

June 6, 2011



American
Clinical Laboratory
Association

Ms. Lynda England, Director
Tennessee Medical Laboratory Licensing Board
Division of Health Related Boards
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Heritage Place Metro Center
Nashville, Tennessee 37243

Ms. England:

On behalf of the American Clinical Laboratory Association, I am writing to seek clarification of the April 15, 2011 policy statement from the Tennessee Medical Laboratory Licensing Board regarding “Patient Test Management/Laboratory Reports” (hereinafter “Policy Statement”). ACLA is an association representing local, regional and national laboratories across the country, many of whom provide services to Tennessee residents. As a result, ACLA members are directly affected by this Policy Statement.

As you know, the Policy Statement appears to take the position that a laboratory should not send the results of any test it performs to anyone other than the physician or other practitioner who requested the service or to another clinical laboratory. However, the Policy Statement does say that a referring physician can give permission to another physician, such as a pathologist, to give results to the patient. The Bulletin concludes, “however, the medical laboratory shall not be used as the agent/intermediary of the health care provider or the physician.”

The Policy Statement has created some confusion for laboratories doing business in Tennessee and we are asking that the Board clarify its position. If strictly applied, this Policy Statement would frequently prevent a laboratory from disclosing results to another health care provider or the patient himself, even if the ordering physician requested it to do so. This seems an overly strict application of the state laws at issue and one that is likely to interfere with the efficient provision of care, cause significant patient inconvenience, and increase medical costs.

It appears that Tennessee state laws in this area have several key purposes. First, they ensure that laboratories report directly to the individual who ordered the test and do not report results to those who are not qualified to receive such results. Such laws protect the privacy of the information by ensuring that it is reported back to the person who ordered the tests. Further, they may also protect the patient from unnecessary stress or confusion, because the laws prevent the patient from obtaining laboratory test results without the involvement of the patient’s physician. In such a situation, the ordering physician is fulfilling his vital role as the intermediary protecting the patient and the patient’s health care information.

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Tennessee Medical Laboratory Licensing Board
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However, these goals still may be achieved, if the ordering physician gives his or her permission to the laboratory to release the information. As the Board recognizes, it is appropriate for one physician to share information with another physician, if the original ordering physician has given permission to do so. Thus, as a general policy matter, the Board obviously believes sharing is appropriate where the ordering physician has given permission, and that such action does not violate the terms or purpose of the statutes.

The Board also notes that it is permissible, under this interpretation, for a pathologist to share test results with another physician, where the pathologist has the permission of the referring physician. There seems little reason, however, to distinguish between a pathologist, who in all likelihood works for a laboratory, and the laboratory for which that pathologist works. The key issue, in either case, is that the referring physician has given his explicit permission to share the information, in which case the patient and the patient's information are protected. Further, to the extent that the ordering physician is authorized to disclose test results to another party himself, we see no reason why the clinical laboratory that performed the test would be prohibited from sending the same result to another party, so long as the ordering physician has authorized the disclosure.

Therefore, we ask the Board to review its Policy Statement to clarify its position. We urge the Board to confirm that a laboratory is permitted to release test results to another physician or the patient himself, if it has a clear statement from the ordering physician to do so.

In addition, we ask the Board to give its views on the very common situations set out below, which are likely to arise as a result of the Board's Policy Statement. As noted, the Policy Statement has created confusion among laboratories doing business in Tennessee, and the following questions have already been raised in response to that statement. We respectfully request that the Board give its opinion on these examples, so that laboratories have clear guidance on how to proceed in these circumstances.

- 1) The ordering physician indicates on the test requisition that he wants the lab to send a copy of the test result report to the patient and to another physician specialist treating the patient. Can the lab release the test results report to the patient? To the other physician specialist treating the patient?
- 2) A physician treating a patient needs to see the results of laboratory tests that he did not order. The treating physician contacts the ordering physician to request the results, but the physician is not in the office; however, he authorizes the lab to send the results to the non-ordering treating physician. Can the lab release the test results to the non-ordering treating physician?
- 3) A patient requests his test results from the laboratory so that he can share them with another physician from whom he is seeking a second opinion. The ordering physician authorizes the lab to send

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June 6, 2011

the results to the patient. Can the lab release the test results to the patient?

- 4) A health plan participating in the TennCare program needs test beneficiaries' test results for disease management and payment purposes under a pay for performance program. The health plan requests the lab to send it test results for its beneficiaries for those purposes. Can the laboratory send the results to the health plan if the physicians who ordered the tests have authorized the disclosure? Can the laboratory send the results to the health plan even if the physicians who ordered the tests have not authorized the disclosure?
- 5) A health information exchange designed to create an electronic health record on behalf of patients, health plans and providers needs laboratory test results as part of the data available to its participants. The health information exchange was not authorized to order (request) the tests, but requests that the lab send results of all Tennessee patients to be accessible to authorized participants (including parties who did not order the tests) for uses and disclosures for purposes permitted under HIPAA without patient authorization. Can the lab release the results to the health information exchange if the physicians who ordered the tests have authorized the disclosure? Can the laboratory send the results to the health information exchange even if the physicians who ordered the tests have not authorized the disclosure?

As these examples suggest, in many instances, strict enforcement of the Board's Policy Statement will result in unnecessary delays in communicating test results to members of a patient's health care team, poor coordination among health care providers, duplicative efforts, and increased health care costs.

Thank you very much for your time and attention. Please feel free to contact me to discuss these questions.

Sincerely,



JoAnne Glisson
Senior Vice President