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

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TO: ALL PROVIDERS OF PRENATAL HEALTH CARE IN CALIFORNIA

FROM: GENETIC DISEASE SCREENING PROGRAM, CALIFORNIA PRENATAL SCREENING PROGRAM

This letter is to inform you about major changes to the California Prenatal Screening (PNS) Program that will impact the way you provide prenatal screening services to pregnant individuals in California. The Office of Regulations will notify all stakeholders of the Public Notice of the Proposed Action, which will include the date and time of the Public Hearing for the Prenatal Screening Program regulation package, DPH-23-005.

Effective **April 1, 2024**, the PNS Program will add sex chromosome aneuploidy (X, XXY, XYY, XXX) screening to its cell-free DNA (cfDNA) prenatal screening panel, in addition to the already available fetal autosomal trisomies (trisomy 21, trisomy 18, and trisomy 13) offered in the first and second trimesters of pregnancy.

You should know the following regarding the addition of sex chromosome aneuploidies to the PNS Program cfDNA panel:

- All patients drawn for cfDNA who have a blood collection date of April 1, 2024, and beyond, will receive screening for sex chromosome aneuploidies (in addition to the already available autosomal trisomies), regardless of when the screening order was placed on the CalGenetic Portal or when the cfDNA back- up form was given.
- Starting April 1, 2024, sex chromosome aneuploidies will be ordered simultaneously when a cfDNA order is submitted on the CalGenetic Portal or via back-up cfDNA patient forms. There will not be a separate ordering process for sex chromosome aneuploidy screening.
- The cfDNA panel will continue to be available throughout pregnancy beginning at 10 weeks 0 days of gestation. The recommended time window for screening is through 21 weeks 0 days gestation, so patients can receive all authorized follow-up services.

- The PNS Program will continue to make maternal serum alpha-fetoprotein (MSAFP) screening for neural tube defects available, from 15 weeks 0 days through 21 weeks 0 days of gestation..

- The PNS Program will cover authorized follow-up services for sex chromosome aneuploidy screening and will continue to provide follow-up services for autosomal trisomies (trisomy 21, trisomy 18, and trisomy 13).

- With the addition of sex chromosome aneuploidies, the PNS Program will continue to contract with the following **cfDNA laboratories: Natera, Quest Diagnostics, Revvity Omics, and Southern California Permanente Medical Group (Kaiser).**

- Starting April 1, 2024, sex chromosome aneuploidy screening will be synonymous with cfDNA screening. Therefore, when a patient elects to have cfDNA screening, there will be only one consent for the patient to participate in the PNS Program.

Title 17 of California Code of Regulations (CCR) section 6527 refers to Clinician Requirements, which provide that:

> Prenatal care providers must provide information regarding the PNS Program to pregnant individuals who then must consent to participate in the PNS Program to receive prenatal screening for autosomal trisomies and sex chromosome aneuploidies, as well as prenatal screening for neural tube defects. Patient participation in all PNS Program screening is voluntary.

CCR section 6540 requires the participation fees shall be paid to the Department by the individual being tested or by any third party which is legally responsible for a participating individual's care, including any health care service plan, managed health care plan, managed care plan, prepaid health plan or prepaid group practice health care service plan.

With the addition of sex chromosome aneuploidies to the cfDNA panel, there will be a change to the cfDNA screening test participation fee.

Effective July 1, 2024, the Department proposes a participation fee increase for cfDNA of $112.00. The increase raises the fee from $232.00 to $344.00 due to the addtion of SCAs. The change in the participation fees will be reflected in the billing by adjusting the amount of the existing CPT Codes, as follows:

CPT Code: 81420 Fetal chromosomal aneuploidy autosomal trisomies (trisomy 21, 18, and 13) and sex chromosome aneuploidies (X, XXY, XYY, XXX) **$344.00**

or;

PLA Code: 0327U Fetal aneuploidy autosomal trisomies (trisomy

21, 18, and 13) and sex chromosome aneuploidies (X, XXY, XYY, XXX) **$344.00**

CPT Code: 82105 Alpha Fetoprotein, maternal serum **$85.00**

Please note that the final fee increase amount will be determined in accordance with the rulemaking process and will be provided in the 2024-25 May Revision.

Providers may continue to additionally offer other expanded prenatal screening options to their patients, when there is appropriate patient understanding about the benefits, limitations and alternatives of such testing. Expanded screening options are not currently included as services covered in the public health PNS Program and would be separately coded and billed to patients or insurance payers.

Lastly, there will be additions made to patient and provider PNS Program educational materials. Please visit the **PNS Program Information for Providers web page** (https://bit.ly/PNS4Providers) to stay up-to-date on current PNS Program information, materials, and resources for providers. Information there includes the following:

1. Links to provider training videos about how to order MSAFP and cfDNA screening on the CalGenetic Portal;
2. A link to the Portal for ordering PNS Program supplies;
3. The Prenatal Screening Patient Booklet in English, Spanish, Chinese and other languages, with a new insert on SCAs (SCA information will be incorporated into the booklets in new editions to be published by July 1, 2024).
4. Other patient education materials, including screen-positive booklets on the four most common SCAs.
5. An addendum to the PNS Prenatal Screening Provider Handbook on SCAs.

If you have any questions, please email the PNS Program at PNS@cdph.ca.gov.

Thank you for partnering with CDPH to provide prenatal screening to California's pregnant individuals through our unique public-private partnership.