



WEST VIRGINIA SECRETARY OF STATE

MAC WARNER

ADMINISTRATIVE LAW DIVISION

eFILED

7/26/2019 1:03:38 PM

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: Pharmacy TITLE-SERIES: 15-04
RULE TYPE: Legislative Amendment to Existing Rule: Yes Repeal of existing rule: No
RULE NAME: 15-04 Record Keeping and Automated Data Processing Systems

PRIMARY CONTACT

NAME: Ryan Hatfield
ADDRESS: 2310 Kanawha Blvd E
Charleston, WV 25311
EMAIL: ryan.l.hatfield@wv.gov
PHONE NUMBER: 304-558-0558

CITE STATUTORY AUTHORITY: 30-5-7

EXPLANATION OF THE STATUTORY AUTHORITY FOR THE LEGISLATIVE RULE, INCLUDING A DETAILED SUMMARY OF THE EFFECT OF EACH PROVISION OF THE LEGISLATIVE RULE WITH CITATION TO THE SPECIFIC STATUTORY PROVISION WHICH EMPOWERS THE AGENCY TO ENACT SUCH RULE PROVISION:

All provisions are promulgated pursuant to 30-5-7.

DATE eFiled FOR NOTICE OF HEARING OR PUBLIC COMMENT PERIOD: 6/26/2019

DATE OF PUBLIC HEARING(S) OR PUBLIC COMMENT PERIOD ENDED: 7/26/2019

COMMENTS RECEIVED: Yes

(IF YES, PLEASE UPLOAD IN THE COMMENTS RECEIVED FIELD COMMENTS RECEIVED AND RESPONSES TO COMMENTS)

PUBLIC HEARING: No

(IF YES, PLEASE UPLOAD IN THE PUBLIC HEARING FIELD PERSONS WHO APPEARED AT THE HEARING(S) AND TRANSCRIPTS)

RELEVANT FEDERAL STATUTES OR REGULATIONS: No

WHAT OTHER NOTICE, INCLUDING ADVERTISING, DID YOU GIVE OF THE HEARING?

None

SUMMARY OF THE CONTENT OF THE LEGISLATIVE RULE, AND A DETAILED DESCRIPTION OF THE RULE'S PURPOSE AND ALL PROPOSED CHANGES TO THE RULE:

Record Keeping and Automated Data Processing Systems

Removing specific requirements to allow more flexibility.

STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE RULE:

The Board felt changes were necessary.

SUMMARIZE IN A CLEAR AND CONCISE MANNER THE OVERALL ECONOMIC IMPACT OF THE PROPOSED LEGISLATIVE RULE:

A. ECONOMIC IMPACT ON REVENUES OF STATE GOVERNMENT:

none

B. ECONOMIC IMPACT OF THE LEGISLATIVE RULE ON THE STATE OR ITS RESIDENTS:

none

C. FISCAL NOTE DETAIL:

Effect of Proposal	Fiscal Year		
	2019 Increase/Decrease (use "-")	2020 Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0	0	0
Personal Services	0	0	0
Current Expenses	0	0	0
Repairs and Alterations	0	0	0
Assets	0	0	0
Other	0	0	0
2. Estimated Total Revenues	0	0	0

D. EXPLANATION OF ABOVE ESTIMATES (INCLUDING LONG-RANGE EFFECT):

none

BY CHOOSING 'YES', I ATTEST THAT THE PREVIOUS STATEMENT IS TRUE AND CORRECT.

Yes

Ryan L Hatfield -- By my signature, I certify that I am the person authorized to file legislative rules, in accordance with West Virginia Code §29A-3-11 and §39A-3-2.

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 4
RECORD KEEPING AND AUTOMATED DATA PROCESSING SYSTEMS

§15-4-1. General.

1.1. Scope. -- Recordkeeping requirements, and outlining the proper use of an automated Data Processing System.

1.2. Authority. -- W. Va. Code §30-5-7.

1.3. Filing Date. -- ~~June 24, 2016.~~

1.4. Effective Date. -- ~~July 1, 2016.~~

1.5. Sunset Provision-- This rule shall terminate and have no further force or effect upon the expiration of five years from its 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.

2.2. Two or more pharmacies may establish and use an automated data processing system as a common data file or database 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 renewal dispensed.

§15-4-3. Definitions.

3.1. Except as otherwise specifically stated in this rule, the definitions set forth in Title 15, Series 1, Section 2 are incorporated by reference, and are fully applicable hereto.

3.2. "Automated Data Processing System (ADP)" means a system utilizing computer software and hardware for the purpose of recordkeeping.

3.3. "Printout" means a readable printed copy of the output of a computer.

3.4. "Common database" means 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.

3.5. "On-line retrieval" means the producing of sight-readable documents on a suitable computer screen or monitor.

3.6. "Hardware" is the fixed components of a computer, server, or other such devices used for the electronic storage and retrieval of data.

3.7. "Software" is a computer program used to direct the operation of a computer, as well as the documentation giving instructions on how to use it, and directs the storage of required data on the hardware.

§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 from the date of last dispensing. Information beyond one (1) year but up to five (5) years from the date of dispensing may be maintained other than on-line, but must be produced within ~~forty-eight (48)~~ seventy-two (72) hours upon request by proper authorities. The information contained in the records shall include, but not be limited to:

4.1. the information required to be placed upon the label for the dispensed medication as set forth in Title 15, Series 1, Section ~~22~~ 18;

4.2. the full name of the pharmacist responsible for dispensing the drug; and

4.3. a record of renewals to date.

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

5.1. The pharmacy must be able to provide a current history of all authorized prescription activity required to be kept by section 4. In addition, this information must be capable of production on a patient-by-patient basis in the form of patient profiles which allows immediate review of any other data necessary to make rational judgments about pharmacist care. ~~at least the following data about the patient which may be reasonably obtained by the pharmacist:~~

~~(a) The patient's biographical data;~~

~~(b) The patient's medications;~~

~~(c) The patient's disease states and drug allergies;~~

~~(d) The pharmacist's notes; and~~

~~(e) Any other data necessary to make rational judgments about pharmacist care.~~

5.2. An ADP system, if used, must provide this information by a suitable computer screen or monitor display and be capable of providing a printout.

5.3. 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:

5.3.1. The ADP system shall provide on-line retrieval (via computer screen or monitor 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: 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.

5.3.2. The ADP system shall provide on-line retrieval (via computer screen or monitor display or printout) of the current refill history for Schedule III, ~~or IV,~~ or V controlled substance prescription order (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.

5.3.3. 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,~~ or V Controlled Substance. A ~~printout~~ verified record of the day's controlled substance prescription order refill data must be retrievable by ~~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. The book or file must be maintained at the pharmacy employing the system for a period of two (2) years after the date of dispensing the appropriately authorized refill.~~

5.3.4. The ADP system shall have the capability of producing a printout of any refill data which the user pharmacy is responsible for maintaining under W. Va. Code §30-5-1 et seq. and its implementing regulations. This includes 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). The 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 the 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).

5.3.5. In the event that pharmacy which employs a computerized system experiences system downtime, the pharmacy must have an auxiliary procedure which will be used for documentation of refills of Schedule III, ~~and IV,~~ and V 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.

5.3.6. When filing refill information for original prescription orders for Schedule III, ~~or IV,~~ or V 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 authorized pharmacy personnel licensed or registered by the Board may have access to the ADP.

§15-4-8. Records of Provision of Pharmacist Care Outside of a Licensed Pharmacy.

8.1 A pharmacist practicing pharmacist care services outside the premises of a licensed pharmacy shall maintain the records or other patient-specific information used in such activities in a readily retrievable form in a system that is secured and managed by the pharmacy with whom the pharmacist is providing such services; or, if acting independent of a pharmacy without the dispensing of prescription drugs to provide direct patient-care activities of patient counseling and medication therapy management, when the patient is unable to present to the pharmacy for a personal, face-to-face interaction, a secure system maintained by the pharmacist. The records or information shall:

- (a) provide accountability and an audit trail;
- (b) be provided to the Board upon request;
- (c) be preserved for a period of at least five years from the date relied upon or consulted for the purposes of performing any such function; and
- (d) secure from unauthorized access and use.