

Insights

Indiana's New 340B Hospital Reporting Requirement — First Filing Due April 1, 2026

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By: Brandon W. Shirley

Beginning April 1, 2026, and every year thereafter, 340B hospital covered entities with an Indiana service address must file an annual 340B report with the Indiana Department of Health (“IDOH”) covering activity from the prior calendar year. The requirement applies to DSH hospitals, children’s hospitals, and critical access hospitals that participate in the 340B Program. Failure to submit the report by April 1 triggers a statutory fine of \$1,000 per day until the report is filed. Indiana enacted this requirement in Senate Enrolled Act 118 (2025), and IDOH has now issued the long awaited guidance along with a REDCap survey link for submissions.

Background: Senate Enrolled Act 118 (2025)

As has been done in other states, Senate Enrolled Act 118 expanded state-level oversight of the 340B Program in Indiana by imposing new reporting and transparency requirements on certain covered entities in Indiana. Specifically, the new law requires annual, detailed disclosures of 340B drug purchasing, reimbursement, vendor payments, and use of program savings. SEA 118 establishes a firm April 1 annual reporting deadline, backed by a \$1,000-per-day penalty for late filings, and requires IDOH to publish a statewide aggregated report each year.

IDOH Guidance

As stated in its guidance and REDCap reporting tool, the IDOH makes clear that data must be complete, accurate, and defensible, not high-level estimates or aspirational summaries. IDOH confirms that all affected 340B hospitals with an Indiana service address must file, regardless of where the hospital system is headquartered. The IDOH guidance also resolves a key structural question by requiring parent entities to submit a single consolidated report that captures all associated child sites, outpatient and off-site locations, contract pharmacies, and other related organizations. This approach places the compliance burden squarely on system-level coordination and data aggregation.

Critically, IDOH emphasizes that reports must be based on actual, verified calendar-year data. Estimates are permitted only where reporting is truly infeasible, and only if the hospital clearly identifies the estimate, explains why actual data could not be provided, and supplies a detailed methodology with supporting documentation. In effect, estimates are treated as an exception that must be justified, not a convenience.

What Affected Entities Should Do Now

With the April 1 deadline fast approaching, covered entity hospitals should promptly convert the guidance into repeatable reporting workflows, align pharmacy, finance, and compliance teams, and validate data sources to ensure timely, accurate, and defensible submissions each year.

Hospitals should also keep CMS's 340B drug acquisition cost survey on their compliance calendar; although CMS has set a March 31, 2026, due date, hospitals continue to evaluate whether to submit in the absence of a clear legal requirement. If you have any questions about your 340B Program, contact Brandon W. Shirley.

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