

Chapter HFS 116

WISCONSIN BIRTH DEFECT PREVENTION AND SURVEILLANCE SYSTEM

HFS 116.01 Authority and purpose.
HFS 116.02 Applicability.
HFS 116.03 Definitions.

HFS 116.04 Reporting of birth defects.
HFS 116.05 Confidentiality.

Note: Chapter HSS 116 was renumbered ch. HFS 116 under s. 13.93 (2m) (b) 1., Stats., and corrections were made under s. 13.93 (2m) (b) 6. and 7., Stats, Register, May, 1998, No. 509.

Note: Chapter HFS 116 as it existed on March 31, 2003, was repealed and a new chapter HFS 116 was created effective April 1, 2003.

HFS 116.01 Authority and purpose. This chapter is promulgated under the authority of ss. 227.11 (2) and 253.12 (3) (a), Stats., to implement the Wisconsin birth defect prevention and surveillance system established by s. 253.12, Stats. The purpose of the program is to provide for:

(1) Reporting to the department of information about birth defects in infants and children from birth to age 2.

(2) Analysis by the department of that information.

(3) Dissemination by the department of that information in a collective, non-identifying form for public policy formulation and epidemiological research uses.

(4) Release by the department of that information in certain circumstances in a form that specifically identifies a child only with informed written consent of the parent or guardian to selected persons and agencies.

History: CR 02-117: cr. Register March 2003 No. 569, eff. 4-1-03.

HFS 116.02 Applicability. This chapter applies to all of the following:

(1) The department.

(2) A physician who diagnoses a birth defect in a child, treats a child with a reportable condition or identifies a child with a suspected case of a reportable condition.

(3) A pediatric specialty clinic that diagnoses a birth defect in a child, treats a child with a reportable condition or identifies a child with a suspected case of a reportable condition.

(4) A hospital that diagnoses a birth defect in a child, treats a child with a reportable condition or identifies a child with a suspected case of a reportable condition.

(5) Local health officers, local birth to 3 programs, and agencies under contract with the department to administer the children with special health care needs program.

(6) Any other agency that requests reportable information from the department.

(7) A child about whom the department collects, maintains and discloses reportable information.

(8) The parent or guardian of the child about whom the department collects, maintains and discloses reportable information.

(9) Researchers who request reportable information from the department.

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HFS 116.03 Definitions. In this chapter:

(1) "Agency" means an organization that assists or uses information about persons with birth defects.

(2) "Birth defect" has the meaning given in s. 253.12 (1) (a), Stats.

(3) "Child" has the meaning given for "infant or child" in s. 253.12 (1) (c), Stats.

(4) "Child-identifiable data" means information that would identify a child, including the child's name, address or social security number, or the parent's or guardian's name, address or social security number.

(5) "Department" means the Wisconsin department of health and family services.

(6) "Guardian" has the meaning given in s. 48.02 (8), Stats.

(7) "Local health officer" has the meaning given in s. 250.01 (5), Stats.

(8) "Parent" has the meaning given in s. 48.02 (13), Stats.

(9) "Pediatric specialty clinic" has the meaning given in s. 253.12 (1) (b), Stats.

(10) "Physician" has the meaning given in s. 448.01 (5), Stats.

(11) "Registry" means a database comprised of birth defect or suspected birth defect reports submitted by pediatric specialty clinics, physicians, and hospitals.

(12) "Reporter" means a physician, pediatric specialty clinic or hospital that is required or authorized by s. 253.12 (2), Stats., to convey birth defect or suspected birth defect information to the department.

(13) "Suspected birth defect" means that, on the basis of recognized medical testing and evaluation, a child is thought to have a birth defect, but the results of the testing and evaluation are not conclusive.

(14) "Wisconsin birth defects prevention and surveillance system" means the program established by s. 253.12, Stats.

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HFS 116.04 Reporting of birth defects. (1) BIRTH DEFECTS FOR WHICH REPORTING IS MANDATORY. Reporters shall report to the department a birth defect or suspected birth defect listed in Appendix A for children in whom the condition is diagnosed or treated by age 2.

(2) RESPONSIBILITIES FOR REPORTING. (a) Except as provided in par. (b), the following persons shall report a birth defect or suspected birth defect to the department:

1. A physician who diagnoses a birth defect or treats a child with a birth defect or identifies a suspected birth defect or treats a child with a suspected birth defect.

2. A pediatric specialty clinic that diagnoses a birth defect or treats a child with a birth defect or identifies a suspected birth defect or treats a child with a suspected birth defect.

(b) No person specified under par. (a) 1. or 2. need report under this subsection if that person knows that another person specified under par. (a) 1. or 2. or par. (c) has already reported to the department the information required under sub. (3) with respect to the same birth defect or suspected birth defect of the same child.

(c) A hospital that diagnoses a birth defect or treats a child with a birth defect or identifies a suspected birth defect or treats a child with a suspected birth defect may report the birth defect or suspected birth defect to the department.

(d) The department may not require a reporter under par. (a), (b) or (c) to provide the name of a child to the department if the child's parent or guardian does not consent in writing to the release of the name or address of the child to the department.

(3) REPORT CONTENT AND FORMAT. (a) Each report of a child with a birth defect or suspected birth defect shall include the core data items for collection listed in Appendix B, except as provided in sub. (2) (d).

(b) Reports shall be submitted to the department on paper or electronically in a format prescribed by the department.

Note: Reports may be mailed to the Wisconsin Children with Special Health Care Needs Program – Attention Birth Defects Registry, 1 West Wilson Street, P.O. Box 2659, Madison, WI 53701-2659. Reports may be faxed to the Birth Defects Registry at 608-267-3824. A copy of the form to be used for reporting birth defects or suspected birth defects may be obtained by writing the Birth Defects Registry at the preceding address or by calling 608-267-9184 or by sending a fax to 608-267-3824.

(4) TIMELINESS OF REPORTS. A report shall be submitted to the department within 15 calendar days after a birth defect or suspected birth defect is identified.

(5) DEPARTMENT RESPONSIBILITIES. (a) The department shall establish and keep an up-to-date registry that complies with s. 253.12 (3) (a) 1., Stats.

(b) The department shall do all of the following:

1. Review each report it receives for completeness and accuracy.

2. Review child-identifiable data to ensure each child is counted only once to maximize the utility of registry information for population-based epidemiological studies as needed.

3. Query reporting sources to substantiate conflicting data.

4. Resolve differences between inconsistent data.

5. Obtain missing or incomplete data.

6. Include submitted data in the registry within 60 calendar days of receiving the data.

(c) If the department determines there is a discrepancy in any data reported to the department, the department may request that the reporter provide the department with related birth defect or suspected birth defect information contained in the child's medical records. The reporter shall provide the information to the department within 10 working days after the date the department transmits the request.

(d) With informed consent, the department shall refer a child with a birth defect or suspected birth defect to a local health officer, a local birth to 3 program or an agency under contract with the department to administer the children with special health care needs program for information, referral or follow-up services.

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HFS 116.05 Confidentiality. (1) RELEASE OF INFORMATION. The department shall keep Wisconsin birth defects prevention and surveillance system reports confidential and may release information from them only in accordance with s. 253.12 (5), Stats., and following the procedures in s. 253.12 (2), Stats.

(2) ACCESS TO INFORMATION. (a) The department may release child-identifiable data only to the following persons:

1. The parent or guardian of a child for whom a report was submitted under s. HFS 116.04 (3), and following a written request. The department may require verification of the parent's or guardian's identity. The department shall send the requested information to the parent or guardian within 10 calendar days following receipt of the written request.

Note: Written requests may be sent to the Wisconsin Children with Special Health Care Needs Program – Attention Birth Defects Registry, 1 West Wilson Street, P.O. Box 2659, Madison, WI 53701-2659. Questions may be directed to the CSHCN Program via telephone at 800-441-4576.

2. The local health officer, the local birth to 3 program, or an agency under contract with the department to administer the children with special health care needs program upon receipt of a written request for information and written informed consent from the parent or guardian of the child.

3. A reporter specified under s. HFS 116.04 (2) for the purpose of verifying information included in a report.

4. a. A representative of a federal or state agency, upon written request from the federal or state agency, and to the extent the information is necessary to perform a legally authorized function

of that agency. In its written request, the agency shall provide the department with written evidence of its legally authorized function.

b. The department shall review and approve or disapprove specific requests by an agency for child-identifiable data.

c. The department shall notify the parent or guardian of a child about whom information is released under this subdivision on the same day that the information is being released to the agency and the purpose for which it is being released.

5. A person performing research under par. (c).

(b) The local health officer, the local birth to 3 program or an agency under contract with the department to administer the children with special health care needs program may disclose information it receives from the department under par. (a) 2. only to the extent necessary to render or coordinate necessary follow-up care or, for local public health officers, to conduct a health, demographic or epidemiological investigation. The local health officer shall destroy all information received from the department under this subdivision no later than 365 calendar days after receiving it.

(c) 1. The department may release child-identifiable information to a person requesting, in writing, information for the purpose of demographic, epidemiological, health or social services research specific to birth defects prevention and surveillance. The person proposing to conduct the research shall submit an application to the department that includes a written protocol for proposed research, the researcher's professional qualifications, a signed agreement to ensure data confidentiality and subject privacy, and any other information requested by the department. If the proposed research involves direct contact with a child or the child's family, the requester shall provide proof of approval by a certified institutional review board or a committee for the protection of human subjects in accordance with the regulations for research involving human subjects required by the federal department of health and human services for projects supported by that agency. The contact may only be made with the written informed consent of the parent or guardian of the subject of the report and the department shall determine whether such contact is necessary to meet the research objectives.

2. The department shall acknowledge the request within 10 calendar days after receiving the request, review the request and, if the request is approved, furnish the information within 30 calendar days after receipt of the approved request.

3. Any person requesting information under this paragraph shall agree in writing to all of the following:

a. That the information provided by the department will be used only for the research approved by the department.

b. That the child-identifiable data provided by the department will not be released to any person except other persons involved in the research.

c. That the final product of the research will not reveal information that may specifically identify the subject of a report under s. HFS 116.04.

d. Any other conditions imposed by the department.

(d) Any informed consent required under this subsection shall contain the name of the requestor, the name of the child whose record is to be disclosed, the purpose of or need for the disclosure, the specific information to be disclosed, the time period for which the consent is effective, the date on which the consent document is signed and the signature of a parent or guardian.

(3) CHARGES FOR REQUESTED INFORMATION. The department may charge all requestors the total actual and necessary costs of producing the requested information.

(4) DATA DESTRUCTION. The department shall, not more than 10 years from the date of receipt of a report under s. HFS 116.04, delete from any file of the department the name of a child that is contained in the report.

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