



## West Virginia's Pharmacy Audit Integrity Act

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# Importance of 340B in West Virginia

***The 340B program is a vital lifeline for safety-net providers, supporting critical health services in our communities***

- Clinical pharmacists throughout the system
- Cash Card program for patients
- Meds to beds program
- The MOMS program
- Neonatal Therapeutic Unit
- Financial and Spiritual Care support to PROACT
- Offer community clinics and health care screenings
- Provide medically indicated food box program
- Provide free care to patients in our region
- School based clinics

*\*over \$200 million in uncompensated care at our hospitals*

## West Virginia hospital to close, lay off 600 employees

Ayla Ellison (Twitter) - Wednesday, February 19th



Fairmont (W.Va.) Regional Medical Center notified a buyer failed, according to *West Virginia MetroNews*.

The 207-bed hospital, owned by Irvine, Calif.-based Fairmont Regional Medical Center, announced a buyer failed after more than a year of searching for a buyer, according to *MetroNews*. Fairmont Regional CEO Bob Adcock

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## West Virginia Hospital Announces Closure Amid Pandemic

West Virginia Public Broadcasting | By Associated Press

Published March 31, 2020 at 10:28 AM EDT

The only hospital in a southern West Virginia county is closing after the coronavirus crisis disrupted attempts to sell the business, news outlets report.

Williamson Memorial Hospital in Mingo County announced plans on Monday to close in three weeks. In a statement, hospital officials explained that they went into bankruptcy proceedings in February and obtained a loan to fund operations until the business could be sold. The idea was to stay open until a sale closed in early April. But all potential buyers were health care providers who are now focused on preparing their own facilities for waves of coronavirus patients, delaying any sale.

"There is no option to obtain sufficient additional financing given its existing level of debt and the large losses currently being sustained by the hospital," officials said. "The only option available to the hospital is to shut down its operations."

U.S. Sen. Joe Manchin called it "unconscionable" that any hospital would close while the virus spreads. "I will continue to work with hospital leadership and state and local officials on next steps to ensure that Mingo County will not go without treatment during this terrible pandemic," the West Virginia Democrat's statement said.

## West Virginia hospital closing in 'days,' owner says in letter

(WVCI)

By ANTHONY IZAGUIRRE, Associated Press

Published: Mar. 17, 2020 at 3:04 PM EDT



The Fairmont Regional Medical Center is shutting down ahead of schedule and will cease operations over the next several days, the hospital's owner said in a letter Monday.

int Michael J. Sarrao wrote that the hospital will complete its winding down of services and will stop next several days." Hospital officials said on Feb. 18 that the facility would close within 60 days.

ek's announcement that West Virginia University Medicine would take over portions of the facility while in the area. Gov. Jim Justice and Albert L. Wright Jr., CEO and president of the WVU Health System, said enter would be closed for around a month to allow for administrative turnover at the facility.

in to shutter in the coming days was "based on Governor Justice's and WVU Medicine's announcement."

**Will lose their jobs. Hospital officials and Retraining Notification Act notice, according to West Virginia**

sed two other hospitals. In tins Ferry and Ohio Valley Medical

**4 Closures | 2 Bankruptcies**

**340B Program \$300 million+ in WV**

# PBM Reform– Pharmacy Audit Integrity Act

WV Code, Chapter 33 (Insurance), Article 51, Pharmacy Audit Integrity Act.

*PBM regulation and 340B protections are intertwined*

2017

**SB 522** “Pharmacy Audit Integrity Act” created (auditing entity registration and “Bill of Rights”)

2019

**SB 489** Banned PBMs from 340B discriminatory reimbursement and adjustments. oversight, and legislative rules

2021

**HB 2263** Provided pharmacy choice for patients and set PBM limitations, ensures minimum reimbursement (NADAC + \$10.49 dispensing fee used by WV Medicaid), Drug rebates should be shared with consumers at the point of sale. *(added ERISA)*

*\*WVOIC rules 114 CSR 99*

2018

**SB 46** PBM gag clauses prohibited, required all PBM fees to be itemized and described, prohibit PBMs from cost shares exceeding total submitted charges by a pharmacy.

**Rutledge v. PCMA**, 141 S. Ct. 474 (2020) (Rutledge), the U.S. Supreme Court ruled that ERISA does not preempt states from enforcing PBM regulations affecting drug costs and pricing.

**HB 4058** Required rule making and set fines for PBMs to not be less than \$1,000 or more than \$10,000

2020

**HB 4112** Removes decision-making about what is a specialty drug from pharmacy benefits managers (PBMs)/insurance companies, codifies the 340B entity protections of WVOIC rules, prohibits requirements on pharmacies that are more stringent than state requirements for licensure or certification, requires pharmacies to receive at least 30 business-days’ notice of a PBM/insurance company contract or manual change.

2022

# Pharmacy Audit Integrity Act

## **§33-51-3. Definitions.**

- “340B entity” means an entity participating in the federal 340B drug discount program, as described in 42 U.S.C. § 256b, including its pharmacy or pharmacies, or any pharmacy or pharmacies, contracted with the participating entity to dispense drugs purchased through such program.
- “Affiliate” means a pharmacy, pharmacist, or pharmacy technician which, either directly or indirectly through one or more intermediaries: (A) Has an investment or ownership interest in a pharmacy benefits manager licensed under this chapter; (B) shares common ownership with a pharmacy benefits manager licensed under this chapter; or (C) has an investor or ownership interest holder which is a pharmacy benefits manager

## **§33-51-9. Licensure of pharmacy benefit managers.**

- A pharmacy benefit manager, or any other third party, that reimburses a 340B entity for drugs shall not reimburse the 340B entity for pharmacy-dispensed drugs at a rate lower than that paid for the same drug to pharmacies similar in prescription volume that are not 340B entities, and shall not assess any fee, charge-back, or other adjustment upon the 340B entity
- With respect to a patient eligible to receive drugs subject to an agreement under 42 U.S.C. § 256b, a pharmacy benefit manager, or any other third party that makes payment for such drugs, shall not discriminate against a 340B entity in a manner that prevents or interferes with the patient’s choice to receive such drugs from the 340B entity

## **340B Specific Protections Legislative Rule (2021)**

- The term "other adjustment" includes placing any additional requirements, restrictions or unnecessary burdens upon the 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug
- It shall be considered a discriminatory practice that prevents or interferes with a patient's choice to receive drugs at a 340B entity if a PBM places additional requirements, restrictions or unnecessary burdens upon a 340B entity that results in administrative costs or fees to the 340B entity that are not placed upon other pharmacies that do not participate in the 340B program, including affiliate pharmacies of the PBM, and further includes but is not limited to requiring a claim for a drug to include a modifier or be reprocessed or resubmitted to indicate that the drug is a 340B drug.

# Legislation in Action– ESI Complaint/ Insurance Bulletins

***What happened?*** On February 24, 2021 Express Scripts, one of the largest pharmacy benefit managers (PBMs) in the United States, issued a notice stating that, beginning March 1, pharmacies must retrospectively identify drugs dispensed by 340B safety-net providers and their pharmacies.

***Thanks to 340B/PBM legislation and legislative rules, we were able to file a complaint against ESI with the WVOIC***

- “ESI’s 340B modifier mandate is an unlawful adjustment under the Pharmacy Audit Integrity Act, per W.Va. Code §33-51-9(d). The 340B modifier mandate serves no legal purpose under state law other than to create additional, onerous work for contract pharmacies (i.e., meaning a pharmacy not owned by a 340B entity). Thus, the mandate is a de facto cut to our members’ reimbursement. Moreover, we contend that the 340B modifier mandate violates W.Va. Code §33-51-9(e) by “...prevent[ing] or interfere[ing]” with a patient’s choice to receive prescriptions from a 340B entity, which includes contract pharmacies per West Virginia law.”

***“In What Is Believed to Be the First State Action, W.Va. Says Express Scripts’ 340B Policy Violates State Law”***

- On December 8, 2021, Allan McVey, the West Virginia Insurance Commissioner, approved the recommended decision of the hearing examiner regarding the complaint filed by West Virginia Primary Care Association, et. al. against ESI.
- The order finds that ESI violated W.Va. Code 33-51-9(d) by requiring a post claim adjudication modifier to identify 340B claims. Specifically, per page 22 of the order, "It is recommended that the Complainants proved, by a preponderance of the evidence, that the Respondent's new submission policy is discriminatory and violates W.Va. Code 33-51-9(d) since the costs associated with this change will be assessed on 340B entities and not upon other similar entities."

# Recommendations

***What are the essentials of a comprehensive, effective 340B discriminatory reimbursement law at the state level?***

- A comprehensive PBM regulatory structure that falls under a strong regulator
- 340B discriminatory reimbursement provisions
  - Prohibit “modifiers”
- Include broad definitions
- Include protections for ALL 340B covered pharmacy types and contract pharmacies
- Provide network adequacy provisions
  - If PBMs cannot pay 340B covered entities less than others, they may try to restrict 340B CEs out of pharmacy networks.
- Provide patient choice
- Allow for broad rulemaking authority and willingness to regulate and enforce the law





*Senator Capito and Congresswoman Miller visit the  
Hoops Family Children's Hospital*

**Thank you!**

**Questions?**

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