Navigating the Ever-Changing 340B Landscape

R. Logan Yoho, PharmD, BCACP, 340B ACE
Director of Advocacy & Education
FQHC 340B Compliance

Pharmacy Forward: Advancing Practice for a Healthier Tomorrow!

OPA Annual Conference & Trade Show April 9-11, 2026

OHIO PHARMACISTS ASSOCIATION

Disclosure Statement

- R. Logan Yoho has no relevant financial relationship(s) with ineligible companies to disclose.
  and
- None of the planners for this activity have relevant financial relationships with ineligible companies to disclose.

Learning Objectives

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

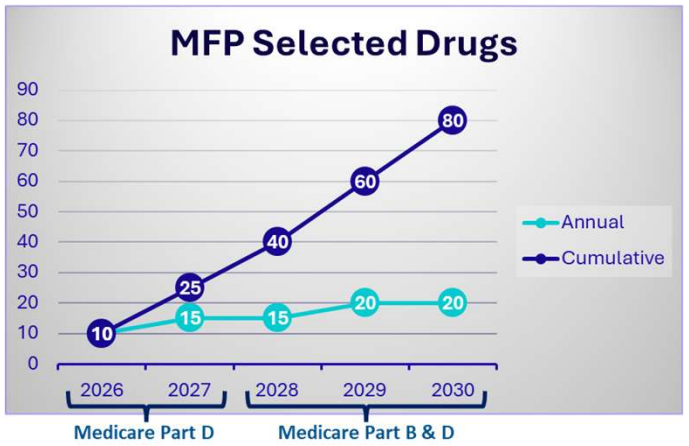
1. Illustrate the current status of the Medicare Drug Price Negotiation Program and its interactions with the 340B program.
2. Evaluate the current status of HRSA's 340B Drug Rebate Model Pilot and any pending litigation.
3. Assess pending legislation impacting the 340B program.

Medicare Drug Price Negotiation Program

The Inflation Reduction Act: Medicare Impact

- Inflation Reduction Act was signed into law Aug 16th, 2022.
  - Included provisions to address rising drug prices:

Provision	Effective	Applies To
Inflationary Rebate Penalties	2023	Part B & D drugs
$35 Insulin Co-Pay Cap	2023	Medicare
Vaccine Cost-Sharing Elimination	2023	Medicare Part D
$2,000 Out-of-Pocket Cap	2025	Medicare Part D
Medicare Drug Price Negotiation	**2026***	**Part B & D**



  - To be included in Medicare Drug Price Negotiation, must be:
    - A **single-source** brand-name drug or biological product (with no bona fide generic or biosimilar)
    - On the market for at least 9 years for small-molecule drugs & 13 years for biologics
    - High Medicare spend in previous 12 months
  - Negotiation starts with **Part D** in 2026 & adding **Part B** in 2028.
    - Drugs selected for 2028 are due to be announced February 1st, 2026.

2026 Negotiated MFP Drugs

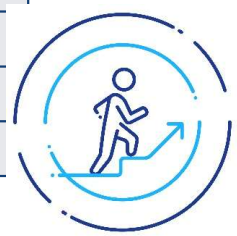
Brand	Manufacturer	Indication	Exit List
Eliquis	Bristol-Myers Squibb	Anticoagulant	
Enbrel	Amgen (Immunex Corp)	Rheumatology	
Entresto	**Novartis**	**Heart Failure**	**12/31/2026**
Farxiga	AstraZeneca (& Prasco)	Diabetes	
Imbruvica	AbbVie (Pharmacyclics)	Oncology	
Januvia	Merck	Diabetes	
Jardiance	Boehringer Ingelheim	Diabetes	
Novolog/FIASP	Novo Nordisk	Diabetes	
Stelara	**Johnson & Johnson (Janssen)**	**Rheumatology**	**12/31/2026**
Xarelto	**Johnson & Johnson (Janssen)**	**Anticoagulant**	**12/31/2026**

2027 Negotiated MFP Drugs

Brand	Manufacturer	Indication
Austedo	Teva	Huntington Dz
Breo Ellipta	GSK (& Prasco)	Asthma & COPD
Calquence	AstraZeneca	Oncology
Ibrance	Pfizer	Oncology
Janumet; Janumet Xr	Merck	Diabetes
Linzess	Allergan	GI Indications
Ofev	Boehringer Ingelheim	Pulmonary Fibrosis
Otezla	Amgen Inc	Rheumatology
Ozempic; Rybelsus; Wegovy	Novo Nordisk	Diabetes & Weight Loss
Pomalyst	Bristol-Myers Squibb	Oncology
Tradjenta	Boehringer Ingelheim/ Lilly	Diabetes
Trelegy Ellipta	GlaxoSmithKline	Asthma & COPD
Vraylar	Allergan	Antipsychotic
Xifaxan	Bausch	GI Indications
Xtandi	Astellas	Oncology

2028 Negotiated MFP Drugs

Brand	Manufacturer	Indication
Anoro	GSK	COPD
Biktarvy	Gilead	HIV
Botox; Botox Cosmetic	AbbVie	Migraines, Cosmetic Treatments
Cimzia	UCB	Rheumatology
Cosentyx	Novartis	Rheumatology
Entyvio	Takeda	GI Indications
Erleada	Johnson & Johnson (Janssen)	Oncology
Kisqali	Novartis	Oncology
Lenvima	Eisai	Oncology
Orencia	Bristol Myers Squibb	Rheumatology
Rexulti	Otsuka	Antipsychotic
Trulicity	Eli Lilly	Diabetes
Verzenio	Eli Lilly	Oncology
Xeljanz; Xeljanz XR	Pfizer	Rheumatology
Xolair	Genetech & Novartis	Allergenic Conditions



Duplicate Discount Language in 340B Statute

(5) REQUIREMENTS FOR COVERED ENTITIES.

(A) PROHIBITING DUPLICATE DISCOUNTS OR REBATES.—

(i) IN GENERAL.—A covered entity shall not request payment under title XIX of the Social Security Act for medical assistance described in section 1905(a)(12) of such Act with respect to a drug that is subject to an agreement under this section if the drug is subject to the payment of a rebate to the State under section 1927 of such Act.

(ii) ESTABLISHMENT OF MECHANISM.—The Secretary shall establish a mechanism to ensure that covered entities comply with clause (i). If the Secretary does not establish a mechanism within 12 months under the previous sentence, the requirements of section 1927(a)(5)(C) of the Social Security Act shall apply.

https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

Deduplication of Claims – MFP & 340B

- ‘‘(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.
- ‘‘(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1192(c).
- ‘‘(c) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.
- ‘‘(d) NONDUPLICATION WITH 340B CEILING PRICE.—Under an agreement entered into under this section, the manufacturer of a selected drug— ‘‘(1) **shall not be required to provide access to the maximum fair price** under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and
- ‘‘(2) **shall be required to provide access to the maximum fair price** to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf

Requirement.

"(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

Compliance. Requirements. Determination.

"(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

"(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1192(c).

Determination.

"(c) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

"(d) NONDUPLICATION WITH 340B CEILING PRICE.—Under an agreement entered into under this section, the manufacturer of a selected drug—

"(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

Requirement.

"(2) shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

Notice: End of Section. There is no additional language delegating responsibility to CEs.

"SEC. 1194. NEGOTIATION AND RENEGOTIATION PROCESS. 42 USC 1320f–3.

"(a) IN GENERAL.—For purposes of this part, under an agreement under section 1193 between the Secretary and a manufacturer

Dispensing Fees for Negotiated Drugs

- Starting January 1, 2026, Part D plan payments for selected drugs must not exceed the drug's MFP plus any dispensing fees. **Pharmacies should be reimbursed at least the MFP plus a fair dispensing fee.**
- CMS is aware of concerns that pharmacies may be reimbursed below acquisition cost or MFP. The agency will monitor for any practices that undermine fair compensation and may adjust program requirements if needed.
- **Definition of Dispensing Fee**: Dispensing fees cover pharmacy costs beyond the drug's ingredient cost, including:
  - Salaries
  - Time for coverage checks
  - Filling containers
  - Packaging
  - Overhead (e.g., IT)
- Network Adequacy Requirements: Part D sponsors must ensure enough pharmacies participate in their networks to provide convenient access to covered drugs.

https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-5-august-25-29

Dispensing Fees Example – FQHC Pharmacy

Plan	Number of Claims	Average Dispensing Fee Paid
Medicare Plan A	74	$0.75
Medicare Plan B	83	$0.03
Medicare Plan C	11	$0.05
Medicare Plan D	27	$0.25
Medicare Plan E	3	$0.00
Medicare Plan F	94	$1.08
Medicare Plan G	8	$10.50
Medicare Plan H	3	$0.00
Medicare Plan I	1	$1.50
Medicare Plan J	61	$1.92
Totals (10 Plans)	**365**	**$1.01**

Note: We are seeing at least one plan paying less than MFP for Ingredient Cost in addition to low dispensing fees.

340B Rebate Model

340B Rebate Pilot Litigation Timeline

Nov 11, 2024

Eli Lilly sues HRSA after the agency rejects Lilly's proposed rebate model; similar action by J&J the same week.

Nov 2024

Manufacturers move forward with Rebate models with Beacon

July 31, 2025

HRSA publishes 340B Rebate Model Pilot Program in Federal Register for comment

Oct 30, 2025

OPA Announces 8 initial manufactures selected & post summary of plans

Dec 1, 2025

AHA *et al* files lawsuit in Maine to block rebate model for APA violations

Dec 29, 2025

Preliminary injunction & TRO granted by Maine District Court &, HRSA appeals to 1st Circuit

Dec 31, 2026

Maine District & 1st Circuit courts initially denied HHS request

Jan 1, 2026

Medicare Maximum Fair Prices go-live

Jan 7, 2026

1st Circuit denies HHS preliminary stay request after hearing

Jan 12, 2026

HHS *& AHA signal intentions with appeal case*

Feb 6, 2026

HRSA submits "340B Drug Pricing Program Manufacturer Rebate Models" for OMB for regulatory review

Feb 18, 2026

HRSA publishes "Request for Information: 340B Rebate Model Pilot Program"

Feb 26, 2026

HRSA publishes extension on RFI comment period & information collection request for 340B Rebate Pilot

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Notice

Request for Information: 340B Rebate Model Pilot Program

A Notice by the Health Resources and Services Administration on 02/17/2026

Comments Due: April 20, 2026

https://www.federalregister.gov/documents/2026/02/26/2026-03838/request-for-information-340b-rebate-model-pilot-program-extension

Elements Requested

1. Cost to Covered Entities
2. Payment Timing & Potential Cash Flow Impacts for Covered Entities
3. Rebate Denials
4. Data Collection by Covered Entities
5. Manufacturer Efforts to Avoid Duplicate Discounts
6. Required Reporting
7. 340B Program Integrity & Other Potential Benefits of a Rebate Model

Cost to Covered Entities

- What are your current administrative costs for the 340B program?
- What are your expected administrative costs under a rebate model?
- What are the expected staffing impacts of a rebate model?
- What systems & infrastructure changes will be required to comply with a rebate model?
- What are the other anticipated costs or impacts?

Payment Timing & Potential Cash Flow Impacts for Covered Entities

- Would payment timing affect cash flow?
- Describe current payment terms
- Would a rebate model alter wholesaler payment timing?
- How could a rebate model be structured to ensure manufacturers pay on time?
- Other ways a rebate model could address payment timing & cash flow

Rebate Denials

What guardrails should be built into a potential rebate model to ensure denials are limited to appropriate circumstances?

What process elements should be required for rebate denials including template forms and timeline for adjudications?

Data Collection for Covered Entities

- How does your organization collect, maintain, and retain data related to the 340B program?
- Current measures to ensure data accuracy, completeness, and consistency
- Would a rebate model change your current data collection activities?
- What specific pharmacy and medical claim data elements should be included in a rebate model? Are those elements available?
- What guardrails should be in place to mitigate any privacy and security concerns regarding PHI?

Manufacturer Efforts to Avoid Duplicate Discounts

- What efforts are you using to avoid paying both 340B discounts and Medicaid rebates on the same claim?
- What operational or administrative changes have you made to avoid paying 340B discounts on drugs subject to a MFP?
- Describe your organization's experience identifying 340B claims for MFP de-duplication
- Describe challenges encountered identifying potential "duplicate discounts" under 340B and CMS payment programs
- What are the minimum data elements you believe are necessary for a manufacturer to identify potential "duplicate discounts" under 340B and CMS payment programs?

Required Reporting

What specific data should manufacturers be required to submit to ensure compliance in a rebate model?

What manufacturer data should be shared publicly?

What should the frequency and duration of manufacturer data collection?

340B Program Integrity & Other Potential Benefits of a Potential Rebate Model

- How would a rebate model affect the integrity of the 340B program?
- Would a rebate model:
  - Assist manufacturers in their efforts to avoid paying “duplicate discounts” under 340B and CMS payment programs?
  - Reduce diversion?
  - Increase pricing transparency?
- Provide any recommendations for improving data collection and reporting to strengthen the 340B program’s integrity while minimizing administrative burden
- Describe any other potential benefits of a rebate model

FEDERAL REGISTER

The Daily Journal of the United States Government

Notice

Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: 340B Rebate Model Pilot Program Application, Implementation, and Evaluation, OMB Number 0906-NEW

A Notice by the Health Resources and Services Administration on 02/26/2026

Comments Due: April 27, 2026

https://www.federalregister.gov/documents/2026/02/26/2026-03833/agency-information-collection-activities-proposed-collection-public-comment-request-information

What is an ICR?

- An Information Collection Request (ICR) is a set of documents that describes reporting, record keeping, survey, or other information collection requirements imposed on the public by a federal agency.
- The Paperwork Reduction Act stipulates that every federal agency must obtain approval from the Office of Management and Budget (OMB) before collecting the same or similar information from 10 or more members of the public.
- What is covered in an ICR?
  - A description of the information to be collected
  - The reason the information is needed
  - An estimate of the time and cost for the public to answer the request.

https://www.epa.gov/icr/icr-basics

Rebate 2.0: Potentially 13 Manufacturers

The scope of the potential 340B Rebate Model Pilot Program will be limited to manufacturers with Medicare Drug Price Negotiation Program Agreements with the Centers for Medicare & Medicaid Services' for the initial price applicability years 2026 and 2027.

Manufacturer & Selected Drugs	Count
AbbVie	**1**
IMBRUVICA	
Allergan	**2**
LINZESS	
VRAYLAR	
Amgen	**2**
ENBREL	
OTEZLA; OTEZLA XR	
Astellas	**1**
XTANDI	
AstraZeneca	**2**
CALQUENCE	
FARXIGA	
Bausch & Lomb	**1**
XIFAXAN	
Boehringer Ingelheim	**3**
JARDIANCE	
OFEV	
TRADJENTA	

Manufacturer & Selected Drugs	Count
Bristol-Myers Squibb	**2**
ELIQUIS	
POMALYST	
GlaxoSmithKline	**2**
BREO ELLIPTA	
TRELEGY ELLIPTA	
Merck	**2**
JANUMET; JANUMET XR	
JANUVIA	
Novo Nordisk	**2**
OZEMPIC; RYBELSUS; WEGOVY	
NOVOLOG; FIASP	
Pfizer	**1**
IBRANCE	
Teva	
AUSTEDO; AUSTEDO XR	1
Grand Total	**22**

Total Estimated Annualized Burden Hours

Name	Number of respondents *	Number of responses per respondent	Total responses	Average burden per response (in hours)	Total burden hours
340B Rebate Model Pilot Program Plan Submission	13	1	13	8	104
Manufacturer monthly purchase reports	13	12	156	2	312
Covered Entities reporting claims data to third party platform	14,600	52	759,200	5	3,796,000
Total	14,613		759,369		3,796,416

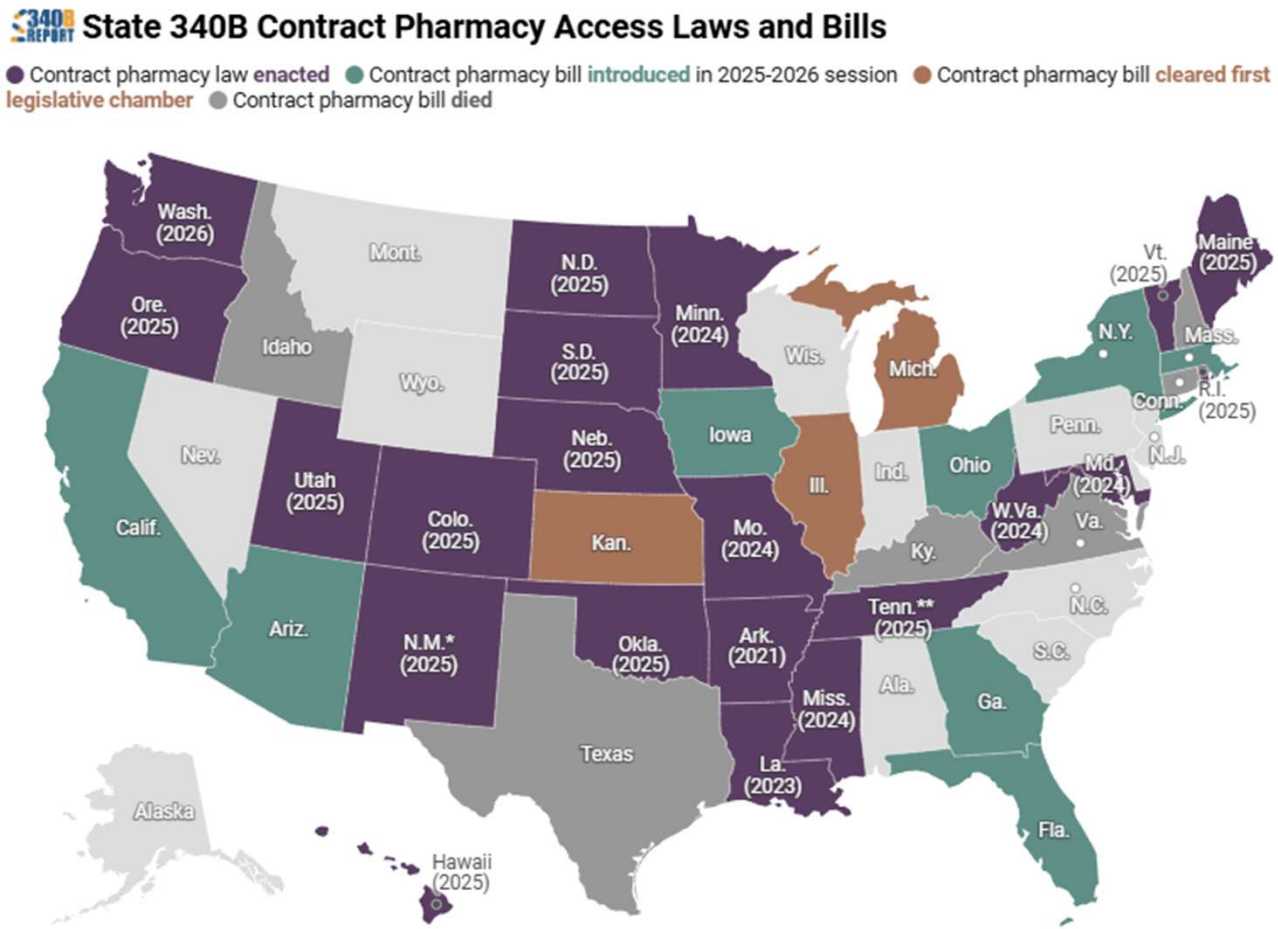
** Potentially 13 manufacturers will submit Plans and Monthly Purchase Reports (first two rows, above), while the 14,600 Covered Entities will submit Claims Data (third row, above). Therefore, the total number of respondents is 14,613.*

https://www.federalregister.gov/documents/2026/02/26/2026-03833/agency-information-collection-activities-proposed-collection-public-comment-request-information

340B Rebate ICR Comments Areas:

- Necessity & utility of 340B Rebate for proper performance of the agency's (HRSA) functions.
- The accuracy of the estimated burden (5 hours per week for Covered Entities)
- Suggestions to improve the quality, utility, and clarity of the rebate data collected.
- Recommendations for automated collection techniques or other methods to reduce the burden of information collection for 340B Rebate Model.

State 340B Legislative & Litigative Battles



* New Mexico's law only applies to community health centers.

**Tennessee's bill only applies to drugmaker 340B restrictions placed after July 1, 2025.

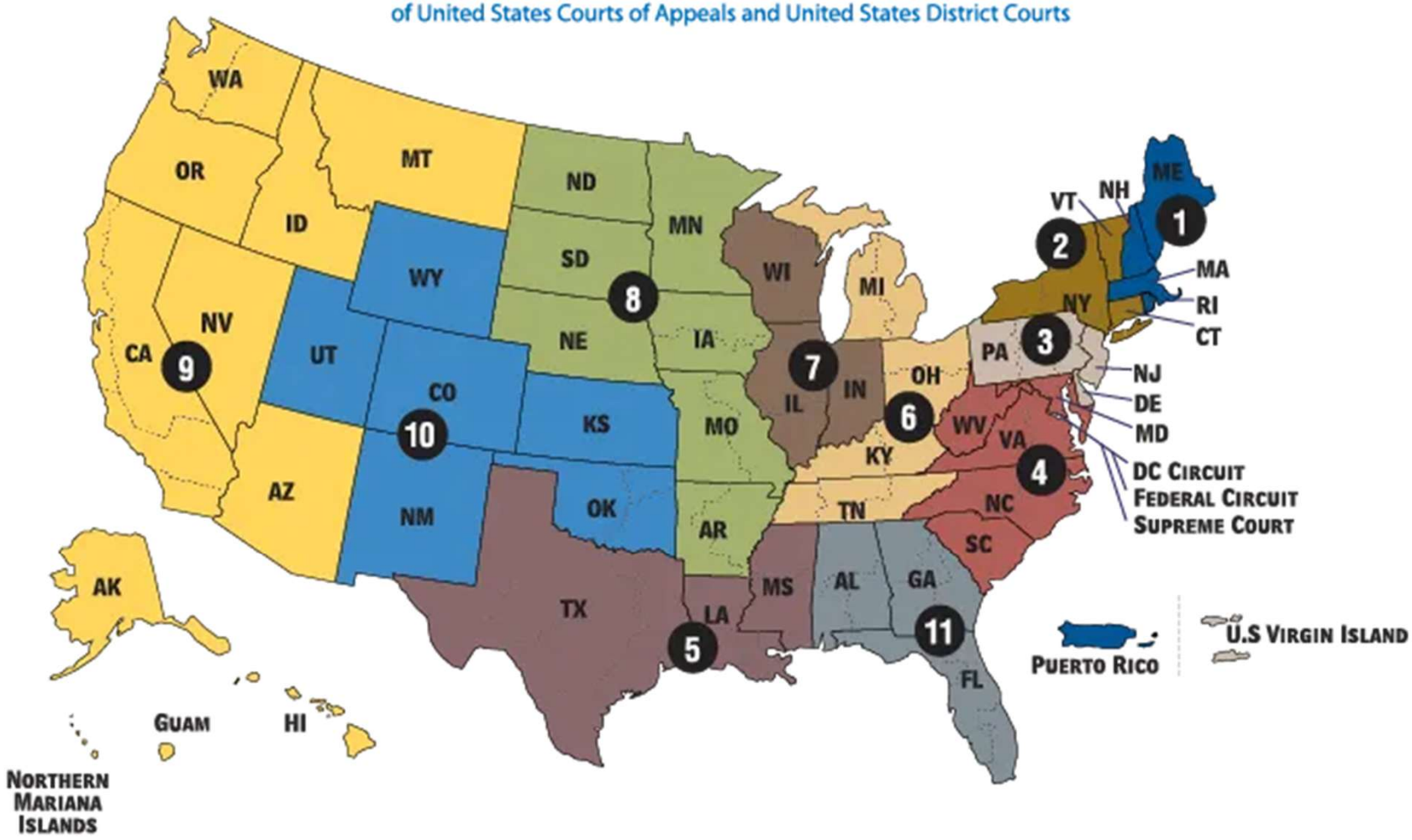
Map: updated as of March. 26, 2026 • Created with Datawrapper

State Legislation: Contract Pharmacy Access

https://340breport.com/legislative-map/contract-pharmacy-protection-bill/

Geographic Boundaries

of United States Courts of Appeals and United States District Courts



https://www.uscourts.gov/about-federal-courts/court-role-and-structure/court-website-links

State Litigative Wins: 8th Circuit

340B REPORT

Circuit Judge Michael Melloy of the U.S. 8th Circuit Court of Appeals wrote the opinion that upheld Arkansas' state 340B contract pharmacy law.

BREAKING NEWS

In Key Decision That Could Have National Implications, Federal Appellate Court Upholds Arkansas 340B Contract Pharmacy Protection Law

March 12, 2024 William Newton, Associate Editor/Senior Writer 340B Report

State Litigative Wins: 5th Circuit

340B REPORT

The U.S. 5th Circuit Court of Appeals affirmed a lower court's ruling denying AbbVie's bid to block enforcement of Mississippi's 340B contract pharmacy access law.

BREAKING NEWS

Federal Appeals Court Unanimously Upholds Mississippi's 340B Contract Pharmacy Access Law Against AbbVie Challenge

September 12, 2025 William Newton, Associate Editor/Senior Writer 340B Report

340B REPORT

A three-judge panel of the U.S. 5th Circuit Court of Appeals in New Orleans unanimously upheld Louisiana's 340B contract pharmacy access law.

BREAKING NEWS

5th Circuit Unanimously Upholds Louisiana's 340B Contract Pharmacy Access Law

February 9, 2026 William Newton, Associate Editor/Senior Writer 340B Report

State Litigative Woes: 4th Circuit

340B REPORT

BREAKING NEWS

4th Circuit Blocks West Virginia's 340B Contract Pharmacy Access Law in First Federal Appeals Court Win for Drugmakers

March 31, 2026 William Newton, Associate Editor/Senior Writer 340B Report

A three-judge panel for the U.S. 4th Circuit Court of Appeals issued a 2-1 decision affirming a lower court's ruling blocking enforcement of West Virginia's 340B contract pharmacy access law.

340B as a Federal “Spending-Power Bargain”

Congress created a federal bargain:	Manufacturers receive access to Medicaid markets In exchange, they provide statutorily defined discounts
States:	Are not parties to this bargain May not rewrite or expand it
The court emphasized:	340B sets price terms only Delivery and distribution conditions are not mandated by statute

Implications for 340B Policy Nationwide

Strengthens manufacturer challenges to:	• State 340B delivery mandates • State restrictions on audit-related data access
Deepens a national circuit split:	• 4th Circuit: State delivery laws likely preempted • 5th & 8th Circuits: Similar laws upheld
Increases likelihood of:	• Supreme Court review • Congressional intervention
Key takeaway:	• 340B rules must come from Congress or HHS — not individual states

References

1. Inflation Reduction Act of 2022, Pub. L. No. 117-169, 136 Stat. 1818 (2022). https://www.congress.gov/bill/117th-congress/house-bill/5376/text
2. https://www.hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf
3. https://www.congress.gov/117/plaws/publ169/PLAW-117publ169.pdf
4. https://www.cms.gov/about-cms/information-systems/hpms/hpms-memos-archive-weekly/hpms-memos-wk-5-august-25-29
5. https://www.federalregister.gov/documents/2026/02/26/2026-03833/agency-information-collection-activities-proposed-collection-public-comment-request-information
6. https://www.epa.gov/icr/icr-basics
7. https://340breport.com/legislative-map/contract-pharmacy-protection-bill/
8. https://www.uscourts.gov/about-federal-courts/court-role-and-structure/court-website-links
9. https://340breport.com/federal-appeals-court-unanimously-upholds-mississippis-340b-contract-pharmacy-access-law-against-abbvie-challenge/
10. https://340breport.com/5th-circuit-unanimously-upholds-louisianas-340b-contract-pharmacy-access-law/
11. https://340breport.com/4th-circuit-blocks-west-virginias-340b-contract-pharmacy-access-law-in-first-federal-appeals-court-win-for-drugmakers/

Need More Information?

R. Logan Yoho, PharmD, BCACP, 340B ACE
logan@fqhc340b.com

Pharmacy Forward: Advancing Practice for a Healthier Tomorrow!

OPA Annual Conference & Trade Show April 9-11, 2026

OHIO PHARMACISTS ASSOCIATION