THE
NATIONAL LAW REVIEW

Hospitals File Suit Against HHS for Delaying Implementation of 340B Final Rule

Monday, September 24, 2018

Summary

On September 11, 2018, the American Hospital Association (AHA) and several other hospital system and hospital association stakeholders[1]; (Plaintiffs) filed a lawsuit (Complaint) against the U.S. Department of Health and Human Services (HHS) alleging that HHS violated the Administrative Procedures Act (APA) by delaying implementation of a 2017 regulation (Final Rule) addressing certain statutory provisions relating to the 340B program. The Complaint asked the court to find that HHS violated the APA and order the Secretary to make the Final Rule effective within 30 days after judgment.

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The Final Rule and Implementation Delays

Section 340B of the Public Health Service Act, known as the "340B Program," was enacted in 1992 to lower drug costs for certain safety net providers, including public and not-for-profit hospitals and health clinics funded with federal grants (Covered Entities), by requiring drug manufacturers to provide discounts to Covered Entities on certain outpatient drugs as a condition of the manufacturers' participation in the Medicaid program.

Although HHS does not have statutory authority to issue regulations governing many key aspects of the 340B Program, such as Covered Entity eligibility and the scope of drugs subject to discounts under the 340B Program, the Patient Protection and Affordable Care Act (ACA) gave HHS the authority to promulgate regulations intended to increase the accuracy and transparency of prices that manufacturers can charge for drugs under the 340B Program (known as "ceiling prices"). The Final Rule, issued in January 2017, would require manufacturers to calculate the ceiling price for each covered outpatient drug—generally equal to the drug's average manufacturer price minus the drug's unit rebate amount[2] —on a quarterly basis.

In addition, the Final Rule would require HHS to publish the ceiling prices. Any manufacturer that knowingly and intentionally charged a Covered Entity more than the ceiling price would be subject to a civil monetary penalty (CMP) of up to $5,000 for each instance of overcharging, where each order for a national drug code (NDC) would constitute a single instance, regardless of the number of units of each NDC ordered. The CMPs would be in addition to the manufacturer's pre-existing obligation to issue a refund to Covered Entity in the event of an overcharge.

The Final Rule was originally slated to become effective on March 6, 2017. However, HHS delayed the effective date on five occasions:

- January 24, 2017: HHS delayed the effective date of the Final Rule for 60 days pursuant to a regulatory "freeze."
- March 20, 2017: HHS further delayed the effective date of the Final Rule to May 22, 2017, "[t]o provide affected parties sufficient time to make needed changes to facilitate compliance, and because questions were raised."
- May 19, 2017: HHS delayed the effective date to October 1, 2017, after reviewing comments to the

proposed delay.
- September 29, 2017: HHS delayed the effective date to July 1, 2018, after considering further comments.
- June 5, 2018 – HHS delayed the effective date to July 1, 2019.

When announcing the most recent delay, HHS asserted that it was necessary to provide manufacturers time to implement the requirements of the Final Rule, and to consider alternative and supplemental regulatory provisions and allow time for such additional rulemaking.

The Complaint and Motion for Summary Judgment

The Complaint alleges that by delaying the implementation of the Final Rule, HHS violated the APA. The APA authorizes courts to set aside agency actions that are arbitrary, capricious or an abuse of discretion, as well as to compel agency action that has been unlawfully withheld or unreasonably delayed. To support its allegation, the Plaintiffs looked to a seminal 1983 case, *Motor Vehicle Manufacturers Association of United States v. State Farm Mutual Auto Insurance Company*, to suggest an "elevated" arbitrary and capricious standard should apply to an agency "changing course" by delaying a rule's effective date.

The Complaint argues that HHS's change of course was arbitrary and capricious because HHS did not provide a coherent explanation for the decision to delay the Final Rule or HHS's claim that 340B providers would not be affected by the delays. The Plaintiffs also argue that delaying the Final Rule to engage in future rulemaking is arbitrary and capricious because HHS has not initiated another rulemaking process and is statutorily obligated to adopt certain measures set forth in the Final Rule.

The Plaintiffs reject HHS's contention that manufacturers require more time to implement the Final Rule's requirements, noting that HHS has already given manufacturers almost 18 months to comply with the Final Rule, and that manufacturers have been on notice of the changes since 2010 when the ACA was passed. The Plaintiffs also attempted to rebut HHS's claim that the delay would not affect Covered Entities by arguing a lack of accurate pricing data and enforcement activity is a pervasive issue under the 340B Program. For example, the memorandum supporting the Plaintiffs' motion for summary judgment cites a number of HHS Office of Inspector General reports claiming manufacturers overcharged Covered Entities millions of dollars among sampled 340B drug purchase transactions.

Other 340B Program Litigation

The Complaint follows another complaint that the AHA and several other hospitals and hospital groups filed on November 13, 2017, in response to the Centers for Medicare and Medicaid Services (CMS) final rule reducing Medicare reimbursement for 340B covered outpatient drugs from average sales price (ASP) plus 6 percent to ASP minus 22.5 percent, which we discussed here. The November 13 complaint similarly alleged HHS's action was arbitrary and capricious under the APA and requested interim injunctive relief to stay the implementation of the rule pending resolution of the matter. On July 17, 2018, the U.S. Court of Appeals for the District of Columbia held that the plaintiffs failed to satisfy the presentment requirement of the Social Security Act, and the case was dismissed for lack of subject-matter jurisdiction. On September 5, 2018, the AHA filed an amended lawsuit.

Analysis

Both Congress and the Trump administration have drawn attention to a variety of alleged drug pricing issues, including concerns regarding the growth of the 340B Program and the Covered Entities use of funds generated from participation in the 340B Program. The delay in implementing the Final Rule, while simultaneously adopting a significant cut in Medicare payments for 340B drugs dispensed by participating hospitals, provides insight into the current political environment for the 340B Program and suggests a potential trajectory for future payment policies and legislative proposals. However, the ongoing efforts of the Covered Entity stakeholder community to use litigation as a method to effectuate Covered Entity-favorable policies, as well as the AHA's recent effort to counter congressional proposals that would impose 340B reporting obligations on hospitals by implementing a voluntary 340B reporting framework, indicate that Covered Entities are actively working to ensure the future integrity and viability of the 340B Program.

Court filings related to both lawsuits described above can be accessed on the AHA's website, as can information about the AHA 340B Good Stewardship Principles.

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[1]The additional plaintiffs include Association of American Medical Colleges, America's Essential Hospitals, 340B Health, Genesis Healthcare System, Kearny County Hospital and Rutland Regional Medical Center.

[2]The "unit rebate amount" generally equals the greater of: (a) a minimum rebate percentage (13, 17.1 or 23.1 percent, depending on the type of drug), or (b) the difference between average manufacturer price and the "best

price" the drug company has charged during the rebate period. For some drugs, the statute provides for a larger rebate (and thus lower ceiling price) when a drug company has increased its drug prices faster than the rate of inflation.

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