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More Drug Company Oversight Needed to Maintain Compliance with 340B Program Rules: Trends in Audit Findings for 340B Hospitals and Drug Companies

Drug companies have repeatedly challenged the integrity of the 340B program, particularly among 340B hospitals.[1] In fact, several drug companies have cited these concerns as a basis to pursue unilateral, unlawful self-enforcement of the program, including their recent efforts to impose a 340B "rebate model."[2] To investigate the veracity of these claims, the American Hospital Association (AHA) reviewed the publicly available federal audit data and observed trends in findings for both 340B hospitals and drug companies over a 5-year period of fiscal years (FY) 2018-2022.[3] The findings demonstrate that not only are hospitals subject to disproportionately greater oversight by the federal government, but that they outperform drug companies in terms of program compliance to a substantial degree. These discrepancies underscore the need for increased federal oversight of drug manufacturers, as well as rejection of their unlawful approach to convert the discount program to a rebate model.

Background

For over 30 years, the 340B Drug Pricing Program has been a vital resource for covered entities[4] to stretch their limited federal resources and provide more comprehensive care to more patients. In codifying the 340B program into law, Congress recognized the importance of program integrity and entrusted this responsibility to the Health Resources and Services Administration (HRSA).[5] The law gives HRSA both the authority to promulgate regulations and guidance that establish program rules, as well as the ability to annually conduct audits of 340B covered entities and drug companies to ensure they are in compliance with these rules.

340B covered entities are subject to numerous rules. Chief among them are statutory prohibitions against diversion (i.e., giving a 340B drug to an ineligible patient) and duplicate discounts (i.e., receiving both a 340B discount and a Medicaid rebate on the same drug).[6] The agency monitors compliance with these rules by reviewing patient records to identify any instances of diversion or duplicate discounts. In the event a violation is found, HRSA requires the covered entity to take corrective action, which can include repayment of 340B discounts erroneously obtained back to drug companies.

Drug companies participating in the program are also subject to HRSA oversight and audits. Those companies are statutorily required to ensure they do not overcharge 340B covered entities by selling a 340B-eligible drug at above the 340B ceiling price. Similar to the requirement for covered entities, if a violation is found, drug companies must engage in corrective action, which can include payment to the covered entity for the total amount of the overcharge.

HRSA's audit program dates back more than a decade. HRSA began auditing 340B covered entities in 2012 and performs 200 audits annually, of which approximately 160 are for 340B hospitals (or ~6% of participating hospitals). HRSA began audits for drug companies in 2015 and performs approximately five audits every year (~0.6% of participating drug companies). The results of these audits are posted publicly on HRSA's 340B program integrity website,[7] including the nature of any audit findings and the corrective action taken, including whether repayment was required.

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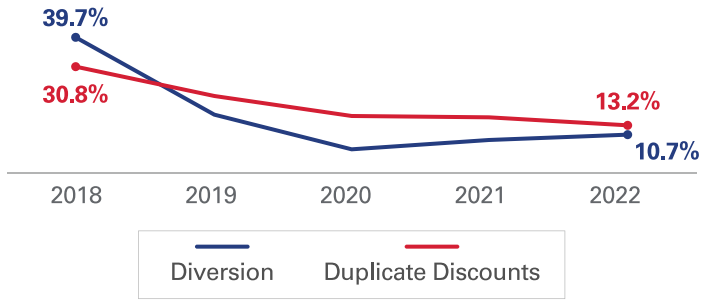
Results

The analysis of federal audit data shows high rates of compliance for audited 340B hospitals and consistently high rates of noncompliance among audited drug companies.

Duplicate discount and diversion findings in 340B hospital audits have declined significantly, reflecting very high rates of compliance in recent years. Between FY 2018 and FY 2022, 340B hospital audit findings for duplicate discount and diversion decreased by a combined 62.1%. Specifically for duplicate discount findings, in FY 2018, 30.8% of 340B hospital audits included at least one duplicate discount finding. This percentage dropped to 13.2% by FY 2022 or a 57% decrease over this 5-year period. Similarly, in FY 2018, 39.7% of audited 340B hospitals had at least one diversion finding. That dropped to just 10.7% in FY 2022 or a 73% decrease over this 5-year period (see Figure 1).

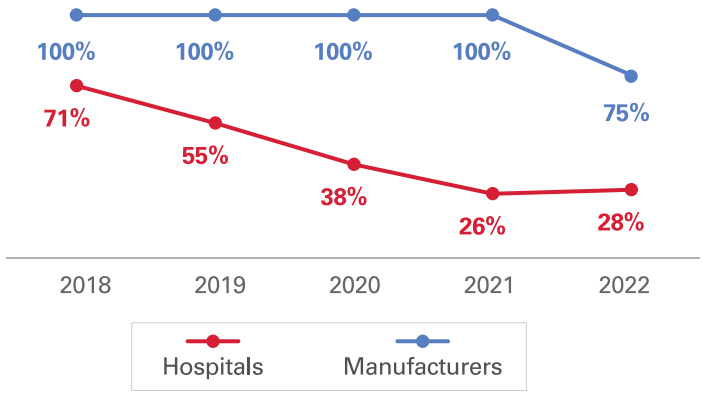
Figure 1. Share of Audit Findings for Diversion and Duplicate Discounts, FYs 2018-2022



In contrast to hospitals, drug company audits reveal a consistent pattern of noncompliance. There was a total of 30 audits conducted for drug companies between FY 2018 and FY 2022 with 60% of these audits having at least one adverse finding. Of those drug companies that had at least one adverse finding, 93% were required to issue repayments to covered entities, underscoring a pattern of noncompliance among drug companies.

Repayment requirements following audit findings highlight key differences in the nature of noncompliance between hospitals and drug companies. The most egregious audit findings by 340B hospitals and drug companies require repayment to the other entity. As shown in Figure 2, the percent of audit findings where 340B hospitals were required to repay manufacturers either due to a diversion or duplicate discount finding was consistently lower and decreased from 71% in FY 2018 to 28% in FY 2022, or a 61% decrease. In contrast, 100% of drug companies with an adverse finding in FYs 2018-2021 required repayment to covered entities, with only a drop-off in FY 2022 to 75%. However, it is important to note that this drop-off represents only one fewer drug company that was required to repay covered entities in FY 2022 compared to prior years.[8]

Figure 2. Share of Adverse Audit Findings Resulting in Repayment Sanctions, FYs 2018-2022



Discussion

The data above demonstrate 340B hospitals' commitment to ensuring program integrity, reflecting ongoing efforts to strengthen internal oversight, including regular self-audits of their 340B programs. Many hospitals have also established 340B committees to develop rigorous compliance frameworks, modify workflows, and hold staff accountable when errors occur, among other actions.[9]

At the same time, drug companies continue to demonstrate a high degree of noncompliance with program rules and regulations. Strikingly, nearly all audit findings require drug companies to repay 340B covered entities for overcharges. This lack of compliance is particularly concerning given that drug companies have the ability to audit covered entities when they have a legitimate concern of noncompliance, but there is no reciprocal ability of covered entities to audit drug companies when they are being overcharged for 340B drugs. Moreover, HRSA scrutinizes 340B hospitals at 10 times the rate of drug companies (6% vs. 0.6%), despite the fact that it is 340B hospitals that have shown greater rates of compliance as compared to drug companies.

Compliance with rules and regulations is absolutely critical for the success of any government program. This is why Congress gave HRSA the responsibility to audit both drug companies and 340B covered entities. These findings contradict allegations made by drug companies against 340B hospitals and instead unequivocally demonstrate that drug companies — not 340B hospitals — are in great need of increased scrutiny to improve compliance with 340B program rules and regulations.

Policymakers should reject the baseless claims made by drug companies of widespread program abuse by 340B hospitals and urge HRSA to increase their audits of drug companies. Greater oversight of these drug companies is necessary to ensure the continued success of the 340B program for the millions of vulnerable patients and communities nationwide who rely on it.

End Notes:

1 phrma.org/resources/phrma-statement-on-the-340b-drug-pricing-program

2 See September 2024 Johnson & Johnson rebate model announcement: transparencyreport.janssen.com/johnson-johnson-rebate-model-summary-letter

3 FY 2022 is the latest year of complete data available. Currently, HRSA has only posted 171 of its 200 audit results for FY 2023.

4 Covered entities include six types of hospitals (CAH, SCH, RRC, DSH, PED, CAN), community health centers, and other select federal grantee organizations. hrsa.gov/opa/eligibility-and-registration

5 hrsa.gov/sites/default/files/hrsa/rural-health/phs-act-section-340b.pdf

6 Ibid.

7 hrsa.gov/opa/program-integrity

8 Between 2018 and 2021, every drug company that had at least one adverse audit finding also required repayment to covered entities. However, in 2022, three out of the four drug companies that had an adverse audit finding required repayment to covered entities, hence the drop from 100% to 75% in FY 2022.

9 utmb.edu/policies_and_procedures/IHOP/Clinical/Pharmacy/IHOP%20-%2009.14.05%20-%20Roles%20and%20Responsibilities%20in%20the%20340B%20Drug%20Pricing%20Program.pdf