S T A T E O F N E W Y O R K

5190

2009-2010 Regular Sessions

I N S E N A T E

April 27, 2009

Introduced by Sen. DUANE -- read twice and ordered printed, and when printed to be committed to the Committee on Health

AN ACT to amend the public health law, in relation to clinical laboratories and biological data analysis

THE PEOPLE OF THE STATE OF NEW YORK, REPRESENTED IN SENATE AND ASSEMBLY, DO ENACT AS FOLLOWS:

Section 1. Section 576-b of the public health law, as added by chapter 572 of the laws of 2002, is amended to read as follows:

S 576-b. Performance of certain clinical laboratory services upon request. 1. (A) A clinical laboratory may perform a clinical laboratory service (including accepting a specimen or assignment for examination and rendering a report), that it is otherwise allowed to perform, upon the request of the person on whom the service is to be performed and render a report directly to the person, where the service is for the same purpose as a test or collection device that has been approved or cleared by the Food and Drug Administration of the United States Department of Health and Human Services for sale or distribution to the public on a direct or over-the-counter basis without a prescription from a qualified health care practitioner.

(B) IN ADDITION TO ANY CLINICAL LABORATORY SERVICE AUTHORIZED UNDER PARAGRAPH (A) OF THIS SUBDIVISION, A CLINICAL LABORATORY MAY PERFORM A CLINICAL LABORATORY SERVICE (INCLUDING ACCEPTING A SPECIMEN OR ASSIGNMENT FOR EXAMINATION AND RENDERING A REPORT), THAT IT IS OTHERWISE ALLOWED TO PERFORM, UPON THE REQUEST OF THE PERSON ON WHOM THE SERVICE IS TO BE PERFORMED FOR PERSONAL GENOMICS OR BIOLOGICAL DATA COLLECTION.

2. All services conducted pursuant to this section shall comply with the standards for testing established by the department and with any other laws of this state, including requirements for confidentiality and pre-test and post-test counseling.

3. [The] (A) EXCEPT AS PROVIDED IN PARAGRAPH (B) OF THIS SUBDIVISION, THE results of any test conducted pursuant to this section shall be

EXPLANATION--Matter in ITALICS (underscored) is new; matter in brackets [ ] is old law to be omitted.

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provided only to the person who requested the test. Such results shall be provided in a clear and concise manner that is understandable by lay persons and that identifies results indicating the need for referral to a physician or other qualified health care practitioner.

(B) WHERE A CLINICAL LABORATORY PERFORMS A CLINICAL LABORATORY SERVICE AS PROVIDED FOR IN THIS SECTION, AND WHERE SUCH SERVICE IS FOR PERSONAL GENOMICS OR BIOLOGICAL DATA COLLECTION, WHEN DIRECTED BY THE PERSON REQUESTING SUCH SERVICE, A CLINICAL LABORATORY MAY SEND THE RESULTS OF THE SERVICE TO AN ENTITY FOR BIOLOGICAL DATA ANALYSIS SERVICES. SUCH BIOLOGICAL DATA ANALYSIS SERVICES SHALL NOT BE CONSIDERED A CLINICAL LABORATORY SERVICE UNDER THIS ARTICLE. THE RESULTS OF ANY BIOLOGICAL DATA ANALYSIS SERVICES SHALL BE PROVIDED IN A CLEAR AND CONCISE MANNER THAT IS UNDERSTANDABLE BY LAY PERSONS, AND SHALL BE SENT DIRECTLY TO THE PERSON REQUESTING SUCH ANALYSIS.

4. Nothing in this section shall authorize a clinical laboratory, OR AN ENTITY PROVIDING BIOLOGICAL DATA ANALYSIS SERVICES, to engage in the practice of any health care profession under title eight of the education law. The report issued to a person for a test conducted pursuant to this section shall contain a clear statement, presented in a prominent manner, to the effect that the report should not be viewed as medical advice and is not meant to replace direct communication with a physician or other health care practitioner.

S 2. This act shall take effect immediately.