

2. HOSPITAL ELIGIBILITY

Section 340B extends 340B program eligibility to twelve categories of covered entities.⁷¹ One of these categories is acute care DSH hospitals that meet the following three criteria: (1) the hospital is government-owned or -operated or is obligated by statute or government contract to provide indigent care; (2) the hospital has a Medicare disproportionate share adjustment percentage greater than 11.75 for the most recent cost reporting period; and (3) the hospital does not obtain covered outpatient drugs through a GPO or other group purchasing arrangement while participating in the 340B program.⁷² Each of these criteria is discussed in greater detail below. Also discussed below is a provision in the DRA intended to add freestanding children's hospitals to the 340B program and HRSA's proposal on how to implement this provision.

2.1. *Criterion One: Government Function*

The first 340B eligibility requirement for DSH hospitals focuses on whether the hospital performs a governmental function. The government function requirement mandates that the qualifying hospital:

[be] owned or operated by a unit of state or local government, [be] a public or private non-profit corporation which has been formally granted governmental powers by a unit of state or local government, or [be] a private non-profit hospital with a contract with a state or local government to provide health care services to low income individuals who are not entitled to benefits under [Medicare or Medicaid].⁷³

Essentially, three types of hospitals can satisfy the government function requirement: (1) hospitals owned or operated by a state, county, or city; (2) hospitals to which a state or local government has formally delegated, by law or other means, the responsibility to provide care for patients regardless of the patients' ability to pay; or (3) private non-profit hospitals that have contracted with state or local government to provide indigent care.

⁷¹ See 42 U.S.C. § 256b(a)(4), *attached at* Tab 1-1.

⁷² See 42 U.S.C. § 256b(a)(4)(L), *attached at* Tab 1-1. Psychiatric hospitals, long term care facilities, cancer hospitals and rehabilitation hospitals do not qualify because, under the DSH eligibility portion of the 340B statute, they are not "subsection (d) hospitals." See *id.* (requiring the 340B hospital to be a subsection (d) hospital as defined in section 1886(d) of the Social Security Act). A subsection (d) hospital generally refers to an acute care hospital that is reimbursed by Medicare through the program's prospective payment system. See 42 U.S.C. § 1395ww(d)(1)(B).

⁷³ See 42 U.S.C. § 256b(a)(4)(i), *attached at* Tab 1-1.

The common thread among these three types of hospitals is the requirement to provide indigent care. Type (1) hospitals have a responsibility to provide indigent care by virtue of being a part of the government. Types (2) and (3) hospitals, though not government-owned, have a government-delegated responsibility to provide indigent care. Note that type (2) hospitals may also include “public” corporations which are not defined in the law but probably refer to legal entities that are organizationally distinct from state or local government (such as having its own governance structure like a board of directors) but which operate under government control or oversight (e.g. if a majority of the board is appointed by government).

For type (1) hospitals, direct government ownership or operation is relatively clear-cut and simple to prove to OPA. Type (2) hospitals may find it more complicated to prove that they have been formally delegated governmental powers. OPA has indicated that in order to qualify as a type (2) hospital, a hospital’s state must grant the hospital “a type of power usually exercised by the State, for the purpose of providing health care services to the medically indigent population of the State.”⁷⁴ Essentially, this requires the existence of a state law or other government mandate that requires the hospital to provide a certain level of charity care or to treat patients regardless of their ability to pay. To date, OPA has not clarified the types of rights and responsibilities that a state law must include in order to open up the possibility of 340B eligibility for the hospitals subject to that law. OPA has stated instead that it will evaluate indigent care laws on a case-by-case basis.⁷⁵ Several hospitals in New Jersey entered the 340B program as type (2) hospitals by relying on a state statute requiring all of New Jersey’s DSH hospitals to provide indigent care.⁷⁶ Presumably a facility can also qualify as a type (2) hospital by virtue of being obligated to provide indigent care under local rather than state law, even though OPA’s only written guidance on type (2) hospitals refers exclusively to state obligations.

⁷⁴ OPA, DSH-340B Frequently Asked Questions, Answer ID 416, <http://answers.hrsa.gov> (last visited Oct. 26, 2007), *attached at* Tab 2-1.

⁷⁵ *Id.*

⁷⁶ Meeting between William von Oehsen, President and General Counsel, SNHPA, with John Guhl, Director, Division of Medical Assistance and Health Services, New Jersey Department of Human Services (Aug. 20, 2007).

Convincing OPA that a hospital has followed the third statutory pathway to meeting the government function requirement is less complex. The qualification process for type (3) hospitals is easier because, in contrast to the case-by-case approach adopted by OPA for type (2) institutions, the agency has defined more clearly what supporting documentation a type (3) hospital must submit with its application. To qualify for 340B, type (3) hospitals must be private non-profit institutions that have a contract with state or local government to provide health care services to low income individuals who are not eligible for Medicare or Medicaid benefits. Rather than requiring the hospitals to submit their government contracts for review or specifying certain language that must be included in the contracts, OPA and HRSA simply require that the hospital applicant submit a one-page form executed by a state or local government official certifying that a contract exists and meets 340B standards. The one-page form, which is available on the OPA website, requires an “appropriate” public official to certify that the contract “is currently valid and requires that the named private non-profit hospital provide health care services to low income individuals who are not entitled to benefits under Title XVIII of the Social Security Act or eligible for assistance under the State plan of Title XIX under this Act.”⁷⁷ The official further certifies, pursuant to the form, that he or she will notify OPA if the contract is no longer valid.⁷⁸

Interestingly, the contracting requirement for type (3) private non-profit hospitals used to be stricter. According to a 2002 frequently-asked-questions (“FAQ”) document that no longer exists on the OPA website, the contract between a private non-profit hospital and state or local government had to (1) “specifically state” that the DSH hospital will provide health care services to low income individuals who are not entitled to Medicare or Medicaid benefits, (2) represent that the DSH hospital is “acting in the public interest,” and (3) acknowledge that the DSH hospital is “accepting no reimbursement or considerably less than full reimbursement for the services provided.”⁷⁹

⁷⁷ See HRSA, Certification by Appropriate State or Local Government Official That (a Private Non-Profit Hospital) is Under Contract to Provide Health Care Services to Low Income Individuals, <http://www.hrsa.gov/opa/dsh.htm>, *attached at* Tab 2-2.

⁷⁸ *See id.*

⁷⁹ OPA, DSH Hospitals Frequently Asked Questions and Forms, Question 3 (last revised July 31, 2002), *attached at* Tab 2-3.

One can speculate that very few private non-profit hospitals have contracts in place that satisfy these three standards, which would explain why the FAQ was withdrawn.

Noticeably absent from the contract requirements for type (3) hospitals is any mention of how much indigent care a hospital must provide. Following years of repeated requests by OPA to recommend standards in this area, SNHPA developed and submitted to OPA in July 2006 a proposed charity care policy which, according to SNHPA, could be required of all type (3) hospitals via their contracts with state or local government.⁸⁰ SNHPA resubmitted this proposal in March 2007 as part of its comments to HRSA's proposed changes to the definition of patient.⁸¹ HRSA's proposed patient definition notice included a specific request for comments with respect to which elements should be required in private non-profit hospitals' contracts with state or local government.⁸² In resubmitting its recommendations, SNHPA cautioned that, if HRSA chooses to adopt them, it should apply them prospectively so that existing contracts between 340B hospitals and state or local governments would not have to be renegotiated.

There are at least three possible explanations for why HRSA is interested in establishing indigent care standards for type (3) hospitals. First, it would effectuate Congressional intent. According to the legislative history of the 340B program, Congress did not intend to extend covered entity status to hospitals that provide indigent care pursuant to "minor" contracts representing an "insignificant" portion of their operating revenue.⁸³ Second, by establishing specific indigent care standards for private non-profit hospitals, HRSA would ensure that type (3) hospital eligibility is limited to only those hospitals that are truly safety net institutions. Participation of private non-profit hospitals in the 340B program has experienced explosive growth in the last decade and many 340B stakeholders are concerned that one or more non-profits have slipped into the program that really are not carrying their share of the indigent caseload.⁸⁴ Finally, private non-

⁸⁰ Letter from SNHPA to Jimmy Mitchell, Director, OPA (July 13, 2006), *attached at* Tab 2-4.

⁸¹ Letter from SNHPA to Bradford Lang, Public Health Analyst, OPA at 5 (March 13, 2007), *attached at* Tab 2-5.

⁸² Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient", 72 Fed. Reg. 1543, 1544 (Jan. 12, 2007), *attached at* Tab 1-14.

⁸³ H.R. Rep. No. 102-384(II) at 14 (1992).

⁸⁴ SNHPA memorandum to members (attaching and explaining SNHPA's letter to OPA dated July 13, 2006) (available in 'Members Only' section of SNHPA website).

profit hospitals are increasingly being scrutinized by policy makers, regulators, and enforcement authorities over whether these institutions are living up to the terms of their tax-exempt non-profit status and whether stricter oversight is needed to ensure that private non-profits are not falling short of these standards. Such inquiries have spilled over to the 340B program. In the 109th Congress, for example, staffers on the House Ways and Means Committee grilled SNHPA with questions about how 340B hospitals are charging indigent patients for services and what kinds of charity care policies are being used by the hospitals.⁸⁵

SNHPA's new proposed contract language for type (3) hospitals would mandate that the contracting hospital have an indigent care policy in place whereby (1) hospital patients who are low income and uninsured would be entitled to discounts on their care (based on, for example, a sliding fee schedule) and (2) uninsured patients in the lowest income bracket would pay little or nothing for hospital services.⁸⁶ This proposal is patterned on a recommended charity care policy developed by the American Hospital Association. SNHPA's proposal would further require that private non-profit hospitals utilize the 340B program in accordance with the above policy such that low income patients could never be denied access to pharmacy services based on an inability to pay.⁸⁷ It is unclear whether HRSA will issue guidance in this area based on SNHPA's recommendations or an alternative approach. If it does, such guidance would likely be included in HRSA's final patient definition guidelines.

2.2. *Criterion Two: Medicare DSH Adjustment Percentage Above 11.75*

Under the Medicare program's inpatient acute care prospective payment system ("PPS"), hospitals in the same geographic area generally receive the same payment amount for providing care to any patient with a given diagnosis. Hospitals that serve a disproportionate number of indigent patients, however, may receive an add-on payment to their PPS rates in the form of a "DSH adjustment." DSH adjustment payments are calculated by multiplying a DSH hospital's Medicare DSH adjustment percentage by the

⁸⁵ *Id.*

⁸⁶ Letter from SNHPA to Jimmy Mitchell, Director, OPA (July 13, 2006), *attached at* Tab 2-4.

⁸⁷ *Id.*

hospital's diagnosis-related group ("DRG") operating revenues. To be a 340B-eligible "covered entity," a hospital must have a Medicare DSH adjustment percentage that exceeds 11.75 percent.⁸⁸ Whether a hospital meets this statutory threshold depends primarily on whether it serves a comparatively large number of patients eligible for Medicaid and/or supplemental security income ("SSI"). Another way is if the hospital serves a relatively large number of low income patients whose care is paid for out of state or local government subsidies rather than by Medicaid. These latter hospitals are commonly referred to as "Pickle" hospitals in recognition of the former Texas Congressman J. J. Pickle who sponsored the legislation that established this method to qualify for DSH. The requirement of a hospital applicant having a Medicare DSH adjustment percentage above 11.75 percent ensures that 340B eligibility extends only to hospitals that serve a very large number of low-income patients. The vast majority of 340B hospitals qualify for the 340B program by virtue of serving large numbers of Medicaid and SSI patients rather than by being Pickle hospitals.

In assessing whether a DSH hospital has a DSH adjustment above 11.75 percent, OPA relies on a spreadsheet created by CMS as "the official source used to verify a hospital's DSH adjustment percentage."⁸⁹ This file is available online⁹⁰ and is updated around the middle of each quarter. Hospitals identified on the spreadsheet as having a DSH adjustment percentage exceeding the 11.75 percent threshold need not worry about the mechanics of the DSH adjustment calculation since they are automatically deemed by the government to meet the 11.75 percent DSH adjustment eligibility requirement. Hospitals listed as having a DSH adjustment percentages below the threshold (and are therefore considered to be 340B-ineligible) may wish to double-check the CMS numbers by using their own data and by doing their own calculations. SNHPA has advocated on behalf of its members to establish a way for hospitals to appeal eligibility determinations that OPA makes based on the spreadsheet that the agency receives quarterly from CMS.⁹¹ As explained below, the quarterly CMS spreadsheets may be based on outdated or

⁸⁸ 42 U.S.C. § 256b(a)(4)(L)(ii), *attached at* Tab 1-1.

⁸⁹ See OPA, Disproportionate Share Hospitals, <http://www.hrsa.gov/opa/dsh.htm> (last visited Oct. 26, 2007).

⁹⁰ See OPA DSH Hospitals Database, <http://opanet.hrsa.gov/opa/Login/DSHHospitals.aspx> (last visited Oct. 26, 2007).

⁹¹ See Letter from SNHPA to Jimmy Mitchell, Director, OPA (Sept. 13, 2005), *attached at* Tab 2-6.

inaccurate data. As a result, if a hospital believes that its DSH adjustment percentage for the previous cost reporting period exceeds 11.75 percent but the percentage is listed as lower on the CMS list, OPA allows a DSH hospital to challenge the adjustment percentage reported by CMS by providing OPA with (1) a copy of Worksheet E, Part A, of the hospital's Medicare cost report reflecting a percentage above 11.75 percent and (2) a signed letter from the hospital's chief financial officer certifying the accuracy of the DSH adjustment percentage as reflected on Worksheet E.⁹² Another option is for the hospital to seek documentation from its Medicare fiscal intermediary ("FI") supporting the hospital's calculations that its DSH adjustment exceeds 11.75 percent. OPA sometimes accepts documentation from FIs verifying hospitals' 340B eligibility, even if the CMS database indicates that the hospital's DSH adjustment is below the statutory threshold.

Hospitals sometimes confuse the Medicare DSH adjustment percentage with the Medicare disproportionate patient percentage ("DPP"). The DPP is the percentage that determines whether a non-Pickle hospital is eligible for DSH adjustment payments. The DPP is always higher than the DSH adjustment percentage, so confusion about the two percentages may lead a hospital to conclude incorrectly that it qualifies for the 340B program. To understand the relationship between the Medicare DPP and DSH adjustment calculations, we refer you to subsection 2.2.1 which describes how to determine the Medicare DSH adjustment percentage. Subsection 2.2.1 also describes Pickle hospital eligibility in more detail. Hospitals that have DSH adjustments that barely exceed 11.75 percent should monitor their DPP and DSH adjustment calculations closely so that they can be prepared for the possibility of losing their 340B eligibility as a result of a declining DSH adjustment percentage. Likewise, hospitals that fall just short of the 11.75 percent threshold should monitor their calculations in case they may qualify for 340B participation sometime in the future. Either way, they should be aware of certain factors that could increase or decrease their DSH adjustment percentages, which is the focus of subsection 2.2.2.

2.2.1. *Determining the Medicare DSH Adjustment Percentage*

⁹² See OPA DSH Hospitals Database, *supra* note 90.

to Medicare Part A benefits.⁹⁶ 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.⁹⁷ Note that this number will include patient days attributable to Medicaid-eligible patients even if the hospital did not receive payments from Medicaid for those days (because, for example, the patient's stay exceeded a Medicaid coverage limitation or a third-party insurer paid for those days).⁹⁸ The Medicaid ratio's denominator is the hospital's total patient days.⁹⁹ Thus, this fraction uses the Medicaid program as a proxy for determining the percentage of a hospital's total patients that are indigent and not entitled to Medicare.

To arrive at the DSH adjustment percentage and thus determine whether a hospital exceeds the 11.75 percent threshold for 340B program eligibility, the hospital must apply a formula that includes its DPP. At one time, the applicable formula varied significantly depending on whether the facility at issue was urban or rural, small or large, a sole community hospital or a rural referral center. For some categories of DSH hospitals – in particular, small rural and urban hospitals – the Medicare statute and regulations set caps and other parameters on DSH adjustment percentages such that, prior to April 1, 2004, no hospital within that category could ever receive a DSH adjustment payment above 11.75 percent. This changed, however, when Congress enacted the MMA, which eliminated the relevance of these categories for purposes of determining 340B eligibility.¹⁰⁰ Under the amended DSH statute, which applies to discharges occurring on or after April 1, 2004,¹⁰¹ one key principle emerges for purposes of evaluating 340B eligibility: for any hospital, the Medicare DSH adjustment percentage will always exceed the 11.75 percent threshold if the hospital has a DPP of at least 27.32

⁹⁶ 42 U.S.C. § 1395ww(d)(5)(F)(vi)(I).

⁹⁷ 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II).

⁹⁸ Interpretation of Medicaid Days Included in the Medicare DSH Adjustment Calculation, HCFA Ruling 97-2 (Feb. 1997).

⁹⁹ 42 U.S.C. § 1395ww(d)(5)(F)(vi)(II).

¹⁰⁰ MMA, Pub. L. No. 108-173, § 402, 117 Stat. 2066, 2264-65 (2003), codified at 42 U.S.C. § 1395ww(d)(5)(F)(xiv).

¹⁰¹ For discharges occurring before April 1, 2004, different formulas applied to different categories of hospitals. See 42 U.S.C. § 1395ww(d)(5)(F)(vii)-(xiv). The pre-MMA categorization rules and applicable formulas are set forth at 42 C.F.R. § 412.106.

percent.¹⁰² Following the passage of MMA, HRSA sent letters to all DSH hospitals advising them that, as a result of the new law, small rural and urban hospitals could now enroll in the 340B program.¹⁰³ HRSA sent a similar letter to manufacturers.¹⁰⁴

2.2.2. *Strategies for Maintaining a 340B-Eligible Medicare DSH Adjustment Percentage*

A 340B hospital that has a Medicare DSH adjustment slightly above 11.75 percent is at risk of losing its 340B eligibility by dipping below the 11.75 percent threshold. Of course, unavoidable circumstances may arise in which a hospital cannot help falling below the 340B qualification threshold. For example, a sharp decline in Medicaid admissions may cause a hospital's DSH adjustment percentage to drop below 11.75, leading to disqualification from the 340B program.

In certain circumstances, however, a hospital may avoid disqualification if it works cooperatively with its Medicare FI. The role of the FI is significant because when OPA evaluates a hospital's Medicare DSH adjustment percentage, it relies on the DSH adjustment spreadsheets generated quarterly by CMS which, in turn, is based on data that FIs submit to CMS and which CMS maintains in a database called the Provider Specific File ("PSF").¹⁰⁵ FIs are obligated to update the PSF regularly.¹⁰⁶ A hospital may be able to increase the Medicare DSH adjustment percentage used to evaluate its 340B eligibility by working with the FI to ensure: (1) the data in the PSF is accurate and current; and (2) the FI has properly estimated the hospital's Medicaid ratio.

¹⁰² The formula for calculating the DSH adjustment percentage for hospitals with a DPP above 20.2 percent is:

$$((\text{DPP} - 20.2) \times 0.825) + 5.88$$

42 C.F.R. § 412.106(d)(2). Using this formula, a hospital's DSH adjustment percentage will be higher than 11.75 percent if its DPP is 27.32 percent or higher. The DSH adjustment percentage for hospitals with a DPP below 20.2 percent cannot reach the 11.75 percent 340B eligibility threshold.

¹⁰³ Model Letter to Hospital Executive, by Elizabeth M. Duke, Administrator, HRSA (April 1, 2004), *attached at* Tab 2-7.

¹⁰⁴ Model Letter to Manufacturer, by Elizabeth M. Duke, Administrator, HRSA (April 1, 2004), *attached at* Tab 2-8.

¹⁰⁵ See CMS, Medicare Intermediary Manual § 3656.3, <http://www.cms.hhs.gov/Manuals/PBM/list.asp> (last visited Oct. 26, 2007).

¹⁰⁶ *Id.* at § 3850.

With respect to the first strategy, a hospital may be able to increase its Medicare DSH adjustment percentage by ensuring that its FI is using data that is accurate and current. Intermediaries often update the PSF using outdated data, such as a hospital's last settled Medicare cost report. According to CMS guidelines, however, intermediaries are supposed to use the "latest available" information when preparing these updates.¹⁰⁷ This means that they should rely on data that is more recent than the last settled cost report, which often lags behind the current fiscal year by two or more years. For example, the FI can rely on data from the most recently filed cost report or even on data that has not yet been submitted on a cost report. A hospital's DPP can change significantly from year to year. If a hospital's DPP has been climbing since its most recently settled cost report, the hospital should try to persuade its FI to update the PSF using a more recent DPP.

The second intermediary-related factor which can affect a hospital's 340B eligibility is the possibility that an FI has underestimated the hospital's interim DSH payments. Sometimes intermediaries purposely underestimate a hospital's DPP in an effort to avoid overpaying the hospital prior to settlement of the hospital's cost report for the current fiscal year. This practice typically does not harm the hospital because the FI will correct the underpayments by making an additional payment when it settles the cost report.¹⁰⁸ Intermediaries usually are unaware that, although interim Medicare DSH payments can be adjusted retroactively when the hospital's cost report is settled, HRSA and OPA do not recognize retroactive eligibility for the 340B program.¹⁰⁹ By educating FIs about the potential loss of 340B eligibility based on artificially low DPP estimates, hospitals can reduce the risk of 340B disqualification.

¹⁰⁷ *Id.*

¹⁰⁸ See 42 C.F.R. § 412.116(b)(2) (2006).

¹⁰⁹ See *Univ. Med. Ctr. v. Shalala*, 173 F.3d 438 (D.C. Cir. 1999), *attached at* Tab 2-9, a hospital was excluded from the 340B program because the numbers available to OPA made the hospital's Medicare DSH adjustment percentage appear low. In fact, however, the percentage exceeded 11.75. By the time this information arrived at OPA and OPA was able to admit the hospital into the program, nineteen months had passed. The hospital brought an action in federal court, seeking a judgment declaring the hospital retroactively eligible for 340B prices. Because the lawsuit was dismissed on procedural grounds, the court never decided the question of whether UMC was entitled to retroactive eligibility. Nonetheless, the government's position throughout the case was that a hospital's exclusion from the program based on an underestimation of the hospital's Medicare DSH adjustment percentage does not entitle the aggrieved hospital to retroactive eligibility. Neither OPA nor HRSA have wavered from this position.

Hospitals with DSH adjustment percentages just above or just below the 11.75 percent threshold may want to consider other strategies for increasing that percentage so that their eligibility for the 340B program is not jeopardized. The most common way to do so is to make sure that all Medicaid days are included in the DSH calculation, which includes both paid days and eligible but unpaid days. Medicaid paid days include out-of-state patient days, Medicaid managed care days, Medicaid waiver days and days for which Medicaid eligibility is determined retroactively. Medicaid eligible but unpaid days include days attributable to Medicaid patients who exhausted their inpatient benefits or for which Medicaid did not make payment because it was a secondary payer. Another option for increasing Medicaid days that some hospitals have considered is decertifying a distinct part unit to make it part of the acute care area of the hospital. Because patient days in a distinct part unit are excluded from the DSH calculation, a distinct unit with high Medicaid utilization may cause a substantial increase in a hospital's Medicaid days if the unit is added to the acute care part of the hospital.¹¹⁰ Many hospitals have also reviewed their Medicare/SSI percentage to determine if it is accurate. The data underlying the Medicare/SSI fraction is available through CMS.¹¹¹ CMS has stated that it is willing to correct errors to the Medicare/SSI percentage,¹¹² although in practice it is has been resistant to making changes.¹¹³

2.3. *Criterion Three: Purchase No Covered Outpatient Drugs Through GPOs*

Section 340B restricts 340B hospitals' ability to purchase covered outpatient drugs through GPOs. The statute's definition of "covered entity" excludes from the 340B program otherwise-eligible DSH hospitals that "obtain covered outpatient drugs through

¹¹⁰ A change from distinct part status to acute care status raises other issues as well. For example, if a distinct part psychiatric unit converts to acute care status, it will be paid under acute care Medicare PPS rather than the psychiatric PPS, which will obviously affect Medicare reimbursement to the hospital. Accordingly, all aspects of this type of conversion, not only the change to Medicaid days, should be considered before the change is made.

¹¹¹ See Medicare Program; Changes to the Hospital Inpatient Prospective Payment Systems and Fiscal Year 2006 Rates, 70 Fed. Reg. 47,278, 47,438-41 (Aug. 12, 2005).

¹¹² See *id.*

¹¹³ Baystate Medical Center v. Mutual of Omaha Ins. Co., CMS Administrator Decision, Medicare and Medicaid Guide [CCH] ¶ 81,506 (2006).

a group purchasing organization or other group purchasing arrangement.”¹¹⁴ This requirement is commonly referred to as the “GPO exclusion.” Importantly, the GPO exclusion does not prohibit a DSH hospital from applying for 340B enrollment if it currently purchases covered outpatient drugs through a GPO. Rather, it requires the hospital to cease purchasing covered outpatient drugs through a GPO once the hospital begins buying covered outpatient drugs through the 340B program.¹¹⁵ This subsection discusses three aspects of the GPO exclusion: (1) the basic scope of the GPO exclusion, (2) the question of whether the GPO exclusion applies to drugs dispensed or administered to patients who are not entitled to receive 340B-discounted drugs, and (3) compliance considerations.

2.3.1. *Scope of the GPO Exclusion*

The actual language of the GPO exclusion is broad in some respects and narrow in others. It is broad insofar as it prohibits DSH hospitals from using not only GPOs, but *any* group purchasing arrangement. It is narrow because it only applies to “covered outpatient drugs,” which means that GPOs can still be used to purchase inpatient drugs and outpatient drugs that fall outside the definition of a “covered outpatient drug.”¹¹⁶ A narrower construction of the GPO exclusion is reflected in the statute’s legislative history. The House Energy & Commerce Committee offered the following comments on the GPO exclusion.

The Committee recognizes that the public disproportionate share hospitals which the Committee is seeking to protect from high drug prices may participate in, or themselves maintain, group purchasing arrangements for a variety of purposes, including the purchase of supplies and equipment as well as pharmaceuticals. The Committee does not intend to disturb these arrangements or to require the withdrawal of these hospitals from these organizations or arrangements.¹¹⁷

¹¹⁴ 42 U.S.C. § 256b(4)(L)(iii), *attached at* Tab 1-1.

¹¹⁵ *See* HRSA, 340B Program Certification Regarding Non-Participation in a Group Purchasing Organization, <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHNonPartGPO.pdf> (last visited Oct. 26, 2007), *attached at* Tab 2-10.

¹¹⁶ *See id.*; Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110 (May 13, 1994), *attached at* Tab 1-6. A more detailed discussion of which drugs meet the definition of “covered outpatient drug” can be found in Chapter 4.

¹¹⁷ H.R. Rep. No. 102-384(II), at 14-15 (1992).

The Committee further clarified that, although a hospital would not qualify as a “covered entity” if it purchases covered outpatient drugs through a GPO or other group purchasing arrangement, the GPO exclusion only applies during the period for which participation in the program is sought.¹¹⁸

Notwithstanding this legislative history, OPA’s most detailed guidance on the GPO exclusion reflects a rather rigid interpretation of the law. In a September 1998 letter to SNHPA, OPA stated that a 340B hospital risks violating the GPO exclusion and consequently becoming ineligible for the 340B program if the hospital purchases a covered outpatient drug through a GPO in any of the following situations:

- when the drug is administered in an emergency room or during a clinic procedure rather than dispensed by the hospital’s outpatient pharmacy;
- when 340B pricing is unavailable for a particular drug because the drug’s manufacturer is unaware of its obligation to give a discount, mistakenly believes that the hospital or drug is ineligible, or is late in loading in the discounted pricing;
- when a facility that is part of a 340B hospital but is not participating in the program (because it is waiting for the next quarterly update of the covered entity list or because the facility is not able to operationalize the program) uses GPO-priced drugs that meet the definition of “covered outpatient drug;”
- when a GPO-priced drug is accidentally used on an outpatient basis due to human error; or
- when the hospital “carves out” its Medicaid outpatient drugs from the 340B program in order to be able to bill Medicaid above acquisition cost, and then chooses to buy the “carved out” drugs through its GPO.¹¹⁹

Concerned that the September 1998 letter could jeopardize the continued participation of most DSH facilities in the 340B program, SNHPA asked both OPA and HRSA – during an initial face-to-face meeting in November 1998 and in subsequent written communications – to reconsider the policies articulated in the September 1998 letter, at least with respect to the scenarios having the most significant impact on DSH

¹¹⁸ *Id.*

¹¹⁹ Letter from Jimmy Mitchell, Director, Office of Drug Pricing, to SNHPA (Sep. 15, 1998), *attached at* Tab 2-11. See Chapter 6 for a description of section 340B’s Medicaid billing restrictions and a discussion of the Medicaid “carve out” option.

hospitals.¹²⁰ OPA responded by sending SNHPA a short letter stating that OPA would consider SNHPA's request as part of a strategic planning initiative.¹²¹ This initiative, however, did not yield any further clarification from the government on the scope of the GPO exclusion.

The rather strict interpretation of the GPO exclusion reflected in OPA's September 1998 letter may be attributable, in part, to the impact of a federal court decision that was issued four months prior to the letter. The decision was rendered by a federal district court in a case brought by a DSH hospital that was erroneously excluded from the 340B program for nineteen months and that was seeking retroactive eligibility during this period in order to recover the 340B savings that it would otherwise have received. In this case – called *University Medical Center v. Shalala* – the court dismissed the plaintiff hospital's lawsuit based on a broad reading of the GPO exclusion.¹²² Hence, OPA's apparent unwillingness in September 1998 to accommodate the concerns of DSH hospitals regarding the GPO exclusion may have been based on an attempt to follow the *UMC* decision. Importantly, the district court's broad construction of the GPO exclusion was rejected on appeal in 1999.¹²³ The federal court of appeals, which affirmed the lower court decision *on different grounds*, was persuaded by the government's position that HRSA has the discretion to apply the GPO exclusion in a flexible manner in order to allow DSH hospitals to request and obtain 340B discounts on a retroactive basis, even if they use a GPO to purchase some covered outpatient drugs during the retroactive period.¹²⁴ In other words, the court agreed with the government that purchasing covered

¹²⁰ See Letter from SNHPA to Jimmy Mitchell, Director, Office of Drug Pricing (March 23, 1999) (enclosing a description of the limits on the GPO exclusion requested by SNHPA and a legal analysis supporting the request), *attached at* Tab 2-12. In the wake of the September 1998 letter, SNHPA surveyed its members in an effort to quantify the impact of OPA's interpretation. SNHPA discovered that the letter placed more than 80 percent of 340B hospitals at risk of disqualification. *Id.*

¹²¹ Letter from Jimmy Mitchell, Director, Office of Drug Pricing, to William von Oehsen, Counsel, and Ted Slafsky, Director, SNHPA (May 28, 1999), *attached at* Tab 2-13.

¹²² See *Univ. Med. Ctr. v. Shalala*, 5 F. Supp. 2d 4, 8 (D.D.C. 1998) (“Congress clearly expressed its intent that the 340B program prohibit ‘double-dipping’ into two drug price-reducing mechanisms. Because UMC elected, for whatever reason, to continue participation in its pre-existing group purchasing agreements, it cannot now also claim eligibility for the 340B program discounts”) (citations omitted), *attached at* Tab 2-14.

¹²³ See *Univ. Med. Ctr. v. Shalala*, 173 F.3d 438, 440-41 (D.C. Cir. 1999); *attached at* Tab 2-9.

¹²⁴ See *id.* at 441-42.

outpatient drugs through a GPO does not always render a DSH hospital ineligible to participate in the 340B program.

One cannot help but wonder if OPA would have written its September 1998 letter differently if it had known that the lower court's broad construction of the GPO exclusion would later be overturned. Indeed, based on 340B policies developed by OPA and HRSA in other areas, it appears that the government's stance on the GPO exclusion is actually more relaxed than one would think by reading the September 1998 letter. For example, the government does not interpret the GPO exclusion as prohibiting DSH hospitals from enrolling in the 340B prime vendor program and taking advantage of the price breaks that the prime vendor has negotiated with vendors on behalf of program participants.¹²⁵ HRSA also allows new 340B hospitals to continue using their GPOs for the first three months after enrolling in the 340B program in order to ease their transition into the program.¹²⁶ Finally, as discussed in the *UMC* case, HRSA authorized DSH hospitals to collect retroactive discounts on outpatient drugs purchased during the initial eighteen months of the 340B program (from November 1992 to May 1994), even if the drugs were purchased through a GPO.¹²⁷ HRSA's rationale, which was embraced in the *UMC* appellate decision, was that, during the start-up phase of the 340B program, the GPO exclusion should not act as a barrier to hospitals receiving the benefit of the 340B program, as long as collection of the retroactive discounts did not result in "double dipping," i.e., receiving both a 340B price and a GPO discount on the same drug.¹²⁸

In light of the foregoing examples, it is hard to draw any conclusions about how the GPO exclusion should be interpreted and applied because, in some instances, the exclusion is construed narrowly and, in other cases, it is applied broadly. Hospitals should therefore be careful to use the 340B program in a way that minimizes group purchasing of covered outpatient drugs. That said, there appear to be two kinds of group purchasing that carry little to no risk. First, if more than one 340B hospital is part of the same legal entity – such as a state or municipal government or a non-profit corporation –

¹²⁵ Letter from Jimmy Mitchell, Director, Office of Drug Pricing, to SNHPA (Sep. 15, 1998), *attached at* Tab 2-11; Telephone call from Amy Nordeng, Powers Pyles Sutter & Verville, PC, to Laila Akhlaghi, OPA (Mar. 20, 2002).

¹²⁶ OPA, DSH-340B Frequently Asked Questions, Answer ID 422, <http://answers.hrsa.gov> (last visited Oct. 26, 2007), *attached at* Tab 2-15.

¹²⁷ *Univ. Med. Ctr. v. Shalala*, 173 F.3d 438, 440-41 (D.C. Cir. 1999); *attached at* Tab 2-9.

¹²⁸ *Id.*

these commonly owned hospitals can probably purchase together without violating the GPO exclusion. Such hospitals are properly viewed as components of a single entity rather than as a group. Second, HRSA has specifically stated that the GPO exclusion does not prevent covered entities from using purchasing agents, subject to certain carefully defined limits that exist to ensure that the purchasing agent is not a GPO. HRSA guidelines allow DHS hospitals to use purchasing agents without violating the GPO exclusion if all the following conditions are met: (1) the purchasing agent is not associated with a GPO or other group purchasing arrangement; (2) no collective bargaining by a group of hospitals occurs; (3) the negotiations for 340B pricing are separate activities for each individual DSH hospital; (4) a separate agreement with each hospital is executed; (5) as part of the agreement, there will be no sharing of pricing information; and (6) all final decisions concerning product and price acceptance will be made by each individual institution.¹²⁹ The essence of this rule is that the GPO exclusion does not preclude the use of purchasing agents, as long as the agents do not operate like GPOs.

2.3.2. Application to Drugs Dispensed to Non-340B Outpatients

340B hospitals sometimes dispense drugs to individuals who do not meet the 340B definition of “patient.” It is unclear from the language of the GPO exclusion whether its scope is co-extensive with the 340B definition of “patient” or whether the exclusion extends to all purchases of “covered outpatient drugs” regardless of a hospital’s ability to receive 340B prices on such drugs. Historically, most 340B hospitals have assumed the former. Common sense tells them that, if a patient does not qualify to receive 340B-discounted drugs from the hospital, the patient should not be precluded from getting the lowest price drugs outside the 340B program, which generally means drugs purchased under the hospital’s GPO contract. Outside the 340B program, non-profit hospitals have access to discounted drugs under the Non-Profit Institutions Act, which allows certain non-profit institutions, including hospitals, to purchase supplies for their “own use” at prices lower than those charged to for-profit and retail purchasers

¹²⁹ Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110 (May 13, 1994), *attached at* Tab 1-6.

(without running afoul of the Robinson Patman Act's anti-discrimination standards).¹³⁰ This law creates an opportunity for non-profit hospitals to negotiate significant drug discounts. To maximize these savings, most non-profit hospitals pool their purchasing power by forming GPOs. 340B hospitals therefore have used their GPO contracts to purchase drugs that they dispense to non-340B outpatients. Under a broad interpretation of the GPO exclusion, however, a 340B hospital might lose its 340B eligibility by using a GPO to purchase any drug that meets the definition of "covered outpatient drug," even when the hospital dispenses that drug to non-340B outpatients. At least one email exchange between OPA and SNHPA suggests that the government may follow the latter interpretation.¹³¹

SNHPA's view is that the GPO exclusion only extends to drugs dispensed to 340B-eligible patients, and that the exclusion does not prohibit 340B hospitals from using GPOs to purchase outpatient drugs for patients who do not qualify for 340B drugs. Under well-established rules of statutory construction, the 340B statute and the Non-Profit Institutions Act can and should be read such that neither statute negates the other.¹³² Thus, the GPO exclusion should be interpreted such that it applies only to covered outpatient drugs dispensed or administered to 340B-eligible patients. This interpretation gives meaning to both statutes, and it makes sense in the broader context of the 340B statute. Congress included the GPO exclusion among the DSH hospital eligibility criteria in order to force hospitals to choose between buying discounted drugs through GPOs or through the 340B program. Prohibiting non-340B outpatients from accessing GPO pricing would serve no purpose, because a hospital cannot access multiple drug discount programs for this population.

In an October 2004 letter to OPA, SNHPA articulated the foregoing interpretation of the statute, along with several policy reasons for applying the GPO exclusion only to

¹³⁰ See 15 U.S.C. § 13c.

¹³¹ Email from Kathy Kovarcik, OPA, to Claire Holloway, Powers Pyles Sutter & Verville, P.C. (June 2, 2004), *attached at* Tab 2-16.

¹³² See *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 143-44, 122 S. Ct. 593, 605 (2001) ("[W]hen two statutes are capable of co-existence, it is the duty of the courts, absent a clearly expressed congressional intention to the contrary, to regard each as effective.") (quoting *Morton v. Mancari*, 417 U.S. 535, 551, 94 S. Ct. 2474, 2483 (1974)).

drugs dispensed or administered to 340B “patients.”¹³³ OPA never explicitly resolved the ambiguity regarding the breadth of the GPO exclusion with regard to non-340B patients. SNHPA initially hoped OPA would post an FAQ clearly stating that the GPO exclusion is co-extensive with the definition of a 340B “patient.” Unfortunately, the only FAQ discussing the GPO exclusion merely reiterates that a DSH official must submit a certification that the hospital will not participate in a group purchasing arrangement for outpatient drugs.¹³⁴

Although application of the GPO exclusion to drugs dispensed or administered to non-340B patients remains unsettled, there are two other situations where use of GPO drugs probably does not violate the GPO exclusion. This is because these uses of GPO-priced drugs can be distinguished from the hospital’s 340B participation. First, it is probably safe to use GPO-priced drugs in facilities that are not part of the DSH hospital (*i.e.* not reimbursable on the hospital’s Medicare cost report). Second, it is probably safe to use GPO-priced drugs that fall outside the definition of “covered outpatient drug.”

2.3.3. *Compliance with the GPO Exclusion*

Compliance with the GPO exclusion poses significant challenges for 340B hospitals. Most 340B hospitals rely on GPOs to negotiate prices on inpatient drugs (and prices on other drugs that do not meet the definition of “covered outpatient drug”), so hospitals face the daunting responsibility of ensuring that their separate stocks of GPO and 340B drugs are used in the appropriate settings. Although HRSA does not require hospitals to maintain physically separate inventories, 340B hospitals must develop some

¹³³ Letter from Bill von Oehsen and Claire Holloway, Counsel, SNHPA, to Jimmy Mitchell, Director, OPA, regarding the use of GPO drugs for 340B hospitals’ non-340B-eligible patients (Oct. 5, 2004), *attached at* Tab 2-17. The policy arguments against extending the GPO exclusion to drugs dispensed or administered to non-340B-eligible patients include: (1) the higher drug costs resulting from a broad interpretation of the GPO exclusion would lead to a reduction in available health care products and services; (2) under a broad interpretation of the GPO exclusion, free care and other safety net facilities that rely on GPO-priced drugs transferred from DSH hospitals would be forced to spend significantly more for drugs; and (3) an expansive GPO exclusion would create a strong disincentive for 340B enrollment.

¹³⁴ OPA, DSH-340B Frequently Asked Questions, Answer ID 412, <http://answers.hrsa.gov> (last visited Oct. 26, 2007), *attached at* Tab 2-18.

sort of internal control system to prevent GPO-purchased drugs from being used improperly.¹³⁵

Notwithstanding the operational challenges of protecting against a violation of the GPO exclusion, SNHPA is not aware of any 340B hospital that has faced either an investigation or an enforcement action for failing to comply with this eligibility requirement. There are three possible explanations for this observation. First, drug manufacturers have little economic incentive to police a hospital's potential overuse of GPO-priced drugs. The sale of GPO-priced drugs to outpatients likely would result in the hospital using fewer 340B-discounted drugs which, in turn, will increase industry profits. Second, most hospitals have developed inventory management systems that allow them to rectify any intentional or unintentional GPO-exclusion violations by replacing the GPO-priced drugs used inappropriately with 340B-discounted drugs. Finally, violations of the GPO exclusion, to the extent that they have occurred, mostly have escaped detection because manufacturers generally have declined to exercise their right to audit 340B hospitals.

2.4. *DSH Hospital Enrollment Process*

A hospital that satisfies the three criteria described above is eligible to participate in the 340B program, but its participation is elective, not automatic.¹³⁶ In order to receive 340B prices, an eligible hospital must enroll in the 340B program. DSH hospitals enroll in the 340B program by sending OPA an enrollment letter, along with certain required attachments.

The basic 340B application document for DSH hospitals is the enrollment letter. In its enrollment letter, a hospital must explain how it satisfies the three 340B eligibility criteria. First, the hospital must state which statutory pathway it is using to satisfy the government function requirement. Essentially it must identify whether it is a type (1),

¹³⁵ See OPA, DSH-340B Frequently Asked Questions, Answer ID 418, <http://answers.hrsa.gov> (last visited Oct. 26, 2007), *attached at* Tab 2-19; OPA, DSH-340B Frequently Asked Questions, Answer ID 97, <http://answers.hrsa.gov> (last visited Oct. 26, 2007), *attached at* Tab 2-20; OPA, DSH-340B Frequently Asked Questions, Answer ID 424, <http://answers.hrsa.gov> (last visited Oct. 26, 2007), *attached at* Tab 2-21.

¹³⁶ See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110 (May 13, 1994), *attached at* Tab 1-6.

type (2) or type (3) hospital. Second, the hospital must state its Medicare DSH adjustment percentage. Third, the hospital must certify that it will not obtain covered outpatient drugs through a GPO once it joins the 340B program. In addition, a DSH hospital's enrollment letter must include eight basic pieces of information: (1) the entity's name (as it will be listed on the OPA website); (2) the entity's address; (3) the name and job title of a contact person; (4) the contact person's telephone number; (5) the contact person's fax number; (6) the contact person's email address; (7) the entity's Medicare provider number; and (8) either the entity's Medicaid pharmacy provider number (if the entity plans to purchase Medicaid drugs at 340B pricing); or notice that the entity will "carve out" its Medicaid drug purchases from its 340B participation.¹³⁷ SNHPA strongly recommends that a hospital applying for the 340B program separately enroll each of its pharmacies that will be buying 340B-discounted drugs, including any acute care pharmacy that will be used to purchase drugs for hospital outpatient clinics. The hospital may use one enrollment letter to do so, but the above information should therefore be listed for each hospital pharmacy that will purchase 340B drugs. Template enrollment letters and related forms can be found on the OPA website.¹³⁸ Note that state Medicaid agencies often do not assign separate billing numbers to DSH acute care pharmacies, so the pharmacy should use the hospital's general Medicaid provider number as an alternative.

OPA requires DSH hospitals to attach supporting documentation to the enrollment letter with respect to the first and third eligibility criteria. With respect to the first criteria, the DSH applicant must attach documentation that demonstrates how the hospital satisfies the government function criterion. With respect to the third criterion, the applicant must attach a form that certifies the hospital's intent to comply with the GPO exclusion requirement.¹³⁹ The kind of documentation that must be submitted in support of an application depends on whether the hospital is a type (1), type (2) or type (3) institution. If the hospital is owned or operated by a state, county or city, it must attach documentation that verifies the hospital's governmental status. A type (2) hospital that

¹³⁷ See HRSA 340B Program Enrollment Letter for Disproportionate Share Hospitals (DSH), <http://www.hrsa.gov/opa/dsh.htm> (last visited Oct. 27, 2007), *attached at* Tab 2-22.

¹³⁸ See <http://www.hrsa.gov/opa/dsh.htm> (providing links to enrollment letters and related forms).

¹³⁹ HRSA, 340B Program Certification Regarding Non-Participation in a Group Purchasing Organization, <http://hrsa.gov/opa/dsh.htm> (last visited Oct. 26, 2007), *attached at* Tab 2-10.

satisfies the government function requirement due to a formal grant of government power and responsibility to provide indigent care must submit the law that purportedly grants that power and responsibility so that OPA can evaluate whether the law truly meets the 340B statute's requirements. Finally, type (3) hospitals – hospitals that provide indigent care pursuant to a contract with state or local government – must attach to their enrollment letters a form completed by an “appropriate” state or local official certifying that the contract is valid and that the contract meets statutory eligibility requirements.¹⁴⁰ The certification form used to prove compliance with the GPO exclusion is the same regardless of whether the applicant is a type (1), type (2) or type (3) hospital.

For a time after the MMA was signed into law, OPA required rural and small urban DSH hospitals to submit a letter from the rural hospital's FI certifying that the hospital's Medicare DSH adjustment percentage exceeded 11.75 percent. OPA imposed this requirement as a temporary means of evaluating the Medicare DSH adjustment percentages of rural hospitals while CMS was updating its database to reflect the new law's changes to the rural hospital DSH adjustment calculation.¹⁴¹ This step is no longer required because the CMS database now includes the DSH adjustments for these hospital groups.¹⁴²

Once OPA has made a determination about the 340B eligibility of an applicant, the agency will send an email to the applicant informing him or her of OPA's decision. A covered entity that has applied for admission into the 340B program also may check to see if OPA has posted the entity's name in the online database of participating covered entities as an “entity to be added next quarter.”¹⁴³ OPA admits applicants into the 340B program on the first day of each calendar quarter. Thus, entities are admitted into the 340B program only four times each year. To be enrolled for a particular quarter, an eligible covered entity must apply at least one month prior the beginning of that quarter.

¹⁴⁰ HRSA, Certification by Appropriate State or Local Government Official That a Private Non-Profit Hospital is Under Contract to Provide Health Care Services to Low Income Individuals, <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHGovtCert.pdf> (last visited Oct. 26, 2007), *attached at* Tab 2-2.

¹⁴¹ OPA, DSH-340B Frequently Asked Questions, Answer ID 417, <http://answers.hrsa.gov> (last visited Oct. 26, 2007), *attached at* Tab 2-23.

¹⁴² *Id.*

¹⁴³ The database is located at <http://opanel.hrsa.gov/opa/CE/CEExtract.aspx>. An applicant entity can search the database under “entities to be added next quarter” to find out whether OPA has admitted it to the program.

For example, a covered entity that submits its application on March 1 will be eligible to participate April 1, but a covered entity that submits its application on March 2 normally will not be eligible to participate until July 1.¹⁴⁴

A hospital must continue to meet the 340B eligibility criteria throughout its participation in the program.¹⁴⁵ For example, if a hospital's DSH adjustment percentage falls below 11.75 percent, OPA will notify the hospital that it will disenroll the hospital from the program effective on the first day of the next calendar quarter. For this reason, OPA requires every hospital that participates in the 340B program to keep its current contact information on file with the office.¹⁴⁶

2.5. *Children's Hospitals*

Section 6004 of the DRA amended the Social Security Act by adding children's hospitals (those whose inpatients are predominantly individuals under 18 years of age) to the list of "covered entities" to whom a manufacturer must agree to provide 340B discounts, in order for the manufacturer to participate in the Medicaid program.¹⁴⁷

Pursuant to Section 6004 of the DRA, a children's hospital may only participate in the 340B program if it (1) "is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under [Medicare or Medicaid];" (2) has a disproportionate share adjustment percentage (taking into account the care provided to Medicaid recipients) greater than 11.75 percent; and, (3) "does not obtain covered outpatient drugs through a group purchasing organization or other group

¹⁴⁴ OPA, Introduction to the 340B Program, <http://www.hrsa.gov/opa/introduction.htm> (last visited Oct. 27, 2007).

¹⁴⁵ See 42 U.S.C. § 256b(a)(1), (a)(4)(L), *attached at* Tab 1-1.

¹⁴⁶ See HRSA, 340B Program Enrollment Letter for Disproportionate Share Hospitals (DSH), <ftp://ftp.hrsa.gov/bphc/pdf/opa/DSHEnroll.pdf> (last visited Oct. 26, 2007), *attached at* Tab 2-22.

¹⁴⁷ Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006), *attached at* Tab 17, codified at 42 U.S.C. § 1396r-8(a)(5)(B), *attached at* Tab 1-2.

purchasing arrangement.”¹⁴⁸ This would include up to 80 free-standing children’s hospitals.

Although the children’s hospital provision became effective upon enactment of the DRA in February 2006, the federal government’s position was that no children’s hospital was approved for participation in the 340B program until HRSA issued guidelines in the Federal Register about the measure.

On July 9, 2007 HRSA issued the long-awaited proposed guidelines addressing the participation of children’s hospitals in the 340B program. As anticipated, the proposed guidelines address manufacturers’ obligations to provide 340B discounts, prohibitions against duplicate discounts and drug diversion, the process and criteria for admission of children’s hospitals into the 340B program, and eligibility of children’s hospitals for retroactive discounts.¹⁴⁹ Each of these provisions is outlined below.

2.5.1. *Retroactive Discounts*

Under the proposed guidelines, children’s hospitals are eligible for discounts retroactive to the date of the enactment of Section 6004 on February 8, 2006. Until 120 days after the publication of the final notice, children’s hospitals which have been included in the OPA database of covered entities may request such discounts for covered outpatient drugs provided that (1) the drugs were purchased on or after February 8, 2006, (2) the drugs have not generated Medicaid rebates (and the hospital can provide documentation demonstrating same), and (3) the covered outpatient drugs were purchased on or after the date on which the children’s hospital satisfied all criteria for participation in the 340B program. For a children’s hospital to satisfy this second criterion, it must demonstrate that it “did not have a group purchasing agreement for covered outpatient drugs.”¹⁵⁰ Thus, pursuant to the proposed guidelines, a children’s hospital that engaged in a group purchasing arrangement for covered outpatient drugs during the interim period between the enactment of Section 6004 and the publication of final children’s hospital guidelines would be ineligible for retroactive discounts.

¹⁴⁸ *Id.*

¹⁴⁹ See Notice Regarding the 340B Drug Pricing Program; Children's Hospitals, 72 Fed. Reg. 37,250 (July 9, 2007), *attached at* Tab 1-15.

¹⁵⁰ *Id.* at 37,252.

2.5.2. *Standards for Children’s Hospitals’ Participation*

In order to qualify for participation in the 340B program, a children’s hospital must, as a threshold matter, demonstrate that it has received a 3300 series Medicare provider number identifying the hospital as a “children’s hospital.” The hospital must also certify that it will comply with all the requirements of Section 340B pertaining to the prohibition on resale of covered outpatient drugs and the prohibition on duplicate discounts, and that it will refrain from the use of a GPO or other group purchasing arrangement for covered outpatient drugs “as of the effective date in the 340B covered entity database.”¹⁵¹

In accordance with the terms of the DRA, the proposed guidelines also require that children’s hospitals demonstrate that the hospital is (1) owned or operated by a unit of state or local government; (2) a public or private non-profit corporation which is formally granted governmental powers by a unit of state or local government; or (3) a private non-profit hospital under contract with state or local government to provide health care services to low income patients who are ineligible for Medicare or Medicaid. Additionally, children’s hospitals must meet certain criteria pertaining to the volume of care provided to low-income patients. The proposed guidelines require that, for the most recent cost reporting period, children’s hospitals either (1) demonstrate a DSH adjustment percentage of greater than 11.75 percent in order to qualify for 340B program participation, or (2) demonstrate compliance with a variation of the “Pickle” criteria, which require that the hospital be located in an urban area, have 100 or more beds, and receive 30 percent or more of its inpatient care revenue – exclusive of revenues attributable to Medicare – from state or local government payments or Medicaid.¹⁵²

Under the proposed guidelines, HRSA will seek verification of compliance with the DSH adjustment percentage requirement via the hospital’s cost report. The proposed guidelines also state that HRSA is considering requiring a statement from an independent auditor certifying that a children’s hospital meets the requirements for the provision of indigent care in situations where there is no established method of verification

¹⁵¹ *Id.* at 37,251.

¹⁵² *Id.*

comparable to the annual cost report. HRSA invited comment regarding 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.¹⁵³

2.5.3. *Manufacturers' Obligation to Provide 340B Discounts*

Section 6004 of the DRA of 2005 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 covered entities. As amended by Section 6004, Section 1927(a)(5)(B) defines "covered entities" to include those entities identified in the 340B statute as well as certain children's hospitals.

Pursuant to the proposed guidelines, existing pharmaceutical pricing agreements between HHS and drug manufacturers, which require manufacturers to provide 340B discounts on covered outpatient drugs to covered entities, are deemed to include children's hospitals by virtue of Section 6004's inclusion of children's hospitals in the definition of covered entities. HRSA notes that this is consistent with Congress' clear intent to expand the category of covered entities via its amendment to Section 1927(a).¹⁵⁴

2.5.4. *Next Steps*

Children's hospitals have waited nearly two years for the issuance of final guidelines that would effectuate their participation in the 340B program in accordance with the intent of Section 6004. It is difficult to know when or in what form HRSA will issue final guidelines, although, in comments to the propose guidelines, SNHPA has strongly urged that final interim guidelines be published quickly, in order to allow the immediate participation of children's hospitals in the 340B program.¹⁵⁵ Additionally, SNHPA has urged that HRSA amend its proposed policy regarding retroactive discounts,

¹⁵³ *Id.* at 37,252.

¹⁵⁴ *Id.* at 37,251.

¹⁵⁵ Letter from SNHPA to Bradford Lang, Public Health Analyst, OPA (Sept. 7, 2007), *attached at* Tab 2-24.

so as not to further penalize children's hospitals for the government's delay in issuing the proposed guidelines.