

INITIAL STATEMENT OF REASONS

Summary of Proposal

This amendment to Title 17, California Code of Regulations (17 CCR), Section 6540, increases the Prenatal (Multiple Marker) Testing Program's (Program) all-inclusive participation fee for maternal serum alpha fetoprotein (AFP) and additional markers for prenatal screening from \$207.00 to \$221.60.

Informative Digest/Policy Statement Overview

Problem Statement:

The California Department of Public Health's (Department)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 (HSC) 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 360,000 pregnant women participate in the voluntary Program each year and caseloads have remained steady or increased slightly over the last few years, but increased costs for the administration of the Program must be addressed.

Without a fee increase, the 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 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.

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 Safety Code, Section 131052.

Objectives (Goals):

This amendment to 17 CCR, Section 6540 is necessary to increase the voluntary participation fee to ensure the Program remains self-sufficient 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 Program to fund the continuous maintenance costs of the operational and administrative functions of the Program.

Benefits:

HSC 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 Program remains self-sufficient and able to meet this legislative mandate.

Background/Authority

HSC 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. HSC 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 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.

HSC 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. Fees for participation in the 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 woman does not have insurance coverage, 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 HSC Section 124977(b). HSC 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 (HSC § 124977(c)(1)).

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) increased the participation fee for the Program from \$105 to \$155 in order for the Department to meet the legislative mandate. 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. The last increase was in 2014 and increased the fee from \$162 to \$207 with \$197 allocated to the GDTF and \$10 to the Birth Defects Monitoring Program Fund.

The HSC provides authority for the Department to adopt emergency regulations. HSC 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 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. HSC 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 OAL the adopted regulation, a final statement of reasons, and an updated informative digest. HSC Section 124977(d)(2) specifies that this emergency regulation shall not be repealed by OAL and shall remain in effect until revised or repealed by the Department.

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

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 regulation is inconsistent or is incompatible with existing state regulations. This evaluation included a review of the Department's existing state regulations and those regulations specific to prenatal screening. An Internet search of other state agency regulations was also performed and it was determined that no other state agency regulation addressed the same subject matter and that this proposal was not inconsistent or incompatible with other state regulations. Therefore, the Department has determined that this rulemaking is not inconsistent or incompatible with existing state regulations.

Specific Discussion of Regulatory Action

Title 17, Division 1., Chapter 4., Subchapter 9., Group 5., Article 4.
Prenatal Screening Fee Collection
Section 6540. Program Participation Fee.

The regulation amends section 6540 to increase the Program's all-inclusive participation fee for maternal serum alpha fetoprotein (AFP) and additional markers for prenatal screening from \$207 to \$221.60.

The amendment increases the participation fee as necessary for the Program to remain self-sufficient and for the continuous maintenance costs of the operational and administrative functions of the Program to be funded.

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 Program and protect the public interest in maintaining a statewide screening Program.

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

– Not applicable.

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). For further information, please see the attached Cost Estimating Methodology.

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 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 prenatal screening 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 \$14.60 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 Section 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 Program ensures that the Program remains self-sufficient and protects 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.

FY 16/17 PNS Fee Increase Breakdown

A portion of the increase of \$14.60 can be attributed to one-time only expenditures that include the transfer of the enhancement and management of SIS from the DHCS to CDPH. Other one-time costs include to the migration and operation the Accounts Receivable business system that no longer has the complete information in order to properly bill insurance companies for its services. The costs will include training and support for GDSP staff for a period of two years.

Other costs associated with the new proposed fee are a contract with an outside vendor (Sutherland) to provide medical billing services. GDSP has not been able to effectively bill for their services which is a highly specialized process. There are no job classifications with this specialty in State service. This agreement will allow GDSP to meet its financial goals by accelerating revenue collection, reducing uncollectable accounts and reducing the overall risk and cost to collect.

A smaller portion of the increased fee will be utilized for the purchase of new hardware and software to manage the SIS system as it transitions to the CDPH. The DHCS has managed the SIS server since the split of the Department of Health Services in 2007.

DHCS no longer wishes to support SIS and their data center and this will allow the CDPH to consolidate all of those functions at the CDPH Tenant Managed Services Premier (TMSP) data center.

Table 1 - FY 16/17 PNS Fee Increase Breakdown

SIS Data Center Transfer	Costs for the GDSP Screening Information System (SIS) Computer System Transfer from DHCS to CDPH	\$ 2.19
SIS M & O /Billing Support	Increased cost for maintenance, operation and enhancement of SIS.	\$ 5.04
AR M & O, Operations	Pay for additional costs of migration and support of the Accounts Receivable (AR) transfer. Includes two years of support for new system	\$ 3.21
Sutherland	Support contract with outside vendor (Sutherland) to provide a robust billing system to meet financial goals by accelerating revenue collection.	\$ 3.80
GSMART Loan	Support a loan from the Department of General Services to cover software and hardware needs for upgrades to SIS	\$ 0.36
Total Fee Increase		\$ 14.60

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 \$14.60 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.