



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



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

GAVIN NEWSOM  
Governor

**NOTICE OF PUBLIC HEARING**  
**Title 17, California Code of Regulations**  
**Prenatal Screening (DPH-23-005)**  
**Notice Mailed: June 3<sup>rd</sup>, 2024**

NOTICE IS HEREBY GIVEN that the California Department of Public Health 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 July 15, 2024 (See below for further details). Please consider submitting written public comments to [Regulations@cdph.ca.gov](mailto:Regulations@cdph.ca.gov) or by fax: (916) 440-5747 or mail: California Department of Public Health, 1415 L Street, Suite 500, Sacramento, CA 95814. Written comments can be submitted now and will be accepted after the hearing until July 24<sup>th</sup>, 2024. The public will also be able to provide public comment when prompted during the hearing.

To request copies of the regulatory proposal in an alternate format, please contact Jasmine Fullwood, CDPH Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814, or at (916) 558-1710 or email [Regulations@cdph.CA.Gov](mailto:Regulations@cdph.CA.Gov), or use the California Relay Service by dialing 711.

**PUBLIC HEARING**

The hearing will be held via Microsoft Teams®, on July 15, 2024, from 11:00 A.M. to 12:00 P.M.



Microsoft Teams ® [Need help?](#)

[https://teams.microsoft.com/l/meetup-join/19%3ameeting\\_YWM1ZTVhMWQtMDA5ZS00NmNmLWJlYzAtMmJmYzFIZjYWRj%40thread.v2/0?context=%7b%22Tid%22%3a%221f311b51-f6d9-4153-9bac-55e0ef9641b8%22%2c%22Oid%22%3a%2244621d52-0bc7-4ff8-9f05-b04383296617%22%7d](https://teams.microsoft.com/l/meetup-join/19%3ameeting_YWM1ZTVhMWQtMDA5ZS00NmNmLWJlYzAtMmJmYzFIZjYWRj%40thread.v2/0?context=%7b%22Tid%22%3a%221f311b51-f6d9-4153-9bac-55e0ef9641b8%22%2c%22Oid%22%3a%2244621d52-0bc7-4ff8-9f05-b04383296617%22%7d)

Meeting ID: 262 080 788 494  
Passcode: cxAgan

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**Dial-in by phone** (916) 306-8051 United States, Sacramento  
Phone conference ID: 944 515 900#

**Find a local number:** <https://dialin.teams.microsoft.com/78c43e68-2867-4a4f-af8d-e771e376b3ee?id=944515900>

Phone conference ID: 944 515 900#

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. For the Department to provide copies of any notices for proposed changes to the regulation text of which additional comments may be solicited, include your name and your mailing address or email address. All comments, including email or fax transmissions, should include the regulation package identifier, DPH-23-005 Prenatal Screening Program. 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.

### **AUTHORITY AND REFERENCE**

The Department's PNS Program is administered by the Genetic Disease Screening Program (GDSP) under the authority of the Hereditary Disorders Act in the HSC, specifically HSC sections 124977, 124980, 124996, 125000, 125050, 125060, 125065, 125070 and 131200.

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CDPH Office of Regulations • 1415 L Street, Suite 500 • Sacramento,  
CA 95814-7377 (916) 558-1710 • (916) 636-6220 eFAX  
[Department Website](http://www.cdph.ca.gov) (www.cdph.ca.gov)



HSC section 124975, subdivision (h) specifies that the state's policy regarding hereditary disorders should be constantly reviewed to ensure full public protection. HSC sections 124977 and 124996 require that GDSP activities be "fully supported from fee collected."

### **Background and Policy Statement Overview**

Since 1986, the PNS Program has worked to ensure prenatal screening services, including follow-up services, are available to all pregnant individuals in California. Participation in the program is voluntary, and the program participation fees are currently \$232.00 for cfDNA screening and \$85.00 for Maternal Serum Alpha-Fetoprotein (MSAFP) screening. The program directly bills Medi-Cal, the patient's insurer or, in the absence of insurance information, bills the patient directly. The program provides quality-assured prenatal screening tests for approximately 223,000 pregnant individuals in California each year. While MSAFP is performed directly under supervision of the Department's Genetic Disease Laboratory, cfDNA screening is performed by private laboratories under contract with the Department. Participants with positive or other high-risk screening results are authorized for referral of follow-up genetic counseling, ultrasound, and other diagnostic services, which are provided free of charge at state-approved Prenatal Diagnosis Centers and authorized laboratories (HSC section 125065 requires that all state-approved Prenatal Diagnosis Centers meet standards developed by the Department).

MSAFP in the second trimester was developed in the early 1980s. Testing methodologies subsequently evolved to include measurement of the levels of two additional pregnancy hormones: unconjugated estriol and human chorionic gonadotropin.

As intended by SB 1555, the PNS Program regularly updates its testing activities to provide the most current procedures. Over the years the PNS Program has expanded to include:

- Screening of inhibin (dimeric inhibin A, a protein produced by the ovaries and fetal placenta) in the second trimester to more accurately detect pregnancies at risk of Down syndrome.
- Screening of pregnancy-associated plasma protein A (associated with an abnormal number of fetal chromosomes) in the first trimester.
- Nuchal translucency (NT) scan for Down syndrome in the general population.

In 2011, a new screening methodology known as "cell-free DNA" (cfDNA) screening demonstrated improved performance for prenatal screening, producing lower false positive and showing 99% accuracy in detecting Down syndrome and trisomy 18 (Edward's syndrome).

In 2016, the American College of Medical Genetics and Genomics (ACMG) published "practice Guidelines" that recommend the use of cfDNA tests as the highest standard of care for PNS screening. In 2020, the American College of Obstetricians and

Gynecologists (ACPG) released Practice Bulletin 226, describing cfDNA as the most sensitive and specific screening test for common fetal autosomal trisomies. Trisomy 21 (Down syndrome), trisomy 18 (Edwards syndrome), and trisomy 13 (Patau syndrome) are recommended prenatal cfDNA screening and diagnostic testing options be discussed and offered to all pregnant individuals regardless of maternal age or risk of chromosomal abnormality.

On September 19, 2022, GDSP made cfDNA screening for fetal autosomal trisomies available statewide.

On December 16, 2022, ACMG released updated clinical practice guidelines recommending that noninvasive prenatal screening (NIPS, which is another term for cfDNA screening) be expanded to include screening for SCAs beyond trisomies 21, 18, and 13 in all singleton and twin pregnancies. Because the PNS Program has statutory mandate to provide the highest standard of care to the state's pregnant individuals, the proposed regulations would adopt the standards of care recommended by ACOG and ACMG for prenatal screening and follow-up services.

On September 16, 2022, to enjoin the Department's ability to regulate which clinical laboratories in California may offer cfDNA screening to pregnant individuals against the Department in the litigations of *Laboratory Corporation of America Holdings, and Myriad Genetics, Inc. v. California Department of Public Health* and *BillionToOne, Inc. v. California Department of Public Health*.

On May 31, 2023, the court's judgment permanently enjoined the Department from such regulatory authority and imposed a requirement that the Department consult with the public prior to adopting any regulations. In accordance with the court's ruling, the Department conducted extensive community partner engagement, including informational webinars, prior to undertaking the present regulatory amendment.

### **Problem Statement**

To comply with its mandate under SB 1555 and expand its screening activities to meet the most stringent standard of care, the PNS Program proposes to raise its all-inclusive screening fee from \$232.00 to \$344.00.

### **Objectives (Goals):**

The broad objectives of this regulatory action are to:

- Expand the PNS Program's screening activities to meet the most stringent standard of care.
- Continue to fund the PNS Program from fees collected in accordance with HSC section 124996, subdivision (b).
- Update the Department's regulations to meet the current standard of care for prenatal screening.

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**Benefits:**

The Department anticipates that the regulations will benefit the health and welfare of California residents. Improvements in methods for prenatal screening risk assessment, early diagnosis and other testing options help prevent or reduce the severity of health problems associated with conditions such as chromosomal abnormalities, neural tube defects, and other related health problems. Screening and diagnosis allow for consideration and planning for resources necessary to treat and care for the child, including fetal and /or neonatal surgery, delivery at a tertiary care facility, newborn care in a neonatal intensive care unit, social services, and financial aid. These measures can reduce and/or ameliorate costs and the severity of the infant's condition and contribute to an enhanced quality of life. Participation in the California PNS Program also provides pregnant individuals with information to assist them in reproductive health decisions. Pregnant individuals, children, families, insurance companies, health plans, the state, and communities all benefit from the PNS Program offering screening at the current standard of care.

**Other Statutory Requirements**

None.

**Local Mandate**

The Department has determined that the rulemaking does not impose a mandate on local agencies or school districts, nor are there any cost for which reimbursement is required by part 7 (commencing with section 17500) of Division 4 of the Government Code.

**Alternatives Statement**

In accordance with Government Code section 11346.5(a)(12), the Department has determined 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 and equally effective in implementing the statutory policy or other provision of law.

**CONTACT PERSON**

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

All other inquiries concerning the action described in this notice may be directed to Jasmine Fullwood, Office of Regulations, at [Jasmine.Fullwood@cdph.ca.gov](mailto:Jasmine.Fullwood@cdph.ca.gov), 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-23-005.**

**INTERNET ACCESS**

Materials regarding the action described in this notice (the text of the emergency regulation) are available via the Internet and may be accessed at <https://www.cdph.ca.gov/Programs/OLS/Pages/DPH-23-005.aspx> by clicking on these links, in the following order: Programs, Office of Regulations, Proposed Regulations.

