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## MEMORANDUM

TO: Maine Board of Pharmacy

FROM: Carrie L. Carney, Assistant Attorney General *Carrie L. Carney*

DATE: April 5, 2013

SUBJECT: Clinical Laboratory Improvement Amendments (CLIA) Program

This Memorandum clarifies two questions: 1) Whether or not testing under the CLIA Program falls within the scope of practice of a pharmacist; and 2) If so, whether or not an individual doing the testing must be a pharmacist or another licensed professional.

The CLIA Program sets standards and issues certificates for clinical laboratory testing. For facilities doing testing, the law requires either a certificate for nonwaived tests or a certificate of waiver.

42 CFR 493 addresses the CLIA Program, and breaks up the categories of tests performed by complexity: waived tests, and nonwaived tests which further categorized into tests of moderate complexity, including the subcategory of PPM procedures, and tests of high complexity. (493.5)

Waived tests are those that are simple laboratory examinations and procedures cleared by the FDA for home use; employ methods so simple and accurate as to render the likelihood of erroneous results negligible; or pose no reasonable risk of harm to the patient if performed incorrectly. (493.15(b)) These tests are limited to what is listed in the CFR. (493.15(c))

The CFR specifies that nonwaived testing must be performed by individuals meeting certain qualifications, depending on whether or not the testing is of moderate or high complexity, and what kind of test it is. In contrast, the CFR is also silent as to the qualifications of personnel who perform waived testing. Unlike the requirements for individuals performing nonwaived testing, there are no special qualifications—essentially anyone can do the testing.

Therefore, it is reasonable to conclude that it is within the scope of practice of a pharmacist to perform waived tests. However, this is not a duty exclusive to pharmacists. One does not need to be licensed as a pharmacist, or hold any other license, to perform these tests.