

WISCONSIN DEPARTMENT OF HEALTH SERVICES PROPOSED ORDER TO ADOPT PERMANENT RULES

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

RULE SUMMARY

Statute interpreted

Section 49.688 (1) (c) 2., (4), (6), (7), (10m) and (11), Stats.

Statutory authority

The department is authorized to promulgate the proposed rules based upon ss. 227.11(2) and 49.688 (4) and (7), Stats.

Explanation of agency authority

Section 227.11 (2), Stats., gives the department authority 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, but a rule is not valid if the rule exceeds the bounds of correct interpretation.” Section 227.11 (2) (b), Stats., provides authority “to 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” Chapter DHS 109 was promulgated to implement the prescription drug benefits for the elderly called “SeniorCare” and interpreted the following statutes administered by the department:

- Section 49.688 (4), Stats., which provides that 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).
- Section 49.688 (6), Stats., which requires the department or any entity with which the department contracts to provide a drug manufacturer with documents for entering into a rebate agreement that is modeled on 42 USC 1396r-8. Paragraphs (a) and (b) provide additional requirements for rebate agreements.
- Section 49.688 (7), Stats., which requires the department to utilize 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 [for SeniorCare].” The subsection further provides that the department shall “devise and distribute a claim form for use by pharmacies and pharmacists,” and to limit payment to prescription drugs for which claims are submitted directly to the department.
- Section 49.688 (11), which requires the department to request a waiver of federal medicaid laws under 42 U.S.C s. 1315 (a) to permit the department to create a program to expand eligibility for prescription drugs for elderly persons, and to implement that program.

The following provision provide explicit authority for ch. DHS 109:

- Section 49.688 (7), which permits the department to apply to the SeniorCare program “the same utilization and cost control procedures that apply under rules promulgated by the department to medical assistance under subch. IV of ch. 49.”

The proposed rule interprets two new provisions in s. 49.688, Stats., which were added by 2019 Wis. Act 185. Section 49.688 (1) (c) 2., Stats., expanded the definition of “prescription drug” to include “a vaccination recommended for administration 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 49.688 (10m), Stats., requires the department to provide payments for vaccinations provided to eligible SeniorCare participants under a schedule that is “identical to that used by the department for payments of claims under the Medical Assistance programs” and at a rate of payment for the identical vaccination under and the dispensing fee under s. 49.46 (2) (b). Subsection (10m) also permits the department to to the SeniorCare program “the same utilization and cost control procedures that apply under rules promulgated by the department to medical assistance under subch. IV of ch. 49.”

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 vaccinations are 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

The department solicited the input of SeniorCare providers, including small businesses, as required by state and federal law.

Effect on small business

The proposed rule changes have the potential to impact SeniorCare providers including pharmacies that are small businesses. These providers have the opportunity to provide designated vaccinations as covered services "prescription drugs," which expands services covered by SeniorCare.

Agency contact person

Bailey Dvorak, 608-267-5210, DHSAdminRules@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 (10) (intro.) and amended to read:

DHS 109.03 (10) "Prescription drug" or "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) (bm) is created to read:

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

SECTION 4. DHS 109.13 (2) (c) (title) is amended to read:

DHS 109.13 (2) (c) *Exclusion for drugs.*

SECTION 5. DHS 109.13 (2) (d) and (e) are created to read:

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 6. 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 7. 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 8. 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 9. 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 10. 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 11. INITIAL APPLICABILITY. This rule first applies to vaccines administered on or after June 6, 2022.

SECTION 12. 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.