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Probing HHS for Consistency on the 340B Pricing Program Rules on Contract Pharmacies

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Recently, the U.S. Department of Health and Human Services has shifted its approach to several aspects of how drug manufacturers, not-for-profit hospitals and health care facilities, public health clinics, and pharmacies dispense drugs to some of the country's most needy patients under the "340B Drug Pricing Program." HHS's changes (at best) short-circuit the formal rulemaking process and (at worst) defy it altogether. The result for the 340B Program is an ever-changing haze of informal guidance and hurriedly implemented, problematic proposed rules in order to satisfy, solve, or settle litigation filed by opposed stakeholders. Given the importance of the program and its complexities, developments to how the government oversees the 340B Program require thoughtful and pragmatic approaches and mandate that HHS undertake meaningful, proper notice-and-comment rulemaking to fully vet and validate these policy shifts.

Established by Congress in 1992, the 340B Program requires drug manufacturers participating in Medicaid to sell outpatient drugs at deep discounts to public and not-for-profit health care organizations that serve low income or rural patients. This includes federally qualified health centers, children's hospitals, disproportionate share hospitals, certain rural facilities, hemophilia treatment centers, and other clinics that serve certain designated populations. Under the 340B Program, these facilities pay a substantially reduced 340B "ceiling price" for certain outpatient drugs, which can be as little as $0.01. Those "covered entity" facilities can purchase the medications for their patients under the 340B Program, but bill the patient's insurance company at the insurance company's standard rate, allowing the covered entity to keep the difference to help finance the covered entity's operations. Congress conditioned drug makers' ability to receive reimbursement under the Medicare Part B and Medicaid programs on their participation in the 340B Program.

Not every clinic and facility has its own pharmacy to dispense these drugs. In fact, many of these facilities rely on contract pharmacies to handle the job of physically dispensing drugs to their qualifying patients. The pharmacy dispenses the medication and receives the reimbursement, part of which is passed on to the covered entity. Because the prices of 340B medications are so low, there is a legitimate concern about so-called drug diversion. Drug diversion, for purposes of the 340B Program means selling or reselling a covered outpatient drug at the low 340B "ceiling price" to someone who is not eligible to receive lower pricing. This could involve dispensing 340B drugs at ineligible facilities or written by ineligible providers. But it could also involve dispensing 340B drugs to patients at a contract pharmacy who are not patients of the covered entity hospital.

In response to these legitimate diversion concerns, many drug manufacturers have chosen to implement policies that prohibit dispensing 340B drugs to hospitals or facilities without an in-house

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pharmacy, unless the hospital or other facility designates just a single contract pharmacy location to receive and dispense their 340B products. Manufacturers are also increasingly considering exercising their right to audit a covered entity to ensure compliance with 340B drug diversion and duplicate discount prohibitions. For example, Merck in 2020 audited numerous covered entities for duplicate discounts. Other manufactures such as Sanofi and Novartis have also challenged the 340B Program by requiring additional information and audits from covered entities. It is unclear how successful these manufactures will be in curbing any non-compliance by covered entities.

The government believes that these manufacturer-imposed restrictions violate the 340B statute and could subject drug makers to civil monetary penalties. Indeed, the Health Resources & Services Administration, or HRSA—the federal agency within HHS that administers the 340B program—recently found six drug makers in violation of the 340B statute, because "their policies that place restrictions on 340B Program pricing to covered entities that dispense medications through pharmacies under contract have resulted in overcharges and are in direct violation of the 340B statute." A recent seventh drug maker has stepped forward to limit 340B sales to only one designated contract pharmacy.

The 340B program is not easy for drug manufacturers, pharmacy benefit managers, wholesalers, and pharmacies to implement. It requires not only detailed patient and product tracking, but also accurate reporting amongst multiple entities on various prices charged to patient or clinics. It involves government audits, accurate price reporting to the various federal agencies, and the exchange of detailed patient and sales information between pharmaceutical manufacturers, covered entities, and (when utilized) contract pharmacies.

Over the years, HHS (via HRSA) has faced difficulties in implementing this complex drug-pricing scheme. And its recent actions on the question of contract pharmacies reflects yet another unstable regulatory position that is not fundamentally rooted in notice-and-comment rulemaking. HHS's statements and policies on contract pharmacy usage only add to the complexity and confusion of the regulatory landscape—not to mention the administrative burden on drug makers, covered entities, contract pharmacies, pharmacy benefit managers, and others.

Specifically:

Changing Guidance. HHS has not issued clear and consistent guidance on how to implement the 340B program. For example, HHS's first guidance document from 1996, directed at covered entities, acknowledged that there were "many gaps" in the 340B statute including silence "as to permissible drug distribution systems." With respect to contract pharmacies, the original guidance permitted covered entities to contract with *one (and only one) outside pharmacy* to dispense 340B drugs. Fourteen years later, in a guidance document for covered entities from 2010, HHS changed course and allowed covered entities to use an *unlimited number of contract pharmacies* to dispense 340B drugs. And then in late 2020, the HHS General Counsel issued an advisory opinion directed at pharmaceutical manufacturers which stated that restrictions imposed by drug makers on the distribution of 340B-covered drugs to contract pharmacies violated federal law. Unsurprisingly, litigation ensued, and a federal district judge found that the advisory opinion was not a restatement of the federal government's long-held position, as the government had alleged, but rather a shift in policy. Ultimately, HHS withdrew its opinion to avoid confusion. But this has not stopped HHS from moving forward with threatening drug makers with civil monetary penalties if they continue to limit 340B drug dispensing to one contract pharmacy.

Actions driven by Litigation. There has likewise been litigation regarding the ADR process HHS was obligated to undertake to help referee conflicts between pharmaceutical manufacturers and covered entities over things like contract pharmacies. Although Congress directed HHS to create the ADR Rule within 6 months of the Affordable Care Act's passage in 2010, HHS did not even propose an ADR Rule until 2016. Following the close of the notice-and-comment period, the proposed rule began appearing on the government's unified agenda of all federal regulations under development. In early 2017, following President Trump's inauguration, the proposed rule was apparently frozen in accordance with the January 20, 2017 regulatory-freeze memorandum. Later in 2017, however, the ADR Rule was withdrawn from that unified agenda without explanation. Several years later, in October 2020, a number of covered entities filed lawsuits against HHS regarding the 340B program demanding that the Secretary implement an ADR Rule. Within a couple months after covered entities filed those lawsuits, the Secretary implemented the ADR Rule as a final rule as if the prior proposed rule had not been withdrawn. The decision to implement the final rule, apparently in response to the litigation, was all the more curious in light of the fact that 6 months earlier in March 2020, an HHS official was quoted as saying that "[i]t would be challenging to put forth rulemaking on a dispute resolution process when many of the issues that would arise for dispute are only outlined in guidance" and therefore HHS "does not plan to move forward on issuing a regulation due to the challenges with enforcement of guidance." Several ADR petitions have been filed to challenge drug makers' restrictions on the distribution of 340B drugs to contract pharmacies. And other entities, including PhRMA, have sought to repeal these regulations.

Regardless of whether one agrees with HHS's guidance on the use of contract pharmacies or believes that drug makers are entitled to limit the number of contract pharmacies to which it dispenses 340B product, and whether the particular provisions of the ADR Rule are appropriate or not (a topic not even addressed in this post), HHS's actions—spanning across multiple administrations—leave covered entities, pharmaceutical manufacturers, and other stakeholders without a clear consistent understanding of how the complex program should be implemented. In this area, as well as others, industry participants and the public at large would be better served with clear, consistent, notice-and-comment rulemaking clarifying the relevant parties' roles, responsibilities, and requirements.

