

California Prenatal Screening Program Changes

What Providers Need to Know

Webinar 2 of 3

July 26, 2022

Welcome

Introduction, Lisa Feuchtbaum, DrPH, MPH, Program & Policy Branch,
Genetic Disease Screening Program (GDSP)

Overview of PNS Program Changes, Richard Olney, MD, MPH,
Division Chief, GDSP

Presenters

- Robyn Jiménez, PhD, Chief, Prenatal Screening (PNS) Section, GDSP
- Faith Raider, MA, MCHES, Communication and Education Unit, GDSP
- Jean Spitz, MPH, CAE, RDMS, Director, Perinatal Quality Foundation

Continuing Medical Education (CME)

- GDSP is accredited by the California Medical Association to provide Continuing Medical Education (CME) for physicians. **This webinar will constitute 1.5 AMA PRA Category 1 Credits™**
- The webinar recording will be on [PNS Program Webinars web page \(https://bit.ly/PNS_Webinars\)](https://bit.ly/PNS_Webinars). For CME credits, complete the evaluation survey
- CMEs may also be used for continuing education credits by other professional credentialing organizations (e.g., nursing, genetic counseling)

Overview of Program Changes



Richard Olney, MD, MPH

Division Chief

Genetic Disease Screening Program

PNS Program moving to cell-free DNA (cfDNA)

You may have read about it...



e-Newsletter: <https://tinyurl.com/GDSPOnline>

Revised PNS Program: Two Types of Screening



Revised PNS Program: cfDNA

Cell-free DNA (cfDNA) will be a primary screen for chromosome abnormalities

Genetic screening that examines fetal DNA circulating in maternal blood:

- Screens for trisomy 21 (Down syndrome), trisomy 18, and trisomy 13
- Includes fetal sex, if requested by the participant/provider
- Offered at 10 weeks of gestation or later
- State pays for follow up counseling & diagnostic services
- Provider can order additional screening tests outside of the state program
- Provider choice of labs

Revised PNS Program: MSAFP

MSAFP Screening – for neural tube defects

Biochemical screening that measures maternal serum alpha-fetoprotein (MSAFP)

- Screens for anencephaly, open spina bifida, etc.
- Offered from 15 weeks 0 days through 21 weeks 0 days of gestation

Revised PNS Program Details

Both cfDNA and MSAFP screening should be offered because they screen for different disorders

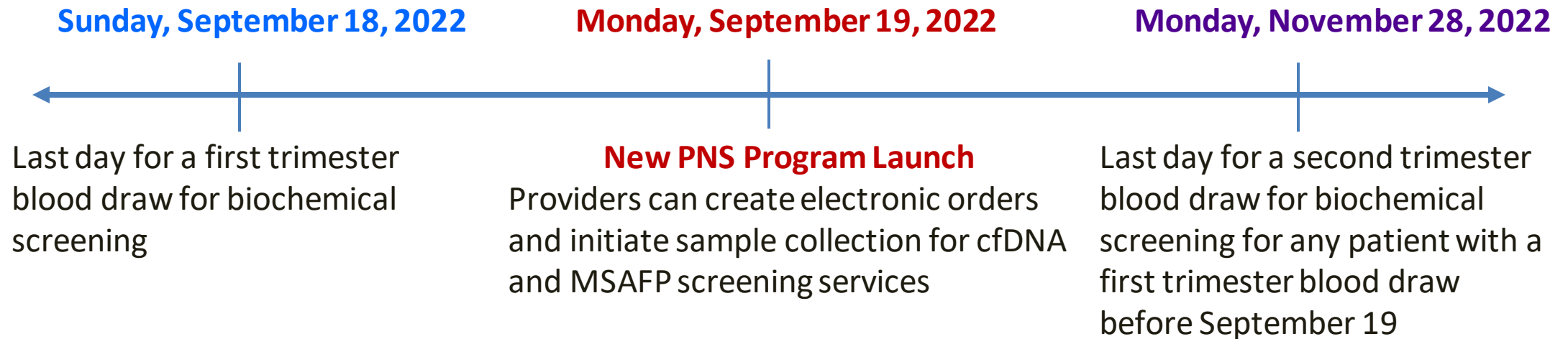
- Fees will be: **\$232 for cfDNA**; and **\$85 for MSAFP**
- Both are covered by Medi-Cal or patient insurance
- Follow-up services included in fees
- For screen-positive individuals services include genetic counseling and diagnostic services at state-approved Prenatal Diagnosis Centers (PDCs)

Revised PNS Program: Additional Changes



- CalGenetic Portal for ordering and reviewing screening results
- No screening for Smith-Lemli-Opitz syndrome (SLOS)

Planned Timeline for Changes



Details on Program Changes



Robyn Jiménez, PhD

Chief

CA Prenatal Screening Program

California Prenatal Screening Program History

- **1986:** AFP screening for neural tube defects
- **1995:** Expanded 2nd trimester screening: “Triple Marker screening” for trisomy 21 and 18, and NTDs
- **2002:** Addition of SLOS screening
- **2007:** “Quad Marker Screening” for trisomies 21 and 18, and NTDs
- **2009:** Added screening options for 1st and 2nd trimester screening


Current Screening Algorithms for Trisomy 21 & Trisomy 18

	1 st tri serum	NT	2 nd tri serum
First Trimester Screening:	✓	✓	
Serum Integrated Screening:	✓		✓
Sequential Integrated Screening:	✓	✓	✓
Quad Marker Screening:			✓
Quad Marker + NT Screening:		✓	✓

PNS Program Transition Period

- The last day for first trimester blood collection under the current biochemical program is Sunday, September 18.
- The transition period is critical for patients who have already initiated biochemical screening before the program revision begins on September 19. The last day patients can be drawn for 2nd trimester screening is Monday, November 28.
- The transition period for state-contracted Case Coordination Centers to manage biochemical cases will extend from Monday, September 19 through Monday, December 26.

PNS Program Redesign: Dates to Know



Transition Period	Important Dates
Last day to order first trimester Test Request Forms (TRFs)	August 28, 2022
Last day for first trimester biochemical blood draw	September 18, 2022
Redesigned PNS Program launch. There will not be any results available on first trimester biochemical specimens drawn on or after this date	September 19, 2022
Last day to order second trimester Test Request Forms (TRFs)	October 28, 2022
Last day for patients to get second trimester biochemical blood draw for integrated screening results	November 28, 2022
Last day for NT information to be accepted	November 28, 2022
Last day for first trimester biochemical patients to receive PDC follow-up services based on 24 weeks 0 day mark	December 26, 2022

Benefits of cfDNA Screening

- cfDNA as primary screen makes high-quality prenatal screening accessible to all CA pregnant individuals at an affordable price;
- cfDNA provides higher sensitivity, lower false-positive rates; fewer screen-positive cases referred for unnecessary follow-up diagnostic services;
- Earlier gestational age window - 10 weeks 0 days of gestation;
- cfDNA provides results for additional aneuploidy (trisomy 13)

Limitations of cfDNA Screening*

- Cannot detect mosaicism
- Results may indicate underlying maternal aneuploidy or maternal malignancy
- Test failure possible depending on fetal fraction or patient factors such as high BMI
- Test failure associated with aneuploidy
- Not recommended for higher-order multifetal gestations beyond twins
- Positive predictive value changes with age (PPV lower for younger age groups)

* ACOG Practice Bulletin 226: Screening for Fetal Chromosomal Abnormalities. *Obstet Gynecol*, Vol 136, No 4, October 2020.

Big Reveal: State-Contracted Labs



State-Contracted cfDNA Laboratories

- **Natera**
- **Quest Diagnostics**
- **PerkinElmer**

Laboratories that have completed the required onboarding process will be available for providers to choose in the PNS Orders Application on the CalGenetic Portal on September 19, 2022. Any laboratories that have not completed the required onboarding process by then will become an available choice for providers as quickly as possible after that.

Provider Choice on Labs

- Providers will select one of three state-contracted cfDNA labs when ordering cfDNA screening, with same \$232 program fee no matter what lab selected
- Screening test result communications and interpretations will be standardized
- Each state-contracted cfDNA laboratory requires patients to use their proprietary blood collection kits that must be ordered directly from the lab or provided at a designated location. Instructions for how to order and collect patient blood for each of the state-contracted laboratories will be distributed widely.
- Kaiser Permanente providers should consult their own genetics department for cfDNA ordering through the PNS Program

Ordering Additional Screenings

- The PNS Program does not include screening for sex chromosome abnormalities or microdeletions as those are not currently recommended for routine population-based screening.
- Providers can order additional screenings, including sex chromosome abnormalities, as a separate test request process. Specific instructions for each state-contracted laboratory will be distributed.
- For any additional testing, providers must:
 - Do or arrange for pre and post test counseling
 - Do or arrange for any diagnostic testing that may be recommended
 - Separately bill the patient for testing and follow up.

Nuchal Translucency

- PNS Program will no longer accept NT measurements (mm) on PNS orders
- PNS Program will no longer refer patients to prenatal diagnosis centers solely based on a large NT measurement
 - *If the patient is referred to prenatal diagnosis through the PNS Program, large NT will continue to be an indication for microarray*
- ACOG and ACMG guidelines: patient with a 3.0 mm or larger NT measurement should be referred for prenatal diagnosis

Ordering Screening Tests

- The Test Request Form (TRF) will be replaced by placing orders online through the CalGenetic Portal (for both cfDNA & MSAFP screens)
- Back up, fillable PDFs will be on website
- Online orders confirmation page will be printed on PNS Program label stationery
 - Consent on form to be signed and dated by patient or their representative
 - Form to be sent with specimen to the cfDNA or MSAFP screening laboratory
- Decline forms will be on website
- Consent or decline forms should be filed in medical record

PNS Program Label Stationery

California Department of Public Health
Consent & MSAFP Order Confirmation
California Prenatal Screening Program

Attach Accession Label
For state lab use only
Do not cover

Patient Last Name: Dominguez First Name: Jane Medical Record #: 185253 Date of Birth: 10/12/1995 Patient Phone #: (415) 334-3267	Order PNS Form #: S 21 F234F 77 Clinician Last: Johanssen Clinician First: Nicholas Clinician Phone #: (916) 354-3456
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Patient Consent

If you give consent to prenatal screening by signing below, your blood will be collected and sent to a state-contracted laboratory for prenatal screening.

- I consent to participate in the California Prenatal Screening Program.
- I authorize the release of medical and any other information about myself needed for my health insurance claim.
- I authorize payment of medical benefits to the Genetic Disease Screening Program (GDSP) for the services provided to me.
- I consent to be billed directly for services provided to me if I do not have health insurance coverage or Medi-Cal.
- I agree my blood sample may be used for research by GDSP or GDSP-approved researchers, unless the box below is marked.

I decline the use of my specimen for research.

Patient Signature: _____ Date: MM / DD / YYYY

Attestation that verbal consent from patient was obtained:

Provider/Representative Name	Relationship to Patient
_____	_____

Based on Gestational Age, the recommended patient blood draw date range: 04/22/2022 – 05/23/2022

Blood Sample

Blood Draw Facility Name	NAPS Lab Notes		
_____	_____		
Blood Draw Date	Collector's Initials	Blood Draw Facility Phone #	
MM / DD / YYYY	____	____ - ____ - ____	

Copy of insurance card +	Blood draw tube +	Extra label ✓	Do not remove ✕
Dominguez, S S 21 F234F 77 Collected on: ___/___/____	Dominguez, S S 21 F234F 77 Collected on: ___/___/____	Dominguez, S S 21 F234F 77 Collected on: ___/___/____	Dominguez, S S 21 F234F 77 Collected on: ___/___/____

Labels with unique barcode and PNS Form Number



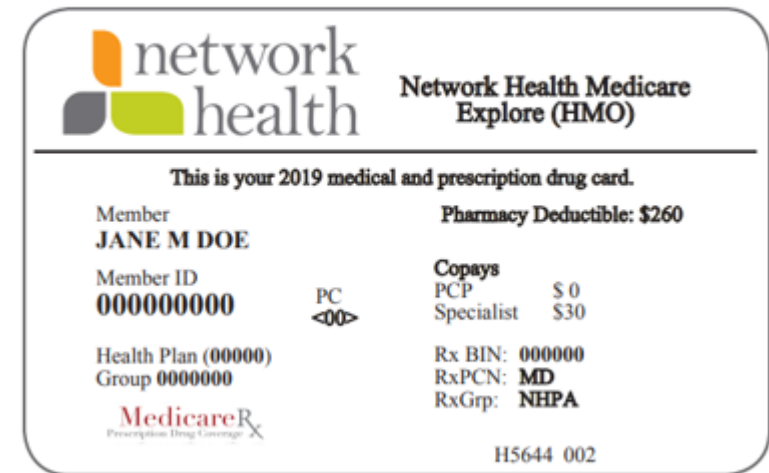
Electronic Confirmation and Consent Form - MSAFP

Barcode Labels



Put on Specimen Tube, Insurance Card, other paperwork



Patient Insurance Card



Back up, Fillable PDF (MSAFP)

 MSAFP Consent & Order Form Gestational Age Range: 15 Weeks 0 Days - 21 Weeks 0 Days			Accession Label For state lab use only Do not cover		
/ Blue/black ink * - required MM/DD/YYYY date format Fill boxes completely Capital Letters					
1. Patient Information					
Last Name*		First Name*		Int. Maiden Name	
Biological Date of Birth*		Social Security #		Medical Record #	
Race and Ethnicity*		Patient currently diabetic?*		Does patient take insulin?	
Patient Street Address* (for medical/confidential mail)		Address Line 2 (APT, STE, UNIT, etc.)		City*	
State*		ZIP Code*		Patient Phone #*	
2. Pregnancy Information					
Number of Fetuses* <input type="checkbox"/> 1 <input type="checkbox"/> 2 <input type="checkbox"/> Unknown					
Dating Method* (Complete only one Dating Method. Ultrasound is best. If no U/S, provide LMP)					
<input type="checkbox"/> Ultrasound		Ultrasound Date Performed		GA on Ultrasound Date	
<input type="checkbox"/> LMP		First Day of Normal LMP		Most Recent Physical Exam Date	
		<input type="checkbox"/> Physical Exam		Uterine Size	
3. Clinician & Facility Information (Clinician must be a licensed medical professional)					
Last Name*		First Name*			
NPI #*		Medical License #*		Medical License Type*	
Facility Name*		Facility Phone #*		Ext.	
Facility Street Address*		Address Line 2 (BLDG, FL, STE, etc.)		City*	
State*		ZIP Code*		Facility Fax #	
CDPH 4095 (07/2022) - Genetic Disease Screening Program (866) 718-7915 Toll Free (Page 1 of 2)					
 MSAFP Consent & Order Form Gestational Age Range: 15 Weeks 0 Days - 21 Weeks 0 Days			Accession Label For state lab use only Do not cover		
Form Completed By*					
Patient Last Name*		Patient Date of Birth*			
4. Billing Information					
Bill To* (Choose one, to allow for correct billing, provide Medi-Cal or other Insurance information.)					
<input type="checkbox"/> Insurance <input type="checkbox"/> Medi-Cal <input type="checkbox"/> Self Pay					
Policy or Medi-Cal #		Group ID		Insurance Provider Name	
Relationship to Insured (If patient is not the primary insured, provide insured details which are required for billing.)					
<input type="checkbox"/> Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other					
Insured Last Name		Insured First Name		Insured Date of Birth	
Insured Sex		Insured Phone #		Insured Date of Birth	
<input type="checkbox"/> Female <input type="checkbox"/> Male					
5. Patient Consent					
If you give consent to prenatal screening by signing below, your blood will be collected and sent to a state-contracted laboratory for prenatal screening.					
<ul style="list-style-type: none"> I consent to participate in the California Prenatal Screening Program. I authorize the release of medical and any other information about myself needed for my health insurance claim. I authorize payment of medical benefits to the Genetic Disease Screening Program (GDSP) for services provided to me. I consent to be billed directly for the services provided to me if I do not have health insurance coverage or Medi-Cal. I agree my blood sample may be used for research by GDSP or GDSP-approved researchers, unless the box below is marked. <input type="checkbox"/> I decline the use of my specimen for research. Date* 					
X		Signature of Patient/Authorized Person*		Date*	
<input type="checkbox"/> Attestation that verbal consent from patient was obtained:					
Provider/Representative Name		Relationship to Patient			
6. Blood Sample					
Blood Draw Facility Name*		NAPS Lab Notes			
Blood Draw Date*		Collector's Initials*		Blood Draw Facility Phone #*	
CDPH 4095 (07/2022) - Genetic Disease Screening Program (866) 718-7915 Toll Free (Page 2 of 2)					

Supplies and Educational Materials



- PNS Program label stationery available to order
- PNS Program website will have information on using the state-contracted cfDNA laboratories
- Educational materials will be on the program website.
[Supplies and materials are available for ordering online](https://bit.ly/PNSSupplies)
(<https://bit.ly/PNSSupplies>)

Who Can Access CalGenetic Portal

Visit the [PNS Program Portal Resources web page](https://bit.ly/PNSPortalResources) (<https://bit.ly/PNSPortalResources>) for a chart showing which professionals can access the CalGenetic Portal

Provider Access to the CalGenetic Portal

Professions	All access with license verified by IDEAL*	All access with license verified by IDEAL*	Can access results as licensed users?	Can place orders as licensed users?	Can place orders as delegates?	Can add delegates?
Start Date	June 2021	May 16, 2022	May 16, 2022	September 19, 2022	September 19, 2022	June 2021
Physicians and Surgeons	Yes	-	Yes	Yes	-	Yes

Online CalGenetic Portal

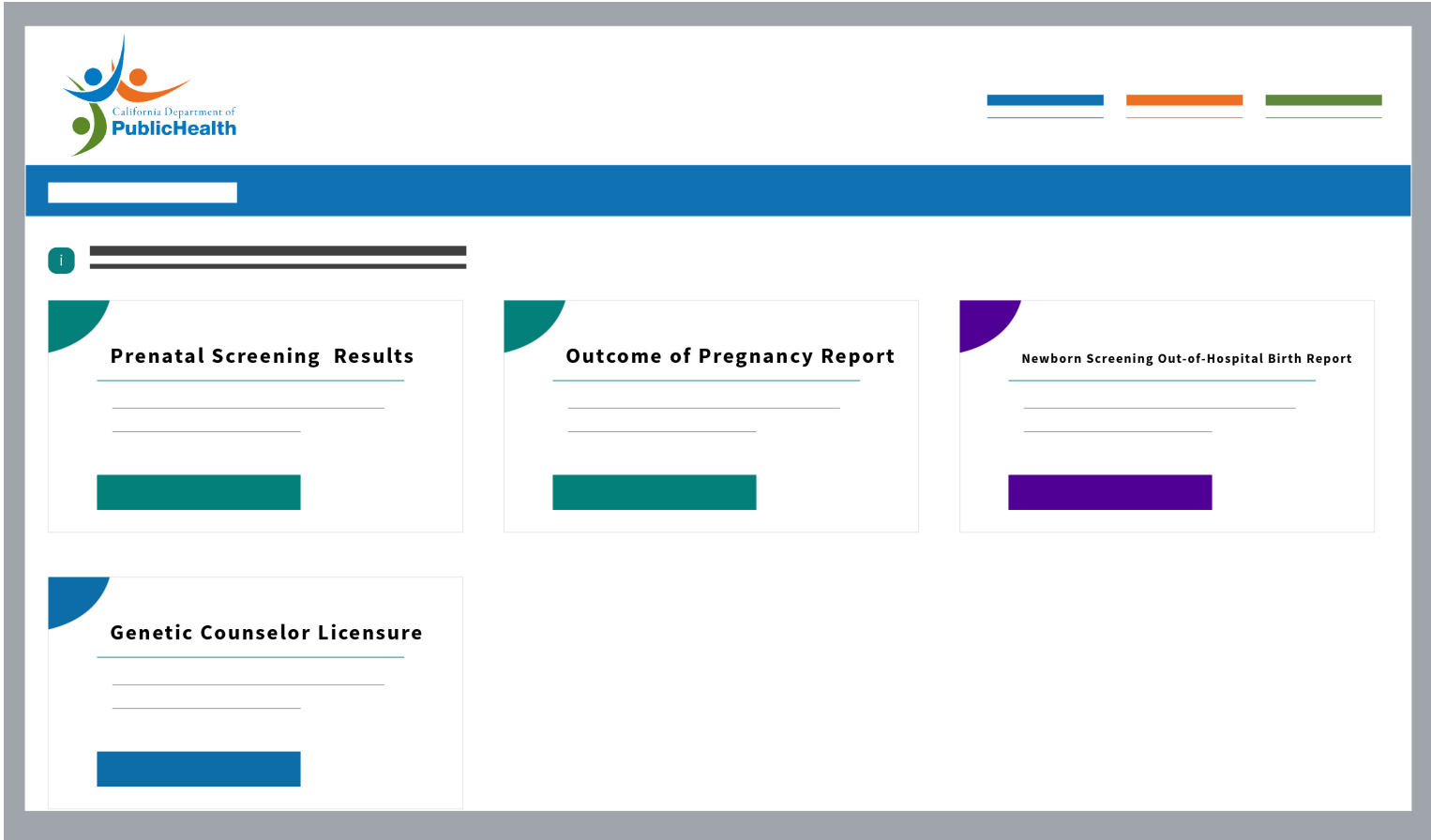
- Register and assign delegates on the [CalGenetic Portal](https://calgenetic.cdph.ca.gov) (<https://calgenetic.cdph.ca.gov>)
- You can now
 - view patient screening results and
 - fill out outcome of pregnancy surveys
- After program launch, you can place cfDNA and MSAFP screening test orders through the Orders Application on the CalGenetic Portal

CalGenetic Portal Videos

Visit the [PNS Program Portal Resources web page](https://bit.ly/PNSPortalResources)
(<https://bit.ly/PNSPortalResources>) for these training videos:

- 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

DEMO: Online CalGenetic Portal



Questions?

Write your questions in the Q&A box

Facilitated by Sara Goldman
Assistant Division Chief
Genetic Disease Screening Program





PNS Program Communications

Faith Raider

Chief


Communication and Education Unit, GDSP

Patient and Provider Communications

- Describe both the benefits and limitations of prenatal screening
- Describe the difference between screening and diagnostic testing
- Emphasize availability of follow-up genetic counseling and diagnostic services for high-risk individuals
- Are intended to be “accessible”
- Highlight consent/decline for program participation

Educational Materials



- **Videos: patient & provider**
 - **Main written materials**
 - Provider Handbook (PDF)
 - Patient Booklet (printed & PDF); 2-page summary; translated
 - **Other written materials**
 - 4 Screen-positive Booklets (T21, T18, T13, NTDs)
 - Prenatal Diagnosis for Birth Defects
 - **Newsletters/Website**
- 

Prenatal Screening Provider Handbook

Prenatal Screening Provider Handbook



California Prenatal Screening Program
What Providers Should Know

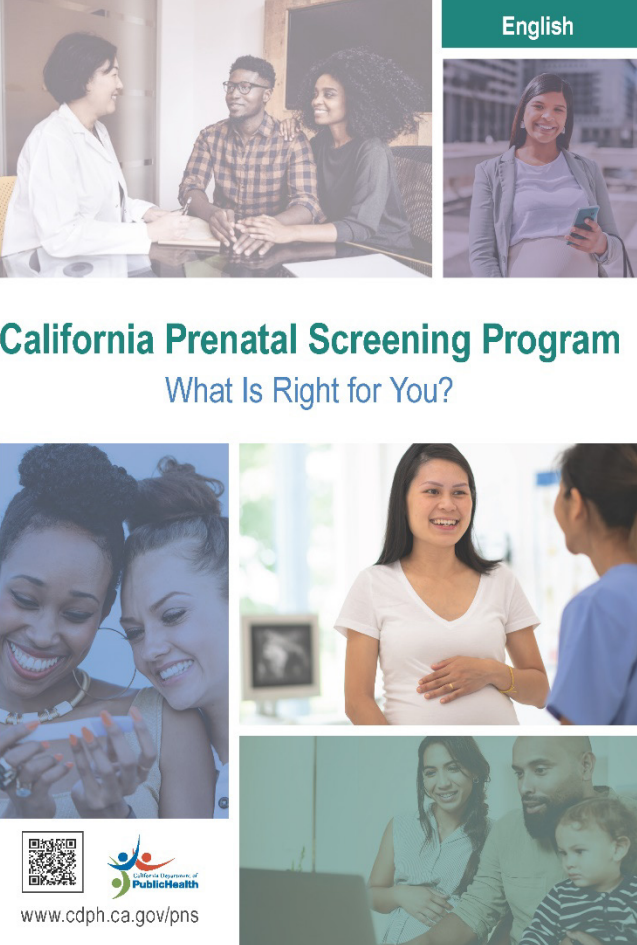


www.cdph.ca.gov/pns



Prenatal Screening Patient Booklet

Prenatal Screening Patient Booklet

English



California Prenatal Screening Program
What Is Right for You?



www.cdph.ca.gov/pns

Prenatal Screening Patient Video



Quick Poll Questions




PNS Program Webinars

Visit [PNS Program Webinars web page](https://bit.ly/PNS_Webinars)
(https://bit.ly/PNS_Webinars)

- **Webinar (1):** *cfDNA Screening: A Clinical Overview*. Recording from April 18 is posted
- **This Webinar (2):** *PNS Program Changes: What Providers Need to Know*, will be posted shortly
- **Webinar (3):** *PNS Program Educational and Training Materials*, Wednesday, August 24, 12 - 1:30 pm.

Communications Next Steps

- **Sign up for our e-Newsletter:**
(<https://tinyurl.com/GDSPOnline>)
- Bookmark: **PNS Program Information for Providers web page**
(<https://bit.ly/PNS4Providers>)
- Register: August 24, 12 noon, Webinar 3: **PNS Program Webinars web page** (https://bit.ly/PNS_Webinars) 
- Stay tuned for cfDNA company instructions to be posted on the web and emailed soon

Genetic Education Modules (GEM)



Jean Spitz, MPH, CAE, RDMS

Director

Perinatal Quality Foundation

CME Evaluation

- Please [complete the evaluation survey online \(https://forms.office.com/g/9T8Ywz1gAG\)](https://forms.office.com/g/9T8Ywz1gAG) to receive CME credit. CME certificate will be emailed to you.
- Webinar recording will be posted on [PNS Program Webinars web page \(https://bit.ly/PNS_Webinars\)](https://bit.ly/PNS_Webinars).
- You will receive follow up emails



Scan QR
code to
access the
evaluation

Thank You!

California Prenatal Screening Program

Send questions and comments: PNS@cdph.ca.gov

www.cdph.ca.gov/PNS

