AMENDED IN ASSEMBLY JUNE 8, 2022

AMENDED IN ASSEMBLY APRIL 28, 2022

AMENDED IN SENATE MAY 11, 2021

AMENDED IN SENATE MAY 3, 2021

SENATE BILL No. 771

Introduced by Senator Becker
(Principal coauthor: Assembly Member Akilah Weber)

February 19, 2021

An act to amend Section 125055 of the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

SB 771, as amended, Becker. Prenatal screening program.

Existing law requires the State Department of Public Health to administer a statewide program for prenatal testing for genetic disorders and birth defects, including, but not limited to, ultrasound, amniocentesis, chorionic villus sampling, and blood testing. Existing law requires the department to expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations. Existing law requires a clinical laboratory performing laboratory tests or examinations classified as moderate or high complexity under the federal Clinical Laboratory Improvement Amendments of 1988 (CLIA) to obtain a clinical laboratory license from the department. Existing law generally exempts specified clinical laboratories from rules and regulations of the department, including clinical laboratories owned and operated by the United States and certified under CLIA. Under existing regulations, a certificate of accreditation issued by the United States Department of

Health and Human Services is considered a state license or registration issued by the department, as specified. Existing law requires a city or county public health laboratory, as specified, to be approved by the department and to comply with the requirements of CLIA.

This bill would prohibit the department, by way of rule, regulation, contract, or any other manner, from preventing a laboratory with both a CLIA certificate of accreditation and a current state clinical or public health laboratory license from offering noninvasive prenatal tests to pregnant ~~women who~~ *persons who have an order from a prenatal care provider, as defined, and* have opted out of the California Prenatal Screening Program or have chosen to have testing done in addition to the genetic tests offered as part of the California Prenatal Screening Program. *The bill would also prohibit the department from limiting the number of noninvasive prenatal tests that the laboratory may provide.*

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 125055 of the Health and Safety Code is amended to read:

125055. The department shall:

(a) Establish criteria for eligibility for the prenatal testing program. Eligibility shall include definition of conditions and circumstances that result in a high risk of a detectable genetic disorder or birth defect.

(b) (1) Develop an education program designed to educate physicians and surgeons and the public concerning the uses of prenatal testing and the availability of the program.

(2) (A) Include information regarding environmental health in the California Prenatal Screening Program patient educational information. This environmental health information shall include the following statement:

"We encounter chemicals and other substances in everyday life that may affect your developing fetus. Fortunately, there are steps you can take to reduce your exposure to these potentially harmful substances at home, in the workplace, and in the environment. Many Californians are unaware that a number of everyday

consumer products may pose potential harm. Prospective parents should talk to their doctor and are encouraged to read more about this topic to learn about simple actions to promote a healthy pregnancy."

(B) The department shall include in the patient educational information links to educational materials derived from peer-reviewed materials based on the best available evidence relating to environmental health and reproductive toxins.

(C) The department shall post the environmental health information described in subparagraphs (A) and (B) on its internet website.

(D) The department shall send a notice to all distributors of the patient educational information informing them of the change to that information. In the notice, the department shall encourage obstetrician-gynecologists and midwives to discuss environmental health with their patients and to direct their patients to the appropriate page or pages in the patient educational information to provide their patients with additional information.

(E) In order to minimize costs, the environmental health information described in this paragraph shall be included when the patient educational information is otherwise revised and reprinted.

(F) The department may modify the language in the patient educational information after consultation with medical and scientific experts in the field of environmental health and reproductive toxins.

(c) Ensure that genetic counseling be given in conjunction with prenatal testing at the approved prenatal diagnosis centers.

(d) Designate sufficient prenatal diagnosis centers to meet the need for these services. Prenatal diagnosis centers shall have equipment and staff trained and capable of providing genetic counseling and performing prenatal diagnostic procedures and tests, including the interpretation of the results of the procedures and tests.

(e) Administer a program of subsidy grants for approved nonprofit prenatal diagnosis centers. The subsidy grants shall be awarded based on the reported number of low-income women referred to the center, the number of prenatal diagnoses performed in the previous year at that center, and the estimated size of unmet

need for prenatal diagnostic procedures and tests in its service area. This subsidy shall be in addition to fees collected under other state programs.

(f) Establish any rules, regulations, and standards for prenatal diagnostic testing and the allocation of subsidies as the director deems necessary to promote and protect the public health and safety and to implement the Hereditary Disorders Act (Section 27).

(g) (1) The department shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibin.

(2) The prenatal screening fee increase for expanding prenatal screening to include those tests described in paragraph (1) is forty dollars ($40).

(3) The department shall report to the Legislature regarding the progress of the program with regard to implementing prenatal screening for those tests described in paragraph (1) on or before July 1, 2007. The report shall include the costs of screening, followup, and treatment as compared to costs and morbidity averted by this testing under the program.

(4) (A) The expenditure of funds from the Genetic Disease Testing Fund for the expansion of the Genetic Disease Branch Screening Information System to include the expansion of prenatal screenings, pursuant to paragraph (1), may be implemented through the amendment of the Genetic Disease Branch Screening Information System contracts, and shall not be subject to Chapter 2 (commencing with Section 10290) or Chapter 3 (commencing with Section 12100) of Part 2 of Division 2 of the Public Contract Code, Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of Title 2 of the Government Code, or Sections 4800 to 5180, inclusive, of the State Administrative Manual as they relate to approval of information technology projects or approval of increases in the duration or costs of information technology projects. This paragraph shall apply to the design, development, and implementation of the expansion, and to the maintenance and operation of the Genetic Disease Branch Screening Information System, including change requests, once the expansion is implemented.

(B) (i) The department may adopt emergency regulations to implement and make specific the amendments to this section made during the 2006 portion of the 2005–06 Regular Session in accordance with Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code. For the purposes of the Administrative Procedure Act, the adoption of regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, these emergency regulations shall not be subject to the review and approval of the Office of Administrative Law. Notwithstanding Sections 11346.1 and 11349.6 of the Government Code, the department shall submit these regulations directly to the Secretary of State for filing. The regulations shall become effective immediately upon filing by the Secretary of State. Regulations shall be subject to public hearing within 120 days of filing with the Secretary of State and shall comply with Sections 11346.8 and 11346.9 of the Government Code or shall be repealed.

(ii) The Office of Administrative Law shall provide for the printing and publication of these regulations in the California Code of Regulations. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the regulations adopted pursuant to this chapter shall not be repealed by the Office of Administrative Law and shall remain in effect until revised or repealed by the department.

(h) *(1)* The department shall not, by way of a rule, regulation, contract, or any other manner, prohibit a laboratory that has both a current Clinical Laboratory Improvement Amendments certificate of accreditation and a current state clinical or public health laboratory license from offering noninvasive prenatal tests, *or otherwise limit the number of tests that the laboratory may provide,* including, but not limited to, testing for autosomal trisomies (trisomies 21, 18, and 13) and fetal sex, to a pregnant ~~woman who has~~ *person who has an order from a prenatal care provider and* either:

~~(1)~~

(A) Opted out of the California Prenatal Screening Program.

~~(2)~~

(B) Chosen to have tests in addition to the genetic tests offered as part of the California Prenatal Screening Program.

(2) As used in this section, "prenatal care provider" means a health care provider licensed pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, or pursuant to an initiative act referred to in that division, who provides prenatal medical care within their scope of practice. This definition shall not include a licensed health care professional who provides care other than prenatal care to a pregnant patient.

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