Pharmacy Law Update 2025: Knowing the Current State and Federal Requirements

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Statement of Disclosure

- **Krista Capehart h**as nothing to disclose concerning possible financial relationships with ineligible companies that may have a direct or indirect interest in the subject matter of this presentation.

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Learning Objectives

- Explain new WV Board of Pharmacy Rules that have recently become effective.
- Discuss laws impacting pharmacy practice that have recently passed in WV.
- Identify requirements and updates related to the Drug Supply Chain Securities Act (DSCSA).
- Discuss recent changes and final rules related to telemedicine and the Drug Enforcement Administration (DEA).

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Updated WV Code of State Rules

- Updates and modernization for 3 legislative rules
  - §15-1 Licensure and Practice of Pharmacy
  - §15-2 Rules for Controlled Substances
  - §15-15 Regulations Governing Pharmacy Permits

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§15-1 Licensure and Practice of Pharmacy

- "Beyond-use date" means a date placed on a medication package or prescription label at the time of dispensing or repackaging that is intended to indicate to the time beyond which the contents are not recommended to be used.
- "Expiration date" means the time assigned by manufacturers based on analytical and performance testing of the sterility, chemical and physical stability, and packaging integrity of the product during which it can be expected to meet the requirements of a compendial monograph, if one exists, or is guaranteed to be safe and potent provided it is kept under the prescribed storage conditions.

USP 797 and USP 795

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Beyond use dates for repackaged products

- All extemporaneous unit dose, unit of use, punch card or any other specialized packaging shall be done by pharmacists, pharmacy interns, or pharmacy technicians or pharmacy technician trainees under the direct supervision of a pharmacist.
- Six months from the date of repackaging; or
- The manufacturer's expiration date, or
- Except as modified in W.Va. Code R. § 15-5 *et seq.*

WV CSR 15-1

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REMOVED

- ~~To possess a list of the drugs which may be prescribed by a physician's assistant with prescriptive privileges and also to possess prescriptive authority of nurse practitioners prior to dispensing prescription orders from those prescribers;~~

WV CSR 15-1

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§15-1-15.14.1 Violation of the rules of professional conduct.

- Rules of Professional Conduct apply to pharmacy technician trainees in addition to pharmacists, pharmacy interns, and pharmacy technicians

WV CSR 15-1

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§15-1-19 Pharmacy Consultants

- Clarified the language around continuing education required
- Annual Renewal
- Excluded dental practices from needing a consultant pharmacist

USP 15-1

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§15-2 Rules of the Board of Pharmacy for the Uniform Controlled Substances Act

- Defined "Acute care hospital" means a hospital licensed by the West Virginia Office of Health Facility Licensure and Certification that provides acute hospital care and treatment.
- Included the definitions of pharmacist in charge, pharmacy technician, and registered nurse in rule to facilitate the addition of so of the other changes in the rule

WV CSR 15-2

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§15-2 Drugs "abandoned" at acute care hospital

9.2.3 In acute care hospitals, discontinued individual patient medications not supplied by the hospital should be sent home with the patient. Those that remain in the hospital after discharge may be considered abandoned and shall be destroyed in the following manner and in compliance with federal law:

WV CSR 15-2-8.2.3

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§15-2 Drugs "abandoned" at acute care hospital

9.2.3.a. Drugs listed in Schedules I, II, III, IV, V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, or by W.Va. Code §60A-1 *et seq.* shall be destroyed in the presence of two pharmacists, a pharmacist and pharmacy technician, or a pharmacist and a registered nurse employed by the hospital. The name of patient or patient medical record number, the name and strength of the drug, the amount destroyed, the date of destruction, and documentation of the required witnesses shall be recorded and maintained in the medical record. The destruction should also be recorded without patient specific information and maintained with the pharmacy's controlled substance records.

- 9.2.3.b. Drugs not listed in Schedules I, II, III, IV, V of the Federal Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended, or W.Va. Code §60A-1 *et seq*, shall be destroyed in the presence of a pharmacist.

WV CSR 15-2-9,2,3

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§15-2-9.3 Reporting theft or significant loss of drugs

A registrant shall notify the Board in writing, of the theft or significant loss of any controlled substances within one business day of discovery of such loss or theft. The registrant must also file a complete and accurate DEA Form 106 with the Board within 45 days after discovery of the theft or significant loss.

- The Pharmacist-in-charge must immediately notify the Board of the separation of employment of any pharmacist, pharmacy intern, pharmacy technician, or pharmacy technician trainee for any confirmed drug-related reason, including but not limited to, adulteration, abuse, theft, or diversion as required in W.Va. CSR §15-1-16.2.7.e-f.

WV CSR 15-2-9

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§15-15 Regulations Governing Pharmacy Permits

- Lots of questions arise as pharmacies are shortening hours and patient access to medications decreases.
- "Direct-to-patient system" or "DTP system"

WV CSR 15-15

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§15-15 Direct to patient system

"Direct-to-patient system" or "DTP system" means any delivery system through which a pharmacy dispenses drugs, devices, or medical equipment to a patient through any means other than:

In-person dispensing to a patient by pharmacy personnel inside a pharmacy, or

In-person dispensing by delivery to a patient's residence or to a health care provider treating that patient, or

Shipping through common carrier to a patient or to a health care provider treating that patient.

Except as provided in this rule or in the exceptions in subdivisions 1-3 of this definition, no person holding any license or permit from the Board shall participate in any arrangement whereby prescriptions may be left at, picked up from, accepted by, or delivered to any other place. The only DTP system allowed are "lockers."

WV CSR 15-15

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§15-15-12 Direct-to-Patient Delivery Systems

- Any DTP system located within West Virginia (lockers) shall meet the following requirements:
  - Before any drugs, devices, or medical equipment may be picked up from a DTP system, the home pharmacy shall have been issued a pharmacy permit by the Board.
  - The home pharmacy shall notify the Board via the form on the website at www.wvbop.com prior to beginning to use any DTP system. The home pharmacy shall notify the Board within 10 days after discontinuing patient use of any DTP system.
  - Any DTP system shall be located at the physical address of the permitted home pharmacy.

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems (cont.)

- Any DTP system located within West Virginia (lockers) shall meet the following requirements:
  - The home pharmacy shall prohibit access to the DTP system and its contents by unauthorized personnel and maintain confidentiality of patient information. The DTP system shall be under the continuous supervision of a pharmacist employed by the home pharmacy or under contract with a licensed pharmacy, which may be satisfied by real-time remote supervision of the pharmacy through video and audio connections.
  - The home pharmacy shall ensure that there is continuous, recorded video surveillance of the DTP system and any persons using or accessing the DTP system. It shall maintain any recordings for a minimum of 90 days.

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems (cont.)

- The home pharmacy shall develop, maintain, and follow a manual of policies and procedures that includes policies and procedures for:
  - Maintaining the security of the DTP system and the drugs, devices, and medical equipment within the DTP system.
  - Determining and applying criteria regarding which drugs, devices, and medical equipment are appropriate for placement in the DTP system and which patients are eligible to use the DTP system.
  - Maintaining any drugs, devices, and medical equipment at temperatures, humidities and other environmental conditions to ensure that they do not become adulterated and to ensure that they are transported and stored in accordance with manufacturer's specifications, if any, for those items.

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems (cont.)

- The home pharmacy shall develop, maintain, and follow a manual of policies and procedures that includes policies and procedures for:
  - Removing outdated drugs, devices, and medical equipment from the DTP on a regular basis so that patients do not receive drugs, devices, and medical equipment with a beyond use date during the period when the patient is to use the item.
  - Describing the assignment of responsibilities to, and training of, pharmacy personnel regarding the maintenance and filling procedures for the DTP system.
  - Orienting participating patients on use of the DTP system; notifying patients when expected drugs, devices, or medical equipment are not available in the DTP system or when the DTP system is not functioning and notifying them of alternate methods for having those prescriptions filled; and ensuring that patient use of the DTP system does not interfere with the delivery of drugs, devices, and medical equipment to patients.
  - Self-inspection of the DTP system for required compliance with West Virginia Code and the Rules of this Board and all Federal laws and regulations.

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems

- Any DTP system located within West Virginia (lockers) shall meet the following requirements:
  - The home pharmacy shall comply with any federal and state controlled substance laws and rules before any controlled substances are picked up from any DTP systems. The home pharmacy shall comply with WV Code §60A-3-308.d.2.B in delivering any drugs covered by that statute from a DTP system, and shall visually confirm that the person seeking the dispensation is the same as the person on the government issued photo identification.
  - Only pharmacy personnel who are licensed with this Board as pharmacists or registered with this Board as pharmacy technicians, pharmacy technician trainee, or pharmacy interns may stock prepared drugs, devices, and medical equipment in, or remove drugs, devices, and medical equipment from the inventory of a DTP system. The home pharmacy shall maintain records of any access to the DTP system by pharmacy personnel stocking or otherwise accessing the DTP system.

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems

- Any DTP system located within West Virginia (lockers) shall meet the following requirements:
  - Before a home pharmacy allows pick up of drugs, devices and medical equipment to a patient through a DTP system, the home pharmacy shall secure the written consent of the patient to use the DTP system.
  - The dispensing pharmacist on any drugs, devices, or medical equipment picked up from a DTP system in West Virginia shall be licensed with this Board.
  - The counseling pharmacist on any drugs, devices, or medical equipment picked up from a DTP system in West Virginia shall be licensed with this Board or be employed at a non-resident pharmacy licensed with this Board.
  - Before a prescription is picked up from the DTP system, the dispensing pharmacist shall verify each prescription and shall conduct a drug utilization review and otherwise assure that the drug, device, or medical equipment may safely be picked up by the patient.

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems

- Any DTP system located within West Virginia (lockers) shall meet the following requirements:
  - The labels of any drugs, devices, and medical equipment picked up from a DTP system shall be labeled for the individual patient and contain all information required by law.
  - The home pharmacy shall create and maintain records for any drugs, devices, and medical equipment picked up from a DTP system in compliance with State and federal law.
  - The DTP system shall have a means to identify each patient (or that patient's authorized agent) and release only that patient's prescription drugs, devices, or medical equipment to the patient (or the patient's authorized agent).

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems

- Any DTP system located within West Virginia (lockers) shall meet the following requirements:

__The DTP system shall convey the home pharmacy's offer to counsel a patient as required by W.Va. 15 CSR 1.15.13.6 and shall provide the ability for the patient to have an immediate real-time consultation with a pharmacist licensed by this Board and employed by the home pharmacy who has access to all of the home pharmacy's information related to the patient. The communication link shall protect the confidentiality of the patient's information. The home pharmacy shall check the communication link at least daily and the DTP system shall be closed if the link malfunctions or if a licensed pharmacist is not available for counseling, unless a licensed pharmacist is physically present at the DTP system. A pharmacist who is responsible for counseling may not provide that service for more than three sites simultaneously. If the dispensing pharmacist has determined that the patient should receive counseling before the prescription is dispensed, the DTP system shall provide the ability for the pharmacist to force counseling before the DTP system allows pick up of the drug, device, or medical equipment.

WV CSR 15-15-12

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§15-15-12 Direct-to-Patient Delivery Systems

- Any DTP system located within West Virginia (lockers) shall meet the following requirements:
  - The home pharmacy shall record and review any incident involving a complaint, delivery error, or omission regarding a DTP as part of the home pharmacy's quality assurance program
  - Drugs, devices, or medical equipment that are not picked up by a patient may be returned to stock under the same conditions as if the item had been maintained in the pharmacy, as long as the requirements of this Rule for operating the DTP system have been followed.

WV CSR 15-15-12

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WV SB 291 Annual to Biennial

- Technical Cleanup
- Changes pharmacy renewal from annual to biennial
- This was done in rule in 2020 and needed to be fixed in Statute. No change in fees

Effective June 12, 2025

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SB 299 Modifying WV regulations on pubertal modulation, hormonal therapy, and gender reassignment

- Prohibits physicians, physician assistants, and nurse practitioners from prescribing gender altering medication as defined in the bill to a person under individual age 18 years of age
- Permits for immediate revocation of their license and the minor may bring action before reaching 18, and the Atty General may bring action against the health care professional

WV SB 299 awaiting Governor signature

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SB 458 Universal Professional and Occupational Licensing Act of 2025

- Establish residence
- Is married to active-duty member of US armed forces
- Currently licensed in at least one other state
- License in good standing
- Not under investigation for unprofessional conduct
- No discipline
- Pays fees
- Passes background check
- MUST STILL TAKE A LAW EXAM SPECIFIC TO THE LAWS OF THIS STATE

SB 458 Effective July 1, 2025

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SB 526 Pharmacist Prescribing Authority Act

- Prescribe drugs, excluding controlled substances, that are in accordance with the product's federal Food and Drug Administration-approved labeling and that are limited to conditions for which a relevant patient medication history has been taken and:

WV SB 526 Pharmacist Prescribing Authority Act

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SB 526 Pharmacist Prescribing Authority Act

- (i) Have a test that is used to guide diagnosis or clinical decision-making that is waived under the federal Clinical Laboratory Improvement Amendments of 1988 that indicates the existence of the following conditions only: influenza; SARS-COV-2; and RSV; or
- (ii) refill an expired prescription for an epinephrine injection device.

WV SB 526 Pharmacist Prescribing Authority Act

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SB 526 Pharmacist Prescribing Authority Act

- (B) The pharmacist shall, within 72 hours, notify the patient's primary care physician of the test result and the permissible drug prescribed and dispensed.
- (C) A prescription dispensed or prescribed pursuant to this article is limited to up to a 30-day supply within a six-month period, if more than 10 days is prescribed or dispensed, then the pharmacist shall notify the primary care physician. If no primary care physician is identified, the pharmacist shall attempt to make a patient referral to a primary care physician.

WV SB 526 Pharmacist Prescribing Authority Act

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SB 526 Pharmacist Prescribing Authority Act

- The law does not provide for additional protocols or rule making, thus, if signed by the Governor, it will become effective on the date determined by the legislature.
- As with other tasks stated withing the pharmacist's scope of practice, it is not granted to any other personnel and may not be delegated.
- Pharmacists must also ensure that appropriate training and education has been completed prior to providing additional medication administration

WV SB 526 Pharmacist Prescribing Authority Act

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HB 2354 Banning certain products from food in WV

- If it contains any added substance or ingredients which are poisonous or injurious to the health, including butylated hydroxyanisole, propylparaben, FD&C Blue No. 1, FD&C Blue No. 2, FD&C Green No. 3, FD&C Red No. 3, FD&C Red No. 40, FD&C Yellow No. 5, and FD&C Yellow No. 6;
- This bill does NOT include prescription medications. It would include products in the front end.

HB 2354

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Drug Supply Chain Security Act

- Passed Nov 27, 2013 to track and trace meds during entire supply chain
- Pharmacies must only deal with "authorized trading partners".
- "Product identifiers" are on products. Drug containers could have the same lot number but different serial numbers.
- Lot number: same number on a batch of manufactured drug
- Serial number: could be the same lot number but identifies and differentiates each individual package from one another
- This information enables secure tracking from active pharmaceutical ingredient at the manufacturer level through the entire distribution chain to the pharmacy level

Drug Supply Chain Security Act https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf

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Who does DSCSA name as dispensers?

- A retail pharmacy;
- A hospital pharmacy;
- A group of chain pharmacies under common ownership and control that do not act as a wholesale distributor; or
- Any other person authorized by law to dispense or administer prescription drugs and the affiliated warehouses or distribution centers of such entities under common ownership and control that do not act as a wholesale distributor.

Drug Supply Chain Security Act https://www.govinfo.gov/content/pkg/PLAW-113publ54/pdf/PLAW-113publ54.pdf Accessed 5/1/2022

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Requirements at pharmacy level by new implementation dates

- Only purchase pharmaceutical products from verified primary wholesale distributors/manufacturers
- Have policies/procedures to:
  - Ensure Rx product shipments have TI and TS
  - Verifying product appearance of Rx products when they arrive looking for legitimacy
  - Manage suspect and illegitimate products with quarantine process
  - Report suspect product to FDA withing 48 hours of receipt
  - Make sure transaction data is secure

https://dscsa.pharmacy/wp-content/uploads/2023/02/ASHP_DSCSA_Member_02062023-Update.pdf

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Exemptions Granted for Stabilization Period

- Applies to any product transacted by eligible trading partners, which are trading partners who have successfully completed or made documented efforts to complete data connections with their immediate trading partners, but still face challenges exchanging data.
- New Dates:
  - Manufacturers and Repackagers: May 27, 2025
  - Wholesale Distributors: August 27, 2025
  - Dispensers with 26 or more full-time employees: November 27, 2025
  - small dispensers (pharmacies with 25 or fewer full-time employees as of 11-27-24), and where applicable their trading partners, until November 27, 2026.
- Entities are to continue to efforts to implement the necessary measures to comply with the enhanced drug distribution security requirements

https://www.fda.gov/drugs/drug-supply-chain-security-act-dscsa/waivers-and-exemptions-beyond-stabilization-period

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DEA proposed rule on Special Registration for Telemedicine Prescribers

- Proposed rule January 17, 2025, open for comment until March 18, 2025. No known date for a final rule
- Creates 3 special registration types for telemedicine providers:
  1. Telemedicine prescribing Schedule III-V
  2. Advanced Telemedicine Prescribing Schedule II-V
  3. Telemedicine Platform Registration

https://www.federalregister.gov/documents/2025/01/17/2025-01099/special-registrations-for-telemedicine-and-limited-state-telemedicine-registrations

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DEA Final Rule - Continuity of Care via Telemedicine for Veterans Affairs Patients

- Establishes parameters where VA providers can utilize telemedicine to prescribe controlled substances for VA patients
- Requires reviews of the VA Electronic Health Record, internal prescription database and the prescription drug monitoring program (PDMP) for previous 12 months among other requirements

https://www.federalregister.gov/documents/2025/01/17/2025-01044/continuity-of-care-via-telemedicine-for-veterans-affairs-patients#:~:text=SUMMARY%3A,an%20in%20person%20medical%20evaluation.

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Expansion of Buprenorphine Treatment via Telemedicine Encounter (Final Rule)

- Delayed effective date until Dec 31, 2025
- Requires prescriber to check PDMP and has provisions for if info cannot be reviewed
- Time limitation for buprenorphine prescriptions: Telemed prescriptions may be issued for up-to 6 months. If at that point an in-person visit is held no other need to adhere to telemedicine rules

https://www.federalregister.gov/documents/2025/01/17/2025-01044/continuity-of-care-via-telemedicine-for-veterans-affairs-patients#:~:text=SUMMARY%3A,an%20in%20person%20medical%20evaluation.

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Expansion of Buprenorphine Treatment via Telemedicine Encounter (Final Rule)

- Pharmacy Requirements
  - prior to filling a prescription that was issued pursuant to the authorities created by this final rule, the pharmacist will be required to verify that, as a general matter, the identity of the individual picking up the prescription at the pharmacy matches the name of the patient listed on the prescription itself
  - Before the pharmacist can fill a prescription issued pursuant to the regulations found in this final rule, they must inspect the patient's state or Federal Government-issued photographic identification card, or in the absence of such identification

https://www.govinfo.gov/content/pkg/FR-2025-01-17/pdf/2025-01049.pdf

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Summary

- Changes to WV CSR 1, 2, 7, and 15
- A few new laws impacting WV, including licensing, pharmacist prescribing, and dyes.
- DSCSA is in a period of "industry stabilizing" and is set to become effective various dates based on the size of the dispenser. Be certain your pharmacy is ready.
- Several DEA Statements recently have provided some clarification on the Agency's position on several topics.

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Question 1

- Pharmacists must maintain a list of the prescriptive authority of physician assistants.

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Question 2

- A date placed on a medication package or prescription label at the time of dispensing or repackaging that is intended to indicate to the time beyond which the contents are not recommended to be used.
- Beyond use date
- Expiration date
- Manufacture date

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Question 3

- When you have identified a theft or significant loss of a controlled substance, a registrant is required to file an accurate completed DEA 106 within _____ day(s).

A. 1
B. 3
C. 45
D. 60

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Question 4

- The Universal Professional and Occupational Licensing Act of 2025 will still require a pharmacist who is seeking license transfer/reciprocity in WV still have to take the WV MPJE.

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Question 5

- The DEA final rule on Buprenorphine telemedicine prescribing will go/Went into effect _____.

A. January 17, 2025
B. November 27, 2025
C. December 31, 2025
D. Never…they'll still be discussing it

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Questions?

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CE Evaluation Access Code

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Capital Letters, No spaces, complete by 05/02/2025

Note: CE credit will be reported to NABP CPE Monitor within 4-6 weeks

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