WISCONSIN DEPARTMENT OF HEALTH SERVICES PROPOSED ORDER TO ADOPT EMERGENCY RULES

The Wisconsin Department of Health Services proposes an order to: **amend** ss. DHS 107.10 (2) (e), and (3) (a), (d), (e) and (h).

FINDING OF EMERGENCY

Preservation of the public peace, health, safety, or welfare necessitates adoption of an emergency rule because strict compliance with provisions of s. 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.

RULE SUMMARY

Statute interpreted

Not applicable.

Statutory authority

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.

<u>Section 227.11 (2) (a), Stats.</u>: 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 rulemaking authority on the agency or augment the agency's rule-making authority beyond the rulemaking 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.

<u>Section 227.24 (1) (a), Stats.</u>: 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.

Explanation of agency authority

The Department's authority to promulgate the emergency rules to allow Medical Assistance program flexibilities to ensure member access to prescription drugs is explicitly granted by the Legislature in Section 252.02 (4) and (6), Stats.

Related statute or rule

The following statutes or rules directly relate to Medical Assistance member access to prescription drugs: Section 1905(a)(12) of the Social Security Act of 1935, as amended. Section 1927 of the Social Security Act of 1935, as amended. 21 CFR 1306.22. Section 49.45 (49) and (49m), Stats.. Section 252.02 (4) and (6), Stats..

Plain language analysis

The intent of the emergency rule is to grant Medical Assistance program flexibilities to ensure member access to prescription drugs including the flexibility to remove prior authorization requirements for prescription drugs not included in the federal rebate agreement, certain limits on the number of medication refills and days' supplies of prescription drugs, and the list of non-legend drugs covered by the Medical Assistance program.

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

The Social Security Act of 1935, as amended, provides Medical Assistance coverage for prescription drugs and provides limits to payment rates. Federal regulations do not limit the flexibilities granted under the emergency rule.

Comparison with rules in adjacent states

Illinois:

Illinois Medical Assistance requires prior authorization for prescription drugs not on its preferred drug list and covers a 90-day supply of designated maintenance medications. In March 2020, Illinois suspended prior authorization requirements, expanded its preferred drug list and designated maintenance medications as a result of the public health emergency.

lowa:

lowa Medical Assistance requires prior authorization for designated prescription drugs and generally covers a 31-day supply of drugs.

Michigan:

Michigan Medical Assistance requires prior authorization for designated prescription drugs. In March and April 2020, respectively, Michigan began allowing for suspension of prior authorization requirements and some early drug refills.

Minnesota:

Minnesota Medical Assistance requires prior authorization for prescription drugs designated as noncovered and generally covers a 34-day supply of covered drugs. On April 2, 2020, Minnesota temporarily increased the prescription drug coverage limit for certain therapeutic non-controlled drug classes to a 90-day supply for all Medical Assistance Members. On April 27, 2020, Minnesota allowed for suspension of prior authorization requirements.

Summary of factual data and analytical methodologies

The Department relied upon requirements under s. 227.24, Stats., and information provided to the Department by the Legislative Reference Bureau.

Analysis and supporting documents used to determine effect on small business

The emergency rule is not anticipated to have an effect on small business. See the associated Fiscal Estimate & Economic Impact Analysis.

Effect on small business

The emergency rule is not anticipated to have an effect on small business.

Agency contact person

Laura Brauer, DHSDMSAdminRules@dhs.wisconsin.gov, (608) 266-5368.

Statement on quality of agency data

See "summary of factual data and analytical methodologies" section above.

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 107.10 (2) (e), (3) (a), (d), (e) and (h) are amended to read:

DHS 107.10 (2) (e) Any drug Drugs as identified by the Medical Assistance program that are produced by a manufacturer who has not entered into a rebate agreement with the federal secretary of health and human services, as required by 42 USC 1396r–8, if the prescribing provider under sub. (1) demonstrates to the department's satisfaction that no other drug sold by a manufacturer who complies with 42 USC 1396r–8 is medically appropriate and cost–effective in treating the recipient's condition;

DHS 107.10 (3) (a) Dispensing of schedule III, IV and V drugs shall be limited to the original dispensing plus 5 refills, or 6 months from the date of the original prescription, whichever comes first in accordance with 21 CFR 1306.22.

DHS 107.10 (3) (d) Except as provided in par. (e), legend Legend drugs shall be dispensed in the full amounts prescribed, not to exceed a 34-day supply.

DHS 107.10 (3) (e) The following drugs may be dispensed in amounts up to but not to exceed a 100-day supply, as prescribed by a physician:

1. Digoxin, digitoxin, digitalis;

- 2. Hydrochlorothiazide and chlorothiazide;
- 3. Prenatal vitamins;
- 4. Fluoride;
- 5. Levothyroxine, liothyronine and thyroid extract;
- 6. Phenobarbital;
- 7. Phenytoin; and

8. Oral contraceptives Medical Assistance program will maintain a list of drugs which may be dispensed in amounts up to but not to exceed a 100-day supply as described in MA provider handbooks.

DHS 107.10 (3) (h) To be included as a covered service, a non-legend drug shall be used in the treatment of a diagnosable medical condition and be a rational part of an accepted medical treatment plan. The following general categories of non-legend drugs are covered: 1. Antacids;

2. Analgesics;

3. Insulins;

4. Contraceptives;

5. Cough preparations;

6. Ophthalmic lubricants; and

7. Iron supplements for pregnant women. The Medical Assistance program shall identify nonlegend drugs covered as described in MA provider handbooks.

SECTION 2. EFFECTIVE DATE: This rule shall take effect upon publication in the official state newspaper, as provided in s. 227.24 (1) (c), Stats. The rule shall remain in effect until the end of the time period provided in ss. 227.24 (1) (c) and (2), Stats.

Wisconsin Department of Health Services

Dated: _____

Andrea Palm, Secretary-designee

SEAL: