

**WEST VIRGINIA**  
**SECRETARY OF STATE**  
**KEN HECHLER**  
**ADMINISTRATIVE LAW DIVISION**

Form #3

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1991 MAR 11 AM 10:07

OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

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

AGENCY: WV Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY W. Va. Code §30-5

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: 4

TITLE OF RULE BEING PROPOSED: Computer Regulations

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.

  
\_\_\_\_\_

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: COMPUTER REGULATIONS - - AUTOMATED DATA PROCESSING SYSTEM

Type of Rule: Legislative  Interpretive  Procedural

Agency WEST VIRGINIA BOARD OF PHARMACY Address 236 CAPITOL STREET  
CHARLESTON, WEST VIRGINIA 25301

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$	\$
Personal Services	0	0	0	0	0
Current Expense	0	0	0	0	0
Repairs and Alterations	0	0	0	0	0
Equipment	0	0	0	0	0
Other	0	0	0	0	0

2. Explanation of above estimates: THE BOARD OF PHARMACY RECOGNIZES THE NEED FOR RULES AND REGULATIONS REGARDING THE COMPUTER AS A SYSTEM TO UTILIZE SOFTWARE AND HARDWARE FOR THE PURPOSE OF RECORDKEEPING. THE ABOVE ESTIMATES ARE BASED ON THE COSTS OF THE AGENCY TO ENFORCE THE RULES AND REGULATIONS SINCE THE COMPUTER WILL ENHANCE OUR INSPECTORS DURING REGULAR INSPECTIONS.

3. Objectives of these rules: AN AUTOMATED DATA PROCESSING SYSTEM IS CAPABLE OF MULTIFUNCTIONS INCLUDING BUT NOT LIMITED TO STORAGE, RETRIEVAL AND PROCESSING OF INFORMATION. THIS IS A PROCESSING SYSTEM THAT ENABLES AUTHORIZED USERS TO HAVE COMMON ACCESS TO THE FILE REGARDLESS OF PHYSICAL LOCATION. PATIENT INFORMATION IS READILY AVAILABLE WITH THIS SYSTEM.



DATE: March 11, 1991

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM: Larry Barker, Secretary  
WV Board of Pharmacy  
236 Capitol St. Charleston, WV 25301

LEGISLATIVE RULE TITLE: Computer Regulations

1. Authorizing statute(s) citation §30-5

2. a. Date filed in State Register with Notice of Hearing:  
January 28, 1991

b. What other notice, including advertising, did you give  
of the hearing?

Kanawha County Courthouse Board

c. Date of hearing(s): March 6, 1991

d. Attach list of persons who appeared at hearing, comments  
received, amendments, reasons for amendments.

Attached \_\_\_\_\_ No comments received  \_\_\_\_\_

e. Date you filed in State Register the agency approved  
proposed Legislative Rule following public hearing:  
(be exact)

March 11, 1991

f. Name and phone number(s) of agency person(s) to contact  
for additional information:

Larry Barker, Secretary

WV Board of Pharmacy

236 Capitol Street

Charleston, WV 25301

3. If the statute under which you promulgated the submitted rules requires certain findings and determinations to be made as a condition precedent to their promulgation:

a. Give the date upon which you filed in the State Register a notice of the time and place of a hearing for the taking of evidence and a general description of the issues to be decided.

N/A  
\_\_\_\_\_

b. Date of hearing: N/A

c. On what date did you file in the State Register the findings and determinations required together with the reasons therefor?

N/A  
\_\_\_\_\_

d. Attach findings and determinations and reasons:

Attached \_\_\_\_\_



## Board of Pharmacy

PUBLIC HEARING

Office

236 Capital Street

Phone (304) 348-0558

FEBRUARY 6, 1991  
9 A.M.

236 CAPITOL STREET  
CHARLESTON, WEST VIRGINIA 25301

Charleston, West Virginia 25301

President Sam Kapourales opened the meeting by reading the notice to the Secretary of State of the Public Hearing on a proposed Legislative Rule as authorized by Chapter 30, Article 5, Section 19 of the code of West Virginia, as amended. Said section is titled Rules and Regulations of the West Virginia Board of Pharmacy.

Secretary Larry Barker, at the request of President Kapourales, stated that a copy of the Rules and Regulation had been filed with the Secretary of State at 10:17 a.m. on January 28, 1991 which was at least thirty (30) days prior to March 6, 1991 and no more than sixty (60) days after the aforesaid date.

Secretary Barker stated that a brief summary of the proposed rule was also filed at 10:17 a.m. on January 28, 1991 and was titled Series 4, Computer Regulations To Establish Automatic Data Processing Rules.

President Kapourales requested comments or written statements. There being none, Mr. Jody Hedrick moved to adopt the rules, seconded by Mr. George Malott, and the motion passed. Secretary Barker moved that the Public Hearing on the proposed computer regulations be closed, seconded by Mr. Malott. The motion passed.

The following were present:

President Sam Kapourales, R.Ph.  
Vice President George Karos, R.Ph.  
Secretary Larry Barker, Public Member  
Mrs. Lydia Main, R.Ph.  
Mr. George Malott, Public Member  
Mr. Jody Hedrick, R.Ph.  
Inspector Charles Campbell  
Inspector A. B. Meadows  
Inspector Arlie Winters  
Investigator Robert Blair  
Office Administrator Betty Jo Payne  
Deputy Attorney General Bruce Ray Walker

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OFFICE OF WEST VIRGINIA  
SECRETARY OF STATE

TITLE 15  
LEGISLATIVE RULE  
BOARD OF PHARMACY

SERIES 4  
COMPUTER REGULATIONS

15-4-1. General.

- 1.1. Scope. -- To establish automatic data procesing rules.
- 1.2. Authority. -- W.Va. Code §30-5
- 1.3. Filing Date. --
- 1.4. Effective Date. --

## 15-4-2. Automated Data Processing System

### 2.1. Definitions

- (a) Automated Data Processing System (ADP) is the system utilizing computer software and hardware for the purpose of recordkeeping.
- (b) Cathode Ray Tube (CRT) is vacuum tube in which a hot negatively charged electrode is used to impose visual information on a screen.
- (c) Computer is a programmable electronic device capable of multifunctions including but not limited to storage, retrieval and processing of information.
- (d) Downtime is that period of time when a computer is not operable.
- (e) Printout is a hard-copy produced by computer that is readable without the aid of any special device.
- (f) Common data base is a file or collection of information created by the automated data processing system that enables authorized users to have common access to the file regardless of physical location.
- (g) Computer Operator is the person charged with the responsibility of entry and retrieval of patient information.

### 15-4-3. Record of Dispensing.

Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for five (5) years. Information must be immediately accessible for a period of not less than one (1) year from the date of last entry. Information beyond one (1) year but up to five (5) years from the date of entry may be maintained off-line but must be produced no later than forty-eight (48) hours upon request from proper authorities. The information shall include, but not limited to:

- (a) Quantity dispensed
- (b) Date of dispensing
- (c) Serial number (or equivalent if an institution)
- (d) The identification of the pharmacist responsible for dispensing
- (e) Record of renewals to date
- (f) Name and strength of medication

15-4-4 Record of Retrieval (Documentation of Activity)

1. Any such automated data processing system must provide by Cathode Ray Tube display and/or hard copy printout a current history of all authorized prescription activity. This information shall include, but not limited to:

- (a) Serial number of prescription (or equivalent if an institution)
- (b) Date of dispensing
- (c) Quantity dispensed
- (d) The identification of the pharmacist responsible for dispensing
- (e) Medication dispensed

2. An automated data processing system may be used for the storage and retrieval of refill information for prescription orders for controlled substances in Schedule III and IV, subject to the following conditions:

(a) Any such proposed computerized system must provide on-line retrieval (via CRT display or hard-copy printout) of original prescription, order information for those prescription orders which are currently authorized for refilling. This shall include, but is not limited to, data such as the original prescription number, date of issuance of the original prescription order by the practitioner, full name and address of the patient, name, address, and DEA registration number of the practitioner, and the name, strength, dosage form, quantity if the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed), and the total number of refills authorized by the prescribing practitioner.

(b) Any such proposed computerized system must also provide on-line retrieval (via CRT display or hard-copy printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those authorized for refill during the past six months.) This refill history shall include, but is not limited to, the name of the controlled substance, the date of refill, the quantity dispensed, the identification code, or name or initials of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

Documentation of the fact that the refill information entered into the computer each time a pharmacist refills an original prescription order for a Schedule III or IV controlled substance is correct must be provided by the individual pharmacist who makes the use of such a system. If such a system provides a hard-copy printout of each day's

controlled substance prescription order refill data, that printout shall be verified, dated, and signed by the individual pharmacist who refilled such a prescription order. The individual pharmacist must verify that the data indicated is correct and then sign this document in the same manner as he would sign a check or legal document (e.g., J. H. Smith or John H. Smith). This document shall be maintained in a separate file at that pharmacy for a period of two years from the dispensing date. This printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using such a computerized system within 72 hours of the date on which the refill was dispensed. It must be verified and signed by each pharmacist who is involved with such dispensing. (In lieu of such a printout, the pharmacy shall maintain a bound log book, shall sign a statement (in the manner previously described) each day, attesting to the fact that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing the appropriately authorized refill.

(d) Any such computerized system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under the Act and its implementing regulations. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance (by either brand or generic name or both). Such a printout must include name of the prescribing practitioner, name and address of the patient, quantity dispensed on each refill, date of dispensing for each refill, name or identification code of the dispensing pharmacist, and the number of the original prescription order. In any computerized system employed by a user pharmacy, the central recordkeeping location must be capable of sending the printout to the pharmacy within 48 hours, and if a DEA Special Agent or Compliance Investigator requests a copy of such printout from the user pharmacy, it must, if requested to do so by the Agent or Investigator, verify the printout transmittal capability of its system by documentation (e.g., postmark).

(e) In the event that pharmacy which employs such a computerized system experiences system down-time, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III and IV controlled substance prescription orders. This auxiliary procedure must insure that refills are authorized by the original prescription order, that the maximum number of refills has not been exceeded, and that all of the appropriate data is retained for on-line data entry as soon as the computer system is available for use again.

(f) When filing refill information for original prescription orders for Schedule III or IV controlled substances, a pharmacy may use only one of the two systems described in paragraphs of this CFR 21, CH II, SEC 1306.22.

#### 15-4-5 Auxiliary Recordkeeping System

##### An auxiliary Recordkeeping System

An auxiliary recordkeeping system shall be established for the documentation of renewals if the ADP is inoperative for any reason. When the ADP is restored to operation, the information regarding prescriptions dispensed and renewed during the inoperative period shall be entered into the automated data processing system within 72 hours.

#### 15-4-6 Common Data Base

Two or more pharmacies may establish and use a common data file or base to maintain required or pertinent dispensing information. Pharmacies using such a common file are not required to transfer prescriptions or information for dispensing purposes between or among pharmacies participating in the same common prescription file or data base; provided however any such common file must contain complete and adequate records of each prescription and renewals dispensed.

#### 15-4-7 Operating the ADP System

A registered pharmacist shall view and interpret all computer functions relative to filling and refilling prescriptions.

M E M O R A N D U M

TO:       Subscribers of the West Virginia State Register  
          And All Agency Heads

FROM:      Ken Hechler, Secretary of State

RE:        New Emergency Rule Procedures

DATE:      May 7, 1991

On June 6, 1991, the procedures for filing emergency rules in West Virginia will change significantly. With the passage of H. B. 2627, in the 1991 session of the Legislature, agencies will no longer be able to implement emergency rules on the same day that they are filed. Effective June 6, the provisions of West Virginia Code §29A-3-15 will provide that emergency rules shall be effective "upon the approval of the secretary of state . . . or upon the thirty-fifth day following such filing whichever occurs first." The new law shortens the filing deadline for a notice of public hearing to thirty days after the rule was filed as an emergency, sets the deadline for filing a proposed rule with the legislative rulemaking review committee to ninety days after the emergency rule has been filed, and also extends this new emergency rule review process to all amendments to emergency rules made by an agency. In addition, fourteen copies of all emergency rules and emergency rule amendments are to be filed with the secretary of state and one copy is to be filed with the legislative rulemaking review committee.

If you should have any questions about the contents of the new law, please contact Bob Wilkinson or Judy Cooper at 345-4000.