

**WISCONSIN DIVISION OF PUBLIC HEALTH
BUREAU OF COMMUNITY HEALTH PROMOTION
WISCONSIN BIRTH DEFECT PREVENTION AND SURVEILLANCE SYSTEM
WISCONSIN BIRTH DEFECTS REGISTRY
SECURITY AND CONFIDENTIALITY POLICY**

I. Background

As a public health authority for maternal and child health under sections 250.04 and 253.02 Wisconsin Statutes, as required by section 253.12 Wisconsin Statutes, and with the support of the Wisconsin Department of Health Services (DHS), the Division of Public Health (DPH) has created the Wisconsin Birth Defect Prevention and Surveillance System (WBDPSS) that includes the Wisconsin Birth Defects Registry (WBDR).

The WBDPSS goals are to: (1) obtain a baseline count of birth defects, (2) help identify risk factors for birth defects, (3) help assess prevention strategies, (4) aid in planning for service needs, and (4) provide services to affected individuals. The WBDR is a data reporting system used for reporting birth defects throughout Wisconsin for children born in Wisconsin and/or receiving services in Wisconsin from birth to age two.

Protecting the privacy and rights of clients and the security of information contained in the WBDR is a high priority for the Department of Health Services, Division of Public Health. Access to the WBDR is limited to public health authorities and their authorized agents. Public health and other agency staff employed by a state or local agency who wish to have access to and use the WBDR must read this Security and Confidentiality Policy and sign the WBDR User Security and Confidentiality Agreement (DHS form F-40056). The signed document contains details about the use of data contained in the WBDR. Breach of confidentiality will result in the removal of the user's access privileges to the WBDR and may result in civil or criminal penalties for improper disclosure of health information.

II. The WBDR and the Health Insurance Portability and Accountability Act of 1996 (HIPAA)

The WBDR data model is based on the CDC National Electronic Disease Surveillance System (NEDSS) which is compliant with the data privacy standards established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Balancing the protection of individual health information with the need to protect public health, the Privacy Rule permits disclosures without individual authorization to public health authorities authorized by law to collect or receive information for the purpose of preventing or controlling disease, injury, or disability, including but not limited to public health surveillance, investigation, and interventions.

In the administration of the WBDR, DPH as a Public Health Authority is allowed by the HIPAA regulations in 45 CFR 164.512(b) to obtain protected health information. For purposes of this program, DPH is not a Health Plan, Health Care Clearinghouse, or Health Care Provider under HIPAA. DPH also does not engage in activities, which fall within the HIPAA "business associate" definition set forth in 45 CFR 160.103.¹

State and local organizations may use the WBDR to document the incidence of birth defects, report information about children affected, and document whether children have been referred for services. This may include HIPAA-exempt public health authority functions, exempt non-covered functions, and HIPAA-covered functions. It remains the responsibility of HIPAA-covered state and local organizations using the WBDR to abide by the privacy rule provisions.

III. Access to the Wisconsin Birth Defects Registry Data

Access to the WBDR is limited to DHS public health authorities and their authorized agents. Public health authorities include federal public health agencies, tribal health agencies, state public health agencies, local public health agencies, and anyone performing public health functions under a grant of authority from a public health agency. Public health agencies often conduct authorized public health activities with other entities using different mechanisms (e.g., contracts and memoranda or letters of agreement). These other entities are public health authorities with respect to the activities they conduct under a grant of authority from such a public health agency.

The information contained in the Wisconsin Birth Defects Prevention & Surveillance System is accessed in the following manner:

Client demographic information is in the secure statewide WBDR to aid in deduplication of records and to coordinate and refer clients for appropriate public health services. Required WBDR fields include the child's and parents' first and last names, child's and parents' race and ethnicity, child's full address, child's and parents' dates of birth, child's birth

¹ Department of Health and Human Services, Centers for Disease Control and Prevention, 2003. HIPAA Privacy Rule and Public Health, Morbidity and Mortality Weekly Report Vol. 52 (1-20).

plurality and birth order (if a multiple birth), the name and address of the birth hospital, and at least one reportable birth defect. All individually identifiable information is protected by privacy and confidentiality requirements.

Information is reported via a secure website or on paper forms that are entered into the secure database by the WBDR state administrator. Reporters may enter and submit one report at a time or create a flat file from electronic medical records and upload the file to the secure website. Access to the website and database is strictly controlled according to the user's role. Users are categorized into one of the following user roles:

- State Administrator – employed by the DHS Division of Public Health; oversees the WBDR
- Epidemiologists – DHS Division of Public Health data users/analysts
- Local Administrators – assign and oversee reporters and may also submit reports
- Reporters – directly access the WBDR to submit reports

The State Administrator is primarily responsible for granting user access and is the gatekeeper for the WBDR and all data contained within. Epidemiologists are granted temporary access to the database for specific program needs and to create reports and perform analyses. Local Administrators are responsible for all reporters within their reporting entity. Reporters can submit reports and view reports from their own reporting entity and not from any other reporting entity.

IV. User Participation

Every individual who wishes to participate as a user of the WBDR must sign and adhere to the WBDR User Security and Confidentiality Agreement. Any misuse of the WBDR will subject the user to revocation of access privileges and may result in civil or criminal penalties for improper disclosure of health information.

In accordance with the HIPAA Privacy Rule, state and local organizations that are HIPAA covered entities will provide privacy training regarding their internal policies and procedures to all personnel who access the WBDR. Participating individuals assume responsibility for their own use of WBDR. Only personnel whose assigned duties include functions associated with public health services will be given access to the WBDR. All personnel including permanent and temporary employees, volunteers, contractors and consultants are required to sign a WBDR User Security and Confidentiality Agreement before gaining access to the WBDR. When users terminate employment or take an extended leave of absence, the WBDR account must be removed immediately.

Access to the WBDR will be allowed only through WBDR approved access procedures. Each user granted access to the WBDR must have a unique login ID and password. Users are prohibited from disclosing WBDR access codes or protocol to unauthorized persons. Site administrators will ensure that users are adequately trained to use the WBDR and are not given any higher level of access than necessary to perform assigned duties.

The parent, guardian, or legal custodian has the right to examine any data about the child in the WBDR and to request amendments to information. Disclosure of information from the WBDR must be in accordance with state and federal applicable laws. All subpoenas, court orders, and other legal demands for WBDR data received by any authorized user of the WBDR must be forthwith brought to the attention of the WBDR local organization administrator and the local organization security officer who will consult with the local organization legal counsel.

If the client, parent, guardian or legal custodian chooses to request that personally identifiable information be removed from the WBDR, that decision will be honored. Under the provisions of DHS 116.01, as of September 2017, identifying information may be removed from the WBDR by completing and submitting an opt-out form available on request from DHS or available for download on the Wisconsin Birth Defects Prevention and Surveillance System website at: www.dhs.wisconsin.gov/cyshcn/birthdefects.

State and local organizations using WBDR data for research purposes must adhere to existing state and federal research provisions and confidentiality laws and statutes. The WBDR State Administrator, DPH State Security Officer, and their authorized agents, may audit activities on the WBDR to ensure the ongoing security of the data contained therein. Each DHS employee or agent having access to the WBDR is required to sign a WBDR User Security and Confidentiality Agreement.