340B Drug Pricing Program Reform Considerations

 The 340B Drug Pricing Program is a government program, administered by the Health Resources and Services Administration (HRSA), that allows qualifying hospitals and clinics that treat low-income and uninsured patients to buy certain prescription drugs at a steep discount from drug manufacturers. Drug manufacturers participate in the 340B Program as a condition of obtaining Medicaid coverage of their drugs. For the many drug manufacturers who want their products to reach the broadest patient population, participation in the 340B Program is essentially mandatory.

The program is intended to help safety-net health care providers' financial resources reach more financially vulnerable patients and deliver comprehensive services.[1] At the same time, drug manufacturers have concerns about the program:

- Manufacturers are concerned that deeply discounted prescription drugs should only go to covered entity patients and not diverted to individuals who are not covered entity patients, i.e., a practice commonly known as drug diversion.
- Manufacturers are concerned that the covered entities do not get both a deep Section 340B discount and any additional discounts and rebates under Medicaid, i.e., duplicate discounts.

Balancing the interests of covered entities and drug manufacturers has been a challenge, and one that has come under scrutiny in recent years. Drug manufacturers have no way of tracking how covered entities use the discounts paid under the Section 340B program, and there is no legal requirement for covered entities to pass the savings they received from manufacturers to patients.

There are four emerging areas of tension between the interests of covered entities and drug manufacturers related to the 340B program :

- Section 340B telemedicine standards and patient eligibility;
- Contract pharmacy utilization;
- Section 340B covered entity child sites; and
- Drug manufacturer audit limitations.

Until these four key areas are addressed, the Section 340B program will not serve its true goals; and drug manufacturers and covered entities will face increasing conflict over ambiguous and outdated regulations.

For more information regarding these controversies in the 340B Program, please see our recent Health Law360 and Life Sciences Law360 article, "**4 Key Issues Driving Drug Discount Abuse Must Be Addressed**" (Jan. 9, 2023) as well as our recent Goodwin Procter LLP client alert, **Federal Court of Appeals Rejects HHS Stance on Section 340B Contract Pharmacies** (Feb. 1, 2023).

[1] Health Resources & Servs. Admin., 340B Drug Pricing Program (Dec. 30, 2022).