STATEMENT OF SCOPE
WISCONSIN DEPARTMENT OF HEALTH SERVICES

CHAPTER: DHS 109
RELATING TO: SeniorCare Prescription Drugs
RULE TYPE: Permanent
SCOPE TYPE: Original
FINDINGS OF EMERGENCY: Not applicable

SUMMARY

1. Description of rule objective/s

2019 Wis. Act 185 ("Act 185"), which took effect on April 17, 2020, expands the definition of a "prescription drug" covered under the SeniorCare program to include designated vaccinations. In accordance with s. 227.29 (4), the department of health services ("the department") has determined that Act 185 necessitates rulemaking.

2. Existing policies relevant to the rule

Chapter DHS 109, relating to SeniorCare.

3. Policies proposed to be included in the rule

The department intends to promulgate administrative rules necessary to effectuate the purpose of Act 185 to expand the definition of prescription drug to include designated vaccinations under the SeniorCare program.

4. Analysis of policy alternative

There are no reasonable alternatives to the proposed rulemaking. The Wisconsin Legislature has directed the department to expand the definition of prescription drug to include designated vaccinations under the SeniorCare program. 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.

5. Statutory authority for the rule

a. Explanation of authority to promulgate the proposed rule

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

b. Statute/s that authorize/s the promulgation of the proposed rule

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.

c. Statute/s or rule/s that will affect the proposed rule or be affected by it

Chapter DHS 109, relating to SeniorCare.

6. Estimates of the amount of time that state employees will spend to develop the rule and other necessary resources

The estimated time for state employees to develop the rule is 2,080 hours.

7. Description of all of the entities that may be affected by the rule, including any local governmental units, businesses, economic sectors, or public utility ratepayers who may reasonably be anticipated to be affected by the rule

- Members receiving SeniorCare services.
- The department.
- Providers providing SeniorCare services.

8. Summary and preliminary comparison of any existing or proposed federal regulation that is intended to address the activities to be regulated by the rule

The Department of Health and Human Services regulations also define prescription drugs.

- 21 CFR § 203.3 Prescription drug means any drug (including any biological product, except for blood and blood components intended for transfusion or biological products that are also medical devices) required by Federal law (including Federal regulation) to be dispensed only by a prescription, including finished dosage forms and bulk drug substances subject to section 503(b) of the act.
- 21 CFR § 205.3 (e) Prescription drug means any human drug required by Federal law or regulation to be dispensed only by a prescription, including finished dosage forms and active ingredients subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act.

These definitions do not preclude the proposed rule.

9. Anticipated economic impact, locally or statewide

The proposed rule may have a moderate economic impact.

10. Agency contacts

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