

INITIAL STATEMENT OF REASONS

Summary of Regulatory Action

This emergency amendment to Title 17, California Code of Regulations (17 CCR), Section 6540, increases the California Prenatal Screening (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.

Policy Statement Overview

Problem Statement:

The California Department of Public Health's (the Department's)¹ 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

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. 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 the California Department Public Health through Health and Safety Code, Section 131052.

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 or 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.

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.

Background/Authority

Health and Safety Code, Section 125050 requires the Department 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.

The California PNS Program works to ensure quality-assured voluntary serum screening services are available to all pregnant women in California, and follow-up services are provided where indicated. Serum screening is performed by private sector

laboratories under contract with the Department and functioning under the authority of the Department's Genetic Disease Laboratory. If a maternal serum screening test result is positive, indicating an elevated risk for a chromosomal anomaly or birth defect, follow-up genetic counseling and other authorized services are provided free of charge at State-approved Prenatal Diagnosis Centers.

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 California PNS 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. Fees for participation in the California 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 Genetic Disease Testing Fund (GDTF), with \$10 deposited in the Birth Defects Monitoring Program Fund, as mandated by Health and Safety Code Section 124977(b). Health and Safety Code Section 124996 specifies that the 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. GDSP is not funded by the State's General Fund.

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)). With the enactment of Senate Bill (SB) 1555 (Speier, Chapter 484, Statutes of 2006), the Department was required to expand the California PNS Program to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including the addition of inhibin to the existing second trimester screening panel, which was the sole option for serum screening at that time.

The recommended standard of care was subsequently updated and now includes the option for women to receive maternal serum screening in both the first and second trimesters. Combining both screening results (Serum Integrated Screening) improves risk assessment for birth defects. If Nuchal Translucency (NT) ultrasound results are available, Sequential Integrated Screening can also provide a preliminary risk assessment in the first trimester. Serum screening is currently able to provide pregnant women with a risk assessment for open neural tube defects (NTD), abdominal wall defects, Down syndrome (trisomy 21), trisomy 18 and Smith-Lemli-Opitz syndrome (SLOS).

SB 1555 (Speier, Chapter 484, Statutes of 2006) amended Health and Safety Code Sections 124977(b) and 125055(g) to increase the participation fee for the California PNS Program from \$105 to \$155 in order for the Department to meet legislative mandates. A subsequent \$7 fee increase was enacted through regulatory action in

2011 to maintain program solvency, bringing the participation fee to a level of \$162, with \$152 allocated to the GDTF and \$10 to the Birth Defects Monitoring Program Fund.

Health and Safety Code Section 124977(d)(1) provides authority for the Department to adopt emergency regulations and 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 the 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 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.

In April 2014, GDSP sent a letter to all insurers of prenatal health care in California informing providers that the all-inclusive program participation fee for the California PNS Program would be increased, from \$162 to \$207, effective July 1, 2014.

GDSP will continue to monitor program revenues and expenses in order to determine whether future increases or decreases in the California PNS Program participation fee are warranted.

Specific Discussion of Regulatory Action

Section 6540. Program Participation Fee.

The regulation amends this Section to increase 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.

The amendment increasing the participation fee is necessary for the California PNS Program to remain solvent and for the continuous maintenance costs of the operational and administrative functions of the program to be funded.

The amendment deleting the reference to single marker screening for a single birth defect is necessary as this is no longer an option offered by the Department, since it does not meet the standard of care for prenatal screening, as mandated by SB 1555 (Speier, Chapter 484, Statutes of 2006). A single program participation fee now applies to all women participating in the program, irrespective of the screening option/s pursued. Multiple analytes are now tested in the first and/or second trimester.

The note is amended to correct the legislative authority for the Department to meet screening costs through fees established by regulation.

STATEMENTS OF DETERMINATION

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.

Technical, Theoretical, and/or Empirical Study, Reports or Documents Relied Upon

None.

Economic Impact Assessment

A. The Department has determined that the rulemaking will not significantly impact the following pursuant to Government Code Sections 11346.3(b)(1)(A), (B), (C) and (D):

1. The Creation or Elimination of Jobs within the State of California. The regulation will not create or eliminate jobs in California. The regulation provides for an increase in the California PNS Program participation fee, but does not affect laboratory test procedures or authorized follow-up services. The impact to insurers in processing the participation fee increase, and to insurance/health plan members, will be minimal. Based on the Department's analysis, the demand for PNS services is driven more by service level than by price. Even with the fee increase, the fee remains significantly lower than private sector pricing, and includes both testing and authorized follow-up services.
2. The Creation of New Businesses or the Elimination of Existing Businesses within the State of California. The regulation will not create new businesses or eliminate existing businesses within the State of California. The regulation does not affect contracts or reimbursement rates for contract vendors. The cost impact to insurers of \$45 for each covered pregnancy is unlikely to have a significant impact on any affected business, or insurance/health plan members.
3. The Expansion of Businesses Currently Doing Business within the State of California. The regulation will not expand businesses within the State of California. The regulation does not affect contracts or reimbursement rates for contract vendors. The impact to insurers in processing the participation fee increase will be minimal.
4. Worker Safety. This regulation does not affect worker safety because it does not impact workers.

5. California's Environment. This regulation does not affect the State's environment.

B. The Department has determined that the rulemaking impacts the following pursuant to Government Code Sections 11346.3(b)(1)(D):

1. Health and Welfare of California Residents. The regulation is expected to increase and strengthen the health and welfare of California residents. An increase in the participation fee for the California PNS Program will ensure the program remains solvent and protect statewide access to prenatal screening and follow-up services, thereby reducing the emotional and financial burden of disability and death caused by genetic and congenital disorders.

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 participation fee increase 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.

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.

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.

Effect on Housing

The Department has determined that the rulemaking has no impact on housing costs.

Reporting Requirements

The Department has determined that the rulemaking would have no new or additional reporting requirements applicable to businesses.