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# MEMORANDUM

TO: Pharmacies

FROM: Massachusetts Board of Registration in Pharmacy (Board)

DATE: November 6, 2025

SUBJECT: Automated Non-Sterile Compounding Devices

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The Pharmacy Advisory Committee to the Board has issued an opinion regarding 503A pharmacy use of automated non-sterile compounding devices. In general, the pharmacy is responsible, regardless of the equipment or device(s) utilized, for the accuracy of the compounding process and quality of the final compounded preparation in accordance with all laws and regulations, including USP standards, especially <795> and <800>.

**The Board has voted to allow** 503A pharmacies to utilize automated non-sterile compounding devices as long as the pharmacy ensures compliance with all relevant USP chapters, all applicable state and federal laws and regulations, and the Pharmacy Advisory Committee's recommendations as below:

1. The pharmacy must determine if the device has or requires FDA approval or otherwise can verify through documentation that the manufacturer has validated the device for its use in non-sterile drug compounding.
2. The pharmacy must confirm that any FDA-approved Active Pharmaceutical Ingredients (APIs) or ingredients for an approved Investigational New Drug (IND) study, as applicable, are compatible with the device they intend to utilize.
3. The pharmacy must confirm that such devices are easily cleanable to minimize cross-contamination. Pharmacies must ensure that hazardous drug compounding is conducted in full compliance with USP <800>.