



Newborn Screening HIPAA Guidance

Newborn screening programs may have questions regarding HIPAA regulations and their applicability to NBS program operations. Programs may be interested in more information on:

1) *Their status as a HIPAA covered entity.*

Each NBS program should undergo a HIPAA analysis that is periodically reviewed by their state department of health legal counsel. HIPAA covered entity status is based on billing transactions. The following resources can assist in determining whether your program is considered a HIPAA covered entity:

[CMS covered entity guidance tool](#)

[CMS guidance on electronic transactions](#)

[HHS guidance for covered entities and business associates](#)

[CMS transactions overview](#)

2) *Whether they can obtain protected health information (PHI) from HIPAA covered entities.*

A covered entity must obtain a written authorization from the individual, for the use and disclosure of PHI **unless** the disclosure is to the individual for treatment, payment, or health care operations, or **the disclosure falls under one of the specified exceptions.**

The HIPAA privacy rule, specifically 45 CFR¹ §164.512, addresses the uses and disclosures of PHI for which an authorization or an opportunity to agree or object is not required. Specifically:

- Section 164.512(a) permits disclosures that are required by law, including state statutes and rules²; and
- Section 164.512(b) permits a covered entity to disclose PHI to:

“(i) A public health authority that is **authorized by law to collect or receive** such information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to, the reporting of disease, injury, vital events such as birth or death, and the conduct of public health surveillance, public health investigations, and public health interventions; . . .”

Under the HIPAA privacy rule, 45 CFR 164.501, **public health authority** is defined as “an agency or authority of

... a State . . . **that is responsible for public health matters as part of its official mandate.**”

Therefore, to the extent that a public health authority is authorized by law to collect or receive information for public health purposes, covered entities may disclose PHI to the public health authority without the patient's authorization.

Please note that the above information should not be construed as legal advice. For legal advice, consult with a lawyer in your state. If you have further questions related to HIPAA and NBS program operations, the APHL Legal and Legislative Issues in Newborn Screening Workgroup is willing to provide assistance. Please contact [Laura Russell](#) for more information.

References

¹ CFR is the Code of Federal Regulations

² 45 CFR 164.103, Definition of "Required by law."

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