The Future of the 340B Program: 2023 Key Decisions

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Critical decisions are pending before courts and legislators in 2023 that promise to shape the future of the 340B Drug Pricing Program (340B Program), which provides discounts on outpatient drugs for certain health care providers, referred to as “covered entities.” The resolution of these issues will have an enormous financial impact on the health care industry, including pharmaceutical manufacturers, 340B hospitals, and federal grantees.

Use of 340B Contract Pharmacies

One critical question relates to the ability of 340B covered entities to dispense medications purchased under the 340B program to their patients through networks of contracted pharmacies. So-called “340B contract pharmacies” have been in place for decades and were greatly expanded in 2010, when the Department of Health and Human Services (HHS) Health Resources & Services Administration (HRSA) issued guidance permitting 340B covered entities to contract with multiple pharmacies if certain conditions were met.

Beginning in 2020, an ever-increasing number of pharmaceutical manufacturers implemented policies that restrict the availability of 340B discounts for drugs distributed through 340B contract pharmacies. HRSA opposed these policies, and issued violation letters to several manufacturers, indicating that the manufacturers’ policies do not comport with the requirements of the 340B statute and that further implementation of such policies may result in penalties. Starting in early 2021, multiple pharmaceutical manufacturers initiated litigation to challenge HRSA’s enforcement authority in this area. In 2022, the trial courts in several of these cases issued dichotomous decisions, some siding with the manufacturers and others siding with HRSA’s reading of the 340B statute. Several appeals are now ongoing in various federal appellate courts around the country.

In January, the first appellate decision in this suite of cases was issued by the U.S. Court of Appeals for the Third Circuit, which sided with the three pharmaceutical manufacturers involved in the consolidated case. The court’s decision affirmed the District Court for the District of Delaware’s decision in one case, in which the manufacturer involved won, and reversed the District Court for the District of New Jersey’s decision in the case involving the other two manufacturers, in which the government won. The court held, among other things, that the government may not enforce its reading of the statute against the manufacturers and that Section 340B does not require delivery of drugs at 340B pricing to an unlimited number of contract
We await appellate decisions in two similar cases involving manufacturers. If the appellate courts in each of these cases (D.C. Circuit and Seventh Circuit, respectively) rule in a manner consistent with the Third Circuit, then the use of 340B contract pharmacies will likely be severely limited. If the appellate decisions produce a circuit split, then we would expect the issue to be appealed to the Supreme Court.

**Enforceability of the 340B Definition of Patient**

We are also monitoring 340B-related litigation brought by a 340B covered entity, *Genesis Healthcare, Inc. (Genesis) v. Becerra et al.* (No. 20-1701). This litigation results from HRSA’s attempt to remove Genesis from the 340B Program following an audit. The audit’s findings found, among other things, that Genesis had dispensed discounted 340B drugs to individuals who were not “patients” of Genesis. Genesis filed suit challenging the removal. The lawsuit is significant because – similar to the actions filed by pharmaceutical manufacturers over the contract pharmacy issue – it challenges HRSA’s authority to enforce agency guidance outside of the parameters expressly contained in the 340B statute.

The 340B statute includes a requirement that 340B covered entities may not resell or otherwise transfer drugs purchased under the 340B program to individuals who are not patients of the covered entity. HRSA issued guidance in 1996 interpreting what it means to be a patient of a covered entity for purposes of this statute, which continues to be widely applied. A court ruling that this 1996 guidance is not a comprehensive limit on circumstances when 340B drugs may be dispensed could potentially alter the scope of 340B purchasing and could expand the definition of “patient.”

On July 1, 2022, the United States Court of Appeals for the Fourth Circuit issued its decision to reverse the 2019 decision of the District Court for the District of South Carolina, which had dismissed the case as moot. As a result of the reversal, the case was remanded to the district court for further proceedings, including addressing Genesis’ allegation that the HRSA definition of “patient” is contradictory to the plain language of the 340B statute. The order took effect on August 23, 2022, but the court has not yet addressed the definition of “patient.”

**340B Medicare Payment Remediation**

Another significant issue for 340B hospital covered entities – and potentially other hospitals – is the forthcoming remediation of Medicare payment cuts for 340B drugs billed by hospitals under the outpatient prospective payment system (OPPS). The Supreme Court recently found the Medicare payment cuts to be unlawful, and a trial court has directed the Centers for Medicare and Medicaid Services (CMS) to remedy affected hospitals.

The Medicare payment cuts go back to 2018. The cuts reduced Medicare reimbursement to hospitals by almost 30% for drugs acquired through the 340B Program, from a reimbursement rate tied to the average sales price (ASP) plus 6% to a reimbursement rate tied to ASP minus 22.5%. CMS’s intention was to reduce
reimbursement by an amount that approximates the discounts that the 340B covered entities were receiving on their 340B drug purchases from manufacturers. The 2018 reimbursement changes immediately generated industry push-back and litigation on behalf of 340B hospital covered entities, but CMS continued reimbursing covered 340B drugs at the lower rates in 2020, 2021 and 2022, while the case worked its way up to the Supreme Court.

In June 2022, SCOTUS ruled in favor of the hospitals (American Hospital Association (AHA) v. Becerra (No. 20-1114)), finding the reduced reimbursement rates unlawful. The implications of this decision for 340B covered entities are enormous. CMS estimates that the payment differential could mean an additional $1.96 billion for 340B hospital covered entities.

Remedying the Supreme Court’s decision is complicated by the fact that, when CMS implemented the 340B rate cuts, it was required to do so in a “budget neutral” manner. As a result of the reductions in payment under the OPPS for 340B drugs, payments to other hospitals and for other services were slightly increased as a budget offset. Therefore, remediying the reimbursement rate, or “unscrambling the egg” (as coined by the U.S. District Court for the District of Columbia), could potentially impact all hospitals reimbursed under the OPPS.

Courts have thus far shown a willingness to allow CMS to propose its method for remedying the violation, including a decision on whether it will recoup payments from non-340B hospitals. CMS has not yet issued its proposal, but has indicated that it will do so through notice and comment rulemaking, which we currently expect to be issued around April 2023. Public comment would be taken on the rule, and the rule would need to be finalized before implementation.

**Legislation**

Conflict around the 340B program has not escaped the notice of Congress. Through legislation, Congress could address the conflicts around contract pharmacies, clarify or limit HRSA’s enforcement authority, or establish new rules or parameters around the dispensing of 340B drugs. Members of Congress have also expressed an interest in establishing new transparency or reporting obligations for 340B covered entities.

In January, Rep. Matthew Rosendale Sr. from Montana introduced the [Drug Pricing Transparency and Accountability Act](https://www.congress.gov/bill/116th-congress/house-bill/688), which has been referred to the Committee on Energy and Commerce (which referred it to the Subcommittee on Health) and the Committee on Ways and Means. If passed, the bill would:

- Impose a 2-year moratorium on Disproportionate Share Hospitals registering main locations or child sites in the 340B Program;
- Require 340B covered entities that participate in Medicare to include aggregate 340B acquisition costs and aggregate 340B revenues in their Medicare cost reports;
- Require all claims for covered outpatient drugs to utilize the 340B modifier established under the hospital OPPS; and
- Require 340B hospital covered entities to report to HHS their annual 340B drug revenue minus their
drug acquisition costs.

This bill was only recently introduced, and we cannot predict whether it will pass or whether it will be amended. We expect multiple 340B proposals to be considered by the new Congress, which may have different priorities. Of particular interest are principles issued jointly by trade associations representing pharmaceutical companies and health centers, which have been circulated to Congress.

**Next Steps**

The number of high-value disputes related to the 340B program indicate that the program, while expected to continue for the foreseeable future, is at a crossroads. Stakeholders interested in the 340B program have been awaiting resolution of these fundamental issues for years. Decisions that will be made in 2023 promise to determine the future direction and scope of the program. Foley attorneys are closely monitoring these changes and actions implicating the 340B Program and can help you understand their impact as they occur.

*Foley is here to help you address the short- and long-term impacts in the wake of regulatory changes. We have the resources to help you navigate these and other important legal considerations related to business operations and industry-specific issues. Please reach out to the authors, your Foley relationship partner, or to our [Health Care Practice Group](#) with any questions.*