RESPONSE TO THE PHARMACEUTICAL INDUSTRY REPORT
Setting the Record Straight on 340B
July 9, 2013

A coalition led by pharmaceutical manufacturers and large pharmacy benefit managers has recently launched a coordinated series of attacks on the 340B program. The companies, which have a strong financial interest in limiting the program, published a report in February 2013 entitled, “The 340B Discount Drug Program: A Review and Analysis of the 340B Program” (Industry Report). The Industry Report mischaracterizes the 340B program and makes a number of unfounded allegations. While the companies have a right and obligation to provide input and commentary on how the 340B program is operated, their recommended reforms would place unnecessary and costly restrictions on 340B that would have a profound impact on the tens of millions of vulnerable patients who depend on 340B hospitals and clinics for affordable or free care. We feel compelled to set the record straight and dispel the myths contained in the report. We also note areas in which we agree with its findings and/or recommendations.

1) PROGRAM GOALS


FACT: Based on the original law and report language, as well as Congressional action over the last 20 years in expanding the number of eligible entities, it is clear that Congress intended to provide a discount to covered entities to reduce their cost of operations in recognition of their mission in serving low-income and vulnerable patient populations.

- 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.”1 The Industry Report’s contention that Congress intended for 340B to help only uninsured indigent patients is contrary to the legislative history of the 340B statute.

- 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 indigent patients.

- While all covered entities disproportionately serve the uninsured, the underinsured and other low-income and vulnerable patients, the purpose of providing these entities the

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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.

- 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.

**MYTH:** There is “little concrete evidence of how and whether benefits of the 340B program are reaching the intended beneficiaries of the program – namely uninsured indigent patients.” (Industry Report, p. 2).

**FACT:** Several published reports demonstrate that covered entities are using 340B savings consistent with the intent of the program, which allows covered entities to “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”

- The Government Accountability Office (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. Although the GAO recommended improved program oversight, it also found that the program is being implemented consistent with its original purpose. 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.”

- Hospitals use program savings to improve care and access for patients, exactly as Congress intended. A June 2011 study by two former U.S. Department of Health and Human Service researchers commissioned by SNHPA found that 340B hospitals pass their program savings onto their indigent patients by eliminating or reducing barriers to care. Specifically, the 340B hospitals reported that they 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.

- 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.

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• The Industry Report’s own analysis showed that “on average, 340B hospitals provided more uncompensated care as a share of total costs or gross patient revenues than did non-340B hospitals…” (Industry Report, p. 10). While SNHPA strongly agrees that 340B hospitals provide more uncompensated care than non-340B hospitals, it questions the methodology used in the Industry Report.

• To measure hospitals’ uncompensated care costs, Avalere Health relied on the Worksheet S-10 forms submitted by hospitals as part of their 2008 Medicare cost reports (Industry Report, footnote 52). The Centers for Medicare and Medicaid (CMS) recently announced that the data on the S-10 is not a reliable source for determining hospitals’ uncompensated care costs because it has not been publically available, subject to audit or used for payment purposes. This is especially true for S-10 data dating back to 2008. Accordingly, the data used in the report is widely recognized as unreliable, which calls into question the general reliability of the Industry Report’s findings.

• In a May 2011 report, the National Association of Community Health Centers (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.”

• In a 2004 Mathematica Policy Research report commissioned by the Health Resources and Services Administration (HRSA), the authors categorized how entities used their savings as intended:

  Entities that focused on a specific aspect of health or disease—family planning, STD, TB, and 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.

• 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.

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9 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).
MYTH: “Because Congress established the 340B program to benefit uninsured indigent people, 340B eligibility criteria should reflect the share of uncompensated care a hospital provides to outpatients” in line with new ACA Disproportionate Share Hospital (DSH) rules, which compensates hospitals based on their share of uncompensated care. (Industry Report, p. 8).

FACT: Congress’ intent was to benefit safety net providers that serve large numbers of indigent patients. In determining 340B eligibility requirements, Congress did not intend to limit program benefits to only uninsured indigent patients. Rather, hospitals and other 340B providers can 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 taxpayer dollars.

• Aligning 340B eligibility criteria with the measures for uncompensated care payments under the ACA would not address alleged “shortcomings” of the current 340B criteria, as purported by the Industry Report. 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.

• In 2010, Congress expanded the 340B program to include critical access hospitals, a category of hundreds of safety net hospitals that are not required to meet a DSH threshold, indicating Congress’ recognition that safety net status is not always tied to the amount of low income care that a hospital provides.

• CMS recently rejected using Worksheet S-10 data in the computation of uncompensated care pool payments required under the ACA. CMS decided to rely instead on the data used to calculate DSH payments. CMS, therefore, has adopted an approach that recognizes a correlation between a hospital’s DSH payments and the amount of uncompensated care it provides. This is exactly the approach adopted by Congress in defining 340B hospitals in the original 340B statute and later in the ACA.

• Ironically, uncompensated care payments under the ACA will be based, in part, on the amount of uncompensated care a hospital provides to inpatients, which are measures that the Industry Report argues should not be used to determine 340B eligibility (Industry Report, p.8 and footnote 42).

• 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.” The Industry

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11 CMS stated that the data that is it proposes to use (a hospital’s inpatient days attributable to Medicaid beneficiaries and individuals eligible for both Medicare and SSI) is a reliable proxy for uncompensated care costs. 78 Fed. Reg. at 25,588 - 89.
Report’s contention that Congress intended for 340B to help only uninsured indigent patients is contrary to the legislative history of the 340B statute.

**MYTH:** The 340B Program does not reflect its purpose – to serve the uninsured. “The top 10 states with the highest proportion of eligible and participating 340B hospitals also tend to have lower percentages of uninsured populations than the national average uninsured rate...” Figure 5: Top 10 States with the Highest Proportion of 340B Hospitals and Percentage of Uninsured Population (Industry Report, p. 15).

**FACT:** Almost all of the 10 states listed are rural states that have a high proportion of 340B hospitals because a large number of small rural hospitals are located there. Congress specifically chose to add these hospitals to the 340B program, so it is both illogical and misleading to cite the states where these hospitals have a strong presence as evidence that the program does not reflect its purpose.

- Several of these states have large numbers of rural hospitals – Iowa, Kentucky, Oregon, and North Carolina – and the safety net status of these hospitals is based more on geographic remoteness than serving uninsured populations.

- The chart does not take into account other factors that determine 340B status, such as the amount of care provided to Medicaid patients. It instead merely focuses on the uninsured which, as previously mentioned, is not the only indicator of safety net status.

- As stated above, 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.”

The Industry Report’s contention that Congress intended for 340B to help only uninsured indigent patients is contrary to the legislative history of the 340B statute.

2) **Hospital Eligibility**

**MYTH:** “While the ACA provided payment adjustments to DSH hospitals to reflect the share of uncompensated care they provide, it did not make corresponding changes to the 340B program’s hospital eligibility criteria”, which “reinforc[es] concern that the DSH adjustment percentage is not an appropriate measure to determine whether a hospital is eligible to receive 340b discounts” (Industry Report, p. 9).

**FACT:** 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.

- The fact that Congress did not make changes to 340B eligibility criteria for DSH hospitals supports the contention that uncompensated care is not, nor should it be, a controlling factor for 340B eligibility.

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13 Id.
• Congress determined that critical access hospitals do not need a minimum DSH adjustment percentage to qualify for 340B because they comprise a different part of the safety net and serve a different type of vulnerable patient. The DSH adjustment is not the only indicator of safety net status.

• In any case, SNHPA members are strongly encouraged 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.¹⁴

**MYTH:** The Industry Report suggests that many private nonprofit 340B hospitals have contracted to provide only a minor amount of uncompensated care. “The legislative history similarly stated that the 340B program was meant to allow participation by a private nonprofit hospital that contracts to care for ‘low-income individuals who are not eligible for Medicaid or Medicare’—i.e., who are uninsured—but not by a private nonprofit hospital with a minor contract to provide indigent care which represents an insignificant portion of its operating revenues’”. (Industry Report, p. 7).

**FACT:** SNHPA agrees that private nonprofit hospitals should not qualify for 340B if they only have “a minor contract to provide indigent care”; however, there is no evidence suggesting that this is the case.

• The Industry Report’s allegation that contracts between private, nonprofit 340B hospitals and state and local governments only require the hospitals to provide insignificant amounts of uncompensated care is completely unfounded. Information from the American Hospital Association shows that hospitals, in fact, provide substantially more than “minor” amounts of uncompensated care.

  o 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.¹⁵

  o In Texas, for example, uncompensated care was equal to 9.1% of nonprofit hospital gross patient revenue in 2010.¹⁶ Uncompensated care increased 215% between 2001 and 2010, and three-quarters of that care was provided by nonprofit and public hospitals, even though they comprise slightly less than half of the hospitals in the state.¹⁷

• Although the evidence shows that SNHPA members 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 advocated for HRSA to

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¹⁷ Id.
provide clearer guidance on the statutory requirement for a hospital to have a contract with state or local government to provide indigent care.

3) **Patient Eligibility**

**Statement:** “Today, all outpatients of a 340B facility, both insured and uninsured, may be treated using drugs purchased via the 340B program; current HRSA guidelines allow covered entities to use 340B drugs to treat fully insured patients.” (Industry Report, p. 10).

**Agreement:** SNHPA applauds the authors of the Industry Report for recognizing that 340B drugs can be dispensed to both insured and uninsured patients.

- While we are aware that some believe the 340B law prohibits covered entities from using 340B drugs for insured patients, this 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.” Nothing in the statute suggests that covered entities may use 340B drugs only for uninsured patients. We appreciate the Report’s recognition of this fact.

- The House 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. The House 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.” The Industry Report’s contention that Congress intended for 340B to help only uninsured indigent patients is contrary to the legislative history of the 340B statute.

4) **Program Growth**

**Myth:** The increase in the number of 340B hospitals raises “critical questions about the growth of the 340B program, how the program has evolved and whether the changes that have occurred over the years are consistent with Congress’ intent in creating the program.” (Industry Report, p. 2).

**Fact:** Growth in the number of 340B hospitals is the result of deliberate, policy-oriented actions taken by Congress.

- Congress clearly supports the expansion of 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 DSH payment percentage 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.

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20 Id.
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 children’s hospitals to the program, which HRSA implemented in 2009.\(^{22}\) Since 2009, 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 DSH percentages above 11.75%, and rural referral centers and sole community hospitals with DSH patient percentages at or above 8%.\(^ {23}\) 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.\(^ {24}\) Therefore, even though the number of new hospitals is relatively large, the amount of 340B drugs the hospitals are purchasing is not.

- Congress, under the control of both parties, would not have repeatedly expanded 340B hospital eligibility criteria, including extending DSH payment adjustment formulas for small hospitals, if it did not believe that the 340B program was a success and fulfilling its intent.

**MYTH:** HRSA’s 1994 guidance allowing hospital outpatient facilities to purchase and use 340B drugs has “led to a proliferation of new sites that participate in the program and to significant growth, generating some controversy over whether these new sites are permitted by the 340B law and are consistent with its intent” (Industry Report, p. 7).

**FACT:** 340B is an outpatient drug discount program, so it would make no sense 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 hospital\(^ {25}\) and billed under its Medicare provider number, which is the definition that HRSA adopted for the 340B program.\(^ {26}\) 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.


\(^ {25}\) 42 C.F.R. § 413.65.

The number of offsite facilities registered on the OPA database has grown recently 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 sites that received 340B drugs; now they must register any site 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 in an offsite facility to register separately. Therefore, if one offsite facility of a hospital houses twenty clinics or departments, each of those clinics must be separately registered.

**MYTH:** The report criticizes HRSA’s “subregulatory (i.e., without notice and comment rulemaking) guidance issued in 1996” regarding participation of outpatient facilities in the 340B program and its 2010 contract pharmacy guidelines. (Industry Report, p. 4).

**FACT:** Although HRSA has not issued its 340B policies as formal regulations, all of its Federal Register guidelines have been adopted following notice and comment, including the 1994 guidance (not 1996, as the Industry Report notes) on hospital outpatient facilities and the 2010 contract pharmacy guidelines. Notwithstanding, SNHPA supports re-publication of HRSA’s guidelines so that they can be promulgated as formal regulations.

- Both critics and supporters of the 340B program had an opportunity to review and comment on HRSA’s proposed hospital outpatient facility and contract pharmacy notices prior to those guidelines being finalized.

- For reasons described above, SNHPA strongly supports the policies reflected in the hospital outpatient facility notice. With respect to the contract pharmacy guidance, SNHPA recommends a study to evaluate the growth and effectiveness of contract pharmacy arrangements.

**MYTH:** According to an analysis by the Berkeley Research Group, “drug purchases under the 340B program are estimated to double, from $6 billion in 2010 to $12 billion by 2016” (Industry Report, p. 14). The Berkeley Research Group cites three reasons for its projected increase in drug sales, including Congress’ decision to add several new categories of safety net hospitals to the program as part of the ACA. The report also cites Medicaid Expansion, Multiple Contract Pharmacy Networks, and Organic Growth and Sub-Entity Expansion as drivers of program growth.

**FACT:** 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, suggesting that the Industry Report’s projections are inflated.

- While 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. Further, HRSA has stated that the ACA-eligible hospitals account for only 10% of all 340B spending.
We agree that the other two cited reasons – expansion of Medicaid in 2014 and growth of contract pharmacies – have the potential to lead to program growth, and that is why SNHPA recommends studies on the impact of these developments on 340B.

**MYTH:** “Expansion of coverage and the associated shift in patient mix, resulting in a larger share of insured patients, will increase the size of the 340B program in terms of the amount of revenue achieved.” Further, “(t)he newly insured population, consisting of current and new patients, will allow 340B entities to generate more revenue from the 340B program, as the entities may be able to bill and get paid at a profit for drugs dispensed to those patients” (Industry Report, p. 21).

**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; 27 (2) substantial numbers of underinsured individuals, as expanded Medicaid and health exchange programs are not required to offer the full array of benefits offered under the traditional Medicaid program; 28 and (3) inadequate health care reimbursement rates, particularly under Medicaid programs.

- The CBO estimates that **more than 31 million individuals** will remain uninsured after full implementation of the ACA. 29 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. 30 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. 31 Everyone in the community needs these gaps to be filled, not just the uninsured.

**MYTH:** **Safety net hospitals will recoup disproportionate and unfair benefits from the increased numbers of insured individuals under the ACA.** (Industry Report, p. 21).

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29 Id.


FACT: 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.

- 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 actual 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.” 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.”

- 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.

5) **Market Impact on Non-340B Providers**

MYTH: “The more entities that become 340B eligible... the more difficult it may become for non-340B providers to compete. Non-340B providers—including community pharmacies and oncologists that are not 340B eligible—may be displaced because they must pay more to purchase drugs than competing 340B covered entities do.” *(Industry Report, p. 4)* Further 340B may reduce community pharmacies “patient base, driving utilization down and potentially forcing many community pharmacists out of business” *(Industry Report, p. 16)*.

FACT: There is little 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.

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There are many reasons that community pharmacies are closing.\(^{34}\) Competition from chain drugstores, declining third party reimbursement and stricter regulatory environments are the primary reasons why independent pharmacies are struggling.\(^{35}\) SNHPA is not aware of any 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 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 Industry Report’s criticisms of the 340B program, particularly its 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 in Medicaid, according to a 2012 biopharmaceutical consulting report.\(^{36}\) 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 in Medicaid.\(^{37}\) In all likelihood, these patients receive their cancer care from public and nonprofit 340B hospitals where health care services, 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.\(^{38}\) 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.

**MYTH:** “Another potential market distortion created by the 340B program may result from a recent increase in the number of hospitals with 340B pricing acquiring community oncology practices.” (Industry Report, pp. 15-16).

**FACT:** Mergers between hospitals and physician practices have been occurring for decades and this trend is neither unique to oncology practices nor 340B hospitals. Moreover, many private oncology practices are struggling to stay financially afloat because of inadequate


\(^{37}\) Id.

reimbursement. Without the option of merging with a 340B hospital, these practices would not survive.

- 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.  

39 Availability of low-cost drugs through the 340B program has had a minor impact when viewed against this historical backdrop.

- Many oncologists and cancer treatment centers support the 340B program. The Industry Report’s complaints about the program are not representative of the broader oncology community.

**MYTH:** “Recent evidence also suggests that 340B entities may be expanding into long-term care (LTC) facilities...A 340B entity can purchase drugs at statutorily controlled prices that can undercut the ability of LTC closed-door pharmacies to compete for the LTC facility patient population. If this practice expands, the results will be devastating for LTC pharmacies, which serve more than 1.8 million residents.” (Industry Report, p. 17).

**FACT:** A hospital may dispense 340B drugs to an LTC patient only if that individual is a “patient” of the hospital within the meaning of HRSA’s patient definition guidelines and is treated in a facility that is an integral part of the hospital, or in accordance with other guidance articulated by HRSA. So-called “evidence” of this theoretical trend cited in the Industry Report is one reported instance.

- HRSA’s patient definition requires that (1) covered entities have an established relationship with the individual such that the hospital maintains the individual’s medical records and (2) the individual receives health care services from a professional who is either employed by the covered entity or provides health care under contractual or “other arrangement” with the covered entity such that responsibility for the care remains with the covered entity.  

40 HRSA’s test 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. This test is not easily met, particularly because LTC facilities typically do not rely on the services of a hospital to care for their patients. HRSA has also articulated other guidance indicating that prescriptions written for follow-up treatment that is proximate in type and time to prior services provided in an eligible hospital facility may be filled with 340B drugs.  


• The Industry Report cites an anecdotal instance in which a 340B hospital used the 340B program for LTC patients. There is nothing to suggest that the individuals who received 340B drugs at the LTC facility did not meet the patient definition and, in any case, this one instance is hardly evidence of a trend.

**MYTH:** “Another potential market distortion as a result of 340B is the possibility that costs will be shifted to third-party payers, as 340B entities capture dollars that would otherwise flow to payers through rebates.” (Industry Report, p. 17).

**FACT:** The impact of the 340B program on rebate arrangements between manufacturers and PBMs does not constitute cost-shifting to third party payers. 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.

• Manufacturers pay rebates to PBMs as a reward for PBMs successfully incentivizing their customers to use the manufacturer’s drugs. PBMs, in turn, use formularies and patient co-pays and deductibles to steer their insured patients to a preferred manufacturer’s product line.

• 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.

• 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.”

6) **IMPACT ON PATIENT CARE/CHANGING CLINICAL PATHWAYS**

**MYTH:** “340B covered entities may have a financial incentive to alter patient care pathways so that individuals who would otherwise receive inpatient care are treated on an outpatient basis, allowing the drugs used in treatment to be purchased at 340B-discounted prices.” (Industry Report, p. 4). And, “clinical decision-making may also be skewed by efforts to take advantage of the profit margins available from 340B outpatient drugs.” (Industry Report, p. 17). Further, the Industry Report asserts that some patients are steered away from inpatient facilities to outpatient care and therefore may lose eligibility for Medicare skilled nursing care benefits. (Industry Report, footnote 82).

**FACT:** SNHPA is deeply dismayed that the Industry Report includes unfounded characterizations that 340B hospitals are prioritizing financial gains over patient care. These allegations are an affront to the integrity of safety net caregivers across the country.

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There is no evidence that hospitals are changing clinical treatment protocols in a way that adversely impacts patient care. Hospitals are highly regulated entities that are responsible both legally and ethically for the care of their patients. Further, 340B hospitals are either nonprofit 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.

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. In such cases, CMS and its contractors ruled that patients should have remained in outpatient status rather than being admitted. Hospitals cannot win, facing simultaneous and paradoxical allegations from 340B critics that they are holding patients in outpatient status for too long, while CMS’s contractors maintain that they are admitting patients unnecessarily.

Nonprofit hospitals are dependent on community support and have an obligation to operate for the community’s benefit under federal laws governing their tax-exempt status. 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.

Footnote 82 of the Industry Report contends that “if a patient is never admitted as an inpatient to a facility because of the entity’s incentive to capture the outpatient spread, he or she would not qualify to be admitted into a skilled nursing facility under Medicare.” Medicare covers skilled nursing facility (SNF) stays only after an inpatient discharge, but there is no basis for speculating that 340B hospitals are steering patients to outpatient care and causing them to forgo Medicare SNF benefits.

While SNHPA, our member hospitals and their clinicians find these allegations to be offensive, 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.

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44 Administrator Ruling CMS-1455-R at 3.


MYTH: “In some cases, the presentations [made at 340B conferences] reflect specific examples that HRSA has in fact raised as diversion risks (e.g., covered entity employees who do not receive health care services from the entity, and thus do not qualify as patients.)” (Industry Report, p. 18).

FACT: SNHPA is not aware of any 340B conference presentation that promoted an illegal or improper use of the 340B program. To the extent that program use for employees was described, the presentation would have been limited to employees who qualify as covered entity patients under HRSA’s patient definition guidance.

- HRSA’s patient definition policy requires that (1) the 340B hospital have a relationship with the individual such that it maintains the individual’s medical records and (2) the individual receive health care services from a professional who is either employed by or under contractual or “other arrangement” with the covered entity such that responsibility for care remains with the hospital. 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. Although reasonable people can disagree over how HRSA’s definition of patient should be applied to a particular set of facts, SNHPA is confident that the examples cited at 340B conferences were based on a careful analysis of the law and a sincere desire to be compliant. As far as SNHPA is aware, presentations at 340B conferences have not suggested that covered entities deviate from HRSA’s guidance.

- Many hospitals care for their employees through contractual arrangements with a network of preferred providers. These hospitals feel strongly that not only do such arrangements comply with HRSA’s patient definition, they allow the hospitals to “stretch scare federal resources as far as possible” consistent with the intent of the 340B program.

- 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.

- 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.

MYTH: “Another diversion threat arises from ‘stockpiling’ behaviors, which can create artificial shortages that incite problematic practices such as gray-market activity.” (Industry Report, p. 18).

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

- While SNHPA does not believe that its member hospitals are diverting drugs or buying inappropriate amounts, we strongly encourage 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 purchasing in excess of immediate need to be only that which is necessary to meet public health, homeland security and other medical requirements.

- 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 percent 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.”

- The problem of manufacturers withholding 340B pricing on drugs subject to allocation arrangements is real. In its 2011 report, the GAO noted reports from covered entities that drug manufacturers allocated too little of IVIG for the 340B market, forcing 340B entities to purchase large quantities at non-340B prices.

STATEMENT: “The GAO found that operating the 340B program in a hospital environment creates more opportunities for drug diversion than with other covered entity types” (Industry Report, p. 19).

AGREEMENT & ELABORATION: While we agree that drug diversion issues are more complex in hospitals than some of the other covered entity providers, there is absolutely no evidence that there is widespread diversion taking place in hospitals.

- 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

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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.

**STATEMENT:** “As noted by the GAO in its recent report on the 340B program, HRSA has relied almost exclusively on self-policing by program participants.” (Industry Report, p. 18).

**AGREEMENT & ELABORATION:** SNHPA supports increased oversight of the 340B program by HRSA through audits of both covered entities and manufacturers, and similar oversight measures. SNHPA also has asked HRSA for clearer and more detailed guidance on many occasions.

- The Government Accountability Office’s 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.”

- Although manufacturers are authorized to audit covered entities, covered entities have no way of auditing manufacturers.

- The HHS Office of Inspector General (OIG) has issued a series of reports documenting the 340B overcharge problem. In 2006, for instance, the OIG sampled pricing over the course of a month and found that 14% of total purchases were overcharges. 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, even though Congress has directed HHS to conduct selective audits of manufacturers. This lack of oversight is alarming in light of the longstanding problem of manufacturers overcharging 340B covered entities.

**STATEMENT:** “[G]iven the myriad issues outlined above, a significant number of areas remain in need of continued sustained oversight, and HRSA may not have sufficient resources to address these and other issues without additional assistance.” (Industry Report, p. 19).

**AGREEMENT:** 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.

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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. The following are among the provisions that HRSA has not implemented:

  o 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.

  o 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;

  o The provision to covered entities of secured, protected internet access to applicable ceiling prices;

  o 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;

  o The selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program;

  o 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; and

  o 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.  

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**RECOMMENDATIONS AND CONCLUSION**

We believe 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

56 42 U.S.C. § 256b(d).
clarify and modernize the definition, which would eliminate a great deal of strife between drug manufacturers and 340B providers. The lack of transparency in 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, establishing a meaningful dispute resolution process and auditing drug manufacturers and covered entities alike.

SNHPA agrees with some of the analysis in the Industry Report and even with certain suggestions on how to improve its administration. At the same time, SNHPA finds many statements in the Industry Report to be inaccurate and/or based on flawed analysis or an incorrect understanding of the 340B program and its purpose. 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.

For more information, please contact SNHPA Associate Counsel Jeff Davis at jeff.davis@snhpa.org or 202-552-5867.

_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](http://www.snhpa.org)._