340B PROGRAM OVERSIGHT

340B Oversight in an Era of Accountability

What is changing, what it means for revenue cycle, and what to do now

Presented by:



Emily Pfister PMP, CHC
emily_pfister@ajg.com



Steve Zielinski RPH
steve_zielinski@ajg.com

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Insurance | Risk Management | Consulting

Where We Are Going

I **The 340B environment is changing**

II **Regulatory and policy developments**

III **How oversight changes expectations**

IV **Building a future ready framework**

V **Key takeaways and questions**

You will leave with

1. A **status map** of major 340B developments
2. **Five oversight areas** to test in your own shop
3. A **30-day action list**

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The 340B Environment Is Changing

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Scrutiny Is Coming from Three Directions

Policymakers

Budget proposals, agency reorganization, and payment policy are all putting 340B in the spotlight. Questions now focus on who benefits and how savings are used.

Manufacturers

Claim level data demands, contract pharmacy limits, and a new rebate model. Manufacturers are asking hospitals to prove eligibility transaction by transaction.

Regulators

CMS and HRSA want better data. The trend is a move from checking a box to showing evidence on demand.

The compliance conversation is shifting to demonstrable accountability.

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Six Questions Every Leader Should Be Asking

1 Who owns it?
Who is the named executive accountable for 340B compliance and financial results?

2 Can we prove it?
Can we produce claim level 340B data within 45 days of dispensing?

3 What is at risk?
What is our dollar exposure if proposed Medicare payment changes are finalized?

4 Where do savings go?
Can we show how retained 340B savings are used, with documents?

5 Are we audit ready?
Would our last self or external audit hold up in an HRSA or manufacturer audit?

6 Who else touches it?
What do our vendors do on our behalf, and who checks their work?



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Regulatory and Policy Developments

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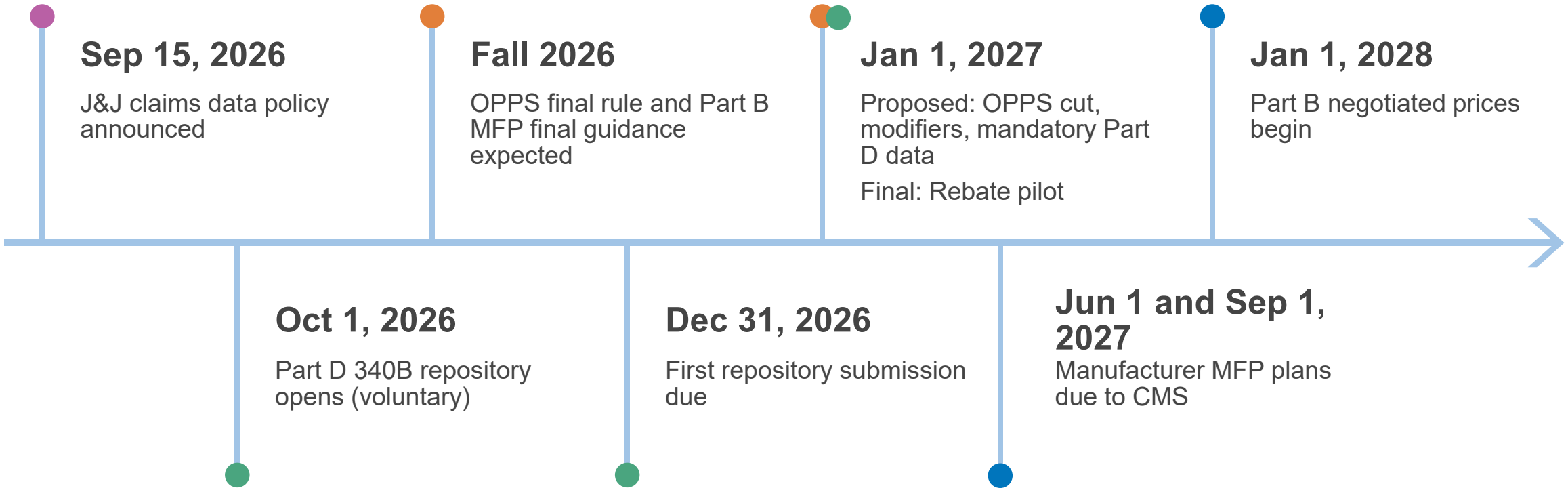
Status Map: What Is Real and What Is Not

Status as of October 13, 2026

Development	Status	Key date	What it means
HRSA oversight moves to CMS	PENDING	Expected Quarter 4 2026	Possible CMS style data and payment rules
CY2027 OPPS 340B payment	PROPOSED	Final rule expected this fall; effective 1/1/2027	ASP plus 6% to ASP minus 33.4% for most 340B drugs
Mandatory Part D 340B data (CY2027 PFS)	PROPOSED	Claims dated 1/1/2027 forward	Claim level reporting required
Part D 340B claims repository	GUIDANCE	Opens 10/1/2026; first submission 12/31/2026	Voluntary now; test your data
Part B negotiated price (MFP) effectuation	DRAFT	Comments closed 9/18/2026; final this fall, drugs to be included in 2028	Lower of MFP or 340B ceiling; TB modifier
Medicaid changes (OBBBA)	FINAL	Phasing in over years	Pressure on DSH percentage and hospital financing
Manufacturer claims data policies	POLICY	Merck, J&J, Eli Lilly throughout mid 2026	340B pricing suspension for non compliance
HRSA rebate model pilot (revised)	FINAL	Starts 1/2027; 10 manufacturers for 21 drugs	Buy at WAC; claims in 45 days; rebate in 10

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The Next 18 Months at a Glance



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HRSA Oversight May Move to CMS

What is happening

- Reported: HHS expected to move the Office of Pharmacy Affairs from HRSA to CMS in quarter 4 2026.
- Neither agency has confirmed in the sources we reviewed.
- Also proposed in the FY2026 and FY2027 budget requests.
- Why it matters:
  - CMS already writes 340B payment, modifier and data rules for Medicare.
  - HRSA focuses on access and safety and this may conflict with CMS focus on payment

Do now

1. **Assign** an owner to track HHS announcements weekly.
2. **Map** affected registration, recertification, audit and reporting processes.
3. **Prepare** for quarterly, claim-level reporting deadlines.
4. **Brief** leadership regularly on impacts and decisions.

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PENDING: reported, unconfirmed

CY2027 OPPS Payment for 340B Drugs

ASP minus 33.4%	about 37%	$2.3 billion	Jan 1, 2027
proposed rate for most 340B drugs (today: ASP plus 6%)	lower payment per drug	estimated CY2027 remedy offset	proposed effective date

What is happening

- Basis: CMS drug acquisition cost survey. About 23.1% of 340B hospitals gave usable data.
- Administration is saying hospital wide budget neutral.
  - Infusion and Oncology heavy programs will probably not be able to stay budget neutral due to high cost products
- Remedy offset would rise from 0.5% to 3% for hospitals enrolled before 1/1/2018.
- New modifiers: JG (discounted 340B), TB (exempt 340B), XX (non 340B).
- Proposed exemptions: sole community, PPS exempt cancer, and children's hospitals.

Do now

1. **Model** exposure by service line, site, payer and product: about $394 less per $1,000 ASP.
2. **Verify** JG, TB and XX across charge master, claim scrubber and billing before January.
3. **Confirm** enrollment date and exemption status.
4. **Budget** low, base and high FY2027 scenarios before the rule takes effect.

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Part D 340B Claims Repository

Oct 1, 2026 — repository opens

Dec 31, 2026 — first quarterly submission

Jan 1, 2027 — proposed mandatory start (CY2027 PFS)

What is happening

- Purpose: test whether entity data can identify 340B units to exclude from Part D inflation rebates.
- Seven fields: 340B ID, record indicator, date of service, Rx reference, fill number, NDC-11, dispensing pharmacy NPI.
- 340B Administrators may submit for you, but you stay accountable for accuracy.
- CMS says the data is not used for MFP effectuation now.

Do now

1. **Decide** on voluntary participation.
2. **Verify** all 7 fields. Keep claim evidence ready on demand.
3. **Test** Jan–Sep 2026 claims before Dec 31.
4. **Oversee** vendor/340B Administrator accuracy and timing. Review agreements.

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GUIDANCE: voluntary now

PROPOSED: mandatory 2027

Part B Negotiated Prices in 2028

What is happening

- Applies to Part B selected drugs starting January 1, 2028 (IPAY 2028). Draft guidance issued July 16, 2026.
- Manufacturers may pay prospectively or by refund, within 14 days of claim data from the Medicare Transaction Facilitator.
- For 340B, the manufacturer provides the lower of MFP or 340B ceiling price.
- CMS will use the TB modifier to flag 340B claims.
- Comments closed September 18. Final guidance expected this fall.

Do now

1. **Identify** Part B drugs on the 2028 selected list.
2. **Compare** MFP and 340B ceiling prices by drug on an ongoing basis.
3. **Prepare** for Transaction Facilitator enrollment and NDC-11 claims.
4. **Model** refund cash flow and operational impacts in advance.

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Coverage and Financing Pressure

about $1 trillion
10-year federal Medicaid reduction

314 of about 2,500
hospitals could lose DSH eligibility (analysis)

37 states
with state directed payment cuts (analysis)

What is happening

- CMS estimated 2.3 million people could lose Medicaid coverage in 2027 due to new work requirement and related administrative processes
- Disproportionate Share Hospital (DSH) 340B eligibility depends on the DSH patient percentage which combines the Medicare/SSI fraction and the Medicaid fraction
- Fewer Medicaid days can push some hospitals below the threshold. Effects phase in over years.
- Medicaid duplicate discount rules still apply, so carve in and carve out accuracy matters.
- The projections are third party analyses, not CMS or HRSA figures.

Do now

1. **Stress-test** DSH eligibility under Medicaid volume scenarios.
2. **Reconcile** carve-in/out choices and the Medicaid Exclusion File with each state.
3. **Monitor** and document duplicate discount controls.
4. **Review** eligibility options, including reclassification, with counsel.
5. **Include** Medicaid scenarios in long-range planning.

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FINAL: enacted law (OBBBA)

Data Demands and Restrictions

Data reporting

- 16 manufacturers have announced programs that will now also include in house hospital pharmacies
- Most programs include:
  - Allowing for at least two notices before 340B pricing is suspended.
  - Pricing restored within 10 business days of a compliant submission.
- Example: the J&J policy includes claim level data within 45 days of dispensing; 60 days for specialty drugs.

Restrictions

- Contract pharmacy limits continue, and now reach FQHC's, Ryan White facilities, etc.
- State contract pharmacy laws are being litigated, with federal involvement.
- Legal challenges to these policies are ongoing.
- Watch for other manufacturers to adopt similar terms.

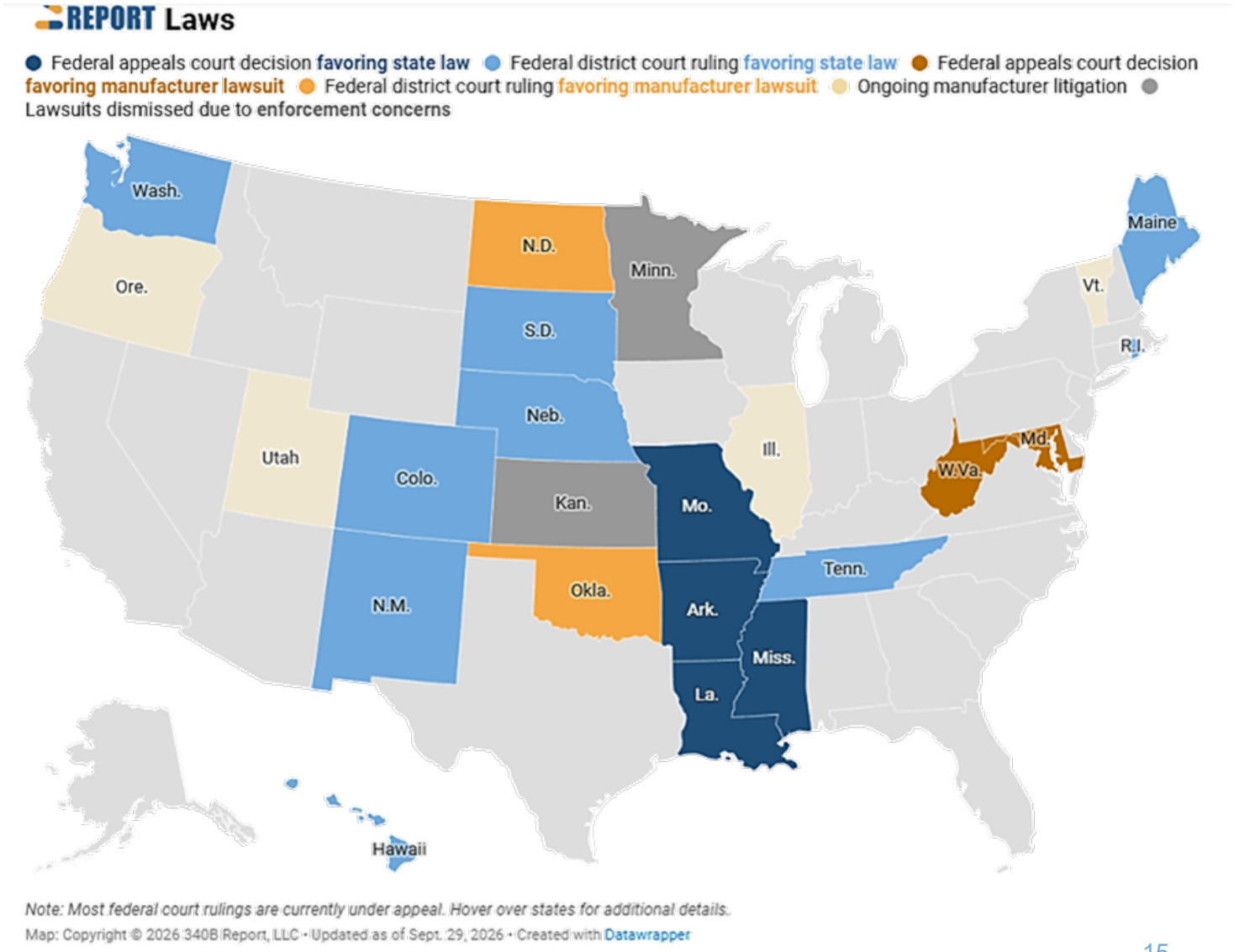
Do now

1. **Log** and triage manufacturer notices with dates and legal review.
2. **Test** claim-data workflows against the 45-day deadline.
3. **Respond** in writing with counsel. Retain the record.
4. **Track** above-ceiling purchases after a suspension.

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Federal Court Rulings on State 340B Contract Pharmacy Access

State-by-state litigation status for 340B contract pharmacy access



Source: https://340breport.com/trackers/contract-pharmacy-access-laws/

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The HRSA Rebate Model Pilot

Jan 1, 2027	about 5.5%	45 days	10 days
pilot start	of 340B purchases	to submit claims	for rebate payment

What is happening

- Scope: 10 manufacturers for 21 drugs chosen for Medicare negotiation in price years 2026 and 2027.
- Manufacturers opt in. Once approved, covered entities must participate.
- Hospitals buy at WAC, then submit claims with NDC-11, quantity, prescriber ID, 340B ID and plan ID.
- Manufacturers cannot deny a rebate over duplicate discounts. Disputes go to HRSA and 42 CFR Part 10.
- The August 2025 pilot was enjoined and later vacated (Feb 10, 2026).

Do now

1. **Model** WAC funding needs during the 10-day rebate lag.
2. **Build** a claims workflow that meets the 45-day window.
3. **Confirm** HRSA-approved manufacturers.
4. **Define** the dispute process and denial log before disputes arise.

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FINAL NOTICE: approvals pending

All of It Converges on Data and Oversight

Medicare and CMS
Payment cuts, modifiers, repository

Medicaid
Eligibility and financing pressure

Manufacturers
Claims data, restrictions, rebates

Regulators
Audits and program integrity



Better data. Better oversight.

- Claim level data on demand
- Documented governance
- Accountable vendors

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How Oversight Changes Expectations

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Five Areas of Oversight



Governance and Oversight

Named owner, cross functional committee, clear authorities



Data integrity

Transaction level proof, audit trails, reports on demand



Finance

Know retained savings, timelines and reimbursement risk



Vendors

Data quality and delegation oversight



Transparency

Track and document how savings are used. For example – Charity care, medication assistance, infrastructure, new service lines

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Governance and Oversight:

Who Is Accountable

What is happening

- Executive accountability: a named executive owns 340B results and compliance.
    - More than just the OPAIS signatory
- Cross functional oversight: pharmacy, revenue cycle, finance, compliance, legal, IT and supply chain at one table.
- Regulations impacting change: know which authorities are law and which are proposals.
- Oversight: 340B dashboards and reporting

Do now

1. **Name** the accountable executive in writing.
2. **Charter** a 340B oversight committee. Set a meeting schedule.
3. **Report** to the board or audit committee at least twice a year.
4. **Maintain** a current policy and regulatory change log.

Core authorities: final

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Data Integrity:

Transaction Level Proof



What is happening

- Transaction level accountability: each 340B unit traces from encounter to purchase.
- Audit trails: who changed what, and when.
- Reporting capability: 45 days to produce claim data upon request

Do now

1. **Trace** 25 claims end to end. Document each break.
2. **Map** and document all 7 repository fields and rebate data elements.
3. **Test** JG, TB and XX billing logic.
4. **Retain** audit logs. Test reports on demand and reconcile results.

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Finance:

Savings, Timelines and Scrutiny

$10,600	$6,660	$3,940
Medicare pays today (ASP plus 6%, $10,000 ASP)	Proposed (ASP minus 33.4%)	less per claim in this example

What is happening

- Retained 340B savings: know the number by source, net of program cost.
- Financial timelines: 10 day rebate, 45 day claims, 14 day MFP refunds, remedy offset to about 2029.
- Reimbursement scrutiny: CMS, payers and PBMs are all asking what 340B drugs cost and pay.

Do now

1. **Track** gross and net savings by payer on a dashboard.
2. **Model** cash flow scenarios and payment calendars.
3. **Reconcile** 340B purchases and claims monthly.
4. **Review** 340B and modifier terms in payer contracts.

Exposure figures are proposed

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Vendors:

Outsourcing Does Not Outsource Risk

Select → Contract → Monitor → Test → Report

What is happening

- Data integrity: TPAs, split billing software and contract pharmacies produce your evidence.
- Delegation oversight: CMS says entities stay accountable for accuracy even when a TPA submits.
- Contracts often say little about data timing, audit rights or subcontractors.

Do now

1. **Maintain** a current vendor inventory and each vendor's scope.
2. **Close** contract gaps in data deadlines, audit rights and subcontractor disclosure.
3. **Test** vendor output quarterly.
4. **Require** support for repository and manufacturer data requests.

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Transparency:

Show How Savings Are Used

What is happening

- Tracking and documenting use: link savings to services, charity care and access programs.
- Community benefit reporting: expect more questions beyond Form 990 Schedule H, from states, payers and policymakers.
- Evidence should be recorded when decisions are made, not rebuilt later.

Do now

1. **Record** savings use: project, amount, date and approver.
2. **Align** the register with community benefit reporting.
3. **Explain** 340B impact in plain language the board can support.
4. **Review** and update the register at each committee meeting.

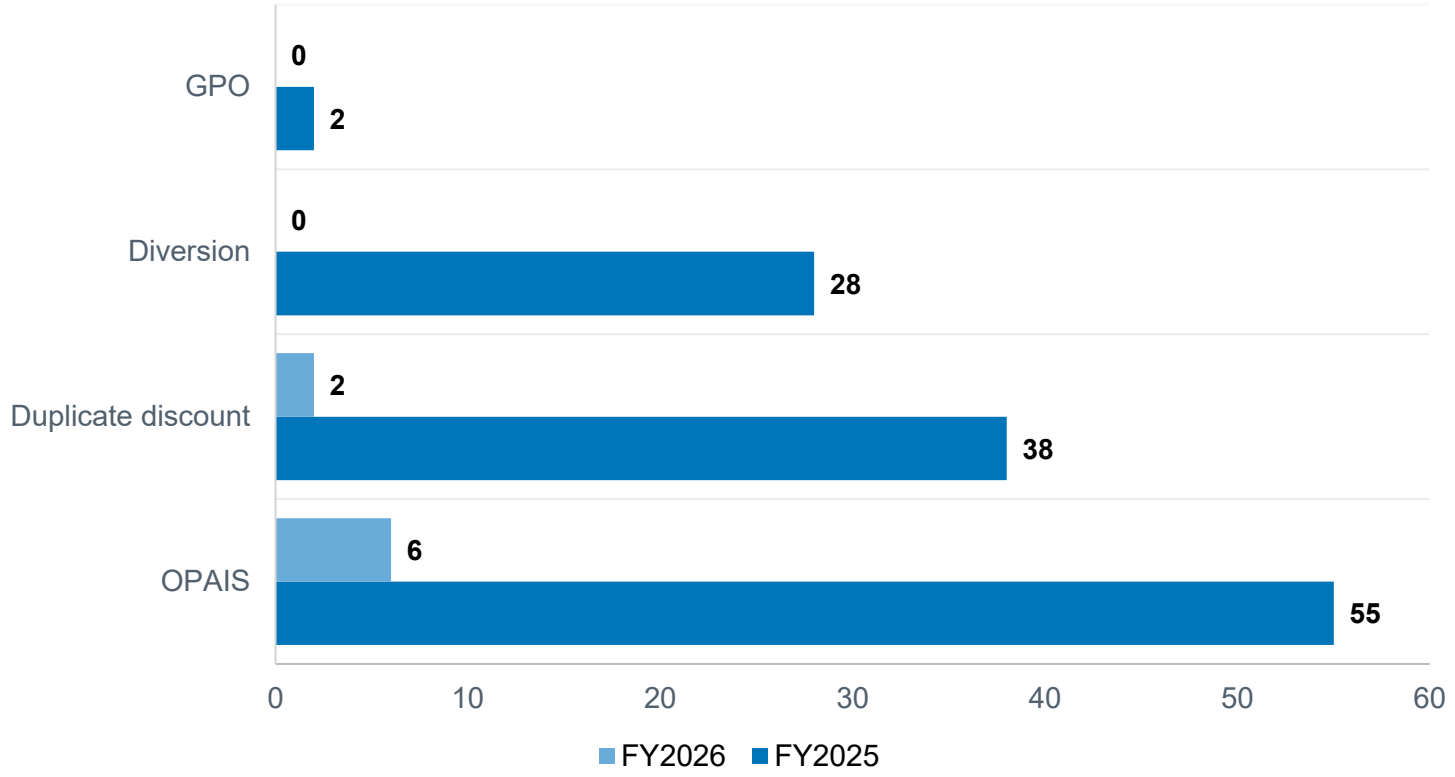
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Recent Audit Findings

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OPAIS records remain the dominant hospital audit finding

Audit-level category counts; an audit can appear in more than one category



54.2%

of FY2025 hospital audits had an adverse finding

22.6%

of currently posted FY2026 hospital audits had an adverse finding

FY2026 is partial: 31 hospital audits posted versus 142 in FY2025.

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HRSA Audit Findings and Remediation

Use this taxonomy to distinguish formal penalties from operational corrective action

NOTE: FY2026 is partial; counts reflect posted hospital audits reviewed September 2, 2026. Categories may overlap

Action	FY25	FY26	Classification	Hospital response
Manufacturer repayment	44	1	Formal sanction	Identify affected claims; offer repayment to affected manufacturers.
Termination	14	0	Formal sanction	Terminate cited facility or contract-pharmacy registration and stop 340B use.
OPAIS update	55	6	Required remediation	Correct records, add eligible sites, and remove inaccurate registrations.
State Medicaid remediation	38	2	Required remediation	Correct MEF/billing indicators; reconcile with the state; document the outcome.
Diversion controls	28	0	Required remediation	Correct patient, prescriber, site, and inpatient eligibility controls; test affected claims.
GPO remediation	2	0	Required remediation	Correct procurement and inventory controls for covered outpatient drugs.

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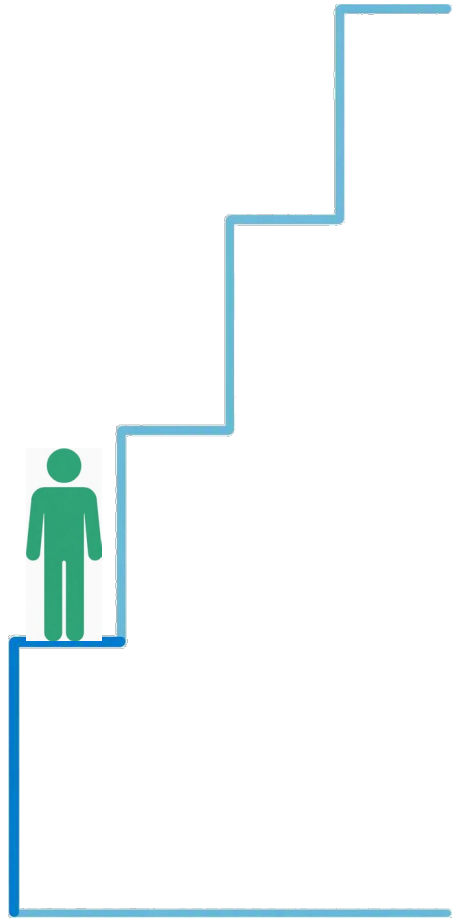
Building a Future-Ready Framework

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Step 1: Run a Readiness Assessment

Area	Key test	Evidence to collect
Governance	Is there a named owner and active committee?	Charter, minutes, board reports
Finance	Can we state net savings and OPPS exposure?	Dashboard, scenario model
Transparency	Can we show how savings were used?	Savings use register
Data integrity	Can we trace 25 claims and pull data in 45 days?	Trace results, timed report
Vendors	Do contracts and testing cover data and delegation?	Vendor list, contracts, test logs

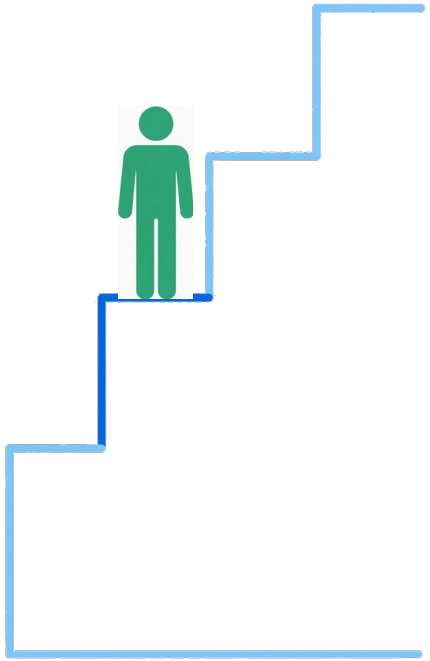


- Score each area 1 (ad hoc) to 4 (monitored).
- Interview 6 to 8 stakeholders.
- Document everything.

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Step 2: Find the Oversight Gaps

- No named executive owner or charter
- Policies not updated for 2027 changes
- Cannot produce claim level data within 45 days
- Modifier logic (JG, TB, XX) untested
- Savings use not tracked
- Medicaid carve in or out not reconciled with the state
- Vendor contracts silent on data timing and audit rights
- Self audits rare or undocumented



Rank by likelihood and impact.
Fix the top three within 30 days.

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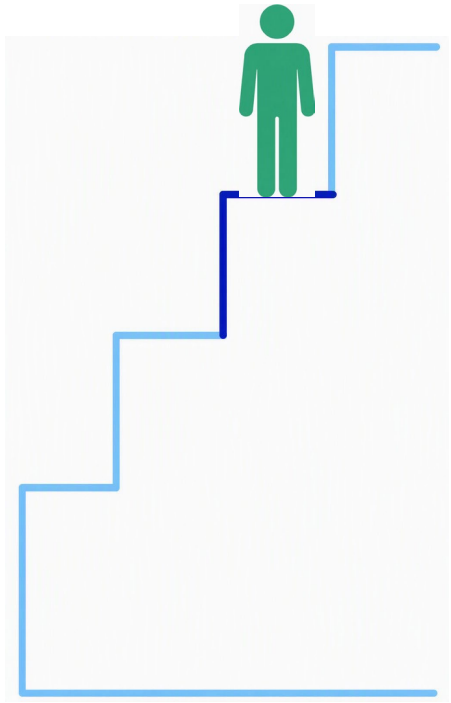
Step 3: Strengthen Audit Readiness

Audit scope and evidence

- Prepare for HRSA, manufacturer and internal audits covering eligibility, diversion, duplicate discounts and GPO prohibition.
- Maintain an audit binder with policies, registration records, contracts, eligibility support and self-audit results.
- Document an audit response playbook, including the process for disclosing a material breach to HRSA.

Testing and follow-through

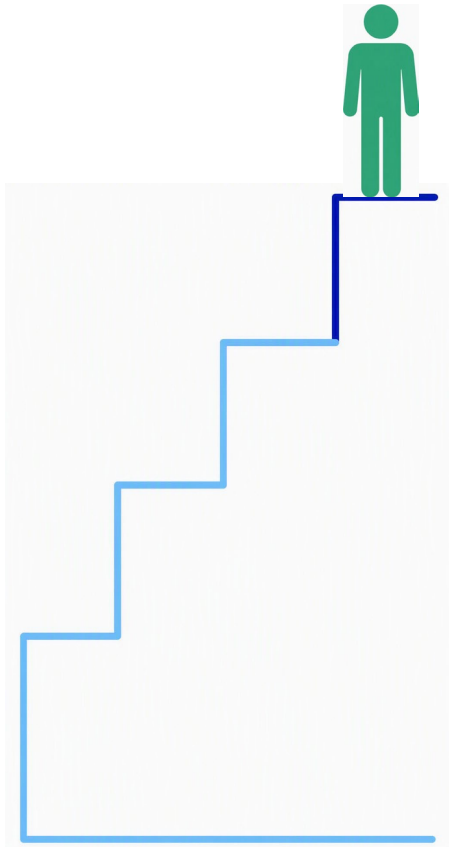
- Design a self-audit program with a regular schedule. Test a sample each quarter and document the results.
- Run one mock audit before year end.
- Maintain a corrective action log. Assign each finding an owner and date, and track it to closure.



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Step 4: A Proactive Governance Model

Governance	Cadence	Responsibility
Board or audit committee	**Quarterly or twice yearly**	Sets expectations and reviews results
340B oversight committee	**Monthly**	Owns policy, risk, findings and regulatory change
Operations	**Daily and weekly**	Pharmacy, revenue cycle and IT run controls and testing



Measures to report

- Share of claims passing validation
- Duplicate discount exceptions
- Days to produce claim level data
- Savings tracked and documented
- Vendor findings closed on time
- Regulatory changes assessed

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How BluePeak Can Help

340B readiness assessment

Scored review across all five areas

Regulatory watch and impact

Status tracking and briefs for leaders

Governance design

Charter, committee, policies, change log

Data and reporting

Field mapping, modifiers, repository readiness

Vendor oversight

Inventory, contract review, testing

Audit readiness

Mock audits and corrective action tracking

BluePeak: experts in compliance and operations for regulated programs

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Key Takeaways

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Key Takeaways

1. **The future regulatory landscape remains uncertain.** Plan for scenarios, not one outcome.

2. **Oversight expectations are rising** regardless of which policy is finalized.

3. Organizations that strengthen **governance, transparency and accountability** now will be best positioned to adapt.



Your first 30 days: see Appendix A

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Appendix

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Appendix A: Your first 30 days

Weeks 1 and 2

- [ ] Name the executive owner and 340B committee chair
- [ ] Log all manufacturer notices received
- [ ] Confirm status of each item on the status map
- [ ] List every vendor that touches 340B data
- [ ] Pull enrollment date and exempt status for OPPS

Weeks 3 and 4

- [ ] Model OPPS exposure with low, base and high cases
- [ ] Test JG, TB and XX modifier logic
- [ ] Trace 25 claims end to end; time a 45 day data pull
- [ ] Decide on the Part D repository voluntary window
- [ ] Start a savings use register

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Appendix B: Sources

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Appendix C: The 340B Report Difference

- ***Authoritative*** – Combined 8 decades of experience in journalism and 340B leadership
- ***Timely*** - Alerts you in real time
- ***Independent*** – Hear from all sides
- ***Digestible*** - Concise and understandable
- ***Focused*** - We live and breathe 340B

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