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## WISCONSIN LEGISLATIVE COUNCIL RULES CLEARINGHOUSE

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**Ronald Sklansky**  
*Clearinghouse Director*

**Richard Sweet**  
*Clearinghouse Assistant Director*

**Terry C. Anderson**  
*Legislative Council Director*

**Laura D. Rose**  
*Legislative Council Deputy Director*

### CLEARINGHOUSE REPORT TO AGENCY

[THIS REPORT HAS BEEN PREPARED PURSUANT TO S. 227.15, STATS. THIS IS A REPORT ON A RULE AS ORIGINALLY PROPOSED BY THE AGENCY; THE REPORT MAY NOT REFLECT THE FINAL CONTENT OF THE RULE IN FINAL DRAFT FORM AS IT WILL BE SUBMITTED TO THE LEGISLATURE. THIS REPORT CONSTITUTES A REVIEW OF, BUT NOT APPROVAL OR DISAPPROVAL OF, THE SUBSTANTIVE CONTENT AND TECHNICAL ACCURACY OF THE RULE.]

#### CLEARINGHOUSE RULE 01-154

AN ORDER to repeal Phar 8.05 (5); and to amend Phar 8.05 (4), relating to requirements for the dispensing of prescription orders for schedule II controlled substances.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

12-17-01 RECEIVED BY LEGISLATIVE COUNCIL.

01-16-02 REPORT SENT TO AGENCY.

RNS:PC:ksm;tlu

**LEGISLATIVE COUNCIL RULES CLEARINGHOUSE REPORT**

This rule has been reviewed by the Rules Clearinghouse. Based on that review, comments are reported as noted below:

1. STATUTORY AUTHORITY [s. 227.15 (2) (a)]

Comment Attached      YES       NO

2. FORM, STYLE AND PLACEMENT IN ADMINISTRATIVE CODE [s. 227.15 (2) (c)]

Comment Attached      YES       NO

3. CONFLICT WITH OR DUPLICATION OF EXISTING RULES [s. 227.15 (2) (d)]

Comment Attached      YES       NO

4. ADEQUACY OF REFERENCES TO RELATED STATUTES, RULES AND FORMS  
[s. 227.15 (2) (e)]

Comment Attached      YES       NO

5. CLARITY, GRAMMAR, PUNCTUATION AND USE OF PLAIN LANGUAGE [s. 227.15 (2) (f)]

Comment Attached      YES       NO

6. POTENTIAL CONFLICTS WITH, AND COMPARABILITY TO, RELATED FEDERAL  
REGULATIONS [s. 227.15 (2) (g)]

Comment Attached      YES       NO

7. COMPLIANCE WITH PERMIT ACTION DEADLINE REQUIREMENTS [s. 227.15 (2) (h)]

Comment Attached      YES       NO



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## CLEARINGHOUSE RULE 01-154

### Comments

**[NOTE: All citations to "Manual" in the comments below are to the Administrative Rules Procedures Manual, prepared by the Revisor of Statutes Bureau and the Legislative Council Staff, dated September 1998.]**

#### **2. Form, Style and Placement in Administrative Code**

In s. Phar 8.05 (4), the hyphen in "prescription-order" should be deleted to reflect the current rule.

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 01-154)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 8.05 (5); and to amend Phar 8.05 (4), relating to requirements for the dispensing of prescription orders for schedule II controlled substances.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

Statutes authorizing promulgation: ss. 15.08 (5) (b), 227.11 (2), 450.02 (3) (a), (d) and (e), and 961.31, Wis. Stats.

Statutes interpreted: ss. 450.01 (7), (16) (b) and 450.02 (2g) (b), (3) (a), Wis. Stats.

Current requirements of s. Phar 8.05 (4), Wis. Admin. Code, for the dispensing of prescription orders for schedule II controlled substances provide in part that a prescription order may not be dispensed unless the order is presented for dispensing within 7 days following the date of its issue, and may not be dispensed more than 60 days after the date of issue. The proposed rule modification would remove the 7 day limitation. A prescription order presented past the 7 day limit currently will not be filled, which necessitates a return to the prescriber for a new prescription. This result occurs even when a legitimate reason exists for the late presentment. The result of the 7 day limit therefore becomes at times an arbitrary cutoff that doesn't allow for a pharmacist and a prescriber to take into account a patient's specific needs in a given situation. The modification of this rule will therefore allow pharmacists and prescribers to exercise their professional judgment in the dispensing of controlled substances.

Current requirements of s. Phar 8.05 (5), Wis. Admin. Code, for the dispensing of prescription orders provides that no pharmacy, individual practitioner or other DEA registered dispenser may dispense at any one time, and no individual practitioner may prescribe for dispensing at any one time, a controlled substance in any quantity exceeding a 34-day supply, except that up to a 90 day supply of any schedule III or IV anticonvulsant substance as determined by the directed dosage and frequency of dosage, may be prescribed and dispensed at one time. The proposed rule modification would repeal s. Phar 8.05 (5), Wis. Admin. Code to make the dispensing requirements for controlled substances consistent with federal dispensing law. This consistency allows practitioners and pharmacists to better meet legitimate patient need, not inconsistent with federal controlled substances prescription rules. Removing the 34-day and 90 day restriction currently contained in s. Phar 8.05 (5), Wis. Admin. Code, will better meet legitimate patient *cite?*

need in instances where a proper course of treatment as determined by a practitioner necessitates ongoing drug therapy such that dispensing a greater supply of any controlled substance will promote efficiency and continuity of treatment as well as patient convenience. The repeal of this rule will therefore allow pharmacists and practitioners to more fully exercise their professional judgment in prescribing of controlled substances, consistent with federal dispensing law.

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TEXT OF RULE

SECTION 1. Phar 8.05 (4) is amended to read:

Phar 8.05 (4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written order signed by the prescribing individual practitioner, except in emergency situations. ~~No prescription containing a controlled substance listed in schedule II shall be dispensed unless the order is presented for dispensing within 7 days following the date of its issue.~~ A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order.

SECTION 2. Phar 8.05 (5) is repealed.

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(END OF TEXT OF RULE)

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The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated \_\_\_\_\_ Agency \_\_\_\_\_  
Chairperson  
Pharmacy Examining Board

FISCAL ESTIMATE

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

INITIAL REGULATORY FLEXIBILITY ANALYSIS

These proposed rules will be reviewed by the department through its Small Business Review Advisory Committee to determine whether there will be an economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

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12/14/01

**STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD**

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**IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 01-154)**

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TO: Senator Judy Robson, Senate Co-Chairperson  
Joint Committee for the Review of Administrative Rules  
Room 15 South, State Capitol  
Madison, Wisconsin 53702

PLEASE TAKE NOTICE that the PHARMACY EXAMINING BOARD is submitting in final draft form rules relating to requirements for the dispensing of prescription orders for schedule II controlled substances.

Please stamp or sign a copy of this letter to acknowledge receipt. If you have any questions concerning the final draft form or desire additional information, please contact Pamela Haack at 266-0495.

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**STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD**

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<b>IN THE MATTER OF RULE-MAKING :</b>	<b>REPORT TO THE LEGISLATURE</b>
<b>PROCEEDINGS BEFORE THE :</b>	<b>ON CLEARINGHOUSE RULE 01-154</b>
<b>PHARMACY EXAMINING BOARD :</b>	<b>(s. 227.19 (3), Stats.)</b>

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**I. THE PROPOSED RULE:**

The proposed rule, including the analysis and text, is attached.

**II. REFERENCE TO APPLICABLE FORMS:**

No new or revised forms are required by these rules.

**III. FISCAL ESTIMATES:**

These rules will have no significant impact upon state or local units of government.

**IV. STATEMENT EXPLAINING NEED:**

Current requirements of s. Phar 8.05 (4), Wis. Admin. Code, for the dispensing of prescription orders for schedule II controlled substances provide in part that a prescription order may not be dispensed unless the order is presented for dispensing within 7 days following the date of its issue, and may not be dispensed more than 60 days after the date of issue. The proposed rule modification would remove the 7 day limitation. A prescription order presented past the 7 day limit currently will not be filled, which necessitates a return to the prescriber for a new prescription. This result occurs even when a legitimate reason exists for the late presentment. The result of the 7 day limit therefore becomes at times an arbitrary cutoff that doesn't allow for a pharmacist and a prescriber to take into account a patient's specific needs in a given situation. The modification of this rule will therefore allow pharmacists and prescribers to exercise their professional judgment in the dispensing of controlled substances.

Current requirements of s. Phar 8.05 (5), Wis. Admin. Code, for the dispensing of prescription orders provides that no pharmacy, individual practitioner or other DEA registered dispenser may dispense at any one time, and no individual practitioner may prescribe for dispensing at any one time, a controlled substance in any quantity exceeding a 34-day supply, except that up to a 90 day supply of any schedule III or IV anticonvulsant substance as determined by the directed dosage and frequency of dosage, may be prescribed and dispensed at one time. The proposed rule modification would repeal s. Phar 8.05 (5), Wis. Admin. Code to make the dispensing requirements for controlled substances consistent with federal dispensing law. This consistency allows practitioners and pharmacists to better meet legitimate patient need, not inconsistent with federal controlled substances prescription rules. Removing the 34-day and 90 day

restriction currently contained in s. Phar 8.05 (5), Wis. Admin. Code, will better meet legitimate patient need in instances where a proper course of treatment as determined by a practitioner necessitates ongoing drug therapy such that dispensing a greater supply of any controlled substance will promote efficiency and continuity of treatment as well as patient convenience. The repeal of this rule will therefore allow pharmacists and practitioners to more fully exercise their professional judgment in prescribing of controlled substances, consistent with federal dispensing law.

**V. NOTICE OF PUBLIC HEARING:**

A public hearing was held on March 12, 2002. There were no appearances at the public hearing nor were any written comments received.

**VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:**

The recommendation suggested in the Clearinghouse Report was accepted in whole.

**VII. FINAL REGULATORY FLEXIBILITY ANALYSIS:**

These rules will have no significant economic impact on small businesses, as defined in s. 227.114 (1) (a), Stats.

STATE OF WISCONSIN  
PHARMACY EXAMINING BOARD

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IN THE MATTER OF RULE-MAKING : PROPOSED ORDER OF THE  
PROCEEDINGS BEFORE THE : PHARMACY EXAMINING BOARD  
PHARMACY EXAMINING BOARD : ADOPTING RULES  
: (CLEARINGHOUSE RULE 01-154)

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ANALYSIS

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allows practitioners and pharmacists to better meet legitimate patient need, not inconsistent with federal controlled substances prescription rules. Removing the 34-day and 90 day restriction currently contained in s. Phar 8.05 (5), Wis. Admin. Code, will better meet legitimate patient need in instances where a proper course of treatment as determined by a practitioner necessitates ongoing drug therapy such that dispensing a greater supply of any controlled substance will promote efficiency and continuity of treatment as well as patient convenience. The repeal of this rule will therefore allow pharmacists and practitioners to more fully exercise their professional judgment in prescribing of controlled substances, consistent with federal dispensing law.

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TEXT OF RULE

SECTION 1. Phar 8.05 (4) is amended to read:

Phar 8.05 (4) A prescription containing a controlled substance listed in schedule II may be dispensed only pursuant to a written order signed by the prescribing individual practitioner, except in emergency situations. ~~No prescription containing a controlled substance listed in schedule II shall be dispensed unless the order is presented for dispensing within 7 days following the date of its issue.~~ A prescription for a controlled substance listed in schedule II may not be dispensed more than 60 days after the date of issue on the prescription order.

SECTION 2. Phar 8.05 (5) is repealed.

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(END OF TEXT OF RULE)

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The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22 (2) (intro.), Stats.

Dated \_\_\_\_\_ Agency \_\_\_\_\_  
Chairperson  
Pharmacy Examining Board

FISCAL ESTIMATE

1. The anticipated fiscal effect on the fiscal liability and revenues of any local unit of government of the proposed rule is: \$0.00.
2. The projected anticipated state fiscal effect during the current biennium of the proposed rule is: \$0.00.
3. The projected net annualized fiscal impact on state funds of the proposed rule is: \$0.00.

INITIAL REGULATORY FLEXIBILITY ANALYSIS

These rules will have no significant economic impact on a substantial number of small businesses, as defined in s. 227.114 (1) (a), Stats.

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4/9/02