

**WEST VIRGINIA
SECRETARY OF STATE**

KEN HECHLER

ADMINISTRATIVE LAW DIVISION

Form #3

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WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF AGENCY APPROVAL OF A PROPOSED RULE
AND
FILING WITH THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE**

AGENCY: Board of Medicine TITLE NUMBER: 11

CITE AUTHORITY §30-3-7(a)(1); §60A-3-301

AMENDMENT TO AN EXISTING RULE: YES NO

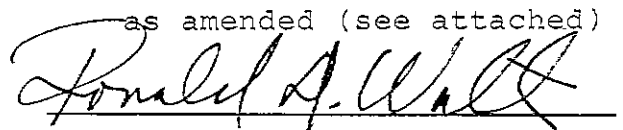
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____

TITLE OF RULE BEING AMENDED: _____

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 5

TITLE OF RULE BEING PROPOSED: Board of Medicine Rules for
Dispensing of Legend Drugs by Physicians and Podiatrists

THE ABOVE PROPOSED LEGISLATIVE RULE HAVING GONE TO A PUBLIC HEARING OR A PUBLIC COMMENT PERIOD IS HEREBY APPROVED BY THE PROMULGATING AGENCY FOR FILING WITH THE SECRETARY OF STATE AND THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE FOR THEIR REVIEW.

as amended (see attached)




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State of West Virginia

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WEST VIRGINIA BOARD OF MEDICINE
100 Dee Drive, Suite 104, Charleston 25311
(304) 348-2921

September 16, 1988

WEST VIRGINIA BOARD OF MEDICINE AMENDMENTS TO BOARD OF MEDICINE RULES FOR DISPENSING OF LEGEND DRUGS BY PHYSICIANS AND PODIATRISTS.

The West Virginia Board of Medicine files the above-referenced rules with the following amendments:

I. At Section 2. Definitions, add the following definition:

2.12 Free Clinic means a clinic where medical and other health-related services are rendered at no charge.

II. At Section 3.3(c) after the word "provided" add the words "by free clinics or" so that 3.3(c) reads as follows:

3.3(c) Legend drugs which are not controlled substances are provided by free clinics or under West Virginia State authorized programs, including the Medicaid, family planning, maternal and child health, and early and periodic screening and diagnosis and treatment programs, except that all labeling provisions of Section 8 shall be applicable.

III. In Section 4.1 after the word "nor" delete the words "to a nurse or" so that Section 4.1 reads as follows:

4.1 A dispensing physician may not delegate the dispensing function to another physician or podiatrist, nor to other office personnel. However, a dispensing physician may delegate nonjudgmental functions to supportive personnel, subject to the requirement that the dispensing physician must personally perform the following duties:

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David K. Heydinger, M.D.
Charleston

COUNSEL
Deborah Lewis Rodecker
Charleston

EXECUTIVE DIRECTOR
Ronald D. Walton
Charleston

AMENDMENTS

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- IV. In Section 4.1 delete "a." and re-letter the remaining Sections "b." and "c." as "a." and "b."
- V. In Section 4.3 strike the words "maintain a library of" and insert in lieu thereof the words "have access to" so that the section reads:
- 4.3 A dispensing physician must have access to reference books relating to the dispensing of medication, including the most recent edition of USP DI.
- VI. In Section 4.6 in the first sentence after the word "area" strike out the remainder of the sentence and put a period. Also strike the last sentence of the paragraph and insert the following words, "Legend drugs must be stored in a locked or otherwise secure area to prevent access when the dispensing physician is not present in the office." so that the Section reads as follows:
- 4.6 A dispensing physician must maintain a dispensing area. Within the dispensing area there shall be sufficient space for the dispensing physician and supportive personnel to be free of distraction while preparing legend drugs for dispensing. All stock quantities of legend drugs maintained for dispensing to patients must be stored in the dispensing area under conditions that meet USP criteria as published in USP DI, to prevent deterioration. Legend drugs must be stored in a locked or otherwise secure area to prevent access when the dispensing physician is not present in the office.
- VII. In Section 5.1 the third sentence should be deleted so that Section 5.1 now reads as follows:
- 5.1 The sale at retail of legend drugs by dispensing physicians is prohibited. This means that the charge for drugs may not be separately listed, but must be incorporated into the charge for other professional services and products.
- VIII. Section 8.2 is rewritten so as to read as follows:
- 8.2 Labels must be machine-made or printed legibly.

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #1

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1988 AUG -5 AM 8:52
SECRETARY OF STATE

NOTICE OF PUBLIC HEARING ON A PROPOSED RULE

AGENCY: Board of Medicine TITLE NUMBER: 11
RULE TYPE: Legislative; CITE AUTHORITY §30-3-7(a)(1); §60A-3-301
AMENDMENT TO AN EXISTING RULE: YES ___ NO x
IF YES, SERIES NUMBER OF RULE BEING AMENDED: _____
TITLE OF RULE BEING AMENDED: _____
IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: 5
TITLE OF RULE BEING PROPOSED: Board of Medicine Rules for
Dispensing of Legend Drugs by Physicians and Podiatrists

DATE OF PUBLIC HEARING: September 6, 1988 TIME: 9:00 a.m.
LOCATION OF PUBLIC HEARING: 100 Dee Drive
Charleston, WV 25311

COMMENTS LIMITED TO: ORAL ___ , WRITTEN ___ , BOTH x

COMMENTS MAY ALSO BE MAILED TO THE FOLLOWING ADDRESS: Bd. of Medicine

100 Dee Drive

Charleston, WV 25311

ATTN: Ronald D. Walton

The Department requests that persons wishing to make comments at the hearing make an effort to submit written comments in order to facilitate the review of these comments.

The issues to be heard shall be limited to the proposed rule.

ATTACH A **BRIEF** SUMMARY OF YOUR PROPOSAL

J. L. Rodecker