



State of California-Health and Human Services Agency  
Department of Health Services



ARNOLD SCHWARZENEGGER  
Governor

N.L: 09-0607  
Index: Benefits

DATE: JUNE 18, 2007

TO: ALL COUNTY CALIFORNIA CHILDREN SERVICES (CCS) PROGRAM  
ADMINISTRATORS, MEDICAL CONSULTANTS, AND STATE  
CHILDREN'S MEDICAL SERVICES (CMS) STAFF

SUBJECT: AUTHORIZATION OF DIAGNOSTIC AND TREATMENT SERVICES FOR  
INFANTS REFERRED BY THE CALIFORNIA NEWBORN SCREENING  
(NBS) PROGRAM FOR CYSTIC FIBROSIS (CF) AND BIOTINIDASE  
DEFICIENCY (BD)

## I. Background

The California NBS Program currently screens more than 550,000 newborns annually for phenylketonuria (PKU), galactosemia, primary congenital hypothyroidism, hemoglobinopathies including sickle cell disease, over 40 metabolic conditions detectable via Tandem Mass Spectrometry (MS/MS), and classical congenital adrenal hyperplasia (CAH) including the salt-wasting and simple virilizing forms. All the conditions for which the NBS Program screens are CCS-eligible (see Attachment 1 for the list of disorders).

The NBS Program will expand on or before August 1, 2007, to include screening for CF and BD (see Attachment 2 for more information on these disorders). Pilot testing for these two disorders is already occurring around the state. It is estimated that with this new expansion, approximately 800 referrals will be made to metabolic centers (including 110 for BD) and 100 referrals will be made to pulmonary centers for diagnostic evaluations annually.

Through the expanded California NBS program, approximately 725 newborns could be identified and treated every year. It is imperative that all of these disorders are diagnosed early to avoid serious disabilities and even death in some cases.

In order to expedite the authorization of diagnostic services for infants identified with a positive NBS report for CF or BD, the procedure identified in N.L. 08-0505 will be adopted for these disorders. The CCS program's "Expedited Diagnostic Service

Request” form revised to include CF/Pulmonary Special Care Centers (SCCs) (see Attachment 3 for this form) will be used. Receipt of this form (completed by the NBS Coordinator) will ensure that the SCC Medical Director will be guaranteed reimbursement for the initial office visit and evaluation, and ensure that the SCC will make timely appointments for these services and see the patient prior to receipt of a CCS authorization (see Attachment 4 for the letter to SCCs).

The NBS Coordinator will facilitate the referral and evaluation process by:

- Notifying the infant’s primary care provider;
- notifying the specialist at the CCS-approved SCC of the positive NBS result and requesting that the specialist contact the primary care provider to discuss the diagnostic evaluation;
- contacting the family to verify notification from the infant’s primary care provider and provide information; and
- completing the “Expedited Diagnostic Service Request” form and fax it to the SCC and CCS offices;
- faxing a blank CCS application form and a copy of the positive NBS report, to the SCC.

The SCC will facilitate the referral and evaluation process by:

- Contacting the primary care provider to discuss the diagnostic evaluation;
- scheduling the appointment at the SCC;
- reporting the diagnostic test results and the diagnosis to the NBS Coordinator and the CCS program; and
- completing the referral process by assisting the family to complete and sign the CCS application at the time of the visit and faxing the completed application to the local CCS office.

## **II. Policy**

- A. CCS shall issue an authorization to the appropriate CCS-approved SCC to perform a diagnostic evaluation on all infants referred by the California NBS Program for CF and BD. The authorization shall be for three months. The NBS Program staff will identify the SCC to which the infant will be referred.

The SCC will be a CF/Pulmonary (CF) or Metabolic (BD) SCC (see Attachment 5 for a list of SCCs that can be currently authorized).

- B. These authorizations shall be issued within five working days of receipt of all the following documentation:
1. An "Expedited Diagnostic Service Request" form (to be faxed by the NBS Coordinator).
  2. The positive NBS report (to be faxed by the NBS Coordinator).
  3. A "New Referral CCS/GHPP Client Service Authorization Request" form (signed and faxed by the NBS Coordinator).
  4. A signed CCS application for infants who do not have full scope no share of cost Medi-Cal or who are not Healthy Families subscribers. Authorizations shall be issued without a signed CCS application for infants who have full scope no share of cost Medi-Cal or who are Healthy Families subscribers.
- C. The CCS \$20 assessment fee shall be waived for these services.

### **III. Policy Implementation**

- A. Authorizations for diagnostic evaluations should be given to the SCC for medical Service Code Group (SCG) 02.
- B. The initial diagnostic evaluation shall be issued for three months and may be modified as needed if the diagnostic evaluation is not completed in three months.
- C. Authorizations shall include the following information in CMS Net web selected from special instructions or similar language for a legacy authorization:

**Provider must bill other health insurance (OHC) first; submit Explanation of Benefits (EOB) with claim.**

- D. For infants whose diagnostic evaluation confirms the presence of CF or BD, the CCS program shall initiate the steps to determine eligibility for ongoing treatment services. These disorders are medically eligible for CCS.

1. Authorizations for treatment services shall be issued to CCS approved CF/Pulmonary or Metabolic SCCs for infants who have full scope, no share of cost Medi-Cal or who are Healthy Families (HF) subscribers.
  2. Families of other infants who are not eligible for full scope, no share of cost Medi-Cal, and who are not HF subscribers must complete CCS program eligibility requirements prior to the issuance of treatment authorizations.
- E. Authorizations for treatment should be provided to the SCC for medical SCG 02. (Note: This authorization, or the one provided for in III.F., will cover the dispensing of the biotin necessary to treat those individuals identified with BD.)
- F. Authorizations for primary care physicians may be issued for treatment of the CCS eligible condition, in conjunction with the SCC or specialist, for medical SCG 01.

If you have any questions regarding the above policy, please contact your Regional Office Medical Consultant.

Original signed by Marian Dalsey, M.D., M.P.H.

Marian Dalsey, M.D., M.P.H., Chief  
Children's Medical Services Branch

Attachments

California Department of Health Services  
Genetic Disease Branch  
Newborn Screening Program

**Disorders Detectable by NBS Program  
August 1, 2007**

I. Cystic Fibrosis (*new*)

II. Metabolic Disorders

A. Classical galactosemia

B. Biotinidase deficiency (*new*)

C. Amino Acid Disorders

- classical phenylketonuria (PKU)
- variant PKU
- guanosine triphosphate cyclohydrolase 1 (GTPCH) deficiency (biopterin deficiency)
- 6-pyruvoyl-tetrahydropterin synthase (PTPS) deficiency (biopterin deficiency)
- dihydropteridine reductase (DHPR) deficiency (biopterin deficiency)
- pterin-4 $\alpha$ -carbinolamine dehydratase (PCD) deficiency (biopterin deficiency)
- argininemia/arginase deficiency
- argininosuccinic acid lyase deficiency (ASAL deficiency)
- citrullinemia, Type I/argininosuccinic acid synthetase deficiency (ASAS deficiency)
- citrullinemia, Type II (citrin deficiency)
- gyrate atrophy of the choroid and retina
- homocitrullinuria, hyperornithinemia, hyperammonemia –HHH
- homocystinuria/cystathionine beta-synthase deficiency (CBS deficiency)
- methionine adenosyltransferase deficiency (MAT deficiency)
- maple syrup urine disease – (MSUD)
- tyrosinemia

D. Organic Acid Disorders

- 2-methyl-3-hydroxybutyryl-CoA dehydrogenase deficiency
- 2-methylbutyryl-CoA dehydrogenase deficiency
- 3-hydroxy-3-methylglutaryl-CoA lyase deficiency (HMGCoA lyase deficiency)
- 3-methylcrotonyl-CoA carboxylase deficiency (3MCC deficiency)
- 3-methylglutaconic aciduria (MGA), Type I (3-methylglutaconyl-CoA hydratase deficiency)
- beta-ketothiolase deficiency (BKT)
- ethylmalonic encephalopathy (EE)
- glutaric acidemia type-1 (GA-1)
- isobutyryl-CoA dehydrogenase deficiency
- isovaleric acidemia (IVA)

- malonic aciduria
- methylmalonic acidemia, mut –
- methylmalonic acidemia, mut 0
- methylmalonic acidemia (Cbl A, B)
- methylmalonic acidemia (Cbl C, D)
- multiple carboxylase deficiency (MCD)
- propionic acidemia (PA)

#### E. Fatty Acid Oxidation Disorders

- carnitine transporter deficiency
- carnitine-acylcarnitine translocase deficiency (CAT deficiency)
- carnitine palmitoyl transferase deficiency-type 1 (CPT-1 deficiency)
- carnitine palmitoyl transferase deficiency-type 2 (CPT-2 deficiency)
- long chain hydroxyacyl-CoA dehydrogenase deficiency (LCHAD deficiency)
- medium chain acyl-CoA dehydrogenase deficiency (MCAD deficiency)
- medium/short chain L-3-hydroxy acyl-CoA dehydrogenase deficiency (M/SCHAD deficiency)
- multiple acyl-CoA dehydrogenase deficiency (MAD deficiency)/glutaric acidemia type-2 (GA-2)
- short chain acyl-CoA dehydrogenase deficiency (SCAD deficiency)
- trifunctional protein deficiency (TFP deficiency)
- very long chain acyl-CoA dehydrogenase deficiency (VLCAD deficiency)

#### III. Endocrine Disorders

- primary congenital hypothyroidism
- variant hypothyroidism
- congenital adrenal hyperplasia-salt wasting (21-hydroxylase deficiency)
- congenital adrenal hyperplasia-simple virilizing (21-hydroxylase deficiency)

#### IV. Hemoglobin Disorders

- sickle cell anemia (Hb S/S disease)
- sickle C disease (Hb S/C disease)
- sickle D disease (Hb S/D disease)
- sickle E disease (Hb S/E disease)
- Hb S/ hereditary persistence of fetal hemoglobin (Hb S/HPFH)
- sickle cell disease variant (other sickle cell disease, Hb S/V)
- Hb S/ Beta<sup>0</sup> thalassemia
- Hb S/Beta<sup>+</sup> thalassemia
- Hb C disease (Hb CC)
- Hb D disease (Hb DD)
- alpha thalassemia major
- Hb H disease
- Hb H/ Constant Spring disease
- beta thalassemia major
- Hb E/ Beta<sup>0</sup> thalassemia
- Hb E/Beta<sup>+</sup> thalassemia
- Hb E/ Delta Beta thalassemia

- Hb C/ Beta<sup>0</sup><sub>+</sub> thalassemia
- Hb C/Beta<sup>0</sup><sub>+</sub> thalassemia
- Hb D/ Beta<sup>0</sup><sub>+</sub> thalassemia
- Hb D/Beta<sup>0</sup><sub>+</sub> thalassemia
- Hb Variant/ Beta<sup>0</sup><sub>+</sub> thalassemia
- Hb Variant/Beta<sup>0</sup><sub>+</sub> thalassemia
- other hemoglobinopathies (Hb variants)

<sup>i</sup> Due to biological variability of newborns and differences in detection rates for the various disorders in the newborn period, the Newborn Screening Program will not identify all newborns with these conditions. While a positive screening result identifies newborns at an increased risk to justify a diagnostic work-up, a negative screening result does not rule out the possibility of a disorder. Health care providers should remain watchful for any sign or symptoms of these disorders in their patients. A newborn screening result should not be considered diagnostic, and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable health care provider.

G/MS/MS/NBS Expansion/All Disorders as of 8/1/07 (060107update)



# NEWBORN SCREENING *News*

SUMMER 2007

THE CALIFORNIA NEWBORN SCREENING PROGRAM

## Upcoming Addition to Newborn Screening: Cystic Fibrosis and Biotinidase Deficiency

In accordance with Chapters 47 and 48 Statutes of 2006, commonly referred to as the 2006 Budget Act, the California Newborn Screening Program will be expanding to include Cystic Fibrosis (CF) and Biotinidase Deficiency (BD). This expansion will mean that by August 1, 2007, the over half a million babies born in California will be screened for these two disorders in addition to the current panel of metabolic, hemoglobin, and endocrine diseases.

### Biotinidase Deficiency

Individuals with BD have an inactive biotinidase enzyme that cannot release biotin so it can be recycled. Biotin, a vitamin cofactor, is necessary for organic acid metabolism. Untreated BD may lead to severe metabolic decompensation in the newborn period. Affected children may exhibit seizures, hypotonia, ataxia, developmental delays, vision problems, hearing loss, skin rashes and/or other cutaneous abnormalities. If left untreated, BD can lead to mental retardation and death.

Activity of the biotinidase enzyme is measured directly using a colorimetric measurement. If the sample has no color development, confirmatory testing is indicated. A serum specimen will be sent to the state confirmatory laboratory at Stanford University.

There are two types of biotinidase deficiency, partial and profound. The

California Program will be screening only for profound deficiency, since these babies require prompt treatment. National data indicates a prevalence rate of 1/83,000 for profound deficiency. This translates to about 7 profound cases per year in California. Since the expected number of cases is based on data from other states whose populations are demographically different than California, and the incidence is low and variable, the actual number of cases may vary.

Based on an analysis of about 5000 California samples, preliminary estimates of the expected positive rate is 0.02%. This should be considered tentative since it is based on such a small number.

Although the Program is screening for profound BD, some (but not all) babies with partial deficiency will be detected through screening. Newborns with positive screening results will be referred to a CCS-approved Metabolic Center. The Metabolic Center will work with the primary care provider to arrange for confirmatory testing.

For more information about BD, and copies of the provider fact sheet, please visit our website at [www.dhs.ca.gov/nbs](http://www.dhs.ca.gov/nbs) or call your local NBS Area Service Center (see list of ASCs on page 4).

### Cystic Fibrosis

This summer cystic fibrosis will be added to the panel of newborn disorders that are screened for in California. The expansion follows six years of research to determine the most favorable screening method possible in California's heterogeneous population. A recent review of the benefits of newborn screening for cystic fibrosis can be found on the CDC website (<http://www.cdc.gov/mmwr/preview/mmwrhtml/rr5313a1.htm>).

Cystic fibrosis is an autosomal recessive disease requiring a mutation on each of the two copies of chromosome 7 inherited from our parents. CF can cause damage to a number of different body organs, including the lungs and upper respiratory tract, gastrointestinal tract, pancreas, liver, sweat glands, and genitourinary tract.

One or more of the following cystic fibrosis symptoms are typical in the first few months of life: slow growth and failure to thrive; recurrent respiratory infections, including respiratory syncytial virus (RSV); salty sweat; malnutrition and frequent runny stools. In 15-20% of cases, meconium ileus (a congenital intestinal obstruction by thickened viscous meconium) will be present in the first days of life. In hot environments, persons with cystic

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fibrosis can dehydrate and develop life-threatening electrolyte imbalance.

Cystic fibrosis prevalence rates at birth differ widely across race/ethnicity groups (Exhibit 1), as do the types of mutations that cause the disease. To date, over 1400 different CFTR mutations have been identified. Around 92 cases of cystic fibrosis are expected out of about 540,000 births per year in California.

**Exhibit 1:**

Cystic fibrosis prevalence rates and expected annual births with cystic fibrosis by race/ethnicity.

Race/Ethnicity	CF Prevalence Rate	Number of Births
Non-Hispanic Whites	1/3,000 births	59
Hispanics	1/9,000 births	30
Non-Hispanic Blacks	1/15,000 births	2
Asians and Others	1/45,000 births	1
<b>Total</b>	<b>1/5,876 births</b>	<b>92</b>

In California, a four-step screening model for cystic fibrosis will be implemented as described below. (A flow chart with expected annual numbers can be found in Exhibit 2.) All newborn blood spots are tested for immunoreactive trypsinogen (IRT) at the regional Neonatal and Prenatal Screening (NAPS) Laboratory (Step One). Newborns with values in the top 2.2% of the IRT distribution (n~11,844 per year) will have their blood spots tested at Stanford University for the presence of 38 different CFTR mutations (Step Two). Newborns with low IRT values or zero mutations are deemed to be screen negative for cystic fibrosis (n~539,882). Those with one mutation found (n~876 per year) will have one of their existing filter paper blood spots sent to Ambry Genetics for more sophisticated testing using DNA sequencing methods capable of detecting over 98% of all CFTR mutations (Step Three). Newborns with two or more mutations identified are screen positive for cystic fibrosis (n~104 per year) and, in conjunction with the newborn's primary care provider, will be referred to

a Cystic Fibrosis Special Care Center for a diagnostic work up and sweat chloride test (Step Four).

The parents of newborns with only one mutation identified (about 900 per year) will be sent a letter informing them that their baby is a carrier (as is one or both of the parents) and will be offered genetic counseling by telephone.

Annually, 92% (n~85) of the expected 92 newborns with cystic fibrosis will be detected by the Newborn Screening Program: 69 cases at around seven days of age (Step Two), and 16 cases at around one month of age (Step Three). Maternity hospitals and primary care physicians will be sent an initial results mailer after Step One (for those newborns with a negative IRT result) or Step Two (for those with a positive IRT result) but with no mutations identified.

For approximately 876 newborns whose blood spots were sent on for Step Three testing, hospitals and primary care physicians will receive a preliminary report of a single CFTR mutation, stating that further cystic fibrosis testing is in process. Because over 98% of these newborns will be carriers and not have cystic fibrosis, it is important for primary care physicians to wait to refer newborns for diagnostic sweat testing until after Step Three results are received, with three exceptions:

- The newborn has clinical symptoms of cystic fibrosis
- There is a family history of cystic fibrosis, or
- Both parents are known carriers of a CFTR mutation.

After Step Three, a DNA Sequencing Results Mailer will be sent with final mutation results.

The California CF newborn screening model has been designed to detect at least 90% of CF cases in California's Hispanic, Black and White populations. Because no newborn screening model for cystic fibrosis can detect 100% of the

cases while minimizing false positives, primary care providers need to remain vigilant for signs and symptoms of cystic fibrosis regardless of newborn screening results. Reporting to GDB will be mandatory for all newly diagnosed cases of cystic fibrosis in California, whether or not screened by the newborn screening program.

For additional information about cystic fibrosis newborn screening, please visit our website at [www.dhs.ca.gov/nbs](http://www.dhs.ca.gov/nbs) or call your local NBS Area Service Center. ■

## Additional Information for Health Care Providers and Families

The Program booklet called *Important Information for Parents about the Newborn Screening Test* is being updated to reflect the upcoming expansion. A note indicating when to start using them will be included inside the boxes containing the booklet. We will be requesting you destroy/recycle all copies of the old version of the booklet and only use the updated version once expansion begins.

Many other educational materials are being developed in preparation for expansion, including fact sheets for providers and booklets for parents of babies diagnosed with CF or biotinidase deficiency. These and other NBS educational materials can be ordered by calling (510) 412-1542. They will also be available from the NBS website, [www.dhs.ca.gov/nbs](http://www.dhs.ca.gov/nbs). Recent Program newsletters and letters to hospitals and providers are also posted on the website.

# Referral for Diagnostic Evaluation and Treatment

All newborns identified with a disorder through the NBS Program should have access to a diagnostic evaluation through a CCS-approved Special Care Center (SCC). (See list on last page of this newsletter.) Specialists at the SCC will work closely with the primary care provider in determining appropriate follow-up and in the development of a treatment plan when necessary. When a disorder is confirmed, the NBS Program strongly recommends that newborns receive ongoing care at a SCC where a multi-disciplinary team (physicians, dietician, nurse, social worker, genetic counselor) can provide a comprehensive approach to assisting the family.

## Who Will Pay for the Diagnostic Evaluation and Treatment if Needed?

All newborns referred to a CCS-approved SCC by the California Newborn Screening Program are eligible for a diagnostic evaluation through the SCC regardless of income. The ASC will work with the primary care provider in determining which SCC to refer the baby to based upon location, insurance plan coverage and provider preference. Because the disorders screened for by the NBS Program require immediate follow-up, the CCS program has developed an expedited authorization process to assure a prompt initial diagnostic evaluation at a SCC.

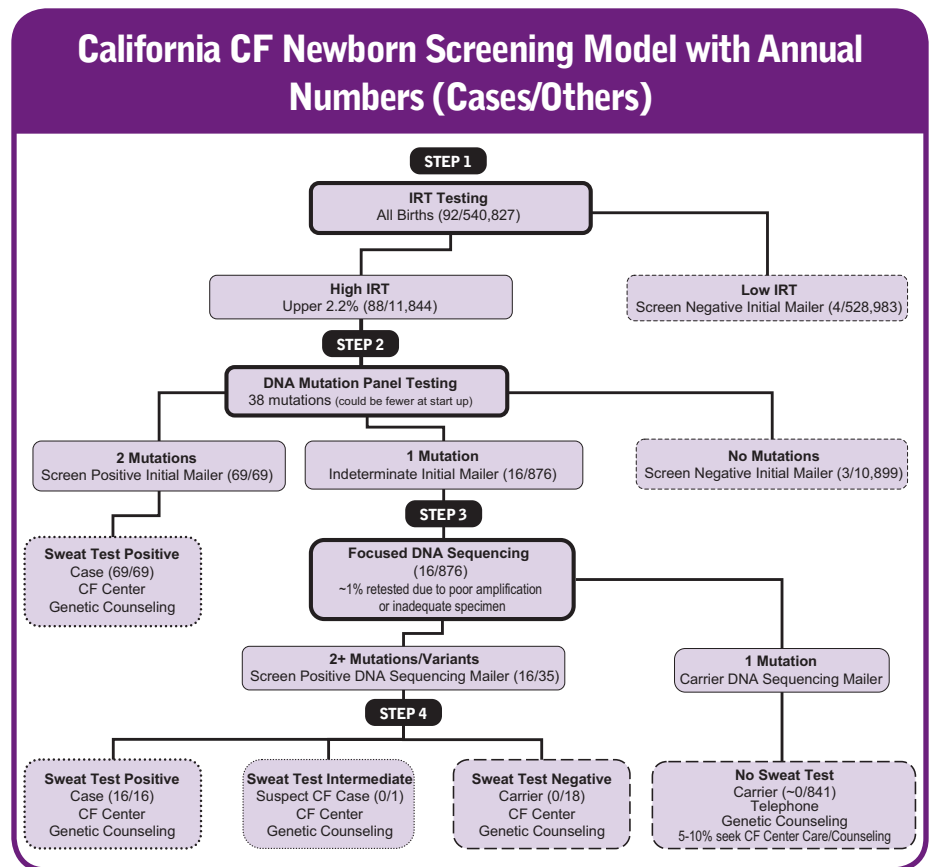
Parents will be asked to complete an application form to determine eligibility for CCS payment for the diagnostic evaluation. Most health insurance and health maintenance organizations (HMOs) provide at least some coverage

for the diagnostic evaluation and any necessary treatment. If a baby has health insurance the SCC will bill the health insurance company or HMO for the services. Infants who have Medi-Cal full scope, no share of cost, or Healthy Families subscribers will be authorized by CCS for diagnostic and treatment services and parents will not need to pay anything for services. If parents do not have health insurance, or their insurance only covers partial payment, the infant may be eligible for the CCS program. Eligibility for coverage of treatment costs through the CCS program is based on having a CCS eligible medical condition, and meeting CCS financial and residential eligibility criteria. For more information on the CCS program visit their website at: <http://www.dhs.ca.gov/pcfh/cms/ccs/>. For a list of SCCs see page 4 of this newsletter. ■

## Limitations of the Newborn Screening Program

Due to biological variability of newborns and differences in detection rates for the various disorders in the newborn period, the Newborn Screening Program will not identify all newborns with these conditions. While a positive screening result identifies newborns at an increased risk to justify a diagnostic work-up, a negative screening result does not rule out the possibility of a disorder. Health care providers should remain watchful for any signs or symptoms of these disorders in their patients. **A newborn screening result should not be considered diagnostic, and cannot replace the individualized evaluation and diagnosis of an infant by a well-trained, knowledgeable health care provider.** ■

EXHIBIT 2:



## California Children's Services Approved Special Care Centers including Metabolic, Endocrine, Sickle Cell Disease/Hemoglobin and Cystic Fibrosis\*

### **Cedars-Sinai Medical Center**

Los Angeles, CA 90048  
Metabolic – (310) 423-9914  
SCD/Hb. – (310) 423-4423

### **Children's Hospital & Research Center at Oakland**

Oakland, CA 94609  
Metabolic – (510) 428-3550  
Endocrine – (510) 428-3654  
SCD/Hb. – (510) 428-3651  
Cystic Fibrosis – (510) 428-3305

### **Children's Hospital Central California**

Madera, CA 93638  
Metabolic – (559) 353-6400  
Endocrine – (559) 353-8700  
SCD/Hb. – (559) 353-5461  
Cystic Fibrosis – (559) 353-5587

### **Children's Hospital of Los Angeles**

Los Angeles, CA 90027  
Metabolic – (323) 660-2450  
Endocrine – (323) 660-2450  
SCD/Hb. – (323) 660-2450  
Cystic Fibrosis – (323) 669-4539

### **Children's Hospital of Orange County**

Orange, CA 92868  
Metabolic – (714) 532-8852  
Endocrine – (714) 532-8634  
SCD/Hb. – (714) 532-8459  
Cystic Fibrosis – (714) 532-8620

### **Rady's Children's Hospital, San Diego**

San Diego, CA 92123  
Metabolic – (619) 543-7800  
Endocrine – (858) 966-4032  
SCD/Hb. – (858) 966-5811  
Cystic Fibrosis – (858) 966-6790

### **City of Hope Medical Center**

Duarte, CA 91010  
SCD/Hb. – (626) 256-4673 ext. 62913

### **Harbor/UCLA Medical Center**

Torrance, CA 90509  
Metabolic – (310) 222-3756  
Endocrine – (310) 222-2394  
SCD/Hb. – (310) 222-2394

### **Kaiser Permanente No. California**

Oakland, CA 94611  
Metabolic – (510) 752-7703  
SCD/Hb. – (510) 752-6192  
Cystic Fibrosis – (510) 752-6596\*\*

### **Kaiser Permanente So. California**

Los Angeles, CA 90033  
Metabolic – (323) 783-6970  
SCD/Hb. – (800) 734-5155  
Cystic Fibrosis – (818) 375-2909\*\*

### **Loma Linda University**

Loma Linda, CA 92354  
Endocrine – (909) 558-2827  
SCD/Hb. – (909) 558-2617  
Cystic Fibrosis – (909) 558-2301

### **Los Angeles County/USC**

Medical Center  
Los Angeles, CA 90033  
Metabolic – (323) 226-3816  
SCD/Hb. – (323) 226-3853

### **Lucile Salter Packard Children's Hospital at Stanford**

Palo Alto, CA 94301  
Metabolic – (650) 723-6858  
Endocrine – (650) 723-5791  
SCD/Hb. – (650) 725-1072  
Cystic Fibrosis – (650) 723-5191

### **Miller Children's at Long Beach Memorial Medical Center**

Long Beach, CA 90801  
Endocrine – (562) 933-8562  
SCD/Hb. – (562) 492-1062  
Cystic Fibrosis – (562) 492-6383

### **Pediatric Diagnostic Center Ventura County Medical Center**

Ventura, CA 93003  
Cystic Fibrosis – (805) 641-4490

### **Pediatric Specialties Clinic**

Walnut Creek, CA 94598  
Cystic Fibrosis – (925) 280-8131

### **Saint Agnes Medical Center**

Fresno, CA 93720  
SCD/Hb. – (209) 449-5121

### **Santa Clara Valley Medical Center**

San Jose, CA 95128  
Endocrine – (408) 885-5405

### **Sutter Memorial Hospital**

Sacramento, CA 95819  
Metabolic – (916) 733-6023  
Endocrine – (916) 733-6006  
SCD/Hb. – (916) 733-1757  
Cystic Fibrosis – (916) 453-1454

### **UC Davis Medical Center**

Sacramento, CA 95817  
Metabolic – (916) 734-3112  
Endocrine – (916) 734-3112  
SCD/Hb. – (916) 734-2781  
Cystic Fibrosis – (916) 734-3189

### **UC San Francisco Medical Center**

San Francisco, CA 94143  
Metabolic – (415) 476-2757  
Endocrine – (415) 476-1016  
SCD/Hb. – (415) 502-8034  
Cystic Fibrosis – (415) 476-2072

### **UC Irvine Medical Center**

Orange, CA 92868  
Metabolic – (714) 456-8513  
SCD/Hb. – (714) 456-5680

### **UC Los Angeles Medical Center**

Los Angeles, CA 90095  
Metabolic – (310) 206-6581  
Endocrine – (310) 825-6244  
SCD/Hb. – (310) 825-6708

## Newborn Screening Area Service Centers (NBS-ASCs)

**Stanford University**  
(650) 812-0353

**Children's Hospital Central CA**  
(559) 353-6416

**UCLA Medical Center**  
(310) 826-4458

**Harbor/UCLA Medical Center**  
(310) 222-3751

**San Diego Region**  
(800) 793-1313

**Kaiser Permanente, Northern CA**  
(510) 752-6192

**Kaiser Permanente, Southern CA**  
(626) 564-3322

\*CF Centers must also be Cystic Fibrosis Foundation Accredited. / \*\*Not CCS approved - Kaiser members only

*Newborn Screening News is published by:*

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850 Marina Bay Parkway, F175, Richmond, CA 94804, (510) 412-1502  
[www.dhs.ca.gov/nbs](http://www.dhs.ca.gov/nbs)



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**MARK HORTON, MD, MSPH, DIRECTOR**  
California Department of Public Health

**Expedited Diagnostic Service Request**  
For Infants With A Positive Newborn Screening (NBS) Test  
To: The Special Care Center (SCC)

- Metabolic
- Endocrine
- Sickle Cell Disease
- Cystic Fibrosis/Pulmonary

The purpose of this request is to expedite the diagnostic evaluation for an infant with a positive newborn screening test. **The CCS program will authorize these evaluations, but due to the scheduled appointment occurring quickly, the SCC may not have the authorization at the time of the visit.** The authorization will be forthcoming.

The infant named below will be scheduled for a diagnostic evaluation with the following SCC:	
SCC _____	Physician _____
SCC Contact _____	Fax _____
Date of Visit (If known) _____	
Infant's Name _____ (as on the positive newborn screening report)	AKA _____ (when applicable)
Infant's Date of Birth _____	NBS Number _____ (initial NBS screening test accession #)
Mother's Name _____ (as on the positive newborn screening report)	AKA _____ (when applicable)
Mother's Date of Birth _____	
Primary Care Provider _____	Phone _____

**The attached application\* must be completed by the parent/legal guardian at the time of the SCC visit and then faxed to the appropriate CCS program.**

The CCS program will issue an authorization to cover the diagnostic services within five working days of receipt of all necessary documents. **The SCC shall not charge the infant's family for any services (including room fees) related to this diagnostic evaluation.**

If you have any questions, please contact the following:

NBS Coordinator \_\_\_\_\_ Phone \_\_\_\_\_

Area Service Center \_\_\_\_\_ Phone \_\_\_\_\_

Attachments: (1) CCS Application    (2) Copy of the positive NBS report

\*The application can also be downloaded from  
<http://www.dhs.ca.gov/pcfh/cms/ccs/publications.htm>. Click on DHS 4480 (English or Spanish)

cc: \_\_\_\_\_ County CCS program \_\_\_\_\_ Fax \_\_\_\_\_

TO: MEDICAL DIRECTORS OF CALIFORNIA CHILDREN'S SERVICES (CCS) APPROVED METABOLIC AND CYSTIC FIBROSIS (CF)/PULMONARY SPECIAL CARE CENTERS (SCCs)

SUBJECT: EXPEDITING DIAGNOSTIC SERVICES FOR INFANTS REFERRED BY THE CALIFORNIA NEWBORN SCREENING (NBS) PROGRAM

The California NBS Program will expand on or before August 1, 2007, to include CF and Biotinidase Deficiency (BD), both CCS eligible medical conditions. Pilot testing has already begun around the state. In the past, the Genetic Disease Branch (GDB) and the CCS program have jointly developed a plan to ensure that infants with positive NBS reports receive timely diagnostic evaluations at CCS-approved SCCs. This plan will also apply for babies with positive NBS reports for CF and BD. Your assistance is needed to ensure expedited diagnostic evaluations for infants with positive NBS tests for CF and BD.

CCS and the NBS programs have developed an "Expedited Diagnostic Service Request" form (enclosed with this letter). Receipt of this form (completed by the NBS Coordinator) ensures that the SCC Medical Director will be guaranteed reimbursement for the initial office visit and evaluation, and ensures that the SCC will make timely appointments for these services prior to receipt of a CCS authorization.

When the NBS Coordinator notifies the specialist at the SCC of the positive NBS result, the Coordinator will fax the SCC a completed "Expedited Diagnostic Service Request" form, along with a CCS application and the positive NBS report. The only variation to this procedure would be when the NBS Coordinator receives the positive screen on a holiday or weekend. The Coordinator may instead give the information verbally to the SCC and fax the documents on the next business day. The NBS Coordinator will also fax a "New Referral CCS/GHPP Client Service Authorization Request" to the county CCS office or CMS Branch Regional Office.

To facilitate receipt of the authorization from the CCS program, the SCC should assist the family in completing and signing the CCS application. The CCS application will be faxed by the NBS Coordinator. The application can also be downloaded from <http://www.dhs.ca.gov/pcfh/cms/ccs/publications.htm> by clicking on DHS 4480 (English or Spanish). Please fax the completed application to the local County CCS program. Your assistance with the completion of the CCS application will further enable timely evaluations of these infants with positive screening tests.

The County CCS program or CMS Regional Office will authorize a diagnostic evaluation for **ALL** infants referred by the NBS Program. The initial authorization

will be for three months and may be extended as needed. These authorizations shall be issued within five working days of receipt of all the following documentation:

- “New Referral CCS/GHPP SAR” form (from NBS Coordinator),
- “Expedited Diagnostic Service Request” form (from NBS Coordinator),
- Positive NBS report (from NBS Coordinator), and
- The CCS application (preferably faxed from the SCC).

CCS authorizations will include the following information or similar language: Provider must bill other health insurance (OHC) first; submit Explanation of Benefits (EOB) with claim.

Thank you for your continued commitment to infants and children with special health care needs and their families. I realize scheduling appointments for these infants with positive screens will require juggling of appointment calendars, but the critical need for these babies to be seen quickly necessitates that we all make adjustments in the way we normally provide services.

If you have questions about the described procedure, you may contact the appropriate NBS Coordinator/Area Service Center.

Marian Dalsey, M.D., M.P.H., Chief  
Children’s Medical Services Branch

Enclosure

cc: Fred Lorey, Ph.D., Acting Chief  
Genetics Disease Branch  
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Kathleen Velazquez, M.P.H., M.A., Chief  
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Genetics Disease Branch  
Department of Health Services  
850 Marina Bay Parkway, Room F175  
MS 8200  
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### **CCS Approved Metabolic SCCs**

Cedars –Sinai Medical Center  
Children’s Hospital and Research Center at Oakland  
Children’s Hospital of Central California  
Children’s Hospital of Los Angeles  
Children’s Hospital of Orange County  
Harbor-UCLA Medical Center  
Kaiser Permanente Northern California (Oakland)  
Kaiser Permanente Southern California (Los Angeles)  
LAC-USC Medical Center  
Lucile Salter Packard Children’s Hospital  
Rady Children’s Hospital, San Diego  
Sutter Medical Center (Sacramento)  
UC Davis Medical Center  
UC Irvine Medical Center  
UC Los Angeles Medical Center  
UC San Francisco

### **CCS Approved Endocrine SCCs**

Cedars –Sinai Medical Center  
Children’s Hospital and Research Center at Oakland  
Children’s Hospital of Central California  
Children’s Hospital of Los Angeles  
Children’s Hospital of Orange County  
Harbor-UCLA Medical Center  
Loma Linda University Medical Center  
Lucile Salter Packard Children’s Hospital  
Miller Children’s at Long Beach Memorial Medical Center  
Rady Children’s Hospital, San Diego  
Santa Clara Valley Medical Center  
Sutter Medical Center (Sacramento)  
UC Davis Medical Center  
UC Los Angeles Medical Center  
UC San Francisco

### **CCS Approved Sickle Cell SCCs**

Cedars –Sinai Medical Center  
Children’s Hospital and Research Center at Oakland  
Children’s Hospital of Central California  
Children’s Hospital of Los Angeles  
Children’s Hospital of Orange County

City of Hope Medical Center  
Harbor-UCLA Medical Center  
Kaiser Permanente Northern California (Oakland)  
Kaiser Permanente Southern California (Los Angeles)  
Loma Linda University Medical Center  
LAC-USC Medical Center  
Lucile Salter Packard Children's Hospital  
Miller Children's at Long Beach Memorial Medical Center  
Rady Children's Hospital, San Diego  
Sutter Medical Center (Sacramento)  
UC Davis Medical Center  
UC Irvine Medical Center  
UC Los Angeles Medical Center  
UC San Francisco

### **CCS Approved Pulmonary SCCs**

California Pacific Medical Center (San Francisco)  
Children's Hospital and Research Center at Oakland  
Children's Hospital of Central California  
Children's Hospital of Los Angeles  
Children's Hospital of Orange County  
John Muir Medical Center (UC San Francisco Satellite)  
Loma Linda University Medical Center  
Lucile Salter Packard Children's Hospital  
Miller Children's at Long Beach Memorial Medical Center  
Rady Children's Hospital, San Diego  
Sutter Medical Center (Sacramento)  
UC Davis Medical Center  
UC San Francisco  
Ventura County Medical Center (CHLA Satellite)