

REPORT OF THE COUNCIL ON MEDICAL SERVICE

CMS Report 9-I-14

Subject: Regulation of Provider-Performed Microscopy Procedures
(Resolution 715-A-14)

Presented by: Jack McIntyre, MD, Chair

Referred to: Reference Committee J
(Melissa J. Garretson, MD, Chair)

1 At the 2014 Annual Meeting, the House of Delegates referred Resolution 715, “Overregulation of
2 Provider-Performed Microscopy Procedures for Ambulatory Health Care,” which was introduced
3 by John Spurlock, MD, Delegate from Pennsylvania. Resolution 715-A-14 asked:

- 4
5 (1) That our American Medical Association (AMA) vigorously advocate for recognition of
6 current certification systems that are in place without placing financial and temporal barriers to
7 care; and (2) That our AMA oppose overregulation of professional practitioners without clear
8 demonstration of harm under current regulations and/or policies.
9

10 This report provides background on federal regulation of provider-performed microscopy
11 procedures (PPMP); summarizes relevant AMA policy; and presents policy recommendations.
12

13 BACKGROUND

14
15 Resolution 715-A-14 was crafted in response to Joint Commission standards requiring practitioners
16 furnishing provider-performed microscopy procedures (PPMPs) to undergo annual competency
17 assessments. A PPMP is a microscopic examination of a specimen obtained during a patient visit.
18 Clinical Laboratory Improvement Amendments (CLIA) regulations stipulate that, because PPMPs
19 are moderately complex tests, the competence of providers must be assessed annually. Resolution
20 715-A-14 contends that competency testing takes time away from patient care, increases the cost of
21 patient care and potentially delays patient care.
22

23 CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

24
25 Enacted by Congress in 1988, CLIA established quality standards for all non-research specimen
26 testing performed in commercial, hospital and physician office laboratories. The intent of the
27 standards is “to ensure the accuracy, reliability and timeliness of patient test results regardless of
28 where the test is performed.”¹ According to the Centers for Medicare & Medicaid Services (CMS),
29 data has shown that CLIA has contributed to improvements in the quality of laboratory testing.²
30

31 CMS certifies laboratories to perform three categories of tests: waived complexity; moderate
32 complexity; or high complexity, while stipulating that “the more complicated the test, the more
33 stringent the requirements.”³ PPMPs are considered moderately complex tests and must achieve
34 accreditation by a CMS-approved accrediting body (e.g., The Joint Commission or College of
35 American Pathologists). Anyone performing PPMPs must undergo annual competency assessments
36 that utilize six methods of evaluation including direct observation of routine testing, recording of
37 test results, instrument maintenance and quality control.

1 RELEVANT AMA POLICY

2
3 Existing AMA policy calls for modifications to CLIA requirements, including exemptions for
4 physician office laboratories or changes that would make the regulation of physician office
5 laboratories more reasonable and appropriate (Policies H-260.966, H-260.975 and H-260.980).
6 Policy H-220.946 urges The Joint Commission to eliminate standards that increase health care
7 costs without demonstrably improving quality of care. Policy H-180.973 calls for intensifying
8 efforts to reduce the burden of government and third-party regulation on medical practice.
9

10 DISCUSSION

11
12 The Council agrees that federal regulation of physician office laboratories in which PPMPs are
13 performed may be burdensome for physicians as well as their practices, and that the competency
14 testing requirements in particular may be a drain on physicians' time. The Council believes there
15 are practices capable of performing microscopic examinations during patient visits that instead use
16 more costly and time-consuming referrals because certification requirements have not been met.
17

18 Nevertheless, the Council points to existing AMA policy on CLIA regulations, Joint Commission
19 standards and the burden of regulations on medical practice, and does not perceive a need for new
20 policy development on this topic. Accordingly, the Council recommends that Policies H-260.980,
21 H-220.946 and H-180.973 be reaffirmed in lieu of Resolution 715-A-14.
22

23 RECOMMENDATIONS

24
25 The Council recommends that the following be adopted in lieu of Resolution 715-A-14, and that
26 the remainder of the report be filed:
27

- 28 1. That our American Medical Association (AMA) reaffirm Policy H-260.980, which affirms
29 that it is the policy of the AMA to: seek appropriate modifications to the Clinical
30 Laboratory Improvement Amendments (CLIA); communicate to Congress and to the
31 Centers for Medicare & Medicaid Services (CMS) the positive contribution of physician
32 office laboratory testing to high-quality, cost-effective care; continue to work with
33 Congress, CMS and other stakeholders to make the regulations for physician office
34 laboratories reasonable; protest the high costs of certification of laboratories; and protest
35 the very limited list of waived tests. (Reaffirm HOD Policy)
36
- 37 2. That our AMA reaffirm Policy H-220.946, which urges The Joint Commission to eliminate
38 standards that increase health care costs without demonstrably improving quality of care.
39 (Reaffirm HOD Policy)
40
- 41 3. That our AMA reaffirm Policy H-180.973, which states that the AMA will greatly
42 intensify its efforts to reduce the burden of regulations on medical practice and its intrusion
43 into the physician-patient relationship. (Reaffirm HOD Policy)
44
- 45 4. That our AMA send a letter to CMS stating that the CLIA requirements regarding
46 provider-performed microscopy procedures and annual competency assessments are overly
47 burdensome for physicians and their practices. (Directive to Take Action)

Fiscal Note: Less than \$500.

REFERENCES

¹ U.S. Department of Health and Human Services: Centers for Medicare & Medicaid Services. Clinical Laboratory Improvement Amendments (CLIA). May 2013.

² Ibid.

³ Ibid.