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Insights

Top 5 Takeaways from the Winter 340B Coalition Conference – San Diego, CA

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The 340B Coalition Winter Conference wrapped up its annual conference last week in San Diego, California. A consistent message throughout the conference was that the 340B Program remains a critical lifeline for covered entities, but it is operating in an environment of heightened legal risk, political scrutiny, and operational complexity. Below are five key themes that emerged consistently across federal panels, state updates, provider sessions, and regulator discussions, each with practical implications for covered entities and their partners.

1. The Fight Over a 340B Rebate Model Is Down but Not Out

HRSA's proposed rebate model is currently stalled, but reform is not over. Federal courts blocked the rebate program from taking effect on January 1, 2026, and on February 10, 2026, the District Court effectively ended HRSA's rebate proposal at HRSA's request. However, just three days later, HRSA filed a request for information seeking to understand administrative, operational, financial, and drug access concerns with rebates, with comments due by March 19, 2026. Conference panelists repeatedly emphasized the importance of providing information about the operational and fiscal challenges of a rebate proposal to HRSA during such notice and comment periods.

2. The Inflation Reduction Act Is Reducing 340B Savings

Multiple sessions confirmed that the Inflation Reduction Act ("IRA") is already having a material financial impact on covered entities, particularly for high-cost and specialty drugs. Some systems reported projected 340B savings reductions of 30–35%, with multi-million-dollar implications concentrated among a small number of medications. The overlap between the IRA's Maximum Fair Price ("MFP") framework and 340B non-duplication requirements remains unsettled. There is no reliable, automated mechanism to prevent duplication, and both providers and manufacturers are struggling with inconsistent data, optional coding fields, and limited access to remittance information. For now, covered entities should assume manual oversight will remain necessary and should track refunds, credits, and liabilities carefully to avoid repayment exposure.

3. Reporting and Contract Pharmacy Laws Are Expanding Across the United States

States continue to be highly active in the 340B space, particularly through contract pharmacy protection statutes and stand-alone or bundled reporting requirements. Over 20 states now have contract pharmacy protection laws, and courts are mostly upholding these laws. On February 9, 2026, the Fifth Circuit Court of

Appeals upheld Louisiana's contract pharmacy laws, disagreeing with drug manufacturers' contentions that federal law supersedes the state law and that the state law is unconstitutional. At the same time, 340B reporting and transparency laws are becoming more common. The challenge with such laws is that aggregated reporting data can be misleading when removed from clinical and financial context, increasing the importance of proactive education, advocacy, and internal data validation. Multiple panelists stressed the need for strategic advocacy to counter prevailing narratives and misinformation about the 340B program.

4. HRSA Audit Risk Is Rising and the Scope Is Expanding

HRSA audit activity continues to increase, with recurring findings tied not to diversion, but to data integrity and registration accuracy. Common issues include: inaccurate OPAIS records; incorrect Medicaid Exclusion File entries; ownership documentation for entity-owned pharmacies; and incomplete or outdated cost report information. Notably, recent updates to the FY 2026 HRSA Data Request List expanded expectations around documentation of where drugs are furnished, not just dispensed, signaling broader audit scrutiny across care settings. These changes are located and described in Sections 2B, 2C, 3C, 5A, 7, and 9, Covered entities were encouraged to review these findings and test compliance against actual operational capacity and avoid policies that cannot be consistently executed.

5. Operational Optimization Is No Longer Optional

Several panelists emphasized the need to innovate to cope or adapt to growing restrictions and program scrutiny. With margins tightening and external pressure increasing, providers are increasingly focused on operational strategies to stabilize 340B program value, including: increasing in-house pharmacy and referral capture; expanding specialty pharmacy services; and improving data governance across vendors, TPAs, and EMR systems. Several panels emphasized that even modest improvements in capture rates can translate into six-figure revenue impacts, while poor data integration remains one of the most common sources of compliance exposure.

Looking Ahead

Despite increased scrutiny, litigation, and regulatory complexity, the message from the conference was not that the 340B Program is unraveling. The program remains operational, legally viable, and capable of delivering meaningful savings to covered entities that rely on it to support access to care. At the same time, the environment in which 340B operates has changed. Innovation, disciplined compliance, and close operational oversight are no longer optional, but are essential to sustaining program value.

If you would like help assessing how these developments affect your organization or would like a deeper dive on any of the issues above, please contact Brandon W. Shirley.
