WHEREAS, Federal regulation requires all physicians who do specimen testing to purchase a federal CLIA permit that must be renewed every 2 years; and

WHEREAS, The same CLIA tests performed in a physician’s office are deemed CLIA-waived tests, the same tests that any consumer may purchase and use without a CLIA permit; and

WHEREAS, The use of a microscope by a physician is likewise subject to additional payment and regulation as per the CLIA Amendment; therefore be it

RESOLVED, That our American Medical Association adopt the position that it is proper to remove the CLIA certification mandate requirement for physicians who only use CLIA-waived tests and physician-performed microscopy. (New HOD Policy)

Fiscal Note: Not yet determined

Received: 04/25/18

RELEVANT AMA POLICY

Clinical Laboratory Improvement Act of 1988 H-260.980

1. It is the policy of the AMA to (a) continue and intensify its efforts to seek appropriate and reasonable modifications in the proposed rules for implementation of the Clinical Laboratory Improvement Amendments (CLIA) 88; (b) communicate to Congress and to the Centers for Medicare & Medicaid Services (CMS) the positive contribution of physician office laboratory testing to high quality, cost effective care so that through administrative revision of the regulations, clarification of Congressional intent and, if necessary, additional legislation, the negative impact of these proposed regulations on patient care and access can be eliminated; (c) continue to work with Congress, CMS, the Commission on Laboratory Assessment, and other medical and laboratory groups for the purposes of making the regulations for physicians’ office laboratories reasonable, based on scientific data, and responsive to the goal of improving access to quality services to patients; (d) protest the reported high costs being considered for certification of laboratories and the limited number of laboratory categories proposed; (e) encourage all components of the federation to express to CMS and members of Congress their concerns about the effect of the proposed rules on access and cost of laboratory services; and (f) protest the very limited list of waivered tests.

2. Our AMA will send a letter to CMS stating that CLIA requirements regarding provider-performed microscopy procedures and annual competency assessments are overly burdensome for physicians and their practices.


1 The Clinical Laboratory Improvement Amendments of 1988 statute is an amendment to the Public Health Services Act of 1967 [Public Law 90-174, Dec 5, 1967] in which Congress revised the federal program for certification and oversight of clinical laboratory testing. Two subsequent amendments were made after 1988. The law continues to be cited as CLIA ’88 as named in legislation. The Clinical Laboratory Improvement Amendments of 1988 (CLIA) regulations include federal standards applicable to all U.S. facilities or sites that test human specimens for health assessment or to diagnose, prevent, or treat disease. CDC, in partnership with CMS and FDA, supports the CLIA program and clinical laboratory quality.

Waived tests include test systems cleared by the FDA for home use and those tests approved for waiver under the CLIA criteria. A list of waived tests can be found at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/analyteswaived.cfm