As regular readers of our blog know, the Centers for Medicare & Medicaid Services (CMS) intensified its push for drug pricing transparency in 2019. In 2020, we see a continuation of those efforts, and their impacts on the 340B program are now starting to reveal themselves.

2019 Sunlight on 340B Ceiling Prices

On January 1, 2019, the Health Resources & Services Administration (HRSA) finally implemented the ceiling price and manufacturer civil monetary penalties (CMPs) regulations that the agency proposed in 2017. The regulations implement certain provisions of the Affordable Care Act and were initially scheduled to go into
effect on February 28, 2017, but were repeatedly delayed.

The regulations addressed transparency in two ways. First, the regulations established CMPs for pharmaceutical manufacturers that “knowingly and intentionally charge a covered entity a price for a 340B drug that exceeds the 340B ceiling price.” Second, and most relevant here, in the final rule, HRSA acknowledged its plan to grant covered entities access to HRSA’s ceiling price verification website for 340B drugs in conjunction with the establishment of a new 340B ceiling price reporting system. HRSA had been using this website internally, but previously declined to provide access to covered entities. As a result, covered entities had no way of determining that manufacturers from whom they purchased 340B drugs were abiding by the 340B ceiling price.

Following the implementation of the ceiling price regulations, HRSA initiated covered entity access to the ceiling price verification website effective April 1, 2019. The ceiling price website is a powerful tool for covered entities to determine the amount manufacturers can lawfully charge for 340B drugs.

With Sunlight, a Shift in Audit Findings

Shortly after HRSA granted covered entities access to the ceiling price verification website, the agency announced that it had conducted an audit of Belcher Pharmaceuticals and found the manufacturer “did not offer covered outpatient drugs to eligible covered entities at the statutory ceiling price.” HRSA ordered the company to repay the overcharges to impacted covered entities. To our knowledge, this announcement represents the first time HRSA has ever substantiated that a manufacturer overcharged covered entities and subsequently required the manufacturer to issue refunds. On January 6, 2020, HRSA announced that it had substantiated through an audit that a second manufacturer overcharged covered entities from 2012 to August 2019. That manufacturer is now also required to pay refunds. Since the January 6 announcement, HRSA has identified two additional manufacturers that overcharged covered entities.

CMS’s 340B Acquisition Cost Survey: Another Step towards Transparency

In another step towards drug pricing transparency in the 340B program, CMS published a notice in the Federal Register on February 7, 2020, stating that the agency intends to survey hospitals to collect data on hospital acquisition cost of Part B covered outpatient drugs purchased through the 340B program. The survey instructions state that any “hospital that was enrolled in the 340B program as a covered entity in the last quarter of 2018 and/or the first quarter of 2019 is required to complete the survey.”

The survey tool is part of CMS’s response to the ongoing litigation surrounding the agency’s proposed cuts to Part B reimbursement of 340B drugs. For a detailed walk-through of the litigation to this point, please see our prior blog posts here, here, and here.

Through this survey tool, CMS is trying to determine whether Medicare Part B
reimbursement rates for 340B drugs, in fact, approximate a hospital’s acquisition cost. We can expect CMS to use data acquired through the survey to: (1) fashion a remedy if it loses the 340B rate cut litigation at the Court of Appeals, and (2) support another run at rulemaking to lower 340B reimbursement rates in Part B.

Closing Thoughts

The appearance of manufacturer ceiling price audit findings aligns with HRSA’s implementation of the new ceiling price reporting requirements and HRSA’s grant of access to its ceiling price verification website for covered entities. With increased transparency has come increased enforcement.

Of course, HRSA’s regulatory and enforcement authority over much of 340B was curtailed in 2014 when a federal court struck down HRSA’s proposed regulations and limited the agency’s regulatory authority to three areas: (1) resolving disputes relating to compliance with the program’s statutory requirements; (2) imposing CMPs against manufacturers that intentionally overcharge a covered entity; and (3) defining standards for calculating 340B drug prices. While we await a ruling from the Court of Appeals in the Part B reimbursement litigation, CMS’s new survey tool will further its push towards transparency and (along with the appearance of manufacturer audit findings) may signal a shift in the agency towards exercising whatever limited authority it can.

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