

**NOTICE OF PRELIMINARY PUBLIC HEARING**  
**OFFICE OF THE COMMISSIONER OF INSURANCE**

The Office of the Commissioner of Insurance announces that it will hold a preliminary public hearing on SS: 123-19, a Statement of Scope for ss. Ins 18.03, 18.06, and 18 subch. IV, Wis. Adm. Code, relating to step therapy protocols for prescription drug coverage, grievance procedure amendments and affecting small business. In accordance with s. 227.136, Stats., the Commissioner is seeking public input through the hearing and comment period regarding the content of the proposed rule as described in the Statement of Scope at the time and place shown below.

**Hearing Information:**

Date: January 16, 2020  
Time: 9:30 am  
Location: Office of the Commissioner of Insurance  
125 S. Webster St., 2<sup>nd</sup> Floor Rm. 227  
Madison, WI 53703

**Accessibility:**

Pursuant to the American with Disabilities Act reasonable accommodations including the provision of informational materials in an alternative format, will be provided for individuals with disabilities upon request. Please call Karyn Culver at (608) 267-9586 with specific information on your request at least 5 days before the date of the hearing. There is also handicap access to the hearing location.

**Appearances at the Hearing and Submittal of Written Comments:**

Persons wishing to testify or provide oral or written comments regarding the Statement of Scope for the proposed administrative rule may appear during the hearing. Additionally comments may be submitted at <https://docs.legis.wisconsin.gov/code>.

For additional information please contact Julie E. Walsh at (608) 264-8101 or email at [Julie.Walsh@wisconsin.gov](mailto:Julie.Walsh@wisconsin.gov) in the OCI Legal Unit.

Deadline for submitting comments is January 27, 2020 by 4:00 pm.

**Initial Regulatory Flexibility Analysis:**

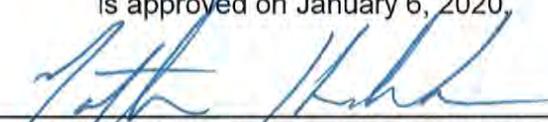
The Statement of Scope for proposed rules will modify ss. Ins 18.03 and 18.06, Wis. Adm. Code, to update grievance procedures and make technical corrections. The proposed rule will add a subchapter to ch. 18 to address any rules necessary to implement 2019 Wis. Act 12 that created Wis. Stat. § 632.886, and to ensure compliance with the statute. 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.

The rule is unlikely to have a significant impact on to insurers, pharmacy benefit managers, utilizations 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..

**Agency Small Business Regulatory Coordinator:**

The OCI small business coordinator is Kate Ludlum and she may be reached at [Kate.Ludlum@wisconsin.gov](mailto:Kate.Ludlum@wisconsin.gov) or (608) 264-6232.

This Notice of Preliminary Public Hearing  
is approved on January 6, 2020,



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Nathan D. Houdek, Deputy Commissioner

# STATEMENT OF SCOPE

## Office of the Commissioner of Insurance

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

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

**Rule Type:** Permanent

**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.

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.

The Commissioner will align existing statutes and regulations with the requirements of the newly enacted step therapy legislation and enact any additional provisions necessary to implement the law.

**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.

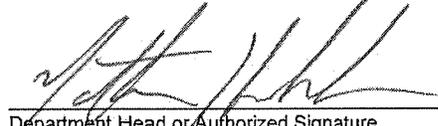
**7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:**

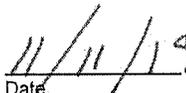
There is no federal regulation at this time addressing the specific content of the proposed rule related to step therapy. Federal regulation requires, for qualified health plans providing essential health benefits, to have procedures for exception requests of clinically appropriate drugs that are not 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.

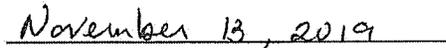
**8. Anticipated economic impact of implementing the rule (note if the rule is likely to have a significant economic impact on small businesses):**

The anticipated economic impact should be negligible to insurers, pharmacy benefit managers, utilizations 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 less burdensome for providers and consumers seeking exceptions from step therapy protocols.

**Contact Person:** Julie E. Walsh, Senior Attorney, [Julie.Walsh@wisconsin.gov](mailto:Julie.Walsh@wisconsin.gov), (608) 264-8101.

  
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Department Head or Authorized Signature

  
\_\_\_\_\_  
Date

  
\_\_\_\_\_  
Date Submitted



# Tony Evers

Office of the Governor | State of Wisconsin

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December 5, 2019

By Electronic Mail Only

Dear Secretaries and Agency Heads:

On this day, I approved the following statements of scope pursuant to Wis. Stat. § 227.135(2):

- A statement of scope by the Department of Health Services, submitted September 12, 2019, relating to Division of Medicaid Services biennial review (Wis. Admin. Code chs. DHS 90, 103, 104, 105, 106, 107, 109, 152, 250, and 251); and
- A statement of scope by the Department of Children and Families, submitted October 14, 2019, relating to technical changes to update Wisconsin Works rules (Wis. Admin. Code ch. DCF 101); and
- A statement of scope by the Department of Public Instruction, submitted November 7, 2019, relating to expanding the assessment of pedagogical knowledge in educator preparation programs (Wis. Admin. Code ch. PI 34); and
- A statement of scope by the Department of Agriculture, Trade, and Consumer Protection, submitted October 24, 2019, relating to Licensing, Practice Scope, and Standard of Practice for Veterinarians and Veterinary Technicians (Wis. Admin. Code chs. VE 1-11); and
- A statement of scope by the Department of Natural Resources, submitted July 30, 2019, relating to the administration, procedures, and enforcement of the Wisconsin Wetland and Waterway regulatory program (Wis. Admin. Code chs. NR 300, 301, 305 and 310); and
- A statement of scope by the Department of Natural Resources, submitted August 20, 2019, relating to Wastewater Discharges from Dental Offices to Sanitary Sewers (Wis. Admin. Code ch. NR 211); and
- A statement of scope by the Department of Natural Resources, submitted September 9, 2019, relating to Well Construction and Pump Installation (Wis. Admin. Code ch. NR 812); and
- A statement of scope by the Department of Natural Resources, submitted November 13, 2019, relating to Establishing the 2020 migratory bird season framework and regulations (Wis. Admin. Code ch. NR 10); and
- A statement of scope by the Office of the Commissioner of Insurance, submitted November 13, 2019, relating to step therapy protocols for prescription drug coverage (Wis. Admin. Code ch. Ins 18); and

- A statement of scope by the Department of Agriculture, Trade and Consumer Protection, submitted October 3, 2019, relating to recreational and educational camps (Wis. Admin. Code ch. ATCP 78); and
- A statement of scope by the Parole Commission, submitted October 25, 2019, relating to parole procedure (Wis. Admin. Code ch. PAC 1).

On this day, I approved the following proposed administrative rules pursuant to Wis. Stat. § 227.185:

- A proposed rule by the Office of the Commissioner of Insurance, submitted on October 15, 2019, relating to holding company supervision amendments and corporate governance disclosure requirements (Wis. Admin. Code chs. Ins 40 and 53); and
- A proposed rule by the Office of the Commissioner of Insurance, submitted on October 7, 2019, relating to the Wisconsin Insurance Plan (Wis. Admin. Code ch. Ins 4); and
- A proposed rule by the Department of Natural Resources, submitted on June 26, 2019, relating to Best Management Practices and Cost Share Rates (Wis. Admin. Code ch. NR 154); and
- A proposed rule by the Department of Natural Resources, submitted on September 26, 2019, relating to Air Permit Streamlining (Wis. Admin. Code chs. NR 406 and 407); and
- A proposed rule by the Department of Natural Resources, submitted on October 24, 2019, relating to Surface Water Grant Program (Wis. Admin. Code chs. NR 190, 191, 192, 195, and 198); and
- A proposed rule by the Department of Natural Resources, submitted on November 7, 2019, relating to Test methods for examining water and wastewater (Wis. Admin. Code ch. NR 538); and
- A proposed rule by the Department of Health Services, submitted on November 1, 2019, relating to Immunization of Students (Wis. Admin. Code ch. DHS 144); and
- A proposed rule by the Department of Natural Resources, submitted on November 12, 2019, relating to Federal hazardous waste regulation (Wis. Admin. Code ch. NR 600); and
- A proposed rule by the Department of Agriculture, Trade and Consumer Protection, submitted on November 13, 2019, relating to animal disease movement and animal markets, dealers and truckers, and affecting small businesses (Wis. Admin. Code chs. ATCP 10 and 12); and
- A proposed rule by the Department of Agriculture, Trade and Consumer Protection, submitted on September 5, 2019, relating to milk, food and water testing laboratories (Wis. Admin. Code ch. ATCP 77); and
- A proposed rule by the Department of Veterans Affairs, submitted on November 5, 2019, relating to the educational assistance program (Wis. Admin. Code ch. VA 18).

Please direct any questions about this letter to my chief legal counsel, Ryan Nilsestuen.

Sincerely,



Tony Evers  
Governor

Cc: Ryan Nilsestuen, chief legal counsel ([ryan.nilsestuen1@wisconsin.gov](mailto:ryan.nilsestuen1@wisconsin.gov))  
Jenni Dye, policy director ([jenni.dye@wisconsin.gov](mailto:jenni.dye@wisconsin.gov))  
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