

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

Form #1

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OFFICE OF WEST VIRGINIA
SECRETARY OF STATE

NOTICE OF PUBLIC HEARING ON A PROPOSED RULE

AGENCY: Board of Pharmacy TITLE NUMBER: 15

RULE TYPE: Legislative; CITE AUTHORITY 30-5

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

DATE OF PUBLIC HEARING: March 6, 1991 TIME: 9:00 a.m.

LOCATION OF PUBLIC HEARING: 236 Capitol Street
Charleston, WV 25301

COMMENTS LIMITED TO: ORAL , WRITTEN , BOTH

COMMENTS MAY ALSO BE MAILED TO THE FOLLOWING ADDRESS: Larry Barker

Bd. of Pharmacy

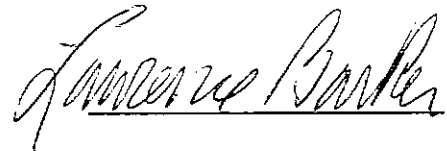
236 Capitol Street

Charleston, WV 25301

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





Board of Pharmacy

Phone (304) 348-0558

Office
236 Capitol Street
Charleston, West Virginia 25301

NOTICE OF PUBLIC HEARING OR COMMENT PERIOD ON A PROPOSED RULE

PUBLIC HEARING

AGENCY: WEST VIRGINIA BOARD OF PHARMACY

RULE TYPE: LEGISLATIVE

RULE TITLE: COMPUTER REGULATIONS

A PUBLIC HEARING ON THE ABOVE PROPOSED RULE WILL BE HELD AT 9:00 A. M. ON MARCH 6, 1991 AT 236 CAPITOL STREET, CHARLESTON, WEST VIRGINIA 25301.

COMMENTS ARE LIMITED TO: ORAL _____ WRITTEN _____ BOTH X

COMMENTS MAY ALSO BE MAILED TO: WEST VIRGINIA BOARD OF PHARMACY, 236 CAPITOL STREET, CHARLESTON, WEST VIRGINIA 25301

THE WEST VIRGINIA BOARD OF PHARMACY REQUESTS THAT PERSONS WISHING TO MAKE COMMENTS AT THE HEARING MAKE AN EFFORT TO SUBMIT WRITTEN COMMENTS IN ORDER TO FACILITATE A REVIEW OF THESE COMMENTS.

THE ISSUES TO BE HEARD SHALL BE LIMITED TO THE PROPOSED RULE.

LAWRENCE BARKER, SECRETARY

15-4-2

~~15-1-17~~. Automated Data Processing System

~~17.1~~. Definitions

- (a) Automated Data Processing System (ADF) 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.

15-43

~~19.2~~. 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

19.2. 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.

~~19.4.~~ ¹⁵⁻⁴⁻⁵ Auxiliary Recordkeeping System

An auxiliary Recordkeeping System

An auxiliary recordkeeping system shall be established for the documentation of renewals if the ADF is inoperative for any reason. When the ADF 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.

~~19.5.~~ 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.

~~19.6.~~ ¹⁵⁻⁴⁻⁷ Operating the ADF System

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