



COLLEGE of AMERICAN PATHOLOGISTS

January 17, 2020

Re: Feedback on Scope of Practice

The College of American Pathologists (CAP) appreciates the opportunity to provide comments on scope of practice concerns. As the world's largest organization of board-certified pathologists and leading provider of laboratory accreditation and proficiency testing programs, the CAP serves patients, pathologists, and the public by fostering and advocating excellence in the practice of pathology and laboratory medicine worldwide.

The CAP shares the CMS' desire to minimize regulatory burden and has previously met with Department of Health and Human Services (HHS) officials to offer suggestions for specific actions to incorporate into the agency's broader regulatory relief agenda. However, consistent with our coalition efforts with the American Medical Association (AMA), the CAP is seriously concerned about the Administration's efforts to eliminate or weaken current Medicare supervision requirements of nonprofessionals, "a critical safeguard to ensure the health and safety of Medicare patients and the cornerstone of the widely adopted team-based approach to health care." As was stated in an October 29, 2019 AMA letter, "scope of practice of health care professionals should be based on standardized, adequate training and demonstrated competence in patient care." Together with our coalition partners, the CAP supports physician-led health care teams, "with each member drawing on their specific strengths, working together, and sharing decisions and information for the benefit of the patient," and believes physicians, "as the most highly educated and trained health care professional," should lead the health care team. The CAP strongly believes that the best interests of patients require that a physician member of the provider team direct the course of the diagnostic and therapeutic care of the patient and that a physician determine appropriate clinical and anatomic laboratory services.

Similarly, the CAP holds that diagnostic laboratory testing should only be performed by those individuals who possess appropriate clinical education and training, and under the supervision of licensed physicians, or consistent with non-waived testing requirements under CLIA 88. Further, the interpretation of clinical laboratory tests is the practice of medicine and should, therefore, be done solely by licensed physicians. No test is so simple and straightforward to perform that erroneous results cannot occur, and no incorrect test result is "risk free" or inconsequential with regard to potential harm.

While only qualified healthcare professionals (QHPs) can directly bill Medicare under the physician fee schedule (PFS), the CAP has concern with efforts to seek recognition by Medicare as QHPs for board-certified doctoral level laboratory professionals (including PhDs) as well as the potential for public confusion about the distinctions between a



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clinical pathologist and a graduate of these programs. A clinical pathologist is a physician who is trained to render diagnoses, interpret laboratory tests, and provide clinical consultations in the field of laboratory medicine to other physicians. In the United States, practicing pathologists undergo specialized training after medical school and are most often certified by the American Board of Pathology. Pathologists direct clinical and anatomic pathology laboratory services; perform biopsies; evaluate surgical, cytology, and autopsy specimens; interpret laboratory tests; and serve as laboratory consultants to other physicians. While all laboratory and other health care professionals share an important role in providing care to patients, their skillset is not interchangeable with that of a fully trained and licensed physician. Likewise, the role of pathologists' assistants is to facilitate the practice of medicine by pathologists, but not to make diagnoses or determine treatment for patients. Those functions, defined as the practice of medicine, are the responsibility of pathologists alone.

Finally, the CMS in 2018 issued a request for information (RFI) on potential revisions to the personnel requirements for the Clinical Laboratory Improvement Amendments (CLIA), which we understand the agency continues to deliberate. CLIAC, the federal advisory panel, made recommendations to the CMS for changes in the CLIA personnel requirements that were developed by the CLIA Personnel Regulations Workgroup. We support the agency's efforts to streamline administrative procedures for personnel and believe the current CLIA personnel requirements should be maintained.

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The College of American Pathologists appreciates your consideration of these comments. Please direct questions to Elizabeth Fassbender, JD, Assistant Director, Economic and Regulatory Affairs, at (202) 354-7125 / efassbe@cap.org.