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Setting the Record Straight on 340B

A Response to Critics



Safety Net Hospitals for Pharmaceutical Access

EXECUTIVE SUMMARY

Twenty years ago, Congress and President George H.W. Bush enacted a bipartisan law creating the 340B Drug Discount Program. The program enables hospitals, community health centers, and other health care providers serving large volumes of indigent and vulnerable patients to make pharmaceuticals and other critical services available to all without regard to ability to pay. On several occasions since that time, Congress, under the control and support of both parties, has expanded the program to other hospitals that are part of the nation's safety net.

Today, the 340B program continues to meet Congress's intent "of enabling these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services." Government and other studies have confirmed many times that 340B providers are using their program savings to benefit their vulnerable patients, consistent with congressional intent. Examples include:

- Providing medications free of charge or at lower cost to patients;
- Establishing programs to help patients use medications properly;
- Expanding access to expensive chemotherapy drugs, and maintaining patient access to medications by providing longer pharmacy hours and other services benefiting vulnerable patients;
- Caring for more patients; and
- Offsetting losses from providing uncompensated care.

The 340B program also reduces government expenditures and reduces the burden on taxpayers who would otherwise be responsible for financing the indigent care that 340B hospitals provide.

Program critics, including some of the world's most profitable drug companies, suggest that 340B may not be operating as Congress originally intended. They have a right to speak out about what they perceive to be misuse. However, a recent spate of misstatements, misunderstandings, and distortions compels us to set the record straight.

Setting the Record Straight on 340B: A Response to Critics, which includes documented independent research, describes the congressional intent of the program and provides evidence of how providers are using their savings. It also clearly shows the program is saving money for federal, state, and local governments and taxpayers. The report also refutes many of the misleading and inaccurate statements made by critics of the program.

The report calls for a number of reforms to modernize the program, including more pricing transparency to ensure that health care providers are not being overcharged, audits of drug manufacturers, as well as a look at the use of contract pharmacies to determine whether the program is helping vulnerable patients better access prescription medications and pharmacy care.

Safety Net Hospitals for Pharmaceutical Access (SNHPA) is both interested and ready to work with both champions and critics of the 340B program. Such collaboration is difficult when both the purpose of the program and how it is being used by hospitals are being distorted. Hopefully, by setting the record straight, this document helps clear the way for meaningful discussion among stakeholders on how to make the 340B program more effective.

INTRODUCTION

Congress enacted the 340B drug discount program in November 1992 with broad bipartisan support.¹ The program, named for the section of the federal statute that established it, requires pharmaceutical manufacturers participating in the Medicaid or Medicare Part B programs to enter into a pharmaceutical pricing agreement (PPA) with the Secretary of the U.S. Department of Health and Human Services (HHS).² The terms of the PPA require manufacturers to provide discounts on covered outpatient drugs purchased by specified safety net providers, known as “covered entities,” that serve the nation’s most vulnerable patient populations.³ Covered entities include not only hospitals serving many low-income or otherwise vulnerable patients (certain disproportionate share hospitals (DSHs), rural hospitals, children’s hospitals and cancer hospitals) but several other types of safety net providers including community health centers, state and local health departments, HIV clinics and hemophilia treatment centers.⁴ Together, these providers serve tens of millions of uninsured and underinsured people every year.

The 340B program is vitally important for safety net providers and their vulnerable patients. It lowers drug costs for providers, allowing them to lower drug costs for their vulnerable patients and maintain and expand other health care services available to them. It also reduces the burden on taxpayers who would otherwise be responsible for financing the indigent care that 340B hospitals provide as a result of their 340B participation. Congress intended for covered entities to use the benefit of the discount to reach more eligible patients and provide more comprehensive services.⁵

Recently, critics of the 340B program, including some in the pharmaceutical industry, have suggested that the program may not be operating as Congress originally intended. The drug industry is a 340B stakeholder that, like covered entities, has both a right and an obligation to provide input and commentary on how the program is operated. As the national association representing 340B hospitals, SNHPA appreciates many of the statements and recommendations advanced by the program’s critics. However, a recent spate of misstatements, misunderstandings, and distortions compels us to issue this white paper to set the record straight.

Setting the Record Straight on 340B: A Response to Critics responds to these critics. Chapter 1 of this white paper briefly outlines the congressional intent behind 340B and provides evidence of the ways in which 340B covered entities use their program savings to benefit the vulnerable patients they serve, consistent with congressional intent. The first chapter also outlines the ways in which 340B reduces government expenditures and saves taxpayers money. Chapter 2 responds to program critics’ contentions and cites legal authority, legislative history, published reports, and other sources to address what we believe to be unfair characterizations of the program’s intentions, purposes, and goals as well as unfounded contentions about the program’s operation, implications, and future. Throughout the report, we note where we agree with program critics and we offer our own modernization recommendations.

¹ Veterans Health Care Act of 1992, Pub. L. No. 102-585, § 602, 106 Stat. 4943, codified as Section 340B of the Public Health Service Act at 42 U.S.C. § 256b.

² Social Security Act § 1927(a)(5), codified at 42 U.S.C. § 1396r-8 (2006).

³ HRSA, Pharmaceutical Pricing Agreement, *available at* <http://www.hrsa.gov/opa/manufacturers/pharmaceuticalpricingagreement.pdf>.

⁴ 42 U.S.C. § 256b(a)(4).

⁵ H.R. REP. 102-384, pt. 2, at 12 (1992).

CHAPTER I

Congressional Intent

Based on the original 340B law and congressional committee report language, as well as congressional action over the last 20 years in expanding the number of eligible entities participating in the program, it is clear that Congress intended for the 340B discount to reduce the cost of operations for covered entities in recognition of their mission to serve low-income and vulnerable patients.⁶ The program does not make a particular patient category eligible for the program; rather, the program makes safety-net providers eligible for the program because of their dedicated health care services to low-income and vulnerable patient populations. The law requires that the discounted drugs only be provided to patients of the covered entity.⁷ The law does not require that discounted drugs only be provided to uninsured patients or that program savings only be used to lower the cost of drugs for uninsured patients, as some critics have suggested.⁸

In fact, the law establishes qualification for the program for Disproportionate Share Hospitals (DSH), free-standing children's and cancer hospitals, rural referral centers (RRCs), and sole community hospitals (SCHs) based, in part, on their level of service to patients who are insured through Medicaid or Medicare/SSI.⁹ In addition, Congress expanded 340B in 2010 to include critical access hospitals (CAHs), which are not required to meet an indigent patient threshold to qualify for the program.¹⁰ CAHs qualify based on the geographically vulnerable patient populations they serve. While all covered entities disproportionately serve the uninsured, the underinsured and other low-income and vulnerable patients, the purpose of providing them the discount has always been to enable them to stretch their scarce resources without dictating the exact manner in which they can best serve their patients.

Covered Entities Use 340B Savings to Benefit Their Vulnerable Patients

Since the program's enactment, the government has observed on numerous occasions that 340B is working properly and covered entities are using their program savings to benefit their vulnerable patients, consistent with congressional intent. Most recently, in September 2011, the Government Accountability Office (GAO) published a study on the 340B program in which all entities surveyed reported using their 340B savings to maintain health care services and lower drug costs for patients, which is "consistent with the purpose of the program."¹¹ The entities reported using program savings to:

⁶ See *id.* at 10, 18. (noting that the legislation enacting 340B was in response to drug price increases for certain safety net providers that "reduced the level of services and the number of individuals that these hospitals and clinics are able to provide with the same level of resources," and also noting that the enactment of the committee's bill would "reduce the cost of operation of these providers").

⁷ See 42 U.S.C. § 256b(a)(5)(B) (prohibiting covered entities from reselling or transferring drugs purchased under the program to "a person who is not a patient of the entity").

⁸ 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), at <http://hrsa.gov/opa/programrequirements/federalregisternotices/patientandentityeligibility102496.pdf>. Nothing in the guidance defining patients eligible to receive 340B drugs limits the definition to a particular category of patient.

⁹ 42 U.S.C. § 256b(a)(4)(L, M, O).

¹⁰ Patient Protection and Affordable Care Act (PPACA), Pub. L. No. 111-148, § 7101(a), codified in 42 U.S.C. § 256b(a)(4)(N).

¹¹ GAO, *Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 17 (Sept. 2011), at <http://www.gao.gov/assets/330/323702.pdf>.

- Provide medications free of charge to indigent patients;
- Establish programs to help patients use medications more properly; and
- Expand access to expensive chemotherapy drugs, and maintain patient access to medications by providing longer pharmacy hours and other services benefiting vulnerable patients.¹²

The Health Resources and Services Administration (HRSA), the agency that administers the 340B program, has also weighed in on the value and benefits of 340B. In a 2004 report commissioned by the agency, Mathematica Policy Research found that covered entities used their 340B savings to:

- Improve the quality and variety of drugs available;
- Care for more patients;
- Provide more services;
- Lower the cost of drugs to patients;
- Reduce drug prices to third parties; and
- Offset losses from providing uncompensated care.¹³

Non-government stakeholders have observed 340B's benefit to vulnerable patients as well. A 2011 survey of member hospitals commissioned by SNHPA found:

- 340B hospitals used their program savings to benefit their vulnerable patients in ways that were consistent with congressional intent.¹⁴
- Hospitals reported using 340B savings to increase patient access to care, reduce the cost of drugs, provide increased pharmacy services or maintain broader hospital operations.¹⁵
- Seventy-four percent of respondents with an outpatient pharmacy reported using 340B savings to reduce the price of drugs paid by patients; 75 percent of respondents reported using 340B savings to increase patient access to prescription drugs.¹⁶
- Of these respondents, nearly all reported using savings to enhance services specifically for the uninsured or underinsured.¹⁷
- Those respondents not reporting these answers reported using their savings in other critical ways to improve care to their vulnerable patients, such as increasing the total number of patients served by the pharmacy, helping maintain an adequate supply of drugs, enabling the entity to provide an outpatient pharmacy and keep it properly staffed, avoiding restrictive formularies and increasing the choices of drugs, reducing patient wait times and extending pharmacy hours.¹⁸

¹² *Id.*

¹³ Schmitz, *et al.*, *The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities*, at 48 (Aug. 30, 2004), at <ftp://ftp.hrsa.gov/opa/340Bsurveyrpt.pdf>.

¹⁴ Madeline C. Wallack and Suzanne B. Herzog, *Demonstrating the Value of the 340B Program to Safety Net Hospitals and the Vulnerable Patients They Serve* (June 29, 2011) (Value of the 340B Program), at http://www.snhpa.org/public/documents/pdfs/340B_Value_Report_06-29-11.pdf.

¹⁵ *Id.* at 8.

¹⁶ *Id.* at 12, 16.

¹⁷ *Id.* at 16.

¹⁸ *Id.* at 8, 17.

Hospitals participating in 340B reported using their savings to increase access to medications for the uninsured in its community. For instance, hospitals in one state have created a prescription drug benefit program for low-income patients who do not qualify for Medicaid. Another hospital has launched an innovative program to keep infants who were born prematurely from developing a life-threatening lung disease.

Another 340B hospital tailors its 340B program to the specific needs of its community and has used program savings to open up clinics to meet the needs of vulnerable patients in the community suffering from particular conditions, including a diabetes clinic operated by a charity care voucher program and a clinic to offer vaccines for newborns.

A 2011 survey by the National Association of Community Health Centers (NACHC) found that community health centers participating in 340B also use their program savings to benefit their vulnerable patients.¹⁹ Nearly all surveyed health centers reported using their 340B savings to enhance the center's ability to serve the uninsured or underinsured.²⁰ Many respondents also reported using their savings to:

- Help maintain a sufficient supply of drugs to meet patient needs;
- Serve more patients in the pharmacy; and
- Increase drug choices available to patients.²¹

A 2009 analysis of the effectiveness of the 340B program for family planning clinics noted that 340B entities, including family planning clinics, use their program savings to “serve more patients, offset losses, reduce prescription drug prices to patients, and increase the scope of services offered.”²²

A 2007 survey of rural hospitals participating in 340B found that 340B “savings are important—especially for safety net organizations such as rural hospitals—in supporting their ability to provide health care services to low-income and other vulnerable populations.”²³ The study also found that program participants may “pass some or all of the savings on to their patients or savings may be passed back to the state and federal agencies, which are struggling to pay for increasing Medicare and Medicaid costs.”²⁴

340B Reduces Government Spending and Saves Taxpayers Money

In addition to using program savings to benefit vulnerable patients, it is also clear that covered entities' use of 340B reduces government expenditures and saves state and federal taxpayers dollars. The program reduces Medicaid spending because most states (a) require 340B covered

¹⁹ NACHC Study: *Benefits of the 340B Drug Pricing Program for Health Centers* (May 2011), at <http://www.nachc.com/client/documents/5.11%20NACHC%20study%20on%20340B%20benefits.pdf>.

²⁰ *Id.* at 4.

²¹ *Id.*

²² The Lewin Group and The Guttmacher Institute, *Analysis of the Effectiveness of Title X Family Planning Providers' Use of the 340B Drug Pricing Program*, at 1 (October 2009), at <http://www.hhs.gov/opa/pdfs/304b-analysis-of-effectiveness.pdf>.

²³ The NORC Walsh Center for Rural Health Analysis and The North Carolina Rural Health Research & Policy Analysis Center, *340B Drug Pricing Program: Results of a Survey of Participating Hospitals*, at 15 (May 2007), at http://www.norc.org/PDFs/Walsh%20Center/Links%20Out/340BReport_May2007.pdf.

²⁴ *Id.*

entities to bill Medicaid for retail prescription drugs at their 340B acquisition cost or (b) enter into mutually beneficial shared-savings arrangements with providers. Entities that use 340B drugs for Medicaid patients, therefore, pass on 340B savings to the state, which in turn reduces the federal government's Medicaid financial obligations to states. Similarly, 340B results in a direct reduction in Medicare spending for CAHs, because Medicare reimburses these hospitals for drugs based on their cost. The lower a hospital's drug expenditures, the lower Medicare's reimbursement would be. The same would be true for states in which the Medicaid program reimburses hospitals based on cost.

For hospitals that are directly supported by taxpayers, many of which participate in 340B, program savings benefit the taxpayers in those jurisdictions because they allow the hospitals to stretch their scarce resources to provide more services with the same or reduced level of public funding.

340B also saves taxpayers money by lowering patients' drug costs and improving health care services, thereby keeping patients healthy. For example, many 340B hospitals use their program savings to implement medication therapy management (MTM) programs.²⁵ These programs curb adverse drug reactions and drug interactions, prevent ineffective therapies and treatment failures, and improve educational services to patients through counseling and pharmacist review of medications.²⁶ Hospitals also use their savings to help patients with accessing prescription drug assistance programs, through which manufacturers provide free or low-cost drugs to uninsured patients. By ensuring that patients have access to medication, hospitals can prevent readmissions and future costs to the health care system. Patients' consistent and appropriate use of prescription medications helps to avoid other, more costly, medical interventions, the cost of which would be borne in large part by federal and state government funds if it were not for the 340B program.

* * *

Although the evidence demonstrating the value of the 340B discount to vulnerable patients and taxpayers across the country is clear, program critics continue to suggest that 340B is not working as Congress originally intended. Chapter II of this white paper will respond in detail to specific allegations made about the 340B program.

²⁵ Value of the 340B Program at 18-19.

²⁶ *Id.*

CHAPTER II

In the previous chapter, we described the purpose behind the 340B program and the evidence demonstrating how the safety net providers participating in the program are using program savings to benefit their vulnerable patients, consistent with congressional intent. We also explained how it reduces the burden on taxpayers who would otherwise be responsible for financing the indigent care that 340B hospitals provide as a result of their 340B participation. The purpose of this chapter is to respond to concerns raised about the program.

The rules governing the program are complex, subject to disagreement, and in need of improvement. The pharmaceutical industry, like the hospital community, is a 340B stakeholder that has both a right and obligation to provide input and commentary on how the program is operated. SNHPA appreciates many of the statements and recommendations advanced by the program's critics, but a recent spate of misstatements, misunderstandings, and distortions compels us to set the record straight. In this chapter, we outline the various contentions raised by our critics and cite legal authority, legislative history, published reports, and other sources to address what we believe to be unfair characterizations of the program's purpose, use, and impact. We also point out areas in which we agree with the critics. Recommendations on how to improve or modernize the program are provided throughout.

* * *

*CRITICS CONTEND: The purpose of the 340B program is to increase access to affordable medications for uninsured indigent patients.*²⁷

FACT: Congress' intent was to benefit safety net providers that serve large numbers of low-income patients. In determining 340B eligibility requirements, Congress did not intend to limit program benefits to only uninsured indigent patients. Rather, Congress intended for safety net hospitals and other 340B providers to use the discounts to support and expand their services to other needy populations and, by so doing, stretch their limited resources so they are less dependent on taxpayers dollars.

- The House report accompanying the 340B statute states that the 340B program is designed “to enable these entities to stretch scarce federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”²⁸ While all 340B providers disproportionately serve the uninsured, the underinsured, and other low-income and vulnerable patients, the purpose of providing these entities with access to the discount has always been to enable them to stretch scarce resources without dictating the exact manner in which they can best serve their patients.

²⁷ See PhRMA et al., *The 340B Discount Program: A Review and Analysis of the 340B Program 2* (Winter 2013) (PhRMA-BIO Report); see also Andrew Pollack, *Dispute Develops Over Discount Drug Program*, N.Y. TIMES (Feb. 12, 2013), at <http://www.nytimes.com/2013/02/13/business/dispute-develops-over-340b-discount-drug-program.html> (NYT Article); Adam Fein, *Hospitals Twist Prescription Assistance Program for Their Own Benefit*, THE HILL (Apr. 29, 2013), at <http://thehill.com/blogs/congress-blog/healthcare/296741-hospitals-twist-prescription-assistance-program-for-their-own-benefit> (Fein Blog); John McManus, *The 340B Discount Program Is In Dire Need Of Reform*, LIFE SCI. LEADER (May 3, 2013), at <http://www.lifescienceleader.com/magazine/current-issue-3/item/4495-the-340b-discount-program-is-in-dire-need-of-reform> (McManus Article).

²⁸ H.R. REP. 102-384, pt. 2, at 12 (1992).

- Indeed, one of the strengths of the 340B program is the discretion it affords safety net providers in tailoring use of program savings to address the unique needs of their communities. Because covered entities are on the front lines of caring for needy patients, they are in the best position to decide how to maximize the value of the program for their patients.
- Critics have stated that the 340B program was originally intended to “extend the Medicaid drug discount” to indigent patients, citing a committee report accompanying a bill introduced by Sen. Ted Kennedy in 1991.²⁹ The quote is taken out of context from a paragraph describing the critical role of safety net providers.³⁰ The bill, which proposed a program very much like the 340B program, stated that its purpose was: “to ensure that certain *entities funded under the Public Health Service Act* receive a discount on prices for prescription drugs comparable to the Medicaid rebate amount...”³¹ Sen. Kennedy’s statement upon introducing the bill makes clear that the program is intended to extend the discount to covered entities.³²
- The program does not make a particular *patient* eligible for the program; rather, the program makes safety net *providers* eligible for the program because of their dedicated health care services to low-income and vulnerable patient populations. The law *does* require that the discounted drugs only be provided to patients of the covered entity, but it *does not* require that discounted drugs only be provided to uninsured patients.

CRITICS CONTEND: *The benefits of the program are not reaching patients.*

FACT: **Several published reports, including two government studies, demonstrate that covered entities are using 340B savings to benefit their patients.**

- The GAO was charged by Congress in the Affordable Care Act (ACA) to undertake a comprehensive study of the 340B program, including whether the program is being used consistent with congressional intent.³³ The GAO found that the ways in which covered entities reported using their program savings were consistent with the program’s original purpose, though it also recommended improved program oversight. The GAO found that “all covered entities reported using the program in ways consistent with its purpose,” and that “all covered entities reported that program participation allowed them to maintain services and lower medication costs for patients.”³⁴

²⁹ See: Letter from Sen. Grassley, *et al.*, to SNHPA (Mar. 5, 2012),
 Letter from Rep. Pitts and Rep. Cassidy to HRSA (July 18, 2012),
 Letter from Sen. Grassley to University of Alabama Hospital (May 10, 2012),
 Letter from Sen. Grassley to Carolinas Medical Center (Sept. 28, 2012),
 Letter from Sen. Grassley to HRSA (Mar. 27, 2013), and
 Letter from Sen. Grassley to Columbus Regional Healthcare System (Apr. 18, 2013),

(all citing “Public Health Prudent Pharmaceutical Purchasing Act, Committee Report to Accompany S. 1729, 102-259, Senate Committee on Labor and Human Resources (Mar. 3, 1992)”).

³⁰ See 102 S. REP. 259 (Mar. 3, 1992) at 7.

³¹ *Id.* at 1.

³² See 102 CONG. REC. 13334 (Sept. 19, 1991).

³³ ACA, Pub. L. No. 111-148, § 7103, 124 Stat. 119, 827-28 (2010).

³⁴ GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, GAO-11-836 (Sept., 2011), at <http://www.gao.gov/assets/330/323702.pdf>.

- A 2004 report commissioned by HRSA categorized how entities used their savings:
 - Entities that focused on a specific aspect of health or disease—family planning, STD, TB, HIV clinics and Ryan White grantees—all devoted the largest share of savings to increasing the number of patients receiving care. Community health centers and migrant health centers were most likely to devote a significant portion of the savings to reducing the price of medication for their patients. Entities with the highest median spending on prescription drugs—disproportionate share hospitals and hemophilia treatment centers—devoted the greatest share of their savings to offsetting losses from providing pharmacy services at less than cost. Tribal contract and urban Indian health centers also devoted the greatest share of their savings to the same purpose.³⁵
- A June 2011 study by SNHPA found that hospitals use program savings to improve both patient care and access as Congress intended. 340B hospitals pass their program savings onto their indigent patients by eliminating or reducing barriers to care.³⁶ They also use 340B savings to reduce the price of drugs to low-income patients (including providing drugs at no cost to some indigent patients), increase patient access to pharmacy services, increase the choice of drugs available to patients, and enhance pharmacy and other health care services.³⁷
- The June 2011 report also found that hospital patients would be adversely impacted if 340B savings were eliminated. Seventy-seven percent of the hospitals reported that the uninsured and underinsured that they serve would see higher drug costs if the hospital did not have access to 340B discounts.³⁸
- In a May 2011 report, NACHC found that “health centers save between 15%-60% on their prescription drug costs by using the 340B program” with centers using their savings in many ways, “such as providing medications at a reduced cost or at no cost to some patients, expanding their formulary, reaching additional low-income patients, or offering new services.”³⁹
- The 340B program benefits not just patients, but taxpayers. Analyses by the Congressional Budget Office (CBO) have consistently projected that expansion of the program will generate savings for the federal government.⁴⁰

CRITICS CONTEND: 340B hospitals are not accountable for how they use program savings.

³⁵ Robert Schmitz, et al., *The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities* (Aug. 30, 2004), at http://www.mathematica-mpr.com/publications/redirect_PubsDB.asp?strSite=PDFs/340BSurveyrpt.pdf.

³⁶ See Value of the 340B Program.

³⁷ *Id.*

³⁸ *Id.*

³⁹ NACHC Study: *Benefits of the 340B Drug Pricing Program for Health Centers* (May 2011), at <http://www.nachc.com/client/documents/5.11%20NACHC%20study%20on%20340B%20benefits.pdf>.

⁴⁰ See, e.g., CBO, *Cost Estimate for S. 1932 – Deficit Reduction Act of 2005* (Jan. 27, 2006); CBO, *Preliminary Estimates of Title VI Sec. 611 of the Affordable Choices Act* (July 13, 2009).

FACT: Hospitals are subject to various levels of accountability under federal, state and local laws because, to qualify for the program, they must be either governmentally owned or non-profit. Nonetheless, SNHPA supports increased transparency of how hospitals are using 340B savings.

- Public hospitals operate under state and local laws requiring them to treat patients regardless of their ability to pay. They are directly accountable to government regulators and legislators.
- To qualify for 340B, non-profit hospitals must have a contract with state or local government requiring them to provide indigent care.⁴¹ They are also required under federal tax laws to assess the health needs of their communities and to report on how they are helping to meet those needs.⁴² They too are legally accountable to serve needy populations.
- Many of the private, non-profit hospitals participating in 340B are religious institutions that were established to serve the poor. Their strong safety net missions provide further evidence of accountability.
- SNHPA recognizes the importance of 340B hospitals being transparent in how they use 340B drug discounts to benefit the patients they serve. 340B hospitals do not, however, have extensive resources to comply with onerous reporting requirements and are concerned about any requirements that might inadvertently misrepresent their true safety net role in the community. SNHPA would like to work with the Administration in developing the means by which to assure transparency without imposing bureaucratic and overly burdensome process requirements.
 - SNHPA members are expected to comply with its *Principles of 340B Program Stewardship*, one of which directs its members to maintain a meaningful charity care policy under which qualifying indigent patients receive medically necessary health care services, medications and pharmacy support services for free or at nominal cost.⁴³

*CRITICS CONTEND: The current 340B hospital eligibility criteria are flawed because they are not aligned with hospitals' true uncompensated care levels.*⁴⁴

FACT: If Congress had intended to align eligibility with hospitals' uncompensated care levels, it would have done so under the original 340B statute or, more recently, under the ACA. The reality is that Congress chose to define eligibility based on a broader set of safety net criteria.

⁴¹ 42 U.S.C. § 256b(a)(4)(L)(i).

⁴² See 26 U.S.C. § 501(r); Barbara Straub Williams, *et al.*, *IRS Proposes Regulations to Implement Tax-Exempt Community Health Needs Assessment Requirement and Enforcement Provisions* (Apr. 5, 2013), at <http://www.ppsv.com/assets/attachments/181.PDF>.

⁴³ See SNHPA, *Principles of 340B Program Stewardship*, Principle Two, at http://www.snhpa.org/public/documents/pdfs/Principles_of_340B_Program_Stewardship.pdf.

⁴⁴ See PhRMA-BIO Report at 9; Ron Schleif, *et al.*, *340B Benefits Some, Not Others*, ONCOLOGY BUS. R. (Sept. 2011) (Oncology Business Review Article).

- Congress did not design the program so that the number of uninsured indigent patients served by a hospital is the only determinant of whether the hospital is eligible for 340B. To be eligible for the program under the 340B law, several categories of hospitals must demonstrate a sufficient DSH adjustment percentage, which is based on a hospital's share of Medicaid and low-income, disabled Medicare patients.⁴⁵ For example, under the ACA, Congress expanded the 340B program to include hundreds of critical access hospitals, a hospital category that is not subject to a DSH threshold.
- Congress's decision not to change the 340B eligibility for DSH hospitals under the ACA signaled its recognition that a hospital's safety net status is not based solely on the amount of uncompensated care it provides. Serving Medicaid and low-income, disabled Medicare patients, as measured by eligibility for Medicare DSH funds, is also an indicator of safety net status.
- A 340B provider's safety net status is based on factors other than just its uncompensated care levels. It encompasses factors such as the unique services provided in the community, geographic remoteness, ability to serve hard-to-reach populations, teaching programs, etc. The safety net is comprised of a variety of providers that struggle to serve a spectrum of vulnerable patients beyond the uninsured.

*CRITICS CONTEND: There are too many hospitals participating in the program. Some were never intended to be eligible because they are not true safety net hospitals.*⁴⁶

FACT: Growth in the number of hospitals qualifying for the 340B program is the result of deliberate, policy-oriented actions taken by Congress. The only hospitals that participate are those that satisfy the eligibility criteria established by Congress. HRSA makes a careful determination of eligibility for each hospital that applies for the program, and there is no evidence that ineligible hospitals are being admitted.

- Congress has clearly supported the expansion of hospital participation in the 340B program as evidenced by the following legislative actions:

Medicare Modernization Act of 2003 (MMA): Sections 402 and 1002 of the MMA respectively increased the cap on DSH adjustment percentages for small urban hospitals (<100 beds) and rural hospitals (<500 beds) and amended the best price exclusion to allow manufacturers to exclude from best price voluntary inpatient sales to DSH hospitals.⁴⁷ Since passage of the MMA, DSH hospital participation in 340B has grown from about 200 to about 1,000. More hospitals now have a qualifying DSH adjustment percentage, and hospitals previously eligible had an additional incentive to register because of voluntary inpatient discounts.

Deficit Reduction Act of 2005 (DRA): Section 6004 of the DRA added to the program free-standing children's hospitals with a payer mix that would give them a DSH

⁴⁵ 42 U.S.C. § 256b(a)(4)(L, M, O).

⁴⁶ See PhRMA-BIO Report at 2, 7, 9-10.

⁴⁷ MMA, Pub. L. No. 108-173, §§ 402, 1002, 117 Stat. 2066, 2264-65, 2431-32 (2003).

adjustment percent above 11.75%.⁴⁸ HRSA implemented the change in 2009.⁴⁹ Since then, about 40 children's hospitals have enrolled.

Affordable Care Act of 2010: Section 7101 of the ACA added critical access hospitals, free-standing cancer hospitals with a payer mix that would give them a DSH adjustment percentage above 11.75%, and rural referral centers and sole community hospitals with DSH adjustment percentages at or above 8%.⁵⁰ Since passage of the ACA, about 1,000 new hospitals have enrolled. HRSA estimates that the newly eligible hospitals account for only 10% of total 340B purchasing volume. Therefore, even though the number of new hospitals is relatively large, the amount of 340B drugs the hospitals are purchasing is not. Further, although the addition of safety net rural and cancer hospitals may have accounted for program growth immediately following passage of the ACA, it should play a relatively small role in program growth this year and beyond.

- Concerns about inappropriate growth in the 340B program should not be based on the addition of new hospitals under the ACA. Congress intentionally added these hospitals because of their vital safety net role in America, especially in rural areas. Moreover, most of the ACA-eligible hospitals have already enrolled.
 - Congress, under the control of both parties, would not have repeatedly expanded 340B hospital eligibility criteria, including increasing the cap on DSH adjustment percentages for small urban and rural hospitals, if it did not believe that the 340B program was a success and fulfilling its intent.

CRITICS CONTEND: There are private, non-profit hospitals that should not be participating in 340B because their contracts with state and local governments do not require them to provide significant amounts of uncompensated care.

FACT: SNHPA agrees that private, non-profit hospitals should not qualify for 340B if they have only a minor contract to provide indigent care. There is no evidence, however, that such hospitals are participating.

- Information from the American Hospital Association shows that hospitals, in fact, provide substantially more than minor amounts of uncompensated care.
 - Annual surveys by the American Hospital Association show that since 2000, its member hospitals have provided \$367 billion in uncompensated care, which represents between 5.4% and 6.0% of the hospitals' operating expenses.⁵¹
 - In Texas, for example, uncompensated care was equal to 9.1% of non-profit hospital gross patient revenue in 2010.⁵² Uncompensated care increased 215%

⁴⁸ DRA, Pub. L. No. 109-171, § 6004, 120 Stat. 3, 61 (2006).

⁴⁹ Final Notice Regarding 340B Drug Pricing Program—Children's Hospitals, 74 Fed. Reg. 45,206 (Sept. 1, 2009).

⁵⁰ ACA, Pub. L. No. 111-148, § 7101, 124 Stat. 119, 821-23 (2010).

⁵¹ *American Hospital Association Uncompensated Hospital Care Cost Fact Sheet* (Jan. 2013), at <http://www.aha.org/content/13/1-2013-uncompensated-care-fs.pdf>.

⁵² Texas Department of State Health Services, *Texas Fact Sheet – Acute Care Hospitals* (Jan. 24, 2012), at <http://www.dshs.state.tx.us/chs/hosp/fact2011.doc>.

between 2001 and 2010, and three-quarters of that care was provided by non-profit and public hospitals—even though they comprise slightly less than half of the hospitals in the state.⁵³

- Although the evidence shows that hospitals are providing significant amounts of uncompensated care, SNHPA members want to be sure that they are meeting all requirements for 340B eligibility. For this reason, SNHPA has been advocating for HRSA to provide clearer guidance on the statutory requirement for a hospital to have a contract with state or local government to provide indigent care.

*CRITICS CONTEND: Hospitals should only be allowed to use 340B drugs for the uninsured and Medicaid populations.*⁵⁴

FACT: Congress was clear in drafting the 340B statute that covered entities may use 340B drugs for “any patient.” The patient’s insurance status is irrelevant to his or her eligibility to receive 340B drugs.

- Critics’ suggestion that 340B drugs should not be used for insured patients is completely at odds with the plain language of the 340B statute, which states that a covered entity may use 340B drugs for “any patient of the entity.”⁵⁵ Nothing in the statute suggests that covered entities may use 340B drugs only for uninsured or Medicaid patients.
- The House committee report accompanying the 340B statute also states that a covered entity may make 340B drugs available to its patients, without distinguishing between insured and uninsured patients.⁵⁶ The report states that the 340B program is designed “to enable these entities to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”⁵⁷ Critics’ contention that 340B drugs should not be used for insured patients is contrary to legislative history of the 340B statute.
- In fact, for hospitals subject to the 340B statute’s prohibition against group purchasing (applicable to DSH, children’s, and cancer hospitals), covered outpatient drugs may not be purchased through a group purchasing organization (GPO), and therefore must be purchased at the 340B price or a non-GPO, non-340B price (wholesale acquisition cost (WAC)).⁵⁸ WAC prices are typically much higher than 340B or even GPO pricing. Clearly, Congress does not expect these hospitals to spend more money on covered outpatient drugs for non-Medicaid and other insured patients by paying more expensive prices than they could access outside the 340B program. Congress expects that hospitals will purchase covered outpatient drugs through 340B for all their patients, regardless of their insurance status.

⁵³ *Id.*

⁵⁴ See PhRMA-BIO Report at 10; Fein Blog; McManus Article; Letter from National Community Pharmacists Association (NCPA) to Chairman Issa (June 1, 2012) available at <http://www.ncpanet.org/pdf/leg/june12/issaletter.pdf>.

⁵⁵ 42 U.S.C. § 256b(a)(5)(B).

⁵⁶ H.R. REP. 102-384, pt. 2, at 12 (1992).

⁵⁷ *Id.*

⁵⁸ HRSA 340B Drug Pricing Notice, Release No. 2013-1, *Statutory Prohibition on Group Purchasing Organization Participation*, at <http://www.hrsa.gov/opa/programrequirements/policyreleases/prohibitionongpoparticipation020713.pdf>.

- Limiting 340B patient eligibility would lead to reduced services for patients, increased government spending and create significant paperwork burdens.
- If patient eligibility were significantly limited, providers would withdraw from the program and higher costs will be passed on to local, state, and federal taxpayers.
- Requiring providers to limit the use of 340B drugs to only a select patient population would require burdensome and costly drug segregation efforts. It would be difficult to separate drugs dispensed to patients based on their insured status, which is often unknown during the course of treatment.
- For the program to have any meaningful value to providers and the patients they serve, 340B entities must be able to generate savings by using 340B drugs for all eligible patients.

CRITICS CONTEND: By allowing hospitals to include their offsite locations in the 340B program, HRSA has inappropriately expanded the size of the program.⁵⁹

FACT: 340B is an outpatient drug discount program, so it would defy logic and reason to limit hospital participation to the hospitals' main facilities where mostly inpatient services are delivered. The recent increase in the number of enrolled offsite clinics is due to a change in HRSA policy requiring registration of all offsite locations and has little to do with program growth.

- The health care industry-accepted definition of “hospital” includes offsite locations that are owned, controlled, operated by the hospital⁶⁰ and billed under its Medicare provider number, which is the definition that HRSA adopted for the 340B program.⁶¹ These criteria are strict and difficult to meet.
- The 340B program allows discounts on *outpatient* drugs. It is nonsensical to suggest that Congress did not intend for a hospital’s outpatient clinics to dispense 340B drugs. A clinic’s offsite location makes it more accessible to patients and is therefore as deserving of 340B discounts as a clinic located at the main facility.
- Both critics and supporters of the 340B program had an opportunity to review and comment on HRSA’s proposed hospital outpatient facility notices prior to those guidelines being finalized.
 - The number of offsite facilities registered on the Office of Pharmacy Affairs (OPA) database has recently grown because HRSA changed its policy in April 2012 to require hospitals to list *all* offsite facilities using 340B drugs on the OPA database. Previously, hospitals had to register only those sites at separate

⁵⁹ See PhRMA-BIO Report at 7.

⁶⁰ 42 C.F.R. § 413.65.

⁶¹ 59 Fed. Reg. 47,884 (Sept. 19, 1994); HRSA FAQs, at <http://www.hrsa.gov/opa/faqs/>.

addresses from the hospital that received shipments of 340B drugs directly.⁶² Now they must register any offsite facility that uses 340B drugs. Under HRSA's new policy, offsite clinics that have been dispensing 340B drugs, some since 1994, had to register in the OPA database. Moreover, HRSA requires any clinic located at an offsite facility to register separately. Therefore, if one offsite facility of a hospital houses 20 clinics or departments, each of those clinics must be separately registered.

*CRITICS CONTEND: There is widespread diversion within the 340B program—including the use of 340B drugs for hospital employees and correctional populations—which has increased the volume of drugs purchased at 340B discounts beyond what Congress intended.*⁶³

FACT: There is no widespread diversion in the program. Rather, there is widespread disagreement over what constitutes diversion. A hospital may dispense 340B drugs to an individual only if that individual is a “patient” of the hospital within the meaning of HRSA’s patient definition guidelines and satisfies other requirements established by HRSA. HRSA’s patient definition guidance is outdated, subject to different interpretations and in need of clarification.

- For hospitals, HRSA’s patient definition requires that (1) hospitals have an established relationship with the individual such that the hospital maintains the individual’s medical records and (2) the individual receive health care services from a professional who is either employed by the hospital or provides health care under contractual or “other arrangement” with the hospital such that responsibility for the care remains with the hospital.⁶⁴
- HRSA’s test for hospitals also requires that to be eligible to receive a 340B drug, a patient must be treated in a facility that has its costs listed on a reimbursable line of the hospital’s cost report.⁶⁵
- In addition, HRSA recognized in a 2001 letter to SNHPA’s predecessor organization that prescriptions written outside the walls of a hospital may still be filled with 340B drugs if the underlying services are proximate in time and type to care previously furnished by the hospital.⁶⁶
- Many hospitals care for their employees through contractual arrangements with a network of preferred providers. Others are contractually obligated to care for state or local correctional populations. These hospitals feel strongly that not only do such arrangements bring these populations within the ambit of HRSA’s patient definition, they allow the hospitals to “stretch scarce federal resources as far as possible” consistent with the intent of the 340B program.⁶⁷

⁶² OPA FAQs, DSH Hospitals, Registering to Participate in 340B, March 2005.

⁶³ See PhRMA-BIO Report at 14, 18; McManus Article; Fein Blog; McManus Article; Oncology Business Review Article.

⁶⁴ 61 Fed. Reg. 55,156, 55,157 (Oct. 24, 1996).

⁶⁵ 59 Fed. Reg. 47,884 (Sept. 19, 1994).

⁶⁶ See Letter from Thomas Morford, Deputy Administrator, HRSA, to William von Oehsen, General Counsel, PHPC (Jan. 26, 2001).

⁶⁷ H.R. REP. 102-384, pt. 2, at 12 (1992).

- In fact, a number of states including Texas, Louisiana, and Georgia have enacted laws or implemented programs to lower their drug spending through the use of 340B, including through partnerships between state and local prisons with 340B covered entities.⁶⁸
- There is an inherent conflict of interest between covered entities and manufacturers over how broadly the patient definition should be applied. Given this reality, HRSA has a special responsibility to be proactive and clear about how it interprets the law.
- It is true that the drug diversion issues are more complex in hospitals than some of the other covered entity providers by virtue of the nature of the health care services that hospitals provide. For example, only hospitals provide inpatient services; thus, distinguishing between when a drug is provided in an "outpatient" setting versus an "inpatient" setting is complicated, such as when a patient is being transferred from an emergency department (outpatient) to an inpatient unit or when a patient is in observational status. Further, hospital outpatient departments provide complex health care services beyond primary care, often necessitating the involvement of specialized physicians, who may or may not be employed by the hospital but who are essential to the provision of the outpatient service. Finally, hospitals often provide home care and other services outside their walls, further complicating the application of the definition of patient.
- Extending the use of 340B to the inpatient setting would eliminate these complexities. There is no sound policy reason for limiting 340B to outpatients.
- SNHPA remains steadfast in its longstanding commitment to promote compliance with 340B anti-diversion requirements. Drug diversion is prohibited by the 340B statute and SNHPA supports a zero tolerance policy for drug diversion. To ensure compliance with the drug diversion prohibition, the 340B community at large would benefit from a clear and concise regulatory framework regarding what constitutes diversion. SNHPA therefore believes that a clearer, more specific definition of "patient" is needed for the 340B program.

*CRITICS CONTEND: The 340B contract pharmacy program has increased the volume of drugs purchased at 340B discounts beyond what Congress intended.*⁶⁹

FACT: Contract pharmacies improve access to affordable medications and, for this reason, SNHPA supported HRSA's proposal to expand the contract pharmacy program to allow multiple contract pharmacy arrangements. Notwithstanding, SNHPA believes that

⁶⁸ See Carole Keeton Rylander, *Recommendations of the Texas Comptroller* (2001) (recommending that the Texas state corrections system use the 340B program to reduce its drug expenditures. The recommendation resulted in S.B. 347, which the Texas legislature enacted in 2001, authorizing the Texas Department of Criminal Justice to use 340B drugs for the Texas prison population), available at <http://www.window.state.tx.us/etexas2001/recommend/ch08/hhs14.html>); see also Louisiana Department of Public Safety and Corrections, *Annual Report 2009-2010* (highlighting the combination of facilities used to process offenders in the department's system, which allowed the use of 340B drugs for the offenders), available at <http://www.doc.la.gov/wp-content/uploads/2010/12/Annual-Report-2009-2010pdf.pdf>; See also Georgia Department of Corrections, *Annual Report - FY 2012* (noting that the Department began using 340B drugs for prisoners in the Augusta State Medical Prison in November 2011), available at http://www.dcor.state.ga.us/Research/Annual/GDC_annual_report_FY2012.pdf.

⁶⁹ See PhRMA-BIO Report at 4; NYT Article; Fein Blog.

such arrangements should be studied to ensure that they are effective and advancing the purpose of the contract pharmacy program.

- One of the purposes of the multiple contract pharmacy guidance is to make patient access to drugs more convenient. SNHPA supports this purpose and has supported allowing multiple contract pharmacy arrangements. Both critics and supporters of the 340B program had an opportunity to review and comment on HRSA’s proposed contract pharmacy notices prior to those guidelines being finalized. Nevertheless, the multiple contract pharmacy model should be evaluated to ensure it is meeting the purpose of helping low-income and other vulnerable patient populations.
- A hospital’s use of contract pharmacy arrangements should be guided and constrained by one of the primary purposes of the 340B program, namely, to maintain or expand access to affordable drugs for vulnerable patient populations in more convenient locations within their communities. SNHPA believes that HRSA needs to closely monitor the development and growth of these contractual arrangements to ensure that there is no diversion and to ensure that the purpose of enabling patient access is properly effectuated within the bounds of the law and the purpose of the program.
- In addition, SNHPA believes that contract pharmacies acting on behalf of 340B covered entities must be able to serve all patients. Unfortunately, if contract pharmacies charge the uninsured population at below-market rates, that could be construed as violating the federal anti-kickback law.
- A covered entity’s decision regarding (1) whether to establish a 340B contract pharmacy arrangement and (2) the scope and size of its contract pharmacy network should be based on its interest in maintaining or expanding access to care for uninsured, underinsured, and other low-income patients. SNHPA is advising its hospitals to consider these factors when pursuing or renewing contract pharmacy arrangements.

CRITICS CONTEND: More hospitals will qualify for 340B as a result of the expansion of Medicaid under the ACA. As the number of insured Americans increases with implementation of the ACA, fewer hospitals will need the 340B program to support their missions.⁷⁰ Congress never intended this result, and therefore eligibility standards should be narrowed.

FACT: Even with more Americans becoming insured under the ACA, 340B providers will continue to provide safety net care because there will continue to be: (1) substantial numbers of uninsured individuals, particularly in states that opt not to expand Medicaid; (2) substantial numbers of underinsured individuals, because individuals covered under expanded Medicaid and health exchange programs are not guaranteed the same minimum benefits offered under the traditional Medicaid program; and (3) inadequate health care reimbursement rates, particularly under Medicaid programs. 340B providers will play a key role in treating newly-insured Medicaid patients and will continue to rely on 340B savings to offset losses incurred by treating America’s most vulnerable patients.

⁷⁰ See PhRMA-BIO Report at 14, 21; NYT Article; Fein Blog; McManus Article; Oncology Business Review Article.

- The CBO estimates that *over 31 million non-elderly individuals* will remain uninsured after full implementation of the ACA.⁷¹ These individuals will continue to turn to 340B hospitals for their health care needs because these hospitals have a legal obligation to treat non-Medicaid, non-Medicare indigent patients as a condition of 340B participation.
- America's Essential Hospitals (formerly, the National Association of Public Hospitals and Health Systems) estimates that the shortfall in health care coverage created by a partial Medicaid expansion could result in \$53.3 billion more in uncompensated care than expected when Congress passed the ACA.⁷² Safety net hospitals are highly dependent on 340B savings to help balance their uncompensated care costs and this dependence will continue after 2014, even with new ACA coverage.
- 340B hospitals use their drug discounts to help fund services in the community that would otherwise not be provided, for example, trauma care, burn units, poison control, etc. Filling these gaps is needed by everyone in the community, not just the uninsured.
- The ACA relies heavily upon Medicaid to expand insurance coverage and safety net providers will serve a disproportionate share of newly eligible Medicaid beneficiaries. Medicaid reimburses providers at lower rates than most private payers and often does not cover or adequately reimburse needed services. For example, it does not cover the costs of comprehensive pharmacy services, including drug preparation, counseling, and administrative overhead. Moreover, most state Medicaid agencies require 340B entities to share their 340B savings with the state or to bill for drugs at average acquisition cost, thereby passing their entire 340B savings on to the state.
- According to a study published in the *Archives of Internal Medicine*, newly insured, low-income patients in Massachusetts (which adopted universal health coverage in 2006) continued to seek care from safety net providers because the patients found safety net provider services to be “convenient” and “affordable.”⁷³ These patients do not think of safety net facilities as providers of last resort and they have continued to be important sources of care for newly insured individuals in Massachusetts. In fact, a study by America's Essential Hospitals noted that, in Massachusetts, “safety net health systems care for the same, or a growing, volume of low-income patients following statewide reform, but have been paid substantially below their costs for treating these patients.”⁷⁴

⁷¹ CBO, *Updated Budget Projections: Fiscal Years 2013 to 2023* (Baseline Data for Table 1), at http://www.cbo.gov/sites/default/files/cbofiles/attachments/44190_EffectsAffordableCareActHealthInsuranceCoverage_2.pdf.

⁷² NAPH, *NAPH Analysis Projects \$53.3 Billion More Uncompensated Health Care Costs by 2019* (Oct. 25, 2012), at <http://www.naph.org/Main-Menu-Category/Newsroom/2012-Press-Releases/NAPHUncompensatedcareanalysisrelease.aspx?FT=.pdf>.

⁷³ Leighton Ku, et al., *Safety Net Providers After Health Care Reform: Lessons from Massachusetts*, 171(15) ARCH. INTERN. MED. 1379 (Aug. 8, 2011), at <http://archinte.jamanetwork.com/article.aspx?articleid=1105879>. See also Mark A. Hall, *The Costs and Adequacy of Safety Net Access for the Uninsured* (Boston, Massachusetts), Robert Wood Johnson Foundation (June 2010), at <http://www.newpublichealth.org/content/dam/supplementary-assets/2010/06/safetynetmass201006.pdf>.

⁷⁴ NAPH, *Massachusetts Health Reform: Lessons Learned about the Critical Role of Safety Net Health Systems* at 1 (Apr. 2009), at <http://naph.org/All-Archives/Publications/MA-Health-Reform-Issue-Brief.aspx?FT=.pdf>.

- Newly insured patients across the country will tend to be sicker than the average population because they opted not to see physicians when they were uninsured, increasing the costs for the safety net providers that will treat these vulnerable patients.
- We agree that expansion of Medicaid in 2014 has the potential to lead to program growth and we recommend studies on the growth of hospitals in 340B.

CRITICS CONTEND: The 340B program has displaced non-340B providers, especially community pharmacies and private oncology practices, and has created a competitive disadvantage for non-340B purchasers in the marketplace.⁷⁵

FACT: There is little to no evidence to support the contention that non-340B entities have difficulty competing with 340B providers or that community pharmacies and oncologists are at risk of being displaced due to the program.

- There are many reasons that community pharmacies are closing.⁷⁶ Competition from chain drugstores, declining third-party reimbursement, and stricter regulatory environments are the primary reasons why independent pharmacies are struggling.⁷⁷ While there might be isolated cases, SNHPA is not aware of any strong evidence supporting the contention that the 340B program is causing community pharmacies to close. In fact, many community pharmacies have expanded their businesses by partnering with 340B covered entities. Because safety net providers have a mutual interest in supporting their local pharmacies, they negotiate dispensing fee arrangements that provide pharmacies with a source of income that is generally more generous and predictable than what they receive under their take-it-or-leave-it pharmacy benefit manager (PBM) agreements. Many contract pharmacies have negotiated payment for additional services such as medication therapy management and home delivery. Covered entities are willing to contract for extra services because they are invested in improving access to care and health outcomes for their patients. For these reasons, many community pharmacies would disagree with the criticisms of the 340B program, particularly allegations that the program is bad for business.
- Community oncologists do not face the same struggles as safety net providers in serving the needs of low-income patients. Only 4% of patients treated by community oncologists were uninsured and only 4% were Medicaid, according to a 2012 biopharmaceutical consulting report.⁷⁸ This is because community oncology practices often refer low-income and uninsured patients to other providers for their cancer treatments. One study indicated that, of the patients referred by community oncologists to outside practices, 15% were uninsured and 26% were Medicaid.⁷⁹ In all likelihood, these patients receive their cancer care from public and non-profit 340B hospitals where health care services,

⁷⁵ See PhRMA-BIO Report at 15-16; NYT Article; McManus Article; Oncology Business Review Article.

⁷⁶ See, e.g., Karen E. Klein, *End of Days for Independent Pharmacies?*, BLOOMBERG BUSINESSWEEK (Mar. 8, 2012), at <http://www.businessweek.com/articles/2012-03-08/end-of-days-for-independent-pharmacies>.

⁷⁷ See, e.g., Bobby Warren, *Independent Pharmacies Dwindle*, THE DAILY RECORD (Ohio) (Sept. 16, 2012), at <http://www.the-daily-record.com/business/2012/09/16/independent-pharmacies-dwindle>.

⁷⁸ Lujing Wang, et al, *Turning Tides: Trends in Oncology Market Access*, at <http://www.campbellalliance.com/articles/Campbell%20Alliance%20-%20Turning%20Tides%20-%20August%202012.pdf>.

⁷⁹ *Id.*

including oncology services, are provided regardless of the patient's financial or insurance status.

- An American Society of Clinical Oncology report found that only 8% of spending by surveyed oncology practices and institutions was for 340B drugs.⁸⁰ Because 340B purchases account for such a small percentage of overall oncology drug spending, it is unlikely that 340B is having a significant impact on non-340B oncology practices.
- Integration of community-based physician practices and institutional providers has a long history that has been propelled by fundamental changes in our nation's health care system. Managed care, integrated delivery systems, capitation and, more recently, accountable care organizations have all created financial and clinical incentives for physicians and hospitals to work more closely together. The logical result of this 30-year trend is physician-hospital mergers.⁸¹ Availability of low-cost drugs through the 340B program has had a minor impact when viewed against this historical backdrop.
- Many private oncology practices are struggling to stay financially afloat because of inadequate reimbursement. Without the option of merging with a 340B hospital, these practices would not survive.

*CRITICS CONTEND: The 340B program has altered clinical decision making to the detriment of patients by providing hospitals with a financial incentive to favor outpatient treatment.*⁸²

FACT: SNHPA is deeply dismayed that critics have charged that 340B hospitals are prioritizing financial gains over patient care. These allegations are false and an affront to the integrity of safety net caregivers across the country.

- There is no evidence that hospitals are changing clinical treatment protocols because of 340B. Hospitals are highly regulated entities that are responsible both legally and ethically for the care of their patients. Further, 340B hospitals are either non-profit institutions or operating under governmental authority and, with respect to the former category, many are affiliated with religious institutions. The mission of these hospitals is to provide the highest quality care to patients regardless of their ability to pay.
- The Centers for Medicare and Medicaid Services (CMS) recently issued an Administrator's Ruling designed to reduce the backlog of appeal claims from hospitals challenging determinations by CMS's contractors that inpatient stays were not reasonable and necessary.⁸³ In such cases, CMS and its contractors ruled that patients should have remained in outpatient status rather than being admitted.⁸⁴ Hospitals cannot win. They

⁸⁰ Elaine L. Towle, et al., *National Oncology Practice Benchmark, 2012 Report on 2011 Data*, 8(6) J. ONCOLOGY PRACTICE 51s, 55s (Nov. 2012), at <http://jop.ascopubs.org/content/8/6S/51s.full.pdf+html>.

⁸¹ Mary Witt & Laura Jacobs, *Physician-Hospital Integration in the Era of Health Reform* (Dec. 2010), at <http://www.chcf.org/~media/MEDIA%20LIBRARY%20Files/PDF/P/PDF%20PhysicianHospitalIntegrationEraHealthReform.pdf>.

⁸² See PhRMA-BIO Report at 4, 17, and n. 82; McManus Article.

⁸³ CMS Administrator Ruling CMS-1455-R (Mar. 13, 2013), at <http://www.cms.gov/Regulations-and-Guidance/Guidance/Rulings/Downloads/CMS1455R.pdf>. See also Medicare Program; Part B Inpatient Billing in Hospitals, 78 Fed. Reg. 16,632 (Mar. 18, 2013).

⁸⁴ Administrator Ruling CMS-1455-R at 3.

face simultaneous and paradoxical allegations from 340B critics that they are holding patients in outpatient status for too long, and from CMS's contractors that they are admitting patients unnecessarily.

- Non-profit hospitals are dependent on community support and they have an obligation to operate for the community's benefit under federal laws governing their tax-exempt status.⁸⁵ Public hospitals operate under state and local laws requiring careful use of taxpayer dollars and subjecting the hospitals to regular audits designed to protect against waste. The 340B program allows these hospitals to hold down the cost of their drug purchases. Foregoing an opportunity to reduce costs – especially an opportunity created under federal law – would contravene these legal and ethical obligations.
- SNHPA strongly encourages its members to comply with its *Principles of 340B Program Stewardship*, one of which directs member hospitals to ensure that they operationalize their 340B programs in a manner that does not alter admission and/or discharge procedures for the primary purpose of expanding use of the 340B program.⁸⁶

*CRITICS CONTEND: The 340B practice of billing third-party payers at the same rates used to reimburse providers for non-340B drugs is fraud.*⁸⁷

FACT: Calling this practice fraud is not only inaccurate, it is irresponsible. Fraud is a deception deliberately practiced in order to secure unfair or unlawful gain. The 340B program's intent—its lawful purpose—is to allow covered entities to lower their drug costs without lowering their revenues. Any other result shifts the program's benefits away from covered entities and toward PBMs, insurers, and other parties in contravention of the program's purpose.

- A detailed list of providers participating in the 340B program is available through a public database that is accessible around the clock.⁸⁸ The implication that covered entities are deceiving payers or hiding their status is ludicrous and patently false. By contrast, the 340B prices charged by drug manufacturers remain a closely guarded secret three years after Congress required that they be made available to covered entities.⁸⁹
- There is no reported instance of a 340B provider or pharmacy charging a third-party payer more than it would charge if it did not participate in the 340B program. Expectations that part or all of the 340B discount would be passed on to private payers would undermine the program's purpose. The benefit of the program is directed towards safety net providers and not private insurance companies, which is consistent with the program's design and does not shift costs onto third-party payers.

⁸⁵ See 26 U.S.C. § 501(c)(3), (r); see also Barbara Straub Williams, et al., *IRS Proposed Regulations to Implement Tax-Exempt Community Health Needs Assessment Requirement and Enforcement Provisions* (Apr. 5, 2013), at <http://www.ppsv.com/assets/attachments/181.PDF>.

⁸⁶ See SNHPA, *Principles of 340B Program Stewardship*, Principle Five, at

http://www.snhpa.org/public/documents/pdfs/Principles_of_340B_Program_Stewardship.pdf.

⁸⁷ See MONEY with Melissa Francis: *Concerns Hospitals are Abusing Discount Drug Program* (FOX Business television broadcast Feb. 15, 2013); PhRMA-BIO Report at 17.

⁸⁸ See <http://openet.hrsa.gov/opa/>.

⁸⁹ 42 U.S.C. § 256b(d)(1)(B)(iii).

- HRSA specifically recognized that covered entities are permitted to “work within the reimbursement policies of the public and private health insurance plans they work with” to exercise “billing flexibility” and generate the “income that 340B was enacted to create.”⁹⁰
- Some have alleged that the 340B program impacts the rebates manufacturers pay to PBMs; therefore, costs will shift to third-party payers.⁹¹ These rebate arrangements have been criticized for inappropriately limiting patient choice, so they hardly deserve to be protected at the expense of helping safety net providers with their outpatient drug costs.

CRITICS CONTEND: Hospitals should not be generating revenue at the expense of the Medicare program.

FACT: Both CMS and the Office of the Inspector General (OIG) have concluded that the program was not intended to have covered entities pass their 340B savings to Medicare. This is because Congress did not create the 340B program to reduce Medicare drug expenditures.

- Since the beginning of the program, Medicare has reimbursed 340B hospitals for outpatient drugs at the same rates as they pay non-340B hospitals, even though 340B hospitals purchase outpatient drugs at lower prices. This is because 340B hospitals serve higher volumes of low-income and otherwise vulnerable patients. Hospitals use these savings to better serve such patients.
- In 2008, CMS considered whether Medicare should reimburse 340B hospitals at lower rates. SNHPA and other organizations, including pharmaceutical companies, explained that 340B hospitals should receive the same level of reimbursement as non-340B hospitals, because that is how Congress intended for 340B to operate. The CMS Ambulatory Payment Classification Panel, which CMS relies upon to make payment determinations, made the same recommendation. CMS agreed and did not change the way 340B hospitals are reimbursed.
- OIG issued a report in October 2010 confirming that Medicare reimbursement to 340B hospitals for outpatient drugs should be higher than a drug’s 340B acquisition cost because this is how the program is supposed to operate.⁹²
- Lowering Medicare reimbursement to 340B hospitals would require 340B hospitals to pass their program savings on to Medicare, which would lead to reduced services for patients and create significant paperwork burdens. Without access to the full benefits of 340B, hospitals would consider withdrawing from the program and higher costs would be passed on to local, state, and federal taxpayers.

⁹⁰ HRSA, Hemophilia Treatment Center Manual for Participating in the Drug Pricing Program Established by Section 340B of the Public Health Service Act, II.K, (July 2005), at <http://www.hrsa.gov/hemophiliatreatment/340Bmanual.htm#2k>.

⁹¹ See PhRMA-BIO Report at 17.

⁹² Letter from Stuart Wright, Deputy Inspector General for Evaluation and Inspections, HHS OIG to Donald Berwick, Administrator, CMS, Payment for Drugs Under the Hospital Outpatient Prospective Payment system, OEI-03-09-00420 (Oct. 22, 2010), at <http://oig.hhs.gov/oei/reports/oei-03-09-00420.pdf>.

- This issue has come up in the context of Medicaid. Covered entities pass their 340B savings to Medicaid for unique reasons that have nothing to do with Medicare. Unlike with Medicare, drug manufacturers are required to pay rebates to Medicaid programs. These rebates are lost by Medicaid when covered entities enroll in the 340B program, as Medicaid is prohibited by law from seeking rebates on 340B drugs.⁹³ Requiring covered entities to pass on a portion of their 340B savings makes up for a state Medicaid program's loss of rebates.⁹⁴ No such rationale exists with the Medicare program; Medicare does not lose revenue as a direct result of a provider's participation in the 340B program.

*CRITICS CONTEND: 340B hospitals are stockpiling low-cost drugs, a practice which is creating and/or exacerbating drug shortage problems in the United States.*⁹⁵

FACT: SNHPA member hospitals' primary reason for advance purchasing of large quantities of drugs is to prepare for future patient medication needs.

- When a given drug is in short supply, the manufacturer is expected to notify HRSA and to submit an allocation plan to ensure that covered entities receive their fair share of the drug. Unless manufacturers notify the government and the public at large, covered entities have no way of knowing whether they are purchasing too much of a drug.
- Stockpiling is not a primary cause of drug shortages. According to a statement by Food and Drug Administration spokesperson Lisa Kubaska, "about 75 per cent of drug shortages are caused by manufacturing issues...most often with manufacturers of sterile drugs, including oncology drugs [due to] compromised sterility and the presence of glass, metal and other material inside drug vials."⁹⁶ Nowhere does the FDA reference the 340B program as a cause or factor in drug shortages.
- The problem of manufacturers withholding 340B pricing on drugs subject to allocation arrangements is real. In its 2011 report, the GAO found that drug manufacturers allocated too little of IVIG for the 340B market, forcing 340B entities to purchase large quantities at non-340B prices.⁹⁷
- While SNHPA does not believe that its member hospitals are buying inappropriate amounts of drug products, we strongly urge our members to adhere to our *Principles of 340B Program Stewardship*. One principle directs 340B hospitals only to purchase drugs in short supply when necessary to serve immediate patient needs, and requires that any

⁹³ Notice Regarding Section 340B Drug Pricing Program – Program Guidance Clarification, 65 Fed. Reg. 13,983 (Mar. 15, 2000)

⁹⁴ Letter from Marsha Alvarez, Office of Drug Pricing (ODP), to Covered Entities (Mar. 9, 1993).

⁹⁵ See PhRMA-BIO Report at 19; McManus Article.

⁹⁶ Outsourcing Pharma, *Propofol Off FDA List but Manufacturing Issues Cause 75% of Shortages* (June 4, 2013), at <http://www.outsourcing-pharma.com/Contract-Manufacturing/Propofol-Off-FDA-List-but-Manufacturing-Issues-Cause-75%of-Shortages>.

⁹⁷ GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement*, at 18-20, GAO-11-836 (Sept., 2011), at <http://www.gao.gov/assets/330/323702.pdf>.

purchasing in excess of immediate need to be only that which is necessary to meet public health, homeland security and other medical requirements.⁹⁸

*CRITICS CONTEND: HRSA has relied too heavily on self-policing by participants and needs to increase program oversight to ensure 340B compliance.*⁹⁹

FACT: SNHPA supports increased oversight of the 340B program by HRSA through audits of both covered entities and manufacturers as well as other oversight measures. SNHPA also has asked HRSA for clearer and more detailed guidance on many occasions.

- The GAO’s 2011 report on 340B included a discussion of how HRSA’s lack of program oversight may be resulting in manufacturers “charging covered entities more than the 340B price for drugs which would limit the benefit of the program for these entities.”¹⁰⁰
- Although manufacturers are authorized to audit covered entities, covered entities have no way of auditing manufacturers.
- The OIG issued a series of reports documenting the 340B overcharge problem. In 2006, for instance, the OIG sampled pricing to a group of covered entities over the course of a month and found that 14% of total purchases were overcharges.¹⁰¹ 340B providers have complained about overcharging for two decades, and the complaints continue today.
- HRSA responded to the GAO report’s concerns about diversion by auditing covered entities. Yet, HRSA has never audited a manufacturer. Congress has directed HHS to conduct selective audits of manufacturers, but HRSA has yet to do so.¹⁰² This lack of oversight is alarming in light of the longstanding problem of manufacturers overcharging 340B covered entities.

*CRITICS CONTEND: HRSA lacks the resources to exercise proper 340B program oversight.*¹⁰³

FACT: HRSA should be applauded for the steps it has taken thus far to increase program oversight. SNHPA agrees that the agency should be adequately funded to continue its oversight efforts. For this reason, we support the enactment of a user fee program, financed by covered entities, to fund HRSA’s program integrity activities.

- HRSA needs additional funding so that it can implement critical integrity provisions enacted by Congress as part of health reform. Among the provisions that HRSA has not implemented include:

⁹⁸ See SNHPA, *Principles of 340B Program Stewardship*, Principle Six, at http://www.snhpa.org/public/documents/pdfs/Principles_of_340B_Program_Stewardship.pdf.

⁹⁹ See PhRMA-BIO Report at 18; NYT Article; McManus Article.

¹⁰⁰ GAO, *Drug Pricing: Manufacturer Discounts in the 340B Program Offer Benefits, but Federal Oversight Needs Improvement* 27, GAO-11-836 (Sept. 2011), at <http://www.gao.gov/assets/330/323702.pdf>.

¹⁰¹ HHS OIG, *Review of 340B Prices*, OEI-05-02-00073 (July 2006), at <http://oig.hhs.gov/oei/reports/oei-05-02-00073.pdf>.

¹⁰² ACA, Pub. L. No. 111-148, § 7102, 124 Stat. 119, 824 (2010); 42 U.S.C. §256b(d)(1)(B)(v).

¹⁰³ See PhRMA-BIO Report at 19.

- The development of a system to enable HHS to verify the accuracy of ceiling prices calculated by manufacturers, which includes “precisely defined standards and methodology for the calculation of ceiling prices,” comparing the ceiling prices calculated by HHS with the quarterly pricing data that is reported by manufacturers, performing spot checks of sales transactions by covered entities, inquiring into the cause of any pricing discrepancies, and either taking or requiring manufacturers to take appropriate corrective action with respect to pricing discrepancies;
- The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge, including providing HHS with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and oversight by HHS to ensure that the refunds are issued accurately and within a reasonable period of time;
- The provision to covered entities of secured, protected internet access to applicable ceiling prices;
- The development of a mechanism for manufacturers to report rebates and other discounts paid subsequent to the sale of covered outpatient drugs and to pay appropriate credits;
- The selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program;
- The imposition of civil monetary penalties against manufacturers for knowingly and intentionally overcharging covered entities for 340B drugs;
- The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and HHS for purposes of facilitating the ordering, purchasing, and delivery of covered outpatient drugs;
- The imposition of sanctions against covered entities for committing diversion under certain circumstances; and
- The implementation of an administrative process for the resolution of claims by covered entities that they have been overcharged for covered outpatient drugs and claims by manufacturers, after audit, that covered entities have violated the diversion or duplicate discount provisions.¹⁰⁴

¹⁰⁴ 42 U.S.C. § 256b(d).

CONCLUSION

The 340B program is a critical lifeline for America's safety net hospitals and the patients they serve. Albeit imperfect, the program continues to protect and preserve the ability of safety net hospitals to care for all of their patients, insured and uninsured.

SNHPA believes that the 340B program should be modernized to reflect a health care industry that has changed drastically in the past two decades. The patient definition guidelines promulgated by HRSA in 1996 do not cleanly fit the modern practice of medicine and pharmacy. HRSA should clarify and modernize the definition, which would eliminate a great deal of strife between drug manufacturers and 340B providers. The lack of transparency in both manufacturers' pricing of 340B drugs and hospitals' use of 340B savings causes each group to suspect that the other is not playing by the rules. Congress, the Administration, drug manufacturers, and safety net providers should work together to develop the means by which to improve program transparency in a way that is not overly burdensome. Lastly, HRSA should implement existing law by publishing 340B price files and auditing drug manufacturers and covered entities alike.

SNHPA agrees with some criticisms of the 340B program. At the same time, SNHPA finds many statements by critics to be inaccurate and based on flawed analysis or an incorrect understanding of the 340B program and its purpose. At worst, some opponents of the program are deliberately attempting to recast it as something it is not. SNHPA is both interested and ready to work with critics of the 340B program. Such collaboration is difficult when both the purpose of the program and how it is being used by hospitals are being distorted. Hopefully, by setting the record straight, this document helps clear the way for meaningful discussion among stakeholders on how to make the 340B program more effective.

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Safety Net Hospitals for Pharmaceutical Access (SNHPA) is an association of nearly 1,000 hospitals with a mission to increase the affordability and accessibility of pharmaceutical care for the nation's poor and underserved populations. For more information about SNHPA and the 340B program, visit www.snhpa.org and 340BFacts.com.