



**Public Hospital Pharmacy Coalition**

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

**OPPORTUNITIES FOR PHARMACEUTICAL  
MANUFACTURERS TO OFFER DEEPER  
DISCOUNTS ON BRAND NAME INPATIENT  
DRUGS FOR 340B HOSPITALS**

**November 2004**



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## PHARMACEUTICAL MANUFACTURERS CAN OFFER LOWER INPATIENT DRUG PRICES AS A RESULT OF THE EXPANDED BEST PRICE EXEMPTION IN THE MEDICARE PRESCRIPTION DRUG BILL

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the “Act”) includes language that exempts prices that 340B hospitals pay for inpatient drugs from pharmaceutical manufacturers’ “best price” calculations. The relevant statutory provision in the Act became effective on December 8, 2003. The Public Hospital Pharmacy Coalition (PHPC), which is a coalition of over 200 hospitals participating in the 340B program, wants to take this opportunity to describe both the history and content of the “best price” exemption provision, and to explain how the provision may impact inpatient drug price negotiations.

### Background

In 1990, Congress established the Medicaid drug rebate program, which generally protects the Medicaid program from paying more for covered outpatient drugs than other purchasers in the U.S. drug market. Under the drug rebate program, pharmaceutical manufacturers that wish to have their drugs reimbursed by Medicaid must enter into agreements with the Department of Health and Human Services (HHS). These agreements obligate the manufacturers of brand name drugs to pay rebates to Medicaid based on the manufacturers’ “best price” for each of their drugs. By tying a manufacturer’s “best price” for a given brand name drug to the size of the rebate that the company must pay for the drug, Congress created a disincentive for manufacturers to offer low drug prices to any purchaser in the U.S. market. Manufacturers have a legitimate concern that by giving a lower price they will establish a new “best price” which, in turn, will increase their rebate obligations.

To eliminate this disincentive with respect to drugs sold to “safety net” providers, Congress revisited the Medicaid drug rebate program in 1992 and established a companion discount program - set forth in section 340B of the Public Health Service Act - for twelve categories of publicly-supported health care providers called “covered entities”. Congress also amended the Medicaid statute so that “any prices” paid by covered entities for brand name pharmaceuticals are exempt from manufacturers’ calculations of “best price”. (42 U.S.C. § 1396r-8(c)(1)(C)) (See Tab A). This “best price” exemption allows manufacturers to offer low drug prices to covered entities without having to extend those prices to the entire Medicaid program. Both the Medicaid rebate and 340B programs require manufacturers to give discounts on “covered outpatient drugs” under the manufacturers’ agreements with HHS. Although the definition of a “covered outpatient drug” has certain exclusions, including drugs paid for as part of inpatient services, the price of these excluded drugs must still be used by brand name manufacturers in reporting their “best price” to the government and in calculating their rebates and 340B discounts.

Despite the clear language of the Medicaid statute exempting “any prices” paid by covered entities from manufacturers’ “best price,” the Centers for Medicare and Medicaid Services (CMS) interpreted the statute as exempting only prices paid for *outpatient* drugs (See Tab B). This interpretation significantly constrained the ability of pharmaceutical manufacturers and hospitals participating in the 340B program to negotiate appropriate prices for inpatient drugs. To rectify this problem, Congress included language in both the House and Senate

versions of the Medicare drug legislation that specifically exempts *inpatient* drug prices paid by 340B hospitals from manufacturers' "best price" calculations. The House and Senate provisions were identical except that the Senate version had an October 1, 2003 effective date, while the House version did not mention an effective date. Congress eventually adopted the House version during conference, which means that the 340B hospital inpatient exemption went into effect when President Bush signed the Act on December 8, 2003. The new provision subjects 340B hospitals' purchases of inpatient drugs to the same auditing and recordkeeping requirements that pertain to covered entities' purchases of outpatient drugs (See Tab C).

Although the new provision is self-implementing, CMS and HRSA formally notified manufacturers of the "best price" changes in separate communications. CMS contacted manufacturers first when it issued Release #64 on March 2, 2004 (See Tab D). The Release makes clear that the new exemption only applies to drugs sold on or after December 8, 2003. Some industry analysts argued that, because the exemption is described as a "clarification" of existing law, the exemption should apply retroactively to 1992 when the original "best price" exemption for 340B covered entities was enacted by Congress. CMS interprets the exemption, however, as only applying to sales on or after December 8, 2003. HRSA's notification to manufacturers was in the form of a letter sent by HRSA Administrator Elizabeth Duke on April 1, 2004 (See Tab E). HRSA's letter, which also addressed another provision in the Act (expanding the 340B program to include rural and small urban hospitals), specifically recognizes how the best price clarification creates an opportunity for companies to sell inpatient drugs at "lower prices" because such prices no longer have the potential to reduce prices paid by other customers or to increase rebate payments to state Medicaid agencies. HRSA sent a similar letter to every hospital in the country (See Tab F).

### **Implementation Options**

Although the newly-clarified exemption does not mandate ceiling prices for inpatient drugs, it should result in lower inpatient drug prices for 340B hospitals. Hospitals participating in the 340B program provide significant amounts of charity care and function as safety net providers for indigent and uninsured patients across the country. Additionally, many of these hospitals serve as teaching hospitals and influence the prescribing patterns of thousands of physicians. We therefore believe that both providers and manufacturers can benefit from the ability to negotiate lower inpatient drug prices that will be exempt from "best price" calculations. We anticipate that 340B hospitals will employ at least three negotiating mechanisms to utilize the newly-clarified exemption.

The first option that 340B hospitals may want to consider is to negotiate lower inpatient drug prices through their existing group purchasing organizations (GPOs). In contrast to outpatient drug purchasing, 340B hospitals are not prohibited under the 340B statute or any other federal law from purchasing their inpatient drugs through a GPO. Indeed, the legislative history of the 340B statute indicates that Congress did not intend to disturb 340B hospitals' relationships with GPOs regarding inpatient drug purchases (See Tab G). GPOs therefore may try to negotiate below-contract prices on inpatient drugs for their 340B hospital members by either entering into new vendor agreements or modifying their existing contracts in order to segregate their inpatient drug purchases for 340B member hospitals from those of non-340B hospitals. In response to pharmaceutical manufacturer concerns over the role of GPOs in negotiating inpatient discounts,

PHPC recently drafted a letter to the GPO industry trade group that explains why these concerns are unfounded (See Tab H).

A second option is for 340B hospitals to negotiate directly with manufacturers to lower their inpatient drug costs. Hospitals interested in this approach likely will analyze their existing formularies and product needs in order to identify classes of drugs in which they can move market share in exchange for lower prices. Hospitals and manufacturers then can enter into market share agreements that would generate lower pricing on inpatient purchases. Note that, if a hospital is interested in negotiating individually with manufacturers, it should consider the impact of this strategy on the activities of its GPO.

A third option for hospitals is to purchase inpatient drugs jointly with other 340B covered entities, both hospitals and non-hospitals. This option will allow the covered entities to combine their purchasing volume to obtain lower pricing. This option is similar to the GPO strategy described above except that, instead of a 340B hospital relying on its existing GPO to negotiate lower inpatient prices, the hospital would initiate a new joint purchasing effort with just those covered entities with which the hospital believes it can make formulary decisions and meet compliance goals. For example, a 340B hospital may wish to purchase jointly with the federally qualified health centers, health departments, and other disproportionate share hospitals within its local service area, or even within its state. To be successful, the hospital will need to select partners and develop a process for creating a formulary that will maximize compliance with the group's formulary decisions. Again, the absence of any prohibition against group purchasing for inpatient drugs means that 340B hospitals may pool their inpatient purchasing volume among themselves or with non-hospital 340B providers. Including hospital's outpatient volume in such negotiations would be prohibited, however, unless the hospitals join the prime vendor program and the prime vendor is willing to negotiate both inpatient and outpatient prices for 340B hospital participants.

### **Impact on VA and FSS Pricing**

Some drug manufacturers may express a concern that lower inpatient drug prices for 340B hospitals will increase the discounts that the manufacturers must extend to the Department of Veterans Affairs (VA) and other federal agencies under the Federal Ceiling Price (FCP) or Federal Supply Schedule (FSS) programs. Under the FCP program, the four largest purchasers of pharmaceuticals within the federal government - the VA, Department of Defense, Public Health Service and Coast Guard - are entitled to discounted prices on brand name drugs equal to or less than 24 percent off of the drugs' non-federal average manufacturer price - often referred to as "non-FAMP". Because the inpatient drug prices paid by 340B hospitals are currently included in non-FAMP calculations, a manufacturer might not want to negotiate on these prices for fear that lower prices will bring down its non-FAMP averages which, in turn, will increase the FCP discount that must be given to the VA. Manufacturers might also be concerned that lower inpatient prices for 340B hospitals could trigger the price reduction clauses in their FSS contracts or be used by federal contract officers to negotiate lower FSS prices based on "most favored customers" requirements. Although such changes to a company's FCP and FSS prices are theoretically possible, we don't anticipate that a manufacturer's FCP or FSS prices would be adversely affected in a significant way, if at all. We say this for several reasons.

First, we believe that the impact of lower inpatient prices on a drug's non-FAMP calculation is too small to pose a meaningful obstacle to negotiations. Non-FAMP is calculated on a yearly basis by taking the average of literally millions of sales transactions. The incremental reduction in non-FAMP (and therefore FCP) due to a 20 to 25 percent discount on inpatient drugs for a group of 200 hospitals should be infinitesimal. Under current VA policy, 340B ceiling prices are exempt from non-FAMP calculations but subceiling prices are not. One would expect that, if the non-FAMP formula truly discourages manufacturers from giving deeper discounts on prices included in the formula, hospitals would be unable to negotiate 340B subceiling prices. Yet, both the number of hospitals receiving subceiling prices and the size of the subceiling discounts have been climbing steadily. We therefore do not think that lower inpatient drug prices for 340B hospitals will have a discernible impact on non-FAMP prices.

Second, even if a company perceives that the impact of non-FAMP is sufficiently problematic to deter it from negotiating with 340B hospitals, the VA has developed an option for manufacturers to exempt 340B inpatient prices from their non-FAMP calculations. This option was first described in a letter to PHPC dated December 4, 1998 (See Tab I). A more detailed description of the option was issued recently to manufacturers in a VA "Dear Manufacturer" letter dated July 8, 2004 (See Tab J). According to the "Dear Manufacturer" letter, the VA will exempt from non-FAMP a hospital's inpatient price for a given brand name drug if the manufacturer satisfies four conditions. In particular, the manufacturer must: (1) commit to providing to all 340B hospitals the 340B ceiling price for inpatient covered drugs; (2) offer the 340B ceiling price on either all of its commercially marketed inpatient covered drugs or specified covered drug product lines (but in the latter case the pricing must be offered on all commercially marketed NDC packages of the specified product lines); (3) communicate its inpatient pricing commitment in a written statement to the VA and HRSA, and notify the VA and HRSA in writing of any changes to its commitment – adding or subtracting product lines or revoking the commitment entirely – within 14 days of such change; and (4) request that the VA issue a "hold harmless" letter. Attached to the VA's "Dear Manufacturer" letter is a template letter suggested by PHPC and approved by the VA that manufacturers can use to satisfy the four conditions described above (See Tab J). The policy reflected in the "Dear Manufacturer" letter affords manufacturers an option that is guaranteed to eliminate any potential problem with FCP that may result from extending lower inpatient drug prices to 340B hospitals.

Finally, we believe that deeper discounts on 340B hospital inpatient drugs will not affect manufacturers' FSS contract prices. This is true with respect to both brand name drugs and generic and over-the-counter (OTC) drugs. If a manufacturer meets the four terms of the VA's "Dear Manufacturer" letter described above, then the resulting "hold harmless" letter that it receives will protect the manufacturer against the VA using the lower inpatient prices to extract deeper discounts under the FSS price reduction or most favored customer provisions (See Tab J). Although the "Dear Manufacturer" letter relates exclusively to brand name drugs, the VA issued an identical policy for generic and OTC drugs (See Tab K). Adherence to these policies will guarantee that deeper inpatient prices will not affect a company's FSS prices. However, deviation from the conditions spelled out in the VA's policies does not necessarily mean that FSS prices will be harmed. For example, if a manufacturer chooses to give an inpatient discount above or below the 340B ceiling price, we doubt that the VA would be successful in seeking to incorporate the new inpatient discount into the company's FSS price list. The company could object on the grounds that any drop in price for 340B hospitals would be predicated on unique terms and conditions that would not apply to an FSS purchaser. Moreover, FSS prices are

derived more frequently from prices negotiated by GPOs and large managed care companies rather than from individual hospitals. So PHPC believes that the risk is negligible that a company's FSS pricing will be adversely affected if the company chooses to lower its inpatient drug prices for 340B hospitals.

### **Industry Response**

It is not surprising that, after several years of trying to convince CMS and Congress to exempt 340B hospital inpatient prices from the best price formula, hospitals had high expectations that inpatient drug prices would decline quickly following enactment of their exemption language. Some manufacturers have stepped forward and lowered their inpatient prices, but most have opted against making any pricing changes. The reason most commonly cited for not lowering prices is the anticipated adverse impact on FCP and FSS prices, notwithstanding our analysis that such impact would be negligible. Other reasons mentioned by manufacturers include the absence of any federal guidance implementing the best price clarification and the 340B prohibition against hospitals negotiating through their GPOs. Complaints about the lack of federal guidance seem to have dissipated following issuance of Release #64 and HRSA's letter to manufacturers. Concerns about the legality of inpatient price negotiations by GPOs also seem to be fading, largely because they are based on a misunderstanding of a provision in the 340B statute prohibiting hospitals from acquiring *outpatient* drugs through GPOs or other group purchasing arrangements. PHPC's analysis of why the 340B prohibition against group purchasing does not apply to inpatient drugs is explained in a letter sent to the GPO industry on April 28, 2004 (See Tab H). One manufacturer has limited inpatient 340B pricing to only those hospitals that purchase through the 340B prime vendor program. PHPC is in the process of following up with this company to learn more about its offer.

Because the inpatient best price exemption does not require manufacturers to lower their prices, a reduction in inpatient prices will only occur if a manufacturer perceives that it will gain certain business or political advantages by discounting its inpatient prices. It is therefore reasonable to expect that 340B hospital inpatient prices will decline over time as the market adjusts to the new law. Hospitals and GPOs can help speed up this process by using formularies and other negotiation strategies to reward manufacturers that lower inpatient prices. PHPC meanwhile has been very active in addressing and helping to clarify federal policies that may be impeding operation of the market. Most of PHPC's efforts have involved encouraging the VA to communicate directly with industry about the impact of lower inpatient prices on FCP and FSS calculations. These efforts, which included a face-to-face meeting between PHPC counsel Bill von Oehsen and VA attorney Mel Noel in Chicago, culminated in the VA's release of the "Dear Manufacturer" letter dated July 8, 2004 (See Tab J). Mel Noel also attended and delivered a presentation about the "Dear Manufacturer" letter at a meeting of manufacturers and 340B hospitals at the 340B Coalition's Eighth Annual Conference on July 12, 2004. In addition, at the request of PHPC, the VA has developed a policy to address any concerns that makers of generic and OTC pharmaceutical products might have regarding FSS pricing (See Tab K).

Of course, if the new best price exemption proves ineffective in encouraging manufacturers to lower their inpatient prices to 340B hospitals, PHPC will seek legislation mandating extension of 340B prices to inpatient drugs. At least one bill has already been introduced in Congress that would achieve this goal: H.R. 4161 sponsored by Congressman

Bobby Rush (D-IL) (See Tab L). PHPC is also urging HRSA to explore the possibility of reinterpreting current law in a manner that would require manufacturers to give 340B discounts on all drugs, inpatient and outpatient. PHPC sent HRSA a letter in March 2004 explaining how the law could be reinterpreted this way. However, a short reply by HRSA in July indicates that HRSA is not inclined to pursue PHPC's recommendation at this time.

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If you have questions about the implementation of the inpatient drug price exemption, please contact Bill von Oehsen or Ted Slafsky at 202-466-6550 or [william.vonoehsen@ppsv.com](mailto:william.vonoehsen@ppsv.com) or [ted.slafsky@phpcrx.org](mailto:ted.slafsky@phpcrx.org).

# **TAB A**

**TITLE 42, CHAPTER 7, SUBCHAPTER XIX**

**SEC. 1396r-8: Payment for Covered Outpatient Drugs**

**(C) Best price defined.**

For purposes of this section -

**(i) In general -**

The term "best price" means, with respect to a single source drug or innovator multiple source drug of a manufacturer, the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding -

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code<sup>[121]</sup>, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program; and

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government.

**(ii) Special rules -**

The term "best price" -

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package; and

(III) shall not take into account prices that are merely nominal in amount.

**TAB B**



MEDICAID DRUG REBATE PROGRAM Release No. 7

\* \* \* IMMEDIATE ATTENTION REQUIRED \* \* \*

NOTE TO: All Participating Drug Manufacturers

50% REBATE CAP - TECHNICAL AMENDMENT PASSED

In Release Number 6 to manufacturers, we notified you that a strict legal reading of section 601(c) of the Veterans Health Care Act of 1992 (VHCA) removed the 50-percent rebate cap of average manufacturer price (AMP) for the October 1, 1992 - December 31, 1992 quarter. However, based on requests from Congressional members, we implemented the Medicaid provisions of the VHCA as though the 50-percent cap remained in effect for this quarter pending a technical correction.

On April 12, 1993, the Veterans Health Care Act of 1992-- Technical Corrections, (Pub. Law 103-18), was signed into law. Section 2(a) of Pub. Law 103-18 amended section 601(c) of VHCA to restore the 50 percent cap for that quarter. This amendment is effective as if it were included in the enactment of section 601(c) of the VHCA. Thus, section 1927(c)(1)(B)(ii)(II) of the Social Security Act has been amended to provide that for the quarter beginning after September 30, 1992 and before January 1, 1993, the amount of the rebate may not exceed 50 percent of the AMP. For all quarters beginning after December 31, 1992, the cap is removed.

MINIMUM REBATE PERCENTAGES MANDATED BY THE VETERANS HEALTH CARE ACT (VHCA) OF 1992 (P.L. 102-585)

Per section 601(c) of the VHCA, the following minimum percentages are to be used when computing the unit rebate amount for single source and innovator multiple source drugs:

<u>PERIOD</u>	<u>PERCENTAGE</u>
10/01/92 - 12/31/93	15.7 *
01/01/94 - 12/31/94	15.4
01/01/95 - 12/31/95	15.2
01/01/96 forward	15.1

\* FOR THE QUARTER 10/01/92 THROUGH 12/31/92, THE AMP CAP OF 50% IS IN EFFECT. EFFECTIVE 01/01/93, THERE IS NO CAP USED IN THE CALCULATION.

The rebate percentages for non-innovator multiple source drugs remain 10 percent through 12/31/93 and 11 percent beginning 01/01/94.

#### AVERAGE MANUFACTURER PRICES (AMPs) FOR TERMINATED DRUGS

There continues to be confusion regarding the difference between what AMP to report for four quarters beyond shelf life for a terminated, specific package size of a drug, as opposed to an entire product line of a drug.

Terminated Product: When you stop selling a product, please use the calculated AMP based on sales for the last quarter you had sales. This AMP is submitted to HCFA, quarter by quarter for all package sizes, until four quarters beyond shelf life have elapsed.

Terminated Package Size: In the case where only a specific package size of a product is terminated, but other package sizes continue to be active, please use the AMP of the active package sizes as the AMP for the terminated package size until four calendar quarters beyond shelf life for that package size have elapsed. At that point, you may stop reporting that package size. Any deviation from this procedure is incorrect and may result in different AMPs for different package sizes of the same drug product.

#### CALCULATING AMP AND BEST PRICE (BP) FOR DIFFERENT QUARTERS

In a discussion with personnel at a drug company, we were consulted about calculating the correct AMP and BP when sales are limited.

Situation: This example involves a single source drug only sold during the first quarter of the year. For the remainder of the year, there are no recorded sales. During the first quarter of the next year, the only sale for the drug is a special sale to an HMO on a one-time basis only.

Background: The drug rebate agreement states that "Best Price means....., the lowest price,..... in the same quarter for which the AMP is computed." Does this mean that the Best Price continues to be the one from last year or should it be the new Best Price?

For the second, third and fourth quarters of the first year, the AMP and BP from the first quarter are used. Because of the special sale during the first quarter of the next year, the BP is calculated from that quarter (and reflects the special lower price given to the HMO). The AMP is not changed since the sale is to a non-retail entity.

Solution: The BP should be changed to reflect the New Best Price even though the AMP is still the one from the first quarter of last year. The reasoning behind this decision is that the AMP is calculated EACH QUARTER without regard to the fact that circumstances may cause it to revert back to a previous quarter for Unit Rebate Amount calculations (as in this example). Thus, manufacturers must report AMP and BP data, if applicable, each quarter regardless of whether there are no changes from the previous quarter.

### BEST PRICE EXCLUSIONS

In our Release Number 6 to manufacturers, we noted that effective October 1, 1992, you must exclude from the best price calculation any prices charged to Public Health Service (PHS) covered entities listed under section 340B(a)(4) of the PHS Act. Several manufacturers have questioned if they can exclude from best price all drug prices charged to those disproportionate share hospitals (DSHs) that qualify as a covered entity under 340B(a)(4)(L). Manufacturers may only exclude from their best price calculation those prices charged for outpatient drugs sold to a DSH covered entity. All prices charged for inpatient drugs sold to a DSH must be included in a manufacturer's best price calculation.

Manufacturers have raised concerns that they may not be able to identify if discounted outpatient drugs are used in the inpatient portion of the DSH which does not qualify for the mandated discount. On March 9, 1993, the PHS sent a letter to its covered entities containing guidelines explaining how the program works and the responsibilities of covered entities. In that PHS letter under section IV, Drug Diversion and Entity Guidelines, PHS states the following:

Covered entities are required not to resell or otherwise transfer an outpatient drug purchased at the statutory price to an individual who is not a patient of the entity. If the entity fills prescriptions for individuals, other than patients of the covered entity, the entity must develop and institute adequate safeguards to prevent the transfer of discounted outpatient drugs to facilities that are not eligible for the discount.

Further, covered entities must only utilize the discounted outpatient drugs in the eligible outpatient clinics and not in other clinics that may be only housed within a larger entity. Section 340B(a)(6) of the PHS Act recognized that a covered entity may be part of a larger facility and states that the larger facility will not be considered eligible for the discounted drug prices unless it is listed as a covered entity.

Thus, a DSH covered entity must have in place separate inventories for its inpatient and outpatient drugs and may not transfer its outpatient drugs purchased at a discount to the inpatient portion of the hospital. Therefore, for purposes of the Medicaid rebate program, these prices for outpatient drugs would be excluded in their entirety.

#### DATA REPORTING REQUIREMENTS

We are reminding all labelers that quarterly pricing data must be submitted by labelers and received by HCFA within 30 days after the end of each quarter. Some manufacturers have failed to comply with this requirement, and in some cases, action has been taken against them.

We are taking this opportunity to cite section 1927(b)(3)(C)(i) of the Social Security Act (the Act) regarding HCFA's authority to impose penalties in these cases.

#### (C) PENALTIES.-

##### (i) FAILURE TO PROVIDE TIMELY INFORMATION.-

In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) [that is, pricing information to HCFA] on a timely basis, the amount of the penalty shall be increased by \$10,000 for each day in which such information has not been provided and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the date of such 90-day period and until such information is reported (but in no case shall such suspension be for a period of less than 30 days).

Additionally, section 1927(b)(4)(B)(i) of the Act provides HCFA with the authority to terminate a rebate agreement for violations of the agreement or other good cause. Section 1927(b)(4)(B)(iii) of the Act specifies the requirement that there must be a delay for reentry into the agreement of one calendar quarter after termination.



MEDICAID DRUG REBATE PROGRAM Release No. 11

\* \* \* IMMEDIATE ATTENTION REQUIRED \* \* \*

NOTE TO: All Participating Drug Manufacturers

BEST PRICE TO DISPROPORTINATE SHARE HOSPITAL (DSH) COVERED ENTITIES

On April 29, 1993, we issued the following statement in Manufacturer Release No. 7:

Manufacturers may only exclude from their best price calculation those prices charged for outpatient drugs sold to a DSH covered entity. All prices charged for inpatient drugs sold to a DSH must be included in a manufacturer's best price calculation.

Some hospitals and manufacturers have questioned this statement with regard to prices for inpatient drugs sold to a DSH. Specifically, some manufacturers claim that they cannot offer the Medicaid best price on inpatient drugs to these DSHs based on the language in Release No. 7. This interpretation is incorrect. Manufacturers can offer the DSH their current best price without setting a new best price specifically for that DSH (e.g., if the manufacturer is selling the drug for 10 cents per tablet to a health maintenance organization or other large-volume buyer, the manufacturer can offer that price to the DSH inpatient side.)

Please refer to UPDATED enclosure C (Manufacturer Data Dictionary) of the Drug Rebate contract included as an attachment to Manufacturer Release 10, dated February 14, 1994, for a complete definition of Best Price, including all exclusions to the calculation of it.

AVERAGE MANUFACTURER PRICE (AMP) CLARIFICATION FOR HEMOPHILIC DRUGS

We wish to clarify that sales of hemophilic drugs to home health care providers MUST be included in the calculation of AMP, and, if applicable, Best Price. If any manufacturer has incorrectly excluded these sales from the pricing calculations, please submit corrected pricing data for any and all affected quarters.

Page 2 - Medicaid Drug Rebate Program Release Number 11

SEPARATE MEDICAID DRUG REBATE AGREEMENTS WITH STATES

**TAB C**

1 (3) EFFECTIVE PERIOD.—This subsection shall apply  
2 through December 31, 2005.

3 **SEC. 1002. CLARIFICATION OF INCLUSION OF INPA-**  
4 **TIENT DRUG PRICES CHARGED TO CERTAIN**  
5 **PUBLIC HOSPITALS IN THE BEST PRICE EX-**  
6 **EMPTIONS FOR THE MEDICAID DRUG RE-**  
7 **BATE PROGRAM.**

8 (a) IN GENERAL.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C.  
9 1396r-8(c)(1)(C)(i)(I)) is amended by inserting before the  
10 semicolon the following: “(including inpatient prices charged to  
11 hospitals described in section 340B(a)(4)(L) of the Public  
12 Health Service Act)”.

13 (b) ANTI-DIVERSION PROTECTION.—Section  
14 1927(c)(1)(C) (42 U.S.C. 1396r-8(c)(1)(C)) is amended by  
15 adding at the end the following:

16 “(iii) APPLICATION OF AUDITING AND REC-  
17 ORDKEEPING REQUIREMENTS.—With respect to a  
18 covered entity described in section 340B(a)(4)(L)  
19 of the Public Health Service Act, any drug pur-  
20 chased for inpatient use shall be subject to the au-  
21 diting and recordkeeping requirements described in  
22 section 340B(a)(5)(C) of the Public Health Service  
23 Act.”

24 **SEC. 1003. EXTENSION OF MORATORIUM.**

25 (a) IN GENERAL.—Section 6408(a)(3) of the Omnibus  
26 Budget Reconciliation Act of 1989, as amended by section  
27 13642 of the Omnibus Budget Reconciliation Act of 1993 and  
28 section 4758 of the Balanced Budget Act of 1997, is  
29 amended—

- 30 (1) by striking “until December 31, 2002”, and
- 31 (2) by striking “Kent Community Hospital Complex in  
32 Michigan or.”

33 (b) EFFECTIVE DATES.—

34 (1) PERMANENT EXTENSION.—The amendment made  
35 by subsection (a)(1) shall take effect as if included in the  
36 amendment made by section 4758 of the Balanced Budget  
37 Act of 1997.

**TAB D**

March 2, 2004

MEDICAID DRUG REBATE PROGRAM

RELEASE #64

# Bulletin

For  
Participating Drug Manufacturers



**INPATIENT DRUG PRICES CHARGED TO CERTAIN PUBLIC HOSPITALS:  
AMENDMENT UNDER THE MEDICARE PRESCRIPTION DRUG,  
IMPROVEMENT, AND MODERNIZATION ACT OF 2003 ENACTED  
DECEMBER 8, 2003**

Section 1002(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) amends section 1927(c)(1)(C)(i)(I) of the Social Security Act (the Act) to exempt inpatient prices charged to disproportionate share hospitals that participate in the 340B program from manufacturer's best price calculations. This exemption applies to drugs sold on or after December 8, 2003.

Section 1002(b) of the MMA amends section 1927(c)(1)(C) of the Act by including inpatient drugs in the provision that subjects these hospital drug purchases to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

The Health Resources and Services Administration (HRSA) maintains a public database of all hospitals that participate in the 340B program, and manufacturers should use this database to properly track sales for purposes of determining best price. The database is available on HRSA's website at <http://bphc.hrsa.gov/opa/downld.htm>.

/s/

Edward C. Gendron  
Director  
Finance, Systems and Budget Group

cc:

All Regional Administrators

All Associate Regional Administrators, Division of Medicaid

# **TAB E**



APR 1 2004

Dear Manufacturer:

This letter provides information about two provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) which affect the Drug Pricing Program established by section 340B of the Public Health Service Act. One provision exempts inpatient drug prices from best price reporting for purchases made by disproportionate share hospitals (DSH) participating in the 340B program. This provision may encourage more eligible DSHs to participate in 340B. The other raises the disproportionate share adjustment percentage for small rural and urban hospitals. This provision may make about 1,000 additional hospitals eligible to participate in the 340B program.

Section 1002 of the MMA, "Clarification of Inclusion of Inpatient Drug Prices Charged to Certain Public Hospitals in the Best Price Exemptions for the Medicaid Drug Rebate Program," amends the section of the Medicaid Rebate law (section 1927(c)(1)(C)(i)(I) of the Social Security Act) that specifies which prices paid for drugs are to be excluded from the quarterly best price reported by drug manufacturers to the Centers for Medicare & Medicaid Services (CMS). The amendment adds inpatient prices charged to DSHs participating in the 340B drug pricing program to the list of exemptions. This provision was effective on December 8, 2003. This provision should make it possible for your company to sell inpatient drugs to these DSHs at lower prices, now that these prices no longer have the potential to lower prices paid by other customers or increase your rebate payments to Medicaid state agencies.

Section 402 of the Act, "Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds," changes the DSH adjustment for a hospital that is not a large urban hospital to the same adjustment formula used for large urban hospitals, subject to an overall cap of 12%. Rural referral centers are not subject to the cap. If this new adjustment process results in an adjustment percentage that is greater than 11.75, the DSH may be eligible to register as a covered entity authorized to purchase outpatient drugs at 340B prices. The actual adjustment percentage for each hospital will be determined by the CMS.

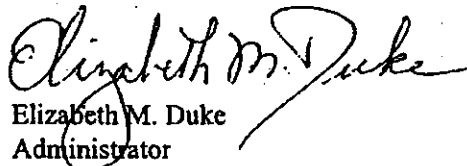
Page 2

To become eligible for the 340B program, the DSH must also meet the two other statutory criteria, as specified by section 340B(a)(4)(L) of the Public Health Service Act:

- Be owned or operated by a unit of State or local government, be a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or be a private non-profit hospital which has a contract with a State or local government to provide health care services to low-income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the Medicaid State plan and
- Not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

If you need any additional information about the impact of these provisions on the 340B program, please contact HRSA's Pharmacy Affairs Branch Pharmacy Support Services Center at 1-800-628-6297.

Sincerely,

  
Elizabeth M. Duke  
Administrator

**TAB F**



APR 1 2004

Dear Hospital Executive:

This letter provides information about two provisions in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) which could lower the prices your hospital now pays for drugs. One provision exempts inpatient drug prices from best price reporting for drug purchases made by disproportionate share hospitals (DSHs) participating in the drug pricing program established by section 340B of the Public Health Service Act. The other raises the disproportionate share adjustment percentage cap for small rural and urban hospitals. This provision may make your hospital eligible to participate in the 340B drug pricing program.

Section 1002 of the MMA, "Clarification of Inclusion of Inpatient Drug Prices Charged to Certain Public Hospitals in the Best Price Exemptions for the Medicaid Drug Rebate Program," amends the section of the Medicaid Rebate law (section 1927(c)(1)(C)(i)(I)) of the Social Security Act that specifies which drug prices are to be excluded from the quarterly best price reported by drug manufacturers to the Center for Medicare & Medicaid Services (CMS). The amendment adds inpatient prices charged to DSHs participating in the Section 340B drug pricing program to the list of exemptions. This provision was effective on December 8, 2003.

Section 402 of the Act, "Enhanced Disproportionate Share Hospital (DSH) Treatment for Rural Hospitals and Urban Hospitals with Fewer than 100 Beds," changes the DSH adjustment formula for a hospital that is not a large urban hospital to the same adjustment formula used for large urban hospitals, subject to an overall cap of 12%. Rural referral centers are not subject to the cap. If this new adjustment process results in an adjustment percentage for your hospital that is greater than 11.75, your hospital may be eligible to register as a covered entity authorized to purchase outpatient drugs at 340B prices. The actual adjustment percentage for your hospital will be determined by the CMS.

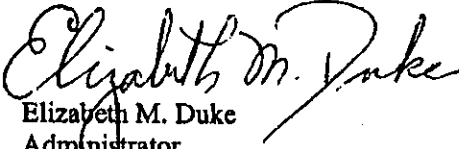
To participate in the 340B program a DSH must meet the following criteria, as specified by section 340B(a)(4)(L) of the Public Health Service Act:

- Be owned or operated by a unit of State or local government, be a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or be a private non-profit hospital which has a contract with a State or local government to provide health care services to low-income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the Medicaid State plan;
- For the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act; and
- Does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.

If your hospital now meets these criteria, it is easy to register as a covered entity authorized to purchase covered outpatient drugs at 340B prices. Visit our Pharmacy Affairs web site (<http://bphc.hrsa.gov/opa>), click on "Legal Resources," download the appropriate form for your type of DSH, and submit the necessary documentation to the Pharmacy Affairs Branch, 4350 East West Highway, 3<sup>rd</sup> Floor, Bethesda, MD 20814.

If you need any advice or technical assistance to determine how best to proceed, contact the HRSA's Pharmacy Affairs Branch Pharmacy Services Support Center at 1-800-628-6297.

Sincerely,

  
Elizabeth M. Duke  
Administrator

**TAB G**

102d Congress

HOUSE OF REPRESENTATIVES

Rept. 102-384

2d Session

Part 2

=====

THE MEDICAID DRUG REBATE AMENDMENTS OF 1992

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September 22, 1992.--Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Mr. Dingell, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 2890 which on July 15, 1991, was referred jointly to the Committee on Veterans' Affairs and the Committee on Energy and Commerce]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2890) to establish limits on the prices of drugs procured by the Department of Veterans Affairs, and for other purposes, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

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The amendments are as follows:

Strike out all after the enacting clause and insert in lieu thereof the following:

SECTION 1. SHORT TITLE.

purposes of determining the Medicaid basic rebate with respect to single source or innovator multiple source drugs any of the following: (1) prices charged to the Department of Veterans Affairs (DVA), the Department of Defense, the Federal Bureau of Prisons, or any other purchaser under the Federal Supply Schedule of the General Services Administration; (2) prices charged to the Indian Health Service; (3) prices used under a State pharmaceutical assistance program by reference to prices charged to the DVA; and (4) prices charged to a "covered entity." For this purpose, a "covered entity" means (a) a Federally-qualified health center; (b) a family planning project receiving a grant or contract under section 1001 of the Public Health Service (PHS) Act; (c) an entity receiving a categorical grant to provide outpatient early intervention services for HIV disease under title XXVI of the PHS Act; (d) a State-operated AIDS drug purchasing assistance program receiving Federal funds under title XXVI of the PHS Act; (e) a comprehensive hemophilia diagnostic treatment center receiving a grant under section 501(a)(2) of the Social Security Act; and (5) a "disproportionate share" hospital that meets certain requirements. As defined under current Medicaid law, a Federally-qualified health center includes entities receiving Federal funds through the Community Health Center, Migrant Health Center, and Health Care for the Homeless programs under the PHS Act, as well as certain entities which do not actually receive Federal funds but are certified by the Secretary meet the requirements for doing so, and outpatient programs or facilities operated by Indian tribes or tribal organizations. In order to qualify as a "covered entity," a clinic, program, or project falling into one of these five categories must also meet requirements relating to the prohibition of duplicate rebates, the prohibition of resale of drugs, and auditing.

The requirements that a hospital must meet in order to be a "covered entity" are as follows. First, the hospital must meet the definition of a hospital set forth in section 1886(d)(1)(B) of the Social Security Act, which in general excludes psychiatric, rehabilitation, children's, chronic care, and cancer treatment or research hospitals. Second, the hospital must be owned or operated by a unit of State or local government. The Committee recognizes that some "public" hospitals are not owned or operated by a unit of State or local government. The bill would therefore also extend "covered entity" status to a public or private nonprofit corporation which is formally granted governmental powers by a unit of State or local government, and to a private nonprofit hospital which has a contract with a State or local government health care to low-income individuals who are not eligible for Medicaid or Medicare. The Committee does not intend to extend "covered entity" status to a private nonprofit hospital that has a minor contract to provide indigent care which represents an insignificant portion of its operating revenues. Third, the hospital, for the most recent cost reporting period ending before the calendar quarter involved, must have had a Medicare disproportionate share adjustment percentage greater than 12.5 percent or, in the alternative, be located in an urban area, have 100 or more beds, and receive more than 30 percent of its inpatient care revenues (excluding Medicare and Medicaid payments) from State and local government payments for indigent care.

Finally, a hospital may not be a "covered entity" under the Committee bill if it obtains covered outpatient drugs through a group purchasing organization or other group purchasing arrangement. The Committee recognizes that the public disproportionate share hospitals which the Committee is seeking to protect from high drug prices may participate in, or themselves maintain, group purchasing arrangements for a variety of purposes, including the purchase of supplies and equipment as well as pharmaceuticals. The Committee does not intend to disturb these arrangements or to require the withdrawal of these hospitals from these organizations or arrangements. However, the Secretary may not certify a hospital as a "covered entity" for

purposes of the Committee bill if the hospital purchases any covered outpatient drug through a group purchasing organization or other group purchasing arrangement during the period for which certification is sought.

The Committee emphasizes that, in defining "covered entities" for purposes of both the exclusion from "best price" and the receipt of price reductions under manufacturer agreements with the Secretary, the bill does not require the receipt of any specified amount of Federal funding. In the case of "look alike" FQHCs and public hospital, an entity need not receive any Federal grants funds to qualify as a "covered entity." With respect to the other categories of "covered entity," the level of Federal grant funds that the entity receives is immaterial to a determination of its status as a "covered entity."

(b) Agreements required to receive payment

Under the Committee bill, in order for Federal Medicaid matching funds to be available for a manufacturer's covered outpatient drugs, the manufacturer must have entered into, and have in effect, an agreement with the Secretary of DVA, and a separate agreement with the Secretary of HHS, relating to the prices charged for drugs to the DVA and to certain Federally-funded clinics. These agreements are independent of, and additional to, the agreement into which manufacturers must enter into with the Secretary of HHS under current law regarding the provision of rebates to States for drugs purchased by Medicaid.

Limitation on prices of drugs procured by "covered entities"

In order to receive Federal Medicaid matching funds with respect to its covered outpatient drugs, a manufacturer must enter into an agreement with the Secretary of HHS that provides that the amount required to be paid to the manufacturer for covered outpatient drugs procured by a "covered entity" (as described above) does not exceed a specified amount. That amount is equal to the average manufacturer price for the drug in the preceding calendar quarter, reduced by an amount (expressed as a percentage) equal to the average total rebate (both basic and additional rebates) required under the Medicaid rebate program during the preceding calendar quarter, divided by the AMP for the drug (for a unit of the dosage form and strength involved). Thus, if the average manufacturer price for a unit of a drug (of a particular dosage form and strength) is \$1.00, and the average Medicaid basic rebate for that unit of the drug is 17 cents, and the average Medicaid additional rebate is 3 cents, then no "covered entity" may be required to pay an amount in excess of 80 cents in the following quarter for that unit of the drug. The Committee bill does not preclude either the Secretary, on behalf of "covered entities," or "covered entities" themselves, from negotiating greater price reductions with manufacturers on one or more covered outpatient drugs.

The Committee emphasizes that the bill does not limit the amount of drugs that a "covered entity" may procure for purposes of receiving price reductions under this agreement. Unlike the general treatment of entities under the CDC-administered consolidated purchase price for vaccines, a "covered entity" under this bill is not limited to purchasing drugs with its Federal grant funds. Instead, it may use any revenues or funds available to it to procure drugs. The Committee bill does not authorize the Secretary to limit in any way the volume of purchases that can be made at the price reduction provided under the Secretary's agreements with manufacturers.

The Committee bill does not specify whether "covered entities" would receive these favorable prices through a point-of-purchase discount, through a manufacturer rebate, or through some other mechanism. A mechanism that is appropriate to one type of "covered entity," such as community health centers, may not be appropriate to another type, such as State AIDS drug

**TAB H**



## Public Hospital Pharmacy Coalition

[www.phpcrx.org](http://www.phpcrx.org)

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

April 28, 2004

Mr. Robert Betz  
President & Chief Executive Officer  
Health Industry Group Purchasing Association  
1100 Wilson Boulevard, Suite 1200  
Arlington, VA 22209

Re: Purchases of 340B Inpatient Drugs Through Buying Groups

Dear Mr. Betz:

This letter follows up our recent meeting with your organization where we discussed strategies for encouraging pharmaceutical manufacturers to offer lower prices on their sales of inpatient drugs to disproportionate share hospitals participating in the 340B program. Among the issues that we addressed is the uncertainty expressed by some manufacturers over whether the language of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (Act) exempting 340B covered entities' inpatient drug prices from manufacturers' "best price" calculations applies when the drugs are purchased through a group purchasing organization (GPO). Manufacturers are apparently concerned that, notwithstanding the new best price exemption language, they might need to include discounted inpatient drug prices offered to 340B hospitals through GPOs in their calculation of best prices. The Public Hospital Pharmacy Coalition (PHPC) would like to take this opportunity to address these concerns and to explain PHPC's view that discounts on inpatient drugs given to 340B hospitals through a GPO will not impact manufacturers' best price.

Section 1002(a) of the Act clarified Title XIX of the Social Security Act by adding language specifically exempting "inpatient prices charged to hospitals [participating in the 340B program]" from the calculation of drug manufacturers' best prices. Congress did not include any qualifying conditions to this language and made no mention of purchases through GPOs in section 1002. Rather, the Act simply makes clear that any hospital participating in the 340B program can purchase inpatient drugs at prices that will not impact manufacturers' best prices. As the language of the Act provides no basis on which manufacturers could conclude that inpatient drug prices obtained by 340B hospitals through a GPO must be included in manufacturers' best prices, the above-mentioned concerns seem to arise from the language regarding GPOs found in the 340B statute.

Section 340B(a)(4)(L) of the statute that created the 340B program defines 340B-eligible disproportionate share hospitals in part as those which "d[o] not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement." Thus, any



**NATIONAL ASSOCIATION OF PUBLIC HOSPITALS & HEALTH SYSTEMS**

1301 Pennsylvania Avenue, N.W. Suite 950, Washington, DC 20004, 202-585-0100, FAX 202-585-0101, [www.naph.org](http://www.naph.org)  
PHPC Counsel: Powers, Pyles, Sutter & Yerville PC, 1875 Eye Street, NW 12th Floor, Washington, DC 20006,  
202-466-6550, FAX 202-785-1756, [www.ppsv.com](http://www.ppsv.com)

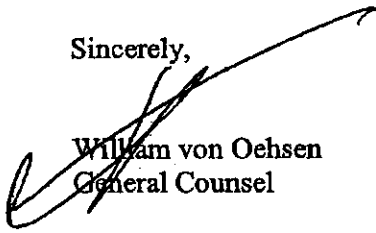
Mr. Robert Betz  
April 28, 2004  
Page 2

hospital participating in the 340B program cannot purchase its covered *outpatient* drugs through a GPO.<sup>1</sup> The language of this restriction on the use of GPOs says nothing about purchases of inpatient drugs. Nor is it in any way tied to the language found in section 1002 of the Act exempting inpatient drug prices from best price calculations. Additionally, the legislative history of the 340B statute indicates that Congress did not intend to disturb 340B hospitals' relationships with GPOs regarding inpatient drugs.<sup>2</sup> Congress simply has not prohibited 340B hospitals from using GPOs to negotiate inpatient drug prices or purchase inpatient drugs.

Finally, since the inception of the 340B program, it has been common practice for 340B hospitals to purchase their inpatient drugs through GPOs. If Congress had intended for the best price exemption to apply only to inpatient drug prices negotiated directly by the hospitals, it would have included language to that effect in section 1002 of the Act. The absence of such language is telling evidence that Congress had no intention of making the best price exemption dependent on the non-participation of GPOs in facilitating inpatient drug purchases.

PHPC feels strongly that inpatient drug prices paid by 340B hospitals for drugs purchased through a GPO are exempt from manufacturers' calculations of best prices. A thorough examination of the relevant statutory language entirely supports this conclusion. Should you have any questions or concerns about this analysis, please feel free to contact me at 202-872-6765.

Sincerely,



William von Oehsen  
General Counsel

---

<sup>1</sup> There is one exception to this requirement established by HRSA several years ago that allows 340B hospitals to purchase off group negotiated contracts for outpatient pharmaceuticals if they enroll into the 340B prime vendor program.

<sup>2</sup> See House Report (Energy and Commerce Committee) No. 102-384(I) to accompany H.R. 2890 (stating that "[t]he Committee recognizes that the public disproportionate share hospitals which the Committee is seeking to protect from high drug prices may participate in, or themselves maintain, group purchasing arrangements for a variety of purposes, including the purchase of supplies and equipment *as well as pharmaceuticals*. The Committee does not intend to disturb these arrangements or to require the withdrawal of these hospitals from these organizations and arrangements. However, the Secretary may not certify a hospital as a "covered entity" for purposes of the Committee bill if the hospital purchases any covered outpatient drugs through a group purchasing organization or other group purchasing arrangement during the period for which certification is sought.") [Emphasis added]

# **TAB I**



DEPARTMENT OF VETERANS AFFAIRS  
Office of the General Counsel  
Washington DC 20420

DEC 04 1998

In Reply Refer To:

Larry S. Gage  
William H.E. von Oehsen  
Public Hospital Pharmacy Coalition  
1212 New York Avenue, NW, Suite 800  
Washington, DC 20006

Gentlemen:

I am now able to reply in writing to your letter of June 12, 1998, addressed to Melbourne Noel of my staff. In that letter, on behalf of the Public Hospital Pharmacy Coalition (a Coalition of NAPH), you requested that the Department of Veterans Affairs (VA) agree to exclude certain sales of covered drugs to PHS covered entities from non-Federal Average Manufacturer Price (non-FAMP) calculations under Section 603 of the Veterans Health Care Act of 1992. This would help to maximize the beneficial impact of Section 602 of the Act (P.L. 102-585) on covered entities. You also asked that the same sales be excluded from consideration by VA contracting officers (CO) for purposes of determining "most favored customers" in FSS contract negotiations.

At its meeting on October 15, 1998, the VA's Federal Ceiling Price (FCP) Nominal Increase Board considered your requests. The Board voted to approve the requested calculation exemption.

Pursuant to the exemption, VA will view Section 602 computed pricing for inpatient drugs to be an extension of the statutory outpatient drug pricing that is already exempt from non-FAMP calculations. Thus, Section 602 inpatient drug prices granted to covered entities will not artificially lower the non-FAMPs and FCPs of those same drugs under our Section 603 program. The exemption is limited to sales to DSHs and PHS grantees (covered entities) and limited to those sales that are made at a 602 calculated price. Cooperating manufacturers will not be permitted to exclude from non-FAMP their sales to covered entities at low prices determined by competition in the marketplace rather than by Federal statute.

Also, on December 3, 1998, the Executive Director of the VA National Acquisition Center (VANAC) concurred with the proposal that sales of inpatient covered drugs at Section 602 (340B) prices to covered entities not be used by VANAC COs in determining most favored customer pricing in FSS negotiations with cooperating drug manufacturers. Additionally, these sales at Section 602 prices will be excluded from consideration under the Federal Supply Schedule (FSS) Price Reduction clause.

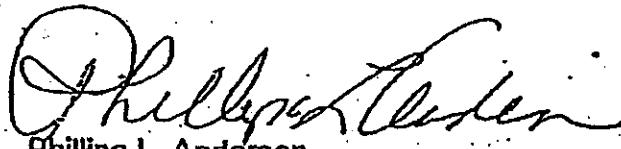
2.

Larry S. Gage  
William H.E. von Oshsen

After your proposals have been accepted by any covered drug manufacturers, VA will furnish cooperating manufacturers with "hold harmless" letters reflecting the VA decisions described in this letter.

If you have any questions on these matters, please call Mel Noel at VANAC, (708) 786-5167.

Sincerely yours,



Phillipa L. Anderson  
Assistant General Counsel

cc: Executive Director (90N)  
Team Leader (53C)  
Associate Chief Consultant PBM (119D)  
Team Leader (025NAC)

**TAB J**



DEPARTMENT OF VETERANS AFFAIRS  
Office of General Counsel  
PO Box 76  
Hines IL 60141

July 8, 2004

Dear Manufacturer of Covered Drugs:

This letter states the policy of the Department of Veterans Affairs (VA) regarding certain situations in which sales of inpatient covered drugs to disproportionate share hospitals (DSHs) participating in the Public Health Service 340B drug discount program may be excluded from your non-Federal Average Manufacturer Price (non-FAMP) calculations for those covered drugs. As you are probably aware, Section 1002 of the Medicare Modernization Act (MMA; P.L. 108-173), amended the Medicaid statute by adding the prices charged to 340B DSHs for inpatient drugs to the list of transactions excluded from Medicaid's "best price" reporting. However, this amendment did not refer to or directly impact the Veterans Health Care Act of 1992, P.L. 102-585, Section 603 (38 U.S.C. 8126), which requires manufacturers to report covered drug non-FAMPs to VA and accept price limits referred to as Federal Ceiling Prices (FCP). Since the enactment of MMA, VA has received many inquiries from covered drug manufacturers and the Public Hospital Pharmacy Coalition (PHPC) asking whether, as a result of Section 1002 of the MMA, VA would agree to allow manufacturers to exclude from their non-FAMP reporting all sales of inpatient covered drugs to the DSHs identified in Section 602 of P.L. 102-585 (Section 340B of the Public Health Service Act).

A similar request was addressed to VA in writing by the PHPC during June of 1998. That request was considered by the VA Federal Ceiling Price Nominal Increase Board and the VA Public Law 102-585 Policy Group during the fall of 1998. Subsequently, Assistant General Counsel Phillipa Anderson responded to the PHPC in a December 4, 1998, letter. This letter stated that, pursuant to decisions of the Board and Policy Group, VA was willing to view manufacturers' voluntary application of Section 602 (340B) computed pricing to DSH inpatient drug purchases as an extension of the statutory outpatient drug pricing that is already exempt from non-FAMP calculations. The letter went on to state, in relevant part: "The exemption is limited to sales to DSHs ... and limited to those sales that are made at a 602 calculated price. Cooperating manufacturers will not be permitted to exclude from non-FAMP their sales to covered entities at low prices determined by competition in the market place rather than by Federal statute." The letter also revealed that the Executive Director of the VA National Acquisition Center concurred with the proposal that sales of inpatient covered drugs at Section 602 (340B) prices to covered entities not be used by contracting officers in determining most favored customer pricing in FSS negotiations with

2.

**Dear Manufacturer of Covered Drugs**

cooperating drug manufacturers or in drawing conclusions concerning operation of the FSS price reduction clause. The 1998 letter concluded by stating that, after PHPC proposals for inpatient 340B pricing were accepted by a covered drug manufacturer, VA would furnish the cooperating manufacturer with a "hold harmless" letter reflecting the VA exclusion decisions.

The December 1998 letter continues to be a valid statement of VA's position regarding the exclusion of inpatient covered drug sales to DSHs from non-FAMPs. By way of fleshing out the details of the potential exclusions and the "hold harmless" letters which will authorize such exclusions, the following additional explanation of VA's policy is provided:

1. In order to qualify for the exclusion described in the 1998 letter, a covered drug manufacturer must first commit to providing all Section 602/340B DSHs with inpatient covered drugs at 602/340B calculated prices.
2. The covered drug manufacturer must offer DSHs 602/340B calculated pricing on either all of its commercially marketed inpatient covered drugs or specified covered drug product lines, but, in the latter case, the pricing must be offered on all commercially marketed NDC packages of the specified product lines.
3. The covered drug manufacturer must commit to the above pricing in a written statement to VA and the Pharmacy Affairs Branch of HRSA. If the manufacturer later decides to revoke its written commitment or to add or subtract product lines, it must inform VA and HRSA in writing within 14 days of the revocation or the change to DSH inpatient drug pricing policy.
4. The covered drug manufacturer must apply in writing to VA for a "hold harmless" letter based upon the above written commitment. "Hold harmless" letters will automatically expire if a manufacturer revokes or reneges on its commitment.

A template letter suggested by the Public Hospital Pharmacy Coalition for manufacturers to use to announce their decisions to make 340B prices available to DSHs for inpatient covered drugs and to simultaneously request "hold harmless" letters from VA is attached hereto for your convenience. However, manufacturers may use any form of letter which provides the same information. VA will consider that manufacturers that submit requests for "hold harmless" letters, by doing so, consent to publication of their 340B pricing commitment on HRSA's informational website. (Disclosure of discounted prices is not required.)

3.

Dear Manufacturer of Covered Drugs

It must be understood that VA will not issue "hold harmless" letters to manufacturers who pick and choose which DSHs will receive the benefit of 340B pricing on inpatient drugs. In order to qualify for a VA exemption from non-FAMP, a manufacturer's commitment must apply to all 340B DSHs. It should also be understood that VA considers that it has no authority to exclude from non-FAMP any discounted inpatient covered drugs sales to DSHs that are made at prices which were not determined according to the methodology required by Section 602 (340B) of P.L. 102-585. With regard to processing requests for "hold harmless" letters, manufacturers should allow 21 days from the day on which VA receives a request for the issuance of the exemption letter. Until an exemption letter is issued, a manufacturer is not authorized to exclude sales of inpatient drugs to DSHs from any non-FAMP calculations.

Information concerning exclusion from non-FAMP of sales through the 340B prime vendor to 340B covered entities can be found in VA's "Dear Manufacturer" letters dated October 19, 2001, and October 18, 2002. (Currently, HRSA's 340B prime vendor is not authorized to handle inpatient covered drugs for covered entities.)

If you have any questions concerning the above policies, please telephone the undersigned at (708) 786-5167.

Sincerely,



Melbourne A. Noel, Jr.  
Senior Contract Attorney  
Office of General Counsel

[MANUFACTURER'S LETTERHEAD]

[DATE]

Mr. Melbourne Noel  
Senior Contract Attorney  
Office of General Counsel  
VA National Acquisition Center  
P.O. Box 76  
Hines, IL 60141

[Express address:  
VA National Acquisition Center  
Bldg. 37  
First Ave., One Block N. of Cermak Rd.  
Hines, IL 60141]

Re: Request for "Hold Harmless" Letter

Dear Mr. Noel:

I am writing to request a 'hold harmless' letter from the Department of Veterans Affairs (VA) pursuant to VA's letter of December 4, 1998, addressed to the Public Hospital Pharmacy Coalition (PHPC), and "Dear Manufacturer Letter" of July 8, 2004 (the letters). According to the letters, VA will exempt certain inpatient drug sales to covered entities participating in the 340B drug discount program from the non-FAMP calculations required by P.L. 102-585, Section 603. Additionally, VA will exempt these 340B-priced inpatient drug sales from consideration under the FSS Price Reduction and Most Favored Customer clauses.

I certify, on behalf of [insert manufacturer's name], that the drugs set forth in the attached chart are currently offered for sale to 340B covered entities (DSHs) for inpatient use and that the offered prices are 340B ceiling prices. I further certify that these inpatient prices are available to all 340B hospitals. Because these prices comply with the conditions set forth in the letters, I hereby request that VA issue to [insert manufacturer's name] a 'hold harmless' letter stating that sales at these prices will be exempt from the company's non-FAMP calculations and FSS price negotiations.

Thank you in advance for your attention to this matter. Should you have any questions or comments about this contents of this letter, please do not hesitate to contact me at ( ) - .

Sincerely,

---

cc: Jimmy Mitchell, Pharmacy Affairs Branch

Attachment



# TAB K



**DEPARTMENT OF VETERANS AFFAIRS**  
**Office of Acquisition and Materiel Management**  
**National Acquisition Center**  
**P. O. Box 76**  
**Hines IL 60141**

September 24, 2004

In Reply Refer To:

William von Oehsen, Esq.  
General Counsel  
Public Hospital Pharmacy Coalition  
c/o: Powers, Pyles, Sutter, & Verville PC  
1875 I Street, NW, 12<sup>th</sup> Floor  
Washington, D.C. 20006

Dear Mr. von Oehsen:

Management at the Department of Veterans Affairs (VA) National Acquisition Center (NAC) has reviewed and discussed the letter that you sent to the FSS Contracting Service on August 23, 2004, regarding NAC FSS contracting officers' treatment of manufacturers' sales of generic and "OTC" inpatient drugs to 340B Disproportionate Share Hospitals (DSHs). In light of the precedent established by VA's Public Law 102-585, Section 603, Policy Group and the NAC in the July 8, 2004 "Dear Manufacturer Letter," we agree in part to your request to change that treatment in some situations. Thus, in the future, manufacturers who agree to sell generics and "OTC" products at 340B prices to all 340B DSHs for their inpatient purposes may exclude these sales from the reporting required by the FSS Commercial Sales Practices Sheets and the Price Reduction Clause, if they first satisfy certain VA NAC requirements.

In order to qualify for exclusion, a generic or "OTC" drug manufacturer must send a written request for a "hold harmless" letter to the NAC's Assistant Director, Pharmaceuticals, Dental and Other Schedules, FSS Service, containing the same information that is required of covered drug manufacturers applying for exclusion under the July 8, 2004, "Dear Manufacturer Letter." Upon receipt of a declaration by a supplier that it has committed itself to sell certain "OTC" and/or generic inpatient drugs to all 340B DSHs at 340B ceiling prices, the NAC will issue a "hold harmless" letter to that supplier. The effect of the letter will be prospective from the date of its issuance. However, this process will not apply to generic or "OTC" drug sales to DSHs at below-340B prices. Such low priced transactions must still be reported on Commercial Sales Practice (CSP) disclosure sheets and under the Price Reduction Clause.

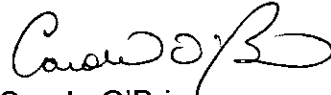
Since FSS pharmaceutical contracts don't give rise to "Dear Manufacturer letters," VA will not be announcing this new exclusion policy in such a letter. Instead, copies of this letter and the July 8, 2004 letter will be passed out at the NAC's October Industry Conference. Your organization may also distribute copies of the letters.

2.

William von Oehsen

If you have any questions about the above, please call Carole O'Brien-Rogan at (708) 786-4957.

Sincerely,

A handwritten signature in black ink, appearing to read "Carole O'Brien". The signature is fluid and cursive, with a large initial "C" and "O".

Carole O'Brien  
Acting Director – FSS Service

cc: Executive Director  
Office of General Counsel (025 NAC)

# **TAB L**

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**340B Program Revision and Expansion Act of 2004 (Introduced in House)**

HR 4161 IH

108th CONGRESS

2d Session

H. R. 4161

To amend the Public Health Service Act to revise and expand the section 340B program to improve the provision of discounts on drug purchases for certain safety net providers.

**IN THE HOUSE OF REPRESENTATIVES**

**April 2, 2004**

Mr. RUSH introduced the following bill; which was referred to the Committee on Energy and Commerce

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**A BILL**

To amend the Public Health Service Act to revise and expand the section 340B program to improve the provision of discounts on drug purchases for certain safety net providers.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE.**

This Act may be cited as the '340B Program Revision and Expansion Act of 2004'.

**SEC. 2. IMPROVEMENTS TO SECTION 340B PROGRAM.**

(a) Expansion of Covered Entities Receiving Discounted Prices- Subsection (a)(4) of section

340B of the Public Health Service Act (42 U.S.C. 256b) is amended by adding at the end the following subparagraphs:

(M) An entity receiving funds under title V of the Social Security Act (relating to maternal and child health) for the provision of health services.

(N) An entity receiving funds under subpart I of part B of title XIX of this Act (relating to comprehensive mental health services) for the provision of community mental health services.

(O) An entity receiving funds under subpart II of such part B (relating to the prevention and treatment of substance abuse) for the provision of treatment services for substance abuse.'

(b) Extension of Discounts to Inpatient Drugs- Subsection (b) of such section is amended by inserting before the period at the end the following: ', except that the terms 'covered outpatient drug' and 'covered drug' include a drug provided in an inpatient setting'.

(c) Elimination of Group Purchasing Prohibition for Certain Hospitals- Subsection (a)(4)(L) of such section is amended--

(1) by adding 'and' at the end of clause (i);

(2) by striking '; and' at the end of clause (ii) and inserting a period; and

(3) by striking clause (iii).

(d) Permitting Use of Multiple Contract Pharmacies- Such section is amended by adding at the end the following new subsection:

(e) Permitting Use of Multiple Contract Pharmacies- Nothing in this section shall be construed as prohibiting a covered entity from entering into contracts with more than one pharmacy for the provision of covered drugs, including such a contract that supplements the use of an in-house pharmacy arrangement or as requiring the approval of the Secretary for entering into such a contract.'

(e) Improvements in Program Administration- Such section is further amended by adding at the end the following new subsection:

(f) Improvements in Program Administration-

(1) In general- The Secretary shall provide, from funds appropriated under paragraph (2), for improvements in the integrity and administration of the program under this section in order to prevent abuse and misuse of discounted prices made available under this section. Such improvements shall include the following:

(A) The development of a system to verify the accuracy of information regarding covered entities that is listed on the website of the Department of Health and Human Services relating to this section.

(B) The establishment of a third-party auditing system by which covered entities and manufacturers are regularly audited to ensure compliance with the requirements of this section.

(C) The conduct of such audits under subsection (a)(5)(C) that supplement the audits conducted under subparagraph (B) as the Secretary finds appropriate and the implementation of dispute resolution guidelines and other compliance programs.

(D) The development of more detailed guidance regarding the definition of section 340B patients and describing options for billing under the medicaid program under title XIX of the Social Security Act in order to avoid duplicative discounts.

(E) The issuance of advisory opinions within defined time periods in response to questions from manufacturers or covered entities regarding the application of the requirements of this section in specific factual circumstances.

(F) Insofar as the Secretary deems it feasible, providing access through the website of the Department of Health and Human Services on the prices for covered drugs made available under this section, but only in a manner (such as through the use of password protection) that limits such access to covered entities.

(2) Authorization of appropriations- There are authorized to be appropriated for fiscal year 2005 and each succeeding fiscal year such sums as may be necessary to carry out paragraph (1).

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