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To Whom It May Concern:

With the advent of the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, we understand you may have concerns about whether hospital, medical office, and California Children's Services Center staff can disclose confidential personal information of their patients who are participants in the California Department of Public Health (CDPH) Newborn Screening (NBS) Program, to the CDPH Genetic Disease Screening Program (GDSP) staff and to CDPH-contracted NBS Area Service Center staff. Therefore, we want to assure you of the legal authority to disclose this information to these entities.

GDSP is authorized to coordinate "a statewide program of information, testing, and counseling services," in the area of genetic disorders, and is responsible for designating the tests and establishing regulations (H&S 125000). Authority for the program is located in Health and Safety Code sections 124975 et. Seq. and in the regulations in Title 17 CCR, sections 6500 et. seq. GDSP operates the statewide NBS Program and is authorized to conduct or contract with NBS Area Service Centers to conduct the tests required (H&S 125000). The regulations define the specifics of the processes. Birth attendants, laboratories and hospitals are required to collect blood specimens from newborns (17 CCR 6505) and submit the specimens to the GDSP contracted laboratories for testing for hereditary disorders (17 CCR 6501 and 6503). The laboratories report the test results to GDSP (17 CCR 6503) and mail the blood specimens to GDSP. NBS Area Service Center personnel function as agents of the GDSP in this function.

The HIPAA Privacy Rule specifically permits health care providers to disclose protected health information for public health activities to a public health authority that is authorized by law to receive such information for the conduct of public health surveillance. (See 45 Code of Federal Regulations (CFR) § 164.512 (b) 1.) California state laws mandate the provision of information to the GDSP and although this information is considered to be Protected Health Information (PHI) under HIPAA, the mandate to provide it to GDSP personnel under state law is not pre-empted by HIPAA. Furthermore, because this information is being transmitted for purposes of "treatment, payment and/or health care operations" it is also permissible under the HIPAA Privacy Rule without the execution of Business Associate Agreements.

Therefore, under HIPAA, you may share medical information with GDSP and NBS Area Service Center staff information collectors without obtaining a separate authorization for this purpose [See Privacy Rule, Section 164.512(b)(1) and California Code of Regulations, Section 6505(j)]. Furthermore, the information being requested represents the minimum necessary to carry out the public health purposes of the GDSP. The Privacy Rule provides that health care practitioners may rely on a requested disclosure as the minimum necessary for the stated purposes when making disclosures to public officials or their contractors or agents.. (See 45 CFR § 164.514(d).)

In addition, GDSP must by regulation keep this information confidential: "All information, records of interview, written reports, statements, notes, memoranda, or other data procured by an individual, group or research team in the course of any testing \* \* \* shall be confidential and shall be used solely for the purposes of medical intervention, counseling, or specific research project approved by the Department." (17 CCR 6502.1(a).))

We appreciate your cooperation with our required data collection efforts and ask you to please share this information with key staff within your facility, including your Privacy Officer. All Newborn Screening Program state and Area Service Center personnel visiting your facility will be carrying identification and copies of this letter to show anyone questioning their authority or activities. Additionally, they will fax these documents to you upon request when they phone your facility to obtain information about specific babies.

Sincerely,



Fred Lorey, PhD, Acting Chief,  
Genetic Disease Screening Program



Kathleen Velazquez, MPH, MA, Chief  
Newborn Screening Branch