

Comments by Robin Stompler
Vice President, Government Affairs
American Society for Clinical Pathology
before the Clinical Laboratory Improvement Advisory Committee
March 12, 2003

Thank you for the opportunity to say a few words regarding direct access testing. I appreciate the information presented this afternoon, and thought it may be useful to add some thoughts from the American Society for Clinical Pathology (ASCP).

As many of you know, ASCP is a nonprofit medical specialty society representing 140,000 members, including board certified pathologists, other physicians, clinical scientists, medical technologists and technicians. It is the world's largest organization representing pathology and laboratory medicine. As the leading provider of continuing education for pathologists and medical laboratory personnel, the ASCP enhances the quality of the profession through comprehensive educational programs and publications and self-assessment materials.

By our definition, direct patient access testing allows patients to have tests performed by licensed laboratories without a physician order.

Because of the complexity of laboratory testing, ASCP recommends that patients who choose direct access testing review all results with their physician. Laboratories that provide direct access testing should have a list and explanation of the tests that are offered.

On the payment side, laboratories that provide direct access to testing should inform patients about restrictions in Medicare and insurance coverage of tests not ordered by physicians. Of course, laboratories providing this testing must comply with local, state and federal regulations.

To learn more about direct access testing rules, ASCP conducted a study on direct access testing, which was published in *Laboratory Medicine* in November 2001. We found that 25 percent more states permit direct access testing since our last study in 1999.

This increase is largely due to an interpretation from the Centers for Medicare and Medicaid Services that in the absence of a state law prohibiting direct access testing, it is permissible under the federal Clinical Laboratory Improvements Amendments of 1988.

Since Ms. Whalen was kind enough to include the ASCP study in her presentation, I will only briefly add some information. Direct access testing is allowed in 34 states and territories, and it is not allowed in 18 states or territories. (In 1999, ASCP identified 27 states and territories permitting direct access testing.)

Of the states allowing direct access testing, there are no limits with regard to what may be provided as direct access testing in 20 states. Typically states without limitations on what may be provided do so because their laws are silent on the issue.

14 states have limitations on what direct access testing may be provided. These limits could include allowing independent labs, but not hospitals, to perform direct access testing, as is the case in Mississippi. The limits also involve limiting the types of tests that may be ordered via direct access. Maine, for example, allows DAT only for glucose, cholesterol, urine pregnancy, and fecal occult blood. In addition, we found that several states, such as Michigan, allow for direct access only for tests classified as waived under CLIA.

In states where direct access testing is not permitted, testing services may be permissible through other means, such as by a physician's standing order or at a health fair. Of course, laboratories are not required to offer direct access testing services.

Since our study, a couple of states expanded their direct access laws -- California (2001) and New York (2002). Both states, however, did allow some limited direct access testing prior to our study.

Some states have considered liability issues related to direct access. Virginia has adopted regulations specifying that it is the patient's responsibility to seek a diagnosis. During our survey, many states noted that laboratory staff should not interpret test results, as this may constitute an unauthorized practice of medicine.

Again, I hope this information from ASCP is helpful to you. I'd like to recognize Matt Schulze on my staff who was responsible for conducting and reporting on the survey. I would be pleased to answer any questions you may have.

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I appreciated the invitation to present at your last meeting information regarding the shortage of medical laboratory personnel and legislative solutions to this problem.

Knowing of your interest, I'm pleased to report that Representatives John Shimkus, Jesse Jackson, Jr., and Michael Bilirakis have introduced HR 623, the Medical Laboratory Personnel Shortage Act of 2003. This legislation takes an educational approach to the laboratory workforce shortage problem.

The American Society for Clinical Pathology is pleased to be working closely with these legislators in developing such a solution to this critical health care issue. I'd be pleased to answer questions.