

ORDER OF THE
DEPARTMENT OF HEALTH AND FAMILY SERVICES
REPEALING AND RECREATING RULES

To repeal and recreate chapter HFS 116, relating to a birth defect prevention and surveillance system.

Analysis Prepared by the Department of Health and Family Services

Beginning in 1989, the Department of Health and Family Services administered a program that collects, analyzes and disseminates information about adverse neonatal outcomes, birth defects, developmental disabilities and other severe disabilities in children from birth to age 6. The program was known as the Birth and Developmental Outcome Monitoring Program.

1999 Wisconsin Act 114, enacted on May 8, 2000, replaced the Birth and Developmental Outcome Monitoring Program with the Birth Defect Prevention and Surveillance System. The new system has several differences from the previous reporting program:

1. The definitions of reportable conditions under Act 114 differ from the old statute language. A birth defect is defined as a structural deformation, disruption or dysplasia, or a genetic, inherited or biochemical disease.

2. Only birth defects in infants and children up to the age of 2 must be reported to the Department.

3. The list of persons who must report a birth defect to the Department is expanded beyond physicians to include pediatric specialty clinics. Hospitals may, but are not required to report birth defects to the Department.

4. The Department becomes responsible for establishing and maintaining an up-to-date registry of birth defects that have occurred in Wisconsin in the previous 10 years.

5. A new entity known as the Council on Birth Defect Prevention and Surveillance is created for the purpose of making recommendations to the Department regarding the establishment of the registry, the Department's administrative rules and the content of the reports required from medical care providers. Beginning in April 2002, the Council is to biennially report to the legislature on the utilization and progress of the registry.

1999 Wisconsin Act 114 maintains the preexisting mechanisms that ensure the confidentiality of data by requiring parental or guardian written consent before reporting or releasing an infant's or a child's name and address.

The Department's authority to repeal and recreate these rules is found in ss. 253.12 (3) (a) and 227.11 (2), Stats. The rules interpret s. 253.12, Stats.

SECTION 1. Chapter HFS 116 is repealed and recreated to read:

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.**

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.

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.

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.

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.

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.

The rules contained in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register as provided in s. 227.22 (2), Stats.

Wisconsin Department of Health
and Family Services

Dated: February 14, 2003

By: _____
Helene Nelson
Secretary

SEAL:

APPENDIX A
BIRTH DEFECTS AND SYNDROMES FOR WHICH REPORTING IS MANDATORY

Achondroplasia	Microphthalmia and Anophthalmia
Ambiguous Genitalia	Microtia/Anotia
Amniotic Bands	Multicystic or Dysplastic Kidney
Anencephaly	Noonan Syndrome
Angelman Syndrome	Obstructive Urinary Tract Defect [not posterior valves; not urethral stenosis/atresia]
Arthrogryposis Multiplex Congenita	Oculoauriculovertebral Association (including Goldenhar Association and Hemifacial Microsomia)
Atrial Septal Defect	Omphalocele
AV Canal/Endocardial Cushion Defect	Osteogenesis Imperfecta
Beckwith-Wiedemann Syndrome	Other Chromosomal Anomaly (not +13, +18, +21, XXY, Turner S., 22q-)
Biliary Atresia	Polycystic Kidney Disease, Autosomal Dominant Form
Bone Dysplasia/Dwarfism, Other (not Achondroplasia)	Polycystic Kidney Disease, Autosomal Recessive Form
Cardiac Arrhythmia (Congenital)	Polycystic Kidney Disease, Uncertain Form
Cataract (Congenital or Early)	Porencephaly
CHARGE Association	Posterior Urethral Valves
Choanal Atresia	Prader-Willi Syndrome
Cleft Lip with or without Cleft Palate	Pyloric Stenosis
Cleft Palate	Rectal/Colonic Atresia/Stenosis
Clubfoot (Congenital)	Reduction Deformity, Arm or Hand
Coarctation of the Aorta	Reduction Deformity, Leg or Foot
Coloboma	Renal Agenesis/Hypoplasia
Craniosynostosis	Robin Malformation Sequence (Pierre Robin Sequence)
Cystic Fibrosis	Scoliosis or Kyphosis/Hemivertebra (Infantile)
De Lange Syndrome (Cornelia De Lange Syndrome)	Small Bowel Atresia/Stenosis
Diaphragmatic Hernia	Smith-Lemli-Opitz Syndrome
Down Syndrome	Sotos Syndrome
Encephalocele	Spina Bifida
Epispadias	Spinal Muscular Atrophy (Infantile)
Exstrophy of the Bladder/Cloaca	Stickler Syndrome
Gastroschisis	Tetralogy of Fallot
Glaucoma (Congenital)	Total Anomalous Pulmonary Venous Return
Hemivertebra	Tracheo-Esophageal Fistula/Esophageal Atresia
Hemophilia	Transposition of the Great Vessels
Hereditary Spherocytosis	Trisomy 13
Hip Dislocation (Congenital)/Developmental Dysplasia of Hip (Congenital)	Trisomy 18
Hirschsprung Disease	Trisomy 21
Holoprosencephaly	Truncus Arteriosus
Hydranencephaly	Turner Syndrome
Hydrocephalus (Congenital or Early)	Urethral Stenosis/Atresia
Hypoplastic Left Heart	Valvular Heart Disease (Congenital)
Hypospadias	VATER Association
Hypothyroidism (Congenital)	Velocardiofacial Syndrome (22q Deletion Syndrome)
Klinefelter Syndrome	Ventricular Septal Defect
Marfan Syndrome	Von Willebrand Disease
Microcephaly (Congenital or Early)	Williams Syndrome

Note: Definitions can be found in the *Birth Defects Encyclopedia: The Comprehensive, Systematic, Illustrated Reference Source for the Diagnosis, Delineation, Etiology, Biodynamics, Occurrence, Prevention, and Treatment of Human Anomalies of Clinical Relevance*, Volumes I and II, Centers for Birth Defects Information Services, Inc. 1990.

APPENDIX B
CORE DATA ITEMS¹ OF THE BIRTH DEFECTS REGISTRY

A. General Data

1. Reporting Source Identifying Information
2. Date of Report
3. Parental Consent Information
4. Referral Information
5. Identifying Information of Person Completing Birth Defects Registry Form

B. Information About the Child

1. Medical Record Number
2. Name and Address, with parent and guardian written consent as provided in s. HFS 116.04 (2) (d).
3. Date of Birth
4. Birth Circumstances
5. Race/Ethnicity
6. Sex
7. Place of Birth
8. Identifying Information of Primary Care Provider
9. Date of Diagnosis
10. Suspected or Confirmed Defects
11. Identifying Information of Physician Making Diagnosis
12. Prenatal Diagnostic Information
13. Child Status Information

C. Information About the Mother

1. Name
2. Date of Birth
3. Race/Ethnicity
4. Residence Location at Time of Child's Birth

D. Information About the Father

1. Name
2. Date of Birth
3. Race/Ethnicity

¹The core data items are based on recommendations of the Centers for Disease Control and Prevention's National Center for Health Statistics.