



# California Prenatal Screening Program

## What Is Right for You?



[www.cdph.ca.gov/pns](http://www.cdph.ca.gov/pns)



# I. Introduction

Pregnancy can cause feelings of joy, as well as fear, stress, and uncertainty about the future. Some expecting parents want to know as much as they can about their fetus (developing baby) during pregnancy.

This booklet explains prenatal screening offered through the California Prenatal Screening Program. Prenatal screening is a way to check on your fetus during pregnancy for birth defects.



You decide if you want prenatal screening. Your prenatal care provider should discuss this information and your choice with you early in your pregnancy.

If you are interested in reading a longer booklet or getting additional information about the California Prenatal Screening Program, the birth defects screened for, your choices after screening, and more, please visit the [Prenatal Screening Patient Booklet web page](https://bit.ly/PNSPatientBooklet) (<https://bit.ly/PNSPatientBooklet>). On that web page, you will also find a video that will tell you more about prenatal screening.



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## What does the California Prenatal Screening Program do?

The **California Prenatal Screening Program** is a statewide program offered by prenatal care providers to all pregnant individuals in California. Prenatal screening uses a pregnant individual's blood samples to screen for certain birth defects in their fetus. Individuals with a fetus found to have an increased chance of one of those birth defects are offered genetic counseling and other follow-up services through state-contracted Prenatal Diagnosis Centers.

## What are birth defects?

Birth defects are conditions in a fetus that can cause physical changes and intellectual disabilities. Birth defects most often happen by chance and usually do not run in families. Down syndrome and other “genetic conditions” that the PNS Program screens for in a fetus are caused by an extra chromosome. Chromosomes help the fetus develop and are found in every cell in the body.

## Checking the health of the fetus before birth

If you decide to do prenatal screening, you will be asked to give two blood samples. Each sample is checked to find out if there is an **increased chance** your fetus has certain birth defects. If there is an increased chance, your prenatal provider will talk with you about next steps. You decide if you want further genetic counseling and other follow-up services. They include an ultrasound exam and diagnostic testing.

### KEY DEFINITION

Research has shown that “**birth defects**” is the most commonly used and best understood term for the genetic conditions and neural tube defects that the PNS Program screens for.

## How is prenatal screening different from diagnostic testing?

Prenatal screening **estimates** the chances of certain birth defects. If screening finds an increased chance of a birth defect, diagnostic testing is needed for a clear answer.

### The PNS Program can detect these four types of birth defects:

Birth defect	Disabilities caused by the birth defect
<b>Trisomy 21</b> Down syndrome	This genetic condition causes mild to severe intellectual disabilities and serious health problems such as heart defects.
<b>Trisomy 18</b> Edwards syndrome	This genetic condition causes severe intellectual disabilities and serious health problems. Most pregnancies with trisomy 18 end on their own through miscarriage.
<b>Trisomy 13</b> Patau syndrome	This genetic condition causes severe intellectual disabilities and serious health problems. Most pregnancies with trisomy 13 end on their own through miscarriage.
<b>Neural tube defects</b>	This birth defect causes problems in the development of the brain or spine, like spina bifida (open spine).

## II. What to expect from the California Prenatal Screening Program



**DISCUSS.** Your prenatal care provider will offer you prenatal screening through this program. It is not required. The prenatal screening will help you learn if your fetus has an increased chance of certain birth defects.



If you choose to participate in the California Prenatal Screening (PNS) Program and have Medi-Cal or private health insurance, they will cover your program fees, with only a few exceptions.



**CONSENT.** If you want prenatal screening, your prenatal care provider will ask you to sign two consent forms, one for each of the two screenings. Both are important because they screen for different things. If you do not want prenatal screening, you will need to sign decline forms.



**SCREEN.** Your prenatal care provider will tell you where to go to get your blood taken for the two prenatal screenings. It may be in a laboratory or at your prenatal care provider's office. For each screening, a staff member will take a small amount of blood from your arm and send it to a laboratory.



**COMMUNICATE.** You will be contacted twice by your prenatal care provider's office to let you know your **cell-free DNA** and **maternal serum alpha-fetoprotein** screening results.



**FOLLOW-UP SERVICES.** If either screening result shows your fetus has an increased chance of one of the birth defects, this does not always mean that there is a birth defect. The PNS Program will offer you follow-up services at a state-approved Prenatal Diagnosis Center. First, you will be able to speak with a genetic counselor. You will be offered a detailed ultrasound exam of your fetus. Then, you decide if you want a diagnostic test to find out if your fetus has a birth defect.

### The follow-up services include:

- Genetic counseling
- Ultrasound exam
- Diagnostic testing: chorionic villus sampling or amniocentesis



If you get prenatal screening through the PNS Program, the follow-up services are available to you at no additional cost.



**Note:** Your prenatal care provider may speak to you about getting **prenatal diagnosis** instead of prenatal screening. If not, you can ask them if prenatal diagnosis is recommended for you.

# III. Prenatal Screening and Results

## Prenatal screening

During your pregnancy, you will be offered two screenings as part of the California Prenatal Screening (PNS) Program. Each screening requires you to give a blood sample. Each screening estimates the chances of your fetus having one of the birth defects screened for in the PNS Program. Below are the details about the two types of screening.

Screening	What it screens for	When to get it
<b>Cell-free DNA (cfDNA)</b>	<b>Genetic conditions:</b> <ul style="list-style-type: none"> <li>• Trisomy 21 (Down syndrome)</li> <li>• Trisomy 18 (Edwards syndrome)</li> <li>• Trisomy 13 (Patau syndrome)</li> </ul>	From 10 weeks to the first day of 21 weeks of pregnancy. cfDNA screening can be done after 20 weeks but the follow-up services are then more limited. Results are available in 10-14 days.
<b>Maternal serum alpha-fetoprotein (MSAFP)</b>	<b>Neural tube defects</b> <ul style="list-style-type: none"> <li>• Open spina bifida (opening in the spine)</li> <li>• Anencephaly (missing parts of brain or skull)</li> </ul>	From 15 weeks to the first day of 21 weeks of pregnancy. Results are available in 7-10 days.

## Understanding prenatal screening results

Your screening results are specific to you and your current pregnancy. Your prenatal care provider will talk to you about your screening results.

Result type	What it means	What happens next	What else to know
<b>No increased chance</b> of birth defects (most common result)	The chances of the fetus having any of the screened birth defects are low, <b>but not zero</b>	The PNS Program does not offer follow-up testing or services for this result	This result does not guarantee that there are no birth defects. No prenatal screening can detect 100% of birth defects
<b>Increased chance</b> of birth defects	The chances of the fetus having one of the screened birth defects are higher than usual	The PNS Program <b>offers</b> follow-up testing and services for this result	This result does not always mean that the fetus has a birth defect. Diagnostic testing can help find out if a birth defect exists
<b>“No call”</b>	Sometimes there is not enough genetic material in your blood, or the blood is drawn too early or too late in the pregnancy, to get a clear screening result	Your provider will communicate why you have a “no call” result and will tell you if screening can be repeated	There are a few different reasons why there would be no results, so your provider will be your guide

## IV. Consent and Decline Information

It is your choice whether you want prenatal screening offered by the California Prenatal Screening (PNS) Program. Your prenatal care provider will review the prenatal screening process and answer any questions you may have so you feel ready to make your decision. Your provider will give you the **consent or decline** forms to sign.

If you decide to have one or both screenings offered by the PNS Program, you will sign and date a separate consent form for each of the two screenings. If you decide not to have one or both screenings offered by the PNS Program, you will sign and date a separate decline form for each of the two screenings.

If you decide not to have one or both screenings, and your provider does not give you decline forms to sign, please request that they do so. The forms are available on the PNS Program website. Your provider should then put your signed decline form or forms in your medical record.

Here is a **quick summary of key points** to remember as you consider your final decision on whether you want one or both screenings offered by the PNS Program.

1. The PNS Program offers prenatal screening to identify these birth defects: trisomy 21 or Down syndrome, trisomy 18, and trisomy 13 (through cell-free DNA or cfDNA screening), and neural tube defects (through maternal serum alpha-fetoprotein or MSAFP screening). The PNS Program does not screen for birth defects other than these. It may screen for more in the future. Screening is not 100% accurate in finding birth defects.
2. There are separate program fees for each of the two screenings, cfDNA screening and MSAFP screening. Medi-Cal and private insurance must cover all program fees, with only a few exceptions for self-insured employers and out-of-state health plans. If you do not have Medi-Cal or health insurance, or the fees are not covered, you must provide full payment.
3. If a screening result shows an increased chance of a birth defect, you can talk to your provider and decide if you want follow-up services. Follow-up services include genetic counseling to learn about follow-up options, an ultrasound examination, and diagnostic testing, either chorionic villus sampling or amniocentesis. It is possible to have normal results after diagnostic testing.
4. If your provider requests additional genetic screening or testing outside of the PNS Program, separate forms and fees will be required. The PNS Program will not handle the billing. Follow-up services will not be available through the PNS Program for the additional screening or testing.

## V. Billing and Payment for Screening

Starting in 2022, the program fees for the two different screenings provided by the California Prenatal Screening (PNS) Program are the following:



- \$232 for cell-free DNA (cfDNA) screening
- \$85 for maternal serum alpha-fetoprotein (MSAFP) screening

The fees cover 1) the cost of the screening, and 2) follow-up services at a state-approved Prenatal Diagnosis Center if there is a screening result showing an increased chance of a birth defect. Medi-Cal and private insurance must cover all program fees, with only a few exceptions for self-insured employers and out-of-state health plans.

You should provide your Medi-Cal number or insurance information at the time of your prenatal screening. The PNS Program mails a bill and an insurance information form to you to complete and return if your Medi-Cal or insurance information is not provided when the screenings are ordered. The PNS Program will not be involved in the billing of prenatal screening or testing outside of the PNS Program. **Note the following:**

- The PNS Program fee does not cover blood draw charges.
- The PNS Program will pay for follow up services at a state-approved Prenatal Diagnosis Center only if prenatal screening provided through the PNS Program finds an increased chance of a birth defect in your fetus.
- The PNS Program does not pay for any other medical services after diagnostic testing.

## VI. Additional Information

### Whether to support research is your choice

If you live in certain counties that participate in birth defects monitoring, after you have your blood drawn for your MSAFP screening, that blood sample is stored and might be used in research to prevent birth defects. The blood sample shall be held confidential without any personal identifying information and may be released to help approved researchers study the causes of birth defects and other childhood health problems.

You can request that your blood sample **not** be used for research when your prenatal care provider orders the MSAFP screening. You can do this by asking your provider to check the required box when ordering the screening. If you say “no” to using your blood sample for research, the sample will be destroyed after your screening result is complete and reported to your provider. Saying no to research will not affect your health care or screening results in any way. For more information, see the [PNS Program Supporting Research web page](https://bit.ly/PNSResearch) (<https://bit.ly/PNSResearch>).





## The California Newborn Screening Program

The California Newborn Screening (NBS) Program routinely screens all newborns for over 80 serious but treatable genetic diseases. All newborns should have blood collected by a health care provider from 12 through 48 hours after birth using a small amount of blood taken from the baby's heel. For more information about newborn screening, ask your health care provider or visit the [California NBS Program web page](http://www.cdph.ca.gov/NBS) (www.cdph.ca.gov/NBS).



## The environment can affect your health

We encounter chemicals and other substances in everyday life that may affect your developing fetus. Fortunately, there are steps you can take to reduce your exposure to these potentially harmful substances at home, in the workplace, and in the environment. Many Californians are unaware that a number of everyday consumer products may pose potential harm. Prospective parents should talk to their doctor and are encouraged to read more about this topic to learn about simple actions to promote a healthy pregnancy.



At the University of California, San Francisco, the Program on Reproductive Health and the Environment produces [All That Matters brochures](https://prhe.ucsf.edu/info) (https://prhe.ucsf.edu/info). These are nontechnical, patient-centered guides that provide tips and suggestions for avoiding toxic chemical exposure at home, in the workplace, and in the community. For more information, see the [PNS Program Reproductive Health web page](https://bit.ly/R-Health) (https://bit.ly/R-Health).

## Whether to bank cord blood is your choice

As the delivery date approaches, expecting parents can consider the option of saving the baby's cord blood. Cord blood banking means collecting potentially life-saving stem cells from the umbilical cord and storing them for future use.



Both private and public cord blood banks are available in California. Parents interested in saving their baby's cord blood should talk with their prenatal care provider by week 34 of pregnancy, or earlier. For more information, see the California [PNS Program Cord Blood Banking web page](https://bit.ly/Cord-B) (https://bit.ly/Cord-B). For more information on both public and private cord blood banking, visit or call:

- [National Cord Blood Program](https://www.nationalcordblood.org): 866-767-6227
- [National Marrow Donor Program](https://www.nationalmarrowdonorprogram.org): 800-627-7692

## Sexual orientation and gender identity survey

As part of a state-required data collection project, the PNS Program must ask for information on the sexual orientation and gender identity of program participants.



This information is collected on a [Sexual Orientation Gender Identity \(SOGI\) Survey](https://forms.office.com/g/LRUWGVE7Xx) (https://forms.office.com/g/LRUWGVE7Xx). You are not required to complete the SOGI survey form. If you choose not to provide this information, it will not affect your participation in the PNS Program. If you choose to provide this information, it will not be traced to you or your prenatal screening test results. Pregnant individuals can complete a new form each time they become pregnant.

## VII. Notice of Privacy Practices

The Genetic Disease Screening Program (GDSP) is defined as a health care provider under the Health Insurance Portability and Accountability Act (HIPAA). HIPAA is a federal law that created rules to protect sensitive patient health information from being disclosed without a patient's consent or knowledge. GDSP is covered under HIPAA and is required to distribute this Notice of Privacy Practice (NPP, effective as of July 2015).

The California Prenatal Screening (PNS) Program is under GDSP as part of the California Department of Public Health (CDPH). The collection and exchange of personal health information between covered providers for the purpose of treatment, payment, or health care operations with GDSP and its agents in connection with the PNS Program is permitted by HIPAA and required by state law without special authorization or business associate agreements. This notice describes how personal and medical information about you may be used and disclosed and how you can get access to this information. Please review it carefully.

### Department's Legal Duties

GDSP is required by law to maintain the privacy of protected health information. The federal and state laws restrict the use, maintenance, and disclosure of personal information obtained by a state agency and require certain notices to individuals whose information is maintained. The law also requires us to let you know promptly if a breach occurred that may have compromised the privacy or security of your information.

State laws include the California Information Practices Act (Civil Code 1798 et seq.), Government Code Section 11015.5, and Health and Safety Code Section 124980. The federal law is the Health Insurance Portability and Accountability Act of 1996 (HIPAA), 42 USC 1320d-2(a)(2), and its regulations in Title 45 of the Code of Federal Regulations Section 160.100, et seq.

In compliance with these laws, you and those providing information are notified of the following: CDPH collects and uses personal and medical information as permitted under Health and Safety Code Sections 124977, 124980, 125000, 125002, 125050, 125055, and 123055, and according to procedures in State regulations (17 CCR §§ 6527, 6529, 6531 and 6532). The information CDPH collects is used to estimate the risk of serious birth defects in the pregnancy and provide diagnostic testing for pregnant women. If personal information is not provided, problems could result such as not detecting an affected baby, falsely reporting increased risk causing unnecessary invasive testing, or not being able to bill properly for the services provided. This information is collected electronically and includes your name, address, testing results, and medical care given to you.

### Uses and Disclosure of Health Information

CDPH uses health information about you for screening, to provide health care services, to obtain payment for screening and administrative purposes, and to evaluate the quality of care that you receive. The law also allows CDPH to use or give out information we have about you for the following reasons:

- For research studies that have been approved by an institutional review board and meet all federal and state privacy law requirements, such as research related to preventing disease.
- For medical research without identification of the person from whom the information was obtained, unless you specifically request in writing that your information not be used, by writing to the address listed below.
- To organizations that help us in our operations, such as by collecting fees. If we provide them with information, we will make sure that they protect the privacy of information we share with them as required by federal and state law.

### GDSP Written Permission

GDSP must have your written permission to use or give out personal and health information about you for any reason that is not described in this notice. You can revoke your authorization at any time, except if GDSP has already acted because of your permission, by contacting Division Chief, Genetic Disease Screening Program, 850 Marina Bay Parkway, F175, Richmond, CA 94804.

# Notice of Privacy Practices (continued)

CDPH reserves the right to change the terms of this notice and to make the new notice provisions effective for all protected health information that it maintains. You may request a copy of the current policies or obtain more information about our privacy practices, by calling the numbers listed on the next page or consulting the [PNS Program web page](https://www.cdph.ca.gov/PNS) (<https://www.cdph.ca.gov/PNS>). You may also request a paper copy of this Notice.

## Individual Rights and Access to Information

You have the right to look at or receive a copy of your health information. If you request copies, we will charge you \$0.10 (10 cents) for each page. You also have the right to receive a list of instances where we have disclosed health information about you for reasons other than screening, payment, or related administrative purposes.

If you believe that information in your record is incorrect or if important information is missing, you have the right to request that we correct the existing information or add the missing information. You have the right to ask us to contact you at a different address, post office box, or telephone number. We will accept reasonable requests. You may request in writing that we restrict disclosure of your information for health care treatment, payment, and administrative Purposes; however, we may not be able to comply with all requests.

## Complaints

If you believe that we have not protected your privacy or have violated any of your rights and wish to file a complaint, please call or write to the: Privacy Officer, CDPH, 1415 L Street, Suite 500, Sacramento, CA 95814, (877) 421-9634. CDPH cannot take away your health care benefits or any other protected rights in any way if you choose to file a complaint or use any of the privacy rights in this Notice.

You may also contact the United States Department of Health and Human Services, Attention: Regional Manager, Office for Civil Rights at 90 7th Street, Suite 4-100, San Francisco, CA 94103, telephone (800) 368-1019, or (800) 537-7697 TDD toll-free, or the U.S. Office of Civil Rights at 866-OCR-PRIV (866-627-7748) or 866-788-4989 TTY.

## Department Contact

The information in this Notice is maintained by GDSP. The Division Chief of the Genetic Disease Screening Program may be reached at: 850 Marina Bay Parkway, F175, Richmond, California, 94804, (866) 718-7915. The Division Chief is responsible for the system of records and shall, upon request, inform you about the location of your records and respond to any requests you may have about information in those records.

## Americans with Disabilities Act

### Notice of Information and Access Statement

Policy of Nondiscrimination on the Basis of Disability and Equal Employment Opportunity Statement. CDPH complies with all state and federal laws, which prohibit discrimination in employment and provide admission and access to its programs or activities.

The Deputy Director, Office of Civil Rights (OCR), CDPH has been designated to coordinate and carry out the department's compliance with nondiscrimination requirements. Title II of the Americans with Disabilities Act (ADA) addresses nondiscrimination and access issues regarding disabilities. To obtain information concerning the CDPH EEO Policies or the provisions of the ADA and the rights provided, you may contact the CDPH Office of Compliance, Civil Rights Unit, at P.O. Box 997377, MS 0504, Sacramento, CA 95899-7377 or (916) 445-0938.

Upon request, this document will be made available in Braille, high contrast, large print, or electronic format. To obtain a copy in one of these alternate formats, call or write: Chief, California Prenatal Screening Program, 850 Marina Bay Pkwy, F 175, Mail Stop 8200, Richmond, CA 94804; Phone: (866) 718-7915. [This notice is online](https://bit.ly/PNSPrivacy) (<https://bit.ly/PNSPrivacy>).



**California Department of Public Health**

[www.cdph.ca.gov/PNS](http://www.cdph.ca.gov/PNS)

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