

340B State Legislative Actions

OHIO CONTRACT PHARMACY BILL & ADVOCACY

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340B Midwest Regional Conference & Expo
September 23 & 24, 2024



DISCLOSURE STATEMENT

Mark Ogunsusi has the following relevant financial relationships or commercial interests in relation to this presentation: minor stock in Pfizer, Merck, and GlaxoSmithKline.

The materials and discussions contained in this presentation may not be relied upon as legal advice.

All of the relevant financial relationships listed for this individual has been mitigated.



DISCLOSURE STATEMENT

Mark Ogunsusi has the following conflicts of interest in relation to this presentation: Mark is an attorney at Powers Pyles Sutter & Verville law firm and represents clients in various federal lawsuits involving 340B contract pharmacy arrangements, including the *PhRMA v. McClain*, 4:21-cv-00864-BRW (E.D. Ark. Sept. 29, 2021) and *AstraZeneca Pharmaceuticals LP v. Landry*, 6:23-cv-01042-RRS-CBW (W.D. La. Aug. 4, 2023) litigation discussed in this presentation.



LEARNING OBJECTIVES

At the completion of this activity, the participant will be able to:

- Review the Ohio and West Virginia legislative process
- Report updates on pending state legislation on 340B
- Demonstrate advocacy strategies for the protection of 340B and the profession of pharmacy
- Identify effective advocacy strategies to advance 340B contract pharmacy legislation
- Analyze new West Virginia law via Senate Bill 325, protecting contract pharmacy arrangements



OHIO CONTRACT PHARMACY BILL

Protecting Distribution of 340B Drugs



Ohio Contract Pharmacy Legislation

S.B.269 and HB 588

- Prohibits delivery restrictions by manufacturers
- Prohibits drugmakers from requiring 340B providers to submit claims data as a condition of accessing 340B drugs
- Investigation and enforcement by attorney general, insurance department, and board of pharmacy
- Permits investigation of wholesalers to ascertain manufacturer violations



Ohio Contract Pharmacy Legislation

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That section 4729.521 of the Revised Code be 5
enacted to read as follows: 6

Sec. 4729.521. (A) As used in this section: 7

(1) "340B covered entity" has the same meaning as in 8
section 5167.01 of the Revised Code. 9

(2) "340B drug" means a drug that meets all of the 10
following criteria: 11

(a) The drug is a covered outpatient drug under the 340B 12
drug pricing program. 13

(b) The drug is subject to any offer for reduced prices by 14
a manufacturer pursuant to the 340B drug pricing program. 15

(c) The drug is purchased by a 340B covered entity or 16
would have been purchased by a covered entity if not for an 17
action prohibited under division (B) of this section. 18



Ohio Contract Pharmacy Legislation

<u>(3) "340B drug pricing program" means the program</u>	19
<u>authorized by section 340B of the "Public Health Service Act,"</u>	20
<u>42 U.S.C. 256b.</u>	21
<u>(4) "Package" has the same meaning as in 21 U.S.C. 360eee.</u>	22
<u>(B) No manufacturer of dangerous drugs, repackager of</u>	23
<u>dangerous drugs, third-party logistics provider, or wholesale</u>	24
<u>distributor of dangerous drugs, or an agent or affiliate of any</u>	25
<u>of those entities, shall do either of the following:</u>	26
<u>(1) Deny, prohibit, restrict, discriminate against, or</u>	27
<u>otherwise limit the acquisition of a 340B drug by or delivery of</u>	28
<u>a 340B drug to a 340B covered entity, unless the purchase or</u>	29
<u>delivery is prohibited by the United States department of health</u>	30
<u>and human services;</u>	31
<u>(2) Require a 340B covered entity to submit any claims or</u>	32
<u>utilization data as a condition for allowing the acquisition of</u>	33
<u>a 340B drug by or delivery of a 340B drug to a covered entity,</u>	34
<u>unless the claims or utilization data sharing is required by the</u>	35
<u>United States department of health and human services.</u>	36



Ohio Contract Pharmacy Legislation

(C) The commission of any act prohibited by division (B) of this section is an unlawful practice under section 1345.02 of the Revised Code. The attorney general may enforce compliance with this section and take the actions permitted under section 1345.02 of the Revised Code, except that the attorney general may assess a civil penalty of \$50,000 for each violation. Each package of 340B drugs determined by the attorney general to be subject to a prohibited act under division (B) of this section constitutes a separate violation. In addition to the civil penalty, the attorney general may refer any complaint of a violation of division (B) of this section to the state board of pharmacy for the board to consider one or more of the sanctions set forth in division (A)(1) of section 4729.56 of the Revised Code.

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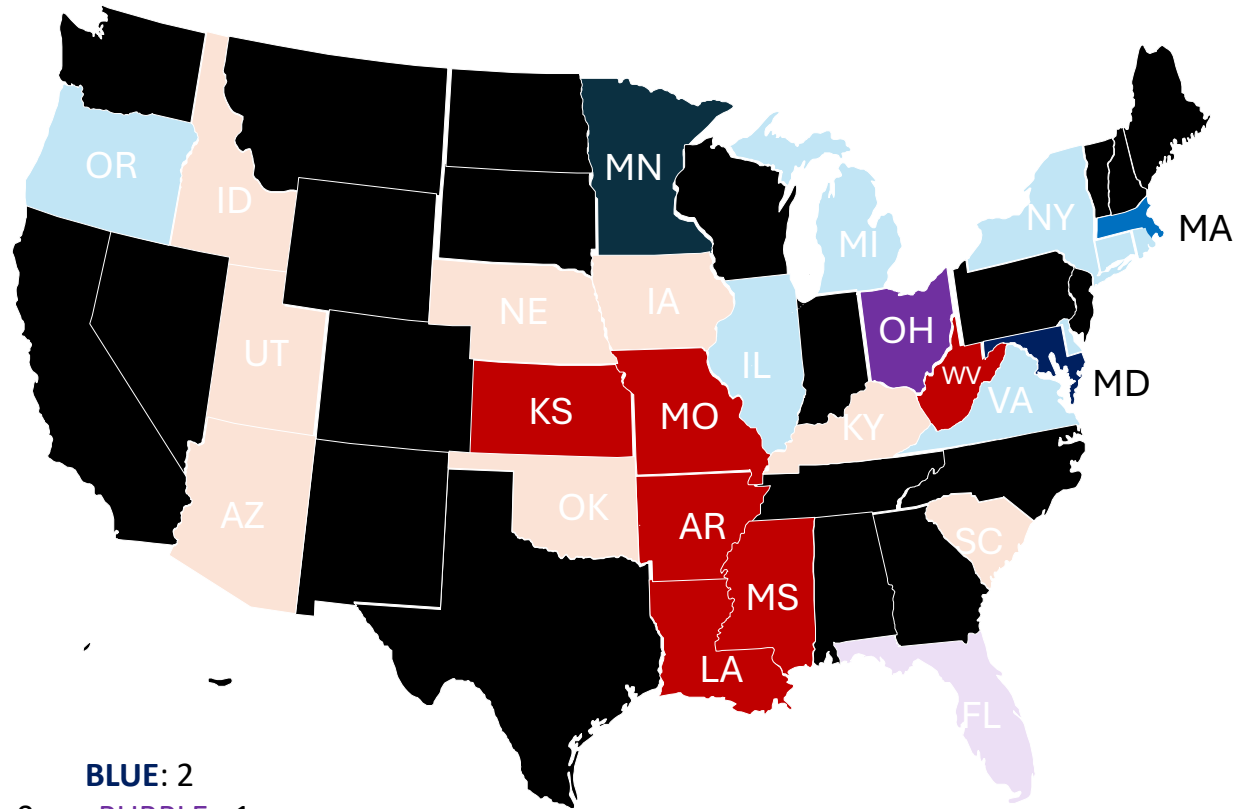
Ohio Contract Pharmacy Legislation

(D) The attorney general may adopt rules, or may delegate authority to the board of pharmacy to adopt rules, pursuant to Chapter 119. of the Revised Code, to implement the provisions of this section. 51
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(E) Nothing in this section shall be construed to conflict with or be less restrictive than applicable federal law or regulations, including 21 U.S.C. 355-1, or applicable laws or regulations of this state. 55
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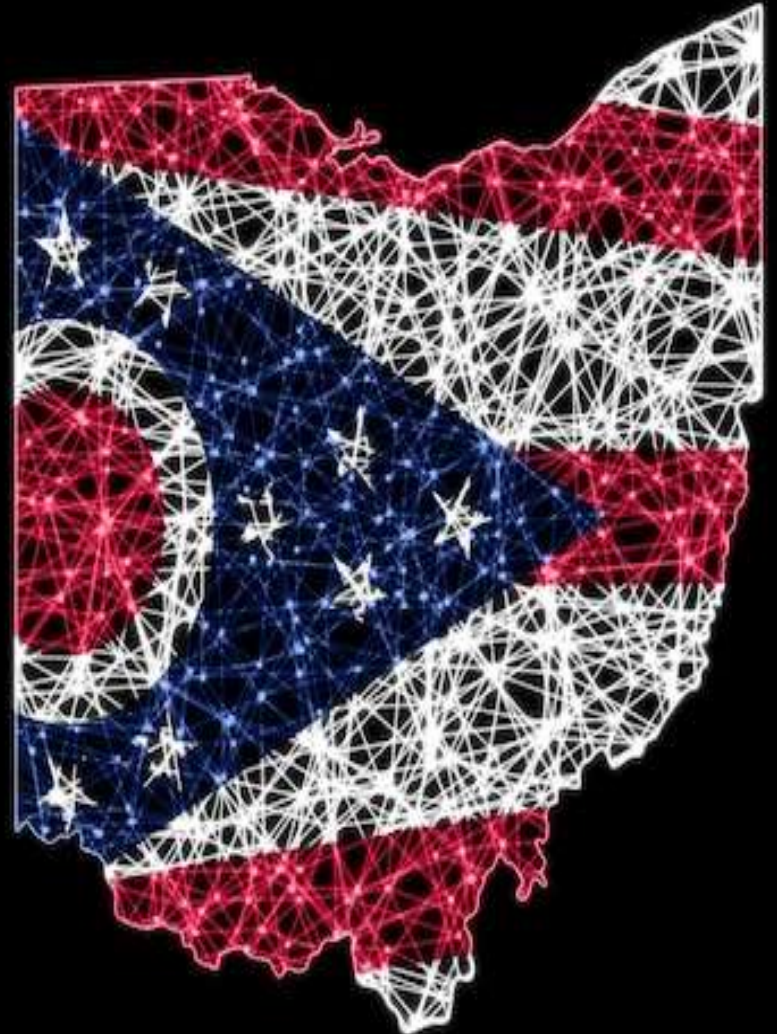
States Pursuing 340B Laws



2023-2024 ENACTED BILLS: RED: 6 BLUE: 2
2024 PENDING BILLS: RED: 0 BLUE: 0 PURPLE: 1
2024 DEAD BILLS: RED: 8 BLUE: 9 PURPLE: 1
(color denotes state voters' party preference)

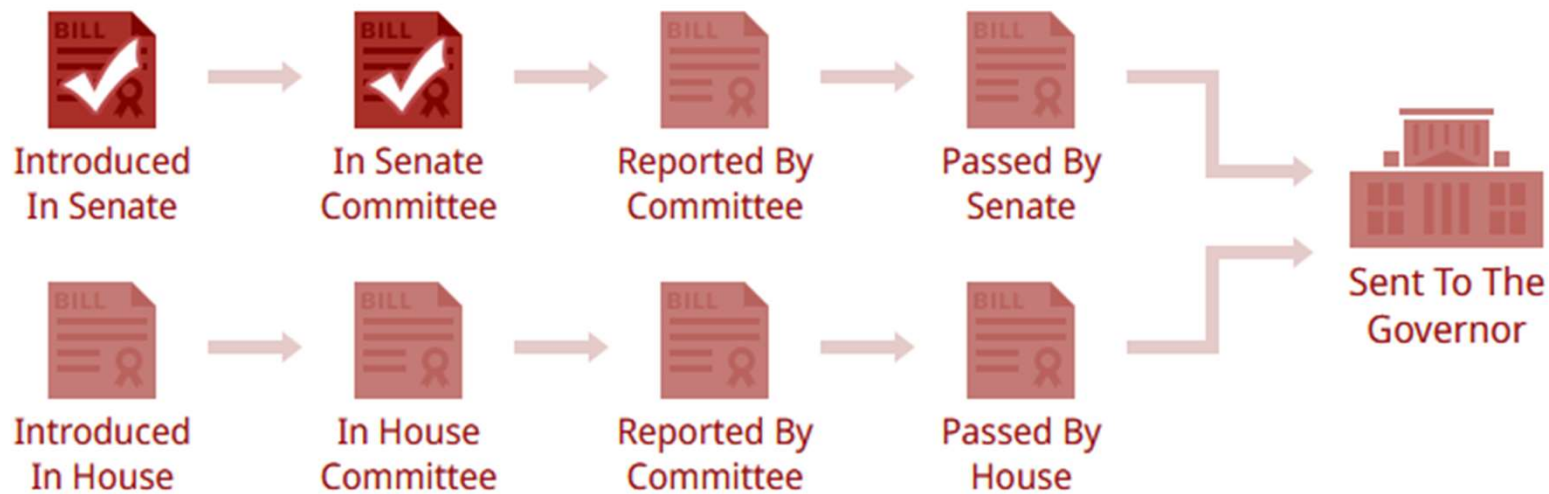


Ohio Legislative Process



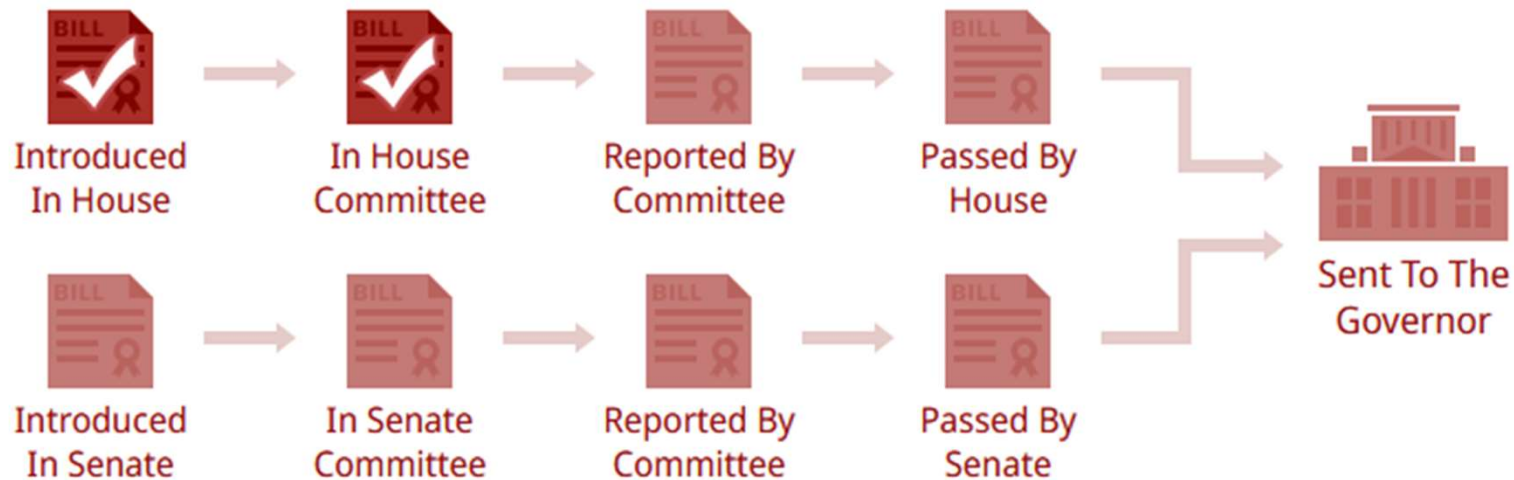
Ohio Contract Pharmacy Legislation

Senate Bill 269 Process



Ohio Contract Pharmacy Legislation

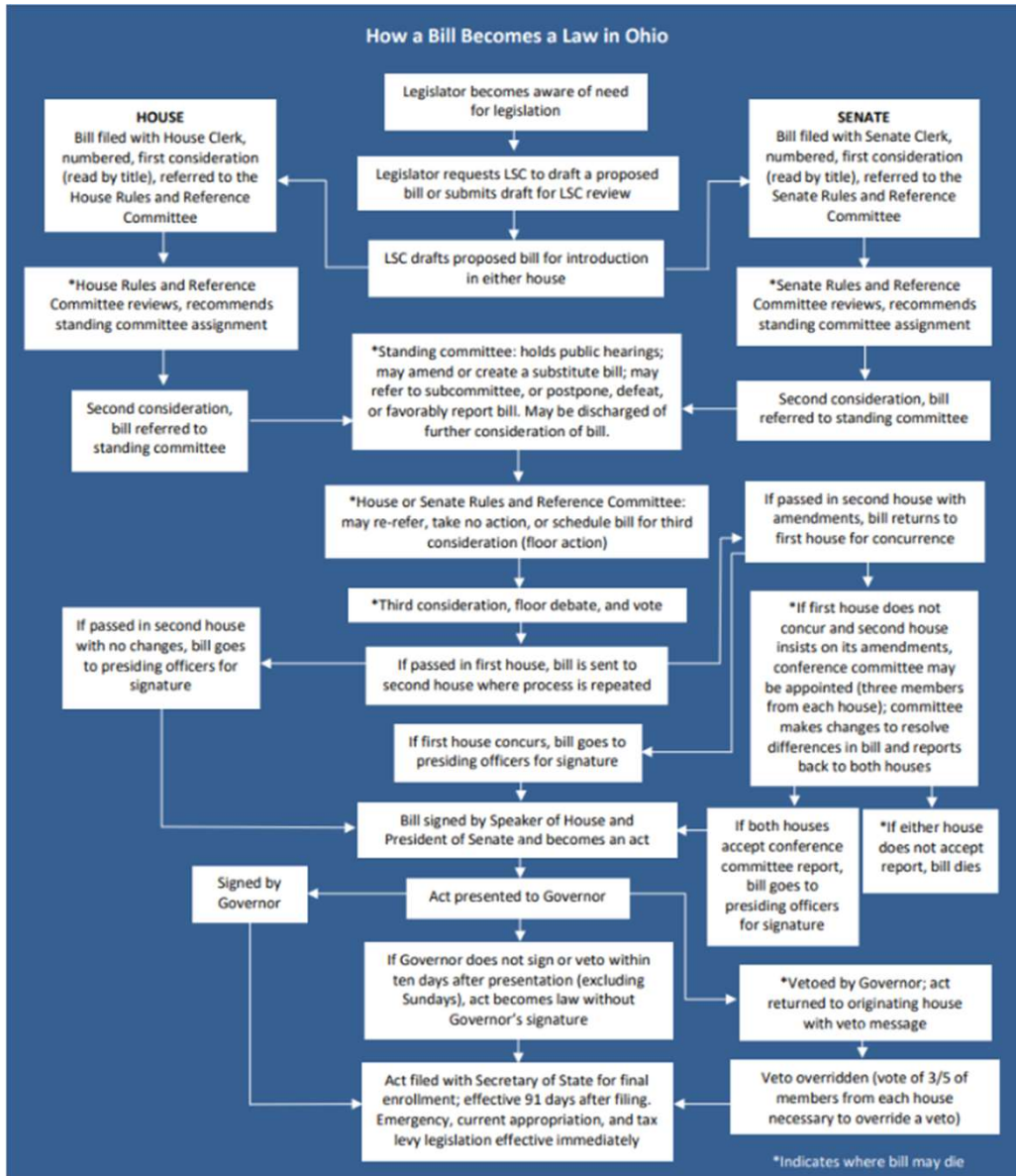
House Bill 588 Process



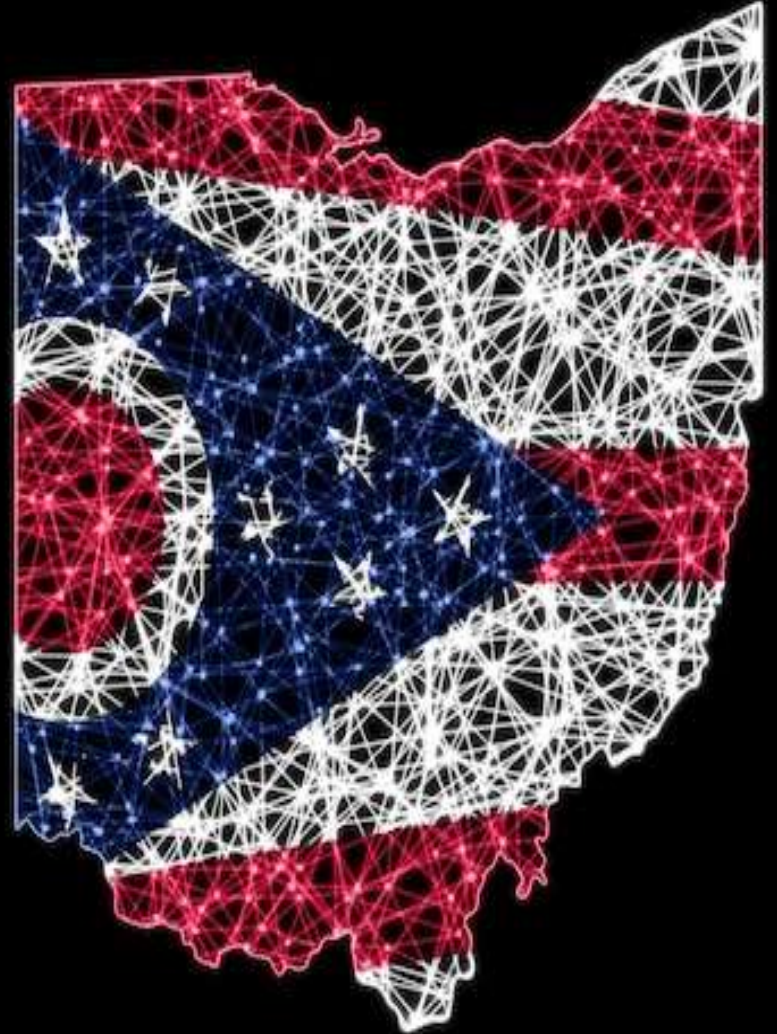
Ohio legislative session will continue in November.

ADVOCATE NOW!

How a Bill Becomes a Law in Ohio



Advocacy Appendix



Advocacy Experiences and Plan

State Law Advocacy

- **Draft Strong Bill Language Focused on Distribution Only, Reasoned Enforcement**
- **Develop a Multistakeholder Advocacy Coalition**
 1. **Community Health Centers** – Should be at the forefront leading advocacy efforts
 2. **Ryan White Clinics** – Should join CHCs at the forefront explaining the impact of contract pharmacies and 340B savings on curbing the spread of HIV and caring for those living with HIV
 3. **Hospitals** – Should be at the forefront or supportive behind the scenes through impact statements and legislator outreach
 4. **Pharmacist Associations** – Critical to supporting and explaining the community impact of providing access to drugs where patients can access them; increased pharmaceutical quality care and access



Advocacy Experiences and Plan

State Law Advocacy (cont.)

- **Direct Legislator Meetings and Constant Outreach**
 - Drugmakers spread misleading and/or false statements behind the scenes, outside of committee/subcommittee hearings – You must combat this by constantly rebutting and speaking the truth (discussed later) – Set up meetings, knock on legislators' doors!
 - Identify bill champion/sponsor and provide ongoing direct outreach and support – Provide ongoing and specific support to clarify how and why 340B works; provide sponsor with counterpoints in reaction to information about legislators who have been reached by drug industry's misleading statements; speak to those legislators
 - Requisition 340B experts with deep familiarity with contract pharmacies, bill language, 340B history/purpose, and litigation – Consider 340B expert committee/subcommittee testimony



Advocacy Experiences and Plan

State Law Advocacy (cont.)

- **Be prepared for PhRMA common talking points:**

1. **Hospitals allegedly abuse 340B** – Show the tremendous amount of safety net services that hospitals provide at no cost to taxpayers (\$100s of millions); explain the many existing hospital reporting requirements (Medicare Cost Report, Community Needs Assessment, IRS 990, Financial Assistance Policies, etc.); explain taxpayer impact, cost to state general fund
2. **340B has expanded out of control** – Rebut this misleading talking point by showing total 340B purchase volume is directly correlated with dramatically high and rising drug costs (especially newly approved specialty drugs); disproportionately high cost imposed on US compared to other developed countries (i.e., 300% relative markup) – drug industry is the fox blaming the henhouse for the hens the fox slaughtered
3. **Contract pharmacies are located out-of-state** – This is because of manufacturer imposed limited distribution networks and vertically integrated payer limited/narrow pharmacy networks



Advocacy Experiences and Plan

State Law Advocacy (cont.)

- **Be prepared for PhRMA common talking points:**

4. **340B discounted drugs are not given to all patients** – Congress intended to support the US public health infrastructure by permitting safety net providers to generate 340B savings by billing private insurers to stretch scarce resources and provide more comprehensive services; not all 340B patients are low-income - 340B was never meant to be an entitlement program; peer-reviewed studies show that wholistic, wraparound care promotes better outcomes and mere discounted drug programs promote lower health outcomes (e.g., adherence)
5. **340B should be exclusively federal** – No federal solution is in sight; Congress never intended for contract pharmacies to be regulated at the federal level; 340B could not be exclusively federal because matters of contracting, the practice of pharmacy, distribution, and even manufacturer licensing are regulated dually by states and federal government



NEED MORE INFORMATION?

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340B State Legislative Actions

Nick Saltsman PharmD, RPh, AAHIVP, 340B ACE
Chief Pharmacy Officer
Equitas Health



340B Midwest Regional Conference & Expo
September 23 & 24, 2024



DISCLOSURE
STATEMENT

Nick Saltsman has no relevant financial relationship with ineligible companies to disclose.

and

None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.



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WHY ADVOCATE??

- Protecting the 340b program
- PBM reform/reimbursement
- Expansion of pharmacist practice
- Provider status



WHY ADVOCATE??

- Other healthcare professionals are advocating for their jobs!
 - Ohio Nursing Association represent 200,000
 - Ohio State Medical Association (OSMA) represents 16,000
 - Ohio Dental Association representing 5,000



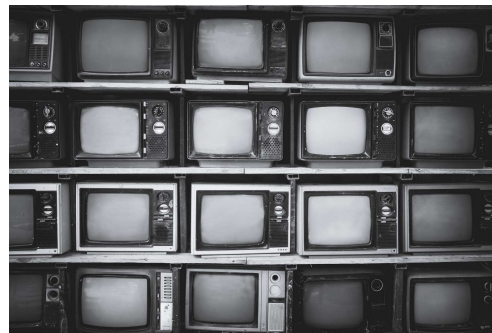
HOW TO BE AN ADVOCATE FOR OUR PROFESSION

Working through advocacy groups/professional associations

- OPA
- Ohio Association of Community Health Centers (OACHC)
- American Pharmacist Association (APhA)

Tell your story to a large audience

- Traditional media outlets (TV, newspaper)
- Social media



HOW TO BE AN ADVOCATE FOR OUR PROFESSION

Telling your story to elected officials

- Most elected officials in the Statehouse are working towards re-election
- Frame your message around how voters within their district are affected by the issue

Many issues we are advocating for have bipartisan support!

- 340b helps provide care in many different ways
 - Rural outreach efforts
 - Urban areas with little or no health care access
- PBM reform
 - Without changes to PBM reimbursement, there will be no access to medications for many Americans



ADVANCING CONTRACT PHARMACY PROTECTION

Contract pharmacy legislation has already been introduced

- Senate Bill 269
- House Bill 588

Contact your elected officials in the house and senate

<https://ohiohouse.gov/members/directory>

<https://ohiosenate.gov/members/directory>



NEED MORE INFORMATION?

Nick Saltsman PharmD, RPh,
AAHIVP, 340B ACE

- nicksaltsman@equitashealth.com



340B State Legislative Actions – West Virginia

Matt Walker

Registered Lobbyist

Walker & Stevens / West Virginia Lobbyist Group



340B Midwest Regional Conference & Expo
September 23 & 24, 2024



DISCLOSURE STATEMENT

Matt Walker is a registered lobbyist for the:

- WV Independent Pharmacy Association
- WV Primary Care Association (FQHCs/CHCs)
- Capital Rx
- Highmark Health Options
- ModivCare
- 24 Hour Nurse Staffing
- 340B Pharmacy Consultants
- i3Verticals
- Thornburg Hospitality Group
- WV Academy of Family Physicians

All relevant financial relationships listed have been mitigated.

None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.





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West Virginia Legislative Process

Regular Legislative Session (60 calendar days)

Republican Governor (Jim Justice)

Republican Senate (31-3)

Republican House of Delegates (89-11)

Republican Governor Jim Justice termed out @ 8 years
Likely headed to U.S. Senate (replacing Democrat Joe Manchin)

Likely next Governor: Republican A.G. Patrick Morrisey

Likely next A.G.: Republican Auditor J.B. McCuskey



West Virginia – Recent Actions on 340B

340B Contract Pharmacy Protections – **SB 325**

Hearings in 4 different legislative committees (rare)

I testified @ all 4, along with others

Senate Health (state PhRMA lobbyist testified)

Senate Judiciary (national PhRMA lobbyist testified)

House Finance (state PhRMA lobbyist testified)

House Prevention & Treatment of Substance Abuse

(**HB 4892** – no opposing testimony)

PhRMA, Individual PhRMA DM members, BIO, others opposed bill throughout session – 15+ lobbyists



SB 325 Screenshot

(b) Distribution of drugs to safety net providers and contract pharmacies. —

(defined broadly as in-house and contract in WV)

(1) A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, deny, restrict, or prohibit the acquisition of a 340B drug by, or delivery of a 340B drug to, a location authorized by a 340B entity to receive such 340B drug, unless the receipt of the 340B drug is prohibited by the United States Department of Health and Human Services.

(2) A manufacturer, agent, or affiliate of such manufacturer shall not, either directly or indirectly, require a 340B entity to submit any claims or utilization data as a condition for allowing the acquisition of a 340B drug by, or delivery of a 340B drug to, a 340B entity unless the claims or utilization data sharing is required by the United States Department of Health and Human Services.

(no claims/utilization data; no identifiers/modifiers; no conditions; nothing!)



Citation: W. Va. Code § 60A-8-6a. Distribution of safety net drugs to contract pharmacies; penalties; and preemption.

SB 325 Screenshot

(c) Penalties and investigations. —

(1) The commission of any act prohibited by subsection (b) of this section constitutes:

(penalty/fine must be adequate deterrent)

(A) A violation of §46A-6-104 of this code and shall subject the violator to a civil penalty of **\$50,000 per each violation**, as well as any and all actions, including investigative demands, remedies, and penalties provided for in §46A-7-101 *et seq.* of this code, except that there shall be no right to bring a private cause of action; and

(B) A violation of §33-11-1 *et seq.* of this code and shall subject the violator to any and all actions, including cease and desist orders, civil penalties, and restitution provided for in §33-11-6 of this code, except that there shall be no right to bring a private cause of action.

(2) **Each package** of 340B drugs determined to be subject to a prohibited act under subsection (b) of this section constitutes a **separate violation** under this section.

*** According to anecdotal evidence – several thousand violations since bill effective!**



SB 325 Screenshot

(3) Upon receipt by the Board of Pharmacy of a complaint that a manufacturer has violated subsection (b) of this section, the Board of Pharmacy:

(A) May investigate the complaint, including by investigating the manufacturer or any agent, affiliate, or contractor thereof, including any wholesaler or third-party logistics provider that may possess evidence supporting such complaint; and

(B) Shall consider appropriate penalties, including imposing discipline, or suspending, or revoking the license or permit of any manufacturer; and

(WVOIC)

(C) Shall share the results of the investigation with the Attorney General and commissioner if an investigation is conducted.

(3) The Board of Pharmacy and commissioner may promulgate rules to implement the provisions of subsection (b) of this section.

*** Pick an able and willing state agency to enforce – same with all DM / PBM regulation!**



SB 325 Complaint Process

340B CE

- Files complaint with WVBP

WVBP

- WVBP investigates, alerts AG / WVOIC

AG / WVOIC
/ WVBP

- \$50,000 penalty per violation
- Licensure actions
- Other

**PhRMA, Novartis, AbbVie, etc filed several lawsuits just before effective date
WV A.G. released RFP for outside counsel (firm selected – Dinsmore
Briefs, Hearings, Other legal proceedings soon**



SB 325 Screenshot

(d) **Preemption.** — (Attempting to avoid preemption challenges and other issues faced by previous states)

(1) Nothing in this section is to be construed or applied to be less restrictive than any federal law as to any person or other entity regulated by this section. Nothing in this section is to be construed or applied to be in conflict with any of the following:

(A) Applicable federal law and related regulations.

(B) Other laws of this state, if the state law is compatible with applicable federal law.

(2) Limited distribution of a drug required under 21 U.S.C. §355-1 is not to be construed as a violation of this section.



West Virginia – Recent Actions in General

- **Other relevant bill introduced in 2024 – SB 453**
 - Hearings in 3 different legislative committees
 - Mandatory NADAC + Medicaid disp fee (currently \$10.49 in WV) for PEIA
 - Applies to WV domiciled pharmacies (not foreign pharmacies)
 - Mandatory PEIA Rx transparency study
 - Several consultants collaborating here
 - Mandatory PBM discloses of 26 + data points to bid for PEIA Rx
 - DMs/PBMs withholding \$15M+ in rebates from PEIA over 340B assumptions



SB 453 Screenshot

(2) A pharmacy benefit manager shall not reimburse a West Virginia pharmacy or pharmacist for a prescription drug or pharmacy service in an amount less than the national average drug acquisition cost for a prescription drug or pharmacy service at the time the drug is administered or dispensed, plus a professional dispensing fee at least equal to the professional dispensing fee paid by West Virginia Medicaid for outpatient drugs. Increases to the professional dispensing fee may be set by the Director in accordance with this subdivision: *Provided*, That if the national average drug acquisition cost is not available at the time a drug is administered or dispensed, a pharmacy benefit manager may not reimburse a West Virginia pharmacy or pharmacist in an amount that is less than the wholesale acquisition cost of the drug, as defined in 42 U.S.C. § 1395w-3a(c)(6)(B), plus a dispensing fee as described in this subdivision. A West Virginia pharmacy is a domestic business entity as registered with the West Virginia Secretary of State. The provisions in this subdivision shall be effective for the Public Employees Insurance Agency plan year beginning on July 1, 2024.

Cultivating Legislative Champions

Relationships are often made & strengthened **outside of the legislative session (in the “off season” in WV)**

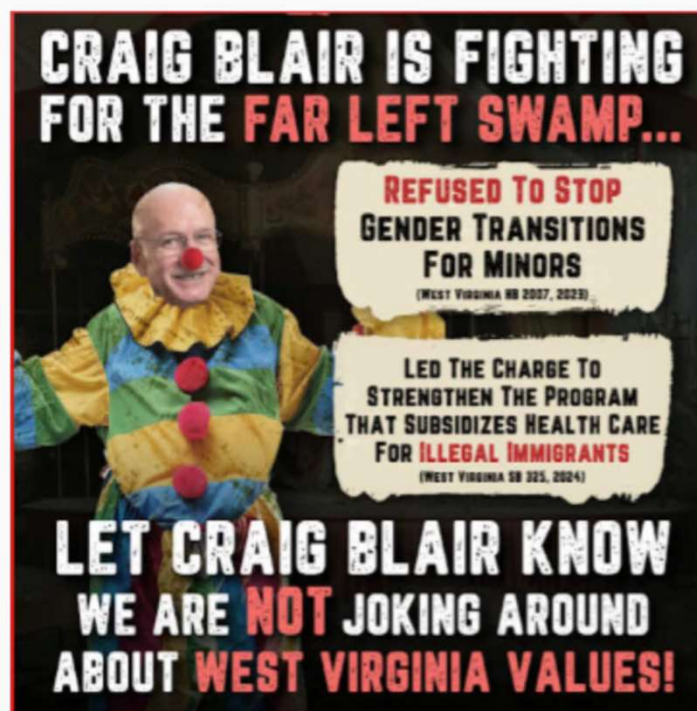
Do the work! Meet your legislators and staff!
Ask providers/staff about existing relationships
Site visit / Board meeting invitations
Dinners/Lunches
Media releases (tell your 340b stories!)
Be especially active in election years
Send out candidate questionnaires
Fundraise!
Lobbyist hiring / accountability

WHO is the #1 best lobbyist in your state re health care?



The Lies Start Flying

But just months later there came a fury of [smear campaign ads](#) against 340B and Senate President Craig Blair.



This is one of the images that was sent out in the May Primary.

Screenshot of one of the "Stand For Us" Pac campaign ad.

"Stand for Us isn't going anywhere, and the results of our efforts have only emboldened us to increase our initial investment," the group said in a press release. "Republicans are now on notice that they support 340B or non-citizen voting at their own political peril."



The group went on to take credit for Blair's lost election. The group says that Blair failed his district (Senate District 15) by protecting the federal 340B program. The 340B program is not taxpayer funded and is in no way related to immigration policy.

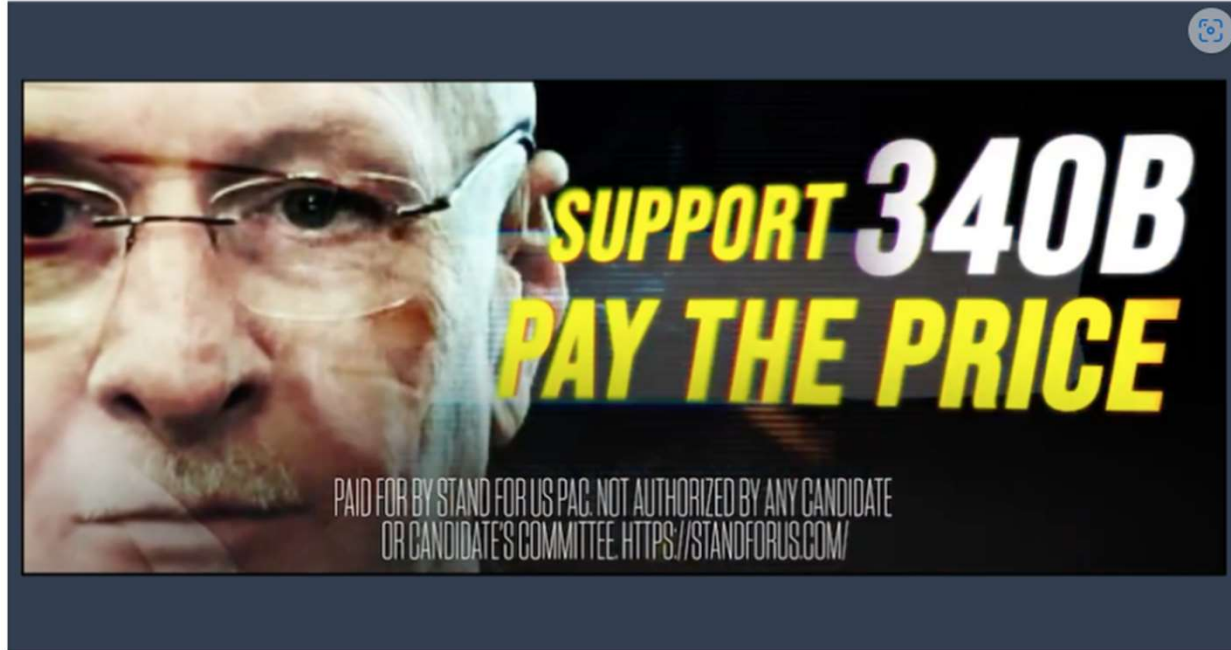
Screenshot of one of the "Stand For Us" Pac campaign ad.



West Virginia Senate President Craig Blair (R), who also serves as the state's lieutenant governor, told 340B Report that he's weighing potential litigation against Stand for Us PAC, which has claimed credit for the GOP leader's May 14 primary loss. (Photo courtesy: WV Senate.)

EXCLUSIVE

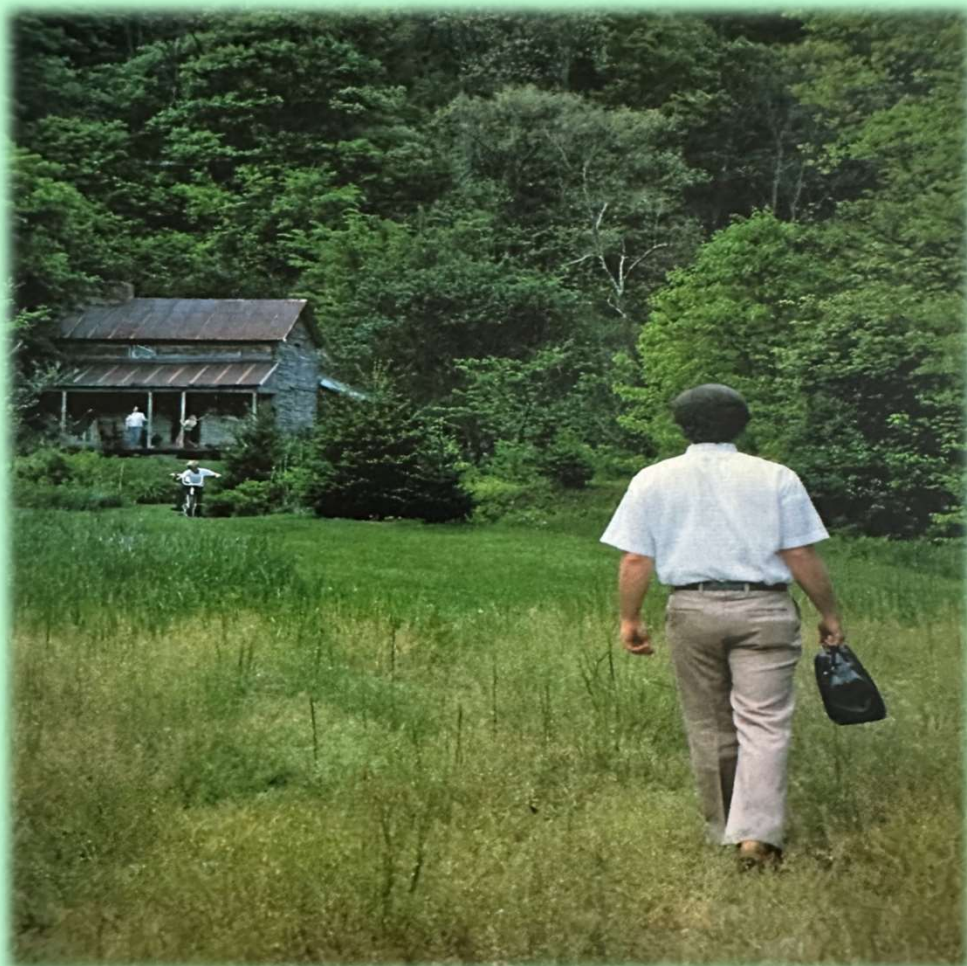
Key West Virginia Lawmaker Considering Legal Action Against Anti-340B PAC Taking Credit for his Election Loss



Stand for Us PAC's latest ad threatens Republican politicians that support 340B and claims disputed credit for a key West Virginia lawmaker's recent primary loss.

Super PAC with Dark Money Ties Launches New Anti-340B Ad





THANK YOU!
NEED MORE INFORMATION?

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