In a December 12, 2017 Advisory Board article, “The 340B drug pricing controversy, explained,” Scott Orwig wrote, “the 340B Drug Pricing Program is one of the most contentious issues in health care: Its critics say it ‘hurts patients’ and is being ‘abused’ by hospitals. Its defenders say it’s ‘vital’ to the health of low-income patients and essential to helping safety-net hospitals care for their communities.”

Mr. Orwig’s words from 2017 can easily be recycled today as an apt description of what’s currently going on in the world of the 340B Drug Pricing Program (“340B Program”). Critics are still saying that 340B Program-participating hospitals and other providers (“Covered Entities”) are enriching themselves on discounts that were meant to bring expensive prescription drug therapy to the vulnerable populations routinely treated by the country’s safety-net hospitals. In reply, 340B Program-participating hospitals are saying that pharmaceutical manufacturers are enriching themselves at the expense of safety-net hospitals and the populations they serve.

In this case, the debate at issue relates to the concerns of pharmaceutical manufacturers and others regarding: (i) “duplicate discounts” under the 340B Program and the Medicaid Drug Rebate Program (“MDRP”) – or, as recently described by the American Hospital Association (AHA), the “unsubstantiated” concerns of pharmaceutical manufacturers regarding duplicate discounts; (ii) and the use of contract pharmacy arrangements by 340B Program-participating hospital
I. Duplicate Discounts

As described in prior articles[1] posted on this Blog, the 340B Program and the MDRP require manufacturers to provide discounts on outpatient drugs in order to have their drugs covered by Medicaid. These discounts take the form of (i) reduced sales prices for Covered Entities (qualifying hospitals and other healthcare providers) that participate in the 340B Program and (ii) manufacturer rebates on MDRP-covered drugs dispensed to Medicaid beneficiaries, such rebates being shared by states and the federal government.

In order to protect drug manufacturers from the potential of having to offer “discounts on top of rebates” when a 340B Program drug is dispensed to a Medicaid beneficiary, federal law includes a mechanism designed to protect manufacturers against the possibility of duplicate discounts. According to the federal statute at 42 U.S.C. §256b(a)(5)(A)(i), revenue related to the sale of 340B Program drugs dispensed to Medicaid beneficiaries is to be excluded from the MDRP rebate calculation.

Implementation of the above statutory protection against duplicate discounts requires that state Medicaid programs, when calculating their MDRP rebates, know when 340B Program-covered drugs are dispensed to Medicaid beneficiaries. Notwithstanding the need for such information, in a January 2020 GAO Report, “340B Drug Discount Program: Oversight of the Intersection with the Medicaid Drug Rebate Program Needs Improvement,” (the “2020 GAO Report”) the GAO concluded that there was insufficient oversight at the federal level to ensure that the necessary 340B Program/MDRP information was being submitted to the state Medicaid agencies to limit the duplicate discount risks as required under the statute. Therefore, the GAO recommended that CMS begin requiring state Medicaid agencies to implement policies and procedures to prevent duplicate discounts, and that the Health Resources and Services Administration (“HRSA”), the federal agency charged with the implementation of the 340B Program, assess Covered Entity compliance with those policies and procedures.

In response to the GAO’s recommendations, the HRSA issued a new Program Update on July 20, 2020, that set forth new Covered Entity registration and recertification requirements, including a requirement that covered entities indicate whether they will or will not be billing Medicaid fee-for-service for drugs, “purchased at 340B prices.” If the Covered Entity discloses that it will be billing Medicaid fee-for-service for 340B Program drugs, the Covered Entity must also identify (i) each state Medicaid program that it plans to bill, and (ii) the billing number(s) it will list on the bill to each state Medicaid program.

II. Contract Pharmacies

Citing the issues raised in the 2020 GAO Report and other governmental reports (see below), pharmaceutical manufacturers have taken action to rein-in what they see as provider abuse of the 340B Program at the expense of drug manufacturers. In 2020, such action has focused on the use of contract pharmacies by 340B Program-
Pursuant to contract pharmacy guidelines[2] published by the HRSA in 2010, Covered Entities including 340B Program-participating hospitals may elect to dispense 340B Program-covered drugs to patients through contract pharmacy services, an arrangement in which a Covered Entity signs a written contract with a pharmacy to provide pharmacy services. As described by the HRSA on its Contract Pharmacy Services Webpage, “the use of an individual contract pharmacy or multiple contract pharmacies is voluntary, and a covered entity should first determine its needs for pharmacy services and the appropriate distribution mechanism for those services when deciding whether or not to utilize a contract pharmacy.”

A. Pharmaceutical Manufacturers

According to pharmaceutical manufacturers, the use of contract pharmacies allows providers to improperly benefit from duplicate discounts under the 340B Program and the MDRP without the knowledge or approval of drug manufacturers. Moreover, drugmakers also argue that the use of contract pharmacies facilitates the diversion of 340B Program discount drugs to persons who are not eligible to receive them.

In making the above assertions, pharmaceutical manufacturers often cite to the 2020 GAO Report (see above) as well as two prior governmental reports issued by the GAO and the Office of Inspector General (“OIG”) of the Department of Health and Human Services (“HHS”), respectively. In a 2011 GAO report, “Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement,” (the “2011 GAO Report”) the GAO concluded that the “increased use of the 340B program by contract pharmacies and hospitals may result in greater risk of drug diversion, further heightening concerns about HRSA’s reliance on participants self-policing to oversee the program. Operating the 340B program through contract pharmacies creates more opportunities for drug diversion compared to in-house pharmacies.” In a 2014 OIG report, “Contract Pharmacy Arrangements in the 340B Program,” (the “2014 OIG Report”) the OIG found that contract pharmacies create “complications” in preventing diversion and duplicate discounts. Moreover, following the concerns raised in the 2011 GAO Report, the 2014 OIG Report concluded that Covered Entities often fail to make sufficient compliance efforts to assure that program integrity requirements are met in the 340B Program when utilizing contract pharmacies. Finally, the 2014 OIG Report found that hospitals that utilize contract pharmacies often fail to pass 340B Program discounts on to uninsured patients who receive their medication at such pharmacies.

Given the above and the perception of drugmakers that the 340B Program has been corrupted, in part, by the use of contract pharmacies and the compliance problems they create, multiple pharmaceutical manufacturers have recently notified 340B Program-participating hospitals that they will no longer provide 340B Program discounts if hospitals purchase and ship 340B Program-eligible drugs to specialty or retail pharmacies for patient pick-ups or deliveries instead of dispensing drugs on site. In addition, drugmakers have notified hospitals that they may halt 340B Program discounts if hospitals fail to provide them with claims data for patients enrolled in health plans other than Medicaid. According to those manufacturers that are requesting such additional data, the data is needed to identify and resolve
duplicate Medicaid and commercial rebates.

**B. Provider Response**

In a September 8, 2020 letter (the “AHA Letter”) to HHS, the American Hospital Association (“AHA”) requested that HHS assist the AHA member hospitals from the “pernicious tactics” of drug manufacturers that, according to the AHA, are attempting to undermine the 340B Program by limiting the distribution of discounted prescription drugs to 340B Program-participating hospitals based upon “unsubstantiated” concerns about duplicate discounts between Medicaid and the 340B Program. Pointing to the financial distress being experienced by its membership during the current public health emergency, the AHA castigated the drug manufacturers as, “attempting to exploit for their financial benefit the current COVID-19 health care crisis.”

In prior correspondence sent by AHA to drug manufacturers on August 21, 2020, AHA wrote that it “is an outrage that this action is being taken at a time when hospitals are in the midst of their response to the COVID-19 public health emergency, which has further demonstrated the fractured, inadequate state of the prescription drug supply chain,” and that the drug companies’ actions are “attempting to compel hospitals to divert critical resources away from the pandemic.”

In specific response to the AHA Letter, drugmakers have accused AHA as mischaracterizing their actions as an attempt to limit the distribution of 340B Program-discounted drugs. As described by the manufacturers, their actions are intended to guard against duplicate discounts and provide protection against the compliance problems associated with the use of contract pharmacies.

**III. Government Action and Reaction**

**A. HRSA Comments and Investigation**

Although HRSA has acknowledged that it has limited enforcement authority in relation to its contract pharmacy guidelines (See, Fn. 2), HRSA believes contract pharmacies are a vital function for 340B providers. According to a statement issued by HRSA on July 8, 2020, “[HRSA believes] that manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of access for obtaining their prescriptions.” To this end, HRSA, “continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.”

In a September 2, 2020 statement, HRSA announced that it is investigating whether recent manufacturer policies to restrict access to 340B Program pricing at contract pharmacies violates the 340B Program statute and whether sanctions may apply. In its announcement, HRSA stated that, “We believe that manufacturers that refuse to honor contract pharmacy orders could significantly limit access to 340B-discounted drugs for many underserved and vulnerable populations who may be located in geographically isolated areas and rely on contract pharmacies as a critical point of
access for obtaining their prescriptions. To this end, HRSA continues to strongly encourage all manufacturers to sell 340B priced drugs to covered entities directly and through contract pharmacy arrangements.”

In response to the HRSA announcement, multiple professional associations representing stakeholders in the 340B Program debate applauded HRSA’s initiative to commence an investigation. For example, in a September 3, 2020 Press Release, “ASHP Applauds HRSA, Congress for Inquiries into Drug Manufacturer Attacks on the 340B Program,” Tom Kraus, Vice-President of the Government Relations Division of the American Society of Health-System Pharmacists, wrote, “We are deeply concerned by what appears to be a coordinated effort by manufacturers to restrict the supply of essential drugs to safety net providers....“It is unconscionable that manufacturers are compromising patient care for their own financial benefit. We hope the investigations by HRSA and Congress will shine a light on the threat these manufacturer actions pose to patient access and the patient services supported by 340B savings.”

**B. Word from the Hill**

The contract pharmacy issue and the recent actions of drug manufacturers have also caught the attention of both parties in both chambers.

On September 14, 2020, a bipartisan group of more than 240 House lawmakers sent a letter to Secretary Azar condemning the drug manufacturer actions, as have several members of the House Committee on Energy and Commerce. As described by in a Press Release from Rep. David B. McKinley, P.E., a signatory to the September 14, 2020 letter, “Protecting access to prescription drugs for underserved communities should be a top priority. Unfortunately, the big pharmaceutical companies’ recent actions to restrict 340B drug discounts could jeopardize the ability of hospitals to provide vital services to vulnerable populations....Our letter shows strong bipartisan opposition to this action, and hopefully will convince HHS to intervene.”

In a September 15th letter, a group of Democratic senators asked PhRMA to stop what they allege are likely illegal moves by drug makers. Finally, on September 17, 2020, a bipartisan group of 30 Senators sent a letter to HHS Secretary Alex Azar to express their concerns regarding recent actions from pharmaceutical manufacturers that, “threaten to undermine the role of contract pharmacies in the 340B Drug Pricing Program.” Noting the increased importance of the 340B Program and the role of contract pharmacies during the COVID-19 public health emergency, the Senators called upon HRSA to, “take immediate and appropriate enforcement action to halt [the drug manufacturer’s] tactics and ensure safety-net providers are able to continue providing life-saving medications to patients across the country.”

**IV. More to Come**

It is clear that the AHA and its 340B Program-participating members are hoping that HHS steps in and compels the drug manufacturers to change course in their efforts to restrict access to 340B Program pricing at contract pharmacies. Certainly, Congress is pressing HHS to do the same.
However, if HHS refuses to take action against the drugmakers, the strident rhetoric of the AHA and other 340B Program stakeholders points to a willingness by such organizations to take matters into their own hands by taking drugmakers to court and lobbying Congress to give HRSA more enforcement authority over the 340B Program and, specifically, the ability to enforce HRSA’s contract pharmacy guidance.

Finally, it is worth noting that the willingness of Congress to step into the fray by exerting pressure on HHS and the Administration will likely embolden Covered Entities and their professional associations to aggressively defend the 340B Program against what they consider to be attacks by the drugmakers. For example, in a September 17, 2020 Press Release issued by 340B Health, a membership organization of 340B Program-participating public and private nonprofit hospitals and health systems, 340B Health President and CEO Maureen Testoni is quoted as saying that “the pharmaceutical manufacturers that are refusing to offer drug discounts are not just ignoring the federal statute,...they also are ignoring a majority of elected officials in Congress, who share our view that this behavior is not only unlawful but also harmful to patients in need and to the dedicated health professionals who care for them. We reiterate our call on Secretary Azar to act now.”  In an August 18, 2020 340B Health Press Release, Testoni stated that 340B Health and its constituents are willing to “pursue all legislative and legal avenues available to us to defend the safety net” if HHS refuses to take action.

Stay tuned.

FOOTNOTES


[2] On July 8, 2020, the HRSA issued a statement saying that, although the contract pharmacy guidelines, remain in effect, the guidelines are not legally enforceable.

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