State of California—Health and Human Services Agency
California Department of Public Health

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NOTICE OF PROPOSED RULEMAKING

Title 17, California Code of Regulations
Prenatal (Multiple Marker) Testing Program, DPH-16-016
Notice Published: October 7, 2016

Notice is hereby given that the California Department of Public Health (Department) has amended the regulation described below. This notice of proposed rulemaking commences a rulemaking to make the regulation permanent after considering all comments, objections, and recommendations regarding the regulation.

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written comment period and will hold a public hearing, during which time, any interested person or such person's duly authorized representative may present statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

PUBLIC HEARING

At the hearing, any person may present statements or arguments orally or in writing relevant to the proposed action described in the Informative Digest. The Department requests, but does not require that persons who make oral comments at the hearing also submit a written copy of their testimony at the hearing.

Date and Time: October 18, 2016, 1:30 PM – 2:30 PM
Place: East End Complex
1500 Capitol Avenue
Hearing Room
Sacramento, CA 95814
Purpose: To hear comments about this action.

An agenda for the public hearing will be posted at the time and place of hearing location.

For individuals with disabilities, the Department shall provide upon request, assistive services such as sign-language interpretation, real-time captioning, note takers, reading or writing assistance, and conversion of written public hearing materials into Braille, large print, audiocassette or computer disk. Note: The range of assistive services available may be limited if requests are received less than five business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write to Laurel Prior, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, or call (916) 440-7673, email Laurel.Prior@cdph.ca.gov, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments must be received by the Office of Regulations by **5:00 pm on November 21, 2016,** which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely.

Written comments may be submitted as follows:

1. By email to: regulations@cdph.ca.gov. Please place the regulation identifier "DPH-16-016" in the subject line;
2. By FAX transmission to: (916) 440-5747;
3. By United States Postal Service to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814; or
4. Hand-delivered to: Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should contain the regulation package identifier: **DPH-16-016**, author's name and mailing address.

AUTHORITY AND REFERENCE

Authority sections: 124977, 124996, 125000, 125055, 125070 and 131200 of the Health and Safety Code. Reference sections: 124996, 125000, 125001, 125050, 125060, 125065, and 131052 of the Health and Safety Code.

INFORMATIVE DIGEST / POLICY STATEMENT OVERVIEW

This amendment to Title 17, California Code of Regulations (17 CCR), section 6540, increased the Prenatal (Multiple Marker) Testing Program's (Program) all-inclusive program participation fee for maternal serum alpha fetoprotein (AFP) and additional markers for prenatal screening from $207 to $221.60 as an emergency effective July 1, 2016.

Background/Authority

Health and Safety Code (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.

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. HSC 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 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 HSC section 124977(b). 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)).

HSC section 124977 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 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 the OAL with the adopted regulation, a final statement of reasons and updated informative digest within 180 days of the emergency filing. HSC 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 must be fully supported by fees charged for maternal serum screening and authorized follow-up services, as required by HSC 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 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.

Objectives (Goals):

The emergency 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 that the program remains self-sufficient and is able to meet this legislative mandate.

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 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 and 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.

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 the section 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 increased 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.

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.

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
Not applicable.

Forms Incorporated By Reference
Not applicable.

Mandated By Federal Law Or Regulations
Not applicable.

Other Statutory Requirements
Not applicable.

FISCAL IMPACT ESTIMATE

A. Fiscal Impact on Local Government: None.

B. Fiscal Impact on State Government: Approximately 45 percent of pregnant women participating in the program are Medi-Cal beneficiaries. The Department estimates the $14.60 fee increase will result in an annual cost to Medi-Cal of approximately $1.2 million from the General Fund. The $14.60 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 in Federal Funding to the State: The Department estimates the $14.60 fee increase will result in an annual cost to Federal Financial Participation in Medi-Cal of approximately $1.2 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: There would be a cost increase of $14.60 per pregnancy in the program fee for those businesses providing health coverage to pregnant women. The full cost is charged to the pregnant woman if the fee is not covered by health care insurance.

E. Other Nondiscretionary Costs or Savings Imposed on Local Agencies: None.

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.

Statement of the Results of the 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 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.

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 $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.

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 $14.60 per pregnancy in the program fee will be incurred by those businesses providing health coverage to pregnant women. The full cost is charged to the pregnant woman if the fee is not 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.

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.

Contact Information

Inquiries regarding the substance of the regulation described in this notice may be directed to Stephen L. Purser, MPH, Health Program Specialist II, Genetic Disease Screening Program, at (510) 412-1484.

All other inquiries concerning the action described in this notice may be directed to Laurel Prior, Office of Regulations, at (916) 440-7673.

Availability Statements

The Department has prepared and has available for public review an initial statement of reasons for the regulation, all the information upon which the amendments to the regulation are based upon and the text of the regulations. The Office of Regulations is located at 1415 L Street, Suite 500, Sacramento, CA 95814, and is the location of the public records, including reports, documentation, and other material related to the proposed regulations (rulemaking file).

In order to request that a copy of this public notice, the regulation text, and the initial statement of reasons or alternate formats for these documents, please call (916) 440-7673 (or the California Relay Service at 711), send an email to regulations@cdph.ca.gov, or write to the Office of Regulations at the address previously noted. Upon specific request, these documents will be made available in Braille, large print, audiocassette, or computer disk.

The full text of any regulation that is changed or modified from the express terms of the proposed action will be made available by the Department's Office of Regulations at least 15 days prior to the date on which the Department adopts, amends, or repeals the resulting regulation.

A copy of the final statement of reasons (when prepared) will be available upon request from the Office of Regulations.

Internet Access

Materials regarding the action described in this notice (including this public notice, the regulation text of the proposed regulations, and the initial statement of reasons) are available via the Internet and may be accessed at www.cdph.ca.gov by clicking on these links, in the following order: Decisions Pending & Opportunity for Public Participation, Proposed Regulations.