RESOLUTION 22-22

Title: Clinical Laboratory Improvement Amendment Requirements

Introduced by: David Whalen, MD, MPA, for the Kent County Delegation

Original Author: Gerald Lee, MD

Referred To: Reference Committee A

House Action: **APPROVED AS AMENDED**

Whereas, the Clinical Laboratory Improvement Amendment was designed to ensure quality and safety when testing human samples, and

Whereas, some manufacturers have sought legal protection by stating all tests need to be confirmed in a laboratory, and

Whereas, physicians are trying to make medical decisions based on the results of such tests at the time of appointment and/or for lower costs to the patient, and

Whereas, in-office testing should only be done by trained staff in accordance with manufacturer's directions, and

Whereas, physicians should use this information in accordance with the clinical history; therefore be it

RESOLVED: That MSMS adopt policy advocating that any confirmatory laboratory testing for urine drug screens should be considered at the discretion of the ordering physician with the best interests of the patient in mind.

WAYS AND MEANS COMMITTEE FISCAL NOTE: $1,000-$2,000 for new MSMS policy.

Relevant MSMS Policy:

Determination of Medical Necessity of Medical Case Management
The treating physician shall be the sole determinant of medical case management and medical necessity. MSMS believes that an insurer, a health care corporation or a government agency may not interfere with the patient/physician relationship by determining medical necessity or medical case management without a fair and reasonable appeals process and independent binding arbitration in a timely fashion. (Board Action Report #14, 1994 HOD, re Res121-93A)
– Reaffirmed (Sunset Policy 2021)

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.

Regulation of Clinical Laboratories H-260.982
Our AMA supports working with medical specialty societies and national medical specialty organizations and CMS to assure that regulations which are promulgated by CMS reflect accurately the intent of Congress and set reasonable requirements and appropriate fees that will allow the continuing operation of physician office laboratories.