Recent 340B Data Policy Changes: Separating the Myths from the Facts

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On Jan. 15, Eli Lilly & Company (Lilly) announced that starting Feb. 1 it will require all 340B covered entities to submit claims-level data (CLD) for all dispenses of Lilly drugs, regardless of setting. This was followed by nearly identical announcements from seven other drug companies between March 2 and June 1.[1] Critically, these new policies would require 340B hospitals to compile and submit a vast range of new data, including for drugs dispensed at both in-house and contract pharmacies or risk losing access to 340B discounts. For example, Lilly's notice stated that "[f]ailure to provide timely, complete, and accurate data for all products dispensed at 340B ceiling prices may result in loss of access to pricing until such time as the outstanding data is provided." In effect, these drug companies are now telling hospitals that treat America's most vulnerable patients that they must hand over an unprecedented amount of data or not receive the discounts they are owed by statute.

The AHA, on multiple occasions[2], has written to the Health Resources and Services Administration (HRSA) urging the agency to take swift action to stop these policies from going into effect. The AHA also explained why these data policies are not authorized by the statute and undermine HRSA's oversight authority, and are extremely costly (and in some cases impossible) to comply with. Many individual hospitals also wrote to HRSA to explain the massive costs and burdens that these policies will impose on them, and the impact that these new costs will have on patient care. To date, we are unaware of any action HRSA has taken to address these policies.

In each of their announcements, drug companies have made several unsubstantiated and misleading claims that are addressed below:

Myth: These claims-level data requirements are "minimal, standard business information."

Fact: The scope and volume of data that these drug companies require goes well beyond standard business information. Indeed, requiring 340B hospitals to submit both pharmacy and medical claims is unprecedented — and unprecedently onerous. For example, data for in-house dispenses are often spread across multiple disparate data systems. Reconciling and aligning those systems would create significant costs for covered entities, requiring them to divert vital dollars away from patient care and toward complying with these new programmatic hurdles. If this sudden change is, as they claim, "part of [its] commitment to ensuring that the reduced prices offered through the 340B program help vulnerable patients," they should not impose needless administrative costs that prevent hospitals from providing comprehensive healthcare services to their rural and underserved communities.

1 In addition to Eli Lilly, Novo Nordisk, Exelixis, AstraZeneca, Bristol Meyers Squibb, Biogen, UCB, Amgen and Sanofi have announced these data demands threatening withholding of 340B pricing. Note, Exelixis' policy was technically announced in October 2025 but was not widely publicized until this year after Eli Lilly's policy was announced.

2 The AHA sent letters to HRSA on Jan. 26, March 3, and April 27.

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Myth: The data that drug companies require are "readily available" because 340B hospitals already provide it to their third-party data vendor, 340B ESP.

Fact: While some hospitals provide a limited amount of 340B contract pharmacy claims data to 340B ESP, many hospitals do not. Moreover, no hospital currently provides medical claims data to 340B ESP (or any drug company). In addition, even if hospitals already provided this data to drug companies or their third-party vendor, those that currently submit data tell us that 340B ESP is rife with problems. There are consistent bugs and breakdowns in the technology, including some that cause improper denials of 340B pricing. Given the problems that already exist with a small number of users, there is no guarantee that 340B ESP can handle the volume of claims that these drug companies are now requiring. Nor can these drug companies ensure that hospitals will not be incorrectly denied 340B pricing. These drug companies also make no assurances that claims data will be protected and secure; hospitals and patients have legitimate patient and data privacy concerns.

Myth: The claims-level data requirements are no different than the data 340B hospitals provide to payers.

Fact: Even though hospitals provide some claims data to payers, there are important differences with what drug companies are now requiring. Claims data are submitted to payers through automated systems that have been built, tested and refined over a number of years. In contrast, these data policies would require hospitals to manually compile data that are housed in multiple disparate systems, provide it to their 340B third-party administrator, and then submit in the format that each drug company requires. In addition, some of the claims-level data elements that are now being required (e.g., wholesaler invoice number and product sterilization number) are NOT provided to payers. Therefore, these data policies introduce a range of expensive, time-consuming and unnecessary burdens that hospitals do not face when submitting data to payers.

Myth: There are "countless" instances of Medicaid duplicate discounts and rampant program abuse.

Fact: Recent government data demonstrates that 340B hospitals do NOT engage in rampant waste and fraud. HRSA's own audit data of 340B hospitals shows that between fiscal year (FY) 2018 and FY 2022, Medicaid duplicate discount audit findings decreased by 57%. During the same period, audit findings for diversion of 340B drugs to ineligible patients decreased by 73%. Conversely, the same HRSA audit data showed a consistent pattern of noncompliance among drug companies. Sixty percent of drug company audits had at least one adverse finding, of which 93% required the drug company to issue repayments to covered entities for illegally overcharging them for 340B drugs. Drug companies have tried to obscure these realities by relying on outdated studies and unsupported allegations, but it is clear that drug companies are imposing this new policy to increase their profit margins, not to improve program integrity.

Myth: Drug companies are entitled to enforce the 340B statute on their own.

Fact: The 340B statute explicitly gives HRSA the authority to oversee the program and enforce its program integrity requirements. Congress has given HRSA the sole right to authorize audits of 340B hospitals, and it has created an Alternative Dispute Resolution process where drug companies can seek redress with factual evidence of instances of duplicate discounts or diversions. The statute does NOT permit drug companies to take the law into their own hands, but these policies would do just that. Drug companies may not wrest authority away from HRSA and transform themselves into the sole arbiters of whether claims are eligible for a 340B discount. We urge Congress to exercise its oversight authority and insist that the administration take action to stop drug companies from continuing these unauthorized restrictions.

Myth: These data policies are the only way to increase transparency within the 340B program.

Fact: 340B hospitals are committed to being transparent to support program integrity. But handing over an unprecedented amount of data to drug companies is not the only way to achieve transparency or program integrity. Nor is it the best way. For example, 340B hospitals and the AHA have long supported the establishment of a neutral, third-party clearinghouse. Overseen by HRSA, this third-party clearinghouse would facilitate the collection of claims data, verify pricing and eligibility, and mitigate duplicate discounts and diversion of 340B drugs. At the same time, this neutral clearinghouse would identify instances where drug companies illegally overcharge 340B covered entities. HHS has ALREADY established two different neutral, third-party clearinghouses:

1. The Medicare Transaction Facilitator to facilitate claims data exchange between drug companies and dispensing entities under the Inflation Reduction Act's Medicare Drug Price Negotiation Program.
2. A clearinghouse established under the FY 2026 Physician Fee Schedule Rule that would allow 340B hospitals to voluntarily submit claims data to identify 340B drug units for exclusion from the IRA's Medicare inflation rebate calculation.

340B hospitals and the AHA have urged the Department of Health and Human Services to adapt either of these clearinghouses to promote transparency and program integrity.