

Federal Privacy, Security, and Laboratory Testing Regulations Relevant to the Sharing of Newborn Screening Test Result Information

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Overview

This document is a companion to the Office of the National Coordinator for Health Information Technology (ONC) Newborn Screening Use Case and provides relevant information on the Federal privacy, security, and laboratory testing regulations that may be applicable to the electronic exchange of newborn screening results by persons implementing the use case. This document does not define new policy or regulatory considerations but rather provides information primarily on the application of certain federal laws to the exchange of mandatory newborn screening test results for treatment and public health purposes. The document also identifies instances where certain organizational relationships may affect the applicability of certain regulations.

The recommendation letter [http://www.hhs.gov/healthit/documents/m20080226/phc_letter.html] presented by the Personalized Healthcare Workgroup to the American Health Information Community (AHIC) at the February 2008 AHIC Meeting [Newborn Screening Tests] includes a discussion of the confidentiality, privacy, and security issues that are specific to newborn screening. As a first step towards identifying some of the challenges that are unique to the electronic exchange of newborn screening in terms of confidentiality, privacy and security, this document aims to support the Newborn Screening Use Case by exploring some of the key aspects of applicable federal law.

The following sections provide a general discussion of how the Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule, HIPAA Security Rule, and the Clinical Laboratory Improvement Amendments of 1988 (CLIA) and implementing regulations govern disclosure in the context of the ONC Newborn Screening Use Case. Also included is a general review of Medicaid regulations that would apply when a state Medicaid program plays a role in the disclosure of newborn screening results.

This Use Case companion document will provide valuable information for the benefit of affected stakeholders, including newborn screening program officials, public health entities, health care providers, parents and other caregivers.

Confidentiality, Privacy, and Security Issues Specific to Newborn Screening

The AHIC, in consideration of the use case development, also addressed the topic of newborn screening data disclosure with the following overview of the issues:

“Secure communication is critical to the patient-family/physician relationship, contributing to the quality of care and improved health outcomes. Sharing of newborn screening results is common and necessary for effective and timely use of newborn screening results and directing appropriate responses to those results. Several aspects of

the newborn screening process present unique challenges with respect to clinically appropriate sharing and transmission of results. First, it is common that a newborn's name changes between when the test is performed and when the results need to be reported. Second, the clinician ordering the newborn screening tests is usually not the same clinician who will be acting as the infant's primary care provider. Third, situations commonly arise when infants are born in one state while their family's primary residence and the location of the primary care provider may be in a different state."

Because state law can impact how newborn screening results are shared, it is important for health care providers and others involved in laboratory test results reporting to better understand the application of privacy and security laws and how the exchange of newborn screening results across state lines may be affected in order to enable appropriate sharing of this information. Improving understanding of these laws may alleviate barriers to the effective and timely exchange of newborn screening results. When considering electronic reporting of newborn screening results, the need for timely communication and sharing of screening results among appropriate clinicians and protections against inappropriate disclosure of screening results are important factors.

Scope of the ONC Newborn Screening Use Case

The Secretary of Health and Human Services accepted the recommendation of the AHIC to develop a Newborn Screening Use Case that includes both early hearing detection and intervention (EHDI) and newborn dried blood spot screening (NDBS) test results. In this document, the term "result" refers to the interpretation of and related data about mandatory laboratory screening tests performed in the newborn period for the purposes of identifying infants that may possibly have clinically undetectable serious health conditions. Additional confirmatory tests are needed in most if not all cases to make a determination of a disease or condition.

The use case recommendation letter includes a discussion of two scenarios regarding the electronic exchange of newborn screening results. The first scenario includes the initial screening tests and ends with review of a normal result or the beginning of confirmatory testing for abnormal or out of range results. The second scenario includes confirmatory testing, consultations and referrals, public health reporting of an established diagnosis, referral for treatment including dietary and educational services, and sharing of de-identified data for research and program evaluation. Privacy considerations for the second scenario are shared with other use cases and practice activities which generally are not unique to newborn screening.

Several other important aspects that relate to the considerations of privacy and security and laboratory test result reporting are important to note, for example, the analytic testing location may differ based on the type of screening tests that is performed. NDBS is performed in a laboratory while EHDI is normally performed at the bedside, office, or clinic. Certain privacy considerations that apply to laboratory tests will apply to NDBS but may not be relevant for disclosure of the results of EHDI testing.

Central Newborn Screening Issues to be addressed in the Use Case

This analysis will focus on two issues central to newborn screening:

- **Disclosure of Results by a laboratory, public health agency, birth hospital, or provider who ordered the test to a treating provider other than the provider who ordered the test:** This activity is essential to newborn screening because the provider who will be treating the infant at the time that the results are available may not be known at the time the initial screening test is ordered. It is also essential to completion of the newborn screening process because consultants and specialists involved in the confirmatory and diagnostic process will need access to initial screening results.
- **Disclosure of Results by a laboratory, public health agency, provider, or birth hospital across state lines:** This is essential to newborn screening because the infant may reside or may receive treatment in a state other than the one in which the child was born and the initial screening test was ordered or the screening test was performed.

Importance of Identifying and Specifying the Actors in the Exchange of Newborn Screening Results

The relevant privacy, security, and laboratory testing regulations depend on the specific entities that are requesting and disclosing newborn screening results electronically. In some cases, the disclosing party may be:

- The laboratory that performed the tests;
- The public health entity that is responsible for the state newborn screening program and is responsible for sending the reports;
- The provider who ordered the screening tests but is not involved in the subsequent patient care; or
- The hospital or other provider that maintains medical records and is the birth facility where an infant was born, which almost always should receive a copy of the results and which may receive requests from other providers because the parents identify the hospital or other provider as the location where the screening was done.

It is also important to identify if the provider or entity who is issuing the request for a patient's test results and will be receiving them:

- Is currently treating the infant or is the specialist to whom the infant has been referred for treatment;
- Was the ordering provider at the hospital; or
- Was identified as a "copy to" provider at the time the original test was ordered.

State Laws Affect the Disclosure of Newborn Screening Results across State Lines

State laws governing the practice of medicine or laboratory operations can dramatically affect the disclosure of results across state lines. Federal privacy laws, such as HIPAA, must also be complied with, but do not distinguish between disclosures within a state or across state lines.

Implications for Health Information Exchanges and the Nationwide Health Information Network

Electronic Health Information Exchanges (HIEs) and the Nationwide Health Information Network (NHIN) support the electronic exchange of personal health information and it is anticipated that newborn screening results will also be exchanged through these methods at some point in the future. An HIE and/or the NHIN may be utilized to carry out discrete point-to-point transmission of the newborn screening results to a specific provider who is the ordering provider or a "copy to" provider that was named on the test order, just as such results may be transmitted directly from the laboratory to the primary care, subspecialty care or other provider. However, federal privacy and security regulations under HIPAA may require the disclosing entities to obtain privacy and security assurances through contract with the HIEs, where applicable.

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Applicability

CLIA regulations apply to certain "laboratories" (as defined in the CLIA regulations) that test human specimens for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings. Such facilities are subject to a number of regulatory requirements and limitations, including limitations on the disclosure of laboratory test results. In determining from whom/what newborn screening results can be obtained, it is therefore necessary to determine whether the entity being asked to make the disclosure is subject to the CLIA regulations (i.e., a CLIA laboratory).

- Public health laboratories that perform their own newborn screening tests would be subject to CLIA. Disclosures by such laboratories of newborn screening test results are subject to the CLIA limitations on such disclosures.
- When a public health laboratory conducts the testing and sends out a laboratory test report containing the newborn screening test results for a patient in accordance with the CLIA requirements, unless the entity receiving the test result is also a CLIA laboratory, the CLIA limitations on disclosure of test results will not apply to any subsequent re-disclosure of the test results by that receiving party.
- When an outside contract laboratory performs the newborn screening tests, it may only disclose the laboratory test results as permitted by CLIA. If that outside contract laboratory sends out a laboratory test report containing the newborn screening test results for a patient in accordance with the CLIA requirements, unless the entity receiving the test result is also a CLIA laboratory, the CLIA limitations on disclosure of test results will not apply to any subsequent re-disclosure of the test results by that receiving party.
- Relevant CLIA provisions are found at 42 CFR §§ 493.2 and 493.1291(f)

Clinical Laboratory Improvement Amendments of 1988 (CLIA) Requirements

- Under CLIA, the laboratory may only disclose results to:
 - Authorized persons (defined below);
 - The person responsible for using the test results (a treating provider); and
 - The referring lab in a reference lab scenario.
- "Authorized persons" is defined by CLIA to be "an individual authorized under state law to order tests or receive test results, or both." Such State laws vary widely, but generally include the ordering provider and may also include the patient or even any licensed practitioner. Newborn screening tests are required by state law and thus the specific

provisions of each state's newborn screening laws and associated reporting requirements will govern to whom CLIA laboratories may disclose newborn screening results under the "authorized persons" provision of CLIA.

- CLIA permits laboratories to send copies of results to “copy to” providers who are identified by the ordering provider at the time the order is placed. This would cover reporting to a primary care provider identified by the patient before the time the specimen is obtained in the hospital.
- In some states, a patient may be an authorized person and thus may obtain copies of their own results from the laboratory, but this is not true in all states.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Applicability

The HIPAA Privacy and Security Rules apply to covered entities. In addition, the Rules require covered entities to obtain certain privacy and security assurances through contract with their business associates. Thus, it is essential to determine if the entity that is disclosing newborn screening results is a covered entity under HIPAA or a business associate of a HIPAA covered entity. The definition of a covered entity is found at 45 CFR § 160.103 and means an entity that is a health plan, health care clearinghouse, or a covered health care provider (a health care provider that electronically conducts certain covered transactions, such as electronically billing a health plan). The HIPAA Security Rule requires reviewing and modifying, where necessary, security policies on a regular basis. This is particularly relevant for organizations that allow remote access to electronic protected health information through portable devices or external systems or hardware not owned or managed by the covered entity.

Provided here are considerations of applicability:

- The hospital where the infant was born and the initial screening test was ordered is generally a covered entity because it is providing health care and conducts some transactions (such as billing) electronically.
- State Medicaid programs are expressly named as covered entities under the HIPAA Privacy Rule. They are "health plans."
- A health department or other public health entity may or may not be a covered entity depending on whether it (including its components) is a health plan or covered health care provider. If a health department or public health entity is a covered entity, it may designate those components that perform covered functions (e.g., those activities that make it a provider or a health plan) as the health care component(s) of the organization and thereby become a type of covered entity known as a “hybrid entity.” In the case of a hybrid entity, most of the requirements of the HIPAA Privacy and Security Rules apply only to the hybrid entity’s health care component(s).
- A laboratory is a covered entity if it electronically conducts covered transactions (such as billing) for any of its health care services.
- Some state public health laboratories or other laboratories may not be covered entities if they do not electronically bill for their services or electronically conduct other HIPAA covered transactions, and if they are not otherwise part of a covered entity. Such laboratories need not comply with HIPAA with respect to the disclosure of newborn screening results.
- The definition of a covered entity is found in 45 CFR § 160.103.

- The definition of a business associate is found in 45 CFR § 160.103.

Health Insurance Portability and Accountability Act of 1996 (HIPAA) Privacy Rule Requirements

- Under the HIPAA Privacy Rule, patient authorization is not required to disclose medical information for treatment purposes. Therefore, the hospital where the infant was born may disclose newborn screening results, without a HIPAA authorization, to a primary care provider or a consulting physician who is seeing the child due to abnormal or out-of-range screening results, since such a disclosure is for the treatment of the infant. However, there nevertheless may be state law that requires consent or authorization in such cases.
- Further, a covered entity is not required to have a business associate agreement in place in order to disclose protected health information to a health care provider concerning the treatment of an individual. Thus, a hospital or a public health laboratory that is a covered entity may disclose protected health information to another laboratory for screening or other treatment purposes, without a business associate agreement.
- The HIPAA public health authority provisions allow a covered entity, such as a covered laboratory or hospital, to disclose newborn screening results, without patient authorization, to a public health authority for public health activities. Whether the reporting of newborn screening results qualifies under this provision depends on whether the disclosure is to a public health authority that is authorized by law to receive the results. The HIPAA public health provision is specified in 45 CFR § 164.512(b).
- The HIPAA Privacy Rule also allows a covered entity to disclose newborn screening results to a public health agency (or other entity) without patient authorization where such disclosure is required by state or other law. The HIPAA provision for disclosures required by law is specified in 45 CFR § 164.512(a).
- HIPAA generally provides for a right of access to records, granting patients the right to review their records. The parent of a minor generally has the right of access to the minor's records, including a right of access to newborn screening results.
- The HIPAA Privacy Rule generally provides patients the right to have corrections made to their records, if errors are identified by the patient. If the covered entity disagrees with the requested changes, the Privacy Rule provides the patient with the right to have a statement of disagreement added to the record.
- When both HIPAA and CLIA apply, HIPAA defers to CLIA regarding a patient's right of access. If applicable state law does not consider a patient an "authorized person" as that term is defined by CLIA, HIPAA does not provide a right of access by patients to their records maintained by a laboratory. However, the patient still has a right of access through any covered entity that receives test results from a laboratory, such as a public health department that is also a covered entity, a covered hospital, or a covered physician's office.

Medicaid Applicability

The Medicaid program has statutory and regulatory provisions governing the use and disclosure of Medicaid beneficiary records that are separate from HIPAA and CLIA. These additional

requirements must be satisfied if a state Medicaid agency is to disclose newborn screening results from their Medicaid records. This may occur through the Medicaid state agency's involvement in administering the Early Periodic Screening and Development Testing (EPSDT) programs that are required by Medicaid. Relevant Medicaid regulations are found at 42 CFR §§ 431.300 and 431.302.

Identifying State Law Requirements

Federal agencies do not generally monitor or interpret state laws. Federal agencies defer to the States' Attorneys General on the interpretation of their respective state laws.

Importance of Review of Individual Situations

This document is intended to provide general information for consideration of key issues regarding the electronic exchange of newborn screening results. The document contains general information but should not be construed as legal advice to be applied to any factual situation. For legal advice, the reader should consult the applicable federal and state laws and a knowledgeable attorney licensed in the appropriate jurisdiction.