

August 20, 2018

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Federal Trade Commission
Office of the Secretary
600 Pennsylvania Avenue, NW
Suite CC-5610 (Annex C)
Washington, DC 20580-0001

RE: Competition and Consumer Protection in the 21st Century Hearings, Project Number P181201

Dear Commissioners:

On behalf of three group purchasing organizations (GPOs), HealthTrust Purchasing Group (HPG), Intalere, and Premier, Inc., we are writing in response to your request for comments related to Competition and Consumer Protection in the 21st Century, including issues specifically impacting the health care industry. We are focusing our response on issues related to topics 1 and 10. Topic 1 concerns the state of antitrust and consumer protection law and enforcement, and their development, since the Pitofsky hearings. Topic 10 addresses the interpretation and harmonization of state and federal statutes and regulations that prohibit unfair and deceptive acts and practices. Our GPOs are in the business of aggregating purchasing volume and driving maximum competition to negotiate discounts with drug manufacturers on behalf of hospitals and other health care providers. Many of our GPO member organizations are children's hospitals and disproportionate share (DSH) hospitals that participate in the 340B drug discount program (340B program) by virtue of serving a large number of low-income patients.

We know the Federal Trade Commission (FTC) takes seriously the potential impact of anticompetitive practices,¹ especially if they are created as part of a federal or state regulatory structure.² We also know that the issue of competitive drug pricing is an issue of great concern to the Chairman and the White House.³ Thus, we write to urge the FTC, as part of its upcoming

¹ See, e.g., *In the Matter of Victrex plc, et al.*, FTC Docket No. C-4586 (April 27, 2016), available at <https://www.ftc.gov/enforcement/cases-proceedings/141-0042/victrex-plc-et-al-matter>.

² See, e.g., Letter of Comment of the Staff of the Bureau of Competition and the Office of Policy Planning of the Federal Trade Commission to the Food and Drug Administration (Nov. 4, 1999), available at https://www.ftc.gov/sites/default/files/documents/advocacy_documents/ftc-staff-comment-food-and-drug-administration-concerning-180-day-generic-drug-exclusivity/v990016.pdf; Voices for Liberty Fireside Chat with Acting FTC Chair Maureen Ohlhausen, FTC Economic Liberty Task Force (Dec. 14, 2017), available at <https://www.ftc.gov/policy/advocacy/economic-liberty/voices-liberty-fireside-chat>.

³ See Testimony of FTC Chair-nominee Joseph J. Simons, Senate Commerce Committee (Feb. 14, 2018) ("I'm very concerned, as you just described with drug pricing. I think the pharma industry is a critical industry for the economy and for the consumers. It affects people who are in a very vulnerable point in their life often. And so I'm very

hearings, to support the use of federal antitrust agency resources to combat governmental initiatives that reduce competition, increase prices, and harm consumer welfare in the health care industry.

Specifically, we are submitting these comments to express our concerns with a policy issued in 2013 by the Health Resources and Services Administration (HRSA), the federal agency charged with administering the 340B program. The 2013 policy, published as Policy Release 2013-1, reflects HRSA's attempt to implement a provision in the 340B statute that prohibits children's, freestanding cancer, and DSH hospitals from participating in the 340B program if they purchase covered outpatient drugs from a GPO or other group purchasing arrangement. Issued without notice and comment, Policy Release 2013-1 has undermined competition where it had previously existed and created an unnecessary government-authorized monopoly vendor that has increased the cost of drugs for 340B safety-net hospitals. We feel strongly that Policy Release 2013-1 is based on a misinterpretation of the law and should be rescinded. Attached is a legal analysis explaining why HRSA's policy is flawed. We ask for the support of the FTC in rescinding Policy Release 2013-1.

I. Background on the 340B Program, the GPO Limitation, and the Prime Vendor

The 340B program was established by Congress based on the common sense notion that the pharmaceutical industry should do its share to address the problem of uncompensated care in this country. The program requires drug manufacturers to sell certain outpatient drugs at significant discounts to health care providers that serve low income and other disadvantaged populations.⁴ These safety net providers, referred to as "covered entities" in the 340B statute, use their 340B drug savings to serve more patients and provide more services *at no cost to the government*. The law conditions coverage of a drug manufacturer's drugs under Medicaid and Medicare Part B on the company's participation in the 340B program.⁵ Because most manufacturers perceive a business advantage in selling drugs to patients on Medicaid and Medicare Part B, most drug manufacturers that do business in the U.S. participate in the 340B program. The 340B program is administered by HRSA's Office of Pharmacy Affairs (OPA).

The 340B statute imposes a number of limitations on covered entities. A limitation unique to hospitals prohibits the purchasing of covered outpatient drugs through a GPO or other group

interested in dealing with that...If the price spikes are caused by something maybe that is regulatory in nature, alert the FDA to that. And if it's something else, then potentially maybe legislation would be appropriate and we'd come talk to you about it."); *see also* Promoting Healthcare Choice and Competition Across the United States, Exec. Order No. 13,813, 82 Fed. Reg. 48,385 (Oct. 12, 2017).

⁴ Congress enacted the 340B drug discount program in November 1992. Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b (2012). The program is named for section 340B of the Public Health Service Act ("PHSA").

⁵ 42 U.S.C. § 256b(a)(1).

purchasing arrangement.⁶ The GPO limitation applies to children’s hospitals, DSH hospitals and freestanding cancer hospitals.⁷ Compliance with the prohibition is a condition of participation for these hospitals.⁸

The 340B statute also requires HRSA to establish “a prime vendor program under which covered entities may enter into contracts with prime vendors for the distribution of covered outpatient drugs.”⁹ After a couple of false starts, the prime vendor program (PVP) was launched in 1999. A company called Apexus has served as the prime vendor since 2003. Until 2012, the prime vendor did not provide technical assistance to the public. From 2002 to 2012, HRSA contracted with the American Pharmacists Association (APhA) to serve as the 340B Pharmacy Services Support Center (PSSC). The PSSC operated a toll-free telephone help line and provided information, education, and policy analysis to covered entities. Beginning in 2013, the prime vendor assumed the PSSC role as part of its prime vendor responsibilities.

HRSA has never considered the prime vendor to be a group purchasing arrangement for purposes of the GPO limitation. This exception has allowed the prime vendor to function as a GPO by aggregating purchasing volume from both hospital and non-hospital covered entities and using that leverage to negotiate discounts below the 340B ceiling price. The prime vendor uses the exemption to negotiate better pricing on not only 340B drugs, but also non-340B drugs. With respect to the latter function, the prime vendor chose to outsource the task of negotiating drug prices to several drug wholesalers under contract with Apexus. Although not called GPOs, some of these wholesalers function as GPOs and would meet HRSA’s definition of a GPO because they “contract[] with purchasers, such as hospitals, nursing homes, and home health agencies, to aggregate purchasing volume and negotiate final prices with manufacturers, distributors, and other vendors.”¹⁰ Nonetheless, HRSA has never applied the GPO prohibition to wholesalers under contract with the prime vendor.

II. Policy Release 2013-1 and HRSA’s Three-Inventory Policy

Although the 340B statute disqualifies DSH, children’s, and freestanding cancer hospitals from the 340B program if they “obtain covered outpatient drugs through a group purchasing

⁶ *Id.* § 256b(a)(4).

⁷ *Id.* § 256b(a)(4)(L), (M). A DSH is a hospital whose patient population is at least 11.75% low-income. *Id.* § 256b(a)(4)(L)(ii).

⁸ *Id.* § 256b(a)(4)(L)(iii). These covered entities may, however, purchase inpatient drugs from GPOs.

⁹ *Id.* § 256b(a)(8).

¹⁰ 340B Drug Pricing Program Omnibus Guidance, 80 Fed. Reg. 52,300, 52,316 (Aug. 28, 2015). Moreover, Apexus maintains an FAQ on its website that expressly describes discounts negotiated by wholesalers as forbidden group purchasing arrangements: “The following situations are not GPO-prohibition compliant contracting practices: . . . A manufacturer extending a discounted price to a group of covered entities (subject to the GPO prohibition) through a wholesaler . . . that is not supported by an individual contract between the 340B covered entity and the manufacturer.” Apexus, FAQ ID: 1187, <https://340bpvp.com/resourceCenter/faqSearch.html?FAQs=GPO%20Prohibition&category=content&method=gn> (4/15/2015).

organization or other group purchasing arrangement,”¹¹ they may use a GPO to purchase inpatient drugs. As a practical matter, it is not feasible for hospitals to maintain two physically separate inventories—a GPO inventory for inpatient drugs and a 340B inventory for outpatient drugs—because they would essentially have to operate and stock two different pharmacies. Hospitals instead keep a single physical inventory of drugs and comply with the GPO limitation by tracking how drugs are used (inpatient versus outpatient) and using that information to order replacement drugs from the proper wholesaler account (GPO versus 340B).

During the first twenty years of the program, HRSA applied a commonsense understanding of the GPO limitation that allowed hospitals subject to the GPO limitation to use two-inventory systems. Under a two-inventory system, hospitals purchase initial inventories from a GPO. If the hospital furnishes a drug to an inpatient, then it replenishes that drug with one purchased from a GPO. If, on the other hand, the hospital furnishes the drug to an outpatient, it replenishes it with a drug purchased at a 340B price. Hospitals strictly align purchase orders with utilization so that, for example, if a hospital uses ten drugs with a common National Drug Code (NDC) for an inpatient, it replenishes those with ten drugs purchased from the hospital’s GPO account using the same NDC number.¹² If a hospital dispenses or administers ten drugs to 340B-eligible patients, it places a replenishment order of ten drugs with the same NDC on the hospital’s 340B account.

HRSA abruptly retreated from allowing hospitals to use GPO-based two-inventory systems, on February 7, 2013, when it issued Policy Release 2013-1. The agency announced in that publication that “HRSA has not authorized [a] GPO replenishment model”:

Through HRSA’s 340B Program integrity initiatives, HRSA has become aware that some hospitals subject to the GPO prohibition have been purchasing covered outpatient drugs through a GPO and subsequently either (1) “replenishing” through accounting by “replacing” the GPO purchased drug with a drug purchased under 340B; or (2) otherwise reclassifying the method of purchase after dispensing. HRSA has not authorized this GPO replenishment model. The GPO prohibition is violated upon use of a GPO to obtain covered outpatient drugs and cannot be fixed or cured by subsequently changing the characterization through accounting or other methods.¹³

¹¹ 42 U.S.C. § 256b(a)(4)(L)(iii). A DSH is a hospital that treats a large number of low-income or underinsured individuals. *Id.* § 256b(a)(4)(L)(ii). The GPO prohibition applies only to “covered outpatient drugs.” *Id.* § 256b(a)(4)(L)(iii). The 340B statute incorporates the Medicaid definition of “covered outpatient drug” at section 1927(k) of the Social Security Act. *Id.* § 256b(b)(1) (incorporating 42 U.S.C. § 1396r-8(k)).

¹² The NDC is a unique ten-digit number assigned to each drug. *See* U.S. FDA, National Drug Code Directory (Nov. 9, 2017), <https://www.fda.gov/Drugs/InformationOnDrugs/ucm142438.htm>.

¹³ OPA, HRSA, 340B Drug Pricing Program Notice Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization participation (Feb. 7, 2013),

The policy also forbid hospitals from making their initial drug inventory purchases through a GPO account.

HRSA claimed that Policy Release 2013-1 was simply a clarification of the GPO limitation in the 340B statute.¹⁴ HRSA instructed that “[h]ospitals using such models should immediately cease this practice or be found in violation of the GPO prohibition. If a covered entity violates the GPO prohibition, it will be removed from the 340B Program as it will no longer be eligible for participation.”¹⁵ The practical effect of the policy was that our member health systems and other 340B hospitals had to start maintaining three inventories: 1) a 340B inventory for drugs that qualify as “covered outpatient drugs” and are dispensed or administered to 340B-eligible patients; 2) a GPO inventory for inpatient drugs or drugs that don’t otherwise qualify as “covered outpatient drugs”; and 3) a non-GPO, non-340B inventory for initial purchases and when a “covered outpatient drug” cannot be replenished with a 340B drug.

HRSA’s mandate that hospitals establish and make initial purchases through a WAC account created an immediate strain on their drug budgets. To provide some relief, the prime vendor established a non-GPO, non-340B portfolio of drug prices below WAC. Creating the sub-WAC contract file entailed group purchasing, which the prime vendor could not have performed absent a government-sanctioned exception to the GPO limitation that is unique to the PVP. Thus, Policy Release 2013-1 created a sub-WAC monopoly for the prime vendor. Today, when our 340B hospital members make their initial purchases through a non-GPO, non-340B account, the prime vendor’s sub-WAC price file is automatically loaded into that account. Hospitals then replenish those drugs with 340B drugs when used as “covered outpatient drugs” for 340B-eligible patients, with GPO drugs when used for purposes outside the “covered outpatient drug” definition, and with non-GPO, non-340B drugs for anything else.

III. HRSA’s Three-Inventory Policy Has Created A Government-Sponsored Monopoly That Impedes Competition and Results in Higher Drug Costs

Prior to issuance of Policy Release 2013-1, 340B hospitals rarely, if ever, purchased any of their drugs at WAC prices. They certainly appreciated the prime vendor’s interest in saving them some money by offering a sub-WAC price file alternative, but they are dismayed by the solution that the prime vendor chose to implement. Rather than negotiating the sub-WAC prices itself, Apexus outsourced that function to a network of wholesalers that were already under contract with and paying wholesaler fees to Apexus. The wholesalers, in turn, simply agreed to open their existing generic source programs to the hospitals participating in the PVP. Apexus’s parent

<https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf>.

¹⁴ *Id.*

¹⁵ *Id.*

company, Vizient, is also a GPO and, not coincidentally, relies on the same wholesaler generic source programs for its members. Our GPOs, by contrast, do their own negotiating of generic drug prices. So, the prime vendor's decision to offer sub-WAC pricing through the wholesalers has succeeded in driving volume to a unique Vizient program that directly competes with other GPO generic source portfolios. The arrangement gives the prime vendor an incentive to market and steer business to the wholesalers' generic source programs to the detriment of our GPOs and the benefit of Vizient and Apexus.

Compounding the anticompetitive impact of the prime vendor's non-GPO, non-340B portfolio is over-utilization of the portfolio by prime vendor participants. Many covered entities not subject to the GPO prohibition – for example, federally qualified health centers and federally-funded clinics that treat patients with HIV or sexually-transmitted diseases – purchase their non-340B drugs through the prime vendor's sub-WAC account, even though they are legally entitled to purchase such drugs through their existing GPOs, often at lower prices. Hospitals participating in the PVP also over-utilize the sub-WAC account. In particular, they often purchase their inpatient drugs through the sub-WAC account even though inpatient drugs are not subject to the GPO prohibition. The prime vendor has steered these covered entities to its accounts through guidance in its "340B University," which ostensibly exists to educate covered entities about the program but also serves as a marketing tool. HRSA has directed Apexus to remove the most problematic materials, but it is difficult, if not impossible, to eliminate the common misperception among covered entities that they are required to buy through the sub-WAC file because it is being offered by a government contractor.

Our organizations firmly believe that the prime vendor has exploited its exemption from the GPO limitation to launch what is essentially a government-sponsored monopoly of non-340B pricing for 340B hospitals subject to the limitation. We further believe that HRSA is facilitating this monopoly rather than trying to stop it. By requiring hospitals to transition from using GPO-based two-inventory systems to WAC-based three-inventory systems, HRSA essentially shifted the non-340B market for these hospitals from their GPOs to the prime vendor. In this manner, HRSA's three-inventory policy has distorted the pharmaceutical market and created a government-sanctioned advantage for its own vendor at the expense of GPOs.

There is little doubt that Policy Release 2013-1 has driven up the cost of drugs for 340B hospitals. A 2015 survey of 340B hospitals showed that approximately 90 percent of respondents affected by the policy reported increased spending on their non-GPO, non-340B accounts. These hospital drug costs have increased for at least three reasons. First, the prices they must pay by being forced to purchase through non-GPO, non-340B accounts, even with access to the prime vendor's sub-WAC prices, are substantially higher than what they would pay through their GPO accounts. Second, the three-inventory system has created tremendous operating burdens for 340B health systems and has increased labor and software costs. One analysis estimates that the

policy has raised costs by \$223 million since its inception. Third, HRSA is enforcing its policy in a draconian fashion which is causing hospitals to err on the side of caution by purchasing through their sub-WAC account when they are clearly entitled to purchase through their GPO account. Our members tell us that, if HRSA discovers that a hospital has used a single GPO drug on a hospital outpatient, even if unintended, HRSA could terminate it from the 340B program or force it to make significant repayments to manufacturers. Hospitals therefore have to invest in rigorous self-auditing programs to prevent inadvertent GPO violations, driving up their operational costs further.

Policy Release 2013-1, and the sub-WAC portfolio program that grew out of that policy, run counter to the FTC's goals of ensuring market competition and preventing unfair and deceptive acts and practices that ultimately hurt consumers. They are also diametrically opposed to the Trump Administration's policy of promoting health care competition and choice. President Trump issued an Executive Order stating the Administration's policy is to "re-inject competition into healthcare markets by lowering barriers to entry, limiting excessive consolidation, and preventing abuses of market power."¹⁶ We believe that Policy Release 2013-1 is inconsistent that Executive Order and should be rescinded. We ask for the FTC's support in achieving that goal.

IV. Allowing Hospitals to Return to Purchasing Through a Two-Inventory System Would Not Violate the GPO Limitation

When HRSA issued Policy Release 2013-1 in February 2013, all 340B hospitals subject to the GPO limitation had to quickly overhaul how they maintained their GPO and 340B drug inventories. The agency directed hospitals to abandon their GPO/340B two-inventory systems, to replace them with a WAC/GPO/340B three-inventory system, and to make initial purchases of each NDC from the hospital's new WAC account.¹⁷ HRSA insisted that hospitals needed to transition to this new WAC-based three-inventory system in order to comply with the GPO limitation.¹⁸ The prior practice of purchasing an initial inventory at GPO and replenishing covered outpatient drugs at 340B violated the statute because, according to the agency, the initial GPO purchases were a *per se* violation of the limitation and the act of replenishment could not "cure" such non-compliance.¹⁹ HRSA also explained that an initial WAC inventory is needed to

¹⁶ Promoting Healthcare Choice and Competition Across the United States, Exec. Order No. 13,813, 82 Fed. Reg. 48,385 (Oct. 12, 2017).

¹⁷ OPA, HRSA, 340B Drug Pricing Program Notice Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization participation (Feb. 7, 2013), <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf>.

¹⁸ *Id.*

¹⁹ *Id.*

protect against non-compliance for those occasions when GPO-purchased covered outpatient drugs cannot be replenished in the first place.²⁰

A close examination of the statute, coupled with an understanding of how hospital drugs are purchased and priced in the U.S., leads to the inevitable conclusion that Policy Release 2013-1 is fatally flawed. It was issued on the mistaken assumption that the GPO limitation is violated the instant a hospital makes an initial purchase of a given drug from its GPO account and takes possession of the drug. A violation of the limitation can never occur in this manner because, at that time, the drug is neither a “covered outpatient drug” nor obtained through a GPO, both of which are clearly required under the plain language of the law. And if that were not enough, the only other way of understanding of the limitation – one which applies the law retroactively after the drug is purchased, used, billed and reimbursed – is consistent with the only Supreme Court precedent relevant to a hospital’s challenge of maintaining two different drug inventories.²¹ The inherent need to apply the GPO limitation based on a retroactive reconciliation of multiple factors is precisely why the Supreme Court, when faced with a surprisingly similar set of facts, accepted the use of “general accounting principles” to satisfy federal drug pricing standards.²² The irony of HRSA’s decision to issue Policy Release 2013-1 is that it supplanted a twenty-year understanding of the GPO limitation that was consistent with not only Supreme Court guidance and the realities of the U.S. supply chain, but also the plain meaning of the law itself.

HRSA cites another reason in defense of issuing Policy Release 2013-1 that, like the first reason, does not stand up to scrutiny. According to the agency, there are occasions when an initial inventory of GPO-purchased drugs cannot be replenished, resulting in a violation of the GPO limitation that could have been avoided if the initial inventory had been purchased at WAC. The problem with this line of reasoning is that it is based on a misunderstanding of the GPO limitation – one in which there is zero tolerance for deviating from the limitation at the individual drug level – that Congress never intended and that HRSA has never implemented. The reality is that the GPO limitation was intended to force hospitals to choose between using the private GPO market or the 340B program to obtain drug discounts, not to disqualify hospitals from the latter when circumstances beyond their control cause outpatient use of GPO drugs. And HRSA, by repeatedly recognizing exceptions to the limitation since the law’s inception, has implemented the GPO limitation in exactly that way.

For 21 years, HRSA was flexible in its interpretation of the GPO limitation, allowing hospitals to initially fill prescriptions for their patients using their portfolio of GPO-priced drugs. HRSA allowed hospitals to purchase covered outpatient drugs through GPOs and only barred “cherry picking” between the lower of the GPO or 340B price.²³ A 2004 HRSA policy let hospitals use a

²⁰ *Id.*

²¹ *Abbott Labs. v. Portland Retail Druggists Ass’n, Inc.*, 425 U.S. 1 (1976).

²² *Id.* at 19-21.

²³ Brief for Appellee at 28, *Univ. Med. Ctr. of S. Nev. v. Shalala*, 173 F.3d 438 (D.C. Cir. 1999) (No. 98-5317).

GPO to purchase “covered outpatient drugs” during the first three months of a hospital’s participation in the 340B program.²⁴ This flexible application of the GPO limitation supported the near universal use of GPO-based two-inventory systems by 340B hospitals. Although HRSA claimed that it was unaware of hospitals’ reliance on such systems until it started auditing hospitals shortly before publishing Policy Release 2013-1, the agency’s claim lacks credibility. HRSA knew prior to 2013 that hospitals used two-inventory systems and permitted this practice. HRSA audit contractors were aware of hospital two-inventory systems, and HRSA participated in conferences with open discussion of the two-inventory systems. The prime vendor issued an FAQ endorsing two-inventory systems and publicly promoted certain preferred vendors of two-inventory “split billing” systems.²⁵ Indeed, Policy Release 2013-1 itself permits limited GPO purchasing of covered outpatient drugs by allowing hospitals to “opt-out” any off-site facility from the program.²⁶

The narrow areas in which hospitals cannot replenish their initial GPO inventories for reasons beyond their control do not represent the kinds of conduct that Congress intended to address through the GPO limitation. Purchasing these drugs at WAC is unnecessary because Congress never intended that the GPO limitation apply to them in the first place. HRSA should therefore invoke its current and longstanding “opt-out” policy to clarify explicitly that use of GPO drugs in these areas falls outside the scope of the limitation.

V. FTC Should Recommend Rescission of HRSA’s WAC-Based Three-Inventory Policy

For the above reasons, we believe Policy Release 2013-1 should be rescinded and that hospitals subject to the GPO limitation be allowed to return to using GPO-based two-inventory systems. We believe withdrawing Policy Release 2013-1 would advance the FTC’s goal of fostering open, marketplace competition, which would result in lower drug prices. We therefore call on the FTC to support rescission of HRSA’s WAC-based three-inventory policy.

Sincerely,

HealthTrust Purchasing Group (HPG)

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Premier Inc.

²⁴ OPA, HRSA, FAQ Answer ID 422, 340B Anti-Diversion and Medicaid Billing Requirements for Hospitals (June 28, 2005) (last visited Jan. 10, 2006).

²⁵ OPA, HRSA, FAQ Answer ID 418, DSH Outpatient Settings & 340B (June 29, 2005) (last visited Jan. 9, 2006).

²⁶ OPA, HRSA, 340B Drug Pricing Program Notice Release No. 2013-1, Statutory Prohibition on Group Purchasing Organization participation (Feb. 7, 2013), <https://www.hrsa.gov/sites/default/files/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf>.