



**Public Hospital Pharmacy Coalition**

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

November 15, 2006

The Honorable Michael Leavitt  
Secretary  
U.S. Department of Health and Human Services  
Hubert H. Humphrey Building  
200 Independence Ave., S.W.  
Washington, DC 20201

**Re: Section 6002 of the Deficit Reduction Act**

Dear Secretary Leavitt:

We are writing on behalf of the Public Hospital Pharmacy Coalition ("PHPC") and its members in regard to a serious problem that appears to be developing in connection with implementation of part of the Deficit Reduction Act of 2005 ("DRA"). PHPC is a coalition of roughly 400 safety-net hospitals that participate as covered entities in the federally sponsored drug discount program administered by the Health Resources and Services Administration ("HRSA") under Section 340B of the Public Health Service Act, 42 U.S.C. 256b (the "340B program"). In particular, we are concerned that absent appropriate federal guidance clarifying the issue, many states will misinterpret Section 6002 of the DRA in a manner that conflicts with pre-existing provisions of the Medicaid statute, undermines the purposes and effectiveness of the 340B program, and is contrary to legislative intent.

Section 6002 of the DRA requires state Medicaid agencies to collect drug coding and utilization data, such as National Drug Code ("NDC") numbers and "J-codes" on certain "physician administered" outpatient drugs billed to Medicaid, so that the States' will be able to require pharmaceutical manufacturers to pay statutory Medicaid rebates on those drugs. Although the term "physician administered drugs" is undefined in Section 6002, both the provision's legislative history and the necessity of reconciling the provision with other, pre-existing law makes it clear that Section 6002 was not intended to change hospitals' present systems for billing drugs administered in their outpatient departments to Medicaid beneficiaries. These drugs are normally billed using a J-code or other drug-related Healthcare Common Procedure Coding System ("HCPCS") code which provides insufficient information to enable states to request rebates.

The Public Hospital Pharmacy Coalition ("PHPC") has learned from members and other sources that some state Medicaid agencies plan to start requiring hospitals to provide NDCs and



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other information for drugs administered in hospital outpatient settings, and to use the NDCs to seek manufacturer rebates on the hospital outpatient clinic drugs billed to Medicaid. For reasons set forth in this letter, we believe this course of action would be contrary to the meaning and intent of Section 6002 of the DRA, and would violate the letter and the spirit of other, related statutory provisions, especially as they pertain to hospitals that are 340B program covered entities.

To begin with, as the Conference Report accompanying the DRA makes clear, in expanding the Medicaid rebate program to "physician administered" drugs, Congress specifically intended to leave unaltered the longstanding exemption from rebate requirements of hospital outpatient clinic drugs covered by Section 1927(j)(2) of the Social Security Act ("the Act" or "SSA"). Section 1927(j)(2) exempts covered outpatient drugs that are administered to Medicaid patients in a hospital setting from the manufacturer rebate requirement that applies to most other "covered outpatient drugs" under Section 1927 of the Act. This statutory exemption applies if the hospital "dispenses covered outpatient drugs using drug formulary systems, and bills [Medicaid] no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State [Medicaid] plan)..."<sup>1</sup> The exclusion extends to drugs administered in hospital outpatient departments because hospitals use drug formularies and bill Medicaid no more than estimated acquisition costs ("EACs") defined by and determined under Title XIX state plans.<sup>2</sup> Notwithstanding passage of DRA Section 6002, there is no question that the statutory provision at Section 1927(j)(2) remains in force, and continues to exempt drugs administered in hospital outpatient settings from the rebate obligations established elsewhere in Section 1927, as it has since passage of the Medicaid rebate law in 1990.

Not only does the DRA contain no language suggesting an intent to revise or repeal the (j)(2) exemption, but the legislation's Conference Report specifically distinguishes between drugs subject to this longstanding statutory exemption from rebate requirements and "certain drugs administered by physicians in their offices or in another outpatient setting, such as chemotherapy.....[that] have often been excluded from the drug rebate program although there is no specific statutory exclusion," and to which Congress intended Section 6002 to apply. This limited scope of the term "physician administered drugs" as used in Section 6002, moreover, is consistent with the history and political context of the provision, which was developed in response to concerns raised by a report from the HHS Office of Inspector General ("OIG") on the millions of dollars lost to Medicaid because states were not collecting manufacturer rebates on drugs administered specifically in physicians' offices. Thus, in light of Section 1927(j)(2), the law is clear that Section 6002 cannot be construed to require the submission of NDC numbers and the collection of manufacturer rebates on outpatient drugs administered in hospital clinics.

Furthermore, a contrary construction of Section 6002 would make compliance with statutory provisions and federal guidance governing the 340B program extremely problematic. Section 340B of the Public Health Service Act requires pharmaceutical manufacturers to provide statutorily-set discounts on covered outpatient drugs purchased by specified government-

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<sup>1</sup> 42 U.S.C. 1396r-8(j)(2). See also, 60 Fed. Reg. 48442, 48482 (Sept. 19, 1995).

<sup>2</sup> If the exclusion did not apply to these drugs, it would have no meaning and therefore violate established principles of statutory interpretation.

supported facilities called "covered entities." Once admitted into the program, covered entities are entitled to receive 340B discounts on all covered drugs and may negotiate discounts below the maximum allowable statutory prices. As a condition of participating in the 340B program, covered entities must comply with procedures established to protect manufacturers from giving both a 340B discount and a Medicaid rebate on the same drug. To avoid such "duplicate discounts," participating covered entities generally must bill Medicaid at acquisition cost (plus a dispensing fee) for 340B drugs, and state Medicaid agencies, in turn, do not collect manufacturer rebates on the drugs that were acquired at discounted, 340B prices. This Medicaid billing requirement is subject to numerous exceptions recognized by HRSA, however. Indeed, it is ordinarily only applied to rebatable drugs dispensed to patients by outpatient hospital pharmacies. There are no billing restrictions applicable to drugs dispensed to non-Medicaid patients.

A state Medicaid agency's collection of rebates on drugs administered in hospital outpatient clinic settings would be incompatible with the 340B statute's prohibition on duplicate discounts. Hospitals in the 340B program purchase their J-code and other HCPCS-code drugs directly from wholesalers and manufacturers at 340B-discounted prices. If a state Medicaid agency subsequently collects rebates on drugs administered to Medicaid patients in hospital outpatient settings, the agency will cause manufacturers to give duplicate discounts on drugs because manufacturers will have already given up-front 340B discounts on those same medications. Because the billing mechanism ordinarily employed by the 340B program to avoid duplicate discounts in the outpatient pharmacy context requires state agencies to forego collection of rebates on 340B drugs, it cannot be applied to solve the problem if rebates are in fact collected<sup>3</sup>. Moreover, even if it were possible to reconcile the usual 340B billing mechanism for avoidance of duplicate discounts with interpretation of Section 6002 such that states would be required to collect rebates on 340B clinic administered drugs, any significant expansion of that billing mechanism would likely drive many 340B providers out of the program. This would not only be counterproductive to the goals of the 340B program, but also, ultimately, would increase state Medicaid net drug costs by depriving Medicaid of savings it now derives from hospitals' 340B participation relating to drugs dispensed by hospital outpatient pharmacies that are distinct from outpatient clinics.<sup>4</sup>

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<sup>3</sup> See Section 1927(a)(5)(C) of the Act, 42 U.S.C. 1396r-8(a)(5)(C).

<sup>4</sup> Since the early stages of implementing the 340B statute, Medicaid has shared in the benefit of the 340B program because – under the mechanism for avoiding duplicate discounts – Medicaid has in essence received 340B discounts passed on by hospitals on their outpatient pharmacy-dispensed drugs (for which hospitals bill Medicaid at their actual, 340B acquisition cost), in lieu of collecting manufacturer rebates on the same drugs that are usually lesser in amount. Notwithstanding giving up the benefit of these discounts on outpatient pharmacy-dispensed drugs to Medicaid, 340B providers have been able to use savings realized on clinic administered drugs and non-Medicaid drugs as intended by the 340B legislation, that is, in order to stretch their resources further in meeting the pharmacy and other health care needs of indigent patients. If this longstanding balance were to be disturbed such that providers no longer were permitted to retain their 340B savings on the often very expensive outpatient clinic drugs, however, the benefits of the 340B program for many safety net providers would no longer be great enough to justify participation, and their departure from the program altogether would eliminate the savings Medicaid now achieves through paying for hospital outpatient pharmacy-dispensed drugs at 340B actual acquisition cost levels. In short, although most 340B hospitals can afford to pass their 340B savings on to Medicaid for pharmacy-dispensed drugs, they generally cannot afford to do the same with clinic administered drugs. According to a PHPC survey, up to 40 percent of hospitals would drop out of the 340B program if they were compelled to bill Medicaid at actual acquisition cost for clinic administered drugs.

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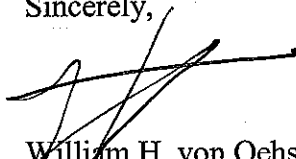
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Finally, it is important to note that collecting rebates on drugs administered in hospital outpatient settings would also create significant, and expensive, administrative burdens for all affected hospitals. In order to comply with the new billing requirements, hospitals would need to completely reorganize their billing systems and alter their staffing. These administrative changes would be very costly and time-consuming, especially for safety net providers participating in 340B. In fact, a survey of PHPC member hospitals suggests that a large percentage of 340B hospitals would prefer to discontinue their use of 340B drugs for Medicaid patients rather than have to undertake these major changes. In addition, resources that hospitals might use to make the necessary administrative changes would be unavailable to dedicate to the hospitals' mission of caring for patients who would otherwise have to go without necessary medical services. In short, implementation of the state Medicaid agencies' proposed billing plan essentially would divert resources away from the very patient populations Medicaid and the 340B program aim to serve.

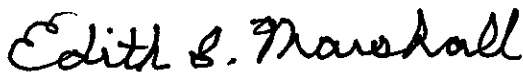
In sum, PHPC is very concerned that state agencies' efforts to collect rebates on drugs administered to patients in hospital outpatient settings violate federal law and the specific legislative intent of the DRA provision at issue, and set an alarming precedent adverse to the interests of hospitals across the country. We therefore urge you to act as expeditiously as possible to assure that CMS clarifies the correct meaning and limits on the application of DRA Section 6002, and that the provision is not implemented in a manner that is inconsistent with Congressional intent and detrimental to the 340B program.

Thank you for your attention to this letter, and please feel free to contact Bill von Oehsen or Edith Marshall at 202-466-6550 if there is a need to discuss these concerns in greater detail.

Sincerely,



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Public Hospital Pharmacy Coalition



Edith S. Marshall  
Special Counsel and Director of Legal Affairs  
Public Hospital Pharmacy Coalition