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College of American Pathologists

Statement to the
Clinical Laboratory Improvement Advisory Committee (CLIAC)
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Presented by

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Dr. Merlin, members of the committee, good afternoon. My name is Jared Schwartz and I am the Director of the Department of Pathology and Laboratory Medicine for Presbyterian

Healthcare in Charlotte, NC. Presbyterian Healthcare is an 800-bed multi-hospital integrated healthcare system that includes hospital rapid response labs, a regional reference lab, physician office labs and point of care testing services. Today I am here as a representative of the College of American Pathologists (CAP). I am currently the Secretary/Treasurer, serve as a member of the CAP Board of Governors, chair the CAP Ad Hoc Committee on Preparedness for National Emergency and previously served as the chair of CAP Council on Scientific Affairs. The CAP is a national medical specialty society representing over 16,000 pathologists who practice anatomic pathology and laboratory medicine in laboratories across the United States and Canada. The College's Commission on Laboratory Accreditation is responsible for the accreditation of over 6,000 laboratories worldwide. College members have extensive expertise in providing and directing laboratory services and serve as inspectors in the accreditation program. In addition, the CAP provides laboratories with a wide array of proficiency testing programs and educational solutions to assist in the improvement of the laboratory's performance and its positive impact on patient care.

Direct access laboratory testing is a growing trend in clinical laboratory testing services and the College is committed to working with the CLIAC as it explores this issue. The College believes that patients are best served when laboratory tests are ordered by a qualified physician where such a physician directs the course of the diagnostic and therapeutic care of the patient, and that a physician should determine which clinical and anatomic laboratory services are appropriate. The College also believes that each individual pathologist, pathology group or laboratory should make its own determination whether to accept requests for diagnostic laboratory studies from patients. This determination should be based on an assessment of the interest of the patient, potential legal exposure of the laboratory, applicable state law, medical staff bylaws, and other relevant considerations. A pathologist, pathology group or laboratory should be able to retain the right not to offer direct-access testing, unless state law requires such testing.

The College has set forth the following criteria that should be considered when a pathologist, pathology group or laboratory decides to permit direct access by patients to laboratory testing.

1. A physician, or other appropriate health care provider, should be available to assist the patient in the proper interpretation of test results, particularly when the test results fall outside an expected range. The patient should designate, in advance and in writing, an appropriate health care provider who should be informed of test results at the same time as the patient.

2. The laboratory director should be able to order appropriate tests and assist the patient with interpretation of results. The College cautions that certain policies that give the laboratory responsibility for ordering additional tests could have legal implications, and recommends that laboratory directors consult appropriate counsel about the potential risks of such involvement.

3. Provisions should be made for compensation for direct-access testing. Most direct access testing services are paid for directly by the patient. Currently, the Centers for Medicare and Medicaid Service (CMS) under the Medicare program restricts reimbursements to tests ordered by "physicians" as defined in Social Security Act. Health insurance policies may not cover non-physician ordered laboratory testing or interpretation of test results.

4. The laboratory should have a policy specifying the levels of testing or particular tests that will be available by direct access.

5. Laboratory policies should comply with legal requirements governing informed consent, confidentiality of patient information, and mandated reporting of test results.

When considering the issue of direct access testing, it is important to review how current CLIA regulations may apply. CLIA regulations defer to state law in determining what entity is authorized to order and receive test results. Specifically under CLIA, an "authorized person" is defined as "an individual authorized under State law to order tests or receive test results, or

both." Thus, CLIA regulations allow the potential for individuals to order their own laboratory tests and receive the results, depending on the state in which the patient resides. Currently, approximately one-third of the states strictly prohibit patients from directly ordering tests, half allow direct access testing without restrictions, and the remaining states with limited restrictions. CLIA requires that pertinent "reference" or "normal" ranges be made available to the authorized person who ordered the tests. The results or transcripts of laboratory tests or examinations must be released only to authorized persons or the individual responsible for utilizing the test results. In addition, CLIA requires the laboratory to develop and follow written procedures for reporting imminent life-threatening laboratory results or panic values. Specifically under CLIA regulations, the laboratory is required to immediately alert the authorized individual when any test result indicates an imminent life-threatening condition. Under a direct access testing scenario, without direct physician or other health care provider involvement, how can we ensure that the patient, who receives laboratory results information, understands the meaning of the information, is appropriately counseled and if required, will seek necessary treatment? The College believes that more risk/benefit information is needed on the provision of direct access testing services. For example, determining the benefits of direct access testing in the form of improved health/wellness or reduction in morbidity or mortality rates. At this time, there is no evidence that demonstrates this benefit. As well, evidence is needed on the potential unintended ill effects of this method of testing, particularly when patients are lost to follow-up for appropriate counseling and treatment. The College believes that patients are best served by comprehensive quality health care, utilizing the clinical context of laboratory results and the knowledge of patient history, which is vital in determining the likelihood of illness. Allowing patients to take control of their health care through direct access testing has some promising benefits. However, we must ensure patients seek medical intervention as indicated by a physician, or other appropriate health care provider to assist in the proper interpretation of laboratory results. On behalf of the College of American Pathologists, I would like to thank the committee for this opportunity to provide comments.