

Clearinghouse Rule 22-046

**WISCONSIN DEPARTMENT OF HEALTH SERVICES
PROPOSED ORDER TO ADOPT PERMANENT RULES**

The Wisconsin Department of Health Services proposes an order to **amend** DHS 109.03 (10), 109.13 (2) (c), 109.51 (5), 109.52 (8) (d) and (11) (b), 109.61 (2), 109.73 and **create** DHS 109.13 (2) (b) 3., (d) and (e) and 109.31 (3) (h).

RULE SUMMARY

Statute interpreted

Not applicable.

Statutory authority

The department is authorized to promulgate the proposed rules based upon the following statutory sections:

Section 227.11 (2), Stats., reads: Rule-making authority is expressly conferred on an agency as follows:

(a) Each agency may 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, but a rule is not valid if the rule exceeds the bounds of correct interpretation. All of the following apply to the promulgation of a rule interpreting the provisions of a statute enforced or administered by an agency:

1. A statutory or nonstatutory provision containing a statement or declaration of legislative intent, purpose, findings, or policy does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

2. A statutory provision describing the agency's general powers or duties does not confer rule-making authority on the agency or augment the agency's rule-making authority beyond the rule-making authority that is explicitly conferred on the agency by the legislature.

3. A statutory provision containing a specific standard, requirement, or threshold does not confer on the agency the authority to promulgate, enforce, or administer a rule that contains a standard, requirement, or threshold that is more restrictive than the standard, requirement, or threshold contained in the statutory provision.

(b) Each agency may prescribe forms and procedures in connection with any statute enforced or administered by it, if the agency considers it necessary to effectuate the purpose of the statute, but this paragraph does not authorize the imposition of a substantive requirement in connection with a form or procedure.

(c) Each agency authorized to exercise discretion in deciding individual cases may formalize the general policies evolving from its decisions by promulgating the policies as rules which the agency shall follow until they are amended or repealed. A rule promulgated in accordance with this paragraph is valid only to the extent that the agency has discretion to base an individual decision on the policy expressed in the rule.

(d) An agency may promulgate rules implementing or interpreting a statute that it will enforce or administer after publication of the statute but prior to the statute's effective date. A rule promulgated under this paragraph may not take effect prior to the effective date of the statute that it implements or interprets.

(e) An agency may not inform a member of the public in writing that a rule is or will be in effect unless the rule has been filed under s. 227.20 or unless the member of the public requests that information.

Sections 49.688 (4), (6), and (7) (a), Stats., read:

(4) The department shall devise and distribute a form for application for the program under sub. (2), shall

determine eligibility for each 12-month benefit period of applicants and shall issue to eligible persons a prescription drug card for use in purchasing prescription drugs, as specified in sub. (5). The department shall promulgate rules that specify the criteria to be used to determine household income under sub. (2) (a) 4. and (b) and (3) (b) 1.

(6) The department, or an entity with which the department contracts, shall provide to a drug manufacturer that sells drugs for prescribed use in this state documents designed for use by the manufacturer in entering into a rebate agreement with the department or entity that is modeled on the rebate agreement specified under 42 USC 1396r-8. A rebate agreement under this subsection shall include all of the following as requirements: (a) That, except as provided in sub. (7) (b), the manufacturer shall make rebate payments for each prescription drug of the manufacturer that is prescribed for and purchased by persons who meet criteria under sub. (2) (a) and persons who meet criteria under sub. (2) (b) and have paid the deductible under sub. (3) (b) 2. a., to the secretary of administration to be credited to the appropriation account under s. 20.435 (4) (j), each calendar quarter or according to a schedule established by the department. (b) That, except as provided in sub. (7) (b), the amount of the rebate payment shall be determined by a method specified in 42 USC 1396r-8 (c).

. . . (7) Except as provided in par. (b), from the appropriation accounts under s. 20.435 (4) (bv), (j), and (pg), beginning on September 1, 2002, the department shall, under a schedule that is identical to that used by the department for payment of pharmacy provider claims under medical assistance, provide to pharmacies and pharmacists payments for prescription drugs sold by the pharmacies or pharmacists to persons eligible under sub. (2) who have paid the deductible specified under sub. (3) (b) 1. or 2. or who, under sub. (3) (b) 1., are not required to pay a deductible. The payment for each prescription drug under this paragraph shall be at the program payment rate, minus any copayment paid by the person under sub. (5) (a) 2. or 4., and plus, if applicable, incentive payments that are similar to those provided under s. 49.45 (8v). The department shall devise and distribute a claim form for use by pharmacies and pharmacists under this paragraph and may limit payment under this paragraph to those prescription drugs for which payment claims are submitted by pharmacists or pharmacies directly to the department. The department may apply to the program under this section the same utilization and cost control procedures that apply under rules promulgated by the department to medical assistance under subch. IV of ch. 49

2019 Wis. Act 185 ss. 16 and 17 read:

Section 16. 49.688 (1) (c) 2. of the statutes is created to read: . . . A vaccination recommended for administration to adults by the federal centers for disease control and prevention's advisory committee on immunization practices and approved for administration to adults by the department.

Section 17. 49.688 (10m) of the statutes is created to read: . . . (a) Notwithstanding subs. (6) and (7) (a), from the appropriation accounts under s. 20.435 (4) (bv), (j), and (pg), except as provided under sub. (7) (b), the department shall, under a schedule that is identical to that used by the department for payment of claims under the Medical Assistance program, provide to health care providers who administer vaccinations, including pharmacies and pharmacists, payments for vaccinations, as described under sub. (1) (c) 2., that are administered by health care providers to persons eligible under sub. (2) who have paid the deductible specified under sub. (3) (b) 1. or 2., or who, under sub. (3) (b) 1., are not required to pay a deductible. The reimbursement to a health care provider for each vaccination under this subsection shall be at the rate of payment made for the identical vaccination under s. 49.46 (2) (b), plus a dispensing fee that is equal to the dispensing fee permitted to be charged for vaccinations for which coverage is provided under s. 49.46 (2) (b). The department shall devise and distribute a claim form for use by health care providers under this subsection and may limit payment under this subsection to those vaccinations for which payment claims are submitted by health care providers directly to the department. The department may apply to the program under this subsection the same utilization and cost control procedures that apply under rules promulgated by the department to medical assistance under subch. IV of ch. 49. (b) The department may provide payment for a vaccination under this subsection only after deducting the amount of any payment for the vaccination available from other sources.

Explanation of agency authority

The department's authority to promulgate the proposed rules is provided in ss. 227.11 (2), Stats.

Related statute or rule

The SeniorCare program is authorized through a s. 1135(a) of the Social Security Act waiver approved by the federal Department of Health and Human Services. As a result, otherwise relevant federal statutes and rules do not apply to the program. Federal requirements are set forth in the SeniorCare program s. 1135(a) waiver approval document.

The following state statutes or rules directly relate to the SeniorCare program:
Section 49.688, Stats.

Plain language analysis

In 2019 Wisconsin Act 185, the Wisconsin Legislature expanded the definition of a "prescription drug" covered under the SeniorCare program to include designated vaccinations. Current rules exclude vaccinations from the prescription drug definition. Expansion of rules to provide for adequate regulation of SeniorCare covered vaccination is needed, including coverage scope, reimbursement and deductible guideline establishment, and record maintenance.

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

The SeniorCare program is authorized through a s. 1135(a) of the Social Security Act waiver approved by the federal Department of Health and Human Services.

Comparison with rules in adjacent states

Illinois:

Not applicable – Illinois does not offer a state pharmaceutical assistance program dedicated to similar population and services to the SeniorCare program population.

Iowa:

Not applicable – Iowa does not offer a state pharmaceutical assistance program dedicated to similar population and services to the SeniorCare program population.

Michigan:

Not applicable – Michigan does not offer a state pharmaceutical assistance program dedicated to similar population and services to the SeniorCare program population.

Minnesota:

Not applicable – Minnesota does not offer a state pharmaceutical assistance program dedicated to similar population and services to the SeniorCare program population.

Summary of factual data and analytical methodologies

The Department formed an advisory committee including representatives of AARP, Board on Aging and Long-Term Care, Dane County Department of Human Services, Fitchburg Family Pharmacy, Greater Wisconsin Agency on Aging Resources, Inc., Pharmaceutical Research and Manufacturers of America, Pharmacy Society of Wisconsin, Inc., Society of St. Vincent de Paul Madison Charitable Pharmacy, and University of Wisconsin-Madison School of Medicine and Public Health. Advisory committee members were provided a copy of draft language of the proposed rule and asked to provide comments.

Analysis and supporting documents used to determine effect on small business

[To be taken from EIA]

Effect on small business

[To be taken from EIA]

Agency contact person

Bailey Dvorak, 608-267-5210, DHSDMSAdminRules@dhs.wisconsin.gov

Statement on quality of agency data

See 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 109.03 (10) is renumbered DHS 109.03 (intro) and amended to read:

DHS 109.03 (10) "Prescription drug" ~~has the meaning given in s. 450.01 (20), Stats., that is included in the drugs specified under s. 49.46 (2) (b) 6. h., Stats., and s. DHS 109.31 and is manufactured by a drug manufacturer that enters into a rebate agreement in force under s. DHS 109.71.~~ means any of the following:

SECTION 2. DHS 109.03 (10) (a) and (b) are created to read:

DHS 109.03 (10) (a) A drug under s. 450.01 (20), Stats., that is included in the drugs specified under s. 49.46 (2) (b) 6. h., Stats., and s. DHS 109.31 and is manufactured by a drug manufacturer that enters into a rebate agreement in force under s. DHS 109.71.

(b) A vaccine recommended and approved for administration to adults by the federal centers for disease control and prevention's advisory committee on immunization practices.

SECTION 3. DHS 109.13 (2) (c) is amended to read:

DHS 109.13 (2) (c) *Exclusion for drugs.* If a drug is covered by a third party and the participant makes a copayment to the SeniorCare provider, the department is not responsible for refunding the copayment amount to the participant.

SECTION 4. DHS 109.13 (2) (bm), (d) and (e) are created to read:

DHS 109.13 (2) (bm) *Exclusion of copayment.* A copayment is not required for a vaccine or vaccine administration.

DHS 109.13 (2) (d) *Exclusion for vaccines and vaccine administration.* The department will not cover reimbursement of a vaccine or vaccine administration in any of the following circumstances.

1. If a vaccine is not on the federal centers for disease control and prevention's advisory committee on immunization practices list of vaccines recommended for immunization to adults.
2. A vaccine is not administered by a SeniorCare provider in an allowed place of service.

DHS 109.13 (2) (e) *Exclusion for vaccines.* The department will not cover reimbursement of a vaccination when the vaccine is allocated through the federal government at no cost to the provider.

SECTION 5. DHS 109.31 (3) (h) is created to read:

DHS 109.31 (3) (h) SeniorCare shall only cover vaccines that are recommended for immunization to adults by the federal centers for disease control and prevention's advisory committee on immunization practices and administered by a SeniorCare provider in an allowed place of service.

SECTION 6. DHS 109.51 (5) is amended to read:

DHS 109.51 (5) **SUBMISSION OF CLAIMS.** A SeniorCare provider shall submit all claims for prescription drugs purchased by a participant during spend-down and deductible periods.

SECTION 7. DHS 109.52 (8) (d) and (11) (b) are amended to read:

DHS 109.52 (8) (d) Prescriptions that support SeniorCare billings, including records of SeniorCare covered vaccines and vaccine administration.

DHS 109.52 (11) (b) *Reimbursement.* A SeniorCare provider may not claim reimbursement for prescription drugs provided to participants on or after the effective date specified in the termination notice. If the SeniorCare provider's notice of termination fails to specify an effective date, the department shall terminate the SeniorCare provider's certification to provide and claim reimbursement for services under the program on the date on which the department receives notice of termination.

SECTION 8. DHS 109.61 (2) is amended to read:

DHS 109.61 (2) **PRIOR IDENTIFICATION OF ELIGIBILITY.** Except in emergencies that preclude prior identification, the participant shall, before receiving prescription drugs, inform the SeniorCare provider that the participant is receiving benefits under SeniorCare and shall present to the SeniorCare provider a current valid SeniorCare identification card.

SECTION 9. DHS 109.73 is amended to read:

DHS 109.73 **Program suspension.** During any period in which funding under s. 20.435 (4) (bv), Stats., is completely expended for the payments to SeniorCare providers, the requirements of ss. DHS 109.71 and 109.72 do not apply to prescription drugs purchased during that period. However, the department shall continue to accept applications and determine eligibility under subchapter II and shall indicate to applicants that the eligibility of program participants to purchase prescription drugs as specified in this chapter, under the requirements of s. DHS 109.72, is conditioned on the availability of funding under s. 20.435 (4) (bv), Stats.

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