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MEMORANDUM

TO: Maine Board of Pharmacy

FROM: Carrie L. Carney, Assistant Attorney General Luni 2 Lung

DATE: April 5, 2013

SUBJECT: Compounding for Office Use

There has been some discussion at recent Board meetings pertaining to whether or not a pharmacy can compound drugs "for office use." In this context, "for office use" means that a pharmacy can compound drugs without a prescription to give to a practitioner to keep in his or her office for patient use. The current Board statute prohibits this practice.

Pursuant to 32 MRS § 13702-A(4), "compounding" is the preparation, mixing, assembling, packaging or labeling of a drug or device by a pharmacist for the pharmacist's patient either for dispensing as the result of a practitioner's prescription drug order, or for the purpose of, or as an incident to, research, teaching or chemical analysis and not for sale or dispensing. "Compounding" includes the preparation of drugs or devices in anticipation of prescription drug orders to be received by the pharmacist based on routine, regularly observed prescribing patterns.

According to the current definition, above, a pharmacist may compound drugs in the following situations:

- 1) For a specific, individually identified patient pursuant to a practitioner's specific prescription drug order;
- 2) For research, teaching or chemical analysis and NOT for sale or dispensing; and
- 3) In anticipation of routine prescription drug orders based on regularly observed prescribing patterns.

Nowhere does this definition all for compounding "for office use."

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14 Access Highway, Ste. J Caribou, Maine 04736 The: (207) 496-3792 Fan: (207) 496-3291 According to a report from the State of Florida, in 2008, there were at least 15 states that allowed compounding for office use. However, these 15 states specified under what circumstances compounding could be done for office use, and some outlined detailed standards of good manufacturing practices in those situations.

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For compounding to be allowed for office use in Maine, a statutory amendment to the definition of "compounding" is required. At the very least, if the statute is amended to allow compounding for office use, there should be requirements that the medication be labeled "for office use" and that compounding for office use be done in a very limited quantity, specified by the statute.