



TOMÁS J. ARAGÓN, MD, DrPH  
Director and State Public Health Officer

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



GAVIN NEWSOM  
Governor

**NOTICE OF PUBLIC HEARING**  
**Title 17, California Code of Regulations**  
**Prenatal Screening (DPH-21-008E)**  
**Notice Mailed: September 15, 2022**

NOTICE IS HEREBY GIVEN that the California Department of Public Health (Department) has adopted the regulations described in this notice on an emergency basis. Health & Safety Code (HSC) section 124977(d)(1) provides that, for the purpose of the Administrative Procedures 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. These regulations are now in effect and this notice of public hearing is pursuant to HSC 124977(d)(1) to consider comments, objections, and recommendations regarding the regulation.

**PUBLIC PROCEEDINGS**

The Department will hold a virtual public hearing on October 26, 2022. (See below for further details.) At a later date, the Department will conduct a 45-day written public comment period, during which time any interested person or such person's duly authorized representative may present written statements, arguments or contentions (all of which are hereinafter referred to as comments) relevant to the action described in this notice.

To request copies of the regulatory proposal in an alternate format, please contact Veronica Rollin, CDPH Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, or at 279-217-0836, or email to [veronica.rollin@cdph.ca.gov](mailto:veronica.rollin@cdph.ca.gov), or use the California Relay Service by dialing 711.

**PUBLIC HEARING**

The hearing will be held via Microsoft Teams®, on October 26, 2022, from 10:00 A.M. to 11:30 A.M.

Attendees should use the following URL:

[https://teams.microsoft.com/join/19%3ameeting\\_NzAzM2U4ZDEtZjQ0OS00ODFmLWE0MDEtNzVkZGMzZmVjNTZh%40thread.v2/0?context=%7b%22Tid%22%3a%221f311b51-f6d9-4153-9bac-55e0ef9641b8%22%2c%22Oid%22%3a%226dfa6eb3-18b9-4554-b57e-f39c4d85e733%22%7d](https://teams.microsoft.com/join/19%3ameeting_NzAzM2U4ZDEtZjQ0OS00ODFmLWE0MDEtNzVkZGMzZmVjNTZh%40thread.v2/0?context=%7b%22Tid%22%3a%221f311b51-f6d9-4153-9bac-55e0ef9641b8%22%2c%22Oid%22%3a%226dfa6eb3-18b9-4554-b57e-f39c4d85e733%22%7d)

Access code: 219 968 245 346

Passcode: mYySa2



Those who do not have access to a computer may call in using the following information:

Call in only: 916-306-8051    Access Code: 898 170 873#    ID#: 898 170 873#

During the hearing, any person may present oral statements or arguments relevant to the proposed action described in this notice. The Department requests but does not require persons who make oral comments during the hearing to also submit a written copy of their testimony by email to [Regulations@cdph.ca.gov](mailto:Regulations@cdph.ca.gov), eFax to (916) 636-6220, or postal service or hand delivered to California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814-7377. An agenda for the public hearing will be made available upon request.

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, and audiocassette or computer disk. Note: The range of assistive services available may be limited if requests are received without adequate preparation time prior to the public hearing.

All comments, including email or fax transmissions, should include the regulation package identifier, DPH-21-008E Prenatal Screening, along with your name and your mailing address or email address in order for the Department to provide copies of any notices for proposed changes to the regulation text of which additional comments may be solicited.

### **AUTHORITY AND REFERENCE**

The Department proposes amendments under the authority provided in HSC Sections 124977, 124980, 124996, 125000, 125055, 125070 and 131200.

This proposal implements, interprets, and makes specific HSC Sections 1367.54, 124975, 124977, 124980, 124990, 124996, 125000, 125001, 125050, 125055, 125060, 125065, 125070, 125075, 125085, and 131052, and Insurance Code Section 10123.184.

### **INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW**

#### **Summary of Proposal**

The Department proposes amendments to Title 17, California Code of Regulations (CCR 17), Division 1, Chapter 4, Subchapter 9, Group 5 (California Prenatal Screening Program) to comply with the mandate of Senate Bill 1555 (SB 1555) (Speier, Chapter 484, Statutes of 2006) that the Department “shall expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations.”

The proposed amendments would establish a new fee structure for the Prenatal Screening (PNS) Program, raising the program’s all-inclusive participation fee from

\$221.60 to \$232.00 to cover the cost of a new “cell-free DNA” screening test for trisomies 21, 18 and 13, and implementing a separate fee of \$85 to cover the costs of the existing neural tube defect screening test. These new fees would take effect on September 19, 2022 and are necessary for the PNS Program to integrate the new screening methods into its testing roster as required by SB 1555. Other non-substantive changes to Title 17 are proposed to eliminate obsolete terminology.

### **Background/Authority**

The purpose of these regulations is to update Title 17, California Code of Regulations (CCR), Division 1, Chapter 4, Subchapter 9, Group 5 (California Prenatal Screening Program) to comply with the mandate of SB 1555 that prenatal screenings include “all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations.”

The proposed changes would establish a new fee structure for the PNS Program, raising the program’s all-inclusive participation fee from \$221.60 to \$232.00 to cover the cost of a new “cell-free” DNA screening test, and implementing a separate fee of \$85 to cover the costs of a new neural tube defect screening test. These new fees would take effect on September 19, 2022, and are necessary for the PNS Program to integrate new screening methods into its testing roster as required by SB 1555. Other non-substantive changes to Title 17 are proposed to eliminate obsolete terminology.

The California PNS Program is administered by the Department’s Genetic Disease Screening Program (GDSP), under the authority of the Hereditary Disorders Act in HSC sections 124977, 124980, 124996, 125000, 125050, 125055, 125060, 125065, 125070 and 131200. HSC section 124975, subdivision (h) specifies the state’s policy that hereditary disorders should be constantly reviewed to consider changing medical knowledge and ensure full public protection. HSC sections 124977 and 124996 require that GDSP activities be “fully supported from fees collected.”

Recently, a new screening methodology known as “cell-free DNA” (cfDNA) has been developed, demonstrating improved performance for prenatal screening. (“cell-free DNA” refers to fetal DNA that can be detected in a pregnant individual’s blood.) cfDNA screening involves the extraction of maternal and fetal cells from a pregnant individual’s blood sample, which can then be used to detect an additional chromosome abnormality for which the PNS Program does not currently screen (i.e., trisomy 13). This new test is more efficient in terms of false positive and detection rates, resulting in fewer pregnant individuals needing referrals for diagnostic follow-up services.

### **Policy Statement Overview**

#### ***Problem Statement:***

Given the emergence of cfDNA screenings as the standard of care for prenatal screening activities, the Department finds that regulatory action is needed to amend CCR 17 to comply with the mandate of SB 1555. The proposed amendments include changes to the PNS Program’s fee structure to cover the costs of the new screening practices.

The Department proposes further amendments to Title 17 to eliminate obsolete terms, references, standards, and clinical methods.

***Benefits and Objectives (Goals):***

Anticipated benefits from this regulatory action are:

- Protecting the health, safety, and welfare of participating individuals and children by updating the PNS Program’s standards of care and testing to reflect current best practices.
- Provide clarity to the regulated population by updating the regulatory text to reflect the most current industry terminology, definitions, and procedures.

The broad objectives of this regulatory action are to:

- Expand the current standard of care for prenatal screening, as required by statute and recommended by ACOG and ACMG.
- Repeal or update obsolete and inaccurate definitions, terminology, and methods.

**Evaluation as to Whether the Proposed Regulations Are Inconsistent or Incompatible with Existing State and Federal 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. As no other state agency regulations address the same subject matter, the Department determined that this emergency rulemaking is not inconsistent or incompatible with existing state regulations.

**Local Mandate**

This 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.

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

- Genetic Disorder Screening Program, Prenatal Diagnosis Standards and Definitions, 2022
- The American College of Medical Genetics (ACMG), Technical Lab Standards for Clinical Genetics Laboratories (2021)
- Noninvasive prenatal screening for fetal aneuploidy, 2016 update: a position statement of the American College of Medical Genetics and Genomics, Genetics in Medicine, Vol. 18, No. 10, October 2016
- The American College of Obstetricians and Gynecologists (ACOG), Practice Bulletin 226 Screening for fetal chromosomal abnormalities, Obstetrics & Gynecology, Vol. 136, No. 4, October 2020

- Department of Finance Demographic Research Unit (DRU), [P-Births: Historical and Projected Fertility Rates and Births, Calendar Year 1990-2040](https://dof.ca.gov/Forecasting/Demographics/Projections/)<sup>1</sup>.  
<[https://dof.ca.gov/ Forecasting/Demographics/Projections/](https://dof.ca.gov/Forecasting/Demographics/Projections/)> (As accessed January 20, 2022)

### **Mandated by Federal Law or Regulations**

No.

### **Fiscal Impact Estimate**

#### **Fiscal Impact on Local Government:**

The Department has made the following determinations concerning the fiscal impact of this regulatory proposal.

**A. Costs to Local Agency or School District**

None.

**B. Costs or Savings to State Agencies**

None.

**C. Non-Discretionary Costs or Savings Imposed on Local Agencies**

None.

**D. Costs or Savings in Federal Funding to the State**

None.

### **Significant Statewide Adverse Economic Impact**

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

### **Cost Impact on Representative Person or Business**

The Department is unaware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed section.

### **Statement of the Results of the Economic Impact Assessment**

The Department has determined that this regulatory proposal will have the following effects on:

**A. The creation or elimination of jobs within the State of California.**

Some contract laboratories may need to hire additional laboratory staff as a result of these regulations. There may be a small fiscal economic impact on businesses and institutions that contract with or are approved by the Department to provide technical and scientific supplies, case coordination services, and authorized follow-up services. There is no new hiring to the insurance industry as a result of these regulations.

**B. The creation of new businesses or the elimination of existing businesses within the State of California.**

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<sup>1</sup> This resource can be accessed under the heading “Birth Projections” on the [Department of Finance’s Demographic Projections webpage](https://dof.ca.gov/Forecasting/Demographics/Projections/).  
([https://dof.ca.gov/Forecasting/ Demographics/Projections/](https://dof.ca.gov/Forecasting/Demographics/Projections/))

The Department anticipates no impact to the numbers of businesses in California as a result of this regulatory proposal.

**C. The expansion of businesses currently doing business within the State of California.**

The Department anticipates minimal impact on the expansion of businesses in California as a result of this regulatory proposal. As a result of new tests being offered, some contract laboratories may choose to expand operations to respond to increased caseloads.

**D. The benefits of the regulation to the health and welfare of California residents, worker safety or the state's environment.**

The Department expects the regulations to benefit the health and welfare of California residents by expanding prenatal screening activities to include the most up-to-date and industry recommended methodologies. These regulations will provide earlier diagnosis of genetic disorders in infants which may allow for better treatment and amelioration of the condition, provide individuals with more time and information to plan the best course of care, and ultimately provide better health outcomes for pregnant individuals, newborns, and their families.

The Department is unaware of any benefits to worker safety or the state's environment that may result from this proposal.

**Effect on Housing Costs**

None.

**Effect on Small Business**

The Department has determined that the rulemaking will not have an effect on small businesses.

**Alternatives Statement**

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.

HSC section 125055, subdivision (g)(1) mandates that the Department expand prenatal screening to include all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations.

HSC sections 124977, subdivision (a) and section 124996 require that the California PNS Program be fully supported by fees collected.

**CONTACT PERSON**

Inquiries regarding the substance of the proposed regulations described in this notice may be emailed to Sara Goldman at the Genetic Disease Screening Branch, [sara.goldman@cdph.ca.gov](mailto:sara.goldman@cdph.ca.gov).

All other inquiries concerning the action described in this notice may be directed to Veronica Rollin, Office of Regulations, at [veronica.rollin@cdph.ca.gov](mailto:veronica.rollin@cdph.ca.gov), or 279-217-0836 or to the designated backup contact person, Michael Boutros, Chief of the Office of Regulations, at [Michael.Boutros@cdph.ca.gov](mailto:Michael.Boutros@cdph.ca.gov).

**In any inquiries or written comments, please identify the action by using the Department regulation package identifier, DPH-21-008E.**

### **INTERNET ACCESS**

Materials regarding the action described in this notice (the text of the emergency regulations) are available via the Internet and may be accessed at [www.cdph.ca.gov](http://www.cdph.ca.gov) by clicking on these links, in the following order: Programs, Office of Regulations, Proposed Regulations.