

32 State-Level Laws to Protect CHCs' 340B Savings

Updated March 2024

Highlighted bills have contract pharmacy-specific provisions

Overview

1. Alabama, <u>SB 227</u> (2021)

Highlights from this Law:

• Prohibit a pharmacy benefits manager from limiting or incentivizing a patient's choice in pharmacies; from denying a pharmacy from participating as a contract provider of pharmacy services for a health benefit plan if the pharmacy meets the terms and conditions of the pharmacy benefits manager's contract; from steering an insured to use a mail-order pharmacy or a pharmacy benefits manager affiliate, with certain exceptions; and from limiting certain powers of a pharmacy or pharmacist.

2. Arizona, <u>SB 1176</u> (2022)

Highlights from the Law:

- A third party shall not do any of the following:
 - Discriminate in reimbursement on the basis that the pharmacy dispenses a 340B drug
 - Assess any fee, chargeback, clawback or adjustment on the basis that a pharmacy dispenses a 340B drug
 - Exclude a pharmacy from a third party pharmacy network on the basis that the pharmacy dispenses a 340B drug
 - Restrict the methods or pharmacies within a third party network by which a 340B covered entity may dispense or deliver 340B drugs

3. Arkansas, <u>HB 1881 (</u>2021)

Highlights from this Law:

- Prohibit "discriminatory contracting", defined as including numerous practices (e.g., differences in reimbursement, refusal to allow 340B pharmacies into networks, requirement to identify 340B drugs using a modifier.)
- Prohibits practices "transferring the benefit of 340B savings" away from 340B providers.
- Seeks to prohibit drug manufacturers from refusing to offer 340B-priced drugs to certain contract pharmacies.
- Addresses issues around patients being forced into mail-order pharmacy, and patient right to use the pharmacy of their choice.

4. California, <u>SB 786</u> (2023)

Highlights from this Law:

- Prohibits a pharmacy benefit manager (PBM) from discriminating against a covered entity or its pharmacy in connection with dispensing a drug subject to federal pricing requirements or preventing a covered entity from retaining the benefit of discounted pricing for those drugs.
- Prohibits PBMs from refusing to contract with, terminate a contract with, or exclude a covered entity or specified pharmacy from a network simply because it is a covered entity or specified pharmacy.
- Prohibits retaliating against a covered entity or specified pharmacy for exercising its rights under the law.
- Prohibits interference with an individual's choice to receive a covered drug from a covered entity or specified pharmacy.

- PBMs cannot restrict or prohibit a covered entity from raising a grievance or speaking publicly about a PBM that violates the law.
- 5. Colorado, <u>HB 1122 (</u>2022)

Highlights from the Law:

• Prohibits health insurers, PBMs, and other third-party payers from discriminating against entities including pharmacies, participating in the federal 340B drug pricing program (340B covered entity), including a pharmacy that contracts with a 340B covered entity to provide dispensing services to the 340B entity (contract pharmacy).

6. Connecticut, <u>HB 6669</u> (2023)

Highlights from the Law:

- after Jan. 1, 2024, a contract between a Connecticut 340B covered entity and a PBM may not contain:
 - A reimbursement rate for a prescription drug that is less than the reimbursement rate paid to pharmacies that are not 340B covered entities
 - A fee or adjustment that is not imposed on providers or pharmacies that are not 340B covered entities
 - A fee or adjustment amount that exceeds the fee or adjustment amount imposed on providers or pharmacies that are not 340B covered entities
 - Any provision that prevents or interferes with a patient's choice to receive a prescription drug from a 340B covered entity, including the administration of the drug
 - Any provision that excludes a 340B covered entity from pharmacy benefit manager networks based on the 340B covered entity's participation in the 340B program.

7. Georgia, <u>SB 313 (</u>2020)

Highlights from the Law:

A pharmacy benefits manager shall not:

- Discriminate in reimbursement, assess any fees or adjustments, or exclude a pharmacy from the pharmacy benefit manager's network on the basis that the pharmacy dispenses drugs Engage in any practice that:
 - In any way bases pharmacy reimbursement for a drug on patient outcomes, scores, or metrics; provided, however, that nothing shall prohibit pharmacy reimbursement for pharmacy care, including dispensing fees from being based on patient outcomes, scores, or metrics so long as the patient outcomes, scores, or metrics are disclosed to and agreed to by the pharmacy in advance;
 - Includes imposing a point-of-sale fee or retroactive fee; or
 - Derives any revenue from a pharmacy or insured in connection with performing pharmacy benefits management services; provided, however, that this shall not be construed to prohibit pharmacy benefits managers from receiving deductibles or copayments.
 - Also applies to pharmacy benefits managers' reimbursements to dispensers

8. Illinois, <u>HB 4595</u> (2022)

Highlights from this Law:

Provides that a contract between a pharmacy benefit manager or third-party payer and a covered entity under Section 340B of the federal Public Health Service Act shall not contain specified provisions. Provides that a violation by a pharmacy benefit manager constitutes an unfair or deceptive act or practice in the business of insurance, and that a provision that violates the prohibition on certain provisions in a contract between a pharmacy benefit manager or a third-party payer and a 340B covered entity that is entered into, amended, or renewed after July 1, 2022 shall be void and unenforceable.

9. Indiana, <u>HB 1405</u> (2021)

Highlights from this Law:

- Prohibits PBMs, including those serving Medicaid managed care plans, from reimbursing for 340B drugs at a level that "diminishes the 340B benefit to a 340B covered entity", imposing different/additional fees, excluding 340B pharmacies from preferred networks, or "discriminating against a 340B covered entity."
- **10. Iowa <u>HF423</u>** (2023)

Highlights from this Law:

- Prohibits plans, carriers, TPAs and PBMs from providing discriminatory reimbursement amounts for prescription drugs or dispensing fees on the basis of a covered entity or a contract pharmacy's status as a covered entity or contract pharmacy.
- Prohibits discrimination on the basis of participation in a 340B drug program, in addition to the status as a covered entity or a contract pharmacy,
- Permits the state Commissioner of Insurance to take enforcement action under the commissioner's authority to enforce compliance. After notice and hearing, the commissioner may issue any order or impose any penalty pursuant to state law upon finding a violation of the bill.

11. Kentucky, <u>SB 50</u> (2020)

Highlights from this Law:

• Requires all Medicaid MCOs to contract with a single PBM and prohibits that PBM from discriminating against 340B providers.

12. Louisiana, <u>HB 548</u> (2023)

Highlights from this Law:

- Prohibits drug manufacturer limits on 340B contract relationships and PBM encroachment on health care providers' 340B program revenues.
- prevents a health insurance issuer, pharmacy benefit manager (PBM), other third-party payor or its agent from reimbursing a 340B entity for 340B drugs at a rate lower than that paid for the same drug to entities that are not 340B entities
- impose terms/conditions on any 340B entity with respect to fees, dispensing fees, charges, clawbacks, restrictions, requirements, or other adjustments or assessments that differ from such terms or conditions applied to non-340B entities;
- require a 340B entity to reverse, resubmit or clarify a claim after the initial adjudication unless in the normal course of business.
- Discriminate against a 340B entity in a manner that interferes with patient choice; and
- Require or compel the submission of ingredient costs or pricing data pertaining to 340B drugs to any health insurance issuer, PBM, or third-party payor.
- Prevents a manufacture or distributor from denying, restricting, prohibiting, or interfering with the acquisition or delivery of a 340B drug by a pharmacy that is under contract with a 340B entity and is authorized under the contract to receive and dispense 340B drugs on behalf of the covered entity.

• A manufacturer or distributor shall not interfere with a pharmacy contracted with a 340B entity.

13. Maryland, <u>HB 1274</u> (2022)

Highlights from this Law:

• Establishes requirements and prohibitions on pharmacy benefits managers related to the federal 340B Program, including requirements related to coverage and reimbursement for drugs purchased under the Program.

14. Michigan, <u>HB 4348</u> (2022)

Highlights from this Law:

• A pharmacy benefit manager or carrier shall not prohibit a 340B Program entity or a pharmacy that has a license in good standing in this state under contract with a 340B Program entity from participating in the pharmacy benefit manager's or carrier's provider network solely because it is a 340B Program entity or a pharmacy under contract with a 340B Program entity. A pharmacy benefit manager or carrier shall not reimburse a 340B Program entity or a pharmacy under contract with a 340B Program entity at 0 a pharmacy under contract with a 340B Program entity. A pharmacy under contract with a 340B Program entity differently than other similarly situated pharmacies. As used in this subsection, "340B Program entity" means an entity authorized to participate in the federal 340B Program under section 340B of the public health service act, 42 USC 256b.

15. Minnesota, <u>SF 278</u> (2019)

Highlights from this Law:

- Prohibits PBM from reimbursing an entity or pharmacy under contract with such entity differently than other similarly situated pharmacies.
- Does not apply to PBMs under contract with state for Medicaid MCO.

16. Mississippi, <u>HB728</u> (2024)

Sponsor: Rep. Manly Barton (R)

Summary:

Prohibits health insurance issuers, pharmacy benefit managers, drug manufacturers, and distributors from:

- Reimbursing 340B entities at a lower rate than non-340B entities for the same drug.
- Imposing different terms or conditions on 340B entities compared to non-340B entities based on their participation in the program.
- Requiring 340B entities to reverse, resubmit, or clarify claims after the initial adjudication unless it's standard practice.
- Discriminating against 340B entities in a way that interferes with patients' choice to receive drugs from them.
- Requiring 340B entities to submit ingredient costs or pricing data.
- Excluding 340B entities from networks or refusing to contract with them solely due to their participation in the program.

Prohibits manufacturers and distributors from:

- Denying, restricting, or interfering with the acquisition or delivery of 340B drugs to contracted pharmacies.
- Interfering with pharmacies contracted with 340B entities.

Violations are considered violations of the Consumer Protection Act, subject to penalties.

The act clarifies that it doesn't conflict with federal law or other compatible state laws.

Upon passage, the act takes effect on July 1, 2024.

17. Montana, <u>SB 395</u> (2021)

Highlights from this Law:

• A pharmacy benefit manager or health carrier may not:(1) prohibit a federally certified health entity or a pharmacy under contract with an entity to provide pharmacy services from participating in the pharmacy benefit manager's or health carrier's provider network;(2) reimburse a federally certified health entity or a pharmacy under contract with an entity differently than it reimburses other similarly situated pharmacies;(3) require a claim for a drug to include a modifier to indicate that the drug is a 340B drug unless the claim is for payment, directly or indirectly, by the Medicaid program provided for in Title 53, chapter 6, part 1; or(4) create a restriction or an additional charge on a patient who chooses to receive drugs from a federally certified health entity or a pharmacy under contract with an entity, including but not limited to a patient's inability to fully pay a copayment.

<u>SB335</u> (passed April 30, 2019)

Highlights from this Law:

• A PBM cannot pay less than the state-surveyed average drug acquisition cost or WAC for 340B dispenses.

18. Nebraska, <u>LB 767</u> (2022)

Highlights from this Law:

- A pharmacy benefit manager that reimburses a 340B entity or a 340B contract pharmacy for a drug that is subject to an agreement under 42 U.S.C. 256b shall not reimburse the 340B entity or the 340B contract pharmacy for the pharmacy-dispensed drug at a rate lower than that paid for the same drug to similarly situated pharmacies that are not 340B entities or 340B contract pharmacy on the basis that the 340B entity or 340B contract pharmacy on the basis that the 340B entity or 340B contract pharmacy for the basis that the 340B entity or 340B contract pharmacy and the basis that the 340B entity or 340B contract pharmacy participates in the program set forth in 42 U.S.C. 256b.
- Shall not discriminate against a 340B entity or 340B contract pharmacy in a manner that prevents or interferes with a covered individual's choice to receive such drug from the corresponding 340B entity or 340B contract pharmacy.

19. Nevada <u>AB434</u> (2023)

Highlights from this Law:

A pharmacy benefit manager or health insurer shall not:

- Discriminate against a covered entity, a contract pharmacy or a 340B drug in the amount of reimbursement for any item or service or the procedures for obtaining such reimbursement;
- Assess any fee, chargeback, clawback or adjustment against a covered entity or contract pharmacy on the basis that the covered entity or contract pharmacy dispenses a 340B drug or otherwise limit the ability of a covered entity or contract pharmacy to receive the full benefit of purchasing the 340B drug at or below the ceiling price
- Exclude a covered entity or contract pharmacy from any network because the covered entity or contract pharmacy dispenses a 340B drug;
- Restrict the ability of a person to receive a 340B drug;

- Restrict the methods by which a covered entity or contract pharmacy may dispense or deliver a 340B drug or the entity through which a covered entity may dispense or deliver such a drug in a manner that does not apply to drugs that are not 340B drugs; or
- Prohibit a covered entity or contract pharmacy from purchasing a340B drug or interfere with the ability of a covered entity or contract pharmacy to purchase a 340B drug.

20. New Mexico, <u>SB 540</u> (2023)

Highlights from this Law: PBMs may not:

- Reimburse a covered entity less for a 340B drug for the same drug sold to non-covered entities
- Assess a fee, chargeback or other adjustment to the covered entity that is not assessed to noncovered entities
- Impose a provision that prevents/interferes with a person's choice to receive 340B drugs from a covered entity
- Impose terms/conditions that differ from terms/conditions imposed on a non-covered entity, including:
 - o restricting or requiring participation in a pharmacy network,
 - o requiring more frequenting auditing/a broader scope of auditing,
 - requiring a covered entity to reverse, resubmit or clarify a claim after the initial adjudication, unless these actions are in the normal course of pharmacy business and not related to the 340B program, or
 - charging an additional fee or provision that prevents or interferes with an individual's choice to receive a 340B drug from a covered entity.

21. North Carolina, <u>SB 257</u> (2021)

Highlights from this Law:

• A contract entered into between a pharmacy benefits manager and a 340B covered entity's pharmacy or between a pharmacy benefits manager and a 340B contract pharmacy shall not do any of the following:(1) Restrict access to a pharmacy network or adjust 340B drug reimbursement rates based on whether a pharmacy dispenses drugs under the 340B drug discount program.(2) Assess any additional, or vary the amount of any, fees, chargebacks, or other adjustments on the basis of a drug being dispensed under the 340B drug discount program or a pharmacy's status as a 340B covered entity or a 340B contract pharmacy. This section does not prevent adjustments to correct errors or overpayments resulting from an adjudicated claim. (b) No pharmacy benefits manager making payments pursuant to a health benefit plan shall discriminate against a 340B covered entity or a 340B contract pharmacy in a manner that prevents or interferes with an enrollee's choice to receive a prescription drug from an in-network 340B covered entity or an in-network 340B contract pharmacy.

22. North Dakota, <u>HB 1492</u> (2021)

Highlights from this Law: PBMs may not:

- Reimburse less for a drug on the basis that it was purchased under 340B;
- Refuse to contract with a pharmacy because it dispenses 340B drugs;
- Otherwise "discriminate against or interfere with" 340B providers or their contract pharmacies.

23. Ohio, <u>SB 263</u> (2021)

Highlights from this Law:

- MCOs must reimburse 340B providers at NADAC and cannot impose different or additional fees or requirements on 340B providers.
- Private payers, PBMs, and contract pharmacies cannot pick-pocket.

24. Oregon, <u>HB 2185</u> (2019)

Highlights from this Law:

• PBMs registered under ORS 735.532 cannot reimburse a 340B pharmacy differently than another network pharmacy based on its 340B pharmacy status.

Oregon, <u>HB 4149</u> (2024)

Highlights from this law:

Specifically states that insurance policies, certificates or other contracts providing for the reimbursement of the costs for prescription drugs may not:

- Differentially reimburse a prescription for 340B drugs versus other prescription drugs;
- Assess a fee, chargeback, clawback or other adjustment for the dispensing of a 340B drug;
- Exclude a pharmacy from a pharmacy network on the basis that the pharmacy dispenses a 340B drug;
- Restrict the methods by which a 340B drug may be dispensed or delivered;
- Restrict the number of pharmacies within a pharmacy network that may dispense or deliver 340B drugs.

25. South Dakota, <u>HB 1137</u> (2019)

Highlights from this Law:

• No PBM can discriminate against a pharmacy participating in a health plan as an entity authorized to participate in 340B program.

26. Tennessee, <u>HB 1398</u> (2021)

Highlights from this Law:

- Reimburse a 340B entity for pharmacy-dispensed drugs at a rate lower than the rate paid for the same drug by national drug code number to pharmacies that are not 340B entities
- Assess a fee, chargeback, or adjustment upon a 340B entity that is not equally assessed on non-340B entities
- Exclude 340B entities from its network of participating pharmacies based on criteria that is not applied to non-340B entities; or
- Require a claim for a drug by national drug code number to include a modifier to identify that the drug is a 340B drug. With respect to a patient eligible to receive drugs, a pharmacy benefits manager, or third party that makes payment for those drugs, shall not discriminate against a 340B entity in a manner that violates § 56-7-2359 or otherwise prevents or interferes with the patient's choice to receive those drugs from the 340B entity.

27. Utah, <u>SB 140</u> (2021)

Highlights from this Law:

• defines terms

• prohibits certain actions by a pharmacy benefit manager or third party with respect to a federally qualified health center that participates in the 340B discount drug program.

<u>SB138</u> (passed March 28, 2020) Highlights from this Law:

- Prohibits PBMs from reimbursing 340B entities at rates lower than non-340B entities; also contains broadly worded prohibitions on ways PBMs discriminate against 340B pharmacies or block them from participating in the program.
 - This language was broad enough to block Express Scripts' efforts in spring 2021.

28. Vermont, <u>H 439</u> (2021)

Highlights from this Law:

• A pharmacy benefit manager shall not: (1) require a claim for a drug to include a modifier or supplemental transmission, or both, to indicate that the drug is a 340B drug unless the claim is for payment, directly or indirectly, by Medicaid; or (2) restrict access to a pharmacy network or adjust reimbursement rates based on a pharmacy's participation in a 340B contract pharmacy arrangement.

29. Virginia, <u>HB 1162</u> (2022)

Highlights from this Law:

• Prohibits carriers and pharmacy benefits managers from discriminating in the requirements, exclusions, terms, or other conditions imposed on a covered entity or contract pharmacy on the basis that the entity or pharmacy is operating under the 340B Program of the federal Public Health Service Act. Such prohibition does not (i) apply to drugs with an annual estimated perpatient cost exceeding \$250,000 or (ii) prohibit the identification of a 340B reimbursement request. The bill also prohibits a carrier or pharmacy benefits manager from interfering in a covered individual's right to choose a contract pharmacy or covered entity.

30. West Virginia <u>SB325</u> (2024)

Sponsors: Sen. Tom Takubo (R), Sen. Robert Plymale (D), Sen. Jack Woodrum (R)

(Passed March 27, 2024, effective June 6, 2024) Summary:

- Defines key terms: 340B drug, 340B entity, etc.
- Protects against unfair practices:
 - Prohibits manufacturers, distributors, etc. from denying or restricting access to 340B drugs for authorized locations.
- Prohibits requiring unnecessary data sharing as a condition for acquiring 340B drugs.
- Establishes penalties:
 - Violations incur civil penalties and potential license/permit suspension.
 - Each affected package is considered a separate violation.
- Collaboration and implementation:
 - Board of pharmacy can investigate complaints and impose penalties.
 - Attorney General, Board, and Commissioner can make rules to enforce the bill.
 - Preserves federal laws and compatible state laws.
- Exempts limited drug distribution required by federal law.

2022: Amends 2019 legislation to prohibits use of modifiers on 340B drugs

West Virginia <u>H 2263</u> (2021)

Highlights from this Law:

- Prohibits a broader range of "pick-pocketing" practices (blocking 340B pharmacies from preferred networks, interfering with a patient's choice to receive a drug from a 340B pharmacy).
- Requires that all pharmacies (not just 340B) be reimbursed a drug's National Average Drug Acquisition Cost (NADAC) plus a \$10.49 dispensing fee.

<u>SB489</u> (passed March 1, 2019, effective February 26, 2019) Highlights from this Law:

• Prohibits PBMs from imposing lower reimbursement rates or higher fees on 340B drugs.

State-Level Legislation Introduced to Protect CHCs' 340B Savings

Updated as of March 7, 2024

Highlighted bills have contract pharmacy specific-provisions

1. Connecticut <u>HB5488</u> (Introduced 03/25/2024)

Sponsor: Senator Martin Looney (D), Representative Susan Johnson (D), House Health Public Health Committee

Summary:

This legislation updates public health statutes across several areas, including:

- Expanding the scope of practice for medical assistants, requiring better reporting of adverse events in hospitals and birthing centers, updating regulations for emergency medical services personnel, and ensuring qualified mental health professionals by addressing accreditation for marital and family therapists.
- Promoting fair practices in the 340B drug pricing program with specific parameters such as:
 - Regulating contracts between PBMs and 340B covered entities (certain safety-net pharmacies).
 - Prohibits PBMs from:
 - Offering lower reimbursement rates to 340B covered entities compared to other pharmacies.
 - Imposing fees or adjustments on 340B covered entities that aren't applied to other pharmacies.
 - Charging 340B covered entities higher fees or adjustments compared to other pharmacies.
 - Limiting a patient's choice to use a 340B covered pharmacy.
 - Excluding 340B covered entities from their networks solely because they participate in the federal 340B program.

Essentially, this law aims to create a fairer system for 340B covered entities by preventing PBMs from using unfair practices. Effective from the date the law is passed.

2. Florida <u>SB1608</u> (Introduced 01/11/2024)

Sponsor: Senator Jason Brodeur (R)

Summary:

- Applies to health insurance issuers, pharmacy benefit managers, other third-party payors, and manufacturers operating in Florida.
 - Does not apply to the Florida Medicaid program for specific drugs.
- Prohibited actions related to 340B drug reimbursement:
 - Payors cannot reimburse 340B entities at a lower rate than non-340B entities or entities owned by the payor.
 - Payors cannot impose different terms or conditions on 340B entities regarding fees, clawbacks, dispensing fees, network participation, audit frequency, drug identification requirements, or other policies.
 - Payors cannot require additional claim clarifications or actions solely due to a drug being 340B.
 - Payors cannot prevent patients from choosing to receive drugs at a 340B entity by imposing additional burdens or restrictions.
 - Payors cannot require submission of ingredient costs or pricing data for 340B drugs.
 - Payors cannot exclude 340B entities from their networks solely based on dispensing 340B drugs.
- Prohibited actions by manufacturers:
 - Manufacturers cannot interfere with acquisition or delivery of 340B drugs to contracted pharmacies unless prohibited by the U.S. Department of Health and Human Services.
 - Manufacturers cannot interfere with a pharmacy's right to contract with a 340B entity.
- Violation and penalties:

- Any violation of these prohibitions is considered a deceptive and unfair trade practice under Florida law, subject to investigations, remedies, and penalties.
- The legislation doesn't explicitly highlight the office of the Attorney General or the Federal Trade Commission as acting overseers, but through the law (Florida Deceptive and Unfair Trades Act), the office of AG, Florida courts, or FTC could oversee the violations.

3. Idaho <u>HSB671</u> (Introduced 02/28/2024)

Sponsor: House Health and Welfare Committee

Summary:

This act relates to amending chapter 3 title 41, Idaho code, to add the new section 41-350 which states:

- Defines 'covered entities' and 'contract pharmacies'
- Health insurance issuers, pharmacy benefit managers, and other third-party payers are prohibited from:
 - Reimbursing covered entities or contract pharmacies at a lower rate for 340B drugs than they would for the same drugs to other entities.
 - Refusing to reimburse covered entities or contract pharmacies for 340B drugs.
 - Imposing different terms or conditions on covered entities or contract pharmacies compared to non-covered entities, based on their participation in the 340B program.
 - Requiring covered entities or contract pharmacies to do extra work to get reimbursed for 340B drugs, such as submitting additional claims information.
 - Preventing patients from choosing to receive 340B drugs from a covered entity or contract pharmacy.
 - The act will be in effect on and after July 1, 2024.
- 4. Iowa HSB590 (Introduced 01/18/2024)

Sponsors: House Health and Human Services Committee

Summary:

This bill prohibits a manufacturer or wholesaler from directly or indirectly, denying, restricting, or interfering with either the acquisition or purchase of a 340B drug covered entity, or the delivery of a 340B drug to a contract pharmacy, unless otherwise prohibited by the United States department of health and human services. The bill prohibits a manufacturer or wholesaler from requiring reporting requirements or imposing contractual restrictions that are not required by law in order for a covered entity or contract pharmacy to purchase and receive 340B drugs.

5. Kansas <u>SB540</u> (Introduced 03/11/2024)

Sponsor: Senate Assessment and Taxation Committee

Summary:

- The bill defines key terms like "340B-covered entity" and "340B drug".
- It prohibits drug manufacturers from interfering with the acquisition or delivery of discounted medications to pharmacies contracted with covered entities.

- Violations are considered breaches of the Kansas Consumer Protection Act. The Kansas consumer protection act violations have civil penalties of up to \$10,000 per violation.
- The bill clarifies that it doesn't weaken federal law or restrict limited distribution of certain drugs.
- 6. Kentucky <u>SB27</u> (Introduced 01/02/2024)

Sponsor: Senator Stephen Meredith (R)

Summary:

- Defines "340B covered entity," "340B price," and "covered drug" based on federal law.
- Prohibits manufacturers from discriminating against Kentucky's 340B entities by refusing or delaying discounted prices for drugs offered at that price in other states.
- Expands the definition of discrimination to include manufacturer-imposed conditions, limitations, or delays on sales unless required by law.
- Gives individuals the right to file complaints with the Attorney General if they believe a manufacturer is violating the law.
- Clarifies that the law does not conflict with any stricter federal or state laws.

7. Maryland <u>SB986</u> (Introduced 02/06/2024))

Sponsor: Senator Clarence Lam (D)

Summary:

This law prohibits unfair practices in acquiring certain discounted drugs (340B drugs) by covered entities. Specifically, it prevents manufacturers, distributors, and logistics providers from limiting or stopping pharmacies from getting these discounted drugs on behalf of covered entities. Violations can be investigated by the Board of Pharmacy or Consumer Protection Division and result in fines, license suspension or revocation. The law goes into effect on July 1, 2024.

8. Minnesota <u>HB4991</u> (Introduced 03/22/2024) Sponsor: Representative Dave Lislegard (D)

Summary:

This is a bill proposes to amend a state statute to prohibit manufacturers and wholesale drug distributors from restricting or interfering with the delivery of 340B drugs to pharmacies that are under contract with a 340B covered entity to receive and dispense these drugs on behalf of the covered entity. The bill also defines what a 340B covered entity is and amends a previous statute to include a list of prohibited conduct for licensees or registrants of the board. Some of the listed prohibited conduct include unprofessional conduct, inability to practice pharmacy safely, and fee-splitting.

9. Nebraska <u>LB984</u> (Introduced 01/05/2024)

Sponsor: Senator Brian Hardin (R)

Summary:

• Defines: "340b drugs", "340b covered entity", and "pharmacy contract"

• Prohibits manufacturers and wholesale drug distributors from interfering with the acquisition or delivery of 340B drugs to pharmacies contracted with 340B entities. It allows the Attorney General or any county attorney to take legal action against violators. Additionally, the section clarifies that it doesn't conflict with federal law or other compatible state laws.

10. New York (SB8992) (Introduced 04/08/2024)

Sponsor: Senator Rivera (D)

Summary:

The bill aims to prevent discrimination against facilities involved in the 340B program, a federal program that provides discounted prescription drugs to certain healthcare providers. The bill defines key terms like "covered entity" and "dispensing" and then outlines three main prohibitions:

- Pharmaceutical manufacturers, pharmacy benefit managers, and other listed entities cannot restrict a covered entity or contract pharmacy from dispensing drugs, except for limitations already set by federal law.
- Covered entities and contract pharmacies cannot be denied access to drugs because of their participation in the 340B program.
- Covered entities and contract pharmacies cannot be subjected to different requirements, fees, or other conditions compared to non-340B entities, except for those explicitly allowed by federal law.

The bill also details enforcement mechanisms, including the authority to void contracts that violate the act and impose civil penalties. Finally, it includes a standard severability clause in case any part of the bill is found to be invalid.

11. Oklahoma (Introduced 02/05/2024)

Sponsor: Senator Howard (R) Summary:

- Drug manufacturers "shall not deny, prohibit, condition, discriminate against, refuse, or withhold 340B drug pricing" to 340B providers and their contract pharmacies.
- PBMs cannot discriminate, offer lower reimbursement, or impose any separate terms on a provider because they participate in 340B drug pricing program.
- Authority
 - Gives the state attorney general the authority to enforce the PBM provisions, although no specification of the enforcement mechanism for the contract pharmacy provisions.
- If passed, SB 1628 would take effect Nov. 1, 2024.

Oklahoma HB3379 (Introduced 02/05/2024)

Sponsor: Rep Marcus McEntire (R)

Summary:

Prohibited Practices for Payors and Manufacturers:

- Payors (health insurance issuers, pharmacy benefit managers, etc.) cannot:
 - Reimburse 340B entities less than non-340B entities for the same drugs.
 - Impose different terms or conditions on 340B entities compared to non-340B entities (e.g., fees, restrictions on pharmacy networks).
 - Require additional claims information for 340B drugs unless mandated by federal agencies.
 - Discriminate against 340B entities in ways that affect patient choice.
 - Include discriminatory provisions in contracts with 340B entities.
 - \circ Require submission of ingredient cost or pricing data for 340B drugs.
 - Exclude 340B entities from their networks.
- Manufacturers cannot:

- Interfere with a 340B entity's acquisition or delivery of drugs through contracted pharmacies.
- Interfere with contracted pharmacies serving 340B entities.
- Enforcement and Penalties:
 - The Attorney General and Insurance Commissioner have authority to:
 - Issue regulations interpreting the law.
 - Take enforcement actions against violators, including license suspensions, civil fines (\$100-\$10,000 per violation).
- Relationship to Existing Laws:
 - The law cannot be interpreted as weaker than existing federal laws regarding 340B programs.
 - It cannot conflict with other state laws compatible with federal law.
 - Limited distribution requirements for certain drugs under federal law are not considered violations.
- Effective Date:
 - The law would take effect on November 1, 2024.

12. Rhode Island H7139 (Introduced 01/11/2024) Sponsor: Rep John Lombardi (D)

Cosponsors: Raymond Hull (D), Leonela Felix (D), Stewart (D), Cruz (D), Tanzi (D)

Summary:

- Some 340B protections are part of this broader PBM-reform bill, including:
 - Consumer protection
 - Clawbacks (taking co-pay money from pharmacies) are banned.
 - PBM-affiliated pharmacies cannot receive preferential reimbursement.
 - Pharmacy steering (favoring affiliated pharmacies) is prohibited.
 - Discriminatory reimbursements for 340B entities are forbidden.
 - Utilization management practices that delay care (prior authorizations, step therapy) are restricted.
- Enforcement:
 - EOHHS, DBR, and OHIC will develop rules and regulations for PBM compliance.
 - The auditor general will audit PBM costs and compliance.
 - \circ The attorney general can investigate and prosecute violations.

Rhode Island H7140 (Introduced 01/11/2024)

Sponsor: Rep John Lombardi (D)

Cosponsors: Raymond Hull (D), Leonela Felix (D), Stewart, Cruz, Tanzi

Summary:

• Grant the state board of pharmacy and the department of health the authority to jointly identify, on an annual basis, up to fifteen prescription drugs deemed to represent a significant financial burden due to cost increases. This list would then be forwarded to the attorney general's office, which would subsequently demand relevant information and documentation from the manufacturers in question to justify said cost increases.

- Mandate the Department of Health to utilize a standardized dispensing fee within its reimbursement formula for 340B prescription drugs, mirroring the fee employed for non-340B drugs under the Medicaid program.
- Require the Department of Health to provide the general assembly and the governor with comprehensive information pertaining to these programs.
- Establish an advisory commission tasked with studying the issue of out-of-pocket prescription drug costs, with the responsibility of submitting reports and recommendations to both the governor and the general assembly.

13. South Carolina <u>SB1239</u> (Introduced 04/04/2024) Sponsors: Senator Scott Talley (R)

Summary:

- The bill defines key terms: "patient," "third party" (likely insurers and pharmacy benefit managers), and "340B drug pricing."
- Patients have the right to choose any pharmacy or provider, and can't be forced to use a mail-order pharmacy unless they sign a waiver.
- Third parties like insurers must make drug coverage decisions based on normal business practices, *not to discriminate against 340B pharmacies*.
- Pharmacy claims processed by a 340B pharmacy are considered final at the point of adjudication (meaning they can't be arbitrarily changed later).
- The Insurance Commissioner can create rules to implement these provisions.
- 14. South Dakota <u>HB1147</u> (Introduced 01/25/2024) Sponsors: Senator Tim Reed (R)

Summary:

Prohibited discriminatory acts:

- Reimbursing 340B entities less than similar non-340B entities for the same drug.
- Charging extra fees or imposing penalties on 340B entities due to their program participation.
- Restricting 340B entities' pharmacy network access or forcing them to contract with specific pharmacies.
- Implementing new restrictions or charges for patients receiving prescriptions from 340B entities.
- Auditing 340B entities more frequently than similar non-340B entities.
- Refusing reimbursement for covered 340B drugs.
- Basing formulary decisions on 340B status or dispensing pharmacy participation.
- Imposing requirements or restrictions that limit 340B entities' ability to maximize program benefits.

• Having different contractual terms for 340B entities compared to non-340B entities.

Consequences of discrimination:

• 340B entities can sue PBMs for damages, including actual, consequential, and attorney's fees.

• Engaging in any prohibited act is also considered an unfair and deceptive practice under state law. Effective date: January 1, 2025

Non-340B Bills that could affect the program

1. Arizona <u>HB2659</u> (Introduced 01/22/2024) Sponsor: Rep. Amish Shah (D)

Summary:

The Act establishes a Wholesale Prescription Drug Importation Program in Arizona with the goal of providing significant cost savings to consumers by importing safe and effective prescription drugs from Canada. Key elements of the program:

- The Department of Health Services (DHS) will design the program in consultation with stakeholders and federal officials, complying with US federal law and ensuring patient safety.
- DHS can either become a licensed drug wholesaler or contract with one to import drugs that are only safe and effective drugs that are expected to generate substantial savings and meet FDA standards.
- The program will comply with US drug tracking and tracing requirements and have a robust audit protocol in place.
- Funding will come from a charge per prescription or another method, ensuring program sustainability and significant consumer savings.
- Implementation:
 - DHS will seek federal certification for the program and consult with the Attorney General's office to monitor potential anticompetitive behavior.
 - 340B covered entities will be allowed to participate fully without jeopardizing their federal program eligibility.
 - Program implementation will only start after the legislature establishes funding.
- Within six months of funding or federal certification, DHS will:
 - Become a licensed wholesaler or contract with one.
 - Contract with distributors and Canadian suppliers and engage with health plans, employers, pharmacies, providers, and consumers.
 - Develop registration processes for program participants and create a public list of imported drug prices.
 - Develop an outreach and marketing plan and establish a hotline for questions and support.
- Establish and staff an audit function as DHS will report annually to the Governor, Legislature, and Secretary of State on program operation, which includes:
 - Drugs included in the program, participating entities, number of prescriptions dispensed, estimated cost savings, and audit implementation and findings.
- 2. Virginia <u>SB186</u> (Introduced 01/08/2024)

Sponsor: Del. Suhas Subramanyam (D)

Summary:

- Directs the Secretary of Health and Human Resources to establish a wholesale prescription drug importation program that complies with the requirements of federal law and to report annually by October 1 to the Governor and the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Senate Committees on Finance and Appropriations and Education and Health on the wholesale prescription drug importation program.
- The bill also requires the Secretary to (i) convene a work group composed of relevant stakeholders to develop a plan for implementation of the wholesale prescription drug importation program and report the plan to the Governor and the Chairmen of the House Committees on Appropriations and Health, Welfare and Institutions and the Senate Committees on Finance and Appropriations and Education and Health by December 1, 2024,
- and seek such federal approvals, waivers, exemptions, or agreements as may be necessary to enable all covered entities enrolled in or eligible for the federal 340B Drug Pricing Program to participate in the wholesale prescription drug importation program to the greatest extent possible without jeopardizing their eligibility for the 340B Drug Pricing Program by July 1, 2025.

Virginia <u>SB274</u> (Introduced 01/10/2024)

Sponsor: Senator Creigh Deeds (D)

Cosponsor: Senator Adam Ebbin (D)

Summary:

Establishes the Prescription Drug Affordability Board for the purpose of protecting the citizens of the Commonwealth and other stakeholders within the health care system from the high costs of prescription drug products.

- The bill directs the Governor to appoint the members and alternate members of the Board and requires the Board to meet in open session at least four times annually, with certain exceptions and requirements enumerated in the bill. Members of the Board are required to disclose any conflicts of interest, as described in the bill. The bill also creates a stakeholder council for the purpose of assisting the Board in making decisions related to drug cost affordability.
- The bill tasks the Board with identifying prescription, generic, and other drugs, as defined in the bill, that are offered for sale in the Commonwealth and, at the Board's discretion, conducting an affordability review of any prescription drug product.
- The bill lists factors for the Board to consider that indicate an affordability challenge for the health care system in the Commonwealth or high out-of-pocket costs for patients. The bill also provides that any person aggrieved by a decision of the Board may request an appeal of the Board's decision and that the Attorney General shall have authority to enforce the provisions of the bill.
- The bill requires the Board to report its findings and recommendations to the General Assembly twice annually, beginning on July 1, 2025, and December 31, 2025. Provisions of the bill shall apply to state-sponsored and state-regulated health plans and health programs and obligate such policies to limit drug payment amounts and reimbursements to an upper payment limit amount set by the Board, if applicable, following an affordability review.
- The bill specifies that Medicare Part D plans shall not be bound by such decisions of the Board. The bill also requires manufacturers of prescription drugs to report information annually by April 1 to the Board instead of a nonprofit organization contracted by the Department of Health. Finally, the bill contains a severability clause and has a delayed effective date of January 1, 2025.

Virginia <u>HB570</u> (Introduced 01/09/2024) Sponsor: Delegate Karrie Delaney (D) Cosponsors: (15) bipartisan

Nearly Identical language to Virginia SB274.