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

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NOTICE OF PROPOSED RULEMAKING
Title 17. Social Security
DPH-08-005E Prenatal Screening Regulations
Notice Published: December 20, 2019

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

PUBLIC PROCEEDINGS

The Department is conducting a 45-day written public proceeding 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 the Informative Digest/Policy Statement Overview section of this notice.

To request copies of the regulatory proposal in an alternate format, please write or call: Anita Shumaker, Office of Regulations, 1415 L Street Suite 500, Sacramento, CA 95814, at (916) 440-7718, email to Anita.Shumaker@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 Office of Regulations by February 3, 2020, 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. It is requested that email transmission of comments, particularly those with attachments, contain the regulation package identifier "DPH-08-005E "Prenatal Screening Regulations" in the subject line to facilitate timely identification and review of the comment;
2. By fax transmission to: (916) 636-6220;
3. By postal service or hand delivered to: California Department of Public Health, Office of Regulations, 1415 L Street, Suite 500, Sacramento, CA 95814.

All submitted comments should include the regulation package identifier, **"DPH-08-005 Prenatal Screening Regulations"**, with the comment author's name and email or mailing address.

PUBLIC HEARING

The Department has scheduled a public hearing to accept comments on the proposed action. Any person may present statements or arguments 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: **February 11, 2020**
Time: **2:00 p.m.**
Location: **1415 L Street Suite 500, Sacramento, CA 95814**

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

ASSISTIVE SERVICES

For individuals with disabilities, The Department will provide assistive services such as the conversion of written materials into Braille, large print, audiocassette, and computer disk. For public hearings, assistive services can include sign-language interpretation, real-time captioning, note takes, reading or writing assistance. To request these assistive services, please call (916) 558-1710 or (California Relay at 711 or 1-800-735-2929), email Regulations@cdph.ca.gov or write to the Office of Regulations at the address noted above. Note: The range of assistive services available may be limited if requests are made less than 10 business days prior to a public hearing.

AUTHORITY AND REFERENCE

The California Prenatal Screening Program is administered by the Department's Genetic Disease Screening Program, under the authority of the Hereditary Disorders Act in the HSC, and specifically HSC sections 124977, 124980, 124996, 125000, 125050, 125055, 125060, 125065, 125070 and 131200.

Health and Safety Code (HSC) Section 124977(d) authorizes the California Department of Public Health (Department) to adopt emergency regulations. The adoption of these regulations is deemed an emergency. These regulations are necessary for the immediate preservation of the health, safety, and general welfare of Californians.

INFORMATIVE DIGEST/POLICY STATEMENT OVERVIEW:

Summary of Proposal

The purpose of these regulations is to require that prenatal screening include "all tests that meet or exceed the current standard of care as recommended by nationally recognized medical or genetic organizations, including, but not limited to, inhibin." The addition of inhibin (dimeric inhibin A, a protein produced by the ovaries and fetal

placenta) as a fourth analyte tested in maternal serum in the second trimester makes the screening more accurate in detecting pregnancies at risk of Down syndrome.

In accord with this legislative mandate, the Department has also responded to ACOG and ACMG recommendations that first trimester screening be offered to pregnant women as the standard of care. This screening involves the testing of a fifth analyte, pregnancy-associated plasma protein A, associated with fetal chromosomal anomalies including aneuploidy (an abnormal number of chromosomes). The Department has also made cfDNA screening and prenatal microarray testing available as follow-up services to certain women participating in the California PNS Program, and updated requirements for State-approved PDCs, personnel and laboratories. This regulatory action is required to reflect this program expansion and the current standards and procedures that contribute to the health and safety of women and children in California.

Background

Health and Safety Code (HSC) Section 125050 requires the California Department of Public Health (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. Testing requirements for prenatal birth defects are established in Title 17, California Code of Regulations (17 CCR), Section 6521, et seq.

HSC Code Section 124977(d)(1) and Section 125055 authorize the Department to adopt emergency regulations under the emergency rulemaking process; specifies that adoption shall be deemed an emergency and necessary for the immediate preservation of the public peace, health and safety, or general welfare; and exempts emergency regulations from review and approval by the Office of Administrative Law (OAL). 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 OAL with the adopted regulation a final statement of reasons and updated informative digest. HSC Section 124977(d)(2) specifies that emergency regulations shall not be repealed by OAL and shall remain in effect until revised or repealed by the Department.

Problem Statement

Senate Bill (SB) 1555 (Speier, Chapter 484, Statutes of 2006) added HSC Section 125055(g)(1) which requires the Department to expand prenatal screening and testing to meet the current standard of care. Regulatory action was required to implement, interpret, and make specific this provision relating to prenatal screening and testing in California by specifying this standard of care and the options offered to women who participate in the California Prenatal Screening (PNS) Program. Additional analytes in maternal serum are now tested in the first and/or second trimester as part of the California PNS Program (originally known as the California Alpha-fetoprotein [AFP] Screening Program, and subsequently as the Expanded AFP Screening Program). The Department has also responded to recommendations that cell-free DNA (cfDNA) screening is available to high-risk women as a follow-up service, and that prenatal

microarray testing is available to women with findings of major structural anomalies on ultrasound through the California PNS Program.

With the program expansion, the regulation text contained obsolete terms, program references, standards, and clinical methods. Definitions were no longer accurate and referred to acronyms no longer associated with the new program name. The regulation text also contained inaccuracies and inconsistent uses of terminology.

Objectives (Goals) of the Regulation
Broad objectives of this regulatory action are to:

- Implement, interpret, and make specific HSC Section 125055(g)(1).
- Specify the current standard of care for prenatal screening, as recommended by the American College of Obstetricians and Gynecologists (ACOG) and American College of Medical Genetics (ACMG) and offered by the California PNS Program. This includes additional analytes tested (dimeric inhibin A and pregnancy-associated plasma protein-A) and the screening options and follow-up services available for women participating in the California PNS Program.
- Update the program name by replacing references to the "Expanded AFP Program" with the "California Prenatal Screening Program."
- Update the period for drawing blood samples and performing serum screenings to include the first trimester.
- Update the clinical process used to assess fetal age.
- Repeal or update obsolete and inaccurate definitions, terminology, and methods, including repeat testing for screen positive results.
- Ensure accurate and consistent use of terminology and definitions.
- Update requirements for State-approved Prenatal Diagnosis Centers (PDCs), personnel and laboratories providing authorized follow-up services to women participating in the California PNS Program.

Anticipated Benefits
Anticipated benefits, including nonmonetary benefits, from this regulatory action are to:

- *Protect the health, safety, and welfare of women and children by specifying the standard of care for prenatal screening and testing offered through the California PNS Program.*
- *Reduce confusion for the regulated community, healthcare providers, the Department's vendors, third party payers, and the general public by removing or updating obsolete terminology, methods, definitions, and standards.*
- *Provide clarity in the use of terminology, definitions, and procedures authorized by the Department.*

EVALUATION AS TO WHETHER THE PROPOSED REGULATION 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; no other state agency regulations address the same subject matter. Therefore, the Department has determined that this emergency rulemaking is not inconsistent or incompatible with existing state regulations.

FORMS INCORPORATED BY REFERENCE

- *Prenatal Diagnosis Standards and Definitions 2018*
- *The American College of Medical Genetics and Genomics (ACMG) Standards and Guidelines for Clinical Genetics Laboratories, 2018 Edition, Revised January 2018*

MANDATED BY FEDERAL LAW OR REGULATIONS

Not applicable.

OTHER STATUTORY REQUIREMENTS

Not applicable.

LOCAL MANDATE

The Department has determined that the emergency 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.

DISCLOSURES REGARDING THE PROPOSED ACTION

FISCAL IMPACT ESTIMATES

A) Cost to any local agencies or school districts that must be reimbursed pursuant to Section 17561 of Government Code:

None.

B) The cost or savings to any state agency:

The Department estimates there will be no impact on the Genetic Disease Testing Fund. SB 1555 increased the California PNS Program participation fee by $40 for the mandated program expansion, and by an additional $10 to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program. This $50 fee increase was reflected in an amendment to 17 CCR, Section 6540 in 2007, pursuant to Title 1, California Code of Regulations, Section 100. A subsequent $7 fee increase was enacted through regulatory action in 2011 to maintain program solvency, followed by a $45 fee increase from July 1, 2014, bringing the participation fee to $207, with $197 allocated to the GDTF and $10 to the Birth Defects Monitoring Program Fund. This $45 fee increase was necessary to correct for overstatements of estimated caseloads and revenue reductions from changes to the Medi-Cal reimbursement rate that had led to a cumulative deficit in GDTF. On July 1, 2016 the fee increased by $14.60 to a total of $221.60 to cover administrative program costs. These fee increases

were necessary to maintain the self-sufficiency of the California PNS Program. The Department has determined that revenues raised through the current California PNS Program participation fee are sufficient to fund program expenses on an ongoing basis.

C) Other nondiscretionary costs or savings imposed on local agencies:
None.

D) Impact on any cost or savings in federal funding of the program:
None.

HOUSING COSTS

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

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

The Department has made an initial 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.

STATEMENT OF THE RESULTS OF THE ECONOMIC IMPACT ASSESSMENT

The Department has determined that the Program changes reflected in this emergency rulemaking may have a minimal impact on the creation of jobs; will not affect the creation of new businesses or the elimination of jobs or existing businesses; and will have a minimal impact on the expansion of businesses (e.g. contract laboratories) currently doing business within the state of California. The regulations will benefit the health and welfare of California residents, but have no impact on worker safety or the environment.

COST IMPACTS ON REPRESENTATIVE PERSON OR BUSINESS

The Department is not aware of any cost impacts that a representative private person or small business would necessarily incur in reasonable compliance with the proposed action. The Department has also determined that the rulemaking has no impact on small businesses because no small businesses are required to comply with this regulation. None of the Department-contracted prenatal screening test entities conducting business in California are small businesses.

BUSINESS REPORTING REQUIREMENT

The proposed regulatory amendments do not change current business reporting requirements.

EFFECT ON SMALL BUSINESS

The Department has determined that the emergency rulemaking has no impact on small businesses because no small businesses are required to comply with this regulation. None of the Department contracted prenatal screening test entities conducting business in California are small businesses.

SPECIFIC TECHNOLOGIES OR EQUIPMENT

The Prenatal Screening Program is run on an on-line customized computer program called the Screening Information System (SIS). SIS is used by the screening laboratories, Case Coordination Centers, Prenatal Diagnosis Centers, and the Genetic Disease Screening Program to enter patient data and test results, to manage and update cases, to receive Prenatal Diagnosis Center data, and to acquire and store data for program evaluation.

ALTERNATIVES CONSIDERED

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 action was taken, would be as effective and less burdensome to affected private persons than the proposed 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 itself has made an initial determination that there are no acceptable alternatives to the regulations to protect the public interest. However, the Department invites interested persons to present alternatives with respect to the proposed regulation either during the public comment period or at the public hearing.

TECHNICAL, THERETICAL, AND/OR EMPIRICAL STUDIES, REPORTS OR DOCUMENTS RELIED UPON

The following documents were relied upon in developing these regulations:

*American Academy of Pediatrics and American College of Obstetricians and Gynecologists, 2007. Guidelines for Perinatal Care (6th ed.), Elk Grove Village, American Academy of Pediatrics.**

*American College of Obstetricians and Gynecologists, "Screening for Fetal Chromosomal Abnormalities," ACOG Practice Bulletin – Clinical Management Guidelines for Obstetrician-Gynecologists, Number 77, January 2007.**

American College of Obstetricians and Gynecologists Committee on Genetics and The Society for Maternal-Fetal Medicine Publications Committee, "Noninvasive Prenatal Testing for Fetal Aneuploidy," Committee Opinion, Number 545, December 2012.

Available at:
http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Genetics/Noninvasive-Prenatal-Testing-for-Fetal-Aneuploidy

American College of Obstetricians and Gynecologists Committee on Genetics, "The Use of Chromosomal Microarray Analysis in Prenatal Diagnosis," Committee Opinion, Number 581, December 2013.

Available at:
http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Genetics/The-Use-of-Chromosomal-Microarray-Analysis-in-Prenatal-Diagnosis

American College of Obstetricians and Gynecologists Committee on Genetics and The Society for Maternal-Fetal Medicine, "Cell-free DNA Screening for Fetal Aneuploidy," Committee Opinion, Number 640, September 2015.

Available at:
http://www.acog.org/Resources-And-Publications/Committee-Opinions/Committee-on-Genetics/Cell-free-DNA-Screening-for-Fetal-Aneuploidy

Driscoll, D.A., and Gross, S.J., "First trimester diagnosis and screening for fetal aneuploidy," American College of Medical Genetics Practice Guidelines, Genetics IN Medicine, January 2008, Vol. 10, No. 1: 73-75.

Available at:
http://www.acmg.net/StaticContent/SGs/First_trimester_diagnosis_and_screening_for_fetal.10.pdf

Gregg, A.R., Gross, S.J., Best, R.G., Monaghan, K.G., Bajaj, K., Skotko, B.G., Thompson, B.H., and Watson, M.S.; The Noninvasive Prenatal Screening Work Group of the American College of Medical Genetics and Genomics, "ACMG statement on noninvasive prenatal screening for fetal aneuploidy," Genetics in Medicine, May 2013;15(5): 395-8.

Available at:
https://www.acmg.net/docs/nips-GiM_galley_text_130301.pdf

**Viewing and Copies:*
Upon request, the Department's Office of Regulations will have these documents available for viewing during the public comment period(s).

Prenatal Diagnosis Center Standards and Definitions 2018

American College of Medical Genetics and Genomics, Standards and Guidelines for Clinical Genetics Laboratories, 2018 Edition, Revised January 2018

CONTACT PERSON

Inquiries regarding the substance of the proposed regulations described in this notice may be directed to Sara Goldman, Genetic Disease Screening Program, (510) 412-1460. All other inquiries concerning the action described in this notice may be directed to, Anita Shumaker, Office of Regulations, at (916) 440-7718, or to the designated backup contact, Linda Cortez, (916) 440-7807.

AVAILABILITY STATEMENTS

The Department has prepared and has available for public review an initial statement of reasons for the proposed regulations, all the information upon which the proposed regulations are based, and the text of the proposed regulations. The Office of Regulations, at the address previously noted, will be the location of public records, including reports, documentation, and other material related to the proposed regulations.

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 be mailed to you, please call (916) 440-7718 (or the California Relay Service at 711), or 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 which 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 text of the proposed regulations, and the initial statement of reasons) that are available via the Internet may be accessed at www.cdph.ca.gov and by clicking on the following: Programs, Office of Regulations, and the Proposed Regulations link.