

STATEMENT OF SCOPE
WISCONSIN DEPARTMENT OF HEALTH SERVICES

CHAPTER: DHS 107
RELATING TO: Medicaid Benefits Management
RULE TYPE: Emergency
SCOPE TYPE: Original

FINDING OF EMERGENCY: Preservation of the public peace, health, safety, or welfare necessitates adoption of an emergency rule because strict compliance with provisions of ss. DHS 107 will: (1) prevent or delay Medicaid recipients from receiving necessary medications due to prior authorization requirements, refill restrictions, and non-legend drug restrictions; and (2) expose vulnerable populations to greater risk of contracting COVID-19 due to restrictions on the number of days' supply of medications that can be provided—thereby requiring Medicaid recipients to go out in public more frequently to obtain medications. Temporary suspension of these provisions will ensure Medicaid recipients continue to receive necessary care and medication without delay or interruption, and will further decrease their risk of contracting COVID-19 in the community.

SUMMARY

1. Description of rule objectives

On March 12, 2020, Governor Evers issued Executive Order 72, which, in accordance with s. 323.10, Stats., declared a public health emergency related to COVID-19. Executive Order 72 further designated the Department of Health Services (“the department”) as the lead agency to respond to the public health emergency. The Governor directed the department to take all necessary and appropriate measures to respond to, and prevent the spread of, COVID-19 in the state—including suspending any administrative rule provisions for which strict compliance would prevent, hinder, or delay necessary actions to respond to the emergency and increase the health threat.

On May 4, 2020 Governor Evers and Secretary-designee Palm issued Emergency Order 35, which ordered the suspension of a number of administrative rules, including various sections of chs. DHS 107. The order suspended s. DHS 107.10 (2) (e), (3) (a) to (d), which, respectively, require prior authorizations before a provider can submit a claim for a drug that is not already subject to a federal rebate agreement, establish limits on the number of medication refills and days' supply that can be provided. The order also suspended s. DHS 107.10 (3) (h), which provides a list of non-legend drugs that can receive Medicaid

funding. The purpose of these suspensions was to prevent delays or interruptions in receipt of necessary medications during the COVID-19 emergency.

The Governor's public health emergency declaration expired on May 11, 2020, per s. 323.10, Stats., and that expiration will effectively nullify Emergency Order 35. In order to preserve the public peace, health, safety, and welfare under s. 227.24 (1) (a), Stats., and in accordance with the department's authority under s. 252.02 (4) and (6), Stats., to promulgate rules and implement emergency measures to protect against, and control the spread of, communicable diseases, the department proposes to temporarily suspend all of the afore-mentioned rule provisions in a manner consistent with Emergency Order 35.

2. Existing policies relevant to the rule and policies proposed to be included in the rule.

The current rule contains several pharmacy-specific provisions that could either prevent Medicaid recipients from receiving necessary medications or increase their risk of contracting COVID-19 by requiring more frequent trips to a pharmacy for refills. Section DHS 107.10 (2) (e), (3) (a) and (b), and (3) (d) and (e), and (3) (h) require prior authorizations for drugs that are not currently covered under a federal rebate agreement, limit the number of refills or number of days' supply that can be provided, and enumerates a list of non-legend drugs that are covered by Medicaid. The spread of COVID-19 has caused a supply chain disruption that limits the availability of drugs authorized under Medicaid; although CMS has authorized states to provide coverage for a drug that is not covered under a federal rebate agreement, strict application of the prior authorization requirement or the non-legend drug list could result in delay's in the program's ability to provide immediate coverage if necessary. Temporarily suspending these provisions will allow Medicaid members to receive necessary medications without delay or interruption. Furthermore, restrictions on the number of refills and days' supply could result in more trips to the doctor to renew a prescription, or to a pharmacy to refill a prescription, thereby posing a greater risk of contracting COVID-19—especially with respect to maintenance medications for vulnerable populations. Temporarily suspending these provisions will allow greater flexibility in prescription orders and result in fewer trips to the doctor or pharmacy to obtain necessarily medications.

3. Analysis of policy alternative

There are no reasonable alternatives to emergency rulemaking. Governor Evers and Secretary-designee Palm jointly ordered that these above-referenced administrative rules and companion directives be suspended on May 4, 2020, and that order expired on May 11, 2020.

4. Statutory authority for the rule

a. Explanation of authority to promulgate the proposed rule

The Department is authorized to promulgate the rule based upon explicit statutory language.

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

The Department is authorized to promulgate the emergency rule based upon the following statutory sections:

Section 252.02 (4) and (6), Stats.:

(4) . . . [T]he department may promulgate and enforce rules or issue orders for guarding against the introduction of any communicable disease into the state, for the control or suppression of communicable diseases, for the quarantine and disinfection of persons, localities and things infected or suspected of being infected by a communicable disease

(6) The department may authorize and implement all emergency measures necessary to control communicable diseases.

Section 227.11 (2) (a), Stats.: 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 rule-making 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.

Section 227.24 (1) (a), Stats.: An agency may, except as provided in s. 227.136 (1), promulgate rule as an emergency rule without complying with the notice, hearing, and publication requirements under this chapter if preservation of the public peace, health, safety, or welfare necessitates putting the rule into effect prior to the time it would take effect if the agency complied with the procedures.

c. Statutes or rules that will affect the proposed rule or be affected by it

There do not appear to be any other statutes or rules that will be affected by the proposed emergency rule.

5. 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 emergency rule is 40 hours.

6. 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 emergency rule

Pharmacies, pharmacists, and prescribing physicians may be affected by the emergency rule.

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

21 CFR 1306.22 – Federal requirement that mandates no prescription for a controlled substance listed in Schedule III or IV shall be filled or refilled more than six months after the date on which such prescription was issued and no prescription for a controlled substance listed in Schedule III or IV authorized to be refilled may be refilled more than five times. This federal regulation will ensure appropriate fill and refill practices for controlled substances and addresses the activities being regulated in s. DHS 107.10 (3) (a).

8. Anticipated economic impact, locally or state wide

The proposed rule will have minimal or no economic impact.

Agency contacts

Mark R. Thompson, Admin. Rules Attorney
Office of Legal Counsel
(608) 266-1279
mark.thompson1@dhs.wisconsin.gov

Jackson Keuler, Admin. Rules Officer
Office of Legal Counsel
(608) 266-0387
jackson.keuler@dhs.wisconsin.gov