

INFORMATIVE DIGEST

Background/Authority

Health and Safety Code Section 125050 requires the California Department of Public Health (Department)¹ 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. Health and Safety Code Sections 125000 and 125050 require the Department to offer information, testing and counseling for genetic disorders and birth defects to all pregnant women in California.

Health and Safety Code Sections 124977(a) and (b), 124996, and 125000(b) require the Department to charge a fee for any tests or activities performed under the program; mandate that the program be fully supported from fees collected; and state that the amount of the fee shall be established by regulation and periodically adjusted by the Director. Health and Safety Code Section 124996 also specifies that the Genetic Disease Testing Fund (GDTF) is a special fund in the State Treasury and is continuously appropriated to the Department to carry out the purposes of the Hereditary Disorders Act. Fees for participation in the California Prenatal Screening (PNS) Program are paid to the Department's Genetic Disease Screening Program (GDSP) by a participating woman's health insurance policy or health care service plan or by Medi-Cal for beneficiaries. If the participation fee is not paid by a third party payer, the fee is paid by the participating woman. The majority of funds are deposited in the GDTF with \$10 deposited in the Birth Defects Monitoring Program Fund, as mandated by Health and Safety Code Section 124977(b). GDSP is not funded by the State's General Fund. The regulation that implements, interprets, and makes specific these provisions for the California PNS Program is Title 17, California Code of Regulations, Section 6540.

The Legislature has found that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory action and administrative procedures (Health and Safety Code Section 124977(c)(1)).

Health and Safety Code Section 124977 provides authority for the Department to adopt emergency regulations. Health and Safety Code Section 124977(d)(1) specifies that the adoption of these regulations shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare, and that the regulations shall not be subject to the review and approval of the Office of Administrative Law (OAL); shall be submitted directly to the Secretary of State for filing; and shall become effective immediately upon filing by the Secretary of State. Section 124977(d)(1) also requires the Department to conduct a public hearing within 120 days

¹ Effective July 1, 2007, the California Department of Health Services was split into two separate agencies; i.e., the California Department of Health Care Services, and the California Department Public Health (CDPH). This split was brought into effect by the passage of Senate Bill 162 (Ortiz, et al., Chapter 241, Statutes of 2005-2006). The subject of this emergency regulation was assigned to CDPH through Health and Safety Code, Section 131052.

of filing with the Secretary of State, and to submit to the OAL with the adopted regulation a final statement of reasons and updated informative digest. Health and Safety Code Section 124977(d)(2) specifies that this emergency regulation shall not be repealed by the OAL and shall remain in effect until revised or repealed by the Department.

Policy Statement Overview

Problem Statement:

The Department's legislatively-mandated statewide program for prenatal testing for genetic disorders and birth defects, known as the California PNS Program, must be fully supported by fees charged for maternal serum screening and authorized follow-up services, as required by Health and Safety Code Sections 124977(a) and (b), 124996, and 125000(b). The Legislature has also found that timely implementation of changes in genetic screening programs and continuous maintenance of quality statewide services requires expeditious regulatory action and administrative procedures.

Approximately 370,000 pregnant women participate in the voluntary California PNS Program each year, but caseloads have been overstated in budget estimates for recent fiscal years and revenue projections have not been met. This, along with rising costs, has led to cumulative and annual deficits since Fiscal Year (FY) 2010-11 which must be addressed.

Objectives (Goals):

This emergency amendment to 17 CCR, Section 6540 is necessary to increase the voluntary participation fee for the California PNS Program to ensure the program remains solvent and continues to meet the legislative mandate of offering information, testing and counseling for genetic disorders and birth defects to all pregnant women in California.

The fee increase will allow the California PNS Program to recoup the cumulative deficit and fund the continuous maintenance costs of the operational and administrative functions of the program.

Benefits:

Health and Safety Code Section 124975(c) declares the findings of the Legislature that detection through screening of hereditary disorders can lead to the alleviation of the disability of some hereditary disorders and contribute to the further understanding and accumulation of medical knowledge about hereditary disorders that may lead to their eventual alleviation or cure. The anticipated benefit from this regulatory action is ensuring the California PNS Program remains solvent and able to meet this legislative mandate.

Without a fee increase, the California PNS Program would need to suspend or reduce prenatal screening and diagnostic testing for pregnant women and their unborn children due to lack of funds. Many pregnant women would not receive genetic screening, counseling or prenatal diagnostic services through the State's program, as required by

statute. Healthcare providers and families would not have the necessary information to plan for appropriate care and/or services before the birth of the child to have resources available to assist the child, such as ready cardiopulmonary resuscitation; neonatal infant transport to a tertiary care facility; early planning for and/or immediate access to pediatric surgery for abnormal cardiac, neurological, and/or gastric conditions; and required social services.

Such planning serves to optimize the health of newborns with birth defects and can reduce stress for the family unit. Advance planning for a high-risk delivery in an appropriate health care setting may reduce and/or ameliorate the severity of the condition and improve quality of life. Without proper planning, some conditions will be compounded. Maintaining the operations and administrative functions of the California PNS Program allows for continued effective planning based on the screening and diagnostic information obtained, resulting in reduced healthcare costs in the short term and over a lifetime for a patient, families, communities, and healthcare businesses.

Summary of Proposal

This emergency amendment to Title 17, California Code of Regulations (17 CCR), Section 6540, increases the California PNS Program's all-inclusive program participation fee for maternal serum alpha fetoprotein (AFP) and additional markers for prenatal screening from \$162 to \$207, and deletes obsolete references to single marker screening.

Authority and Reference

Authority: Sections 124977, 124996, 125000, 125055, 125070 and 131200, Health and Safety Code.

Reference: Sections 124996, 125000, 125001, 125050, 125060, 125065, and 131052, Health and Safety Code.

Evaluation as to Whether the Regulations are Inconsistent or Incompatible with Existing State Regulations

The Department evaluated whether this emergency rulemaking action is inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing prenatal screening regulations; no other state agency regulations address the same subject matter. Therefore, the Department has determined that this emergency rulemaking is not inconsistent or incompatible with existing state regulations.

Local Mandate

The Department has determined that the rulemaking does not impose a mandate on local agencies or school districts, nor are there any costs for which reimbursement is required by Part 7 (commencing with Section 17500) of Division 4 of the Government Code.

Documents Incorporated by Reference

N/A

Forms Incorporated By Reference

N/A

Mandated By Federal Law Or Regulations

N/A

Other Statutory Requirements

N/A

FISCAL IMPACT ESTIMATE

A. FISCAL IMPACT ON LOCAL GOVERNMENT: None.

B. FISCAL IMPACT ON STATE GOVERNMENT: It is estimated that the accumulated deficit in the Genetic Disease Testing Fund will be approximately \$18 million by the end of FY 2013-14. The fee increase will allow the California PNS program to recoup the \$18 million required to offset the cumulative deficit in the Genetic Disease Testing Fund, and ensure program revenue meets program expenses in future years.

Approximately 45 percent of pregnant women participating in the California PNS Program are Medi-Cal beneficiaries. The Department estimates the \$45 fee increase will result in an annual cost to Medi-Cal of \$3.8 million from the General Fund. The \$45.00 fee increase has been fully incorporated into Medi-Cal base data as an ongoing cost; therefore, the fiscal impact will be absorbed by the State's General Fund.

C. FISCAL IMPACT ON FEDERAL FUNDING OF STATE PROGRAMS: The Department estimates the \$45 fee increase will result in an annual cost to Federal Financial Participation in Medi-Cal of \$3.8 million. The additional federal funding required under this emergency regulation has been recognized by Medicaid as an ongoing cost.

D. FISCAL IMPACT ON PRIVATE PERSONS OR BUSINESSES DIRECTLY AFFECTED: A cost increase of \$45 per pregnancy in the California PNS Program fee for those businesses providing health coverage to pregnant women. The full or partial cost is charged to the pregnant woman if the fee is not fully covered by health care insurance.

E. OTHER NONDISCRETIONARY COSTS OR SAVINGS IMPOSED ON LOCAL AGENCIES: None.

Significant Statewide Adverse Economic Impact Directly Affecting Business, Including Ability to Compete

The Department has made a determination that the regulations will not have a significant statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states. The regulation does not affect contracts or reimbursement rates for contract vendors. The impact to insurers in processing the change in the participation fee will be minimal. The cost impact to insurers of \$45 for each covered pregnancy is unlikely to have a significant impact on any affected business. It is unlikely that the fee increase would be sufficient to require any significant increase in premiums charged to insurance/health plan members.

Statement of the Results of the Economic Impact Assessment

The Department has determined that the rulemaking will not significantly impact the creation or elimination of jobs, the creation of new businesses or the elimination of existing businesses, or the expansion of businesses currently doing business within the State of California. This regulation does not affect worker safety or California's environment. This regulation will benefit the health and welfare of California residents.

Cost Impact on Representative Person or Business

The Department has determined that a cost increase of \$45 per pregnancy in the California PNS Program fee will be incurred by those businesses providing health coverage to pregnant women. The full or partial cost is charged to the pregnant woman if the fee is not fully covered by health care insurance.

Effect on Small Business

The Department has determined that the rulemaking has no impact on small businesses, as defined under Government Code Chapter 3.5, Article 2, Section 11342.610. The Department is not aware of any small businesses that provide health insurance to pregnant women.

Alternatives Statement

In accordance with Government Code Section 11346.5(a)(13) the Department must determine that no reasonable alternative considered by the Department or that has otherwise been identified and brought to the attention of the Department would be more effective in carrying out the purpose for which the emergency action was taken, would be as effective and less burdensome to affected private persons than the emergency action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law.

The Department has made an initial determination that there are no acceptable alternatives to the regulation to fund the operations of the California PNS Program and protect the public interest in maintaining a statewide screening program.