340B Court and Policy Update

Court Decisions and Federal and State Developments

Current through July 26, 2026

Three recent federal appellate decisions materially affect the 340B landscape. Strictly measured from July 12 through July 26, the principal new decision is the D.C. Circuit's July 21 rebate ruling. Two additional appellate rulings, issued July 6 and July 1, are also included and are important because they strengthen state authority to protect contract-pharmacy arrangements.

I. Recent Court Decisions

1. D.C. Circuit: Manufacturers Cannot Unilaterally Impose Rebate Models

Case: Novartis Pharmaceuticals Corp. v. Kennedy, consolidated with cases involving Johnson & Johnson, Eli Lilly, and Bristol Myers Squibb.

Court: U.S. Court of Appeals for the District of Columbia Circuit.

Decision date: July 21, 2026.

The court ruled that Section 340B permits the use of rebates in principle, but manufacturers may not replace the traditional upfront discount with a post-purchase rebate system unless the HHS secretary has first approved or "provided for" that mechanism. The court therefore affirmed the lower-court judgments supporting HRSA's refusal to allow the manufacturers to launch their proposed models immediately.

The court rejected the manufacturers' argument that they could implement any rebate methodology not expressly prohibited by their pharmaceutical pricing agreements. It concluded that the phrase "any rebate or discount, as provided by the Secretary" gives HHS—not individual manufacturers—control over the pricing mechanism used to satisfy the statutory ceiling price.

Immediate effect: Novartis, J&J, Lilly, and BMS cannot independently require covered entities to pay full price and subsequently submit claims for rebates under the models at issue. The existing upfront-discount structure remains applicable unless and until HHS approves a different mechanism.

Important limitation: This was not a ruling that rebate models themselves are unlawful. The court expressly held that Section 340B can accommodate rebates. It also did not decide whether HHS's revised rebate pilot would be lawful or whether HHS must approve any particular manufacturer proposal. This preserves a path for the administration to authorize a rebate system after additional administrative procedures.

Primary source: D.C. Circuit opinion

Primary source: American Hospital Association summary

2. Fifth Circuit: Louisiana's Contract-Pharmacy Law Upheld

Case: AbbVie Inc. v. Murrill, consolidated with AstraZeneca and PhRMA challenges.

Court: U.S. Court of Appeals for the Fifth Circuit.

Decision date: July 6, 2026.

The Fifth Circuit issued a substituted opinion affirming summary judgment for Louisiana on every claim challenging the state's Act 358. That law prohibits manufacturers from denying, restricting, or interfering with the acquisition or delivery of 340B drugs through pharmacies contracted with covered entities.

The court held that Louisiana regulates drug distribution and pharmacy conduct—not the federal 340B ceiling-price calculation. Because the federal statute does not regulate the delivery of 340B drugs to contract pharmacies, Louisiana could fill that regulatory space without being preempted by federal law.

The court also rejected:

- AbbVie's Takings Clause claim.
- AstraZeneca's Contracts Clause claim.
- AbbVie's and PhRMA's vagueness challenges.
- Arguments that Louisiana's enforcement provisions impermissibly displaced HRSA's federal enforcement authority.

Immediate effect: Louisiana may continue enforcing Act 358 against manufacturers that refuse to deliver discounted drugs through covered entities' contract pharmacies. This is a final merits ruling at the appellate level, rather than merely a preliminary-injunction decision.

Broader significance: The ruling reinforces the Fifth Circuit's earlier approval of Mississippi's materially similar protections and gives other states in the circuit a strong legal basis for comparable legislation. A manufacturer petition for Supreme Court review remains possible.

Primary source: Fifth Circuit substituted opinion

3. Eighth Circuit: Missouri's Contract-Pharmacy Law Remains Enforceable

Case: Novartis Pharmaceuticals Corp. v. Hanaway.

Court: U.S. Court of Appeals for the Eighth Circuit.

Decision date: July 1, 2026.

The Eighth Circuit affirmed the denial of Novartis's request for a preliminary injunction against Missouri S.B. 751. The law prevents manufacturers from restricting delivery of 340B drugs to contract pharmacies designated by covered entities.

The court concluded that Novartis was unlikely to prevail on its federal-preemption or dormant Commerce Clause arguments. Like the Fifth Circuit, it reasoned that Section 340B regulates price but leaves drug delivery and the role of pharmacies largely unregulated, permitting states to legislate in that area.

Immediate effect: Missouri can enforce S.B. 751 while the underlying litigation continues. Covered entities may continue relying on the state law to challenge manufacturer limits on their contract-pharmacy networks.

Procedural limitation: Unlike the Louisiana decision, the Missouri ruling arose from a motion for preliminary relief. It strongly signals how the Eighth Circuit views the merits, but the district-court litigation has not necessarily reached a final judgment on every claim.

Primary source: Eighth Circuit opinion

II. A Widening Federal Circuit Split

The latest Fifth and Eighth Circuit rulings conflict with the Fourth Circuit's approach. Earlier in 2026, the Fourth Circuit held that West Virginia's contract-pharmacy law was likely preempted because it altered the federal statutory "bargain" between manufacturers and HHS and imposed state conditions solely on federal 340B participants. The court also directed reconsideration of challenges involving Maryland's law.

The practical result is an increasingly geographic 340B system:

- Fifth and Eighth Circuits: Generally receptive to state contract-pharmacy protections as regulation of drug delivery.
- Fourth Circuit: Generally views such protections as impermissibly adding conditions to the federal 340B program.
- Third and D.C. Circuits: Earlier federal cases held that Section 340B itself does not compel manufacturers to recognize an unlimited number of contract pharmacies.

This conflict materially increases the possibility of eventual Supreme Court review, particularly if manufacturers file petitions arising from the Louisiana, Missouri, or related state-law cases.

Primary source: Fourth Circuit opinion concerning West Virginia law

III. HRSA Administrative-Dispute Rulings Favor Manufacturer Contract-Pharmacy Policies

On July 16, HRSA updated its published Administrative Dispute Resolution decisions. The agency's panels rejected hospital overcharge claims involving contract-pharmacy restrictions imposed by AstraZeneca, Novartis, Novo Nordisk, Sanofi, Boehringer Ingelheim, and Merck. HRSA stated that the challenged policies did not constitute federal 340B overcharges under the controlling Third and D.C. Circuit decisions.

Petitioners included St. Croix Regional Medical Center, Emory University Hospital Midtown, the University of Washington Medical Center, and Harborview Medical Center. In two University of Washington matters, HRSA's reconsideration official affirmed the original ADR determinations. No sanctions were imposed against the manufacturers.

These decisions illustrate the current federal-state divide:

- Under federal 340B law alone, manufacturers may generally impose reasonable contract-pharmacy restrictions consistent with the Third and D.C. Circuit precedents.
- A covered entity may nevertheless obtain protection under a valid state law requiring manufacturers to serve contract pharmacies.
- Whether that state protection is enforceable increasingly depends on the governing federal circuit.

Covered entities therefore cannot assume that HRSA's ADR process will restore contract-pharmacy pricing where no enforceable state protection exists.

Primary source: HRSA 340B ADR decision summaries

IV. HRSA Continues Developing a Revised Federal Rebate Pilot

Despite the earlier court order vacating HRSA's original rebate pilot, the agency is developing a revised program. HRSA submitted a new information-collection request to the Office of Management and Budget covering manufacturer applications, monthly purchase reports, and claims-level data that covered entities would submit to obtain rebates. The most recent comment period closed July 15.

The proposed collection anticipates participation by 11 manufacturers with drugs selected for Medicare negotiation for the 2026 and 2027 price-applicability years. HRSA estimated that approximately 15,249 covered entities could make nearly four million annual claims-data submissions.

The July 21 D.C. Circuit ruling arguably strengthens HHS's underlying authority to approve such a pilot because it confirms that the secretary may provide for rebate mechanisms. However, HRSA must still:

- Establish clear program standards.
- Address covered-entity cash-flow and administrative burdens.
- Protect claims-level data.
- Provide a reasoned explanation supported by an administrative record.
- Avoid the Administrative Procedure Act defects that resulted in the original pilot being vacated.

The rebate dispute therefore has shifted from whether manufacturers may act alone—they may not—to whether HHS can design and adequately justify a government-approved model.

Primary source: Federal Register notice regarding the proposed information collection

V. CMS Proposes a Major Medicare Payment Reduction for 340B Drugs

The calendar year 2027 Hospital Outpatient Prospective Payment System proposed rule would pay hospitals ASP minus 33.4 percent for separately payable drugs acquired through 340B, rather than the current general rate of ASP plus 6 percent. CMS based the proposed rate on its 2026 hospital drug-acquisition-cost survey.

CMS estimates that this would reduce Original Medicare payments for 340B drugs by approximately $4.55 billion in 2027 and reduce beneficiary cost-sharing on those drugs by approximately $1.15 billion. Because OPPS drug-payment reductions must be budget neutral, CMS proposes an estimated 8.44 percent increase in payments for non-drug OPPS services.

CMS separately proposes accelerating the recovery of $7.8 billion in additional non-drug payments made during the unlawful 2018–2022 340B payment-cut period. The annual OPPS conversion-factor reduction used for that recovery would increase from 0.5 percent to 3 percent beginning in 2027.

Why This Is Financially Important

The redistribution is unlikely to be neutral at the individual-hospital level. Hospitals with large oncology, infusion, and specialty-drug programs could lose substantially more in 340B drug reimbursement than they recover through higher non-drug payments. Hospitals with comparatively low 340B drug volume could fare better.

The proposal also raises a renewed legal issue. The Supreme Court invalidated CMS's earlier 340B payment reductions because CMS had not conducted the statutorily required acquisition-cost survey.

CMS is attempting to address that defect through the 2026 survey, making a future legal challenge more dependent on the validity, representativeness, and methodology of the survey itself.

Comments are due August 31, 2026.

Primary source: CMS CY 2027 OPPS/ASC proposed-rule fact sheet

Primary source: Federal Register: CY 2027 OPPS/ASC proposed rule

VI. Bipartisan House Legislation: H.R. 9599, the SECURE 340B Act

Representatives Scott Peters, John Joyce, Jake Auchincloss, Dan Crenshaw, and Nanette Barragán introduced H.R. 9599, the SECURE 340B Act, on July 6. It is one of the most comprehensive bipartisan 340B proposals introduced to date.

Codify Contract-Pharmacy Access

Manufacturers would have to offer 340B pricing regardless of whether a drug is dispensed directly or through a contract pharmacy. They could not limit the number or geographic location of contract pharmacies or demand that covered entities submit claims directly to manufacturers outside a federally established clearinghouse.

Prohibit Rebates for Four Years

For four years after enactment, manufacturers generally would have to provide 340B prices as reductions at the time of purchase rather than through retrospective rebates or other post-sale payments. The exception would be preexisting AIDS Drug Assistance Program rebate arrangements.

Establish a Statutory Patient Definition

A patient generally would need to have received an outpatient service from an eligible prescribing provider associated with the covered entity during the preceding 24 months, with auditable records showing the relevant clinical relationship. The bill also contains more limited provisions covering certain referral prescriptions.

Establish a Centralized Claims Clearinghouse

Covered entities and their contract pharmacies would submit standardized claims information through a federally contracted clearinghouse to identify duplicate discounts and diversion. Failure to cure incomplete or untimely submissions could allow a manufacturer to suspend discounts until the deficiency is corrected. Manufacturer and PBM use of the data would be restricted to defined program-integrity purposes.

Impose Patient-Affordability Requirements

Hospital categories including disproportionate-share, children's, critical-access, and sole-community hospitals generally would have to make financial-assistance and sliding-fee policies available to qualifying patients up to at least 400 percent of the federal poverty level. Those policies ultimately would extend to participating child sites and contract pharmacies.

Tighten Child-Site Eligibility

Child sites would face ownership, integration, Medicare and Medicaid participation, provider-based, and community-need requirements. A child site generally would need to be located in a qualifying socially vulnerable area or satisfy an alternative payer-mix or safety-net exception.

Assessment: H.R. 9599 would give hospitals a major statutory victory on contract pharmacies and a temporary shield from rebates, but it would also impose significant new patient-definition, financial-assistance, reporting, child-site, and claims-data obligations.

Primary source: H.R. 9599 bill text

VII. Senator Cassidy's Competing Reform Proposal

Senate HELP Committee Chair Bill Cassidy released the 340B Drug Pricing Integrity and Affordability for Patients Act as a discussion draft on June 29. Stakeholder comments are due August 28, 2026.

The Cassidy draft would generally allow a manufacturer to choose among:

- An upfront discount.
- A discount conditioned on standardized claims submission.
- A retrospective rebate paid after claims submission.

Covered entities that pass the entire discount directly to eligible patients could receive additional control over the discount method. The draft would also create reporting requirements, patient sliding-fee protections, contract-pharmacy standards, child-site requirements, and stronger enforcement authority.

The two congressional approaches establish very different negotiating positions:

- H.R. 9599: Preserves upfront discounts for four years, affirmatively protects unlimited contract pharmacies, and creates a neutral clearinghouse.
- Cassidy draft: More readily permits manufacturer rebate options and places greater emphasis on claims submission, patient pass-through, and restrictions on contract-pharmacy and covered-entity practices.

Neither proposal has advanced through committee, but they are likely to frame future negotiations over comprehensive 340B reform.

Primary source: Senate HELP Committee press release

Primary source: Section-by-section summary of the discussion draft

VIII. Washington's New State Law

Washington's S.B. 5981 took effect June 11. It prohibits manufacturers from imposing specified restrictions on covered entities' use of contract pharmacies while also creating extensive reporting obligations for covered entities and manufacturers.

The law authorizes enforcement actions and civil penalties of up to $5,000 per day for each violation, with each package of affected 340B drugs potentially treated as a separate violation. It therefore represents one of the stronger state enforcement models, but also one of the more demanding state transparency regimes for covered entities.

Whether all provisions survive manufacturer challenges could depend on how courts reconcile Washington's law with the emerging Fifth/Eighth versus Fourth Circuit split.

Primary source: Washington S.B. 5981 session law

IX. HRSA Reports 340B Purchases Reached $100 Billion

On July 13, HRSA reported that covered entities purchased approximately $100.01 billion in 340B drugs during 2025. Disproportionate-share hospitals accounted for approximately $79.24 billion of the total.

Specialty-distribution products represented only 38.1 percent of 340B units but accounted for 61.9 percent—approximately $61.9 billion—of total purchases. The top ten drugs accounted for approximately 28.6 percent of all reported 340B purchases.

These figures will strengthen congressional and administration arguments for increased reporting and oversight. They also demonstrate why oncology, infusion, and specialty-drug reimbursement changes in the OPPS rule could have an outsized impact on hospital 340B economics.

Primary source: HRSA 2025 covered-entity purchase data

Bottom Line

1. Manufacturers cannot impose unilateral rebate systems, but HHS retains authority to approve a rebate mechanism.
2. Louisiana and Missouri contract-pharmacy protections received strong appellate support, deepening a conflict with the Fourth Circuit.
3. HRSA's ADR process is not currently a reliable route for defeating manufacturer contract-pharmacy restrictions under federal law alone.
4. The proposed ASP-minus-33.4-percent Medicare policy is the largest immediate financial threat to hospital 340B revenue.
5. H.R. 9599 offers hospitals substantial contract-pharmacy and rebate protections but pairs them with major compliance obligations.
6. The Cassidy proposal would move the program more decisively toward claims-data submission, rebates, patient discounts, and tighter federal oversight.

The most immediate advocacy deadlines are August 28, 2026, for comments on Senator Cassidy's discussion draft and August 31, 2026, for comments on the CY 2027 OPPS proposed rule.