WEST VIRGINIA
SECRETARY OF STATE
NATALIE E. TENNANT
ADMINISTRATIVE LAW DIVISION

Form #3

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OFFICE WEST VIRGINIA
SECRETARY OF STATE

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

AGENCY: West Virginia Board of Pharmacy TITLE NUMBER: 15

CITE AUTHORITY: West Virginia Code Section 30-5-7

AMENDMENT TO AN EXISTING RULE: YES X NO ____

IF YES, SERIES NUMBER OF RULE BEING AMENDED: 4

TITLE OF RULE BEING AMENDED: Record Keeping and Automated Data Processing Systems

IF NO, SERIES NUMBER OF RULE BEING PROPOSED: ____

TITLE OF RULE BEING PROPOSED: ____

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.

David E. Potters
Authorized Signature

QUESTIONNAIRE

(Please include a copy of this form with each filing of your rule: Notice of Public Hearing or Comment Period; Proposed Rule, and if needed, Emergency and Modified Rule.)

DATE: July 16, 2015

TO: LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

FROM:(*Agency Name, Address & Phone No.*) West Virginia Board of Pharmacy
2310 Kanawha Boulevard East
Charleston, West Virginia 25311

304-558-0558

LEGISLATIVE RULE TITLE: Title 15, Series 4
Record Keeping and Automated Data Processing

1. Authorizing statute(s) citation West Virginia Code Section 30-5-7

2. a. Date filed in State Register with Notice of Hearing or Public Comment Period:

Filed Notice with Secretary of State on May 22, 2015

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

E-mailed copy of proposed rule to various stakeholders for review and input prior to initial filing, and then reviewed in open Board meeting prior to initial filing.

c. Date of Public Hearing(s) ***or*** Public Comment Period ended:

June 24, 2015

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

Attached _____ No comments received x

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

Filed Notice with Secretary of State on July 16, 2015

f. **Name, title, address and <u>phone/fax/e-mail numbers</u>** of agency person(s) to receive all *written correspondence* regarding this rule: (Please type)

David E. Potters
Executive Director & General Counsel
2310 Kanawha Boulevard East
Charleston, West Virginia 25311

304-558-0558
304-558-0572 (fax)
david.e.potters@wv.gov

g. **<u>IF DIFFERENT</u> FROM ITEM 'f'**, please give **Name, title, address and phone number(s)** of agency person(s) who wrote and/or has responsibility for the contents of this rule: (Please type)

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.

b. Date of hearing or comment period:

_____

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

_____

d. Attach findings and determinations and reasons:

Attached _____

BRIEF SUMMARY OF AND STATEMENT OF CIRCUMSTANCES WHICH REQUIRE THE PROPOSED LEGISLATIVE RULE

RULES OF THE BOARD OF PHARMACY FOR THE UNIFORM CONTROLLED SUBSTANCES ACT

15 CSR 4

Summary and Statement of Circumstances: This rule makes simple modifications to pharmacy record keeping and electronic records systems requirements. Its aim is to eliminate outdated provisions, move one recordkeeping provision from Series 1 to here, and provide for recordkeeping with regard to the practice of telepharmacy. Finally, the Board sought to clean up and make minor clarifications to other provisions.

For Further Information: Copies of the proposed rule may be obtained from the website of the West Virginia Secretary of State at www.wvsos.com, or interested parties may call the Administrative Law Division of the Office of the Secretary of State at (304) 558-6000.

Further information may be obtained by contacting the West Virginia Board of Pharmacy, David E. Potters, Executive Director and General Counsel, 2310 Kanawha Boulevard East, Charleston, West Virginia, 25311, telephone (304) 558-0558.

Note: This is a modification of the Series, such that changes are reflected by strike-throughs and underlining in the proposed rule.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Title 15, Series 4, Record Keeping and Automated Data Processing Systems

Type of Rule: [X] Legislative [ ] Interpretive [ ] Procedural

Agency: West Virginia Board of Pharmacy

Address: 2310 Kanawha Boulevard East
Charleston, West Virginia 25311

Phone Number: 304-558-0558 Email: david.e.potters@wv.gov

Fiscal Note Summary

Summarize in a clear and concise manner what impact this measure will have on costs and revenues of state government.

This rule makes simple modifications to pharmacy record keeping and electronic records systems requirements. It does not impact revenue in any way.

Fiscal Note Detail

Show over-all effect in Item 1 and 2 and, in Item 3, give an explanation of Breakdown by fiscal year, including long-range effect.

FISCAL YEAR			
Effect of Proposal	Current Increase/Decrease (use "-")	Next Increase/Decrease (use "-")	Fiscal Year (Upon Full Implementation)
1. Estimated Total Cost	0.00	0.00	0.00
Personal Services	0.00	0.00	0.00
Current Expenses	0.00	0.00	0.00
Repairs & Alterations	0.00	0.00	0.00
Assets	0.00	0.00	0.00
Other	0.00	0.00	0.00
2. Estimated Total Revenues	0.00	0.00	0.00

Rule Title: Title 15, Series 4, Record Keeping and Automated Data Processing Systems

Rule Title: _____

3. Explanation of above estimates (including long-range effect):
Please include any increase or decrease in fees in your estimated total revenues.

This rule makes simple modifications to pharmacy record keeping and electronic records systems requirements. It does not impact revenue in any way.

MEMORANDUM

Please identify any areas of vagueness, technical defects, reasons the proposed rule **would not** have a fiscal impact, and/or any special issues **not** captured elsewhere on this form.

N/A

Date: May 22, 2015

Signature of Agency Head or Authorized Representative

David E. Potter

TITLE 15
LEGISLATIVE RULE
BOARD OF PHARMACY

SERIES 4
~~COMPUTER REGULATIONS~~RECORD KEEPING AND AUTOMATED DATA PROCESSING SYSTEMS

§15-4-1. General.

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

1.2. Authority. -- W. Va. Code §30-5-19.

1.3. Filing Date. -- ~~April 9, 1992~~__.

1.4. Effective Date. -- ~~April 9, 1992~~__.

§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 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~~or~~ each prescription and renewals 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 as if set forth fully herein, and are fully applicable hereto.

~~3.1~~3.2. 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~~3.4. A "printout" is a readable printed copy of the output of a computer.

~~3.6~~3.5. 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~~a suitable computer screen or monitor.

~~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, server, or other such devices used for the electronic storage and retrieval of data.

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

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

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

~~4.2. The date of dispensing~~

~~4.3. The serial number of the prescription (or equivalent if an institution)~~

4.4~~4~~.2. The ~~identification~~ full name of the pharmacist responsible for dispensing the drug

4.5~~4~~.3. A record of renewals to date

~~4.6. The name, and strength of the dispensed drug (name of manufacturer if a generic drug)~~

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

5.1. ~~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:~~ The pharmacy must be able to provide a current history of all authorized prescription activity required to be kept by Section 4 above. 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 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.

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

~~5.1.1. The serial number of the prescription (or equivalent if an institution).~~

~~5.1.2. The date of dispensing.~~

~~5.1.3. The quantity dispensed.~~

~~5.1.4. The identification of the pharmacist responsible for dispensing the drug.~~

~~5.1.5. The prescription drug dispensed.~~

5.2. 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:

5.2.1. A proposed ADP system must provide on-line retrieval (via ~~CRT~~computer screen or monitor display or printout) of the original prescription order information for those precription 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.

5.2.2. A proposed ADP system must also provide on-line retrieval (via ~~CRT~~computer screen or monitor display or printout) of the current refill history for Schedule III or IV 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.

5.2.3. 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 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.

5.2.4. A 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. 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).

5.2.5. 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.

5.2.6. 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~~ a authorized pharmacy personnel licenensed or registered by the Board ~~registered pharmacist~~ may have access to the Automated Data Processing System.

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

8.1 A pharmacist providing 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. Such records or information shall:

8.1.1 provide accountability and an audit trail;

8.1.2 be provided to the Board upon request;

8.1.3 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

8.1.4 secure from unauthorized access and use.

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RESPONSE TO PUBLIC COMMENTS RECEIVED TO PROPOSED RULES

(Including explanation of any amendments made to the proposed rule as a result of comments)

TITLE 15, SERIES 4 (WV CSR 15-4-1, et seq.)
Record Keeping and Automated Data Processing Systems

The Board of Pharmacy did not receive any written public comments or otherwise receive any additional information regarding the proposed rules filed with the Secretary of State on May 22, 2015, making amendments to Title 15, Series 4. The public comment period ended on June 24 2015. Although none were received, the Board held a public meeting on June 28, 2015, determined that no modifications are necessary at this time, and authorized this response and the proposed rules to be filed with the Secretary of State and the Legislative Rule-Making and Review Committee.

Prepared by:

David E. Potters

David E. Potters
Executive Director & General Counsel