Title: Laboratory Testing in Pharmacies Policy No. I.A.36

Approved: 02-17-2022 Revised:

1. The Clinical Laboratory Improvement Amendments of 1988 statute is an amendment of the Public Health Services Act in which Congress revised the federal program for certification and oversight of clinical laboratory testing. Two subsequent amendments were made after 1988; however, the law continues to be cited as CLIA.

2. The section of federal regulations titled “Standards and Certification: Laboratory Requirements” is issued by the Centers for Medicare & Medicaid Services (CMS) to enact the CLIA law passed by Congress. The CLIA regulations establish quality standards for laboratory testing performed on specimens from humans, such as blood, body fluid, and tissue, for the purpose of diagnosis, prevention, or treatment of disease, or assessment of health. The federal regulations are found at 42 CFR 493.

3. Laboratories credentialed by CMS may perform testing classified as:
   a. Waived;
   b. Moderate complexity; and
   c. High complexity.

4. Pharmacies, once properly credentialed by CMS, may perform CLIA-waived tests without the need for a medical order for such testing.

5. Pharmacies, once properly credentialed by CMS, may perform moderately complex laboratory testing pursuant to a medical order for such testing.

6. Pharmacies shall retain evidence of the education, training, and continuing competency, for personnel performing all laboratory testing; and further, shall provide access to such records when requested by the Board.