SNHPA

Safety Net Hospitals for Pharmaceutical Access

April 24, 2007

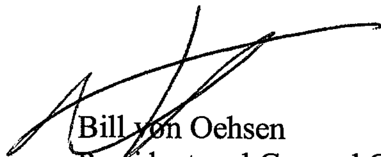
Elizabeth M. Duke, Ph.D.
Administrator
Health Resources and Services Administration
U.S. Department of Health and Human Services
Parklawn Building
5600 Fishers Lane
Rockville, Maryland 20857

Dear Dr. Duke:

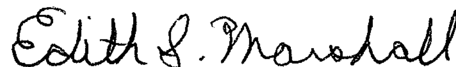
Safety Net Hospitals for Pharmaceutical Access (SNHPA) is writing to express its strong support of recent federal policy implementing the impact of the Deficit Reduction Act of 2005 on the calculation of average manufacturer price (AMP) for purposes of the 340B drug discount program. In particular, we support the letter issued by the Office of Pharmacy Affairs (OPA) on January 30, 2007 to pharmaceutical manufacturers explaining that "manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts." We have heard through various sources that OPA and the Health Resources and Services Administration (HRSA) may be reconsidering this policy and the interpretation of law on which it is based. SNHPA urges HRSA to proceed with implementation and enforcement of this policy. Towards this end, we attach a memorandum drafted by SNHPA's legal staff that sets out an analysis of this issue and the legal principles that we believe support OPA's position.

For the reasons explained in the attached legal memorandum, SNHPA concurs with the analysis set forth in OPA's January 30th letter and urges OPA not to withdraw that letter or the policy it sets forth.

Sincerely,



Bill von Oehsen
President and General Counsel



Edith Marshall
Special Counsel and Director of Legal Affairs

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Safety Net Hospitals for Pharmaceutical Access

MEMORANDUM

To: William von Oehsen

From: Edith Marshall

Re: Impact of the Deficit Reduction Act on Calculation of 340B Ceiling Prices

Date: April 24, 2007

The purpose of this memorandum is to assess the legal validity of the "double AMP" policy articulated by OPA in a letter to pharmaceutical manufacturers dated January 30, 2007. Specifically, that letter instructed its recipients that "manufacturers that have signed pharmaceutical pricing agreements (PPAs) must continue to calculate 340B ceiling prices so that the calculated price continues to reflect a reduction for any prompt payment discounts."

OPA's position, in short, is that the recent statutory amendment of the definition of average manufacturer price (AMP) is effective only for purposes of calculating Medicaid rebates, and does not apply to define AMP for use in calculating 340B ceiling prices. The consequence of this policy is that manufacturers will need to calculate two separate AMPs for the purposes, respectively, of calculating Medicaid rebates and minimum 340B discounts. We are aware of considerable resistance by industry to this "double AMP" policy, and have undertaken our own analysis of the issue to assess the strength of and legal support for the OPA position. As is explained below, this analysis leads to a conclusion that OPA's position is well-founded, and should be maintained irrespectively of industry's opposition.

The maximum or "ceiling" price for purchase of a covered outpatient drug under the 340B program is directly tied to its AMP,[1] as defined by statute for purposes of the 340B program. Section 340B provides, in subsection (b) of the statute, that "average manufacturer price" has the meaning given that term in Section 1927(k) of the Social Security Act (42 U.S.C. 1396r-8(k)).[2] The 340B statute also requires in subsection (c) that "[a]ny reference . . . to a provision of the Social Security Act . . . shall be deemed to be a reference to the provision *as in effect* on November 4, 1992."[3] Section 6001 of the Deficit Reduction Act of 2005 (DRA) amended Section 1927(k)(1) of the Social Security Act to redefine AMP in a manner that specifically does not take into account prompt pay

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[1] *See* §340B(a)(1) of the Public Health Service Act (PHS Act) 42 U.S.C.A. § 256b(a)(1).
[2] 42 U.S.C.A. § 256b(b).
[3] 42 U.S.C.A. § 256b(c) (emphasis added).

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discounts and does not include any reduction to reflect those discounts, while the formerly effective statutory definition expressly required inclusion of prompt pay discounts to reduce AMP figures. Accordingly, as OPA has recognized, if the provision of Section 1927(k) defining AMP to reflect a reduction for prompt pay discounts was "in effect on November 4, 1992," the 340B statute requires that 340B ceiling prices be calculated as they were prior to the DRA (that is, based on AMP figures that continue to reflect reductions for prompt pay discounts), irrespective of the recent DRA amendment of Section 1927(k)(1) to require the reverse approach to prompt pay discounts when calculating Medicaid rebates. This would result, in essence, in manufacturers being required to calculate two different AMP figures for each covered outpatient drug – one according to the current, amended statutory definition of AMP for use in determining Medicaid rebates, and one under the previous definition of AMP to apply in the 340B ceiling price formula.

We understand that some manufacturers and their representatives resist the necessity of calculating two AMPs based on a contention that the language defining AMP to take prompt pay discounts into account as an element of price reduction was not in effect in November 1992. Indeed, the statute as it was enacted in 1992 did not include any mention of prompt pay discounts or reductions to take those discounts into account in AMP calculation. This does not settle the question, however, because one year later Congress amended the law in two ways that are significant for present purposes: (1) to define AMP as it was defined immediately prior to passage of the DRA – such that AMP was required to be determined "after deducting customary prompt pay discounts,"[4] and (2) to further provide that the "amendments . . . shall *take effect as if included* in the enactment of OBRA-1990."[5] Thus, the amended law was expressly made effective retroactive to the effective date of OBRA 1990, or January 1, 1991. From a legal perspective, therefore, the prompt pay deduction provision of the statutory definition of AMP was in effect as of November 4, 1992, despite the fact that on that date the provision had not yet been enacted. By having the amendment "take effect as if included" in the 1990 law, Congress established that as a matter of law the AMP definition including a deduction of prompt pay discounts was "in effect on November 4, 1992," and is thus the AMP definition that must continue to be applied in the 340B program context.

While different stakeholders may disagree on whether Congress' directive that the amended AMP definition "*take effect as if included* in the enactment of OBRA-1990" rendered the definition "in effect on November 4, 1992" within the meaning of the 340B statute, we think any uncertainty must be resolved in favor of continued applicability of the prompt pay deduction provision to future 340B ceiling calculations. Two distinct rationales support this conclusion. First, from a purely linguistic standpoint, we do not think there is any real ambiguity. The legislative command that the AMP definition reflecting prompt pay discounts "take effect" as if it had been enacted in OBRA 1990 (with an effective date of January 1, 1991) plainly made the definition "effective" at least as of November 4, 1992. Even if this proposition is not accepted, however, the relevant

[4] Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66 § 13602(a)(2)(B), (d) (emphasis added).
[5] Id

statutory enactments must at the very least be regarded as ambiguous on whether the prompt pay deduction provision should be considered legally "in effect" in November 1992. Assuming that there is true ambiguity on the point, however, the interpretation of the law by the agency responsible for its administration would be entitled to sufficient deference to be controlling on the issue. Moreover, even if there might be some plausible grounds for disagreement with OPA's previously stated position, it is indisputable that OPA has read the language of the law in a reasonable manner and that it is well within the agency's authority to adopt that construction of the law.

In this regard, it is also important to recognize that the Secretary's longstanding interpretation of relevant law must be seen as construing the prompt pay provision of Section 1927(k)(1) enacted in 1993 to have been "in effect" in November, 1992. This is clear because for the last fourteen years, manufacturers have been required to calculate 340B ceiling prices using the same AMP (i.e. AMP determined by deducting prompt pay discounts) used to calculate Medicaid rebates. If the law including the 1993 amendment had *not* been construed to be "in effect" in November, 1992 for 340B price calculation purposes, then the November 1992 and post-1993 definitions of AMP in the Social Security Act would have been construed to differ, and Section 340B(c) would have required manufacturers to have calculated and applied two different AMPs for Medicaid and 340B purposes during the last fourteen year period. Since calculation of a "double AMP" has not been required of manufacturers in the intervening years since 1993, it follows that the Department of Health and Human Services (including Centers for Medicare and Medicaid Services as well as OPA) has long construed and applied the 1993 version of the Section 1927(k)(1) AMP definition as the one "in effect" in November 1992 and of relevance to 340B price determination.

Thus failure to require calculation of a separate 340B-relevant AMP figure after the DRA would represent a substantial and unexplained change from the agency's longstanding reading of the law, as applied during most of the history of the 340B program.