



- **Implement a Fair Retroactive Policy** The guidelines should include a retroactive discount policy that does not further prejudice children's hospitals and compound the harm of the 17-month delay in issuing the proposed guidelines.
- **Support the Option to Use the "DSH" Percentage Calculation and Clarify How It Applies** N.A.C.H. deeply appreciates HRSA giving the option for a children's hospital to calculate its care for low-income patients using the Medicare disproportionate share hospital (DSH) adjustment criteria. Since children's hospitals are exempt from the Medicare inpatient prospective payment system (IPPS) and therefore do not receive Medicare DSH payment adjustments, it is important to ensure that this calculation is based on the children's hospital's volume of service to low-income patients, not its receipt of Medicare DSH adjustments. We recommend that HRSA provide in the guidelines that a hospital may demonstrate compliance with DSH adjustment criteria through calculation of its disproportionate patient percentage (DPP), which is determined prior to and included in the calculation of the Medicare DSH adjustment. Because a hospital's DPP must be determined in order to calculate its DSH adjustment, the DPP is as reliable as the DSH adjustment in serving as a measure of the care provided by the hospital to low-income patients.
- **Accept Medicare Cost Report Data or an Independent Auditor's Assessment** In order to demonstrate its eligibility to enroll into the 340B program, a children's hospital should be permitted to rely upon its Medicare cost report to determine its DPP. If no Medicare cost report exists, a children's hospital should be permitted to hire its own independent auditor to calculate its DPP.
- **Retain the Deeming of PPAs' Application to Children's Hospitals** N.A.C.H. supports HRSA's proposal that the pharmaceutical pricing agreements (PPAs) be deemed to include children's hospitals by virtue of the language of Section 6004.
- **Provide Alternative Approach to Demonstrating "Integral Part"** In determining whether an off-site children's hospital facility qualifies as an "integral part" of the hospital and is therefore eligible for 340B program participation, HRSA should establish an alternative to the Medicare cost report test applicable to DSH hospitals.
  1. ***Immediate Implementation of Final Interim Guidelines Is Necessary to Avoid a Further Delay of Children's Hospitals' Participation in 340B.***

It is imperative that, immediately following the deadline for submission of comments to the proposed guidelines, HRSA issue interim final guidelines so that children's hospitals may commence application for participation in the 340B drug discount program. Pursuant to Section 6004, the effective date for inclusion of children's hospitals in the 340B program was February 8, 2006 – *more than a year and a half ago*. The language of the legislation clearly indicates that participation of children's hospitals in the 340B program is long overdue, stating that the amendment "shall apply to drugs purchased on or after the date of the enactment of this Act."

Despite congressional intent regarding the immediate inclusion of children's hospitals in the 340B program, HRSA has only now issued proposed guidelines. Many children's hospitals have already applied for 340B participation in the absence of guidelines; some have waited more than a year for HRSA to act on their applications. Without the expeditious issuance of interim final guidelines, children's hospitals may have to wait many more months before the proposed guidelines are finalized and actual program participation begins.

Congress enacted Section 6004 for the purpose of affording children's hospitals, which are among the nation's leading providers of care to low-income patients, the opportunity to reduce the cost of outpatient care. HRSA's 17-month delay in issuing proposed guidelines has forced children's hospitals to continue to bear higher costs of pharmaceutical care for patients, contrary to congressional intent. This delay continues to thwart the promise of Section 6004 and unfairly penalizes children's hospitals. It is also in striking contrast to the 1993 implementation of the 340B program for Medicare disproportionate share hospitals. The law permitting DSH hospitals to participate in the 340B program took effect on November 11, 1992. Four months later, on March 9, 1993, HRSA notified all hospitals of their right to apply for and participate in 340B even in the absence of a Federal Register Notice.

**2. *The Guidelines Should Contain a Fair Retroactive Discount Policy that Does Not Further Prejudice Children's Hospitals.***

The problems posed by the delay in the issuance of proposed children's hospital guidelines are compounded by HRSA's suggested policy with respect to retroactive discounts. To alleviate them, we recommend that HRSA follow established precedent to permit a children's hospital with a group purchasing agreement to obtain retroactive payment adjustments, unless such adjustments would create a "double dipping" problem.

Under the proposed guidelines, children's hospitals are eligible for discounts retroactive to the date of enactment of Section 6004 on February 8, 2006. However, a children's hospital may receive retroactive discounts only to the extent that it has satisfied all program requirements back to the date from which discounts are requested. To do so, a children's hospital must be able to demonstrate, among other things, that the hospital did not have a group purchasing arrangement for covered outpatient drugs during the period of retroactivity.

The effect of this proposed policy would be to preclude children's hospitals from receiving retroactive discounts. Children's hospitals, which have been excluded from the 340B program since its inception, have, in many cases, reasonably relied upon GPOs as a means of lowering and managing drug costs. The cessation of this practice prior to the publication of the proposed requirements for 340B participation would have resulted in substantially increased drug expenditures during the interim period. Moreover, prior to the recent issuance of the proposed guidelines, children's hospitals were not and could not have been aware of HRSA's intended policy with respect to retroactive discounts, and termination of group purchasing arrangements

would therefore have been imprudent.

Clearly, the use of GPOs would cease upon admission to the 340B program, when a viable alternative for reducing drug expenditures exists. We agree with HRSA that children's hospitals – like other 340B eligible hospitals – should be required to certify that they will not participate in a group purchasing arrangement as of the effective date of their entry into the 340B program. Moreover, we recommend that children's hospitals use the same certification currently used by other eligible hospitals to verify compliance with the GPO exclusion. However, children's hospitals should not be penalized for the use of GPOs during the long interval that has elapsed since the enactment of Section 6004.

Additionally, we note that in the early stages of the 340B drug discount program, HRSA applied a more lenient interpretation of the GPO exclusion for DSH hospitals, permitting them to utilize GPOs and to receive 340B discounts, provided a 340B discount was not received for a covered outpatient drug obtained through a group purchasing arrangement.<sup>1</sup> This interpretation was acknowledged by the government and addressed by the Court of Appeals in *University Medical Center of Southern Nevada v. Shalala*, in which the court noted that “HRSA initially interpreted the [GPO exclusion] as barring only ‘double dipping’ – that is, hospitals could participate in both the section 340B discount program and a group purchasing organization provided that the hospital did not receive 340B discounts on the same drugs purchased through the group purchasing organization.”<sup>2</sup>

In May 1994, HRSA amended its policy to disallow 340B participation for DSH hospitals participating in GPOs, regardless of whether or not the DSH hospital was improperly using the GPO and the 340B discount to “double dip.”<sup>3</sup> HRSA did not, however, condition the receipt of *retroactive discounts* upon a covered entity's complete abstention from the use of a group purchasing arrangement during the period of retroactivity. Rather, pursuant to the language of the final notice, DSH hospitals that had utilized GPOs were permitted to receive retroactive 340B discounts, so long as they did not receive such discounts on drugs purchased through a GPO. HRSA stated that “[a] DSH is not eligible for retroactive discounts for covered outpatient drugs *purchased through a group purchasing organization (GPO) or any group purchasing arrangement.*”<sup>4</sup> This language makes clear that covered outpatient drugs *not* purchased through a GPO or other group purchasing arrangement were eligible for retroactive discounts.

We believe that children's hospitals should be afforded the same rights with respect to retroactive discounts as were other covered entities at the start of the 340B program. This is in keeping with HRSA's intention, as articulated in the proposed guidelines, to apply the same rules and standards to children's hospitals as are applied to other covered entities, and its assertion that “unless

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<sup>1</sup> See 58 Fed. Reg. 27289, 27290 (May 7, 1993) (Stating that the 340B discount need not be provided for drugs which the DSH hospital “obtains through a group purchasing arrangement.”)

<sup>2</sup> *University Medical Center of Southern Nevada v. Shalala*, 173 F.3d 438 (D.C. Cir. 1999).

<sup>3</sup> See 59 Fed. Reg. 25110, 25112 (May 14, 1994).

<sup>4</sup> *Id.*,

children's hospitals are subject to all of the same rules as other covered entities, the inclusion of children's hospitals in the 340B program would be difficult, if not impossible.”

We agree with this assertion and support HRSA's efforts to achieve parity in the guidelines and principles pertaining to children's hospitals and those pertaining to other covered entities. Accordingly, we believe that it would be both unfair and inconsistent to hold children's hospitals to a more restrictive standard for retroactive discounts than was applied to DSH hospitals in the early stages of the program. We therefore propose that children's hospitals be permitted to abide by the same policy regarding the GPO exclusion as was initially applied to DSH hospitals and which later applied to their receipt of retroactive discounts. Children's hospitals should be eligible – during a specified start-up period – to receive retroactive discounts for covered outpatient drugs that were not purchased through a GPO or other group purchasing arrangement. We propose that this start-up phase include, at a minimum, the period from the effective date of Section 6004 (February 2006) through the designated 120 days after HRSA's issuance of a final or final interim notice.

**3. *N.A.C.H. Supports HRSA's Option for Children's Hospitals to Qualify for 340B's Low-Income Care Requirement Using the Medicare DSH Percentage and Recommends HRSA Permit Hospitals to Use Just the DPP***

In enacting Section 6004, Congress intended to give children's hospitals the same opportunity as other hospitals to qualify for 340B participation. Prior to the law's enactment, children's hospitals were precluded from participating in the 340B program, not because they could not meet the Medicare DSH requirements for the provision of services to low-income patients, but because they are excluded by law from the Medicare IPPS and are therefore ineligible to receive Medicare DSH payment adjustments. Medicare DSH adjustments are available only to a hospital that receives Medicare payments based upon the IPPS.

The guidelines propose two options for children's hospitals to demonstrate compliance with clause (ii) of section 340B(a)(4)(L) regarding a hospital's level of care to low-income patients: either a hospital must meet the requirements for a so-called “Pickle hospital” or it must satisfy the Medicare DSH percentage requirement. We strongly support HRSA's preservation of both options, and we applaud HRSA's intent to permit Medicare PPS-exempt children's hospitals to qualify based upon the requirements of the Medicare DSH adjustment standard.

In furtherance of that intent, we propose that HRSA include in the guidelines specific guidance regarding the methodology by which children's hospitals may determine whether they meet the DSH adjustment criteria. As children's hospitals do not receive Medicare DSH adjustments, we propose a simplified demonstration of compliance with the DSH adjustment standard through the determination of their disproportionate patient percentage (DPP), which is calculated prior to and

included in the DSH adjustment percentage.<sup>5</sup> Because a hospital's DPP must be determined in order to calculate its DSH adjustment percentage, the DPP is just as reliable as the DSH adjustment in serving as a measure of the level of low-income care provided by the hospital. Moreover, as demonstrated below, a DPP of greater than 27.32 percent is sufficient to meet and satisfy the requisite DSH adjustment percentage of 11.75 percent.

We believe that the use of the DPP formula for measuring compliance with the DSH adjustment standard is in keeping with both HRSA's intent and the intent of Congress as articulated in Section 6004. Section 6004 states that a children's hospital must meet the Medicare DSH percentage requirement of clause (ii) of section 340B(a)(4)(L) "if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this Title [Medicaid]." Thus, the language of Section 6004 reflects Congress' understanding that, for children's hospitals, which are ineligible for Medicare DSH adjustments, compliance with the 340B DSH adjustment percentage requirement will be measured in terms that include the percentage of hospital care provided to Medicaid-eligible patients.

A hospital's disproportionate patient percentage is the sum of two fractions, commonly known as the Medicare/SSI ratio and the Medicaid ratio. The DPP formula, which we propose be included in the guidelines, is as follows:

$$\frac{\text{Patient Days of Medicare Part A and SSI Entitlement}}{\text{Patient Days of Medicare Part A Entitlement}} + \frac{\text{Patient Days of Medicaid Eligibility but not Medicare Part A Entitlement}}{\text{Total Hospital Patient Days}}$$

As demonstrated above, the Medicare SSI ratio's numerator is the number of patient days attributable to patients who are entitled to both Medicare Part A and supplemental security income (SSI) benefits, and the denominator represents the entire universe of patient days attributable to patients entitled to Medicare Part A benefits. The Medicaid ratio's numerator is the number of patient days attributable to patients who are eligible for assistance under the state Medicaid plan but who are not entitled to Medicare Part A benefits. This number includes patient days attributable to Medicaid eligible patients even if the hospital did not receive payments from Medicaid for those days. The Medicaid ratio's denominator is the hospital's total patient days.

Hospitals use one of the following two formulas to determine DSH adjustment percentages depending on the hospital's DPP:

$$\text{If DPP is between 15\% and 20.2\%:} \quad \text{DSH} = 2.5 + (0.65)(\text{DPP} - 15)$$

$$\text{If DPP is equal to or greater than 20.2\%:} \quad \text{DSH} = 5.88 + (0.825)(\text{DPP} - 20.2)$$

Hospitals must have a DPP of greater than 27.32 percent in order to satisfy the 11.75 DSH adjustment percentage necessary for participation in the 340B program. This is so because,

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<sup>5</sup> As children's hospitals do not receive DSH adjustments, it follows that 340B eligibility for children's hospitals cannot be contingent upon the receipt of a DSH adjustment.

pursuant to the second equation:

$$11.75 = 5.88 + (0.825)(27.32 - 20.2).$$

Thus, children's hospitals – which are not Medicare DSH hospitals and not eligible for Medicare DSH adjustments – are nonetheless assured of meeting the 340B DSH adjustment percentage criteria if they have a DPP of 27.32 percent.

Under this approach, children's hospitals would have several alternatives for demonstrating that they meet the requisite DPP of 27.32 percent. First, the hospital would consult its cost report to determine the amount of its DPP, beginning with a calculation of the Medicaid ratio. If the resulting Medicaid ratio is above 27.32 percent, the inquiry would end, as the DPP threshold would be met even without factoring in the Medicare/SSI ratio.<sup>6</sup> If the resulting number is less than 27.32 percent, however, the hospital would continue with the DPP analysis, adding the Medicare/SSI ratio to the equation.

If a children's hospital neither prepares nor files a cost report, the hospital should be permitted to hire an independent auditor, and the independent auditor would undertake the afore-mentioned two-tiered approach to determine the hospital's DPP, beginning with a calculation of the hospital's Medicaid ratio. Only if the Medicaid ratio were below 27.32 percent would the auditor calculate and factor in the amount of the Medicare/SSI ratio.

**4. *A Children's Hospital Should Be Permitted to Rely Upon Its Medicare Cost Report to Determine Its Disproportionate Patient Percentage. If No Cost Report Exists, a Children's Hospital Should Be Permitted to Hire Its Own Independent Auditor to Calculate Its DPP.***

As noted above, pursuant to Section 6004, children's hospitals that do not meet "Pickle" criteria must meet the requirements of clause (ii) of section 340B(4)(L) regarding Medicare DSH adjustment percentages, "if that clause were applied by taking into account the percentage of care provided by the hospital to patients eligible for medical assistance under a State plan under this Title [Medicaid]." The proposed guidelines state that HRSA will seek verification of compliance with this requirement based on the hospital's Medicare cost report. However, as HRSA acknowledges, children's hospitals are excluded by law from the Medicare IPPS and are therefore ineligible to receive Medicare DSH adjustments. The cost report may therefore not provide the required verification. Additionally, many children's hospitals do not file any or full Medicare cost reports.

The proposed guidelines state that HRSA is considering requiring a statement from an

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<sup>6</sup> Children's hospitals have very high percentages of Medicaid patients and therefore very high Medicaid ratios, while Medicare/SSI ratios, based on care provided to Medicare beneficiaries and patients receiving Supplemental Security Income for the Aged, Blind, or Disabled, are negligible. Therefore, the Medicaid ratio will always be the primary component of the DPP calculation for children's hospitals.

independent auditor certifying that a children's hospital meets the requirements of Section 340B(a)(4)(L)(ii) in situations where there is no established method of verification comparable to the annual cost report. HRSA has invited comment regarding the feasibility of the use of independent auditors and other possible alternatives for ensuring that children's hospitals meet this particular criterion for participation in the 340B program.

We recommend that, consistent with HRSA's proposed guidelines, the hospital's Medicare cost report be the first source for verification of compliance with Section 340B(a)(4)(L)(ii). Accordingly, where possible, a hospital's most recently filed cost report would be utilized – using the two-tiered approach discussed above – to determine whether the hospital's disproportionate patient percentage meets the requisite threshold of 27.32 percent.

Where no such cost report exists, we propose that the hospital itself be permitted to choose and hire an independent auditor. Further, if an independent auditor is retained by the hospital, we propose that the scope of the audit be narrowly focused, and that the auditor engage in the two-tiered inquiry discussed above to determine the hospital's DPP. The auditor's inquiry would thus begin with the calculation of the hospital's Medicaid ratio. If the resulting number is above 27.32 percent, the inquiry would end, as the disproportionate patient percentage threshold would already be met. If and only if the resulting number is less than 27.32 percent, the auditor would continue with the DPP analysis, adding to the sum of the first fraction the hospital's Medicare/SSI ratio.

Thus, children's hospitals would implement one or more of the following four steps to calculate their DPP in order to demonstrate compliance with Section 340B(a)(4)(L)(ii): 1) use of a cost report for determining the hospital's Medicaid ratio; 2) use of a cost report for determining the hospital's Medicare/SSI ratio if the cost report indicates that the Medicaid ratio is less than 27.32 percent; 3) if no cost report exists, use of a hospital-chosen independent auditor to determine the hospital's Medicaid ratio; and 4) use of a hospital-chosen auditor for determining the Medicare/SSI ratio if the auditor's initial inquiry has shown that the Medicaid ratio is below 27.32 percent.

**5. *N.A.C.H. Supports HRSA's Proposal that PPAs Be Deemed to Include Children's Hospitals by Virtue of the Language of Section 6004.***

Section 340B requires pharmaceutical manufacturers participating in the Medicaid program to enter into a 340B participation agreement (referred to as a pharmaceutical pricing agreement or PPA) with the Secretary of the Department of Health and Human Services (HHS), in addition to their Medicaid rebate agreement. Under the 340B participation agreement, a manufacturer agrees to provide discounts on covered outpatient drugs purchased by the government owned or sponsored entities that are specifically designated in Section 340B.

Section 6004 of the Deficit Reduction Act did not amend the 340B statute to include children's hospitals in the list of covered entities but instead amended Section 1927(a) of the Social Security Act, which requires manufacturers to enter into agreements with HHS that meet the requirements

of Section 340B with respect to covered outpatient drugs purchased by a covered entity. Section 1927(a)(5)(B), as amended by Section 6004, defines covered entities as those listed in Section 340B, as well as certain children's hospitals.

We support HRSA's conclusion that, because PPAs between HHS and drug manufacturers require manufacturers to provide 340B discounts on covered outpatient drugs to covered entities, and Section 6004 includes children's hospitals in the definition of covered entities, the PPAs currently in place effectively require manufacturers to provide 340B discounts to children's hospitals without need for further amendment to existing PPAs. Moreover, we support HRSA's implicit conclusion that pharmaceutical manufacturers must comply with the terms of Section 1927(a) if they wish to participate in the Medicaid program and therefore must honor the inclusion of children's hospitals in the 340B program via the amendment of Section 1927(a).

**6. *In Determining Whether an Off-Site Facility of a Children's Hospital Qualifies as an "Integral Part" of the Hospital and Is Therefore Eligible for 340B Program Participation, HRSA Should Establish a More Flexible Alternative to the Medicare Cost Report Test.***

The proposed guidelines do not address the issue of whether and how off-site locations of children's hospital can participate in the 340B program. For DSH facilities, the standard for determining whether an off-site hospital location is eligible for participation in the 340B program is whether the off-site location is an "integral part" of the hospital. We propose that the "integral part" requirement, like other 340B requirements for DSH hospitals, apply to children's hospitals as well.

Currently, the measure for determining whether an off-site DSH facility meets the "integral part" requirement is whether the off-site location is included on a reimbursable line of the hospital's Medicare cost report. As many children's hospitals do not file cost reports, this measure is insufficient to determine whether an off-site facility affiliated with a children's hospital meets the requirement. Moreover, even where a children's hospital does file a cost report, application of the cost-report test for inclusion of off-site facilities in the 340B program can result in delays of up to 20 months, depending on the time frame for the filing of the hospital's next cost report. For these reasons, we believe that reliance upon the Medicare cost report test alone is both inappropriate and burdensome. We recommend that HRSA develop an alternative test for determining whether an off-site facility is indeed an "integral part" of a children's hospital.

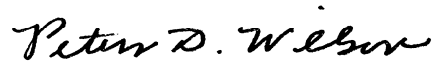
Specifically, we propose that in developing alternate criteria for assessing compliance with the "integral part" standard for children's hospitals, HRSA should be guided by Medicare provider-based standards, which may be useful and instructive in the development of an appropriate "test" for children's hospitals. We do not, however, propose that the provider-based standards be adopted in their entirety, as there may be occasions when an off-site facility of a children's hospital does not meet a technical aspect of the Medicare provider-based requirements. Such a facility may, however, meet all or virtually all of the substantive provider-based requirements

Mr. Bradford Lang  
September 7, 2007  
Page 10

and, as such, would still properly be considered an “integral part” of the children’s hospital. Accordingly, we propose that while HRSA should utilize the provider-based standards as a guide to develop a more appropriate means of assessing compliance with the “integral part” standard, the agency’s focus should be on the creation of a more flexible test that is applicable to the unique circumstances of children’s hospitals.

Thank you for your consideration of our comments and recommendations. We would be pleased to answer any questions you might have. You can reach me at 703/797-6006 or [pwillson@nachri.org](mailto:pwillson@nachri.org).

Sincerely,

A handwritten signature in black ink that reads "Peter D. Willson". The signature is written in a cursive, slightly slanted style.

Peters D. Willson  
Vice President for Public Policy