

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #6

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WEST VIRGINIA
SECRETARY OF STATE

**NOTICE OF FINAL FILING AND ADOPTION OF A LEGISLATIVE RULE AUTHORIZED
BY THE WEST VIRGINIA LEGISLATURE.**

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

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: 4

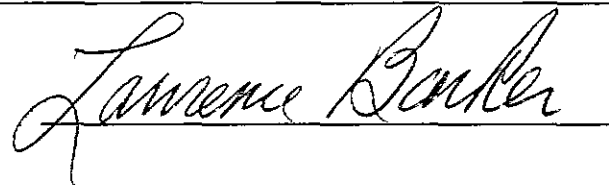
TITLE OF RULE BEING PROPOSED: Computer Regulations

THE ABOVE RULE HAS BEEN AUTHORIZED BY THE WEST VIRGINIA LEGISLATURE.

AUTHORIZATION IS CITED IN (house or senate bill number) Senate Bill 1

SECTION 64-9-20(d), PASSED ON March 14, 1992

THIS RULE IS FILED WITH THE SECRETARY OF STATE. THIS RULE BECOMES EFFECTIVE ON
THE FOLLOWING DATE: April 9, 1992



TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 4
COMPUTER REGULATIONS

FILED
1991 MAY 29 PM 5:16
OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

15-4-1. General.

- 1.1. Scope. To outline the proper use of the automated Data Processing System.
- 1.2. Authority. West Virginia Code 30-5-19.
- 1.3. Filing Date.
- 1.4. Effective Date.

15-4-2. Use of Automated Data Processing Systems - General Provisions.

- 2.1. A pharmacy may establish and use an automated data processing system to keep records of prescription drugs which it dispenses. A pharmacy is not required to establish and use such a system but if it does the pharmacy must comply with the provisions of this rule.
- 2.2. Two or more pharmacies may establish and use an automated data processing system as a common data file or base to maintain required or pertinent prescription drug dispensing information. Pharmacies using a common file are not required to transfer prescriptions or information for dispensing purposes between or among the pharmacies participating in the same common prescription file or data base: Provided that any common file must contain complete and adequate records of each prescription and renewals dispensed.

15-4-3. Definitions.

- 3.1. An Automated Data processing System (ADP) is a system utilizing computer software and hardware for the purpose of recordkeeping.
- 3.2. A Cathode Ray Tube (CRT) is a vacuum tube in which a hot negatively charged electrode is used to impose visual information on a screen.
- 3.3. A computer is a programmable electronic device capable of multifunctions including but not limited to storage, retrieval and processing of information.
- 3.4. Downtime is that period of time when a computer is

not operable.

- 3.5. A printout is a readable printed copy of the output of a computer.
- 3.6. A 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.
- 3.7. A computer operator is the person charged with the responsibility of entry and retrieval of patient information.
- 3.8. The Drug Enforcement Administration (DEA) is the Lead Federal Law Enforcement Agency charged with the responsibility for combating controlled substance abuse.
- 3.9. On-line retrieval means the producing of sight-readable documents on the CRT.
- 3.10. A prescription Drug Order means a lawful written or verbal order by a prescribing practitioner for a drug.
- 3.11. Hardware is the fixed components of a computer.
- 3.12. Software is the program, procedure and storage of required information data.
- 3.13. A refill of a drug order is continued dispensing of the medicine authorized by the practitioner in the original prescription.
- 3.14. A renewal of a prescription is that which is authorized by the practitioner after the original prescription has had the authorized number of refills.

15-4-4. Record of Dispensing Prescription Drugs.

Records of dispensing of prescription drugs 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 for the date of last entry. Information beyond one (1) year but up to five (5) years from the date of entry may be maintained other than on-line but must be produced within forty-eight (48) hours upon request by proper authorities, the information contained in the records shall include, but not be limited to:

- (a) The quantity dispensed
- (b) The date of dispensing
- (c) The serial number of the prescription (or equivalent if an institution)
- (d) The identification of the pharmacist responsible for dispensing the drug
- (e) A record of renewals to date
- (f) The name, and strength of the dispensed drug (name of manufacturer if a generic drug)

15-4-5. Record of Retrieval (Documentation of Activity)

1. An ADP system must provide by CRT display and/or printout a current history of all authorized prescription activity. This information shall include, but not be limited to:

- (a) The serial number of the prescription (or equivalent if an institution)
- (b) The date of dispensing
- (c) The quantity dispensed
- (d) The identification of the pharmacist responsible for dispensing the drug
- (e) The prescription drug dispensed

2. An ADP 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) A proposed ADP system must provide on-line retrieval (via CRT display or printout) of the original prescription order information for those prescription orders which are currently authorized for refilling. Order information includes, but is not limited to, data such as the original prescription number, the date of issuance of the original prescription order by the prescribing practitioner, the full name and the address of the patient, the name, the address, and the DEA registration number of the prescribing practitioner, and the name, the strength, the dosage form and quantity of the controlled substance prescribed and the quantity dispensed if different from the quantity prescribed, and the total number of refills authorized by the prescribing practitioner.
- (b) A proposed ADP system must also provide on-line retrieval (via CRT display or printout) of the current refill history for Schedule III or IV controlled substance prescription orders (those

authorized for refill during the past six (6) months.) This refill history shall include, but not be limited to, the name of the controlled substance; the date of refill, the name of the controlled substance, the date of the refill, the quantity dispensed, the name or initials (or identification code if used) of the dispensing pharmacist for each refill and the total number of refills dispensed to date for that prescription order.

- (c) The ADP system shall contain documentation that an individual pharmacist has taken the responsibility for the accuracy of the information entered into the system for original prescriptions and for refills of the original prescription for a Schedule III or IV Controlled Substance. A printout of the day's controlled substance prescription order refill data must be provided to each pharmacy using the ADP system within seventy-two (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 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 (2) years after the date of dispensing the appropriately authorized refill.
- (d) A ADP system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under West Virginia Code, 30-5-1 et seq. 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 the name of the prescribing practitioner, the name and address of the patient, the quantity dispensed on each refill, the date of dispensing for each refill, the name or identification code of the dispensing pharmacist, and the number of the original prescription order. Any recordkeeping location must be capable of sending the Special Agent or Compliance Investigator a copy of such printout from the user pharmacy

if requested to do so by the Agent or Investigator and must verify the printout transmittal capability of its system by documentation. (e. g., postmark).

- (e) In the event that pharmacy which employs 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 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 the system described in Chapter 11, Drug Enforcement Administration, Department of Justice, as it relates to the Code of Federal Regulations under Section 1306.22, Titled, Refilling of Prescriptions.

15-4-6. Auxiliary Recordkeeping System.

An auxiliary recordkeeping system shall be established by each pharmacy for the documentation of renewals if the ADP is inoperative information regarding prescriptions dispensed and renewed during the inoperative period shall be entered into the automated data processing system within seventy-two (72) hours.

15-4-7. Operating the ADP System.

Only a registered pharmacist may have access to the Automated Data Processing System.

Bill Pharmacy, Computer 15-4

H. B. 4313

(By ~~Delegate Grubb~~)

(Introduced January 27, 1992; referred to the

~~Committee on Government Organization and the Judiciary~~)

10 A BILL to amend and reenact section twenty, article nine, chapter
11 sixty-four of the code of West Virginia, one thousand nine
12 hundred thirty-one, as amended, relating to authorizing the
13 board of pharmacy to promulgate legislative rules relating to
14 computers.

15 Be it enacted by the Legislature of West Virginia:

16 That section twenty, article nine, chapter sixty-four of the
17 code of West Virginia, one thousand nine hundred thirty-one, as
18 amended, be amended and reenacted, to read as follows:

19 ARTICLE 9. AUTHORIZATION FOR MISCELLANEOUS AGENCIES AND BOARDS
20 TO PROMULGATE LEGISLATIVE RULES.

21 §64-9-20. Board of pharmacy.

22 (a) The legislative rules filed in the state register on the
23 second day of October, one thousand nine hundred eighty-four,
24 modified by the board of pharmacy to meet the objections of the

4313

1 legislative rule-making review committee and refiled in the state
2 register on the ninth day of January, one thousand nine hundred
3 eighty-five, relating to the board of pharmacy
4 (parenteral/enteral compounding), are authorized.

5 (b) The legislative rules filed in the state register on the
6 twelfth day of September, one thousand nine hundred eighty-nine,
7 modified by the board of pharmacy to meet the objections of the
8 legislative rule-making review committee and refiled in the state
9 register on the fifteenth day of November, one thousand nine
10 hundred eighty-nine, relating to the board of pharmacy (board of
11 pharmacy), are authorized.

12 (c) The legislative rules filed in the state register on the
13 sixth day of May, one thousand nine hundred ninety, modified by
14 the board of pharmacy to meet the objections of the legislative
15 rule-making review committee and refiled in the state register on
16 the fifth day of June, one thousand nine hundred ninety, relating
17 to the board of pharmacy (continuing education for the licensure
18 of pharmacists), are authorized.

19 (d) The legislative rules filed in the state register on the
20 eleventh day of March, one thousand nine hundred ninety-one,
21 modified by the board of pharmacy to meet the objections of the
22 legislative rule-making review committee and refiled in the state
23 register on the twenty-fourth day of May one thousand nine
24 hundred ninety-one, relating to the board of pharmacy (computer
25 regulations) are authorized.

1

2 NOTE: The purpose of this bill is to authorize the Board of
3 Pharmacy to promulgate legislative rules relating to computers.

4

5 Strike-throughs indicate language that would be stricken from
6 the present law, and underscoring indicates new language that
7 would be added.



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Director, Corporations

(Plus all the volunteer
help we can get)

TO: Betty Jo Payne

AGENCY: Board of Pharmacy

FROM: JUDY COOPER, DIRECTOR, ADMINISTRATIVE LAW DIVISION

DATE: December 11, 1992

THE ATTACHED RULE FILED BY YOUR AGENCY HAS BEEN ENTERED INTO OUR COMPUTER SYSTEM. PLEASE REVIEW, PROOF AND RETURN IT WITH ANY CORRECTIONS. IF THERE ARE NO CORRECTIONS, PLEASE SIGN THIS MEMO AND RETURN IT TO THIS OFFICE. YOU WILL BE SENT A FINAL VERSION OF THE RULE FOR YOUR RECORDS.

PLEASE RETURN EITHER THE CORRECTED RULE OR THIS FORM WITHIN TEN (10) WORKING DAYS OF THE DATE YOU RECEIVED THIS REQUEST. CALL IF YOU HAVE ANY QUESTIONS.

SERIES: 4 TITLE: 15 Board of Pharmacy

* THE ATTACHED RULE HAS BEEN REVIEWED AND IS CORRECT.

SIGNED: Betty Jo Payne

TITLE OF PERSON SIGNING: Office Administrator

DATE: 12/15/92

* THE ATTACHED RULE HAS BEEN REVIEWED AND NEEDS CORRECTING. THE CORRECTIONS HAVE BEEN MARKED.

SIGNED: _____

TITLE OF PERSON SIGNING: _____

DATE: _____

NOTE: IF YOU ARE NOT THE PERSON WHO HANDLES THIS RULE, PLEASE FORWARD TO THE CORRECT PERSON.