

**Tab 2-24**



## Safety Net Hospitals for Pharmaceutical Access

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September 7, 2007

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Health Resources and Services Administration  
5600 Fishers Lane  
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Re: Comments on Proposed Guidelines Regarding Participation in the 340B Program by Children's Hospitals

Dear Mr. Lang,

This letter responds to the Health Resources and Services Administration's (HRSA's) publication in the Federal Register of July 9, 2007 of the "Notice Regarding the 340B Drug Pricing Program; Children's Hospitals" and the accompanying invitation to the public to submit comments on that Notice. These comments are submitted on behalf of Safety Net Hospitals for Pharmaceutical Access (SNHPA), which, as you know, is an association of safety net hospitals that participate in the 340B program. Although SNHPA's membership is currently comprised primarily of disproportionate share hospitals (DSH hospitals) qualifying as covered entities under the 340B statute, a number of these hospitals have components or departments that specialize in hospital care for children, and some children's hospitals have joined (or are imminently expected to join) SNHPA in anticipation of future 340B program participation. SNHPA and its membership, therefore, have a keen interest in HRSA's guidelines regarding children's hospitals, as well as in the manner and promptness with which those guidelines are to be effectuated.

In preparing and submitting these comments, we are mindful of the role of the National Association of Children's Hospitals (NACH) as a representative and organizational "spokesman" for the many children's hospitals that are members of that organization. We strongly support NACH in the substance of its comments on the July 9 Federal Register Notice, which have been independently submitted to you today. We wish in addition, however, to expand upon and to underscore certain of the points advanced by NACH, bringing to those matters SNHPA's unique perspective as a representative and advocate of 340B hospitals participating in the program over almost

one and a half decades.

***Implementation of the Law Should Proceed Now, Pursuant to the Prompt Issuance of Interim Final Guidelines or Less Formal, but Immediately Effective, Policy Guidance***

Like NACH, SNHPA is particularly concerned that the process of issuing final guidelines threatens to further extend a delay in implementation of the law that has already continued too long. Section 6004 of the Deficit Reduction Act (DRA) not only provides for 340B program participation by children's hospitals, it expressly specifies that discounts were to be made available to those hospitals on drugs purchased on or after February 8, 2006. Although effectuating the law undoubtedly required issuance of some procedural guidance or instructions to children's hospitals on how to enroll in the program, the law did not mandate formal publication of administrative rules or guidelines subject to notice and comments procedures. Indeed, nothing prevented HRSA from proceeding to interpret and implement the law immediately after its enactment, through letters to manufacturers, sub-regulatory releases and instructions to providers, or other means of communication, that might have simply and straightforwardly implemented the provisions of the statute itself through adaptation of existing 340B eligibility standards, forms, and enrollment procedures for DSH hospitals to the special circumstances of children's hospitals. Such communications could have facilitated implementation of the essential elements of the law on an interim basis, pending future issuance of federal rules or guidelines with more detail and longstanding effect.

Historically, this was the approach taken by HRSA in initially implementing the 340B legislation when it was enacted in late 1992. Recognizing the immediacy of the needs of safety net health care providers for support in their efforts to serve the indigent and uninsured, and cognizant of Congressional intent that the newly enacted law be faithfully and promptly executed in compliance with effective dates that were legislatively specified, HRSA notified potentially eligible DSH hospitals of core information needed to apply for 340B status and allowed hospitals to enroll and begin benefiting from 340B discounts within less than six months of the statute's enactment. At that time, HRSA did not wait to formalize comprehensive guidance in a Federal Register publication before implementing the law; it acted promptly and effectively to carry out the intent and the timetable contemplated by Congress in passing important new legislation. Numerous elements and principles of the 340B program and the standards for covered entity participation were, to be sure, later clarified and refined through issuance of program guidelines in the Federal Register. It was, however, critical both to effective implementation of legislative intent and to protection of the legitimate statutory interests of 340B covered entities that initiation of the new program not be stalled by bureaucratic factors and the complexities of fine-tuning intricate details of program administration.

The same considerations apply now to incorporating children's hospitals into the 340B program. Having already delayed implementation of the children's hospital provision for almost seventeen months in order to more comprehensively construct a

framework for the requisite enrollment process, HRSA has an obligation to proceed now as expeditiously as is administratively feasible with actual provision of 340B discounts to these facilities. While careful analysis of, and further refinement and revision of the guidelines in response to, public comments undoubtedly should and presumably will occur, a sufficient framework has been constructed for children's hospitals to proceed immediately with 340B enrollment and participation. HRSA should either (1) promptly issue the new guidelines in interim final form following, at most, a very speedy and preliminary review of public comments and revision of the most obviously problematic aspects of the proposed regulations; or (2) proceed now, through *ad hoc* instructions and decision making, with enrollment of children's hospitals and implementation of discounts to those entities under a temporary system, perhaps similar to what has been proposed, but subject to refinement or replacement upon subsequent issuance of final guidelines. Again, it is worth noting that DSH hospitals were enrolled in the 340B program based on the second approach above.

Irrespective of which course HRSA may wish to pursue, it is of paramount importance that actual implementation of the law not be delayed further while HRSA engages in another round of internal reviews and clearances necessary to issue "final" agency guidelines. Children's hospitals that presently meet statutory criteria for discounts that are applicable to drug purchases they are making *now* should not be deprived of those discounts, and the important savings they represent, any longer. The length of the delay in federal action to implement Section 6004 of the DRA already borders on the unconscionable, and should not be perpetuated any further.

***In Light of All the Relevant Circumstances, the "GPO Exclusion" Should Not Be Strictly Enforced with Respect to Determinations of Retroactive Discounts***

Not surprisingly, what SNHPA regards as the most substantively objectionable aspect of policy set forth in the proposed guidelines is inextricably related to the overriding point that federal agency action to finally implement Section 6004 of the DRA has been unreasonably delayed. The proposed guidelines quite appropriately seek to ameliorate delay in implementing 340B discounts for qualified children's hospitals by allowing those facilities to obtain retroactive discounts in the form of refunds for the differential between 340B pricing and the purchase prices for covered outpatient drugs they have paid since the effective date of Section 6004. The utility of this measure as an ameliorative step is drastically undermined in the guidelines, however, by simultaneously imposing a policy of strict, retroactive enforcement of the "GPO exclusion" in determination of the retroactive discounts or refunds to which a children's hospital may be entitled. The GPO exclusion, as you know, is set forth in Section 340B(a)(4)(L)(iii) of the Public Health Service Act and prohibits hospitals from obtaining covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement.

Had Section 6004 of the DRA been implemented on a timely basis as Congress intended, and had federal authorities provided credible and accurate assurances to children's hospitals upon enactment of the provision that the law would be swiftly effectuated and 340B discounts would be available right away to qualified children's facilities, the situation and the relevant equities might have been different. Under that scenario, a children's hospital might have reasonably decided to forego the economies of purchasing outpatient drugs through a GPO in the expectation that an imminent availability of 340B discounts on those drugs would result in a net savings for the hospital. This, of course, was not what happened. Instead, HRSA made it clear, in public statements as well as in informal communications with the hospitals' advocates such as NACH and SNHPA, that it intended to publish formal guidelines in the Federal Register before allowing children's hospitals to actually enroll and participate in the drug discount program. Even more problematic, HRSA expressed concerns about whether it would be able to implement Section 6004 at all absent technical corrections in the law by Congress. Faced with an indeterminate timetable for being able to receive 340B discounts, children's hospitals could not – consistent with responsible fiscal management – purchase outpatient drugs at the substantially higher prices offered outside of their GPO contracts for an indeterminate length of time on the mere hope of eventual access to 340B discounts.

The fact that publication of guidelines and execution of Section 6004 has in fact been so very long delayed both underscores the unreasonableness of any expectation that children's hospitals would have refrained from purchasing drugs through GPOs while awaiting implementing guidelines, and exacerbates the unfairness of now strictly enforcing the GPO exclusion on retroactive discount determinations. By proposing that children's hospitals be in complete compliance with the GPO prohibition during the entire period of any retroactive recoupment of 340B discounts, the proposed guidelines make the opportunity for retroactive discounts utterly ephemeral. It is unlikely that *any* children's hospital will qualify for retroactive discounts because it is utterly unrealistic to expect any of them to have refrained entirely from purchasing outpatient drugs through a GPO over the last year and a half. Yet, given the extended delay in allowing 340B program enrollment by those hospitals, the inability of the hospitals to obtain retroactive discounts is both palpably unfair and contrary to Congressional intent. Section 6004 clearly states that discounts be afforded children's hospitals on drug purchases beginning on or after February 8, 2006.

Although HRSA may not have sufficient authority to waive the GPO restriction altogether in applying eligibility criteria for retroactive discounts, there is some middle ground on which qualifying children's hospitals can and should be afforded retroactive discounts notwithstanding their use of GPOs in purchasing some outpatient drugs during the retroactive period. Specifically, a fair and reasonable solution would be to preclude full retroactive discounts to children's hospitals only to protect against "double dipping", but not to wholly disqualify hospitals from retroactive 340B benefits on the basis of their participation in a GPO to purchase covered outpatient drugs. Double dipping arises when

a hospital receives both a 340B price and a GPO discount on the same drug. Under this alternative policy, children's hospitals would be able to recoup retroactively the 340B discounts they should have received on outpatient drugs that were *not* purchased through a GPO, and would be refunded the difference between the 340B price and GPO price on drugs that were purchased through a GPO.

Importantly, this was the approach HRSA took to retroactive discounts at the inception of the 340B program. DSH hospitals that had continued to use GPOs for purchasing outpatient drugs after the effective date of the 340B statute, but before HRSA acted to implement the statute and assure that 340B discounts were actually available to qualified DSH hospitals, were not prohibited from applying for and receiving retroactive discounts. Instead, the GPO exclusion was flexibly applied to prevent "double dipping" by providers and to protect manufacturers from being forced to provide, in effect, duplicate discounts on the same drugs. But hospitals were nevertheless permitted actually to benefit from 340B discounts, retroactive to the date on which Congress intended those discounts to be available to the hospitals. This flexible application of the GPO exclusion in the special context of retroactive discounts was undoubtedly within HRSA's authority (it was most certainly within HRSA's interpretation of its statutory authority, as it was the policy adopted by the agency), and was in fact acknowledged as valid agency policy, with apparent approval, by a federal Court of Appeals.<sup>1</sup>

No meaningful distinction can be made between the situation respecting DSH hospitals in 1993 and the present policy dilemma regarding how to justly administer an opportunity for qualifying children's hospitals to access retroactive 340B discounts. It is accordingly within HRSA's discretionary authority to adopt this same policy with respect to children's hospitals, a policy which would more faithfully execute Congressional intent respecting drug discounts for children's hospitals than draconian enforcement of a total GPO ban for purposes of retroactive 340B discount eligibility, and would also be far more equitable to hospitals already disadvantaged by the long hiatus between passage of Section 6004 and its actual implementation. HRSA should exercise its administrative discretion in a consistent fashion and afford children's hospitals access to retroactive discounts on the same basis that DSH hospitals were permitted to obtain such discounts in the first stages of 340B program administration, when their capacity to enroll in the program had been delayed (albeit for a much shorter period of time) beyond the effective date of discounts that Congress intended. This course seems especially appropriate and even logically compelled by HRSA's intent, expressed in the proposed guidelines themselves, to afford essentially the same treatment and apply the same standards to children's hospitals as to other 340B participant hospitals.

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<sup>1</sup> See *University Medical Center of Southern Nevada v. Shalala*, 173 F.3d 438 (D.C.Cir. 1999).

***Eligibility Determination Processes for Children's Hospitals Should Be Simplified and Streamlined to the Greatest Possible Extent***

Again, particularly in light of long delay in implementing 340B discounts for children's hospitals, it is important that the process of determining eligibility of those hospitals for program participation be made as simple and as streamlined as possible when it finally gets underway. While the proposed guidelines reflect a good faith attempt to apply the 11.75 threshold DSH adjustment percent criterion to children's hospitals that may or may not file Medicare cost reports reflecting all data needed to calculate that percent, application of this test can be substantially simplified in many or most cases of children's hospitals potentially qualified for 340B program participation.

As specifically prescribed by statute, the DSH adjustment percent is calculated based on, among other elements, a so-called DSH patient percent or "DPP" that is comprised of the sum of two fractions, often referred to, respectively, as the "SSI fraction" and the "Medicaid fraction." Given the relationship between the DPP and the formula for calculating the DSH adjustment percent, it is possible to calculate a minimum DPP figure that, as a mathematical fact, will always result in a DSH adjustment percent figure of 11.75 percent or greater. That figure is 27.32 percent, and a hospital with a DPP in excess of 27.32 percent will always have a DSH adjustment percent that exceeds 11.75 percent. Since the DPP is calculated by adding together a hospital's SSI fraction and its Medicaid fraction, if either one of these fractions (expressed as a percentage) exceeds 27.32 percent, it is certain that the hospital's total DPP will exceed 27.32 percent, and it is a mathematical certainty that the hospital will exceed the 11.75 DSH adjustment percent threshold that must be exceeded to qualify a hospital for 340B participation.

The determination of a children's hospital's compliance with the DSH adjustment percent test for 340B qualification can accordingly be substantially simplified in a high percentage of cases. This is because the populations ordinarily served by children's hospitals include a high percentage of Medicaid patients, which is largely a function of how eligibility for the Medicaid program is structured. It is generally easier for children to qualify for Medicaid than adults because, among other things, children in families that are financially eligible for assistance under the federal Aid to Families With Dependent Children (AFDC) program are automatically eligible for Medicaid. The "Medicaid fraction" for these hospitals is thus likely to be high, whereas the "SSI fraction" – composed of elements reflecting the hospital's patients receiving Supplemental Security Income (SSI) for aged, blind, and disabled persons and those covered by Medicare insurance for aged and certain other, disabled beneficiaries – is likely to be low. In a hospital population comprised entirely of children under the age of 18, very few patients qualify for SSI benefits. Children's hospitals, in short, will almost always qualify for 340B participation by virtue of a high DPP resulting from a large Medicaid fraction in the relevant mathematical formula. In fact, most children's hospitals meeting the 11.75 DSH adjustment percent criterion will attain that status because their Medicaid fraction exceeds 27.32 percent.

To simplify and streamline 340B eligibility determinations, therefore, HRSA should permit children's hospitals to meet the 11.75 percent threshold test by demonstrating a Medicaid fraction of greater than 27.32 percent, or if that fraction alone does not exceed the threshold, a DPP of greater than 27.32 percent. This would avoid pointless complexities and extraneous effort attending any attempt to accomplish full DSH adjustment percent calculations for children's hospitals that, due to their non-PPS status, cannot receive Medicare DSH payments and may have no occasion to compile all of the data relevant to, or to calculate, a DSH adjustment percent, but which are nevertheless likely to have readily available data on their Medicaid eligible patient populations. A children's hospital should be permitted to document and verify a Medicaid fraction (or a total DPP) above 27.32 percent through any available and reliable means, including submission of its most recent Medicare cost report (if it prepared such a report and that report contains the requisite data), or through submission of a report by an independent auditor engaged by the hospital.<sup>2</sup>

***Apart from the Above Comments, SNHPA Supports HRSA's Proposed Guidelines***

SNHPA urges HRSA to adopt the above recommendations and would be pleased to work with HRSA in developing specific language to add to the proposed guidance. Apart from these recommended changes, however, SNHPA generally supports the proposed guidance. For example, SNHPA wishes to express support for HRSA's decision to deem manufacturers' existing Pharmaceutical Pricing Agreements (PPAs) to encompass, *de facto*, their obligation to provide drug discounts to qualifying children's hospitals. Since pharmaceutical manufacturers must, as a matter of law, agree to afford such discounts to children's hospitals in order for the manufacturers' products to continue to be covered by Medicaid, HRSA's approach seems a reasonable means of avoiding additional delays in statutory implementation, which would serve no practical or legislative purpose.

SNHPA supports other aspects of HRSA's proposed guidance. It supports, for example, HRSA's proposal that prior to entry into the 340B program, a children's hospital must certify that it will abide by all the 340B requirements applicable to other covered entities, including the prohibition against diversion, protection of manufacturers from giving duplicate discounts, etc. SNHPA also agrees with HRSA that, with respect to compliance with the GPO exclusion, children's hospital must provide a certification to

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<sup>2</sup> We do not intend to suggest that the opportunity to establish 340B eligibility through establishing a hospital's Medicaid fraction should be to the exclusion of other avenues of demonstrating compliance with criteria described in Section 340B(a)(4)(L)(ii), such as by a full calculation of the hospital's DSH adjustment percent under the applicable Medicare formula or verification of meeting criteria for DSH eligibility under the so-called "Pickle amendment." However, as a practical matter, we believe that the majority of children's hospitals likely to meet enrollment criteria for 340B will do so based on Medicaid fractions that are in excess of 27.32 percent.

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HRSA. SNHPA recommends that HRSA use the same certification form applicable to DSH hospitals.

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Thank you for the opportunity to communicate our views regarding the recent Federal Register Notice respecting enrollment of children's hospitals in the 340B program; and please do not hesitate to contact us if we can be of assistance by discussing or explaining any of the points or recommendations set forth in these comments.

Sincerely,

  
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William H. von Oehsen  
President and General Counsel

  
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Edith S. Marshall  
Special Counsel and Director of  
Legal Affairs