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Client Alert



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# HHS Finalizes 340B Administrative Dispute Resolution Process

## The New 340B Rule Establishing an Administrative Dispute Resolution Process Was Ten Years in the Making

On December 10, 2020, the U.S. Department of Health and Human Services finalized its long-overdue 340B Administrative Dispute Resolution Rule. The Rule is set to take effect on January 13, 2021, and establishes a process for issuing final binding rulings in disputes between manufacturers and covered entities arising under the 340B program.

The Rule is in many respects identical to the proposed rule that was published by HHS in 2016 and withdrawn in 2017. Because it does not clarify the definition of key statutory terms that are necessary for a meaningful dispute-resolution process, the Rule is a disappointment for manufacturers that had hoped HHS would take a more balanced and comprehensive approach. HHS is continuing to ignore its statutory obligation to protect the 340B program's integrity.

The new ADR process is intended to resolve (i) claims by 340B covered entities that they have been overcharged by manufacturers, and (ii) claims by manufacturers that covered entities have violated the prohibitions against diversion or duplicate discounting. The Rule authorizes the appointment of a panel of agency officials and, in the process of adjudicating disputes, the panel is authorized to address critical "related issues," including covered entity eligibility, the patient definition, and pharmacy ownership. The ADR process does not appear to be available to address all potential violations of the 340B program, such as the GPO prohibition. Significantly, HHS has clarified that the ADR process may not be used to adjudicate challenges to manufacturers' calculations of Average Manufacturer Price or Best Price.

## REGULATORY HISTORY

Congress created the 340B program for the public purpose of ensuring that poor, uninsured, and other underserved patient populations would have access to necessary medications and health care services. Because the program requires participating manufacturers to transfer their covered outpatient drugs to covered entities at deeply discounted prices, the program contains essential safeguards to ensure that the program serves its public purpose. For instance, the statute's "anti-diversion" provision prohibits covered entities from transferring or selling 340B drugs to anyone who is not a patient of the covered entity. The statute also prohibits state Medicaid programs from receiving a Medicaid rebate for any drug purchased at the already discounted 340B price. The statute imposes an affirmative obligation on HHS to protect the program's integrity.

Recognizing that disputes would arise between manufacturers and covered entities, in 2010, as part of the Affordable Care Act ("ACA"), Congress directed HHS to issue regulations establishing an ADR process within 180 days of the ACA's enactment. After an extended delay, in 2016, HHS issued a Notice of Proposed Rulemaking ("NPRM") and invited comment. In January 2017, HHS removed the NPRM from its regulatory agenda and, since then, program participants have waited for HHS to issue a new *proposed* rule. Since the NPRM, the program has witnessed significant changes. HHS's failure to update and clarify who qualifies as a "patient," for example, has resulted in widespread violations of the program's anti-diversion prohibition (and a significant erosion of HRSA's ability to audit covered entities for diversion). Similarly, the rapid growth of contract pharmacy arrangements has resulted in pervasive violations of the statute's anti-diversion and duplicate discount provisions, resulting in third parties profiting from the program at a significant cost to manufacturers and the patients who pay full price at contract pharmacy locations.

Because of these abuses and the significant changes that have occurred under the program, the Pharmaceutical Research and Manufacturers of America ("PhRMA") in November urged HHS to issue a new *proposed* rule, noting that the agency could not finalize its withdrawn 2016 proposal without first addressing program abuses and undertaking a new round of public comment. Without responding to that request, HHS finalized the Rule.

HHS's decision to dust off its outdated proposed rule was prompted by ongoing litigation against the Department filed by covered entities. In their complaints, the covered entities have sought injunctive relief requiring HHS to put in place an ADR process. The covered entities have sought this relief in conjunction with raising concerns that certain manufacturers, tired of waiting for HHS, have chosen to exercise their rights to confront program abuses by adopting carefully designed policies to address the risks of diversion and duplicate discounts by restricting covered entities' ability to insist that 340B drugs be delivered to contract pharmacies. HHS rushed to promulgate the Rule, without seeking further public comment, because of the new lawsuits and its concern that the courts would be dissatisfied by HHS's 10-year failure to comply with its obligations under the ACA.

## 340B ADMINISTRATIVE DISPUTE RESOLUTION MECHANICS

HHS expects that manufacturers and covered entities will use the ADR process only as a last resort after good faith efforts to resolve disputes have failed. Importantly, manufacturers are permitted to proceed under the ADR provisions only if they have first exhausted their onerous audit responsibilities (manufacturer audit responsibilities are set out in 340B Drug Pricing Program Notice Release 2011-3). The Rule makes no allowance to toll the three-year window in which to make claims to conduct and complete the audit.

The ADR process is "not intended to be a trial-like proceeding," but rather an administrative process to assist parties in resolving disputes. With that in mind, HHS intends for the adjudicating panel to have wide latitude to define the proper course of conduct, scope of the process, and any additional instructions that may be necessary or desirable.

As an example of this flexibility, the Rule allows for live arguments via telephone, video conference, or other means, where appropriate.

The Rule creates an ADR Board of at least six members appointed by the HHS Secretary with equal numbers from the Health Resources and Service Administration ("HRSA"), the Centers for Medicare & Medicaid Services ("CMS"), and the HHS Office of the General Counsel ("OGC"). When presented with a claim, a panel will be selected from the Board to adjudicate the dispute. Each panel will consist of one member from each of HRSA, CMS, and OGC, and one HRSA employee that will serve *ex officio*. Parties may not challenge the appointment of panelists. One wonders whether the interests of manufacturers will be adequately protected by a panel of federal employees who may be supportive of expanding the 340B program beyond Congress's intent.

Covered entities and manufacturers initiate actions for damages or equitable relief by filing a petition for relief with HRSA and by mailing a copy to the opposing party. The petition must satisfy the pleading requirements of Rules 8, 10, and 11 of the Federal Rules of Civil Procedure, and must set forth the factual basis for invoking the ADR panel's jurisdiction. If the respondent fails to provide a written response to the petition as required under Rules 12 or 56, the panel may enter a final decision by default in favor of the petitioner.

After the ADR panel receives a claim, it may consider information from a variety of sources, including testimony, audit reports, documentation provided by/requested from the parties, and consultation with OPA subject matter experts. The Rule adopts elements of the Federal Rules of Civil Procedure and Evidence. For example, the panel may consider motions to dismiss and motions for summary judgment, authorize limited discovery, and hold evidentiary hearings. Unique procedural considerations include a jurisdictional limit that requires any relief sought to have a value of more than $25,000, special joinder rules, and standing requirements that permit claims against manufacturers by covered entity trade associations. Also, consistent with the three-year record retention expectation for the 340B program, any claim not filed within three years of the date of the alleged violation is time barred.

The Rule contains discovery procedures by which covered entities—but not manufacturers—may demand information and documents from manufacturers and third parties relevant to their claims. While the 340B statute does not explicitly require parallel discovery rights for manufacturers, HRSA could have created them, consistent with the APA's requirements of reasoned decision-making. Presumably, manufacturers will obtain the documents they need in the course of the audits they are required to conduct before filing a claim. The Final Rule provides that covered entities' discovery shall be governed by the Federal Rules of Civil Procedure. The Final Rule permits the panel, at its discretion, to demand additional information from the parties necessary to conduct a fair, efficient, and expeditious review. In this sense, manufacturers may request discovery, but will obtain it only with the panel's permission.

The ADR panel has broad discretion to "resolve all issues underlying any claim or defense, including … those having to do with covered entity eligibility, patient eligibility, or manufacturer restrictions on 340B sales that the 340B ADR Panel deems relevant for resolving an overcharge, diversion, or duplicate discount claim."

Under the Rule, the petitioner bears the burden of persuasion by a preponderance of the evidence. Decisions may be rendered by simple majority of the three-member ADR panel and are deemed to be final agency action. Decisions will be submitted to HRSA for appropriate action regarding refunds, penalties, removal, or referral to appropriate Federal authorities (including to the HHS Office of Inspector General for consideration of civil monetary penalties, consistent with the 2017 rule on CMPs). ADR determinations are precedential and will be published, presumably on a HRSA web page. Final decisions are binding on all parties "unless invalidated by a court of competent jurisdiction." There is no internal HHS appeals process, but parties may seek judicial review under section 10 of the Administrative Procedure Act.

## IMPACT OF THE FINAL RULE

The ADR process could become the primary mechanism for resolving disputes between manufacturers and 340B covered entities. However, the ADR process will be available only as a last resort when good faith efforts to resolve a dispute have failed. Likewise, the jurisdictional limit of $25,000 will ensure that only claims of some magnitude are permitted to access the ADR process. The availability of the ADR process may have an immediate impact on ongoing litigation, including the litigation described above challenging manufacturers' efforts to address program abuses by adopting contract pharmacy distribution policies.

The ADR process is stacked against manufacturers. For example, trade associations for covered entities may bring claims on behalf of their members. Trade associations for manufacturers may not. Manufacturers are required to fulfill onerous audit requirements before they are permitted to file a claim, while covered entities are not. Covered entities may initiate discovery unilaterally, while manufacturers may only do so through information requests granted at the discretion of the Panel. These imbalances may reflect Congressional understanding in 2010—now known to have been too narrow—that manufacturer overcharging would be the principal reason for having an ADR process. After all, the statute expressly prohibits diversion and duplicate discounts and expressly directs HHS to implement program improvements necessary to protect the 340B program's integrity. It may never have occurred to Congress that current-day disputes are largely the result of HHS's failure to manage the program and police abuses that undermine its patient-focused goals and allow third-parties to profit from 340B drugs.

Other foundational guidance is needed to address issues that may arise in the ADR process. For example, manufacturers remain reliant on a 2011 340B Program Notice Release to establish audit procedures while proposed audit guidelines and the 340B mega-guidance remain unfinalized. Similarly, the 1996 patient definition—long understood to be outdated and inadequate—remains unclarified. Without additional rulemaking or guidance, it remains to be seen whether the ADR process established by the Rule will be an effective means for resolving disputes, or whether it will come to be seen as just an expedient way for HHS to avoid litigation.

In the coming months, manufacturers can expect to find themselves navigating the new and unfamiliar ADR process created by the Final Rule. King & Spalding would be happy to assist in answering any questions that you may have prior to or during the process.