

# STATEMENT OF SCOPE

## Office of the Commissioner of Insurance

**Rule No.:** 145 ss. Ins 18.03, 18.06 and 18 subch IV

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**Relating to:** Step therapy protocols for prescription drug coverage, grievance procedure amendments and affecting small business

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**Rule Type:** Permanent

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### 1. Finding/nature of emergency:

NA

### 2. Detailed description of the objective of the proposed rule:

2019 Wisconsin Act 12 created Wis. Stat. § 632.886, that will become effective November 1, 2019 and is applicable to policies issued on or after January 1, 2020. The Commissioner of Insurance proposes promulgating any rules necessary to implement the Act and to ensure compliance with the statute. In addition, the Commissioner will update grievance procedures contained in ss. Ins 18.03 and 18.06, Wis. Adm. Code, with technical corrections.

### 3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:

Currently, Wis. Stat. § 632.853 requires health care plans or self-insured non-federal, governmental health plans that provide coverage of specified prescription drugs or devices to have a process for providers to request an individual exception for coverage of a particular medication or device based upon medical evidence. The process required under Wis. Stat. § 632.853 includes a requirement for handling urgent and nonurgent reviews of exception requests. Similarly, the newly enacted statute requires all insurers, pharmacy benefit managers and utilization review organizations that use step therapy protocols to develop, or use an existing process, to allow providers to request an exception on both an urgent and nonurgent basis. The Commissioner will, through regulations, ensure insurers, pharmacy benefit managers, and utilization review organizations that utilize step therapy protocols are fully compliant. Insurers and pharmacy benefit managers, as applicable, must also comply with Wis. Stat. §§ 632.86, 632.865. Specifically, Wis. Stat. § 632.86 pertains to restrictions for insurers that utilize mail order pharmaceutical services from excluding coverage from a pharmacy selected by the insured that agrees to provide drugs and devices under the terms of the policy at the same cost to the insurer as the mail order plan. Pharmacy benefit managers are required to comply with Wis. Stat. § 632.865 pricing transparency of drugs and devices. Additionally, health benefit plans must also comply with Wis. Stat. §§ 632.83 and 632.835, addressing internal grievance and external, independent, review of adverse determinations, respectively. The Commissioner proposes to update existing grievance processes including terminology, procedures, and requirements.

To fully implement the new statute related to step therapy protocols for prescription drug coverage, the Commissioner will align existing statutes and regulations with the requirements of the newly enacted legislation.

### 4. Detailed explanation of statutory authority for the rule (including the statutory citation and language):

Wisconsin Statute § 632.866 (4), authorizes the Commissioner to promulgate any rules necessary to implement and enforce the step therapy statute. Additionally, Wis. Stat. § 601.41 (3), grants the commissioner authority to draft rules that are necessary and consistent with the commissioner's duty to enforce the Wisconsin Insurance laws contained in Wis. Stats., chs. 600 to 655.

**5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule :**

200 hours.

**6. List with description of all entities that may be affected by the proposed rule :**

The proposed rule will affect insurers, health care providers and consumers, pharmacy benefit managers, and utilization review organizations that use step therapy protocols. The updates to ss. Ins 18.03 and 18.06, Wis. Adm. Code, will affect insurers that are health benefit plans, consumers, and providers.

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

There is no federal regulation at this time addressing the specific content of the proposed rule related to step therapy. Federal regulation requires, for qualified health plans providing essential health benefits, to have procedures for exception requests of clinically appropriate drugs that are not within the formulary on both an urgent and nonurgent timeframe pursuant to 45 CFR § 156.122 (c). Additionally, under federal law, health insurance issuers that are not grandfathered health plans, are required to have internal and external independent review processes pursuant to 45 CFR § 147.136 for both urgent and nonurgent requests.

**8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):**

The anticipated economic impact should be negligible to insurers, pharmacy benefit managers, utilization review organizations, and providers as many insurers will be able to utilize existing appeal processes for compliance with the step therapy and revised grievance procedures. Based upon public testimony during the legislative hearings, the statutory process for handling exceptions from step therapy protocols should be less time consuming and lessen burdens on providers and consumers seeking exceptions from step therapy protocols.

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