

Report From Agency

RULEMAKING REPORT TO LEGISLATURE

CLEARINGHOUSE RULE 24-047

Chs. DHS 105 & 107, relating to pharmacist certification and reimbursement for patient care services through Medical Assistance.

Basis and Purpose of Proposed Rule

Section 49.46 (2) (bh), Stats., which was created by 2021 Wis. Act 98 (“Act 98”), directs the Department to provide reimbursement for services that are reimbursable under s. 49.46 and provided by a licensed pharmacist within the scope of his or her license or performed under s. 450.033, Stats. Section 450.033, Stats., permits a pharmacist to “perform any patient care services delegated to the pharmacist by the physician”

The Department’s rules, specifically s. DHS 105.15, include standards for MA certification of pharmacies and s. DHS 107.10 identifies covered services with respect to dispensing drugs. The Department does not, however, have any policies in place specifically to certify pharmacists (as opposed to pharmacies) rendering physician delegated patient care services to an MA recipient, or to permit reimbursement for those services. Pharmacists practice in a variety of settings outside of the pharmacies certified under s. DHS 105.15, and rules are needed in order to reimburse for services provided in those settings. In order to comply with Act 98, chs. DHS 105 and 107 therefore must be amended to permit certification of, and reimbursement to, pharmacists providing services that are reimbursable under MA and provided within the scope of his or her license or are services performed under s. 450.033.

Department Response to Legislative Council Rules Clearinghouse Recommendations

The Department has reviewed the Legislative Council report and incorporated all recommendations into the proposed rule order.

Final Regulatory Flexibility Analysis

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

No issues were raised by any small businesses during the public hearing.

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 changes were made to the rule’s analysis.

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

Not applicable.

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

The proposed rule changes have the potential to impact Medical Assistance providers and members. Providers have the opportunity to provide some covered services via pharmacists for the first time, which expands the pool of potential services provided beyond what is currently offered. While all providers are required to follow the same requirements, the Department included a number of requirements with the intent to reduce the burden on small business providers such as expanding the pool of potential members and services provided beyond that traditionally available for in-person services.

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.

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

Rule Analysis:

The Department incorporated all changes proposed in Legislative Council’s report and feedback.

Fiscal Estimate/Economic Impact Analysis:

No changes were made to the fiscal estimate/economic impact analysis.

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 8/12/2024. A public hearing was held on 8/26/2024, in Microsoft Teams. Public comments on the proposed rule were accepted until end of business on 8/26/2024.

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

Registrant	Position Taken (Support or Opposed)
Drea Meier, SSM Health	none taken
Danielle Womack, Pharmacy Society of Wisconsin	none taken
Tiaha McGettigan, Reedsburg Area Medical Center	none taken
Richelle Andrae, Wisconsin Primary Care Association	none taken
Jordan Spillane, Froedtert Health	none taken
Hannet Tibagwa Ambord, Reedsburg Area Medical center	none taken
Kari Trapskin, Pharmacy Society of Wisconsin	none taken
Kate Hartkoph, Pharmacy Society of Wisconsin	none taken

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 105.155(2)(a)-(i)	<p>Six commenters during the public hearing offered testimony that the collaborative practice agreement ("CPA") documentation requirements laid out in the proposed rule were onerous and would impose administrative burdens that do not provide additional benefits or improve the delivery of patient care. Specifically, the commenters stated that:</p> <ul style="list-style-type: none"> • Many CPAs are not issued on a 1:1 physician to pharmacist basis. Requiring as much would be both burdensome and inconsistent with s. 450.033, Stats., and ch. Phar. 7. • Many of the requirements, such as a separate dated signatures from the pharmacist and delegating physician, were redundant because that information is already captured electronically by existing documentation platforms. • The three-year limitation on the validity of a CPA was shorter than the 5-year validity period in s. Phar. 7.12 <p>Some commenters referred to the Pharmacy Society of Wisconsin's guidelines for collaborative practice agreements as their current standard, which they support.</p> <p>The Department also received four written comments during the public comment period (three of which were from individuals who also offered testimony during the public hearing to the same effect). These written comments were consistent with the concerns raised during the public hearing.</p>	<p>Based on these comments, the Department revised DHS 105.155 as follows:</p> <ul style="list-style-type: none"> • Documentation requirements were simplified. A pharmacist performing under a CPA must document and maintain the CPA in accordance with ch. Phar. 7 and any other guidelines set by the pharmacy examining board. • Rather than requiring a 1:1 physician to pharmacist CPA, the rule allows for (1) multiple physicians and pharmacists to be listed, or (2) A written protocol identifying the committee or authority delegating services. • The edits simplified the CPA documentation requirements. Pharmacists shall document and maintain the agreement in accordance with ch. Phar 7 and any guidelines set by the pharmacy examining board. This revision is in line with current practices. <p>DHS 105.155 was further revised to include language on what the responsible parties under a collaborative practice agreement (e.g., delegating physician and delegated pharmacist) shall make available for review by the Department upon request.</p>
DHS 107.10 (1)	<p>One written comment identified issues with the list of individuals who can prescribe drugs or drug products covered under MA. Specifically, the commenter noted:</p> <ul style="list-style-type: none"> • The rule referred to "podiatrists licensed under s. 448.04, Stats." Podiatrists are specifically licensed under s. 448.61, Stats. • The rule referred to "optometrists licensed under s. 449.02, Stats." Optometrists are specifically licensed under s. 449.02, Stats. • The rule referred to "advanced practice nurse prescriber[s] licensed under s. 448.04, Stats." Advanced practice nurse prescribers are <i>certified</i>, not licensed. • The rule referred to "physician's assistant[s] certified under s. 448.04, Stats." Physician's assistants are specifically licensed under s. 448.61, Stats. 	<p>Based on these comments, the Department renumbered s. DHS 107.10 (1) as introductory material, and created 7 subunits ((a) through (g)) to identify the individuals who can prescribe drugs or drug products covered under MA with correct statutory or administrative code citations.</p>

	The commenter further identified confusion with the proposed language regarding delegation agreements for pharmacists.	
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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			X
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