



## Safety Net Hospitals for Pharmaceutical Access

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May 1, 2009

Ms. Charlene Frizzera  
Acting Administrator  
Centers for Medicare and Medicaid Services  
Department of Health and Human Services  
Mail Stop C5-11-24  
7500 Security Boulevard  
Baltimore, MD 21244

Dear Ms. Frizzera:

Please accept this correspondence on behalf of Safety Net Hospitals for Pharmaceutical Access (“SNHPA”) urging regulatory action in response to changes to the nominal pricing provisions of the Medicaid rebate law set forth in Section 221 of the FY 2009 Omnibus Appropriations Act, P.L. 111-8 (“Appropriations Act”). SNHPA is an organization of over 500 public and private non-profit hospitals and health systems throughout the United States that participate in the 340B drug discount program. The organization monitors, educates, and serves as an advocate regarding federal legislative and regulatory issues related to drug pricing and other pharmacy matters affecting safety net providers. SNHPA submits this letter in strong support of the recent changes articulated in the Appropriations Act that pertain to nominal pricing, and to encourage the Centers for Medicare & Medicaid Services (“CMS”) to seize upon the opportunities presented by these changes.

In Section 221 of the Appropriations Act, Congress modified the nominal pricing provisions of the Medicaid rebate law to expand the list of providers that are permitted to receive nominal prices, without such prices being included in manufacturers’ best price calculations.<sup>1</sup> These “new providers,” which are now eligible to receive nominal pricing pursuant to the amended Medicaid rebate law, include: (1) 501(c)(3) entities that are exempt from taxes under section 501(a) of the Internal Revenue Code or are state owned or operated, and which provide the same type of services as 340B covered entities and to the same types of populations (but which do not receive funding under the provisions set forth in section 340B) and (2) public or non-profit entities, or entities based at an institution of higher learning whose primary purpose is to provide health care services to students in that institution, which provide a family planning service described in section 1001(a) of the Public Health Service Act. In addition, Section 221 of the Appropriations Act does not limit or remove the authority previously granted to the Secretary of the Department of Health and Human Services to extend nominal pricing to additional facilities or entities.<sup>2</sup>

We are very pleased with Congress’ express additions to the list of providers that are eligible to receive nominal pricing. SNHPA particularly applauds the fact that the language of the Appropriations Act extends nominal price protection to all drugs dispensed or administered by

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<sup>1</sup> 42 U.S.C. § 1396r-8(c)(1)(D)(i).

<sup>2</sup> 42 U.S.C. § 1396r-8(c)(1)(D)(i)(IV).

family planning clinics and university health centers that provide family planning services. Congress apparently recognized that the need for low-cost drugs extends to the totality of pharmaceuticals required by family planning patients. We hope that CMS will move quickly to ensure that nominal pricing is available to these entities for all prescription drugs, not just family planning drugs.

While the designation of two new categories of safety net providers for receipt of nominal pricing under the Medicaid rebate law is a very positive step, we urge CMS to exercise its statutory authority to extend best-price-exempt nominal pricing to other health care entities that serve an equally vital role in caring for indigent and vulnerable populations. SNHPA submits that these should include state and local government providers and other non-profit institutions – such as outpatient clinics, long term care facilities, health departments, and correctional infirmaries – that operate within and are jointly owned by the same health systems of which 340B hospitals are a part. Prior to the Deficit Reduction Act of 2005, manufacturers had nominal price contracts with entire health systems, of which 340B hospitals were just one component. System-wide contracts were both necessary and effective because indigent patients are served by entire health systems, not just their 340B components. Thus, non-340B providers within these health systems, which share in the responsibility of caring for our nation’s poor and indigent, are equally in need of the deep discounts that nominal drug pricing can provide. We strongly encourage CMS to act upon this significant opportunity to improve access to low-cost pharmaceuticals for these providers, whose scarce budgetary resources are strained by rising costs, difficult economic conditions, and a growing number of uninsured and under-insured.

In addition, to ensure consistency and clarity, we urge CMS to amend its regulation which governs the exclusion from best price of certain sales at nominal prices.<sup>3</sup> At present, this regulation limits the best price exemption to sales to 340B covered entities, intermediate care facilities for the mentally retarded, and state-owned or operated nursing homes.<sup>4</sup> The regulation reflects neither the entities that have been most recently added by the Appropriations Act nor the authority of the Secretary to continue to add to this list. The regulation should therefore be amended to reflect the additional entities described in the Appropriations Act and the broader authority of the Secretary to augment the list of safety net providers eligible for nominal pricing. The amended regulation should also create a process by which such safety net providers can petition CMS to be added to the list of entities that qualify for best-price-exempt nominal pricing.

In sum, the nominal pricing provisions set forth in the Appropriations Act represent an important opportunity to expand access to low-cost drugs for providers who serve poor and indigent populations. These changes provide a welcome opportunity for departure from the policies of the previous Secretary who declined, in adopting implementing regulations, to exercise his statutory authority to expand nominal pricing to additional safety net health care providers. That failure, in our view, was ill-advised and resulted in grave “collateral consequences” for safety net providers. In particular, ever since the DRA was enacted in January 2006 and implementing regulations were adopted in October 2007, the decision by Congress and the former Secretary to limit the kinds of entities eligible for best-price-exempt nominal pricing had a negative effect on manufacturers’ willingness to continue nominal price arrangements with

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<sup>3</sup> 42 C.F.R. 447.508.

<sup>4</sup> Id.

safety net health systems. This chilling effect deprived entire systems of nominal price discounts, even the 340B hospitals and other covered entities that are a part of such systems.

Congress clearly intended, in passing the DRA, that providers that serve as the health care safety net for the nation's poor would be identified and afforded access to nominal drug pricing. The agency's failure to exercise its discretion seemed at the time an abdication of responsibility that gave inadequate recognition to the contributions and the budgetary burdens of numerous health care providers that serve large indigent populations. Since that time, a worsening economy and the resulting stress on the safety net provider community has increased the need for these providers to be able to access nominally priced drugs. Accordingly, we hope CMS will seize this opportunity and expand access to nominally priced drugs to the non-340B components of health care systems that serve the uninsured, the underinsured, and other vulnerable and indigent populations across the country.

We thank you for the opportunity to express these crucial concerns.

Sincerely,

A handwritten signature in black ink, appearing to read 'William von Oehsen', with a long horizontal flourish extending to the right.

William von Oehsen  
President and General Counsel

cc: James Mitchell, Director, Office of Pharmacy Affairs, Health Resources and Services Administration