WISCONSIN DEPARTMENT OF HEALTH SERVICES
PROPOSED ORDER TO ADOPT PERMANENT RULES

The Wisconsin Department of Health Services ("the Department") proposes an order to **repeal** DHS 116 Appendix A and B; **renumber and amend** DHS 116.04 (1) and (3) (a); **amend** DHS 116.05 (2) (a) 1. (Note); and **create** DHS 116.03 (4m), 116.04 (1) (a) and (b), (3) (a) 1. to 4., and (b) 7., relating to the Wisconsin birth defect and surveillance system.

RULE SUMMARY

Statutes interpreted

Section 253.12 (3) (a) 2. and (d), and (4), Stats.

Statutory authority

The Department is authorized to promulgate rules based upon explicit statutory language in ss. 253.12 (3) (a) 2. and 3. In accordance with s. 227.11 (2) (a), proposed policies are also based on interpretations of s. 253.12 (3) (a) 2. and (d) and (4), Stats., which require the Department to specify procedures for the Department to maintain a list outside of rules for conditions that are unanimously approved by the Wisconsin Council on Birth Defects and Prevention ("the Council").

Explanation of agency authority

Section 253.12, Stats., relates to the Wisconsin Birth Defect Prevention and Surveillance program ("the Program"). Pediatric specialty clinics and physicians who diagnose a birth defect or provide treatment to a child for a birth defect are required to report certain birth defects in children ages 0 – 2 years of age. Subsection (3) (a) of the statute directs the Department to establish and maintain a registry that "documents the diagnosis in the state of any infant or child who has a birth defect" ("the Registry"). Per s. 253.12 (3) (a) 1. a. to d., Stats., the purpose of the Registry is to facilitate all of the following:

1. The identification of risk factors for birth defects.
2. Epidemiological investigations into the incidence and prevalence of birth defects.
3. The development of preventative strategies to decrease the occurrence of birth defects.
4. Referrals for early intervention and other services.

Section 253.12 (3) (a) 2. and 3., Stats., specifically requires that the Department promulgate rules to specify all of the following:

1. Any birth defects for which a report is required under sub. (2) that the Council does not unanimously decide should be reported.
2. The "content, format, and procedures for submitting a report under sub. (2)."

Section 253.12 (3) (d), Stats., requires that the Department's Secretary maintain a list of conditions unanimously approved by the Council. This section does not require that rules be promulgated to update the Secretary's list. See s. 253.12 (3) (a) 2. and (d), Stats.[1]

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[1] Whenever the Secretary's list is revised, it is sent to those required to report. Reporting forms and data specifications are updated to reflect the revised list of reportable conditions and are posted to the Program's webpage.

Section. 253.12 (4), Stats., identifies the Council's duties with respect to the birth defect prevention and surveillance system. The Council is empowered to make recommendations regarding the reporting process, and it is required to vote on nominations for conditions for which a report is required. Section 253.12 (4) (a), Stats.

Related statute or rule

Section 15.197 (12), Stats.
Section 253.12 (4), Stats.
Chapter DHS 116, Appendices A and B.

Plain language analysis

The proposed rule will clarify the processes the Department will follow when adding or removing conditions from the Registry and update the rule to reflect contemporary recommendations of the Council. In addition to the Secretary's list established under s. 253.12 (3) (d), Stats., ch. DHS 116 Appendix A lists 87 conditions for which a report is required. This appendix has not been updated for over a decade, and it is unclear how and when the Council voted for those conditions, or if any of those conditions received unanimous support.

Consistent with its duties under s. 253.12 (4) (a), Stats., the Council established guidance and criteria for determining whether a condition requires reporting. When the Council receives a condition nomination,[2] the Council considers the following criteria[3] to determine if inclusion on the Registry is appropriate:

1. Whether the condition conforms to the statutory definition of a birth defect.
2. Whether the condition is usually identifiable by two years of age.
3. Whether the condition is a "major anomaly" which requires medical or surgical intervention or interferes with normal growth and development.
4. Whether the condition occurs with sufficient frequency (one in 30,000 births in Wisconsin).
5. Whether the condition is likely to be ascertained through assessment in one or more specialty clinics.

Neither these criteria, nor any process for including formalizing conditions voted on by the Council, are currently contained in ch. DHS 116.

If nominated today, many of the conditions listed in Appendix A would not satisfy the above criteria for inclusion on the registry or receive unanimous or majority approval from the Council. In 2021, the Council reviewed the list in Appendix A and collated it with the International Classification of Diseases, tenth revision ("ICD-10") codes, which ensure uniform medical codes are utilized between organizations. The Council determined that some conditions did not have a unique ICD-10 code and were duplicative, and unanimously recommended removing those duplicative conditions. Next, the Council determined that many conditions in Appendix A did not meet criteria for sufficient frequency, and unanimously recommended removing those conditions. Also in 2021, the Council worked with the National Birth Defects Prevention Network ("NBDPN") to identify conditions which are recommended by the NBDPN, the Centers for Disease Control and Prevention ("CDC"), and the World Health Organization for surveillance and inclusion on the Registry. The NBDPN recommended some conditions that were not historically collected in Wisconsin. Those conditions were nominated and unanimously approved by the

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[2] Proposed new conditions are formally nominated using form, F-02541, which is available at https://www.dhs.wisconsin.gov/forms/f02541.pdf.

[3] Information about the Council, including the criteria for inclusion, is available at https://www.dhs.wisconsin.gov/cyshcn/birthdefects/index.htm.

Council. All of these actions were formalized in the Secretary's updated list, which was unanimously approved by the Council.

Based on all of the above actions by the Council, every condition listed in the Secretary's list reflects the unanimous approval of the council. Appendix A is therefore outdated and should be repealed. In place of Appendix A, the Department proposes to update ch. DHS 116 to include the criteria the Council shall consider for inclusion or deletion of reportable conditions, and a placeholder for inclusion of any future conditions that receive a majority—but not unanimous—support of the Council.

The Department also proposes to update the report content, format, and procedures to reflect best practices for yielding meaningful data points to achieve the Department's duties under s. 253.12 (3) (a) 1. a. to d., Stats. "Core Data Items" for the Registry are currently provided in ch. DHS 116 Appendix B, which has not been updated in over a decade. These items are not reflective of recommendations provided by NBDPN and the CDC. For example:

- The basis for the definition of 'child status information' is unclear and unknown.
- The basis for the definition of "birth circumstances" is unknown, and it should be a collection of numerous items including gestational age, plurality, location of birth, and risk factors associated with pregnant mother.
- For electronic reporting, the reporter information is auto filled.
- Section B.10. requires information about "suspected" defects, but s. 253.12, Stats., only requires the reporting of diagnosed or treated birth defects.
- "Parental consent information" is outdated and inconsistent with s. 253.12, Stats.

The Department therefore proposes to repeal Appendix B and add provisions in ch. DHS 116 to list report format and content requirements consistent with recommendations from the NBDPN and CDC. Broadly, the rule will be updated to resolve the issues listed in the foregoing paragraph, and for consistency with the Confidential Birth Defects Registry Reporting Form.[4]

In order to ensure the collection of meaningful data points, the proposed rule seeks to standardize data points for consistency with NBDPN recommendations to allow comparisons and collaboration between states. The proposed rule will also require that all of the following information be captured and processed:

1. Identification of risk factors for birth defects.
2. Investigation of the incidence, prevalence, and trends of birth defects using epidemiological surveys.
3. Development of primary preventative strategies to decrease the occurrence of birth defects without increasing abortions.
4. Referrals for early intervention or other appropriate services.

The proposal does not make any changes to who is required to report (physicians and specialty clinics, with others being able to report on their behalf), the timeline for submitting reports (monthly or within 30 days of the birth defect being detected), or the available methods for reporting (paper form, online by individual cases, or batch reporting).

Finally, the proposed rule will revise outdated and erroneous provisions in the current version of the rule chapter.

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[4] This form, numbered F-40054, is available at https://www.dhs.wisconsin.gov/forms/f4/f40054.pdf

Summary of, and comparison with, existing or proposed federal regulations

There appear to be no existing or proposed federal regulations that address the activities to be regulated by the proposed rules.

Comparison with rules in adjacent states

Illinois:

Similar to Wisconsin, Ill. Admin. Code tit. 77, s. 840.220 requires specialty clinics and health care providers who are providing care to children (up to age 2) with a birth defect diagnosis to report information to the state. However, Illinois additionally requires information from hospitals, genetics providers, and cytogenic providers. Further, the listed facility types "shall make medical records of mothers and children having a case condition or a risk factor for a case condition available to the [Illinois Department of Public Health]". Illinois requires that entire medical records be reviewed, in contrast with the limited information listed in Wisconsin administrative code.

Iowa:

Iowa Code. § 136A.6 (2025) requires the Iowa Department of Health and Human Services to maintain a central registry that to compile and retain information on the occurrence, prevalence, causes, treatment, and prevention of congenital disorders. Similarly, the department is able to identify which conditions are considered reportable. There is no list included in administrative code that identifies which factors must be included in the registry, allowing the department to add and delete factors as deemed necessary.

Michigan:

Michigan's birth defect reporting program is subject to Mich. Admin. Code. s. R. 325.9071 to 325.9077. Section R. 325.9072 lists reportable birth defects, sometimes in broad categories (i.e. congenital anomalies of the ear, face, and neck) and other times more specific (i.e. Syphilis). Unlike Wisconsin, Michigan rule allows the director of the Michigan Department of Health and Human Services to designate the reporting of birth defects, diagnosed up to and including 12 years of age, for medical conditions that require surveillance and are commonly diagnosed after 2 years of age. Factors to be entered into the registry are not defined by administrative rule but are included in the registry instructional form.

Minnesota:

Sections 144.2215 to 144.2219 of the Minnesota Statutes govern the Minnesota birth defect information system. Unlike Wisconsin, Minnesota statute allows the commissioner for the Minnesota Department of Health to "design a system that allows the commissioner to . . . monitor incidence trends of birth defects to potential public health problems, predict risks, and assist in responsible to birth defects clusters". Minn. Stat. s. 144.2215, Subd. 2 (1). The statute does not limit the birth defect registry to a specific list of information that can be obtained to accomplish this goal. The commissioner has the authority to modify the birth defects information system through demonstration projects. Minn. Stat. s. 144.2215, Subd. 2. (5).

Summary of factual data and analytical methodologies

The CDC supports state birth defect tracking systems in order to improve surveillance methods to collect the highest quality data. In 2004, the CDC and the NBDPN released "Guidelines for Conducting Birth

Defects Surveillance"[5] to support individual states and pool data from state-based programs to estimate national rates, indicate regional variations, and describe the epidemiology of defects that occur rarely. Because state programs may be in different stages of development, employ different methods of ascertainment, or have different goals and objectives, the elements of the case definition used by each must be clearly identified in order to make valid comparisons to minimize birth defects rate variations across surveillance programs and among individual defects ascertained by the same program.

For the purposes of generating and reporting birth defects surveillance data across multiple states, the NBDPN recommends 47 birth defects. These conditions have been chosen on the basis of their frequencies, impact on public health, state of knowledge about their etiologies and risk factors, and other considerations. The Council cross checked the recommended conditions with the Council's established criteria for conditions to be included in the Registry. Along with those conditions, the Council reviewed vital records data to identify other birth defects that meet the established criteria to be included. In total, the Council has recommended 64 conditions. The NBDPN guidelines are recommendations for states to consider. If changes occur to the guidelines in future years, the Council will continue to review each condition added, removed, or changed against the Council condition criteria.

The Council utilized the CDC and NBDPN guidance to establish its condition review criteria summarized in the Plain Language Analysis of this rule order.

NBDPN also provides recommendations on data sources.[6] Although guidance is provided to allow states to identify the most efficient and comprehensive options, NBDPN also encourages the standardization of data elements across birth defects surveillance programs. Using standard data elements is particularly important when aggregating data for regional or national analysis. NBDPN provides a chart of recommended data variables that states can analyze to ensure those variables meet programmatic goals and ensure consistency, accuracy, definability, and collectability. The recommended variables will be considered and reviewed with the Council, during their annual business meeting, to identify applicability and appropriateness to meet the specific needs in Wisconsin. At a minimum, the data variables will include information about the child, information about the mother, and reporting source identifying information.

Analysis and supporting documents used to determine effect on small business

From Monday, August 18, 2025, through Monday, September 1, 2025, the Department solicited information and advice on the economic impact that the rules would have. No public comments were received.

Effect on small business

Based on the foregoing analysis, the permanent rules are anticipated to have little to no economic impact on small businesses.

Agency contact person

Kaitlin Tolliver, LCSW
Birth Defect Prevention and Surveillance Program Coordinator
Wisconsin Department of Health Services
608-266-6967

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[5] Available at https://stacks.cdc.gov/view/cdc/13109.
[6] Available at https://nbdpn.org/birth-defects-surveillance-guidelines/.

Kaitlin.Tolliver@dhs.wisconsin.gov

Statement on quality of agency data

The data used by the Department to prepare these proposed rules and analysis comply with s. 227.14 (2m), Stats.

Place where comments are to be submitted and deadline for submission

Comments may be submitted to the agency contact person that is listed above until the deadline given in the upcoming notice of public hearing. The notice of public hearing and deadline for submitting comments will be published in the Wisconsin Administrative Register and to the department's website, at https://www.dhs.wisconsin.gov/rules/active-rulemaking-projects.htm. Comments may also be submitted through the Wisconsin Administrative Rules Website, at: https://docs.legis.wisconsin.gov/code/chr/active.

RULE TEXT

SECTION 1. DHS 116.03 (4m) is created to read:

DHS 116.03 (4m) "Council" means the Wisconsin council on birth defect prevention and surveillance established under ss. 15.197 (12), Stats. and 253.12 (4), Stats.

SECTION 2. DHS 116.04 (1) is renumbered DHS 116.04 (1) (intro.) and amended to read:

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

SECTION 3. DHS 116.04 (1) (a) and (b) are created to read:

DHS 116.04 (1) (a) Birth defects for which the council unanimously decides to require reporting in accordance with s. 253.12 (4) (a), Stats., and are provided in the secretary's list under s. 253.12 (3) (d), Stats.

Note: The list established in accordance with s. 253.12 (3) (d), Stats., is included in publication P-03419, available at https://www.dhs.wisconsin.gov/publications/p03419.pdf.

(b) In accordance with s. 253.12 (3) (a) 2., Stats., birth defects which the department determines a report is required but are not unanimously decided by the council as requiring a report.

Note: As of [LRB to insert effective date of rule], all conditions for which the department determined a report was required were unanimously approved by the council. Any prospective birth defects which the department determines a report is required but the council does not unanimously approve will be added to this paragraph through future rulemaking.

SECTION 4. DHS 116.04 (3) (a) is renumbered DHS 116.04 (3) (a) (intro.) and amended to read:

DHS 116.04 (3) (a) Each report of a child with a birth defect shall include the content and format of the report found in the department's confidential birth registry form, except as provided in sub. (2) (d). At minimum, each report shall contain all of the following core data items:

SECTION 5. DHS 116.04 (3) (a) 1. to 4. are created to read:

1. An identification of the source of information used in the report and the date that the report was completed.
2. The child's date of birth, race, ethnicity, and suspected or confirmed defects.

3. The child's mother's date of birth, race, and ethnicity.
4. Any other information relevant to the report.

SECTION 6. DHS 116.04 (5) (b) 7. is created to read:

DHS 116.04 (5) (b) 7. Review recommendations from the council regarding updates to the content, format and procedures for submitting a report under s. 253.12 (2), Stats, on an annual basis. When reviewing content, format, and procedure recommendations, the department shall aim for consistency with national recommendations from the centers for disease control and prevention and the National Birth Defects Prevention Network.

SECTION 7. DHS 116.05 (2) (a) 1. (Note) is amended to read:

DHS 116.05 (2) (a) 1. **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~~ Birth Defects Registry via telephone at ~~800-441-4576~~ 608-266-6967.

SECTION 8. DHS 116 Appendix A is repealed.

SECTION 9. DHS 116 Appendix B is repealed.

SECTION 10. EFFECTIVE DATE. This rule shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in s. 227.22 (2) (intro.), Stats.