

INITIAL STATEMENT OF REASONS

Title 17, California Code of Regulations, Section 6540

(a) The Regulation

This emergency amendment to Title 17, California Code of Regulations (17 CCR), Section 6540, increases the Prenatal Screening Program's (PNS) all-inclusive program participation fee for maternal serum alpha fetoprotein and one or more additional markers from \$155 to \$162.

The PNS is administered by the California Department of Public Health (CDPH)¹, as mandated by Health and Safety Code (H&S Code), Section 125050, providing organized quality-assured voluntary screening of approximately 400,000 pregnant women annually in California for several genetic disorders and birth defects. Genetic disorders and birth defects detected through screening and diagnostic follow-up tests and procedures are established in 17 CCR, Section 6521.5. These disorders include neural tube and ventral wall defects, Down syndrome, Trisomy 18, and Smith-Lemli-Opitz syndrome.

SB 1555 (Speier, Chapter 484, Session 2005-2006), mandated that CDPH 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, including, but not limited to, inhibin. SB 1555 also specified that CDPH increase the prenatal screening fee \$40 to expand the prenatal screening program; and an initial \$10 to support the pregnancy blood sample storage, testing, and research activities of the Birth Defects Monitoring Program. Approved by the Office of Administrative Law on February 16, 2007, the resulting \$50 total PNS fee increase (from \$105 to \$155) was made through a change in 17 CCR, Section 6540; pursuant to 1 CCR, Section 100. The rulemaking process was not necessary to implement the \$50 fee increase, as SB 1555 specifically identified the amount and purpose for this increase.

H&S Code, Sections 124977(a) and (b), 124996 and 125000(b), requires CDPH charge a fee for any tests or activities performed by PNS, that PNS be fully supported from fees collected, and states that the amount of the fee shall be established by regulation and periodically adjusted by the Director.

The Legislature has found that timely implementation of the changes recommended by experts in the field of genetic screening and continuous maintenance of quality statewide services requires expeditious regulatory and administrative procedures to obtain the most cost-effective testing equipment, prenatal screening testing and follow-up services, as described in H&S Code, Section 124977, Section (c)(1). In

¹ Effective July 1, 2007, the California Department of Health Services was split into two separate agencies; i.e., the California Department of Health Care Services, and the California Department Public Health (CDPH). This split was effected by the passage of Senate Bill 162 (Ortiz, et al., Chapter 241, Statutes of 2005-2006). The subject of this emergency regulation was assigned to CDPH through H&S Code, Section 131052.

order for PNS to remain solvent, this emergency amendment to 17 CCR, Section 6540 is necessary in order to fund the continuous maintenance costs of the operational and administrative functions of the PNS program. The last PNS prenatal screening fee increase was established by regulation in February 2007, specifically to address the new costs necessary to expand the PNS program as mandated by SB 1555. This emergency regulation is necessary to fund the continuous maintenance costs for the PNS program. (See Exhibit 1, "PRENATAL SCREENING COSTS IN CALIFORNIA")

(b) Necessity of Emergency Regulation

A \$7 prenatal screening fee increase is necessary in order for PNS to remain solvent.²

A \$7 fee increase will fund the continuous maintenance costs of the operational and administrative functions of the PNS program, to include: printing of provider training manuals and patient education brochures, continuous laboratory quality control testing, maintaining office supplies and forms, administering contracts with private vendors for laboratory analysis, tracking of positive test results, data processing and fee collection; State staff traveling to various locations in California to educate, provide technical assistance, follow-up, monitoring prenatal healthcare providers on the policies and processes under the PNS, and monitoring of Prenatal Diagnostic Centers providing services such as genetic counseling, ultrasound, and invasive procedures such as chorionic villus sampling and amniocentesis. (See Exhibit 1, "PRENATAL SCREENING COSTS IN CALIFORNIA")

On December 20, 2006, the Genetic Disease Branch - Prenatal Screening Program, sent out a letter to "All Insurers of Prenatal Health Care in California," informing providers that the all-inclusive program participation fee for maternal serum alpha fetoprotein and one or more markers used for screening for neural tube defects and Down syndrome would be increased, from \$105 to \$162. This increase would be the result of two distinct components; i.e., one component of \$50; the other component of \$7; totaling \$162. As stated above, the first component was implemented through a change in 17 CCR, Section 6540. This emergency amendment to Section 6540 seeks to implement the second component.

Further, H&S Code, Sections 125000 and 125050 requires CDPH to offer prenatal information, testing and genetic counseling for genetic disorders and birth defects to all pregnant women in California.

If the PNS fee is not increased by \$7, PNS would become insolvent. PNS would need to suspend or reduce prenatal screening and diagnostic testing for pregnant women and their unborn child due to lack of funds, constituting an immediate threat

²Implementation of PNS fee increase to the all-inclusive program participation fee for maternal serum alpha-fetoprotein and one or more additional markers for screening for neural tube defects and Down Syndrome became effective January 1, 2007, pursuant to program expansion in Stats. 2006 c.484.

to public peace, health, safety, and general welfare. 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, knowing whether or not a baby was going to have a congenital defect upon birth and to have resources available to assist the child; e.g., 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, social services, genetic counseling, etc. Such planning serves to optimize the health of newborns with birth defects and can reduce severe 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 within minutes, hours, months, and years after birth; potentiating the quality of a child's lifetime. Without proper planning, some conditions will be compounded. Increasing the PNS fee by \$7 to maintain the operations and administrative functions of PNS would allow continued effective planning based on the prenatal screening information obtained; resulting in reduced healthcare costs in the short term and over a lifetime for a patient, families, communities, and healthcare businesses.

There are no reasonable alternatives to this emergency regulation, as H&S Code, Sections 124977(a) and (b), 124996 and 125000(b), requires CDPH charge a fee for any tests or activities performed by PNS, and that PNS be fully supported from fees collected.

This emergency regulation does not duplicate any existing federal or state statute or regulation.

There is no technical, theoretical, or empirical study, report or similar document that CDPH relied upon for this emergency action.

(c) Scientific Documentation

The State is not relying on any specific documentation.

(d) Mandated Specific Technology

No specific technologies are mandated by this emergency regulation.