

PUBLICATION

340B Drug Program: Key Trends for 2023

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Throughout 2022, the 340B Drug Program (340B) and participating hospital systems experienced myriad new developments. From continued disputes with drug manufacturers to a landmark U.S. Supreme Court ruling, 340B made headlines and had an impact on hospitals financially and operationally. This year will continue the trend of challenges to both hospitals and the 340B Drug Program. This is a summary of recent changes and what issues hospitals need to consider for optimizing their program participation in 2023.

Contract Pharmacy Restrictions

In 2022, nine additional pharmaceutical manufacturers implemented policies restricting 340B discounts for drugs dispensed at contract pharmacies. However, certain exceptions apply:

- All nine manufacturers allow for at least one contract pharmacy arrangement if the hospital does not have a retail pharmacy.
- Seven pharmaceutical manufacturers will restore 340B pricing if claims data is submitted.

Data Sharing

- Several pharmaceutical manufacturers offer 340B discounts for multiple contract pharmacies if the Covered Entity submits claims data. However, any data sharing presents the following concerns:
 - Could the data be used to lower reimbursement and/or exclude 340B providers from payer networks?
 - Will there be delays in pricing restoration or pricing lapses?
 - What additional resources are needed to submit data and monitor pricing?
 - What are the HIPAA and state law privacy issues involved sharing data under unclear manufacturer policies?

Patient Eligibility

In *Genesis Health Care, Inc. v. Becerra*, a South Carolina Federally Qualified Health Center (FQHC), filed suit in federal court over audit findings the FQHC received from Health Resources and Services Administration (HRSA) in June 2017. The case is still pending in federal court, with a trial date scheduled for August 2023. The argument in the *Genesis* case centers on the HRSA requirement for 340B prescriptions to originate at the Covered Entity site to qualify for the eligible patient definition. The FQHC argued that the regulatory standard for patient eligibility imposed by HRSA in its audit had been a "proposed" guidance rule that was not finalized. For several years, HRSA has asked Congress for regulatory authority that would allow the agency to issue binding regulations that are more difficult to challenge in court.

While the *Genesis* case is pending, Covered Entities will be wise to concentrate on these considerations when implementing their patient definition policies:

- Can the Covered Entity demonstrate that it maintains health records for the patient?
- Is the health care professional who is providing care either employed by the hospital or providing care under a contractual and/or other arrangement?

Outpatient Prospective Payment System (OPPS)

From 2018 through most of 2022, CMS reduced Medicare Part B payments to certain 340B hospitals under the Outpatient Prospective Payment System (OPPS) for separately payable drugs without pass-through status by nearly 30 percent. In June 2022, the U.S. Supreme Court held in *American Hospital Association v. Becerra* that the cuts in Medicare outpatient drug payments were unlawful.

There is improvement ahead in 2023 for Medicare Part B payments. In its final 2023 OPPS Rule, CMS ended the 30 percent cut for all hospitals paid under OPPS by setting the 2023 Medicare Part B payments for separately payable drugs at ASP plus 6 percent.

If you have any questions about 340B Program matters or Medicare payments to 340B hospitals, please contact a member of Baker Donelson's [Health Law Group](#) with whom you regularly work.