



340B Survival Kit

Chapter 1

Overview of the 340B Drug Discount Program

(Revision June 2008)



1. OVERVIEW OF THE 340B DRUG DISCOUNT PROGRAM

Most consumers, providers and policy makers are unfamiliar with the 340B drug discount program, in part because detailed information regarding the benefits and requirements of the program is relatively hard to find. The laws and guidelines governing the 340B program are complex and, in several areas, still being refined. To fill this void, Safety Net Hospitals for Pharmaceutical Access (“SNHPA”) has developed this report, which we call a “Survival Kit,” to help its members take advantage of the program’s benefits and comply with its requirements. In this introductory section, we provide a brief overview of the history and requirements of the 340B drug discount program. The remaining sections of the Survival Kit focus on key 340B-related issues in more depth.

1.1. Background

The 340B program is governed under two federal statutes, Section 340B of the Public Health Service Act¹ and Section 1927 of the Social Security Act.² Although the Department of Health and Human Services (“HHS”) has not issued regulations implementing these two laws, it has issued numerous interpretive guidelines providing more detailed direction on program operations and compliance standards. These guidance documents address a range of issues including 340B implementation requirements,³ the intersection of the 340B and Medicaid drug rebate programs,⁴ covered entity participation standards,⁵ the eligibility of disproportionate share hospital (“DSH hospital”) outpatient facilities,⁶ calculation of 340B prices for new drugs on the market,⁷

¹ 42 U.S.C. § 256b (2006), *attached at* Tab 1-1.

² 42 U.S.C. § 1396r-8 (2006), *attached at* Tab 1-2.

³ *See* Guidance Regarding Section 602 of the Veterans Health Care Act of 1992 Limitation on Prices of Drugs Purchased by Covered Entities, 58 Fed. Reg. 27,289 (May 7, 1993), *attached at* Tab 1-3.

⁴ *See* Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 27,293, 27,293-94 (May 7, 1993), *attached at* Tab 1-4; Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34,058 (June 23, 1993) (adopting May 7 notice as proposed), *attached at* Tab 1-5.

⁵ *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.

⁶ *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Outpatient Hospital Facilities, 59 Fed. Reg. 47,884 (Sept. 19, 1994), *attached at* Tab 1-7.

⁷ *See* Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 New Drug Pricing, 60 Fed. Reg. 51,488 (Oct. 2, 1995), *attached at* Tab 1-8.

the use of contract pharmacy services,⁸ the definition of patient,⁹ manufacturer audits and dispute resolution procedures,¹⁰ and clarification of Medicaid billing requirements.¹¹ More recently, the government issued a couple of notices proposing significant changes to two of the above guidances, namely, the use of contract pharmacies,¹² and the definition of patient.¹³ The most recent 340B guidance is a proposal describing how children's hospitals would qualify for and enroll in the program.¹⁴

To understand the genesis of the 340B program, one must begin in 1990 when Congress created the Medicaid rebate program to lower the cost of pharmaceuticals reimbursed by state Medicaid agencies. The Medicaid rebate program requires drug companies to enter into a rebate agreement with the Secretary of HHS as a precondition to coverage of their drugs by Medicaid or by Part B of the Medicare program.¹⁵ The agreement specifies that, in order for a brand name outpatient drug to be covered and reimbursed by Medicaid, the manufacturer of the drug must pay a rebate to Medicaid based on the manufacturer's average manufacturer price ("AMP") for that drug in the "retail class of trade." For brand name drugs, the rebate amount increases if the manufacturer's "best price" for that drug in the private market is less than the drug's AMP minus 15.1 percent.

As a result of the Medicaid rebate law, many pharmaceutical companies had a disincentive to continue giving deep discounts on drugs in the private market because such discounts could establish lower "best prices" and AMPs which, in turn, could require manufacturers to pay larger rebates to Medicaid. When manufacturers began raising their prices, the Medicaid savings achieved through the rebate program were

⁸ See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Guidelines Regarding Contract Pharmacy Services, 61 Fed. Reg. 43,549 (Aug. 23, 1996), *attached at* Tab 1-9.

⁹ See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996), *attached at* Tab 1-10.

¹⁰ See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Manufacturer Audit Guidelines and Dispute Resolution Process, 61 Fed. Reg. 65,406 (Dec. 12, 1996), *attached at* Tab 1-11.

¹¹ See Notice Regarding the Section 340B Drug Pricing Program -- Program Guidance Clarification, 65 Fed. Reg. 13,983 (Mar. 15, 2000), *attached at* Tab 1-12.

¹² See Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540 (Jan. 12, 2007), *attached at* Tab 1-13.

¹³ See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of "Patient", 72 Fed. Reg. 1543 (Jan. 12, 2007), *attached at* Tab 1-14.

¹⁴ See Notice Regarding the 340B Drug Pricing Program; Children's Hospitals, 72 Fed. Reg. 37,250 (July 9, 2007), *attached at* Tab 1-15.

¹⁵ 42 U.S.C. § 1396r-8(a)(1) (2006), *attached at* Tab 1-2.

offset by increased public sector spending on drugs at the federal, state and local levels. To address this situation, Congress, in November 1992, passed legislation intended to protect important public sector purchasers from escalating drug prices. More specifically, Congress added several provisions to the Veterans Health Care Act of 1992 that established drug discount programs for (1) the four largest purchasers of prescriptions drugs within the federal government and (2) twelve categories of state, local and/or private non-profit entities receiving government funding to serve low income and other vulnerable patients.¹⁶ The drug discount program designed to help the latter group of purchasers, widely known as the 340B program, was created by Congress under Section 340B of the Public Health Service Act¹⁷ and Section 1927(a)(5) of the Social Security Act.¹⁸

Section 1927(a)(5) requires pharmaceutical manufacturers whose drugs are covered under the Medicaid program to enter into a second agreement with the Secretary called a pharmaceutical pricing agreement (“PPA”), under which the manufacturer agrees to comply with the requirements of Section 340B, and in particular, to provide discounts on covered outpatient drugs purchased by specified government-supported facilities, called “covered entities,” that serve the nation’s most vulnerable patient populations.¹⁹ Language requiring manufacturers of drugs covered under Medicare Part B to enter into PPAs was added to the law by Section 303(i)(4) of the Medicare Prescription Drug Improvement and Modernization Act of 2003 (“MMA”).²⁰ Accordingly, if a manufacturer wants its drugs to be covered and paid for by either Medicaid or the Medicare Part B program, it needs to participate in the 340B program.²¹

¹⁶ See Veterans Health Care Act of 1992, Pub. L. No. 102-585, §§ 601-603, 106 Stat. 4943 (1992).

¹⁷ See 42 U.S.C. § 256b, *attached at* Tab 1-1.

¹⁸ See 42 U.S.C. § 1396r-8(a)(5), *attached at* Tab 1-2.

¹⁹ See OPA, Pharmaceutical Pricing Agreement, <ftp://ftp.hrsa.gov/bphc/pdf/opa/pricingagreement.pdf> (last visited Oct. 26, 2007), *attached at* Tab 1-16.

²⁰ Pub. L. No. 108-173, 117 Stat. 2066 (2003).

²¹ With the effectiveness of the statutory amendments enacted through the MMA, the standard Medicaid drug rebate agreement should properly set conditions for coverage of drugs under Medicare Part B as well as Medicaid. It is unclear, however, whether and to what extent the Centers for Medicare and Medicaid Services have acted to amend manufacturers’ existing rebate agreements to reflect this change in the law. The sample, standard rebate agreement presently available on the government website does not yet reflect any such change.

1.2. *Program Eligibility*

The definition of a 340B-eligible “covered entity” includes certain DSH hospitals that are public or private non-profit institutions serving particularly high percentages of Medicaid or other indigent patient populations.²² The definition of “covered entity” also includes specified federal grantees, including federally qualified health centers (“FQHCs”); FQHC “look-alikes;” state-operated AIDS drug assistance programs; Ryan White CARE Act Title I, Title II, and Title III programs; tuberculosis, black lung, family planning and sexually transmitted disease clinics; hemophilia treatment centers; public housing primary care clinics; homeless clinics; urban Indian clinics; and Native Hawaiian Health Centers.²³ As a result of the Deficit Reduction Act of 2005 (“DRA”), freestanding children’s hospitals serving a high percentage of Medicaid patients and meeting other statutory criteria may also be eligible to purchase drugs at discounted 340B prices.²⁴ Although HRSA has not implemented the relevant DRA provision, it has issued proposed guidelines describing how children’s hospitals would qualify for and enroll in the 340B program once the guidelines are finalized and put into effect.²⁵ According to the government, over 12,000 covered entity sites and more than 700 pharmaceutical companies participate in the program.²⁶

To be eligible for the 340B program, DSH hospitals must meet the following three criteria: (1) the hospital must be governmentally owned or operated or be legally obligated contract with state or local government or pursuant to formally granted governmental powers, to provide a significant level of indigent care; (2) the hospital must have a Medicare disproportionate share adjustment percentage greater than 11.75 for the most recent cost reporting period ending before the calendar quarter involved; and (3) the hospital must certify that it will not obtain covered outpatient drugs through a group purchasing organization (“GPO”) or other group purchasing arrangement.²⁷ A hospital that believes it meets the 340B program’s eligibility criteria may apply to participate by

²² See 42 U.S.C. § 256b(a)(4)(L), *attached at* Tab 1-1.

²³ See 42 U.S.C. § 256b(a)(4), *attached at* Tab 1-1.

²⁴ See Pub. L. No. 109-171, § 6004, 120 Stat. 4, 61 (2006), *attached at* Tab 1-17, amending section 1927(a)(5)(B) of the Social Security Act, 42 U.S.C. § 1396r-8(a)(5)(B), *attached at* Tab 1-2.

²⁵ See Notice Regarding the 340B Drug Pricing Program; Children’s Hospitals, 72 Fed. Reg. 37,250 (July 9, 2007), *attached at* Tab 1-15.

²⁶ See OPA’s online database of 340B participants, www.hrsa.gov/opa.

²⁷ See 42 U.S.C. § 256b(a)(4)(L), *attached at* Tab 1-1.

submitting an application at least one month prior to the start of the next calendar quarter in which the covered entity would like to start purchasing 340B drugs. For example, a covered entity that submits an application by March 1 will be able to participate in the program starting on April 1 if the application is accepted.²⁸ In Chapter 2 we discuss in more detail the application and enrollment process applicable to DSH hospitals, as well as the three eligibility criteria that 340B hospitals must satisfy. Identifying what facilities can be considered part of the hospital for 340B purposes and clarifying the process for enrolling new DSH sites is the subject of Chapter 3.

1.3. *How Does the 340B Program Operate?*

The Office of Pharmacy Affairs (“OPA”) administers the 340B program. OPA is located within the Health Resources and Services Administration (“HRSA”) which, in turn, is part of HHS.²⁹ Prior to 2004, OPA was named the Pharmacy Affairs Branch, and before that, the Office of Drug Pricing.³⁰ HRSA and OPA are responsible for interpreting, implementing and overseeing compliance with Section 340B. HRSA has contracted with the Pharmacy Services Support Center (“PSSC”), a non-profit organization based at the American Pharmacists Association, to assist OPA with its 340B administrative functions, especially in providing guidance and technical assistance to 340B covered entities, manufacturers, wholesalers, retail pharmacies and other interested parties. Because the 340B program is dependent on various definitions and requirements set forth in the Medicaid statute, the policies and interpretations adopted by the Centers for Medicare & Medicaid Services (“CMS”) can also have a significant impact on 340B program operations and compliance. CMS is a sister agency to HRSA within HHS.

Once admitted into the 340B program, covered entities are entitled to receive 340B discounts on *all* covered outpatient drugs, regardless of the patient’s payor status, whether the drug is clinician-administered or intended for patient self-administration, or whether the entity purchases pharmaceuticals through a wholesaler or directly from the manufacturer. A discussion of the kind of drugs that covered entities may purchase at

²⁸ OPA, Introduction to the 340B Program, www.hrsa.gov/opa/introduction.htm.

²⁹ See HRSA Statement of Organization, Functions and Delegations of Authority, 69 Fed. Reg. 56,433 (Sept. 21, 2004), *attached at* Tab 1-18.

³⁰ See *id.*

340B prices is included in Chapter 4. Upon enrollment in the program, a covered entity should contact its wholesaler to set up its 340B account and to request a 340B price list. The entity also may request 340B pricing files directly from manufacturers. If a covered entity suspects it is not receiving the 340B price for a given outpatient drug, it should immediately notify its wholesaler, the manufacturer and/or OPA. In many cases, the absence of a 340B price is a result of human error and is resolved when the mistake is identified and, if necessary, brought to OPA's attention. Chapter 12 contains a more detailed discussion of how to identify and address instances of manufacturer non-compliance.

A facility that meets the definition of "covered entity" but lacks an in-house pharmacy can nonetheless participate in the 340B program. HRSA has developed guidelines to allow such a facility to contract with a local retail pharmacy or other outside pharmacy to act as a dispensing agent.³¹ These guidelines allow a covered entity to use a "ship to – bill to" process whereby the covered entity purchases the pharmaceuticals and has the manufacturer or wholesaler ship them to the contractor, which then provides all pharmacy services related to the dispensing of the 340B drugs.³² The contractor generally must provide the covered entity with financial statements, a detailed status report of collections, and a summary of receiving and dispensing records.³³ The contractor also must work with the covered entity to establish and maintain a tracking system to prevent diversion.³⁴ Under current HRSA guidelines, covered entities that have multiple sites are entitled to have either an in-house pharmacy or a contract pharmacy at each site but may not have more than one contract pharmacy dispensing 340B drugs for any site, absent federal approval as part of an "alternative methods demonstration project."

An alternative methods demonstration project ("AMDP") is a project approved by HRSA that allows one or more covered entities to enter into multiple contract pharmacy arrangements and/or to establish covered entity networks for purchasing and using 340B drugs which, in the absence of AMDP approval, would not be permitted under current

³¹ See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,555-56 (Aug. 23, 1996), *attached at* Tab 1-9.

³² *See id.*

³³ *See id.*

³⁴ *See id.*

HRSA guidelines. Based upon OPA's assessment of AMDP projects involving multiple contract pharmacy arrangements, HRSA recently proposed several changes to its contract pharmacy guidelines to explicitly permit multiple contract pharmacies for a single covered entity facility.³⁵ Thus, although it is uncertain when the new guidelines might be finalized, it appears that HRSA is likely to abandon the current one-contractor-per-site rule and to permit covered entities to contract the services of multiple outpatient pharmacies regardless of whether the pharmacies serve one covered entity site or multiple sites. A comprehensive discussion of 340B contract pharmacies and the AMDP program appear in Chapters 9 and 10, respectively.

Covered entities are free to negotiate discounts that are lower than the statutory 340B ceiling price.³⁶ Toward this end, HRSA has implemented a provision of Section 340B mandating the creation of a prime vendor program³⁷ by entering into an agreement with HealthCare Purchasing Partners International ("HPPI") to help covered entities negotiate discounts below the mandatory 340B ceiling price.³⁸ A covered entity does not have to join the prime vendor program in order to participate in the 340B program and may choose to negotiate sub-ceiling discounts on its own.³⁹ Besides negotiating prices on behalf of prime vendor participants, HPPI offers the participants an opportunity to purchase drugs through a national distribution system, which includes the largest national wholesalers in the United States, as well as many regional distributors.⁴⁰ The prime vendor also has favorable contracts for other value-added services. Chapter 11 provides more information about prime vendor services.

1.4. *Program Restrictions*

Section 340B imposes two important restrictions on covered entities: a prohibition against "diversion" of any drug purchased at a 340B discount to a person who is not a

³⁵ See Notice Regarding 340B Drug Pricing Program-Contract Pharmacy Services, 72 Fed. Reg. 1540 (Jan. 12, 2007), *attached at* Tab 1-13.

³⁶ See 42 U.S.C. § 256b(a)(10), *attached at* Tab 1-1.

³⁷ See 42 U.S.C. § 256b(a)(8), *attached at* Tab 1-1.

³⁸ See Press Release, HRSA, "HRSA Selects Health Purchasing Partners International as Prime Vendor for 340B Drug Pricing Program" (Dec. 8, 2004), <http://newsroom.hrsa.gov/releases/2004/prime-vendor.htm>.

³⁹ See 42 U.S.C. § 256b(a)(10), *attached at* Tab 1-1.

⁴⁰ See PVP, 340B: Agreements, <https://www.340bpvp.com/public/agreements/distributors/default.asp> (last visited Oct. 26, 2007). To learn more about the prime vendor program, see www.340bpvp.com.

“patient” of a covered entity, and a limitation on how much covered entities may bill Medicaid for covered outpatient drugs. The latter restriction implements provisions in both Section 340B(a)(5)(A) of the Public Health Service Act and Section 1927(a)(5) of the Social Security Act, intended to protect manufacturers from having to give both an upfront 340B discount and a Medicaid rebate on the same drug. With respect to DSH hospitals, the 340B statute imposes a third restriction, namely, a prohibition against purchasing 340B drugs through a GPO or any other group purchasing arrangement. Both manufacturers and HHS have the right to audit the records of covered entities to monitor their compliance with the above requirements.⁴¹ The penalty for failing to comply is forfeiture of the 340B discounts back to the manufacturer⁴² or disqualification from the 340B program.⁴³

The 340B statute prohibits a covered entity from reselling or otherwise transferring a drug purchased through the 340B program to anyone other than a patient of the covered entity.⁴⁴ Although the 340B statute does not define a covered entity “patient,” HRSA has issued guidelines designed to assist covered entities with distinguishing between who is and is not a patient eligible to receive 340B-discounted drugs.⁴⁵ In January of 2007, HRSA proposed extensive revisions to its patient definition guidelines and solicited public comment on its proposed changes.⁴⁶ The new guidelines, if finalized in substantially the same form in which they have been proposed, would significantly restrict the use of 340B drugs and diminish the scope of the program. Yet even the current patient definition guidelines are challenging to meet for 340B hospitals, largely because the hospitals have to track which drugs are for inpatient versus outpatient use and, with respect to outpatient drugs, which ones are dispensed or administered to persons meeting the definition of patient and which ones are not. Careful inventory management is therefore essential for any 340B hospital trying to comply with the anti-

⁴¹ See 42 U.S.C. § 256b(a)(5)(C), *attached at* Tab 1-1.

⁴² See 42 U.S.C. § 256b(a)(5)(D), *attached at* Tab 1-1.

⁴³ See 42 U.S.C. § 256b(a)(4) (excluding from the definition of “covered entity” those entities that fail to comply with the prohibition against duplicate discounts or the prohibition against diversion), *attached at* Tab 1-1.

⁴⁴ See 42 U.S.C. § 256b(a)(5)(B), *attached at* Tab 1-1.

⁴⁵ See Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Patient and Entity Eligibility, 61 Fed. Reg. 55,156 (Oct. 24, 1996), *attached at* Tab 1-10.

⁴⁶ See See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Definition of “Patient”, 72 Fed. Reg. 1543 (Jan. 12, 2007), *attached at* Tab 1-14.

diversion restriction. Compliance with 340B anti-diversion and inventory management requirements are described in more detail in Chapters 5 and 8, respectively.

As previously mentioned, the Medicaid billing restrictions applicable to covered entities arise out of Section 340B(a)(5)(A) of the Public Health Service Act and Section 1927(a)(5) of the Social Security Act. These two distinct but similar provisions are intended to protect manufacturers from a duplicate discount problem. The risk of a duplicate discount arises when a state Medicaid agency requests rebates for drugs that manufacturers have already discounted through the 340B program.⁴⁷ The law directs the Secretary of HHS to develop a set of procedures to avoid the duplicate discount problem and, towards this end, HRSA has established a default mechanism that imposes requirements on both covered entities and state Medicaid agencies.⁴⁸ The mechanism requires covered entities that bill Medicaid to submit their pharmacies' Medicaid billing numbers to OPA, which then posts the numbers on the OPA website.⁴⁹ State Medicaid agencies use the billing numbers to identify the pharmacy claims submitted by 340B pharmacies and then excludes those claims from the Medicaid rebate program.⁵⁰ Thus, under this arrangement, manufacturers give only one discount for each covered outpatient drug – an upfront, 340B discount to the covered entity. An alternative to this default mechanism is known as the “Medicaid carve-out.” Covered entities that choose to utilize the Medicaid carve-out option purchase covered outpatient drugs for their Medicaid patients outside the 340B program.⁵¹ As a result, those drugs are not subject to 340B discounts and are subject to Medicaid rebates instead.

Besides protecting manufacturers from giving a 340B discount and Medicaid rebate on the same drug, HRSA's default mechanism protects Medicaid from the losses it otherwise would face as a result of foregoing manufacturer rebates on 340B drugs. Specifically, the mechanism imposes on participating covered entities a requirement that

⁴⁷ See 42 U.S.C. § 256b(a)(5)(A), *attached at* Tab 1-1; 42 U.S.C. § 1396r-8(a)(5)(C), *attached at* Tab 1-2.

⁴⁸ See *id.*

⁴⁹ See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 27,293, 27,293-94 (May 7, 1993), *attached at* Tab 1-4; Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34,058 (June 23, 1993) (adopting May 7 notice as proposed), *attached at* Tab 1-5.

⁵⁰ See *id.*

⁵¹ See Notice Regarding Section 340B Drug Pricing Program – Program Guidance Clarification, 65 Fed. Reg. 13,983 (Mar. 15, 2000), *attached at* Tab 1-12.

they bill Medicaid for covered outpatient drugs at prices that do not exceed the drugs' actual acquisition costs, plus a reasonable, state-determined dispensing fee.⁵² The 340B discount therefore passes through to the state Medicaid program because the covered entities charge Medicaid only their 340B acquisition costs (plus a dispensing fee). There are several exceptions, however, to the general prohibition against billing Medicaid above actual acquisition cost. The prohibition does not apply, for example, if a covered entity dispenses a 340B drug to a Medicaid recipient enrolled in a capitated managed care plan,⁵³ if the entity elects to implement the Medicaid carve-out,⁵⁴ or if the provider and state Medicaid agency agree on a different reimbursement arrangement.⁵⁵ Historically, this has been the case as well for drugs administered in hospital outpatient settings, sometimes referred to as "clinic-administered drugs."

However, the Medicaid billing rules applicable to clinic-administered drugs have been cast into doubt by the federal government's interpretation of a provision in the Deficit Reduction Act of 2005 requiring state Medicaid agencies to collect National Drug Code ("NDC") information from health care providers on "physician administered" drugs billed to Medicaid, for the express purpose of enabling the states to collect manufacturer rebates on these drugs.⁵⁶ SNHPA and its member hospitals are concerned that if, as a result of federal interpretation of the DRA, states begin collecting rebates on clinic-administered drugs purchased by 340B hospitals, the hospitals will be compelled to bill Medicaid at actual acquisition cost for these drugs to avoid the duplicate discount problem. Note that, with respect to drugs dispensed to non-Medicaid patients, there are no billing restrictions. Chapter 7 provides more information on the Medicaid billing restrictions applicable to 340B hospitals and how to comply with them, as well as on the issues surrounding "physician administered" drugs.

⁵² See Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 27,293, 27,293-94 (May 7, 1993), *attached at* Tab 1-4; Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992 Duplicate Discounts and Rebates on Drug Purchases, 58 Fed. Reg. 34,058 (June 23, 1993) (adopting May 7 notice as proposed), *attached at* Tab 1-5.

⁵³ See *id.*

⁵⁴ See *id.*

⁵⁵ See *id.*, see also 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.

⁵⁶ Pub. L. No. 109-171, § 6002, 120 Stat. 4, 59-60 (2006), *attached at* Tab 1-19.

In addition to complying with the 340B anti-diversion and Medicaid billing requirements, DSH hospitals participating in the 340B program are subject to a third restriction, namely, a prohibition against purchasing covered outpatient drugs through a GPO or other group purchasing arrangement.⁵⁷ Importantly, the prohibition against group purchasing does not preclude DSH hospitals from purchasing their inpatient drugs through GPOs.⁵⁸ Chapter 2 offers a more detailed discussion of the GPO exclusion, including an examination of whether the GPO exclusion applies to drugs dispensed or administered to outpatients who are not eligible to receive 340B drugs.

1.5. *Savings*

The statutory 340B ceiling price for a drug is the drug's average manufacturer price reduced by a "rebate percentage" defined as the average total rebate payable to Medicaid for the drug divided by AMP.⁵⁹ AMP is the average price paid to a manufacturer for drugs distributed through the retail pharmacy class of trade.⁶⁰ Because of the relationship between the way 340B ceiling prices are calculated and the Medicaid rebate formula, covered entities are entitled to a discounted price on brand name drugs that should never exceed the lower of the manufacturer's "best price" for the drug or the drug's AMP minus 15.1 percent.⁶¹ Covered entities are entitled to an increased discount if the price of a brand name drug has risen faster than the rate of inflation.⁶² For generic and over-the-counter drugs, the 340B ceiling price is AMP minus 11 percent.⁶³ 340B ceiling prices may be affected by changes to AMP and best price calculations as a result of the DRA and implementing regulations published by CMS.⁶⁴

340B ceiling prices are generally lower than prices that are otherwise available to DSH hospitals. The Congressional Budget Office ("CBO") has estimated that 340B

⁵⁷ See 42 U.S.C. § 256b(a)(4)(L)(iii), *attached at* Tab 1-1.

⁵⁸ See Final Notice Regarding section 602 of the Veterans Health Care Act of 1992 Entity Guidelines, 59 Fed. Reg. 25,110, 25,113 (May 13, 1994), *attached at* Tab 1-6.

⁵⁹ See 42 U.S.C. § 256b(a)(1)-(2), *attached at* Tab 1-1.

⁶⁰ See 42 U.S.C. § 1396r-8(k)(1), *attached at* Tab 1-2. A drug's AMP is, on average, about 20 percent less than the drug's average wholesale price (*i.e.* the average suggested list price). See CONG. BUDGET OFFICE, PRICES FOR BRAND-NAME DRUGS UNDER SELECTED FEDERAL PROGRAMS 4 (2005), *attached at* Tab 1-20.

⁶¹ See 42 U.S.C. § 1396r-8(c)(1), *attached at* Tab 1-2.

⁶² See 42 U.S.C. § 1396r-8(c)(2), *attached at* Tab 1-2.

⁶³ See 42 U.S.C. § 1396r-8(c)(3), *attached at* Tab 1-2.

⁶⁴ See Medicaid Program; Prescription Drugs: Final Rule, 72 Fed. Reg. 39,142, at 39,156, 39,219-39,221, 39,227-39,228, 39,244 (July 17, 2007), *attached at* Tab 1-21.

prices for brand name drugs are, on average, 49 percent lower than average wholesale prices (“AWP”).⁶⁵ According to the same CBO study, 340B prices are, on average, 36 percent lower than AMP, and 19 percent lower than “best price” for brand name drugs.⁶⁶ One reason for the significant savings is that covered entities are free to negotiate discounts that are lower than the statutory 340B ceiling price, either on their own or through the 340B prime vendor program. SNHPA surveys its membership annually in order to quantify savings attributable to sub-ceiling discounts. DSH hospitals participating in the 340B program estimate that, on average, their 340B prices are 27 percent lower than the prices that they otherwise would have paid by buying through their GPOs or off of other contracts.⁶⁷ A more detailed discussion of how 340B hospitals can lower their inpatient and outpatient drug costs is included in Chapter 11.

Section 340B does not address how covered entities should use their 340B savings.⁶⁸ According to a 2004 report prepared for HRSA, on average, DSH hospitals spend 43.3 percent of their savings to offset losses from providing pharmacy services at less than cost, 24.4 percent to increase the number of patients they serve, 10.4 percent to reduce medication prices for patients, 9.5 percent to increase the services available to patients, and 8.0 percent to increase the quantity or variety of drugs available to patients.⁶⁹ Although not required, SNHPA recommends that all 340B hospitals adopt a charity care policy whereby their outpatient pharmacies agree to dispense 340B drugs to the hospitals’ lowest income uninsured patients for free or at nominal cost.⁷⁰

1.6. *Information Resources*

The OPA website, located at www.hrsa.gov/opa, contains a lot of helpful 340B-related information, including the names of participating covered entities and

⁶⁵ See Cong. Budget Office, *supra* note 60, at 12, *attached at* Tab 1-20.

⁶⁶ See *id.* at 4.

⁶⁷ See ROBERT SCHMITZ ET AL., MATHEMATICA POLICY RESEARCH, INC., THE PHS 340B DRUG PRICING PROGRAM: RESULTS OF A SURVEY OF ELIGIBLE ENTITIES 36, 44 (2004), www.mathematica-mpr.com/publications/PDFs/340Bsurveyrpt.pdf.

⁶⁸ See 42 U.S.C. § 256b, *attached at* Tab 1-1; see also Final Notice Regarding Section 602 of the Veterans Health Care Act of 1992, Contract Pharmacy Services, 61 Fed. Reg. 43,549, 43,551 (Aug. 23, 1996), *attached at* Tab 1-9.

⁶⁹ See SCHMITZ, *supra* note 67, at 48.

⁷⁰ A copy of SNHPA’s proposed charity care policy can be found in the “members only” section of the SNHPA website.

manufacturers, relevant Federal Register notices, frequently-asked-questions, and other information useful to 340B participants. You may contact OPA at 301-594-4353 or through PSSC at 1-800-628-6297 or 202-429-7518. PSSC's website is located at <http://pssc.aphanet.org>, and PSSC staff can be reached by e-mail at pssc@aphanet.org. Other helpful information is available at SNHPA's website (www.safetynetrx.org), as well as at the 340B prime vendor website (www.340Bpvp.com). SNHPA publishes a monthly newsletter on the 340B program called the *Federal Drug Discount and Compliance Monitor*, which can be found online at www.drugdiscountmonitor.com.

For questions about Safety Net Hospitals for Pharmaceutical Access, please contact Laurinda Dennis (laurinda.dennis@safetynetrx.org; 202-872-6747). For legal questions, please feel free to arrange a call with SNHPA's President and General Counsel, Bill von Oehsen, at 202-872-6770.