

Report From Agency

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 24-025

Basis and Purpose of Proposed Rule

Chapter DHS 115, relating to the screening of newborns for congenital disorders. The proposed rules seek to do all of the following:

- Revise DHS 115.04 to add X-Linked Adrenoleukodystrophy (“X-ALD”), Mucopolysaccharidosis type I (“MPS I”), hypermethioninemia (“MET”), and trifunctional protein deficiency (“TFP”) to the list of disorders for which newborns are tested in accordance with s. 253.13 (1), Stats.
- Revise DHS 115.055 to increase the base card fee to \$223 and provide for biennial fee increases based on the Medicare Economic Index (“MEI”).

Department Response to Legislative Council Rules Clearinghouse Recommendations

The Department accepted the recommendations made by the Legislative Council Rules Clearinghouse and modified the proposed rules where suggested, except with respect to one of the recommendations in comment 5. The Rules Clearinghouse recommended removing parenthetical acronyms for conditions listed in s. DHS 115.04 (for example, “X-Linked Adrenoleukodystrophy (X-ALD)” in proposed s. DHS 115.04 (18)), but the parentheticals refer to the common, abbreviated names for the conditions that appear on the newborn screening card. Accordingly, the Department will retain all parentheticals for conditions listed. The Department did, however, review abbreviations for consistency throughout the rule and made changes, where appropriate.

Final Regulatory Flexibility Analysis

The issues raised by each small business during the public hearing(s):

No issues were raised by small businesses during the public hearing and comment period.

Any changes in the rule as a result of an alternative suggested by a small business and the reasons for rejecting any of those alternatives:

Not applicable - no issues were raised by small businesses during the public hearing and comment period.

The nature of any reports and estimated cost of their preparation by small businesses that must comply with the rule:

Not applicable - no issues were raised by small businesses during the public hearing and comment period.

The nature and estimated costs of other measures and investments that will be required by small businesses in complying with the rule:

Not applicable - no issues were raised by small businesses during the public hearing and comment period.

The reason for including or not including in the proposed rule any of the following methods for reducing the rule’s impact on small businesses, including additional cost, if any, to the department for administering or enforcing a rule which includes methods for reducing the rule’s impact on small businesses and the impact on public health, safety and welfare, if any, caused by including methods in rules

Not applicable - no issues were raised by small businesses during the public hearing and comment period.

Changes to the Rule Analysis or Fiscal Estimate/Economic Impact Analysis

Rule Analysis:

1. Additional information was added about newly implemented treatments for X-ALD in the plain language analysis section of the rule order.
 2. Additional information about the increases costs of specimen transport was added to the second bullet in the summary of factual data and analytical methodologies section of the rule order.
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Fiscal Estimate/Economic Impact Analysis:

Based on public comments relating to proposed fee increases in s. DHS 115.055, the Department revised the timeline and conditions for future biennial fee increases based on the Medicare Economic Index. The Fiscal Estimate and Economic Impact Analysis were amended to reflect those changes.

Public Hearing Summary

The department began accepting public comments on the proposed rule via the Wisconsin Legislature Administrative Rules website, and the Department's Administrative Rules Website on April 15, 2024. A public hearing was held on April 29, 2024, in a Zoom virtual public hearing. Public comments on the proposed rule were accepted until April 29, 2024.

List of the persons who appeared or registered for or against the Proposed Rule at the Public Hearing.

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Summary of Public Comments to the Proposed Rule and the Agency’s response to those comments, and an explanation of any modification made in the proposed rule as a result of public comments or testimony received at the Public Hearing.

Rule Provision	Public Comment	Department Response
DHS 115.055 (2)	For births occurring outside of hospitals, the fee schedule posted by the Medicaid program shows Medicaid continues to reimburse those providers \$115 for the cost of the card, significantly below the current \$195 card fee. Providers generally do not recoup the increased costs of the NBS card fees from payers, even when the payer is in the same state agency as the NBS program.	<p>All MA-reimbursable services are reimbursed on a group billing cost, which is based on cost reports submitted by hospitals in years prior. The MA group reimbursement rates will reflect the increased card fees in future years.</p> <p>Private insurance companies negotiate reimbursement rates with hospitals, and the Department has no control over those reimbursement rates.</p>
DHS 115.055 (2)	The commenter Objects to DHS’s proposal to increase the fee to \$223, which would be a 105 percent increase since SFY 2023 and would establish the fee as one of the highest NBS fees in the country.	<p>105 percent increase:</p> <p>The fee was first set at \$109 in Wis. Admin. Code ch. DHS 115 in May 2013, and the fee was not increased until 2023 Wis. Act 19 § 438m. raised the minimum allowable fee to \$195, effective July 7, 2023. Since 2013, several conditions have been added which increased the WSLH’s cost of testing despite the fee remaining unchanged prior to July 2023. Additionally, The Department’s and the Wisconsin State Lab oh Hygiene’s (“WSLH’s”) annual costs exceeded card revenues for nearly a decade, in part because the card fee was never increased.</p> <p>Comparing the fee to other states:</p> <p>On its face, the proposed \$223 fee is higher than fees in Illinois, Iowa, and Michigan, but additional context is necessary to account for the differences in those fees.</p> <p>Iowa raised its fee to \$162 in March 2023. Its fee covers the cost for testing and “[s]hort-term [f]ollow-up services” such as care coordination, consultations, and recommendations for treatment—but they do not appear to include long-term dietary treatment or services like Wisconsin’s program does.</p> <p>Michigan’s fee was raised to \$166.38 in January 2024, and this fee covers the cost of “screening, follow-up, and coordination of confirmatory testing for infants . . . affected by the disorders.”</p> <p>Illinois currently charges a fee of \$128 to cover the cost of testing and follow-up services, but statute permits placing additional state or federal</p>

		<p>funds into the state’s Metabolic Screening and Treatment Fund. It appears the Metabolic Screening and Treatment fund is supplemented by appropriations and grants from the state special fund. See 410 ILCS 240/2 & 30 ILCS 105/5 & 5.111; see also Illinois State Budget: Fiscal Year 2024 at 215, 369, 372.</p> <p>Minnesota charges \$235 for administering its newborn screening program. Despite the higher screening fee, Minnesota does not provide for special dietary treatment or ongoing clinical care services—both of which account for a large portion of the Department’s NBS program costs for Wisconsin.</p> <p>The Department remains statutorily obligated to provide the services covered by the NBS program, and it is following the appropriate statutory procedures for increasing the fee via rule in accordance with Chapters 227 and 253 of the Wisconsin Statutes.</p>
DHS 115.055 (2)	<p>Raising the card fee beyond the \$195 provided in statute would “generate revenue in excess of program costs.” 2023 Wis. Act 19 provided an annual increase of over \$4.6 million in the budget by increasing the fee to \$195. The proposed rule would increase revenue by over \$6 million. The commenter “strongly objects” to fees that generate revenue in excess of specified program costs.</p>	<p>The proposed \$223 fee is based on separate projections from the Department and WSLH based on projected declines in NBS card volumes, programmatic costs to eliminate deficits accumulated by multiple years of unsupported overdrafts, to fund the hearing screening program, and to provide ongoing services and special dietary treatment for individuals with conditions included in the newborn screen.</p> <p>Historically, to account for the multi-year rulemaking process, the Department has incorporated long-range estimates of cost growth into proposed fees. This method requires the Department to charge fees that are higher than actual cost when first implemented in order to support costs in later years that are higher than the program’s receivables. On the Department’s end, the fee increase is projected to ensure the program to remain solvent through fiscal year 2035 despite increasing costs and declining card revenues. The WSLH’s estimates are projected through fiscal year 2028.</p> <p>The fees charged under Wis. Stat. § 253.13(2) and Wis. Admin. Code § DHS 115.055 are split between the Department and the WSLH through a Memorandum of Understanding. The proposed \$223 fee would result in the Department receiving \$97.75 per card, and the WSLH</p>

	<p>receiving \$125.25 per card—which is consistent with the historical 45/55 split.</p> <p>Under this agreement, the Department would receive just over \$5 million based in fiscal year 2025 based on an estimated 55,300 births. This amount would: (1) cover annual anticipated program costs in light of increasing caseloads and decreasing birth rates; (2) address the deficit accumulated from years of unsupported overdrafts; and (3) allow the fee to fund the hearing screening program under Wis. Stat. § 253.115.</p> <p>While the Act 19 fee increase helped address growing program costs, the NBS program nonetheless expects to still end the fiscal year in a cash deficit. Notably, “Alternative 4.” in the Legislative Fiscal Bureau’s analysis most closely mirrors the actions taken by the Legislature during the budget process, and this analysis acknowledged that “[t]his increase would be intended to provide additional revenue to only the DHS program and would be cumulative with any separate increase made to the fee to provide additional revenue to the [WSLH].” (emphasis added). The Legislative Fiscal Bureau’s analysis estimated that that the WSLH would require additional revenue totaling \$2.4 million in fiscal year 2024 and \$3.4 million in fiscal year 2025 <i>solely to eliminate its current operating structural deficit in operating its NBS testing program</i>. To replenish the cash reserves that were used to defray the deficits in years prior, and account for future declines in revenue due to declining birth rates, additional increases in the NBS card fee are necessary.</p> <p>Key factors driving the program’s negative balance are declining birth rates reducing revenue despite the overall year-over-year increases in the caseload of those receiving special dietary treatments and counseling services, and related administrative services increasing. As summarized on page 3 of the Legislative Fiscal Bureau’s June 2023 Budget Summary, the total number of annual births declined from 2010 to 2022 by an average of 1% per year, meaning revenues from card fees have steadily declined year over year. Despite declining revenues, the costs for providing services under the congenital disorder treatment program continue to increase, as do the number of individuals served by the program. In 2021,</p>
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DHS 115.055 (2); DHS 115.04 (17) (18)	<p>The proposed rule states that about \$12 per card (or about \$660,000) is related to the addition of X-ALD and MPS I to the NBS test panel. According to the NBS website, however, the program started testing for X-ALD about a month after the program received the more than \$4.6 million annual increase in the state budget and presumably determined it had sufficient funding for the test.</p>	<p>The WSLH is currently administering an X-ALD demonstration project, which is funded by an 18-month CDC grant. The purpose of this demonstration project is to evaluate the efficacy of a novel screening process for testing for X-ALD once it is added to the panel via rulemaking. Inclusion in the demonstration project is optional, and any parent may exclude their child from the demonstration project for any reason. There are no additional funds for the project beyond the 18-month expiration of the CDC grant, so the program does not have “sufficient funding” beyond the expiration of the CDC grant.</p>
DHS 115.055 (2)	<p>The commenter objects to the DHS proposal to create an automatic fee increase equal to the average three-year Medicare Economic Index. The Medicare program does not use the MEI to automatically increase physician reimbursement fees, and the American Medical Association describes as covering, among other things, redistributive costs from other programs and investments in medical practices. These are not costs related to the NBS program and are not the program costs the statute authorizes DHS to include as part of the fee.</p>	<p>As explained in a preceding comment section, the Department’s estimates were based on ensure projections to ensure solvency through the end of fiscal year 2035, and the WSLH’s were projected through fiscal year 2028. Fee increases based on the MEI were requested to account for changes in costs and revenues for WSLH beyond fiscal year 2028.</p> <p>Basis for using the MEI:</p> <p>The proposal to increase fees biennially based on the three-year average of the MEI was crafted after reviewing approaches taken in</p>

	<p>Any proposed increase, but especially an automatic increase, in the NBS card fee that does not reflect specified program costs and that avoids ongoing scrutiny by both the Administration and the Legislature through the administrative rule process is not only bad public policy but also conflicts with current state law and the legislative intent of the rulemaking requirements.</p>	<p>other states, which utilized automatic adjustments to the NBS card fee. For example, Michigan's fees for newborn screening are subject to annual adjustments based on the Detroit Consumer Price Index. In September of 2023, Michigan raised its card fee from \$158.91 to \$166.38 based on a 4.7% annual percentage change in the Detroit Consumer Price Index. The Illinois Department of Health is authorized to "levy additional fees" based on a "reasonable fee structure" beyond the statutory fee of \$118. The Iowa Department of Health also annually reviews and revises the fee for screening.</p> <p>The Department chose to implement the MEI because it is a conservative projection of increase cost estimates moving forward: the three-year average MEI from 2021 to 2023 was 2.4%, while the same three-year average for the consumer price index was 5.6%. The MEI measures price changes in the inputs required to operate a physician practice. These inputs include both the physician's own time as well as practice expenses, which includes non-physician labor, office and telecommunication, and medical supplies costs. Market data used to calculate the MEI has found that practice costs, which are like administrative costs associated with this program, have grown at a greater rate than physician costs since 2018. The special dietary treatment component of the program accounts for much of the Department's non-administrative costs—and the recent crisis caused by soaring baby formula costs and limited manufacturer alternatives therefore had a staggering effect on program expenses. Until a nationwide solution has been implemented to stabilize the supply and cost of formula, the Department believes the MEI is the best method to account for increasing program costs.</p> <p>Changes to s. DHS 115.055 (2) based on comments:</p> <p>The Department recognizes, however, fee adjustments based on the MEI should be permissive (rather than mandatory) because they are based on projections and estimates. Furthermore, the Department recognizes that the primary purpose of the MEI-based increases was to account for years beyond fiscal year 2028. Accordingly, the department further amended the proposed s. DHS 115.055 (2) to read as follows:</p>
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		<p>DHS 115.055 (2) <u>CALCULATION OF FEES</u>. The newborn screening sample collection card fee for testing a newborn under s. 253.13 (1), Stats., and this chapter shall be \$109 <u>\$223 as of [LRB to insert effective date of rule]</u> to cover the costs of testing and to fund follow-up services and other activities under s. 253.13 (2), Stats. <u>Starting on July 1, 2029, the fee charged under this section shall be adjusted by the department on July 1 of each odd numbered year based on the average of the three most recently published Medicare economic indexes. If card fee revenues for the preceding biennium exceed the costs of testing, follow-up services, and other activities under s. 253.13 (2), Stats., then the fee shall not be adjusted for the applicable prospective biennium.</u></p> <p>These amendments are intended to ensure that: (1) MEI fee increases only occur if costs exceed revenues in the preceding biennium; and (2) consideration of the MEI and fee increases only occur <i>after</i> the WSLH's projections end. If, for example, the rule would take effect after July 1, 2025, no biennial adjustments could occur until 2029. If card fee revenues exceeded program costs under Wis. Stat. § 253.13 (2) from July 1, 2027 to June 31, 2029, then the fee would not be adjusted based on the MEI through June 30, 2031.</p>
DHS 115.055 (2)	Biennial fee increases outside of those expressly provided in rulemaking avoids ongoing scrutiny by both the Administration and the Legislature. It is bad public policy but also conflicts with current state law and the legislative intent of the rulemaking requirements.	<p>Biennial fee increases outside of those expressly provided in rulemaking do not facially conflict with Chapter 227 of the Wisconsin Statutes.</p> <p>With respect to biennial adjustments based on the MEI, the Department disagrees that those adjustments would contravene Legislative scrutiny or statutory rulemaking principles. In addition to the analysis provided in the Proposed Rule Order for this rulemaking project, the economic impact analysis contains a detailed analysis of the justifications for the department's proposed rule, and this report includes detailed response responses to public comments regarding the MEI. This gives the Legislature full insight into the Department's justifications for including a biennial adjustment and will allow it to determine the if Department's proposal is consistent with the authority it delegated to the Department in statute. If the</p>

		<p>Legislature needs more information, it has statutory authority to meet with agency or request modifications; if it disagrees with the Department's analysis, it can object to the proposed rule.</p> <p>Furthermore, it is not unprecedented for administrative rules to allow for ongoing adjustments of fees or costs to consumers based on an index. There are several instances in the Department's rules that allow for regular increases based on the Consumer Price Index ("CPI"). For example, ss. DHS 110.16(1) and 158.04(2) provide, respectively, that Department administration fees for emergency medical services licensing, and for monitoring radiation emissions in the vicinity of nuclear power plants "may be increased each year at the annual rate of inflation as determined by movement in the [CPI]. . . ." <i>See also</i> s. DHS 10.34 (providing that the maximum cost share for a family care participant shall be updated annually based on changes in the CPI). Each of these rules was promulgated in accordance with Chapter 227 of the Wisconsin Statutes and subjected to Legislative scrutiny. To further illustrate that the MEI is a conservative estimate, it is worth noting that three-year average MEI from 2021 to 2023 is 2.4%, and that number is significantly lower than the 5.6% average based on the percentage change in the CPI in the same period.</p> <p>As explained in the preceding section of these comments, the Department has revised the proposed amendment to Wis. Admin. Code § DHS 115.055 to preclude a biennial fee increase if card fee revenues for the preceding biennium meet or exceed program costs.</p>
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Summary of Items Submitted with this Report to the Legislature

Below is a checklist of the items that are attached to or included in this report to the legislature under s. 227.19 (3), Stats.

Documents/Information	Included in Report	Attached	Not Applicable
Final proposed rule -- Rule Summary and Rule Text		x	
Department response to Rules Clearinghouse recommendations	x		
Final Regulatory Flexibility Analysis	x		
Changes to the Analysis or Fiscal Estimate/Economic Impact Analysis	x		
Public Hearing Summary	x		
List of Public Hearing Attendees and Commenters	x		
Summary of Public Comments and Department Responses	x		
Fiscal Estimate/Economic Impact Analysis		x	
Revised Fiscal Estimate/Economic Impact Analysis			
Small Business Regulatory Review Board (SBRRB) statement, suggested changes, or other material, and reports made under s. 227.14 (2g), Stats. and Department's response			x
Department of Administration (DOA) report under s. 227.115 (2), Stats., on rules affecting housing			x
DOA report under s. 227.137 (6), Stats., on rules with economic impact of \$20 MM or more			x
Public Safety Commission (PSC) energy impact report under s. 227.117 (2), Stats. and the Department's response, including a description of changes made to the rule			x