

Clearinghouse Rule 19-019

WISCONSIN DEPARTMENT OF HEALTH SERVICES PROPOSED ORDER TO ADOPT RULES

The Wisconsin Department of Health Services proposes an order to **repeal** DHS 181.03 (11) to (13), DHS 181.04 (3) (b) and (c), DHS 181.04 (6), (7) and (Note), DHS 181.06 (1) (j) and (k), DHS 181.06 (3); to **renumber and amend** DHS 181.04 (3) (a); to **amend** DHS 181.02, DHS 181.03 (10), DHS 181.04 (5), DHS 181.06 (1) (c) to (f) and (h) and (i), DHS 181.06 (1) (L) and (n), DHS 181.06 (2), DHS 181.07 and (Note), DHS 181.08 (2) (a); and to **repeal and recreate** DHS 181.04 (2), DHS 181.04 (4), and DHS 181.05, relating to reporting of blood lead test results.

RULE SUMMARY

Statute interpreted

Sections 254.13 and 254.156, Stats.

Statutory authority

Sections 227.11 (2) (a), 250.04 (7), 254.13 and 254.156, Stats.

Explanation of agency authority

The Department's authority to promulgate the proposed rules is provided in statute. Section 227.11 (2) (a), Stats., authorizes the Department to promulgate rules interpreting the provisions of any statute enforced or administered by the agency if the agency considers it necessary to effectuate the purpose of the statute. Section 254.15, Stats., requires the Department to administer a comprehensive statewide lead poisoning prevention program that includes childhood lead poisoning screening requirements. Section 254.13, Stats., requires that the Department promulgate rules specifying the form of the required reports. Section 254.156, Stats., requires the Department to promulgate a rule defining lead poisoning or lead exposure that corresponds to the specification of the centers for disease control and prevention.

Related statute or rule

None

Plain language analysis

The Department proposes to amend ch. DHS 181 in order to comply with statutes governing Wisconsin's lead poisoning prevention program. Specific revisions include: updating the blood lead reference value, updating forfeiture amounts, and updating and clarifying reporting requirements to reflect current definitions, standards and best practices.

The Department proposes to make the following revisions to the rule chapter:

1. In 2012, the U.S. Centers for Disease Control and Prevention (CDC) lowered the blood lead level at which it considers a child to be lead poisoned. The CDC now requires public health interventions at 5 µg/dL, rather than 10 µg/dL. In Wisconsin, "lead poisoning or lead exposure" is currently defined in s. DHS 181.03, as a concentration of lead in the blood of 10 µg/dL or

more. Section 254.156, Stats., requires the Department to promulgate a rule defining “lead poisoning or lead exposure” to correspond to the specification of the CDC. The Department therefore proposes to update the current definition of “lead poisoning or lead exposure” to the blood lead level set by the CDC.

2. Section DHS 181.08 sets the maximum forfeiture penalty for violating provisions of the chapter to \$1,000 per violation per day. This amount was based on s. 254.30 (2) (a), Stats. In 2015, Wisconsin Act 55, Section 4049d, amended s. 254.30 (2) (a), Stats., and increased the maximum forfeiture penalty to \$5,000 per violation per day in compliance with the federal requirements. The proposed rule updates the current maximum forfeiture penalty, as provided in the statute.

3. Chapter DHS 181 has not been substantially revised since 2002. The Department proposes to make non-substantive corrections and clarifications to reflect current definitions, standards and best practices.

There are no reasonable alternatives to the proposed rulemaking. The Department must amend ch. DHS 181 in order to comply with statutory directives provided by the Legislature.

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

In 2012, the CDC began using a reference value of 5 µg/dL to identify children with blood lead levels that are much higher than most children’s levels.

Comparison with rules in adjacent states

Illinois:

Permissible blood lead levels are confirmed (venous) under 10 mcg/dL for children under age 16 years and for pregnant or breast-feeding women, and confirmed (venous) less than 25 mcg/dl for all other persons. Health care providers must report a blood lead level in excess of permissible levels to the department of health within 48 hours. All capillary results of 10 mcg/dL or more for a person under age 16 years must be reported within 48 hours. All negative results must be reported within 30 days. A Medicaid ID number must be included, if applicable. Laboratory name or laboratory code number must be reported but the rule does not specify that the clinical laboratory improvement amendments (CLIA) number is required. Date of sample analysis, occupation, and employer information are not required to be reported. Written or electronic reports are acceptable but the code also states that reports shall be on the form provided in an appendix to the administrative rule. DPH 77 Ill. Adm. Code 845

Iowa:

Blood lead reporting is included with other reportable poisonings and non-communicable conditions. Reporting responsibility is extended to school nurses, school officials, poison control centers, medical examiners, occupational nurses, hospitals, health care providers and clinical laboratories outside the state of Iowa for all reportable poisonings and conditions. Iowa requires reporting all test results for adults and children to the department of health. Test results greater than or equal to 20 mcg/dL in a child under age six or a pregnant woman must be reported immediately by telephone. All other results must be reported at least weekly in an electronic format. The report includes patient’s marital status and if the patient is female, whether the patient is pregnant. A report is not required to include parent/guardian

name, laboratory phone number or CLIA number, date of sample analysis, occupation, or employer information. Iowa Adm. Code 641, Chapter 1.

Michigan:

All test results must be reported within 5 days and must include secondary contact (name, phone number) for parent/guardian if the person tested is a minor; social security number and Medicaid number, if applicable; physician/provider fax number and email address; and a specimen number. The test result must be rounded to the nearest whole number. The laboratory CLIA number is not required to be reported. Michigan requires electronic reporting by laboratories and point-of-care test sites but also allows reports to be mailed or faxed. The rule includes a quality assurance section, which allows the Department to inspect copies of the medical records pertaining to blood lead testing that will be submitted by the clinical laboratory or user of a portable blood lead analyzer to verify the accuracy of the submitted data. The rule includes a section on confidentiality of reports. The rule does not include a section on penalties and enforcement. Michigan Admin. Code R 325.9081-325.9087.

Minnesota:

Results greater than or equal to 15 mcg/dL must be reported within 2 days, results <15 mcg/dL must be reported monthly. In comparison to ch. DHS 181, the following information is not required to be included in the report content: ethnicity, guardian name, laboratory CLIA number, employer, and occupation are not required. Method of analysis is required to be reported. Minnesota Statutes, section 144.9502.

Summary of factual data and analytical methodologies

A technical advisory committee was convened to review all content and proposed changes. The committee met on June 21, 2018 and included representatives from laboratories, local health Departments, Children’s Hospital of Wisconsin and the Department’s Division of Public Health Bureau of Environmental and Occupational Health. The committee unanimously accepted all proposed changes. The Department did not rely on data or analytical methodologies to draft the proposed rule and was instead guided by the specifications provided by the CDC.

Analysis and supporting documents used to determine effect on small business

There was a public commenting period in regards to economic impact from September 24, 2018 through October 9, 2018. No comments were received.

Effect on small business

None. The proposed rules do not impact small businesses.

Agency contact person

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Statement on quality of agency data

The data sources referenced and used to draft the rules and analyses are accurate, reliable, and objective and are discussed in the “Summary of factual data and analytical methodologies.”

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/permanent.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 181.02 and DHS 181.03 (10) are amended to read:

DHS 181.02 This chapter applies to any physician, nurse, hospital administrator, director of a blood drawing site or local health officer who obtains a person's blood sample or orders that a blood sample be taken from a Wisconsin resident for the purpose of measuring the concentration of lead in the blood and to directors of clinical laboratories and persons performing onsite blood lead testing, that analyze human blood samples to determine the concentration of lead in blood.

DHS 181.03 (10) "Lead poisoning or lead exposure" ~~means a concentration of lead in the blood of 10 micrograms or more of lead per 100 milliliters of human blood.~~ has the meaning given in s. 254.11 (9), Stats.

SECTION 2. DHS 181.03 (11) to (13) are repealed.

SECTION 3. DHS 181.04 (2) is repealed and recreated to read:

DHS 184.04 (2) (a) When a health care provider sends a blood sample to a clinical laboratory for determination of the concentration of lead in the blood, the health care provider shall include with the blood sample all the information required under s. DHS 181.06 (1). This shall fulfill the requirement of the health care provider to report under s. 254.13 (1), Stats., unless the health care provider uses a laboratory outside the state of Wisconsin.

(b) If the health care provider sends blood samples to a clinical laboratory outside of Wisconsin, the health care provider shall report the blood lead test results and the other information described in s. DHS 181.06 to the department, unless written assurance is provided by the clinical laboratory to the department that the clinical laboratory is reporting the results to the department within the time specified in s. DHS 181.05, in which case, the health care provider's reporting requirements shall be considered fulfilled as described in par. (a).

SECTION 4. DHS 181.04 (3) (a) is renumbered DHS 181.04 (3) and amended to read:

DHS 181.04 (3) ~~Except as provided in par. (b), directors~~ Directors of clinical laboratories and persons performing onsite blood lead testing shall report to the department the results of all blood lead tests and the other information as described in s. DHS 181.06 for each blood lead test regardless of the concentration of lead in the blood.

SECTION 5. DHS 181.04 (3) (b) and (c) are repealed.

SECTION 6. DHS 181.04 (4) is repealed and recreated to read:

DHS 181.04 (4) The department shall make blood lead test results accessible to health care providers treating the person tested.

SECTION 7. DHS 181.04 (5) is amended to read:

DHS 181.04 (5) ~~Blood sample test results shall be accessible to health care providers treating the person tested.~~ If the blood sample results indicate lead test result indicates lead poisoning or lead exposure, the department shall transmit ~~results of the test~~ the test result to the local health department in the area in which the person tested resides.

SECTION 8. DHS 181.04 (6), (7) and (Note) are repealed.

SECTION 9. DHS 181.05 is repealed and recreated to read:

DHS 181.05 (1) Blood lead concentrations of 45 micrograms or more of lead per deciliter of blood shall be reported to the department within 24 hours from the time the analysis is completed.

(Note) For patients with blood lead results of 45 micrograms lead per deciliter of blood or more, report to the department blood lead test results and other patient information by telephoning or faxing the Childhood Lead Poisoning Prevention Program at telephone (608) 266-5817 or fax (608) 267-0402.

DHS 181.05 (2) Blood lead concentrations meeting the definition of lead poisoning or lead exposure but less than 45 micrograms of lead per deciliter of blood shall be reported to the department within 48 hours from the time the analysis is completed.

DHS 181.05 (3) Blood lead concentrations that do not meet the definition of lead poisoning or lead exposure shall be reported to the department within 10 days from the time the analysis is completed.

SECTION 10. DHS 181.06 (1) (c) to (f) and (h) and (i) are amended to read:

DHS 181.06 (1) (c) The patient's ~~gender, male or female~~ sex.

DHS 181.06 (1) (d) The patient's race: ~~Z=Unknown, W=White, B=Black, A=Asian, N=Native American, O=Other~~.

DHS 181.06 (1) (e) The patient's ethnicity: ~~Z=unknown, H=Hispanic, N= Non-Hispanic~~.

DHS 181.06 (1) (f) The patient's street address, apartment number, city or town, county, ~~and~~ zip code, and telephone number.

DHS 181.06 (1) (h) For a patient under 18 years of age, a parent's or guardian's ~~area code and phone~~ telephone number.

DHS 181.06 (1) (i) For a patient 16 years of age or older, the patient's occupation and ~~if the patient is employed, the employer's name, street full address, and telephone number, street address, city or town, state and zip code if employed.~~

SECTION 11. DHS 181.06 (1) (j) and (k) are repealed.

SECTION 12. DHS 181.06 (1) (L) and (n) are amended to read:

DHS 181.06 (L) The month, ~~date~~ day and year the blood sample was collected.

DHS 181.06 (n) The name of the health care provider submitting the blood sample, ~~the name of that person's facility or practice, street full address, city or town, state, zip code, area code and phone~~ telephone number.

SECTION 13. DHS 181.06 (2) is amended to read:

DHS 181.06 (2) **ADDITIONAL INFORMATION TO BE PROVIDED BY LABORATORY.** A clinical laboratory that determines the lead concentration in a sample of blood ~~submitted to it for a blood lead test~~ shall submit to the department a report on the results of the blood lead test in accordance with ss. DHS 181.05 and 181.07. That report shall include all the information in sub. (1) and, in addition, all of the following information:

(a) The name of the clinical laboratory performing the analysis, and the laboratory's street address, city or town, state, zip code, ~~area code and phone~~ telephone number, and clinical laboratory improvement amendments number.

(b) The month, ~~date~~ day and year the laboratory analysis was completed.

(c) Results of the blood lead test in micrograms of lead per ~~100 milliliters~~ deciliter of blood.

SECTION 14. DHS 181.06 (3) is repealed.

SECTION 15. DHS 181.07 and (Note) are amended to read:

DHS 181.07 Form of report submitted to the department. Reporting to the department shall be by electronic means in a format acceptable to the department unless the laboratory or ~~other person who screens~~ health care provider that tests for lead poisoning or lead exposure does not have suitable electronic data transport capability, in which case, reports may be paper reports in a format acceptable to the department.

DHS 181.07 (Note) ~~See Appendix A to this chapter for an acceptable format for either electronic or paper reporting of blood lead test results.~~ To obtain ~~more~~ information about reporting, including obtaining an acceptable form or information about acceptable formats for reporting, write or call visit the Childhood Lead Poisoning Prevention Program, Division of Public Health website at www.dhs.wisconsin.gov/lead; email dhsleadpoisoningprevention@wisconsin.gov; telephone (608) 266-5817; or mail request to Wisconsin Childhood Lead Poisoning Prevention Program, P.O. Box 2659, Room 145, Madison, WI 53701-2659; telephone (608) 266-5817.

SECTION 16. DHS 181.08 (2) (a) is amended to read:

DHS 181.08 (2) (a) *Civil*. Pursuant to s. 254.30 (2) (a), Stats., any physician, nurse, hospital administrator, local health officer, director of a clinical laboratory or director of a blood drawing site who violates any provision of this chapter may be required to forfeit not less than \$100 nor more than ~~\$1,000~~ \$5000. Each day of continued violation constitutes a separate offense.

SECTION 17. EFFECTIVE DATE: This rule shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, as provided in § 227.22 (2) (intro.), Wis. Stats.