

Tab 2-17



Public Hospital Pharmacy Coalition

www.phpcrx.org

(A Coalition of the National Association of Public Hospitals and Health Systems)

October 5, 2004

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VIA FACSIMILE & U.S. MAIL

Re: Use of GPO Drugs for 340B Hospitals' Non-Patients

Dear Jimmy:

This letter follows up on a recent meeting between the Office of Pharmacy Affairs ("OPA") and the Public Hospital Pharmacy Coalition ("PHPC") to discuss a range of issues relating to the anticipated influx of rural and small urban hospitals into the 340B program. One of the issues that we discussed is whether enrollment into the 340B program has any impact on the existing pricing for drugs dispensed to hospital patients who do not qualify for 340B discounts. As you know, 340B hospitals often serve individuals who do not qualify as "patients" within the meaning of the 340B statute and these individuals are not eligible to receive 340B-discounted drugs due to the program's prohibition against diversion. As we mentioned during the meeting, 340B hospitals are currently buying these drugs through their group purchasing organizations ("GPOs") at prices that are generally lower than those available to retail pharmacies. You raised a concern during our meeting about the scope of the 340B program's "GPO exclusion" and whether the exclusion prohibits purchasing GPO drugs for non-340B patients. It is PHPC's view that the scope of the GPO exclusion is limited to drugs dispensed to 340B patients and therefore does not prohibit the purchase of GPO drugs for patients who are not eligible for 340B drugs. You asked us to explain our position in writing, so we are submitting this letter in response to your request.

I. INTRODUCTION

Prior to enactment of the 340B statute, all nonprofit hospitals that would eventually become eligible to participate in the 340B program had access to discounted



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drugs under a different federal law called the Nonprofit Institutions Act.¹ This act allows pharmaceutical manufacturers and wholesalers to offer and sell to nonprofit institutions lower prices on drugs than those charged to for-profit and retail purchasers without violating the anti-discrimination standards established under the Robinson Patman Act. An important restriction under the Nonprofit Institutions Act limits the nonprofit customer's use of the discounted drugs to the purchaser's "own use."² A 1976 Supreme Court case interpreting the "own use" limitation clarified the scope of the patient population eligible to receive discounted drugs from nonprofit providers.³ For hospitals, the Supreme Court decision permits the discounted drugs to be dispensed or administered to most hospital outpatients, as well as to hospital employees. Recognizing the significant opportunity for drug savings created by the Nonprofit Institutions Act, most nonprofit hospitals decided to purchase in groups in order to pool their purchasing power and maximize their preferred pricing arrangements with manufacturers. GPOs such as Novation, Premier, Amerinet and others are currently taking advantage of this opportunity for its nonprofit members.

Following passage of the 340B statute, nonprofit hospitals eligible to participate in the 340B program had to wrestle with the interaction of two federal laws that each generate discounts on outpatient drugs but use very different means to achieve those discounts. The hospitals quickly discovered not only that the 340B discount mechanism is different from the preferential pricing provision of the Nonprofit Institutions Act, but also that the group of hospital outpatients eligible for 340B-discounted drugs is different from the group of individuals who fall within the nonprofit "own use" standard. For individuals eligible for discounted drugs under both 340B and the "own use" standard, and for others who fall outside the "own use" doctrine but qualify as 340B-eligible patients, hospitals have assumed that the discounts are controlled by the 340B statute. However, for individuals who are ineligible for 340B pricing but are entitled to preferential pricing under "own use," hospitals have assumed that the Nonprofit Institutions Act controls. For purposes of this memorandum, we will refer to these individuals as "own use/non-340B patients" or simply as "own use patients." Given that hospitals participating in the 340B program have historically considered the Nonprofit Institutions Act to be the controlling statute applicable to outpatient drugs dispensed to own use/non-340B patients, these hospitals have purchased these drugs, both in the past and today, off of their GPO contracts. Set forth below is an explanation of why PHPC believes that this practice is both lawful and consistent with congressional intent.

¹ Nonprofit Institutions Act, Act of May 26, 1938, ch. 283, 52 Stat. 446 (codified at 15 U.S.C. § 13c).

² See 15 U.S.C. § 13c.

³ *Abbott Laboratories v. Portland Retail Druggists*, 425 U.S. 1, 96 S.Ct. 1305 (1976).

II. THE NONPROFIT INSTITUTIONS ACT, NOT THE 340B STATUTE, GOVERNS THE PURCHASE AND DISPENSING OF DRUGS TO OWN USE/NON-340B PATIENTS

A good example of an own use/non-340B patient is an employee of a 340B hospital who does not receive any services from the hospital. Under the Nonprofit Institutions Act, and the Supreme Court's interpretation of the "own use" provision therein, the hospital is entitled to dispense to the employee discounted drugs that have been purchased at prices below those available to retail pharmacies and other commercial purchasers.⁴ The hospital has access to these below-market prices by buying through its GPO, which negotiates on behalf of many other nonprofit institutions. In the absence of the Nonprofit Institutions Act, the sale of drugs at prices below those available in the retail market would be at risk of violating the Robinson Patman anti-discrimination law.⁵

Whereas the sale of discounted drugs for own use/non-340B patients falls under the authority of the Nonprofit Institutions Act, it is less clear whether these activities are also governed under the 340B program. The price reduction provisions of the 340B statute do not apply because the statute prohibits the sale or transfer of 340B-discounted drugs to anyone other than a patient of the covered entity and own use patients do not fall within the definition of a patient under 340B guidelines. Other 340B provisions – such as the prohibition against duplicate discounts and manufacturer audit procedures – also do not apply to own use/non-340B patients. Indeed, the only 340B requirement that arguably applies to own use patients is the GPO exclusion. According to the 340B statute, 340B hospitals are precluded from "obtain[ing] covered outpatient drugs through a group purchasing organization or other group purchasing arrangement."⁶ One could argue that the GPO exclusion as stated in the statute applies to all "covered outpatient drugs" regardless of their recipient. Under this argument, 340B hospitals should not purchase any drug that meets the definition of a "covered outpatient drug" through a GPO, even drugs dispensed to own use/non-340B patients.

The problem with this interpretation of the 340B statute is that it renders meaningless the Nonprofit Institutions Act for outpatient drugs purchased by 340B hospitals. Not only would the Nonprofit Institutions Act and own use standard be preempted by the 340B program for drugs dispensed to individuals who fall *within* 340B patient definition standards, but preemption would also occur for individuals who fall *outside* the patient definition. In short, the Nonprofit Institutions Act would be stripped of any relevance with respect to 340B hospitals. This result conflicts with well-

⁴ *Abbott Laboratories*, 425 U.S. at 16, 96 S.Ct. at 1315.

⁵ 15 U.S.C. § 13.

⁶ 42 U.S.C. § 256b(4)(L)(iii). Federal guidelines indicate, however, that this "GPO exclusion" does not apply to inpatient drugs or to outpatient drugs that fall outside the definition of a "covered outpatient drug." See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Entity Guidelines, 59 Fed.Reg. 25,110, 25,113 (May 13, 1994).

established rules of statutory construction. According to the Supreme Court, "where two statutes are 'capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.'"⁷ Thus, if the 340B statute and the Nonprofit Institutions Act can be read such that neither statute is negated by the other, then such an interpretation should be adopted unless Congress clearly intended otherwise.⁸ In the case of these two statutes, it is relatively easy to reconcile them in such a way as to give effect to both. The GPO exclusion can be interpreted such that it applies to covered outpatient drugs dispensed or administered to 340B-eligible patients *only*. Not only does this interpretation give meaning to both statutes consistent with federal preemption law, but it also makes sense in the broader context of the 340B statute. Congress inserted the GPO exclusion into the definition of a covered entity disproportionate share hospital in order to force hospitals to choose between buying their discounted drugs through GPOs or the 340B program. Prohibiting non-340B patients from accessing GPO pricing would serve no purpose because, unlike 340B-eligible patients, the hospital does not enjoy an opportunity to buy through two different discount programs for this population.

Construing the GPO exclusion as co-extensive with the 340B definition of patient would not be without precedent. In fact, PHPC is aware of two examples where the government has interpreted the GPO exclusion as being constrained by other provisions of the 340B statute. First, with respect to hospitals that are presumably ineligible to participate in the 340B program because they purchase covered outpatient drugs through a GPO, the government has upheld the right of these hospitals to participate in the 340B program under certain circumstances. In a 1999 D.C. Circuit Court case – the only federal court opinion regarding the 340B program – the court found that the Department of Health and Human Services ("HHS") had, at one time, interpreted the GPO exclusion in a limited fashion that allowed 340B hospitals to purchase some covered outpatient drugs through GPOs.⁹ Specifically, from the time the 340B statute was enacted until June 1994, HHS interpreted the GPO exclusion such that it prohibited only "double dipping," the practice of obtaining both a 340B discount and a GPO discount on the same drug.¹⁰ The second example is when the government supported the eligibility of 340B hospitals to participate in the 340B prime vendor program, including the program's price negotiation activities, even though such participation could be construed as a violation of the GPO exclusion. Again HRSA and OPA interpreted the exclusion in a flexible manner. These two examples provide instructive precedent for interpreting the GPO

⁷ *Ruckelhaus v. Monsanto Co.*, 467 U.S. 986, 1018, 104 S. Ct. 2862, 2881 (1984)(quoting *Regional Rail Reorganization Act Cases*, 419 U.S. 102, 133-34, 95 S. Ct. 335, 353 (1974)).

⁸ *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124, 143, 122 S. Ct. 593, 605 (2001); *Morton v. Mancari*, 417 U.S. 535, 551, 94 S. Ct. 2474, 2483 (1974); *United States v. Borden Co.*, 308 U.S. 188, 197, 60 S. Ct. 182, 188 (1939).

⁹ See *University Medical Center of Southern Nevada v. Shalala*, D.C. Cir. No. 97c00560 (April 13, 1999).

¹⁰ See *id.*

exclusion consistent with broader policy objectives, in this case, preserving congressional intent to give nonprofit hospitals access to preferred pricing on drugs under the Nonprofit Institutions Act.

Federal courts often turn to an examination of legislative history after reviewing statutory language in cases involving statutory interpretation, and, in this case, the legislative history of the 340B statute does nothing to undermine our conclusion that disproportionate share hospitals are entitled to buy off their GPO contracts for own use patients. Congress enacted the 340B statute, which is Section 602 of the Veterans Health Care Act of 1992, in response to the impact that the Medicaid rebate program had on drug costs.¹¹ Specifically, Congress created the Medicaid rebate program in 1990 to lower the cost of pharmaceuticals reimbursed by state Medicaid agencies, but the program inadvertently raised the prices on drugs purchased by other federal- and state-funded payors. As a result of the Medicaid rebate law, many pharmaceutical companies had a disincentive to continue giving deep discounts on drugs because they would have to pay larger rebates to Medicaid if they gave deeper discounts in the non-Medicaid market (establishing even better “best prices”). When manufacturers began raising their prices, the Medicaid savings achieved through the rebate program were offset by increased government spending on drugs purchased by other federal- and state-supported providers. Congress enacted the 340B statute to correct this situation. Therefore, the legislative intent behind the 340B statute had nothing to do with undermining or repealing the applicability of the Nonprofit Institutions Act to purchasing and dispensing of non-340B drugs.

Federal case law emphatically supports the conclusion that implied repeals of federal statutes by other federal statutes is not favored absent clear congressional intent.¹² As the legislative history of the 340B statute shows, there was no congressional intent to repeal the Nonprofit Institutions Act in its entirety with respect to its application to hospitals eligible to participate in the 340B program. The 340B statute circumscribes the Nonprofit Institutions Act as far as that act had applied to purchases and dispensing of drugs to 340B patients because the 340B statute created a comprehensive scheme for governing those transactions. The restriction of the Nonprofit Institutions Act should be

¹¹ See, e.g., Senate Report (Veterans' Affairs Committee) No. 102-401 to accompany S. 2575; House Report (Veterans' Affairs Committee) No. 102-384(I) to accompany H.R. 2890; House Report (Energy and Commerce Committee) No. 102-384(II) to accompany H.R. 2890; and Hearing on H.R. 2890, H.R. 3405 and H.R. 5614, Prescription Drug Rebate Program, No. 102-156.

¹² See, e.g., *Cook County, Ill. v. United States ex rel. Chandler*, 538 U.S. 119, 132, 123 S. Ct. 1239, 1248 (2003)(stating that “repeals by implication are not favored”); *U.S. v. Fausto*, 484 U.S. 439, 452 (1988)(stating that “a later statute will not be held to have implicitly repealed an earlier one unless there is a clear repugnancy between the two...”); *Watt v. Alaska*, 451 U.S. 259, 266-67, 101 S. Ct. 1673, 1678 (1981)(stating that “repeals by implication are not favored” and declining to find that a later enacted federal statute takes precedence over an earlier federal statute absent a clear intent by Congress, even when the administering agency interprets the earlier statute as partially repealed).

interpreted as narrowly as possible, however, to continue giving effect to the statute. As there is no basis in either statutory language or legislative history for interpreting the 340B statute as repealing the applicability of the Nonprofit Institutions Act to transactions involving drugs given to own use/non-340B patients, HRSA and OPA should refrain from doing so.

III. POLICY CONSIDERATIONS SUPPORT PURCHASING GPO DRUGS FOR OWN USE PATIENTS

Allowing 340B hospitals to purchase GPO drugs for individuals who do not qualify as hospital patients for 340B purposes will foster the aims of the 340B program. Specifically, Congress intended for the program to result in financial savings for 340B hospitals and other covered entities so that they could provide additional services to the needy populations they serve.¹³ By eliminating the possibility of purchasing drugs for own use patients through GPOs, OPA effectively will force 340B hospitals to either (1) expend scarce financial resources by purchasing these drugs at higher retail prices or (2) quit providing drugs to non-patients. The result of either choice will be to limit the health care services and products available to hospital patients. This clearly was not the result Congress intended. On the other hand, if 340B hospitals can purchase own use/non-340B patients' drugs through GPOs, the hospitals will be able to engage in the same negotiating strategies available to all other hospitals and thereby keep their drug costs as low as possible.

Additionally, precluding 340B hospitals from purchasing drugs through GPOs for own use/non-340B patients will be detrimental to many local free care clinics and other non-profit, safety net facilities. In a letter dated January 6, 2004, the U.S. Federal Trade Commission, the agency charged with administering the Nonprofit Institutions Act, held that hospitals that are covered by the act may transfer drugs to other non-profit facilities, such as local clinics, as long as the hospital does not charge the non-profit facility in excess of the hospital's direct costs for the drugs.¹⁴ Thus, if hospitals that enter the 340B program are prohibited from using GPOs to obtain discounts for own use/non-340B patients, free care clinics and other safety net facilities that rely on the discounts previously obtained by such hospitals through GPOs will be forced to spend significantly more on drugs for their patients.

Finally, an expansive reading of the GPO exclusion such that it prohibits hospitals from purchasing GPO drugs for own use/non-340B patients would create a strong

¹³ House Report (Energy and Commerce Committee) No. 102-384(II) to accompany H.R. 2890, Background and Need for the Legislation: Current Law ("[i]n giving these 'covered entities' access to price reductions the Committee intends to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.").

¹⁴ Letter from Jeffrey W. Brennan, Bureau of Competition, U.S. Federal Trade Commission, to Judy Erb, Dunlap Memorial Hospital, available at <http://www.ftc.gov/os/2004/01/040106dunlaplet.pdf>.

Jimmy Mitchell
October 5, 2004
Page 7

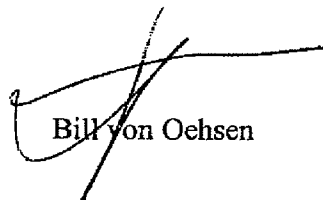
disincentive for hospitals to enroll in the 340B program. Forcing hospitals to purchase some of its drugs at retail prices is a penalty that hospitals would have to evaluate when determining whether enrollment in the 340B program is desirable. Any financial analysis of 340B enrollment would include offsetting the savings a hospital would obtain on 340B drugs by the increased costs of acquiring drugs for own use patients. The increased costs would include not only the higher purchase prices for those drugs but also the extra administrative costs of managing yet another inventory of drugs in addition to the 340B and GPO drugs that the hospital also would have to track. When a similar disincentive to 340B enrollment arose in connection with the 340B program's Medicaid billing rule, the government took action to eliminate the disincentive. In that situation, the government recognized the need for the Medicaid "carve out" so that 340B covered entities would not be financially penalized for joining the 340B program. In a sense, PHPC is asking the government to allow 340B hospitals to "carve out" their own use/non-340B patients' drugs from the GPO exclusion.

It is worth noting that, under PHPC's suggested interpretation, 340B hospitals would not be able to cherry pick which drugs are purchased through 340B and which are purchased through GPOs. 340B hospitals still would have to purchase all drugs dispensed to 340B patients at 340B prices. GPO pricing would be available only for drugs that hospitals could not purchase through the 340B program. Accordingly, government recognition and acceptance of 340B hospitals' historical use of GPO pricing for own use patients would not erode HRSA's policy prohibiting cherry picking.

IV. CONCLUSION

On behalf of PHPC, we hope that we have presented a convincing case for why 340B hospitals should be permitted to use GPO pricing for patients who are ineligible for the benefits of the 340B program. An examination of the relevant statutory language, legislative history and policy considerations all lead to a conclusion that OPA should permit 340B hospitals to purchase drugs through GPOs for their own use/non-340B patients. Please do not hesitate to contact us at 202-466-6550 if you have any questions.

Sincerely,



Bill von Oehsen



Claire Holloway