CR 12-025

ORDER OF
DEPARTMENT OF HEALTH SERVICES
TO ADOPT RULES

The Department of Health Services proposes to create DHS 115.05 (3), relating to a fee for screening newborns for congenital and metabolic disorders and other services.

SUMMARY OF PROPOSED PERMANENT RULE

Statute interpreted

Section 253.13 (2), Stats., as amended by 2011 Wis. Act 32

Statutory authority

Section 253.13 (2), Stats., as amended by 2011 Wis. Act 32

Explanation of agency authority

The legislature under s. 253.13 (2), Stats., as amended by 2011 Wis. Act 32, authorizes the department to impose by rule, a fee sufficient to pay for: 1) the cost of testing newborns for the congenital and metabolic disorders provided by the Wisconsin State Laboratory of Hygiene (WSLH); 2) the provision of services, including follow-up diagnostic services, physician prescribed special dietary treatment and follow-up counseling to the patient and the patient's family; 3) periodic evaluation of infant screening programs; 4) the costs of consulting with experts in reviewing and evaluating the program; 5) the costs of administering the newborn hearing screening required under s. 253.115, Stats.; and 6) the costs of the department to administer the congenital disorder program. The department is required to credit the amounts received to appropriations accounts under s. 20.435 (1) (ja) and (jb), Stats.

Previous to 2011 Wis. Act 32, the fee was imposed by WSLH by policy.

Related statute or rule

See the "Statute interpreted" section.

Plain language analysis

Section 253.13 (1), Stats., requires attending physicians, certified nurse-midwives, and certified professional midwives to cause every infant born in Wisconsin to be screened for the congenital and metabolic disorders specified by the department by rule.

Congenital and metabolic disorders screening, also known as newborn screening, are special tests for all newborns. Newborn screening helps parents find out if their baby has certain health problems. A newborn baby can look healthy, but have a serious disorder that cannot be seen. If not treated, these disorders can lead to slow growth, severe illness, brain damage, or possibly death. Early treatment can help prevent these serious problems.

Section 253.13 (2), Stats. (2009-10) authorized the WSLH to impose a fee in an amount sufficient to pay for the cost of the screening provided by the WSLH, and to fund services, including certain follow-up diagnostic services, physician prescribed special dietary treatment and certain follow-up genetic counseling to the patient and the patient's family, as well as periodic evaluation of infant screening programs, the costs of consulting with experts in reviewing and evaluating the program, the costs of administering the newborn hearing screening required under s. 253.115, Stats. and the costs of the department to administer the congenital disorders program.

To comply with s. 253.13 (1), Stats., hospitals, stand alone birth centers, physicians, certified nurse-midwives, certified professional midwives, and other entities (purchasers) purchase newborn screening sample collection cards from the WSLH for use when obtaining the newborn's blood sample for testing. When the blood sample is obtained, a purchaser or its agent returns the newborn screening sample collection card to the WSLH to test for the conditions specified by the department under s. DHS 115.04. The department provides certain follow-up services as prescribed by a physician or as otherwise determined. The WSLH currently imposes, at the time the newborn screening sample collection card is purchased, a fee of $109. This amount includes amounts to fund the testing, services and programs directed under s. 253.13 (2), Stats., as amended by 2011 Wis. Act 32.

Section 253.13 (2), Stats., as amended by 2011 Wis. Act 32, now requires the department to impose a fee by rule.

The department under this proposed order creates s. DHS 115. 05 (3) to impose, by rule, a fee of $109 for screening newborns for congenital and metabolic disorders and other services as directed under s. 253.13 (2), Stats., as amended by 2011 Wis. Act 32. The fee amount being imposed under this order is the same fee amount that is currently being imposed by the WSLH by policy to fund the same testing, services and programs that will be funded under the proposed rules. In effect, the proposed rules conforms the rule to statute.

As permitted under 2011 Wisconsin Act 32 s. 9121 (9) these rules will be promulgated as emergency rules before these proposed permanent rules become effective.

Summary of, and comparison with, existing or proposed federal regulations
There appears to be no existing or proposed federal regulations that address the activities of this rule.

Comparison with rules in adjacent states
Illinois, Iowa, Michigan and Minnesota require newborns to be screened for congenital and other disorders, and the provision of other services and programs. Also similar to Wisconsin, these states impose a fee for the screening and other services. However, it is not possible to accurately and specifically compare the proposed fee of $109 to the fees set by these states because the disorders to be screened may differ, and the additional services and programs funded as permitted by statute and their level of needed funding may differ.

Illinois

Illinois's Department of Public Health assesses institutions or persons submitting a sample for newborn screening a fee of $78, which may be increased if screening for additional disorders. Statements are mailed on a monthly basis to facilities submitting specimens for analysis. Payment is required upon receipt of the statement. 77 Ill. Adm. Code 660.70

Iowa

Iowa's Department of Public Health assesses a fee of $112 for activities associated with the Iowa Newborn Neonatal Metabolic Screening Program. Included in the fee is an amount to fund a program for eligible individuals with certain inherited diseases identified through the program who may be unable to pay the fee. The Department of Public Health is required to review and determine the fee annually. 641 IAC 4.3(9)

Michigan

Michigan's fee for screening newborns and other services is established under Michigan statute, MCLS s. 333.5431(4) by annual adjustment based on the cumulative annual percentage change in the Detroit Consumer Price Index. The current fee amount is $97.69. Under MCLS s. 333.5430 (3), the newborn screening quality assurance advisory committee must conduct a financial review of any recommended changes to the list of newborn screening tests and make a recommendation to increase or decrease in the amount charged pursuant to section 5431 for newborn screening tests. The recommended change is limited to any net change in the amount of the actual cost of any proposed additional tests and follow-up minus savings from any proposed deleted tests and follow-up.

Minnesota

Minnesota assesses its newborn screening fee in statute. Minn. Stat. s. 144.125 (1) requires its state commissioner of health to charge a fee of $106 per specimen "so that the total of fees collected will approximate the costs of conducting the tests and implementing and maintaining a system to follow-up infants with heritable or congenital disorders, including hearing loss detected through early hearing detection and intervention program". Per an interview of a Minnesota Newborn Screening Program representative, unlike Wisconsin, Minnesota does not pay for special dietary treatment or diagnostic or clinical services. Minnesota pays for intensive review and follow-up for obtaining a blood test and initiating follow-up.

Below is a chart sampling of what the newborn screening fee pays for in Wisconsin, Illinois, Iowa, Michigan, and Minnesota.

		Wisconsin	Illinois	Iowa	Michigan	Minnesota
Newborn Screening Fee		$109	$88	$112	$97.69	$106
What you get for the Newborn Screening Fee						
Lab services (cost - taken from fee)		$58.50	$44 (approx.)	Can not be separated out	$46.79	Can not be separated out
DHS Surcharge		$50.50	$44 (approx.)		$41.42 Admin- $9.48	
Special Dietary Treatment	**Formula (A specialized drink that provides protein and essential nutrients in a safe form for people with certain diseases)**	✓	✓	✓	✓	
	Low-Protein Food (A food source with digestible protein for people with certain diseases)	✓		✓		
	Special Dietary Supplements (Necessary for appropriate growth – similar to vitamins)	✓		✓	✓(some)	
Follow-up (case management, non-clinical follow-up, provider education, short-term follow-up)		✓	✓	✓	✓	✓
Clinical Services (Genetic Counseling, nutritionists, clinical nurses, specialists for follow-up)		✓	✓		✓	
Staffing		✓ (2 + lab)	✓(17 + lab)	✓ (17 + lab)	✓(8 + lab)	✓(16 + lab)
Additional Funding Information						
Does your program have supplemental money to support the Newborn Screening Program?		No	No	Yes	Yes	Yes
Breakdown of additional funding				State Appropriations $160,000	Medicaid $170,000 WIC $87,500 Small Federal grants	Small Federal grants

Summary of factual data and analytical methodologies

In 2010, the department developed the $109 fee amount for the newborn screening sample card which consists of $58.50 to cover the costs of testing provided by the WSLH and $50.50 to cover the services and programs authorized under s. 253.13 (2), Stats. The department analyzed past actual costs and then projected out future costs until SFY 13.

The costs for the Wisconsin Newborn Screening (NBS) program (Program) determine the newborn screening sample card fee. The costs do not solely rely on the number of babies that need to be screened for congenital disorders. The NBS Program costs include the WSLH costs of purchasing, storing, and distributing the cards; laboratory equipment, consumables, and staff salaries to perform the testing for conditions listed under s. DHS 115.04; short term follow up of all non-normal results reported by the laboratory; and education activities for health care providers regarding newborn screening issues such as specimen collection and reporting of test results. The costs for the NBS Program also include the department costs based on the number of participants in the NBS Program; diagnostic and counseling services (i.e. clinical assessment, nutritional and genetic counseling); special dietary treatment (i.e. coordinating payment of specialty formula and vitamins); consulting with experts (i.e. hosting and coordinating the newborn screening advisory group meetings); administering the congenital disorder program (i.e. program staff and program operations); administering the hearing screening program under s. 253.115, Stats.; periodic evaluation of infant screening programs; and testing due to advancements in science or laboratory procedures. The NBS Program pays in part for the expertise to provide follow-up and individual telephone consultation between the pediatric subspecialist experts and the primary care physicians each time an abnormal result is found on a newborn screening test.

The number of people participating in the NBS Program has increased. Each child with a positive screening result gets a confirmatory test in a specialty center and receives the necessary dietary treatment for life. As children live longer and the cumulative number of patients increases, the overall cost of the program rises. In SFY 2004, the program served 824 patients compared to 954 patients in SFY 2009. In SFY 2008 and SFY 2009 there was a 3.9% and 4.5% increase in patient population respectively. (Citation: Number tabulated from NBS Program Annual Reports and recorded in a DHS Excel file: Newborn Screening Population Increases)

NBS Program costs have been increasing.

- The costs of the formula and other food products have been rising. Depending on the vendor and product, the annual price increase has been as high as 20% (Example: Applied Nutrition's PhenylAde MTE Amino Acid Blend for PKU prior to September 1, 2008 was $347.67 per case; after September 1, 2008 the cost was increased to $417.15). Expenditures for special dietary treatment were $1,163,155.87 in SFY 2009, $1,385,646.20 in SFY 2010, and $1,450,197.82 in SFY 2011. (Citation: DHS Excel file: SFY Summaries by Condition 09 to 12). Another contributing factor is the rarity of disorders and limited product. There are few vendors providing product so it is not possible to find the same or similar product at a different vendor for a lower cost.
- The increasing number of adults and growing teens on product is shifting the age (and weight) distribution upward. Adults and growing teens require increased caloric intake compared to that of young children thus increasing the average amount of formula or food product per person.

In order to maintain the NBS Program, revenue should match rising costs; however, revenue has declined because Wisconsin births have declined more than expected. The number of births in Wisconsin has decreased since 2007 which in turn affects the number of blood-testing cards purchased by hospitals. In SFY 2007, 72,453 cards were purchased compared to 66,789 in SFY 2011. (WSLH Surcharge Report (2011))

Statement on the Quality of the Agency Data

To prepare the text and analysis of the proposed rules, the department relied on the following sources or interviews:

1. WSLH Clinical Orders Department NBS Program Customers List (2008)
2. WSLH Surcharge Report (2011)
3. DHS NBS Program Annual Reports
4. DHS Excel file: Newborn Screening Population Increases
5. DHS Excel file: SFY Summaries by Condition 09 to 12
6. Department interview of a Michigan Newborn Screening Program representative (11/30/11)
7. Department interview of a Minnesota Newborn Screening Program representative (11/30/11)

Analysis and supporting documents used to determine effect on small business

The $109 fee imposed under these proposed rules will have no additional economic impact on purchasers of newborn screening sample cards, whether or not the purchasers are small businesses because the rules conform to statute by imposing the fee by rule, instead of by policy. The fee is unchanged from the current amount being imposed by the WSLH.

According to the WSLH Surcharge Report, the number of newborn screening sample cards purchased in SFY 2011 was 66,789. Accordingly, the department estimates that the current economic impact on the private sector, including small businesses in SFY 2011 is approximately $7,280,001 ($109*66,789). This estimate may be higher or lower in future years depending on factors such as the number of births or cards purchased in a given year.

Purchasers of newborn screening sample collection cards may seek reimbursement of the costs of the newborn screening sample cards and any related costs incurred from private insurers, Medicaid, parents of newborns, or the NBS Program for eligible parents.

Effect on small business

The $109 fee proposed under the proposed rules will have no impact on businesses, including small businesses, because the fee is unchanged since it was initially imposed by the WSLH in 2010. The department expects that purchasers will continue to seek reimbursements of their costs related to the NBS Program.

Small Business Considerations

The $109 fee in this proposed order will not have an impact on businesses, including small businesses, because the fee is unchanged since it was initially imposed by the WSLH in 2010. This proposed order only codifies the existing fee amount of $109 in administrative rule. The rule does not include any requirements, including reporting requirements, schedules or deadlines for compliance, or performance standards, from which the department can exempt small businesses. It would be contrary to the objectives of s. 253.13 (2) Stats., as amended by 2011 Wis. Act 32, to exempt small businesses from the fee required under s. 253.13 (2), Stats. Section 253.13 (2), Stats., as amended by 2011 Wis. Act 32, requires the department to impose a fee sufficient to pay for testing provided by the WSLH and include as part of the fee amounts to fund the provision of diagnostic and counseling services, special dietary treatment as prescribed by a physician, and periodic evaluation of infant screening programs, the costs of consulting with experts under s. 253.13 (5), Stats., the costs of administering the hearing screening program under s. 253.115, Stats., and the costs of administering the congenital disorder program operated under s. 253.13 (2), Stats., as amended by 2011 Wis. Act 32. The $109 fee amount is based on the costs to fund the provision of testing and services required under s. 253.13 (2), Stats., as amended by 2011 Wis. Act 32.

Agency contact person

For substantive questions contact:
Katherine Vaughn-Jehring, MPH, MPA
Department of Health Services
1 West Wilson
Madison, WI 53703
608.267.2173
Katherine.VaughnJehring@wi.gov

For rulemaking questions and small business concerns contact:
Rosie Greer
Administrative Rules Manager
Department of Health Services
1 West Wilson
Madison, WI
608.266.1279
Rosie.Greer@dhs.wisconsin.gov

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 will be posted on the Wisconsin Administrative Rules Website at http://adminrules.wisconsin.gov after the hearing is scheduled.

TEXT OF PROPOSED RULE

SECTION 1. DHS 115.05 (3) is created to read:

DHS 115.05 (3) FEES. The newborn screening sample collection card fee shall be $109 for each newborn screened to cover the costs under sub. (1) and to fund follow-up services and other activities under s. 253.13 (2), Stats.

SECTION 2. 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), Stats.

Wisconsin Department of Health Services

Dated: April 12, 2013

Kitty Rhoades, Secretary-Elect

SEAL: