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340B Reporting Requirements Are Unwarranted

Transparency Claims Meant to Shrink 340B Program

Critics of the 340B program allege that the program lacks transparency and that program participants, called “covered entities,” should report both the amount of their 340B savings and how they use 340B savings for patient care. Critics fail to understand, however, that federal grantees, which make up 11 of the 14 categories of entities authorized to participate in the program, are already subject to rigorous reporting requirements to ensure transparency and accountability. The real motivation for these allegations is to discredit the 340B program and to justify its reform.

Grantee Transparency: Detailed and Regulated

Federal grantees must submit detailed budgets with their grant applications and comply with those budgets. They must also report the income received as a result of the grant – called “program income” – and how such income is used. Importantly, federal grantees must use program income consistent with the purposes of their federal grant.⁵ Ryan White grantees are also required to submit a Ryan White HIV/AIDS Program Services Report with client-level data and an allocations and expenditures report. Like other federal grantees, Ryan White clinics are subject to audits to ensure compliance and are required to perform internal monthly audits of prescriptions. Thus, federal regulators already have the data they need to validate proper use of 340B savings by Ryan White clinics. Most of that information is publicly available.

340B Eligibility, Existing Oversight Creates Transparency

Congress carefully limited 340B program eligibility to safety net providers that are already subject to transparency requirements. In addition to federal grantees, 340B-eligible hospitals must be nonprofit and show that they serve a disproportionate share of low-income individuals. Imposing another layer of reporting requirements on covered entities would create undue burden and expense, diverting their limited resources away from patient care.

Ryan White Clinics Use 340B to Effectively Control HIV

Tellingly, Ryan White clinics are making important strides in controlling the HIV epidemic through use of their 340B savings. In 2021, 89.7% of Ryan White clinic clients receiving HIV care were virally suppressed, exceeding the national average of 66%. Ryan White clinics are clearly using their 340B savings to meet the needs of HIV patients. RWC-340B urges Congress to refrain from adding new reporting requirements to the 340B program because, simply put, they would subject covered entities to unnecessary and harmful burden.

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⁵ 45 C.F.R. § 75.307(e)(2).
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