Position Statement
on
The 1988 Clinical Laboratory Improvement Amendments (CLIA) '88
**(Approved by the Board of Directors: December 9, 1993;
Amended by the Board of Directors: November 22, 2014;
Amended by the Board of Directors: May 4, 2024)**

The American Academy of Dermatology recognizes and understands that CLIA was established by the federal government in 1988 for the purpose of setting quality standards for all laboratory testing.

To the extent that the practice of dermatology includes, but is not limited to, diagnosis, treatment, or correction of human conditions, ailments, diseases, injuries, or infirmities of the skin, hair, nails and mucous membranes, by any medical, surgical, pathologic or aesthetic means, medications, methods, devices, or instruments, and inasmuch as dermatopathology is a critical component of dermatologic care, which ensures that skin biopsy specimens receive accurate, reliable, and timely diagnosis for the purpose of delivering quality patient care, the Academy supports quality control methods and practices with respect to laboratory procedures.

Nonetheless, the Academy deplores attempts and compliance requirements that seek to impose ill-conceived, unfair and unreasonable burdens that hamper and impair the ability of board-certified dermatologists, who have extensive knowledge and expertise in cutaneous medicine, surgery, and pathology, to provide their patients with effective, timely and quality-based care. Therefore, the Academy supports the following principles and advocacy objectives outlined in the American Medical Association's (AMA) current and applicable policies addressing ongoing concerns related to CLIA:

1. Revise, amend or modify appropriately sections of CLIA that "do not improve patient care" or create obstacles for physicians that inhibit them from performing simple office tests that enhance patient care[1, 2.]

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[1] ***AMA H-260.975 Repeal of CLIA***
The AMA (1) will work through appropriate regulatory, legislative or judicial channels for changes in CLIA '88 or elimination of those portions of the CLIA '88 regulations that do not improve patient care; and (2) will continue to work to achieve changes that markedly reduce or eliminate the obstacles experienced by physicians under CLIA '88, with the understanding that should this not be successful, the Association shall move to seek legislative repeal of CLIA '88. (Sub. Res. 237, I-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmed: BOT Rep. 28, A-13: BOT Rep 09, A-23)

[2] ***AMA H-260.980 Clinical Laboratory Improvement Act of 1988***

(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 CLIA 88;
(b) communicate to Congress and to 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.

(Sub. Res. 46, A-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: CSAPH Rep. 1, A-10; Appended: CMS Rep. 9, I-14)

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2. Obtain from the federal government relevant and proven evidence, study or data demonstrating the value and benefit of CLIA[3].
3. Exempt physician office labs from onerous requirements that do not enhance the function, efficiency and effectiveness of office-based labs.[4]

To this end, the Academy will work in concert with the AMA and other medical specialty societies to ensure that CLIA requirements are physician friendly and that compliance standards are evidence based and driven by the need to improve patient care.

The Academy continues to educate and supply members and their practice staff with resources to help them keep current on CLIA compliance requirements and is committed to enhancing its practice support resources to assist dermatologists. [5][6]

[3] ***AMA H-260.973 Cost and Benefits of CLIA '88 and Other Health Regulations***
The AMA demands from the government any proven evidence, research, study or any data concerning CLIA '88: (a) showing that this law was actually necessary, and (b) indicating in a quantitative way how any potential benefits of this law outweigh this addition to the already overburdened cost of health care. (Res. 245, I-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmed: BOT Rep. 28, A-13; Reaffirmed BOT Rep 09, A-23)

[4] ***AMA H-260.966 CLIA Physician Office Laboratory Inspections***
The AMA will seek and support legislation which would amend Section 353 of the Public Health Service Act to exempt physicians' office laboratories, except for those which perform a pap smear (Papanicolaou's Smear) analysis, from the clinical laboratories requirements of that section; and if this is not possible, the AMA will seek legislation or modification in the Centers for Medicare & Medicaid Services regulations which would allow physicians' office laboratories which do not do cytology, which have no significant deficiencies on inspection thus triggering a "revisit," which have satisfactory proficiency testing performances, which have no complaints against the lab and which have not undergone any significant changes (i.e., new director), be allowed to perform a self-assessment study called the Alternative Quality Assessment Survey (AQAS) in lieu of the biannual on-site inspection. (Res. 212, A-97; Reaffirmed: BOT Rep. 33, A-07; BOT Rep. 22, A-17)

[5] What are the CLIA requirements for lab operations? https://www.aad.org/member/practice/compliance/clia/requirements

[6] https://www.cdc.gov/clia/index.html

This Position Statement is provided for educational and informational purposes only. It is intended to offer physicians guiding principles and policies regarding the practice of dermatology. This Position Statement is not intended to establish a legal or medical standard of care. Physicians should use their personal and professional judgment in interpreting these guidelines and applying them to the particular circumstances of their individual practice arrangements.