

August 2022

CALIFORNIA PRENATAL SCREENING PROGRAM

Welcome to our newsletter!



California Prenatal Screening Program Changes: Moving to cfDNA

On September 19, 2022, cell-free DNA (cfDNA) will become the primary screen for trisomy 21, trisomy 18, and trisomy 13, replacing biochemical screening for trisomies 21 and 18. A transition period will be in place from September 19 through November 28 for those participants who start the PNS Program before September 19. See the **Provider Checklist** below for steps to prepare for the program launch.

cfDNA screening will be available starting at 10 weeks 0 days gestational age and can be done throughout pregnancy. The PNS Program recommends that cfDNA screening take place from 10 weeks 0 days through 21 weeks 0 days, however, so that there is sufficient time for all follow-up services should individuals' screening result be considered high risk. Patients will also be given the option, if they consent, to find out the sex of the fetus through the cfDNA screening.

As part of the PNS Program redesign, the Genetic Disease Screening Program has contracted with three laboratories to perform cfDNA screening statewide. The state-contracted laboratories are **Natera, Quest Diagnostics, and PerkinElmer.**

The PNS Program screening panel does not include sex chromosome abnormalities or microdeletions. However, clinicians can order these screens at their discretion from any laboratory using a separate laboratory request form since these screenings are not included in the state PNS Program screening panel. Certain state-contracted laboratories have taken steps so the lab can use the same specimen to complete these screenings and then bill the patient's insurance provider separately for these services.

The PNS Program will continue to cover follow-up genetic counseling and diagnostic services for participants with screen-positive results for the three trisomies or maternal serum alpha fetoprotein (MSAFP) at state-approved Prenatal Diagnosis Centers.



Please visit the [PNS Program Information for Providers web page](https://bit.ly/PNS4Providers) (<https://bit.ly/PNS4Providers>) for program materials and resources; links to a Provider FAQ about the revised PNS Program, including the provider checklist to prepare for program changes (see below); and links to educational materials for providers and patients.

Provider Choice of cfDNA Laboratories

The goal is for all three state-contracted laboratories to be available as options for providers to choose in the PNS Program Orders Portal by September 19, 2022. Regardless of what laboratory the provider

selects, the state quality oversight is the same and the same \$232 PNS program participation fee will be **invoiced by the PNS Program** to the patient's insurance company. Screening result communications and follow-up services will be standardized regardless of which laboratory is selected.

Kaiser providers will use their own laboratory processes and should check with their internal systems to find out how ordering screening tests or result communications differs from the summary here.

MSAFP Screening

In addition to cfDNA, MSAFP screening for neural tube defects will be offered from 15 weeks 0 days through 21 weeks 0 days gestational age. MSAFP screening will mostly stay the same as in the current program, with providers using the same collection procedures and supplies as they use now.

The changes are 1) a separate fee for the MSAFP screening will be \$85; and 2) if providers do not ship specimens to our NAPS laboratories via General Logistics Systems (GLS), they will need to preprint the USPS pre-paid MSAFP mailing label. The PNS Program will be providing these blank MSAFP mailing labels for printing at no cost. See below for details on ordering supplies.

What to Know for the PNS Program Transition Period

A transition period between the current biochemical and the revised PNS Program using cfDNA screening for detection of chromosomal anomalies will run from **September 19 to November 28, 2022**. The purpose of the transition period is to give patients who have had first trimester biochemical screening a chance to complete second trimester biochemical screening after the revised PNS Program starts. Visit the PNS program website for more details.

PNS Program Changes Webinars

The PNS Program has created a three-webinar series to support providers with the PNS Program changes. All 1.5-hour webinars are recorded and posted on the [PNS Program Webinars web page](https://bit.ly/PNS_Webinars) (https://bit.ly/PNS_Webinars). Continuing medical education (CME) credits are available on request for live/recorded webinars.

- **Webinar 1:** *cfDNA Screening: A Clinical Overview* (from April 18, 2022)
- **Webinar 2:** *PNS Program Changes: What Providers Need to Know* (From July 26, 2022)
- **Webinar 3:** *Provider Support and Educational/Training Materials* (August 24, 2022)

Ordering Supplies Now

Providers can order free supplies now on the [PNS Program Supplies Ordering web page](https://bit.ly/PNSSupplies) (<https://bit.ly/PNSSupplies>). The supplies available include the PNS Program label stationery, MSAFP mailing labels, and MSAFP blood collection kits. Providers can also order revised PNS Program educational materials now, including the Prenatal Screening Patient Booklet.

Provider Checklist to Prepare for the Revised PNS Program

Visit the [PNS Program Provider FAQ web page](https://bit.ly/PNSProviderFAQ) (https://bit.ly/PNSProviderFAQ) for Provider Checklist.

Steps	What to do	Where to do it
1	Read Prenatal Care Provider FAQ web page to understand program revision details. Watch recorded webinars for more details on cfDNA and program changes	PNS Program Provider FAQ web page (https://bit.ly/PNSProviderFAQ); and PNS Program Webinars web page (https://bit.ly/PNS_Webinars)
2	Watch CalGenetic Portal Training videos to learn how to use the portal, including how to submit orders electronically	PNS Program Portal Resources web page (https://bit.ly/PNSPortalResources)
3	Register on CalGenetic Portal. Ensure delegates are registered on CalGenetic Portal	CalGenetic Portal (https://calgenetic.cdph.ca.gov/)
4	Read state-contracted cfDNA laboratory instructions to understand blood collection details. Order cfDNA supplies directly from cfDNA laboratory, if needed	PNS Program Information for Providers web page (https://bit.ly/PNS4Providers) See Program Materials section for cfDNA Lab Instructions
5	Order program supplies , including MSAFP blood draw kits, PNS Program label stationery, and MSAFP mailing labels. Order printed PNS Program educational materials (Patient Booklet, screen-positive booklets, etc.)	PNS Program Supplies web page (https://bit.ly/PNSSupplies)
6	Download PNS Program Provider Handbook and view its appendices online. Bookmark PNS Program Information for Providers web page to access materials such as patient decline and back-up consent forms	PNS Program Information for Providers web page (https://bit.ly/PNS4Providers)
7	Download PNS Program patient educational materials (Patient Booklet, etc.) from PNS Program website and locate QR code to share patient video	PNS Program Education Resources - For Patients (https://bit.ly/Comms4Pregnancy)

CalGenetic Portal

Providers who have not already done so are encouraged to register for an account and add delegates now to the [CalGenetic Portal](https://calgenetic.cdph.ca.gov/) (https://calgenetic.cdph.ca.gov/). Authenticated CalGenetic Portal users can get secure online access now to do the following:

- **View patient prenatal screening results.** The PNS Program will continue to mail results but accessing them on the portal is quicker and easier for providers.
- **Submit Outcome of Pregnancy forms.** These data are used to evaluate screening performance, and all data requests should be now entered on the portal.

A new **electronic order requisition process** for cfDNA and MSAFP screening on the CalGenetic Portal will be available when the revised PNS Program launches on September 19, 2022. Providers will be required to obtain a signed patient consent (or from patient's representative) on the printed PNS Program *Consent and Order Confirmation* for each screening test, which must accompany the sample sent to the testing laboratory.

Back-up, fillable PDF versions of the cfDNA and MSAFP Consent and Order Form will be available on the PNS Program website for downloading and printing in the rare case the CalGenetic Portal is not available. Screening decline forms will be posted there as well. Providers will put signed decline forms in the patient's medical record.

CalGenetic Portal-related resources on the [PNS Program Portal Resources web page](https://bit.ly/PNSPortalResources) (<https://bit.ly/PNSPortalResources>) include the following:

1. **Professions chart.** This web resource shows which professionals can access the CalGenetic Portal.
2. **Portal training videos.** The PNS Program has created five training videos to help prenatal care providers learn how to use the CalGenetic Portal. They are the following:
 - User Access and Profile Management (for Licensed Clinicians)
 - Manage Delegates (only for doctors, MD and DO)
 - Search, View, and Download Results
 - Access Delegate Account, Search, View, and Download Result
 - Submit Orders for cfDNA and MSAFP screening tests (to be posted by August 24, 2022)

Sign Up for Free Access to Genetic Education Modules (GEM)

California prenatal care providers have **free access** to the [Genetic Education Modules \(GEM\)](https://gem.perinatalquality.org/default.aspx) (<https://gem.perinatalquality.org/default.aspx>) as an additional educational resource. The Perinatal Quality Foundation that provides GEM is a non-profit foundation. GEM includes state of the art education materials on cfDNA screening, as well as provider training materials, videos, and tools.

The PNS Program is offering special access to GEM to the first 500 California prenatal care providers who sign up using a unique "practice code ID." The unique practice code ID is **CDPH1234**.

California providers who use the practice code ID will have free access to the GEM modules until year end 2022, including an opportunity to earn up to **3.5 CME credits** for \$40. The GEM modules are normally subscription only at a substantially higher cost. For instructions on how to use the code, please visit the [California Provider Access to GEM Modules web page](https://bit.ly/CA_GEM) (https://bit.ly/CA_GEM).

Please sign up for the [PNS Program e-Newsletter](https://tinyurl.com/GDSPOnline) (<https://tinyurl.com/GDSPOnline>) for timely updates and information on the revised PNS Program changes!