JUL 19 2000

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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 **00–107**

AN ORDER to repeal Phar 8.05 (6); and to amend Phar 8.05 (1) and (7), relating to the dispensing of controlled substances.

Submitted by **DEPARTMENT OF REGULATION AND LICENSING**

06–13–00 RECEIVED BY LEGISLATIVE COUNCIL.
07–11–00 REPORT SENT TO AGENCY.

RS:DD:jal;rv

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 00–107

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.]

1. Statutory Authority

a. The department's analysis indicates that the objective of the rule is to conform with 21 C.F.R. 1306.05. However, the provisions of s. Phar 8.05 (7) do not appear to be directly included in the federal regulation cited; therefore, it is not clear how that provision conforms with federal regulations.

b. It appears that: (1) s. 450.02 (3) (d), Stats., should be added to the citations under "statutes authorizing promulgation" and "statutes interpreted"; and (2) s. 961.31, Stats., should be added to "statutes authorizing promulgation."

2. Form, Style and Placement in Administrative Code

The second paragraph of the department's analysis, describing SECTION 1 of the rule, fails to indicate with specificity what is new in the rule. The paragraph of the analysis describing SECTION 2 of the rule fails to indicate what is repealed. Similarly, the last paragraph of the department's analysis is insufficiently specific.

5. Clarity, Grammar, Punctuation and Use of Plain Language

a. The last paragraph of the department's analysis refers to "required" elements that "may" be supplied to a prescription order. Clarification is in order.

b. In s. Phar 8.05 (7), second sentence, it is suggested that "with the exception of the" be stricken; after the stricken language, the following should be added: "A pharmacist may not add, modify or clarify for a schedule II, III, IV or V controlled substance the".

c. In the next-to-last sentence of s. Phar 8.05 (7), it is suggested that "any other information required in sub. (1)" be eliminated and the specific information referred to be substituted. (It appears that the only information alluded to is the address of the patient.)

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 00-)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 8.05 (6); and to amend Phar 8.05 (1) and (7), relating to the dispensing of controlled substances.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

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

Statutes interpreted: ss. 450.02 (3) (a) and (e), and 961.31, Stats.

The objective of amending s. Phar 8.05 (1) and (7), and repealing s. Phar 8.05 (6), is to conform with the federal controlled substances prescription rules codified at 21 CFR 1306.05. The amended rules will allow the pharmacist, after consultation with the prescriber or the patient, to add, modify or clarify certain required elements necessary for a valid controlled substances prescription order. The rule would also modify the terminology for the required elements to correspond with their federal rule counterparts.

SECTION 1 amends the provision to define the required elements for a valid prescription order for a controlled substance to correspond with the federal rule counterparts.

SECTION 2 repeals a provision that is no longer required.

SECTION 3 amends a provision to delineate the required elements that may be supplied to a prescription order for controlled substances and the permitted means of obtaining the information required for those elements.

TEXT OF RULE

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

Phar 8.05 (1) All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner~~, the name and quantity of the drug prescribed, and the directions for use~~. Prescription orders shall be written with ink or indelible pencil or be

typewritten and shall be signed by the practitioner. Orders for controlled substances may be issued only by individual practitioners who are authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice and registered or exempt from registration under the federal controlled substances act.

SECTION 2. Phar 8.05 (6) is repealed.

SECTION 3. Phar 8.05 (7) is amended to read:

Phar 8.05 (7) ~~Except as provided in this subsection, a~~ A prescription order for a controlled substance may not be dispensed unless the prescription order contains all of the information required in sub. (1). ~~A~~ After consultation with the prescribing practitioner, a pharmacist may ~~supply any information missing from a prescription order~~ add, modify or clarify the strength, dosage form, quantity prescribed and directions for use for a schedule II, III, IV or V controlled substance ~~that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner, with the exception of the~~ patient's name, the controlled substance prescribed, except for generic substitution as permitted by law, and the prescribing practitioner's signature. A pharmacist may ~~supply the address of the patient and the registration number of the practitioner missing from a prescription order for a schedule II controlled substance~~ add, modify or clarify any other information required in sub. (1) if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner or the patient. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition, modification or clarification of information and the manner by which the pharmacist obtained that information.

(END OF TEXT OF RULE)

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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6/12/2000

OCT 19 2000

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	**PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 00-107**

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 the dispensing of 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.

STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING	**:**	**REPORT TO THE LEGISLATURE**
PROCEEDINGS BEFORE THE	**:**	**ON CLEARINGHOUSE 00-107**
PHARMACY EXAMINING BOARD	**:**	**(s. 227.19 (3), Stats.)**

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:

The objective of amending s. Phar 8.05 (1) and (7), and repealing s. Phar 8.05 (6), is to conform with the federal controlled substances prescription rules codified at 21 C.F.R. 1306.05. The amended rules will allow the pharmacist, after consultation with the prescriber or the patient, to add, modify or clarify certain required elements necessary for a valid controlled substances prescription order which are: the strength, dosage form, quantity prescribed, date of issuance and directions for use. The rule would also modify the terminology for the required elements to correspond with their federal rule counterparts.

V. NOTICE OF PUBLIC HEARING:

A public hearing was held on July 11, 2000. Gregg Parnau, R.Ph., Greenfield, WI, appeared and testified in support of the proposed rules. There were no other appearances at the public hearing nor were any written comments received.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

Comment 1.a. The department's analysis indicates that the objective of the rule is to conform with 21 C.F.R. 1306.05. However, the provisions of s. Phar 8.05 (7). do not appear to be directly included in the federal regulation cited; therefore, it is not clear how that provision conforms with federal regulations.

Response: Section Phar 8.05 (7) conforms to the DEA interpretation of what C.F.R. 1306.05 allows.

The remaining recommendations suggested in the Clearinghouse Report were 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.

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STATE OF WISCONSIN
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	PROPOSED ORDER OF THE PHARMACY EXAMINING BOARD ADOPTING RULES (CLEARINGHOUSE RULE 00-107)

PROPOSED ORDER

An order of the Pharmacy Examining Board to repeal Phar 8.05 (6); and to amend Phar 8.05 (1) and (7), relating to the dispensing of controlled substances.

Analysis prepared by the Department of Regulation and Licensing.

ANALYSIS

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

Statutes interpreted: ss. 450.02 (3) (a) and (e), and 961.31, Stats.

The objective of amending s. Phar 8.05 (1) and (7), and repealing s. Phar 8.05 (6), is to conform with the federal controlled substances prescription rules codified at 21 CFR 1306.05. The amended rules will allow the pharmacist, after consultation with the prescriber or the patient, to add, modify or clarify certain required elements necessary for a valid controlled substances prescription order which are: the strength, dosage form, quantity prescribed, date of issuance and directions for use. The rule would also modify the terminology for the required elements to correspond with their federal rule counterparts.

SECTION 1 amends the provision to define the required elements for a valid prescription order for a controlled substance to correspond with the federal rule counterparts.

SECTION 2 repeals a provision that is no longer required specifying that prescription orders for all controlled substances shall specify dose and frequency of usage per day.

SECTION 3 amends a provision to delineate the required elements that may be supplied to a prescription order for controlled substances and the permitted means of obtaining the information required for those elements, directions for use, name and address and registration number of the practitioner and address of the patient.

TEXT OF RULE

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

Phar 8.05 (1) All controlled substance prescription orders shall be dated as of, and signed on, the day issued and shall contain the full name and address of the patient, the drug name, strength, dosage form, quantity prescribed, directions for use and the name, address and registration number of the practitioner~~, the name and quantity of the drug prescribed, and the directions for use~~. Prescription orders shall be written with ink or indelible pencil or be typewritten and shall be signed by the practitioner. Orders for controlled substances may be issued only by individual practitioners who are authorized to prescribe controlled substances by the jurisdiction in which he or she is licensed to practice and registered or exempt from registration under the federal controlled substances act.

SECTION 2. Phar 8.05 (6) is repealed.

SECTION 3. Phar 8.05 (7) is amended to read:

Phar 8.05 (7) ~~Except as provided in this subsection, a~~ A prescription order for a controlled substance may not be dispensed unless the prescription order contains all of the information required in sub. (1). ~~A~~ For any controlled substance prescription order, a pharmacist may not add, modify or clarify the patient's name, the controlled substance prescribed, except for generic substitution as permitted by law, and the prescribing practitioner's signature. After consultation with the prescribing practitioner, a pharmacist may ~~supply any information missing from a prescription order~~ add, modify or clarify the strength, dosage form, quantity prescribed, date of issuance and directions for use for a schedule ~~III, IV or V~~ II controlled substance ~~that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner, with the exception of the practitioner's signature~~ prescription order. ~~A~~ For a schedule II controlled substance prescription order, a pharmacist may ~~supply the address of the patient and the registration number of the practitioner missing from a prescription order for a schedule II controlled substance~~ add, modify or clarify the registration number of the practitioner, and the address of the practitioner and the patient if that information is verifiable and retrievable from information maintained by the pharmacist or is obtained through consultation with the practitioner. A pharmacist may add, modify or clarify any information allowed in this subsection missing from a prescription order for a schedule III, IV or V controlled substance that is verifiable and retrievable from information maintained by the pharmacist or that is obtained through consultation with a practitioner. A patient may only provide information to a pharmacist to add, modify or clarify the patient's address. The prescription order shall be initialed and dated by the pharmacist and shall indicate the addition, modification or clarification of information and the manner by which the pharmacist obtained that information.

(END OF TEXT OF RULE)

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.

FINAL 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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