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NOTICE OF PROPOSED RULEMAKING
Title 17, California Code of Regulations
Prenatal Screening Fee Increase, DPH-14-001E
Notice Published September 5, 2014

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 23, 2014, 2:00 PM – 4:00 PM
Place: 1500 Capitol Ave., Hearing Room 167, 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 ten business days prior to a public hearing.

To request such services or copies of materials in an alternate format, please write or call Laurel Prior, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, phone (916) 440-7673, email to Laurel.Prior@cdph.ca.gov, or use the California Relay Service by dialing 711.

WRITTEN COMMENT PERIOD

Written comments pertaining to this proposal, regardless of the method of transmittal, must be received by the Office of Regulations by **5:00 pm on October 20, 2014**, which is hereby designated as the close of the written comment period. Comments received after this date will not be considered timely. Comments must be submitted as follows:

1. By email to regulations@cdph.ca.gov. Please place the regulation identifier "DPH-14-001E" in the subject line;
2. By fax transmission to: (916) 440-5747;
3. By postal service to: California Department of Public Health, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377;
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-14-001E, author's name and mailing address.

AUTHORITY AND REFERENCE

The Department has amended the regulation section identified under the authority provided in sections 124977, 124996, 125000, 125055, 125070 and 131200 of the Health and Safety Code. The regulation implements, interprets, and makes specific 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, 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.

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 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 HSC 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 17 CCR, 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 (HSC section 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. 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. 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, 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 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 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:

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:

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 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.

EVALUATION AS TO WHETHER THE PROPOSED REGULATIONS ARE INCONSISTENT OR INCOMPATIBLE WITH EXISTING STATE REGULATIONS

The Department evaluated whether the regulation is inconsistent or incompatible with existing state regulations. This evaluation included a review of the Department's existing state regulations and those regulations specific to prenatal screening regulations. An internet search or 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 regulation is not inconsistent or incompatible with existing state regulations.

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable

FORMS INCORPORATED BY REFERENCE

Not applicable

OTHER STATUTORY REQUIREMENTS

Not applicable

REPORTING REQUIREMENT

None

LOCAL MANDATE

The Department has determined that the regulations would 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.

FISCAL IMPACT ESTIMATE

A. COST OR SAVINGS TO ANY STATE AGENCY:

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.

B. COST TO ANY LOCAL AGENCY OR SCHOOL DISTRICT:

None.

C. OTHER NONDISCRETIONARY COST OR SAVINGS IMPOSED ON LOCAL AGENCIES: None.

D. COST OR SAVINGS 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.

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.

HOUSING COSTS

The Department has determined that the regulation will not have an impact on housing costs.

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.

SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS, INCLUDING THE ABILITY TO COMPETE

The Department has made an initial determination that the regulatory action will not have a significant statewide adverse economic impact directly effecting California business enterprises or individuals, 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 will be sufficient to require any significant increase in premiums charged to insurance/health plan members.

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.

ALTERNATIVES CONSIDERED

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 action is proposed, would be as effective and less burdensome, 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.

CONTACT PERSON

Inquiries regarding the substance of the regulation described in this notice may be directed to Sara Goldman, M.P.H., Chief, Genetic Disease Screening Program, at (510) 412-1463.

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

In any inquiries or written comments, please identify the action by using the Department regulation package identified, DPH-14-003E.

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.

CALIFORNIA DEPARTMENT OF PUBLIC HEALTH



Ron Chapman, MD, MPH
Director and State Health Officer

Date: