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July 26, 2019

Re: WVBOP -- 15 CSR 4

The Board has some revisions to 15 CSR 4 as proposed by the agency.

West Virginia Retailers Association: The first change was better explained to the commenter and rejected. Hours were changed from 48 to 72 hours. Finally, the proposed language for 5.3.3. was accepted.

Sincerely,


Ryan L. Hatfield
General Counsel



WEST VIRGINIA
RETAILERS
ASSOCIATION

July 25, 2019

Ryan Hatfield
WV Board of Pharmacy
2310 Kanawha Blvd., E.
Charleston, WV 25311

Dear Mr. Hatfield,

Please see the recommendations below regarding the rules filed with the WV Secretary of State's office. Our members expressed concerns on only a couple of areas. We appreciate the Board's consideration regarding the recommendations and the explanation provided.

WV Pharmacy Rule 15-04 Record Keeping and Automated Data Processing Systems

Comment: 15-4-5. Record of Retrieval.

- The language under 5.1 is ambiguous, and we are not clear on the Board's intent.
- There could be various clinical details that the pharmacist obtains from external sources, or in consultation with the prescriber, that will affect the pharmacist's judgment. Not all of those items would be captured within the system or readily retrievable. Examples include lab values, patient weight, or morphine milligram equivalents (MME) for opioid drugs.

§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.~~

Comment: 15-4-5. Record of Retrieval.

- We are concerned that the state is reducing the amount of time for these records to be produced. Pharmacy systems may not be able generate all required elements for every requested prescription immediately. Many states allow the reports to be made available within 72 hrs, and this standard is necessary to support any given volume of records requests.
- Generating reports on a daily basis to have the pharmacist sign is a redundant process, since many electronic systems already capture the pharmacist details within the systems. This is one reason why the DEA has also allowed for the logbook to help verify the accuracy of the information captured within the system. However, these proposed rules seem to stray away from that standard.

Existing

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 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. 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.

Proposed by BOP

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 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. 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.~~ Such documentation shall be verified daily and be readily retrievable in accordance with subsection 4 of this rule

New Suggestion

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 verified record printout 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.~~

Best Regards,

Bridget Lambert, President
WV Retailers Association
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