



Public Hospital Pharmacy Coalition

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

July 14, 2006

Mark B. McClellan, M.D., Ph.D.
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244

VIA PDF AND U.S. MAIL

Dear Dr. McClellan:

On behalf of the Public Hospital Pharmacy Coalition ("PHPC"), we are writing with regard to implementation of Section 6001(b) of the Deficit Reduction Act of 2005 ("DRA"). PHPC is a national organization of more than 350 public and private nonprofit hospitals and health systems that participate in the federal drug discount program established by Section 340B of the Public Health Service Act and Section 1927(a)(5) of the Medicaid statute ("the 340B program"). We understand that the Centers for Medicare and Medicaid Services ("CMS") will carry out the HHS responsibilities under DRA Section 6001(b), which amended the Medicaid statute to require the Secretary of the Department of Health and Human Services ("HHS") to publish average manufacturer prices ("AMPs") for both brand name and generic drugs on a publicly-accessible website.

The purpose of this letter is twofold. First, we wish to emphasize to CMS the importance of timely publication of AMP data to the thousands of "safety net" health care providers that participate in the 340B program and have an interest in effective enforcement of its rules and pricing requirements. PHPC is extremely disheartened by your recent announcement indicating that publication of AMP figures will be delayed until significantly after the July 1, 2006 publication deadline established by the DRA, and we question whether this delay comports with applicable statutory law. While we appreciate CMS's interest in refining the definition of AMP prior to publishing AMP calculations, we strongly believe that options exist for CMS to release AMP data in a way that avoids or minimizes potential misuse or misunderstanding of the data. Second, we wish to urge CMS to publish AMP data using all 11 digits of each drug's national drug code ("NDC"); that is, to use complete NDC codes that include reference to a particular package size for each identified drug.

I. BACKGROUND OF 340B PROGRAM

The 340B drug discount program resulted from enactment of the Veterans Health Care Act of 1992, which is codified as Section 340B of the Public Health Service Act. Section 340B limits the cost of covered outpatient drugs to certain federally-supported safety net providers,



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including federal grantees, federally-qualified health center look-alikes and Medicare hospitals serving a highly disproportionate share of indigent patients and owned by or under contract with state or local governments. Providers who participate in the 340B program, referred to in relevant statutory provisions as “covered entities,” are entitled to purchase outpatient drugs at or below “ceiling prices” that are determined according to a statutory formula requiring calculation of prices based on, among other elements, each covered drug’s AMP.¹ Although the 340B program is established by the Public Health Service Act and is administered by the Health Resources and Services Administration (“HRSA”), several provisions of the statutes administered by CMS nevertheless play a major role in defining and controlling the program. The Medicaid statute conditions coverage of manufacturers’ drugs on their compliance with requirements of the 340B statute,² and the two statutes contain numerous cross-references to each other. Also, the Medicaid statute defines a number of key terms, concepts and requirements that are instrumental in 340B program administration and calculation of 340B ceiling prices. These key terms include “AMP,” “best price,” “rebate percentage,” “covered outpatient drug,” and “manufacturer.” The Medicare statute also provides a definition of “subsection (d) hospital” that is central to determination of hospitals’ eligibility to participate in the 340B program. Consequently CMS, as the agency responsible for administering the Medicare and Medicaid statutes, is also responsible for important aspects of the 340B program.

II. LACK OF PRICING TRANSPARENCY IS A FUNDAMENTAL PROBLEM IN ADMINISTRATION OF THE 340B PROGRAM

One area in which the Medicaid statute and its construction by federal authorities has had a particularly significant and detrimental impact on the 340B program concerns the need for transparency of pricing data. The confidentiality provisions at Section 1927(b)(3)(D) of the Medicaid statute³ have been construed, prior to their recent amendment by the DRA, to prohibit disclosure to 340B covered entities of all pricing information, including AMP data, from which providers might be able to discern or estimate the maximum prices manufacturers are permitted to charge covered entities for drugs under the program. This has made it virtually impossible for 340B covered entities to verify that they are receiving the discounts to which they are entitled, and has impeded enforcement of manufacturer compliance with pricing requirements by preventing 340B providers from assisting HRSA in the identification of incidents of overcharging for 340B drugs. As a result, 340B providers have labored for more than 13 years to find some adequate means of determining whether they are receiving the discounts manufacturers are legally obligated to afford them.

The lack of pricing transparency and the inability of covered entities to discern whether they are being overcharged for 340B drugs has been recognized as a fundamental problem with

¹ See 42 U.S.C. § 256b; and 42 U.S.C. § 1396r-8.

² See Section 1927(a) (5) of the Social Security Act, 42 U.S.C. § 1396r-8(a)(5).

³ Those provisions are found at Section 1927(b)(3)(D) of the Social Security Act, 42 U.S.C. § 1396r-8(b)(3)(D).

the program both in reports from the HHS Office of Inspector General (“OIG”)⁴ and Congressional hearings.⁵ However, Section 6001(b) of the DRA has amended the Medicaid statute to ease somewhat the confidentiality restrictions previously imposed by Section 1927(b)(3)(D) of the statute, in the interests of increased pricing transparency and more effective compliance in both the Medicaid and 340B programs.⁶ The DRA mandates that AMP data be posted on a publicly accessible website, thereby addressing and promising to improve the situation to some degree, by enhancing the capacity of 340B covered entities to assess the possibility that they are being charged prices for drugs in excess of statutory ceiling prices. If, for example, the 340B price charged for a brand-name drug exceeds the drug’s published AMP minus 15.1 percent, covered entities would have grounds to assume that they have been overcharged. Similarly, if the 340B price of a generic drug exceeds AMP minus 11 percent, it is clear that an improper, above-ceiling price has been charged.

It should come as no surprise, therefore, that publication of drug AMPs on a publicly-accessible website is eagerly anticipated in the 340B provider community as a very important step forward in the administration and enforcement of the 340B program. Although AMP data will not enable covered entities to determine all 340B ceiling prices with absolute accuracy, it will enable them to approximate the upper limits on permissible prices of drugs purchased under 340B authorities. By knowing those approximate limits, covered entities will be able to play a constructive role in monitoring and promoting manufacturer compliance with pricing restrictions and more effectively look after their own interests in the program. Given the importance of this step towards greater pricing transparency, and the eagerness with which its positive results have been anticipated, the 340B community was both surprised and keenly disappointed when, two months ago, you announced that current AMP figures would not be published and suggested that compliance with the new publication requirement would be delayed until after promulgation of regulations that are unlikely to be finalized for several months.⁷

⁴ See OIG Report OEI-05-02-00072, “Deficiencies in Oversight of the 340B Drug Discount Program” (October, 2005), Executive Summary, pp. 18-19, 22-23; and OIG Report OEI-05-02-00070, “Appropriateness of 340B Drug Prices” (June, 2004).

⁵ *Oversight and Administration of the 340B Drug Discount Program: Improving Efficiency and Transparency: Hearing Before the House Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 109th Congr. (2005).*

⁶ Congress amended Section 1927(b) of the Medicaid statute to require disclosure of AMP data both to State Medicaid agencies concerned with the calculation of Medicaid rebates and to the public at large. It must be assumed that one of Congress’ objectives in requiring publication of AMP data on a publicly accessible website is to increase the transparency of 340B pricing for covered entities. Yet, as we explain herein, any such purpose would be significantly frustrated if AMP data were to be published in a form that, in many instances, renders it of limited value to an evaluation or estimation of 340B pricing limits.

⁷ See Remarks of Mark B. McClellan, M.D., Ph.D., delivered at the NCPA 38th Legislative and Governmental Conference on May 22, 2006. (“I am announcing today that CMS will not publicly release the current AMP figures. They just aren’t the right numbers to use. We do expect to share pricing information with the states, as we do confidentially with other types of drug pricing data, but only for purposes of helping them set up their billing systems appropriately and not for the purposes of setting reimbursements. Instead, we are focusing our efforts on developing a proposed regulation that will assure an accurate and effective AMP calculation ahead of implementation of the drug payment reforms.”)

We realize that the utility and reliability of presently available AMP data are matters of considerable debate, and we are sensitive to the fact that retail pharmacists, in particular, have legitimate concerns about the extent to which publication of AMP data may lead to artificially deflated assumptions about retail pharmacy costs and adequate reimbursement levels, especially for generic drugs. Yet, while we appreciate the fact that existing AMP data is far from perfect and must be utilized with an understanding of its limitations and deficiencies, this does not diminish the government's legal obligation to comply with the statutory timeline mandated by Congress in the DRA. Federal regulations may indeed be needed to better define the calculation and meaning of AMP so that the full benefit of release of that data can be realized; but in the meantime, even imperfect information is more helpful to the 340B community than none at all. If the AMP data that CMS initially publishes is in a form subject to some misconstruction or misuse, the website on which the data is posted could include a detailed disclaimer regarding its limitations. Alternatively, CMS could structure the release of the data in a way that targets the segment of the general public that needs the data for 340B price verification purposes. Given these options for controlling release of AMP calculations, the Secretary has a duty to carry out the statutory directive of the DRA within the time period prescribed by Congress.

In the DRA, Congress explicitly directed that "[b]eginning July 1, 2006, the Secretary ... shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v)[of Section 1927(b)(3) of the Social Security Act]," and further amended Section 1927(b)(3)(D) to provide (in a new clause (v)) for the Secretary's disclosure of average manufacturer prices through a publicly accessible website.⁸ The statute thus unambiguously establishes July 1 as the mandatory "beginning" of the Secretary's obligation to publicly disseminate and update AMP data. Indeed, we believe this provision expresses a clear Congressional directive that the most recently reported AMP data be posted on a publicly accessible website by July 1. But even if Section 6001(b) of the DRA could conceivably be construed to permit publication of AMPs after July 1, at most the statutory language could arguably be read to mandate such publication by a date no more than one quarter following July 1 of this year. That is, although we regard such a reading as strained, we can at least conceive of a construction under which July 1, 2006 triggers a quarterly federal obligation to post on a publicly accessible website the most recently updated AMP data, such that the first publication might permissibly occur as much as one quarter after July 1. The legislative language, however, permits no reasonable reading under which publication of AMP data can be delayed longer than one quarter following July 1 of this year. Should the Secretary decline to post the most recently reported AMP data on a publicly accessible website by this time, such inaction would plainly constitute direct noncompliance with a peremptory provision of the law, and a failure to fulfill a clearly established and nondiscretionary statutory duty.

We accordingly urge you, in the strongest possible terms, to comply with the statutory deadline and publish the required AMP data on a generally accessible HHS website in as complete and comprehensive a form as possible, as close to the July 1 date prescribed by statute as can be achieved, but in any event within no more than a quarter after that date. To the extent

⁸ See Section 6001(b)(1)(B) and (b)(2)(C) of the DRA.

that it may be impossible to publish all AMP data with full, 11-digit NDC codes by the July deadline, the available AMP data should nevertheless be published with a clear explanation of what the data represents.⁹

III. IMPORTANCE OF 11-DIGIT AMP DISCLOSURE TO HRSA AND 340B PROGRAM PARTICIPANTS

Thus, while we recognize that CMS may not have full, 11-digit AMP data for all drugs at this time, this should not preclude CMS from publishing the AMP data that it currently has as quickly as possible, and within the Congressionally-mandated deadline. We urge CMS to publish the AMP data available to it now and to concurrently begin building a database of AMPs for public disclosure, associated with specific, 11-digit NDCs. Whenever a drug's 11-digit AMP is available, CMS should update the publicly-disclosed data already posted for the drug with the new information. Such updates should occur in as fast a manner as possible in order to maximize the usefulness of the published AMP data.

Failure to publish AMP data with a sufficient number of NDC code digits would significantly diminish the benefit of Section 6001(b) to the 340B program. Identification of an AMP figure with an 11-digit NDC includes important information regarding not only the drug product's type and dosage, but also its particular package size. By contrast, 9-digit NDCs (such as have previously been used by CMS in connection with AMP figures used to calculate Medicaid rebates) do not communicate information regarding package size, and therefore can cause confusion and difficulty when associated with AMPs that are used to assess pricing accuracy in government sponsored programs. When a given AMP figure is associated with a 9-digit NDC, it may either represent the AMP for a particular, but unspecified, package size of the drug, or the AMP figure may represent a "weighted average" price for all package sizes in which the drug is distributed (as we understand is generally the case when AMP data is calculated for Medicaid rebate program purposes). In many circumstances, such AMP data has inherent limitations in utility for assessing the accuracy of manufacturers' 340B pricing, since a drug's 340B ceiling price varies depending on the size of the package in which the drug is packed.¹⁰

Where a drug is manufactured in only one form or is distributed in only one package size, of course, a nine-digit NDC number may be sufficient to label an AMP figure for purposes relevant to both Medicaid and the 340B program. Furthermore, even an AMP representing a weighted average of prices of various package sizes could assist 340B providers in making some estimates or assumptions about the likelihood that a given purchase price exceeds the applicable ceiling, especially for drugs in pill form that are not distributed in too wide a variety of package sizes. Therefore publication of existing AMP figures – even if they have been calculated as weighted averages and are not identified with package-size specific NDC numbers – still serves a

⁹ It should be noted that there are situations in which a 9-digit NDC code does meaningfully identify the specific product for which an AMP may be provided – such as where a drug is only manufactured and distributed in one package size.

¹⁰ For example, the AMP and other pricing elements of the formula that determines 340B ceiling prices of a package of 100 pills will differ from the AMP and ceiling price of a package of 20 pills of the same drug – resulting in significantly different 340B ceiling prices for different package sizes.

purpose and should not be delayed pending future refinements of AMP reporting. Nevertheless, it is clear that the usefulness of publicly available AMP data cannot be fully realized, and the legislative goals of making that data accessible to the public cannot be fully met, without package-size-specific identification of AMPs for drugs through the use of complete, 11-digit NDC numbers.

Significantly, the HHS OIG has indicated that a lack of adequate information regarding package size was one of the major deficiencies in data originally used by the OIG to generate findings in a June, 2004 Report on the Appropriateness of 340B Drug Prices, which was subsequently withdrawn due to unreliability and inaccuracy of underlying data.¹¹ While all the details of these data deficiencies have not been made public, the explanation included in a subsequent OIG Report suggests that use of pricing data associated with 9-digit NDCs may well have been a contributing factor to undermining the validity of the OIG's initial findings and conclusions.¹² The OIG's experience in attempting to draw valid conclusions about 340B pricing without detailed and accurate package-size information, therefore, is illustrative of the importance of 11-digit NDCs to meaningful implementation of Section 6001(b) of the DRA.

We understand that manufacturers may want to limit AMP publication to 9-digit NDCs to protect against disclosure of drug-specific pricing information which they consider to be proprietary. Pharmacies may want the same thing for reasons similar to why they want publication of AMP to be delayed, namely, to prevent the data from being misused or misinterpreted in evaluating pharmacy costs and setting reimbursement rates. Again we urge CMS to explore its options in trying to satisfy the business interests of the drug companies and pharmacy groups, on the one hand, and the integrity needs of the 340B drug discount program, on the other. One option is for CMS to share AMP data in 11-digit format with only 340B participants – via a password-protected website for example – and to use a 9-digit format for the rest of the public. As explained above, however, exclusive use of 9-digit AMP information is unacceptable.

IV. CONCLUSION

In closing, PHPC wishes to reiterate its assertion that prompt publication of AMP data, according to the timeline set out in the DRA, is required by federal statute. It is also plainly the legislative intent of the DRA that the publicly accessible data be posted in the form most effective to foster improved administration and compliance efforts in both the 340B program and Medicaid, that is, in a form that associates AMP data with complete, 11-digit NDC designations. Accordingly, we believe that the DRA provision calls for CMS to publicly disclose, by July 1, 2006, or in any event within the quarter commencing July 1, pharmaceutical manufacturers' most recently reported AMPs for their drugs, and to identify those AMPs with 11-digit NDC numbers as soon as practicable. In the light of legitimate concerns regarding the need to improve

¹¹ See OIG Report OEI-05-02-00072, "Deficiencies in Oversight of the 340B Drug Discount Program" (October, 2005), Executive Summary and pp 13-15, explaining reasons for withdrawal of OEI-05-02-00070, "Appropriateness of 340B Drug Prices" (June, 2004).

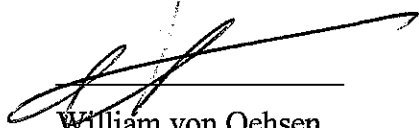
¹² *Id.*

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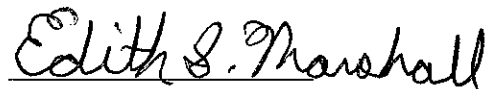
the calculation and accuracy of AMPs, it may be wise for CMS to consider initially publishing the AMP data it currently has with a disclaimer explaining what the data represents and what deficiencies or limitations are inherent in the published information. Publication of the data could also be targeted to users of the 340B program initially and then to non-340B parties after the AMP regulations are promulgated. Either way, prompt publication of AMP in as accurate and complete a form as possible is a necessary step that will help to ensure that covered entities are receiving the drug discounts to which they are entitled under the 340B program, and will greatly enhance the effective administration and enforcement of the 340B program by facilitating covered entities' participation in monitoring pricing compliance.

We thank you for the consideration of our views. If you have any questions, please contact William von Oehsen at 202-872-6765.

Sincerely,



William von Oehsen
General Counsel



Edith Marshall
Special Counsel and Director of
Legal Affairs