

Date of Hearing: August 3, 2022

ASSEMBLY COMMITTEE ON APPROPRIATIONS

Chris Holden, Chair

SB 771 (Becker) – As Amended June 8, 2022

Policy Committee: Health

Vote: 9 - 0

Urgency: No

State Mandated Local Program: No

Reimbursable: No

SUMMARY:

This bill prohibits the California Department of Public Health (CDPH) from preventing a clinical laboratory, as specified, from offering noninvasive prenatal testing (NIPT) to a pregnant person who has opted out of the California Prenatal Screening (PNS) Program or chosen to have testing in addition to the genetic tests offered as part of the PNS Program.

FISCAL EFFECT:

- 1) CDPH reports enactment of this bill will cause an unknown number of providers to order prenatal screening from commercial providers, decreasing the volume for the CDPH PNS Program and dampening economies of scale, which will increase costs to the state. According to CDPH, the planned \$140 laboratory fee for the PNS Program was the result of surveying all Clinical Laboratory Improvement Amendments (CLIA)-certified and state licensed labs that perform cell-free (cfDNA) testing (for NIPT) in California to determine interest in participating in the PNS Program and acceptable prices for performing cfDNA screening with the high volume needed for a statewide program.
- 2) Cost pressure to the Medi-Cal program could be in the tens of millions of dollars per year (General Fund and federal funds), based on the following:
 - a) According to CDPH, Medi-Cal reimburses \$607 per specimen for NIPT using cfDNA screening only, and \$1,500 for follow-up tests when indicated by the screening.
 - b) In the CDPH PNS Program the cost is \$232 per participant, and this would cover follow-up screening when indicated.
 - c) CDPH reports approximately 300,000 people participate in the PNS program each year. Of these, approximately 6,000 (2%) are referred for follow-up testing. Medi-Cal covers more than half of California births.
 - d) If half of the 300,000 people opting to participate have Medi-Cal coverage, and half of the Medi-Cal subscribers opt for a screening from a commercial laboratory, then Medi-Cal will pay $75,000 * \$607 = \$45,525,000$ for those screening tests. If 2% require follow-up testing at \$1500 each, then Medi-Cal will pay an additional $1,500 * \$1,500 = \$2,250,000$. The total would be \$47,775,000.

If those 75,000 Medi-Cal subscribers instead participate in the CDPH PNS program,

Medi-Cal would pay $75,000 * \$232 = \$17,400,000$. This would include the cost of follow-up testing when indicated. The difference in costs for the PNS vs. non-PNS participants is more than \$30 million. However, this assumes that the negotiated payment rate for participating laboratories would be upheld. If the rate is not upheld, costs in the CDPH PNS Program will increase, as would costs to Medi-Cal for those who choose the PNS Program. While Medi-Cal does not reimburse for most services on a fee-for-service basis, this example can be taken to illustrate increased cost pressure to the state.

COMMENTS:

1) **Purpose.** According to the author:

[This bill] gives pregnant Californians a choice in their prenatal screening. Rather than forcing these individuals to enroll in the PNS Program to receive screening for trisomy 21, trisomy 18, and trisomy 13, SB 771 allows the individual to receive that screening regardless of their PNS Program enrollment status, preserving their ability to access the fuller NIPT screening that includes more conditions without having to comply with a convoluted secondary request process.

- 2) **NIPTs.** NIPTs analyze small fragments of cfDNA circulating in a pregnant person's blood, with the goal of determining the risk that the fetus has certain genetic abnormalities. NIPTs are screening tests, not diagnostic tests. Screening tests generally predict a level of risk of the fetus having certain genetic abnormalities; diagnostic tests generally confirm or rule out a suspected genetic abnormality.
- 3) **The PNS Program.** The PNS Program, administered by CDPH's Genetic Disease Screening Program, provides prenatal screening services and follow-up diagnostic services, when indicated, to pregnant people in California, with the goal of detecting birth defects during pregnancy. The PNS Program currently offers screening tests for open neural tube defects, trisomies 21 (Down syndrome), 13 and 18, and Smith-Lemli-Opitz Syndrome through one or two blood tests. When screening results indicate a high risk for a birth defect, the program provides free follow-up diagnostic services at state-approved Prenatal Diagnosis Centers (PDCs). Services offered at PDCs include genetic counseling, ultrasound, and amniocentesis. Participation in the screening testing and follow-up services is voluntary and the fee is currently \$221.60.
- 4) **Changes to the PNS Program.** In the 2021-22 budget, the administration proposed, and the Legislature approved, a transition to cfDNA screening for trisomies 21, 18 and 13. According to CDPH, before it proposed making changes to the PNS Program, it conducted stakeholder meetings, the first of which occurred in 2019. Representatives from laboratories, the American College of Obstetricians and Gynecologists (ACOG), and others from the genetic counseling, prenatal, and bioethics community were invited and participated in a discussion about the PNS Program redesign. CDPH states a detailed summary of this meeting was sent to all key stakeholders, including laboratories. In 2020, when ACOG policy designated cfDNA screening for trisomies 21, 18 and 13 to be the standard of care, CDPH was statutorily required to implement the new standard of care as quickly as possible for the benefit of all pregnant people in California (Health & Safety Code Section 125055(g)(1)). CDPH indicated it continued to consult with stakeholders in the form of webinars for PNS providers, newsletters, and announcements, and invited input throughout

the process. In 2019 and 2021, CDPH surveyed cfDNA labs for input to the PNS program and have had a series of meetings with interested cfDNA labs since then. The general public is also invited to provide input as part of the regulations process, and CDPH indicates a public hearing will be held later this summer.

According to the CDPH website, the PNS Program is planning to make cfDNA screening available to all pregnant individuals in California beginning on September 19, 2022. A transition period between the current biochemical and the redesigned cfDNA screening for detection of chromosomal abnormalities will run from September 19, 2022 through November 28, 2022.

- 5) **Medi-Cal.** CDPH estimates Medi-Cal would likely incur annual General Fund savings ranging from low to high hundreds of thousands of dollars compared to its current prenatal screening costs with the new PNS Program. CDPH will charge a fee of \$232 for cfDNA (there is a separate fee of \$85 for neural tube defects screening). A recent article in the New York Times reports NIPTs can average from \$695 for the basic test to \$1,349 for the expanded panel. These costs do not include follow-up testing when a screening indicates elevated risk.
- 6) **Prohibitions on Non-PNS Program Labs.** CDPH indicates that once new regulations are promulgated, laboratories will only be restricted from offering screening for conditions covered by the PNS Program panel (trisomies 21/18/13). For other types of NIPT, there will be no restrictions and other screening could be done using the same blood sample. CDPH indicates existing statute requires it to screen according to “the current standard of care as recommended by nationally recognized medical or genetic organizations,” which indicate cfDNA (NIPT) is the most sensitive and specific screening test for the common fetal aneuploidies (trisomies 21, 18, 13).
- 7) **Budget and Legislative Processes.** This bill undoes a budget action that was approved by the Legislature and the governor in the 2021 Budget Act. Moreover, the current provisions were only inserted into this bill on April 28, 2022, so this bill will be heard in only one policy committee and one fiscal committee.

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