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Illinois Enacts 340B Contract Pharmacy Protections: 7 Steps Covered Entities Should Take

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Illinois has enacted new 340B laws that expand protections for contract pharmacies while creating new compliance and reporting requirements for covered entities. FQHCs, hospitals, and other covered entities should begin reviewing patient-eligibility rules, duplicate replenishment controls, manufacturer restrictions, and vendor data capabilities now, particularly as federal litigation continues and HRSA-approved rebate plans are scheduled to take effect January 1, 2027.

At a Glance

- **Contract pharmacy protections:** The Patient Access to Pharmacy Protection Act (410 ILCS 660), effective August 7, 2026, bars manufacturers and others from restricting 340B drug acquisition or delivery to authorized contract pharmacies of Illinois covered entities, including qualifying out-of-state pharmacies. Covered entities, including FQHCs and other federal grantees, must also meet an 18-month patient-service requirement and adopt and annually file a duplicate-replenishment policy.
- **Transparency:** A companion law (410 ILCS 665) requires covered entities and manufacturers to respond to Department of Insurance requests for information on 340B participation, pricing, payments, savings, and related matters. Late responses may trigger daily fines, reduced for specified covered entities.
- **Litigation:** Five lawsuits in the Northern District of Illinois challenge the contract pharmacy law. After an October 21, 2026 hearing, the court took the preliminary injunction motions under advisement. The law remains in effect absent a court order.
- **Federal developments:** HRSA has approved manufacturer rebate plans covering specified drugs and manufacturers, effective January 1, 2027.

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Background

The federal 340B Drug Pricing Program (42 U.S.C. § 256b) requires manufacturers participating in the Medicaid Drug Rebate Program to offer covered outpatient drugs to eligible safety-net providers ("covered entities") at or below statutory ceiling prices. Since 2020, manufacturers have limited the number and locations of contract pharmacies to which they will ship 340B-priced drugs or have conditioned access on claims data submission. Illinois and other states have responded with laws barring such interference.

These restrictions most affect covered entities without in-house pharmacies, including most FQHCs, which rely on contract pharmacies (including specialty and mail-order pharmacies) to reach patients. For FQHCs, 340B savings are program income that must further the federally approved health center project, and they commonly fund pharmacy access for uninsured and underinsured patients, sliding-fee discounts, and other unreimbursed services.

The Illinois Contract Pharmacy Law

Scope

The Patient Access to Pharmacy Protection Act (Public Act 104-0758; 410 ILCS 660) (the Act) took effect August 7, 2026. The General Assembly found that regulating drug acquisition and delivery falls within the State's traditional authority and that the federal 340B statute does not expressly address contract pharmacy distribution (410 ILCS 660/5). A covered entity is an Illinois entity qualifying under 42 U.S.C. § 256b(a)(4). A contract pharmacy includes Illinois-licensed pharmacies and pharmacies located in another state, commonwealth, or territory.[1]

"340B grantees" are covered entities under 42 U.S.C. § 256b(a)(4)(A)–(K), including FQHCs, FQHC look-alikes, Ryan White grantees, and Title X family planning entities. Grantees receive deferred reporting and reduced late fines but are otherwise fully subject to the Act, including the 18-month patient-service and duplicate-replenishment policy requirements. References below to covered entities include FQHCs.

Prohibited Conduct (Section 15)

Section 15 bars any person, including a manufacturer, from directly or indirectly:

- interfering with the acquisition or delivery of a 340B drug to a covered entity or an authorized contract pharmacy, unless federal law prohibits receipt;
- restricting a covered entity's ability to contract with or designate contract pharmacies, including by number, location, ownership, or type; or

- conditioning 340B access on ingredient-cost or pricing data, inventory-management requirements, or other information not required by State or federal law.

These protections extend to other locations that a covered entity authorizes to receive 340B drugs, which is important for multi-site entities. Each affected transaction is a separate violation.

The Act does not bar all manufacturer data requests or voluntary data-sharing arrangements; it bars conditioning 340B access on information not required by State or federal law. Covered entities should therefore distinguish voluntary arrangements from manufacturer-imposed conditions.

The Act also preserves applicable federal requirements and recognizes statutory exceptions, including certain requirements for limited-distribution drugs under 21 U.S.C. § 355-1, so manufacturer restrictions should be evaluated under both the Act and federal law.

Covered-Entity Obligations

The Act and its companion transparency law impose the following obligations:

Requirement	Statute	Who	Deadline/Standard	Note
Annual 340B report	§ 20	Covered entities. Hospitals under 100 beds, Critical Access Hospitals, Safety-Net Hospitals, and 340B grantees are exempt until January 1, 2029.	Each August 1; first grantee report due August 1, 2029	Covers recertification, acquisition costs and payments, claims volume and percentage of claims involving 340B drugs, adverse audits, charity care, and community impact
18-month patient-service rule	§ 30	All covered entities; no FQHC or grantee exemption	Patient must have received an outpatient health care service within the preceding 18 months	Applies to drugs dispensed or administered; the federal 340B patient definition continues to apply independently. "Outpatient health care service" is undefined,

				raising questions about telehealth, referrals, laboratory services, care coordination, and services at affiliated or authorized locations.
Duplicate-replenishment policy	§ 35	All covered entities; no grantee exemption	Adopt and file annually with the General Assembly; filing office and date unspecified	Policy must prevent a covered entity from replenishing a dispense that another covered entity will also replenish, and must establish a process for reimbursing manufacturers for duplicate discounts. Requires coordination with TPAs and contract pharmacies. Separate from the federal Medicaid duplicate-discount prohibition.
Medicaid 340B report	§ 25	Department of Healthcare and Family Services	January 1, 2028	Medicaid 340B utilization and net State cost or savings
Transparency data request	410 ILCS 665	Covered entities and manufacturers	Department-prescribed format and time frame	Covered entities must provide requested financial, operational, pharmacy, patient-population, and 340B utilization information. $500 per day for responses more than 30 days late; reduced $100-per-day penalty for specified small hospitals, Critical Access Hospitals, Safety-Net Hospitals, and 340B grantees.

Enforcement (Section 40)

The Attorney General enforces the Act. For Section 15 violations, a court may order injunctive relief, damages payable to the affected covered entity, civil penalties of up to $1,000 per violation, or other relief. Because the Act creates no express private right of action, covered entities facing restrictions should consider referring the matter to an Attorney General and preserving manufacturer correspondence, affected transaction records, claims data, and documentation of lost 340B savings to support enforcement and any request for relief.

The Companion Transparency Law

The 340B Transparency, Reporting, and Accountability Act (Public Act 104-0769; 410 ILCS 665) (the Transparency Act), also effective August 7, 2026, directs the Department of Insurance to study 340B participation by covered entities and manufacturers doing business in Illinois.

Manufacturers must provide prior-year 340B audits, information on 340B restrictions and their rationale, and aggregate discounts since 2020, in dollars and as a percentage of revenue.

Covered entities must provide identification and designation data; aggregate and transaction-level acquisition costs and payments by therapeutic class; payments to contract pharmacies, third-party administrators (TPAs), and pharmacy services administrative organizations; the difference between acquisition costs and reimbursement; use of 340B savings and related operating costs; financial assistance policies; patient demographics, including sliding-fee, Medicaid, uninsured, rural, and medically underserved populations; and the cost of preparing the response.

These requests may impose a substantial data-collection and reconciliation burden on FQHCs. Much of the information will require coordination among pharmacy, finance, and compliance personnel and may need to come from TPAs, contract pharmacies, and other vendors. Some demographic data overlaps with Uniform Data System (UDS) reporting, but most health centers will need additional transaction-level information from vendors. Covered entities should review existing data-sharing agreements and establish procedures for obtaining that information in the format and timeframe the Department prescribes.

Some demographic information overlaps with data FQHCs report through the Uniform Data System (UDS), but most health centers will need additional transaction-level information from their TPAs and contract pharmacies.

Submissions accompanied by a qualifying confidentiality request are protected from subpoena in private civil litigation in Illinois. The protection is not absolute: the Department may share submissions with State or federal authorities investigating potential 340B or State-law violations. Covered entities should identify confidential and proprietary information and submit confidentiality requests with each response.

The Department must report its findings to the General Assembly and Governor by July 1, 2028. The Transparency Act is scheduled to be repealed July 1, 2032.

Litigation and the National Landscape

Novartis, AbbVie, Bristol Myers Squibb, AstraZeneca, and the Pharmaceutical Research and Manufacturers of America (PhRMA) have filed five suits in the Northern District of Illinois. They argue that the Act is preempted because it expands manufacturers' obligations beyond those Congress imposed, impairs federal audit rights by barring claims-data conditions, and impermissibly regulates out-of-state transactions. The State has responded that federal law is silent on contract pharmacy distribution, the Act conflicts with no affirmative federal requirement, and any harm to audit rights is speculative.

At the October 21, 2026 preliminary injunction hearing, Judge Edmond Chang reportedly expressed skepticism about the manufacturers' preemption arguments, observing that states may regulate matters within their traditional public-health authority where federal law is silent.

The State argued that the Act applies only to drugs already purchased and cited evidence that chargeback data can support manufacturer audits without claims-level data. The court took the motions under advisement; its reported comments are not a ruling on the merits. As of this alert, no ruling has been reported, and the Act remains in effect absent a court order.

Court	State Law	Result	Current Status
N.D. Ill.	Illinois (410 ILCS 660)	Preliminary injunction motions argued October 21, 2026	Under advisement; law in effect
8th Cir.	Arkansas	Law upheld	Supreme Court denied review
5th Cir.	Mississippi; Louisiana	Law upheld	Manufacturers have sought extensions to petition for certiorari
4th Cir.	West Virginia	Panel held law likely preempted (April 2026)	Rehearing en banc granted (May 2026)
District courts	Various	Mixed: some laws preliminarily enjoined, others left in effect	Varies by state

These decisions turn on whether a state law regulates an area federal law leaves open or instead impermissibly alters the federal 340B framework and HRSA's enforcement role. The Department of Justice has supported the manufacturers' preemption arguments, and the Seventh Circuit has not addressed the issue. The Illinois outcome

may depend on the specific provisions challenged, and the Act's severability provisions could allow a court to enjoin some provisions, such as the out-of-state pharmacy provisions, while leaving others in effect.

What Covered Entities Should Do

The following steps consolidate recommended actions for FQHCs and other covered entities. Steps 1–3 should begin immediately; Steps 4 and 7 should be implemented before January 1, 2027; and Steps 5 and 6 should be completed as statutory and Department requirements dictate.

Action	Who	Deadline/Trigger	FQHC-specific Note	Evidence to Retain
1. Inventory manufacturer restrictions and quantify the impact, including claims-data conditions and out-of-state specialty and mail-order pharmacies	340B lead; TPA; wholesaler	Now	Most FQHCs rely entirely on contract pharmacies; lost savings since August 7, 2026 support any damages claim	Manufacturer policies and correspondence; affected pharmacies and NDCs; lost-savings calculations; and records of affected transactions
2. Confirm contract pharmacy authorization	340B lead; compliance	Now	Confirm OPAIS registration and a current written agreement; multi-state centers should confirm which arrangements fall within the Act. Review agreements for provisions that may conflict with the Act, such as restrictions on pharmacy locations, drug categories, data	OPAIS records; executed agreements

			submissions, and manufacturer-imposed conditions.	
3. Request restoration of access in writing, citing 410 ILCS 660/15, and consider referring continuing restrictions to the Attorney General	Legal; executive leadership	Now	Consider coordinating with the Illinois Primary Health Care Association. Preserve all manufacturer responses and document resulting financial and patient-access impacts.	Requests; manufacturer responses; transaction records
4. Apply the 18-month rule in TPA and in-house eligibility logic, and audit a sample of claims since August 7, 2026	340B lead; TPA	Before January 1, 2027	No grantee exemption applies. Adopt a written interpretation of qualifying outpatient services that addresses telehealth, referrals, laboratory services, care coordination, and services at affiliated or authorized locations. Confirm that TPA and in-house systems apply the requirement to both dispensed and administered drugs while	Written eligibility policy; TPA configuration records; eligibility settings; sample audit results; and corrective actions

			independently satisfying the federal patient definition.	
5. Adopt and file the duplicate-replenishment policy	Compliance; board or compliance committee	Adopt promptly; file annually. The statute does not specify the initial filing date or filing office. January 1, 2027 is a recommended implementation target, not an express statutory deadline.	Coordinate with other covered entities, TPAs, and contract pharmacies to prevent duplicate replenishment of the same dispense. Establish procedures to identify and reimburse manufacturers for duplicate discounts. Address federal Medicaid duplicate-discount controls separately.	Approved policy; filing confirmation
6. Prepare for the Department of Insurance data request	Finance; 340B lead; TPA	On Department request; fines once 30 days late	Centralize collection and reconciliation of information from finance, pharmacy, TPAs, and contract pharmacies. Compare information requests with UDS and HRSA reporting where appropriate, but do not assume those reports will satisfy the	Vendor data provisions; reconciliation workpapers; submissions

			Department's requests. Submit appropriate confidentiality requests and safeguard patient-level data.	
7. Prepare for the HRSA rebate pilot	Finance; pharmacy; TPA; wholesaler	Approved plans effective January 1, 2027	Identify affected drugs and review each manufacturer's HRSA-approved plan, including covered-entity exceptions, data fields, submission procedures, and rebate timing. Purchase affected drugs at WAC through the existing 340B wholesaler account, submit required claims-level data on time (generally within 45 calendar days), and reconcile rebates against the applicable 340B ceiling price. Model working-capital requirements and potential effects on sliding-fee arrangements and pharmacy access.	Manufacturer-approved plan; affected drug and NDC list; wholesaler purchasing records; claims submissions; rebate reconciliation logs; and cash-flow projections

Ongoing Considerations

Review existing data-sharing arrangements manufacturer by manufacturer; the Act restricts manufacturer-imposed conditions on access, not voluntary data submission. Expect manufacturers to seek to reinstate restrictions if the Act is enjoined. Do not assume the Act overrides an HRSA-approved rebate plan; the interaction will depend on the approved plan's terms and applicable federal law.

Brief the board periodically on litigation developments, 340B savings, compliance risks, and patient-access effects. Avoid committing restored savings to recurring expenses until the litigation is resolved. Continue using 340B program income consistent with Section 330 requirements, and calendar August 1, 2029 for the first Section 20 report applicable to FQHCs.

Hospitals and Health Systems

The same operational recommendations apply. Hospitals outside the statutory reporting deferral should assess their Section 20 reporting obligations, including the initial August 1, 2026 deadline, which preceded the Act's effective date; affected hospitals should seek legal advice on whether that deadline applies. They should also confirm whether they qualify for the reduced $100-per-day transparency penalty.

Manufacturer Considerations

- **Review contract pharmacy, distribution, claims-data, and inventory-management policies** applied to Illinois covered entities, including out-of-state contract pharmacies. The Act is in effect, and each affected transaction may be a separate violation.
- **Evaluate whether existing data-sharing requirements are voluntary** or conditions of 340B access, and review applicable federal requirements and statutory exceptions, including those for limited-distribution drugs, before changing existing policies or agreements.
- **Prepare for Department of Insurance requests concerning audits**, restrictions, and historical discounts, and request confidential treatment where available.
- **Monitor the preliminary injunction ruling**, any Seventh Circuit appeal, and developments in other circuits.
- **Confirm that data requirements** under any HRSA-approved rebate plan remain within approved parameters, including drug coverage, covered-entity exceptions, claims-level data, and rebate procedures.

Transactional Considerations

In acquisitions, financings, and affiliations involving Illinois covered entities, contract pharmacies, or manufacturers, diligence should address 340B revenue and savings, manufacturer restrictions and disputes, compliance with the 18-month patient-service and duplicate-replenishment requirements, and readiness for state reporting and the HRSA rebate pilot. Buyers should also assess the reliability of TPA and contract pharmacy data, outstanding manufacturer disputes, potential duplicate-replenishment exposure, and the effect of rebate timing on working capital and projected 340B savings. Transaction documents should include appropriate representations, covenants, and indemnities addressing 340B compliance, contract pharmacy arrangements, outstanding manufacturer disputes, reporting obligations, and liabilities under the new Illinois laws.

Looking Ahead

Given the Act's severability clauses, a ruling for the manufacturers could be limited to particular provisions, and either outcome will likely be appealed to the Seventh Circuit. With the circuits divided, Supreme Court review is a realistic possibility. Meanwhile, Illinois covered entities should comply with the Act while preparing for the possibility that its contract pharmacy protections are enjoined. We will continue to monitor the litigation, HRSA rebate developments, and the Department of Insurance study.

How We Can Help

Hinshaw advises FQHCs, hospitals, pharmacies, and other healthcare organizations on 340B compliance, contract pharmacy arrangements, and related operational and transactional matters. We help covered entities evaluate the new Illinois requirements, develop patient-eligibility and duplicate replenishment policies, review manufacturer and contract pharmacy arrangements, prepare for Department of Insurance reporting, and assess the operational and financial implications of HRSA's rebate pilot.

We also represent healthcare organizations in disputes over manufacturer-imposed restrictions and advise on 340B issues in acquisitions, affiliations, and other strategic transactions. As the Illinois litigation and federal regulatory landscape continue to evolve, we help clients assess their compliance obligations, protect access to 340B pricing, and preserve the financial resources needed to serve their patients and communities.

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[1] The in-state and out-of-state prongs of the contract pharmacy definition are expressly severable. 410 ILCS 660/97.

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