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Director

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



EDMUND G. BROWN JR.
Governor

NOTICE OF PROPOSED RULEMAKING

California Code of Regulations

Title 17

DPH-06-024E

Notice IS HEREBY GIVEN that the California Department of Public Health (Department) has, under the authority granted by section 131200 of the Health and Safety Code, amended section 6540 of the California Code of Regulations regarding fees related to testing for genetic disorders. Section 124977(d)(1) of the Health and Safety Code provides that for the purposes of the Administrative Procedure Act, 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. This regulation is now in effect. This notice of proposed rulemaking commences a rulemaking to make the regulations permanent.

PUBLIC HEARING

Date and Time: November 17, 2011 – 10:00 a.m. to 12:00 noon
Place: 1500 Capitol Ave, Sacramento, California 95814
Purpose: To hear comments about this action.

An agenda for the public hearing will be posted at the time and place of hearing designated above. For individuals with disabilities, the Department will provide 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 to Dave Rappolee, Office of Regulations, MS 0507, P.O. Box 997377, Sacramento, CA 95899-7377, call (916) 445-9387, email at David.Rappolee@cdph.ca.gov, or use the California Relay Service by dialing 711.

PUBLIC COMMENT PERIOD:

The public comment period will close at 5pm on November 17, 2011. Any person may submit public comments in writing (by mail, fax, e-mail, or in person) regarding the emergency changes. To be considered by the Department, comments must be submitted to the Department, Office of Regulations as follows:

1. By email to: regulations@cdph.ca.gov;
2. By fax transmission to: (916) 440-5747;
3. By mail to: Office of Regulations, P.O. Box 997377, Sacramento, CA 95899-7377; or
4. Hand delivered to: 1616 Capitol Avenue, Sacramento, CA 95814

All submitted comments should contain the regulation package identifier DPH-06-024E

CONTACT INFORMATION:

Questions regarding the subject matter of the regulation should be directed to:

**Genetic Disease Screening Program
Sara Goldman, M.P.H, Chief
Program Standards and Quality Assurance Branch
California Department of Public Health
(510) 412-1463**

Questions regarding the regulatory process described in this notice should be directed to:

**Marylyn Willis, Staff Services Manager II
Office of Regulations
(916) 440-7733**

In the event the contact person named above is unavailable, inquiries should be directed to the following back-up person:

**David Rappolee, Staff Services Manager I
Office of Regulations
(916) 445-9378**

FISCAL IMPACT ESTIMATE:

- A. Fiscal Impact on Local Government: None.
- B. Fiscal Impact on State Government: \$770,900.
- C. Fiscal Impact on Federal Funding of State Programs: \$770,900.
- D. Fiscal Impact on Private Persons or Businesses Directly Affected: The cost impacts known to the Department at the time this regulation was adopted, that a representative private person or business would necessarily incur in reasonable compliance with this regulation, are as follows: cost increase of \$7 per pregnancy in the screening test fee for certain genetic diseases, for those businesses providing health coverage to pregnant women, or to the pregnant woman if she is not covered by health care insurance.
- E. Other Nondiscretionary Cost or Savings Imposed on Local Agencies: None.

LOCAL MANDATE:

The Department has determined that the regulations would not impose a mandate on local agencies or school districts, and that there are not any costs for which reimbursement is required by Part 7 (commencing with section 17500) of Division 4 of the Government Code.

ECONOMIC IMPACT ON BUSINESS:

The Department has made an initial determination that the regulations would not have a significant, statewide adverse economic impact directly affecting businesses, including the ability of California businesses to compete with businesses in other states.

ASSESSMENTS OF EFFECTS ON JOBS AND/OR BUSINESS CREATION, ELIMINATION, OR EXPANSION:

The Department has determined that the regulations will have no effect on the creation of new, or the elimination of existing, jobs or businesses within California, or affect the expansion of businesses currently doing business in California.

EFFECT ON SMALL BUSINESS

The Department has determined that the regulation will not affect small business. None of the business affected by this regulation meet the criteria of small business established by section 11342.610 of the Government Code.

EFFECT ON HOUSING COSTS

The Department has determined that the regulations will have no impact on housing costs.

CONSIDERATION OF ALTERNATIVES:

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 of the emergency action or would be as effective and less burdensome to affected private persons than the emergency action.

AVAILABILITY OF EMERGENCY TEXT AND INITIAL STATEMENT OF REASONS:

The Department has made available the regulation text and the Initial Statement of Reasons (ISOR) for the emergency regulations on the Department's website at <http://www.cdph.ca.gov>. Upon completion of the rulemaking process, the rulemaking file for this regulatory action, which contains those items and all information on which the emergency action is based, will be available to the public upon a request submitted to the Department.

AVAILABILITY OF CHANGES TO PROPOSED TEXT:

After considering all timely and relevant comments received, the Department may finalize the emergency regulations substantially as described in this Notice. If the Department makes modifications which are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days before the Department finalizes the regulations as revised. Copies of modified regulation text may be obtained from the Department's website at <http://www.cdph.ca.gov>.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Background: In July of 2007, the California Department of Public Health was created pursuant to legislation (SB 162, Ch. 241, Stats. 2006) which separated the medical coverage and public health care functions previously consolidated in the former Department of Health Services (now called Department of Health Care Services), and assigned the public health functions to the newly established Department of Public Health (Department).

Department of Public Health Genetic Disease Screening Program (GDSP):

Under authority of sections 124975 through 125119.5 of the Code, the Department has established several programs for testing for genetic disorders. One such Departmental Program, the GDSP, provides, under authority of section 125050 et seq. of the Code, for the testing of the mother's blood, and, in certain instances, intrauterine tissues, to determine the likelihood that the fetus may have a genetic defect such as Down's Syndrome or a neural tube defect.

Under sections 124977, 125000, and 125055 of the Code, the Department has authority to determine and charge fees to cover the costs related to testing for genetic disorders. Pursuant to this authority, the Department promulgated section 6540, which establishes fees for such testing, into Title 17 of the California Code of Regulations.

Purpose of the \$7 Fee Increase: The Department now adopts an emergency amendment to section 6540 to increase one of the two fees established by this regulation. The \$155 fee in existing section 6540 is applicable when two or more constituents (called "markers") of the mother's blood are tested to determine the likelihood that her newborn will have a genetic disease such as Down's Syndrome or a neural tube defect. This fee covers the testing of the alpha-fetoprotein blood marker, and up to 4 additional blood markers: Inhibin A, unconjugated estriol, human chorionic gonadotropin, and pregnancy-associated plasma protein A. This \$155 fee also covers certain diagnostic tests, such as amniocentesis or chorionic villus testing, if deemed by the Department to be medically necessary. If medically necessary, some kinds of ultrasound testing – but not including nuchal translucency testing – may also be covered by this fee.

The emergency amendment to section 6540 provides for a \$7 fee increase from \$155 to \$162. The purpose of this fee increase is to cover the increased costs of the Departmental administrative and operational functions required to maintain the Department's programs for the testing of genetic diseases. Such functions include the printing of brochures and guides on genetic disease testing for patients and health-care providers, and the monitoring of testing facilities to ensure quality control. The Department's authority to include such costs in the fee for testing for genetic disease is provided under section 124977 of the Code.

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

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