Indiana Department of Health

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340B Drug Pricing Program Reporting: Assistance Document for Compliance with IC §16-40-6

This document is provided by the Indiana Department of Health (IDOH) Consumer Services and Health Care Regulation Commission (CSHCR) in order to assist Covered Entities in achieving reporting compliance for certain 340B drug pricing program information required to be reported due to the enactment of SEA 118 in 2025 (collectively, the Report). This guidance document has been drafted after review of similar reporting programs in other states to assist first-time Indiana reporters. The IDOH is dedicated to providing ongoing support; therefore, please note that this document may undergo periodic revisions. These updates will be issued to address emerging questions, incorporate necessary clarifications, and adapt to any evolving insights gathered during subsequent reporting periods.

Definitions

Covered Entity

"340B Covered Entity" or "Covered Entity" for purposes of this reporting requirement in Indiana is only those entities as defined in United States Code, title 42, section 256b(a)(4)(L) through (O), with a service address in Indiana as of January 1 of the reporting year. All facilities that are identified as child sites or grantee associated sites under the federal 340B Drug Pricing Program are considered part of the 340B Covered Entity.

Child Sites

"Child Sites" are associated locations of a covered entity that benefit from the 340B purchasing program. As noted by the Health Resources and Services Administration FAQ document, "For hospitals, all clinics located off-site of the parent hospital, regardless of whether those clinics are in the same off-site building must register as child sites of the parent 340B-eligible hospital if the covered entity purchases and/or provides 340B drugs to patients of those facilities."

Dispensed Drugs

These are 340B eligible medications that are primarily provided to patients for self-administration, typically taken orally or applied topically. Dispensed drugs are commonly sourced through various pharmacy channels, including traditional retail pharmacies, mail-order services, or specialized pharmacies. This category broadly includes all medications distributed via contract pharmacies or in-house pharmacy operations. For billing purposes, these drugs are generally processed through the patient's pharmacy benefit plan and are identified using unique National Drug Codes (NDCs).

Administered Drugs

In contrast to dispensed drugs, "Administered Drugs" are 340B eligible medications that are delivered directly to patients by a healthcare professional within an outpatient setting. Examples of such settings include clinics or outpatient surgery centers. These medications are typically given via injection or infusion. From a billing perspective, administered drugs are usually billed under the patient's medical benefit, utilizing specific procedural codes such as J-, Q-, and certain A-codes, which denote the clinical service provided.

Contract Pharmacy

A "Contract Pharmacy" serves as a critical extension of a 340B Covered Entity. It is an external pharmacy that has a formal, established arrangement with a Covered Entity to dispense drugs that have been purchased under the beneficial pricing terms of the 340B Drug Pricing Program. This partnership allows Covered Entities to expand access to affordable medications to their eligible patient population beyond their immediate physical site.

Payor Type

Accurate categorization of payor types is fundamental for financial reporting and understanding revenue streams related to 340B drugs.

Commercial This category includes all private or commercial health insurance plans. Any entity acting as a payor for 340B drugs that falls outside of government-sponsored programs (Medicare, Medicaid) should be classified here.

Medicare This encompasses all Medicare programs involved in paying for 340B drugs, including Medicare Part D (prescription drug coverage), Medicare Part B (medical insurance), and any

other Medicare-affiliated plans like Medicare Advantage (Part C) or Medigap policies. When reporting, this line should include any co-payments, coinsurance, or other patient cost-sharing amounts collected from Medicare beneficiaries, in addition to the Medicare reimbursement itself. It's important to note that while some identifying numbers (BIN or PCN) might overlap with commercial plans, the primary payor's identity determines the classification.

Medicaid/Indiana Health Coverage Program This category specifically covers any Medicaid plan, including the Indiana Health Coverage Program (IHCP) or Indiana Medicaid, as well as Managed Care Entities (MCEs) operating under Medicaid. Like Medicare, this line should include all co-payments, coinsurance, and other cost-sharing amounts paid by Medicaid/Medical Assistance patients, in addition to the Medicaid reimbursement itself. Again, shared BIN/PCN numbers with commercial plans require careful primary payor identification.

Clarification on Dually Eligible Patients (Medicare and Medicaid) For patients who are dually eligible for both Medicare and Medicaid, drug claims often involve multiple payors. Typically, Medicare Part D acts as the primary payor for its portion of the claim. Medicaid then covers the patient's cost-sharing responsibility (e.g., co-payments, deductibles) that Medicare would otherwise leave to the patient. For reporting purposes, please ensure Medicare's payments for drugs for these dually eligible patients are attributed to the "Medicare Payor" line. The portion covered by Medicaid for patient cost-sharing should be accurately recorded under the "Medicaid/Indiana Health Coverage Program Payor" line.

Other This is a residual category for any payors not falling under Commercial, Medicare, or Medicaid/IHCP. Examples include, but are not limited to, workers' compensation programs, auto insurance claims, grant funding specific to drug costs, and direct cash payments from uninsured individuals. Crucially, this category should not include cost-sharing amounts (co-pays, coinsurance, deductible amounts) paid by enrollees of commercial insurance, Medicare, or Medicaid/IHCP, as those should be allocated to their respective primary payor lines.

Claims

“Claims” is a general term used here to describe each distinct prescription fill that caused a payment to be received by the Covered Entity regardless of the payment source, i.e. insurance reimbursement, cash, etc.

Reporting Year

The reporting year is the calendar year (January 1-December 31) for which the data being provided covers. For example, a report submitted in March 2025 would report data from the 2024 calendar year.

Who Must Report

All covered entities that are approved by HRSA to participate in the 340B drug discount program under Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. § 256b(a)(4)(L) – (O) and have a service address within the state of Indiana as of January 1 of the reporting year are required to submit the 340B Drug Pricing Program Report.

Covered Entities that have a parent/child relationship with another entity should submit a combined report. Each report should include data from the parent entity, as well as any child sites, grantee associated sites, hospital outpatient sites, offsite outpatient sites, contract pharmacies, and any other organization associated with the Covered Entity. For example, all 340B transactions for affiliated sites that share the same root HRSA ID (e.g., DSH12345-00) but have different suffixes (e.g., DSH12345-01) must be submitted in a single consolidated report for the parent Covered Entity.

Where Reports Should Be Sent

Reporting data should be sent to IDOH via completion of the REDCap form accessible at https://redcap.isdh.in.gov/surveys/?s=43EJ4MX7KJE98WMY.

When Reports are Due

Per IC §16-40-6-3, Covered Entities are required to submit timely, accurate, and complete data on 340B program participation for the previous calendar year to IDOH annually by April 1.

What Data Should Be Included in the Report

Covered Entities are mandated to submit data reflecting their program activities from the preceding calendar year. For clarity, submissions due in 2025 must encompass all 340B transactions that occurred during the 2024 calendar year.

Each Covered Entity is required to furnish one comprehensive and consolidated report. This singular submission must integrate data from the parent entity, along with all associated sites, to ensure a complete overview. The scope of this report includes, but is not limited to, child sites, grantee-associated locations, hospital outpatient sites, offsite outpatient facilities, contract pharmacies, and any other organizations formally linked to the Covered Entity.

A critical point for parent entities with child sites located outside of Indiana: the report should exclusively detail activities pertaining to Indiana-based child sites. In instances where it is demonstrably impossible to isolate this data, please ensure that this inability is explicitly noted within the general comments section of the submission.

Furthermore, it is paramount that data is reported with consistent methodology across all elements. The identical approach for incorporating parent and child site data must be uniformly applied throughout the entire submission.

To facilitate a complete and timely submission, all specified fields within the report must be accurately and thoroughly completed. The subsequent descriptions are provided to assist in fulfilling these requirements.

Covered Entities are expected to report actual, verified data. This ensures the highest level of accountability and transparency in 340B operations.

Guidance for Reporting Estimates (When Actual Data is Not Feasible)

There may be exceptional circumstances where reporting actual data proves genuinely infeasible. In such cases, Covered Entities are permitted to submit their best available estimates, provided they adhere to the following strict conditions within their submission:

1. Clear Indication of Estimation: A prominent note must be included in the general comments section of your submission, explicitly stating that the reported data are estimates.
2. Comprehensive Explanation for Infeasibility: An attachment must accompany your submission, detailing the specific reasons why providing actual data is not feasible. This explanation should be thorough and clearly justify the reliance on estimates.
3. Detailed Methodology and Supporting Documentation: A separate attachment is required to describe the precise methodology employed to arrive at the estimates. This should include any supporting documentation or explanations that lend credence to your approximation process.

Aggregate Acquisition Cost

Calculating Acquisition Costs for Administered 340B Drugs: A Step-by-Step Guide

This section outlines the accepted method for accurately calculating these critical costs.

Required Inputs & Documentation:

For audit readiness and accurate calculation, Covered Entities are required to maintain meticulous purchasing documentation. This includes records detailing quantities ordered and the prices paid for each National Drug Code (NDC) across all purchasing accounts (e.g., dedicated 340B accounts, Group Purchasing Organization [GPO] accounts, etc.). Such granular data should be readily available either through your Third-Party Administrators (TPAs) or directly from your wholesalers.

Step 1: Determine Total Acquisition Cost for Purchases in the Calendar Year
Calculate the aggregate acquisition cost for all administered 340B drugs purchased *during the entire 2024 calendar year*. This calculation should encompass all purchases made within this period, irrespective of whether the drugs were immediately utilized or remained in inventory by year-end.

Step 2: Consolidate and Report Grand Total in Rx Data Portal
Add the total amount derived from Step 1 (for administered drugs) to the existing "Total 340B Acquisition Cost" for dispensed drugs. The resulting grand total, encompassing both administered and dispensed 340B drugs, must then be reported in the designated "Total 340B Acquisition Cost" field.

Acceptable Methodology for Estimating Acquisition Costs

Should a Covered Entity determine that providing actual data for required fields is not possible, particularly concerning acquisition costs, please be advised that the methodology established and followed by the Minnesota Department of Health (which can be found here: https://www.health.state.mn.us/data/340b/docs/admindrug2025.pdf) is recognized by IDOH as an acceptable alternative for approximation. This framework provides a structured approach for determining both the acquisition costs for administered 340B drugs and the total 340B payments received, categorized by payor type.

Crucial Distinction: What to Include and Exclude from Acquisition Costs

When reporting acquisition costs, it is vital to adhere to a strict definition:
Include Only: The amounts directly paid for covered outpatient drugs under the 340B program.
Strictly Exclude: Payments for anything beyond the drug itself. This explicitly includes, but is not limited to, labor, supplies, administrative fees, or any other expenses that, while potentially related to purchasing 340B drugs or operating your 340B program, are not the direct cost of the drug.

Reporting Other Operational Expenses:

Costs associated with the administration of your 340B program, such as shipping, handling fees, TPA charges, or internal operational expenses, should not be included in the acquisition cost field. These operational expenditures are to be reported separately in the designated field for "all other expenses." This field is specifically intended to capture the full scope of costs incurred in administering the 340B drug pricing program.

Aggregate Payment Amount Received

This section outlines the accepted method for accurately calculating the total 340B payment received by payor type.

Inputs:
HCPCS codes: HCPCS codes are a system for recording medical procedures, with J-, Q-, and certain A-codes indicating specific types of administered drugs.

Separately payable administered drugs: These can be identified by selecting claims with J-, Q-, and certain A-codes in the HCPCS field and a payment value on the claim line for the drug.

- Note: These drugs may also be called drugs with separately identifiable payment, or "payment line" drugs.

Step 1: Retrieve the payment received amounts ($) of all J-codes that have service line payment amounts for the drugs (i.e. separately payable).

- Note: This step excludes any drugs paid through a bundled payment, including inpatient Diagnosis-Related Groups (DRGs) or bundled outpatient procedures.

Step 2: Using the results from Step 1, sum the service line payment amounts ($) and group by payor.
Step 3: Sum your results from Step 2 with the corresponding *Total 340B Payment Received* by *Payor Type* for dispensed drugs.

Aggregate Payment Made to Pharmacies

Covered Entities should report the total amounts paid to all contract pharmacies to dispense drugs obtained under the 340B program.

Number of Claims

Covered Entities should report the number of prescription events whether or not an insurance claim was generated.

How Savings Are Used

Aggregate Payments Made to Any Other Entity for Managing the Covered Entity's program

Covered Entities should report all aggregated payments made to business organizations that are engaged to oversee, manage, or facilitate any operational dimension of your 340B program. It is important to clearly distinguish these entities. This reporting mandate applies to organizations that are neither the Covered Entity itself, nor its recognized child or associated sites, nor a designated contract pharmacy. In practice, this category predominantly encompasses Third-Party Administrators (TPAs) who offer specialized services for 340B program management, such as inventory management, compliance auditing, or claims processing. The payments subject to this reporting obligation explicitly include any portion of the net 340B revenue that these TPAs retain as remuneration for their administrative duties and services directly related to the 340B program.

Aggregate Payments Made for Any Other Administering Expenses

These reporting requirements pertain to "other aggregated costs" directly associated with the 340B program where payments are made to external vendors or service providers. This category is distinct from contract pharmacy fees, which are captured in a dedicated reporting field. The costs to be reported include, but are not limited to, contractual fees unrelated to the contract

pharmacies, shipping and logistics costs and operational and administrative expenses directly related to the 340B program in the applicable calendar year.

It is important to note that this data element is specifically designed to capture direct, externally incurred administrative costs. Therefore, it must not include fixed internal overhead expenses that are not directly attributable to 340B program administration. Examples of excluded costs include, but are not limited to, general facility operating expenses, utility costs, or the salaries and benefits of your organization's internal staff (e.g., provider staffing), unless they are dedicated to managing the 340B program, as these represent institutional fixed costs rather than direct external outlays for program administration.

Aggregate Number of Prescription Drugs Dispensed or Administered

Covered Entities should report the total number of unique drugs dispensed or administered – each NDC equals one "drug".

Number of Patients Served with Sliding Scale Fees

Covered entities should report the total number of low-income patients served by a sliding fee scale for a prescription drug either dispensed or administered under the 340B program in the reporting year.

Percentage of Patients Served with Sliding Scale Fees

Covered entities should report the percentage of their total population of patients that were served by a sliding fee scale for a prescription drug either dispensed or administered under the 340B program in the reporting year.

Total Operating Costs

Covered entities should report their total operating costs for the reporting year. For covered entities that is required to submit an annual cost report to a Medicare Administrative Contractor (MAC) should report a cost total consistent with the costs reported to the MAC for the same time frame, even though it may cover multiple calendar years.

Total Costs for Charity Care

Covered entities should report their total charity care costs for the reporting year. For covered entities that is required to submit an annual cost report to a Medicare Administrative Contractor (MAC) should report a cost total consistent with the costs reported to the MAC for the same time frame, even though it may cover multiple calendar years.

Why Report 340B Drug Pricing Program Information

IDOH seeks to understand the full scope of the 340B drug pricing program in Indiana. This vital program supports our healthcare safety net, yet its overall effectiveness and true impact often remain obscured by a lack of comprehensive, state-specific data. A transparent data framework allows for a clear and objective analysis of patient benefits. This information can begin to answer whether the substantial revenue generated through the 340B program is genuinely being reinvested into expanding essential safety-net services and directly benefiting low-income patients, or if it is being diverted to other, less impactful endeavors. This ensures the program remains true to its humanitarian goals.

Finally, access to comprehensive, actionable data is foundational for informed state policy formulation. It provides our policymakers with the critical insights needed to deeply understand Indiana's drug spending landscape, pinpoint high-cost pharmaceuticals, and consequently develop targeted, effective strategies to enhance drug affordability and accessibility for all Hoosiers.

By building a clearer, data-driven picture of the 340B program within our borders, Indiana can maximize its positive impact, ensure accountability, and ultimately better serve the health and well-being of its citizens.

IC §16-40-6-4 requires any entity that fails to file its 340B Drug Pricing Program Report with IDOH by April 1 to be fined $1,000.00 per day that the report is late. Because this fine is statutorily mandated, IDOH strongly encourages Covered Entities to begin the submission process early and to communicate any questions to IDOH at hospitalreports@health.in.gov.