without risking violations of federal law and potential legal penalties. Federal preemption further complicates state-level deviations from these requirements.

2. Significant Operational and Technological Burden on Pharmacies

Even if LD 538 were consistent with federal law, its implementation presents substantial technological challenges. Pharmacies use proprietary dispensing software systems designed to comply with current federal and state regulations. These systems are not configured to remove the prescriber's name and substitute it with a facility name for specific medications only.

This change would require:

- **Extensive system reprogramming** to identify and handle exceptions for a narrow drug category.
- **Software validation and testing** to ensure compliance and prevent dispensing errors.
- **Training and workflow changes** for pharmacists and staff.

These modifications would be costly and disruptive. Moreover, it creates inconsistencies in labeling practices, which could affect patient safety and medication tracking.

For these reasons — federal noncompliance and costly technological burdens — we respectfully oppose LD 538. While we appreciate the bill's intent, we urge the Committee to consider the legal and operational consequences for pharmacies and the potential risks to patients. Any effort to change labeling requirements must align with federal law and maintain the integrity of pharmacy operations.

Thank you for your consideration.
Sincerely,

Curtis Picard, CAE
President and CEO

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[2] https://www.law.cornell.edu/uscode/text/21/352

[3] https://www.law.cornell.edu/uscode/text/21/331