DEMONSTRATING THE VALUE OF THE 340B PROGRAM TO SAFETY NET HOSPITALS AND THE VULNERABLE PATIENTS THEY SERVE

6/29/2011 Perspectives from SNHPA Members
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EXECUTIVE SUMMARY

Background

The 340B Drug Pricing Program (340B program) is a federal program designed to reduce the amount that safety net providers spend on outpatient drugs. Safety Net Hospitals for Pharmaceutical Access (SNHPA) has commissioned this report to obtain information on how 340B participating hospitals are utilizing 340B savings. SNHPA is an organization that advocates for over 700 public and private non-profit hospitals and health systems throughout the country that participate in the 340B program.

An electronic survey was administered to the universe of SNHPA membership as of February 1, 2011, which consisted of over 600 hospitals at the time. Due to the urgency of this report, data collection was expedited to three weeks; despite this abbreviated timeframe, the survey received 381 responses, for a response rate of 60 percent.

Key Findings

I. Program Savings Are Critical to Safety Net Hospital Operations

- Respondents reported spending 27 percent less than they would have spent on outpatient drugs as a result of the 340B program, resulting in an average annual savings of $5.2 million in 2010.
- 100 percent of respondents reported that the savings stemming from 340B participation are important to the operation of their institution, with 85 percent characterizing the savings as critical.
- 83 percent credit the cost reductions afforded through 340B to the maintenance of broader hospital operations, including the provision of necessary, non-pharmacy services for patients.
- 98 percent of respondents reported that an elimination of 340B savings would adversely impact the organization and its patients.

II. Program Savings Reduce the Cost of Pharmaceuticals to Vulnerable Patients

- 74 percent of respondents with an outpatient pharmacy use 340B savings to reduce the price of drugs paid by patients.
- More than two-thirds (68 percent) of survey respondents rely on the 340B program to offset low pharmacy reimbursement from public and private sources of insurance.

III. Program Savings Increase Access to and Quality of Pharmaceutical Services for Vulnerable Patients

- 75 percent of respondents use 340B savings to increase patient access to prescription drugs, of which 93 percent use savings to enhance service for the uninsured or underinsured.
- Over half of respondents reported using 340B savings to support cost-effective and patient-focused pharmacy services such as medication therapy management, disease management and patient assistance programs.
IV. Other Issues Facing Participants

- 40 percent of survey respondents reported difficulty obtaining covered outpatient drugs at the 340B price.
- Support for an extension of 340B to inpatient drugs remains strong.
- The orphan drug exclusion is a challenge for newly-eligible hospitals wishing to participate in 340B.

Summary

This report demonstrates the value of the 340B program to hospital systems in meeting the needs of their low-income, uninsured and underinsured patient populations, while stretching tax dollars. Safety net hospitals have been using their program savings to provide, improve and expand services in innovative and cost-effective ways and will continue to rely on the program post-health care reform.

As indicated by the survey respondents, without the 340B program, many safety net hospitals would have to limit services or even close their pharmacy doors. As a result, patients would lose access to health care and communities would suffer.
INTRODUCTION AND BACKGROUND

Congress enacted Section 340B of the Public Health Service Act in November 1992 (Section 602 of the Veterans Health Care Act of 1992). The “340B program”, named for the section of statute under which the program was established, requires pharmaceutical manufacturers participating to enter into a pharmaceutical pricing agreement (PPA) with the Secretary of the Department of Health and Human Services (HHS). The terms of the PPA require manufacturers to provide discounts on covered outpatient drugs purchased by specified government-supported facilities, known as “covered entities,” that serve the nation’s most vulnerable patient populations. Congress intended for covered entities to use the benefit of the discount to reach more eligible patients and provide more comprehensive services.

Eligible “covered entity” hospitals include disproportionate share hospitals (DSHs), children’s hospitals exempt from the Medicare prospective payment system, cancer hospitals exempt from the Medicare prospective payment system, sole community hospitals, rural referral centers and critical access hospitals (CAHs). Hospitals must be not-for-profit and either be owned or under contract with state or local governments. With the exception of CAHs, they must also serve a disproportionate share of low-income patients by meeting payer-mix criteria related to the Medicare DSH program.

Certain non-hospital covered entities are eligible for the program because of their status as federal grantees, including the following: Federally qualified health centers (FQHCs); FQHC “look-alikes”; state-operated AIDS drug assistance programs; the Ryan White CARE Act Title I, Title II, and Title III programs; tuberculosis, black lung, family planning and sexually transmitted disease clinics; hemophilia treatment centers; public housing primary care clinics; homeless clinics; Urban Indian clinics; and Native Hawaiian health centers.

The 340B discount is the average manufacturer price (AMP) reduced by a minimum rebate percentage of 23.1 percent for most brand name prescription drugs, 17.1 percent for brand name pediatric drugs and clotting factor, and 13 percent for generic and over-the-counter drugs. Manufacturers and wholesalers must offer even greater discounts on brand name drugs if the manufacturer’s best price for a drug is lower than AMP minus the minimum rebate percentage for that drug and/or the price of the drug has increased faster than the rate of inflation. This is also true for innovator, multi-source drugs, i.e., brand name drugs that now have generic competition. Covered entities are free to negotiate discounts that are lower than the maximum allowable statutory price.

Safety Net Hospitals for Pharmaceutical Access (SNHPA) has commissioned this report to obtain information on how 340B participating hospitals are utilizing 340B savings. SNHPA is an organization of over 700 public and private non-profit hospitals and health systems throughout the country that participate in the 340B program. SNHPA, which was originally named the Public Hospital Pharmacy Coalition, was formed in 1993.
to advocate for 340B-participating hospitals. Its membership consists of a broad spectrum of 340B hospitals including academic medical centers, religious and community hospitals, and children’s and rural facilities.

DATA COLLECTION

To obtain information on how 340B participating hospitals are utilizing the discount program’s savings, we surveyed the universe of 632 SNHPA members as of February 2011. The 13-question survey was comprised of both closed and open-ended questions and was administered electronically during February 2011. We received responses from 381 SNPHA members for a response rate of 60.3 percent.

To ensure the survey appropriately reflected the unique organizational structure of hospitals and health systems, we allowed SNHPA members to respond to the survey in the way that made the most sense to their organization. In other words, members could respond as an individual hospital or on behalf of a larger health system. The vast majority (79 percent) of respondents included only one hospital, but 19 percent encompassed multiple hospitals. The remaining 2 percent of respondents are networks of clinics that are affiliated with SNHPA member hospitals. Because a single survey response could have been on behalf of multiple members within the same hospital system, we created unique identifications for each system, which resulted in a total of 290 systems.

We analyzed survey responses based on respondent size, hospital type, outpatient pharmacy spending, methods of dispensing 340B savings, and estimated savings rates. For open-ended responses provided by respondents, we systematically grouped responses into categories based on our qualitative analysis key words or phrases. See Appendix A for a more detailed description of the methodology and Appendix B for a copy of the survey.

FINDINGS

To provide context on the ways in which the savings from the 340B program support participants’ role as safety net providers, the survey first requested respondents to supply information on the amount of savings gleaned through the discount. Respondents were asked to estimate the total amount spent on pharmaceuticals in 2010 and to provide a projection on how much they saved through the 340B program. On average, respondents reported saving $5.2 million last year by participating in the 340B program, with over half of respondents reporting savings of over $2.0 million.

Annual savings reported by respondents varied greatly, from $5,000, for one small hospital, to $140 million, for a large hospital system. As expected, respondents whose submission was for more than a single hospital, on average, reported savings of more than double that reported on average by those responding on behalf of one hospital—from $9.3 million to $4.4 million, comparatively. Table 1, below, provides a breakdown of savings reported by respondents by the number of hospitals within the organization.
On average, respondents reported spending 27 percent less than they would have spent on outpatient drugs as a result of the 340B program. The percentage saved by participating in the 340B program varied by respondent, ranging from less than 1 percent to 67 percent. The varying levels of savings reported by respondents may indicate varying levels of program maximization and time enrolled in the program. For example, through the Patient Protection and Affordable Care Act (PPACA), four new entity types were made eligible for the 340B program, effective August 1, 2010. Responses from only newly eligible entity types reported a lower savings percentage (16 percent) versus respondents that include a previously eligible entity type (28 percent). The lower savings could be explained by several reasons. First, these hospitals are generally smaller when compared to the DSHs. Second, due to conditions of participation specific to the new entities, they are unable to save on costly orphan drugs. Third, these entities may have less precise savings estimates because they have not yet been in the 340B program for a full year. Fourth, the lower savings through 340B could also be because not all of the new entity types are subject to the group purchasing organization restriction, so they may be using 340B for a limited number of purchases.

Chart 1, below illustrates the distribution of percent savings reported by respondents.

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Note: Number of respondents does not add to 290 because of non-responses to the survey’s question on reported savings.

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The findings for this report are organized into four sections. The first section broadly discusses the value of 340B program savings to the respondents. In this section, surveyed hospitals were asked to rate the importance of the drug discount program to their organization and to offer their thoughts on the potential impact that they would experience without 340B savings. The next two sections cover the ways in which respondents utilize 340B program savings. Overall, 94 percent of respondents replied that they use 340B savings to do at least one of the following: increase patient access to care, reduce the cost of drugs, provide increased pharmacy services or maintain broader hospital operations. It is important to note that this does not mean that the remaining six percent of respondents did not find the 340B program important. One possible reason that this small subset of entities did not report using savings in one of the provided categories is because several of these respondents are newly eligible entities and may not have felt that they had enough experience with the program to report how savings have been reported. Another possible reason could be that the entities’ use of the program was not included in the provided categories.

Specifically, section II covers the ways in which respondents utilize 340B program savings to reduce patient costs and copayment amounts. It also presents data on the use of 340B to offset low reimbursement from public and private sources of insurance. Section III discusses how 340B program savings impacts patient access to and quality of pharmaceutical services offered by the respondents. The final section lays out other issues mentioned by 340B participants; particularly, the continuing challenges with obtaining certain products at the 340B price, the desire to see the discount program extended to drugs used in inpatient settings and the missed opportunity for savings for entities made eligible for 340B through PPACA.

I: 340B PROGRAM SAVINGS ARE CRITICAL TO SAFETY NET HOSPITAL OPERATIONS

The 340B program does not cost taxpayers; rather, it stretches tax dollars to serve more patients and provide more services. The value of the savings afforded through the 340B program translates into benefits that are quantifiable, such as the cost reduction on drug purchases; however, the survey respondents also see value from the program in several other ways. Because the 340B program has been around since 1992, for many respondents, the program has become an integral part of everyday operations—so much so that all respondents reported that the savings stemming from 340B participation are important to the operation of their institution, with the vast majority characterizing the savings as critical.

Consistent with the legislative intent of the 340B program, the discounts allow participants to maximize the limited resources that they have as safety net providers. As such, the vast majority of respondents (83 percent) agreed that the program was essential to the continuity of their operations. Even more compelling, 98 percent of respondents reported that a loss of access to 340B would result in a number of negative consequences to both the institution and the patients served.

100 percent of respondents reported that savings from the 340B program are important to the operation of their organization, with 85 percent citing them as critically important

On a scale of one to five, with one being not important and five being critically important, all responding organizations rated the 340B program as a three or higher. Out of these responses, 85 percent of characterized the savings garnered through participation in the 340B program as critically important to the operation of their organization.

83 percent of respondents attribute the continuity of operations to the savings accessed through the 340B Program

According to a 1992 committee report for the US House of Representatives, the legislative intent behind the 340B program was so that covered entities could “stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.” Based on the responses received, it is clear that the cost reductions afforded through the 340B program have allowed hospitals to maintain broader operations, including the provision of necessary, non-pharmacy services for patients. For example, a number of respondents specifically reported using 340B savings to offset low reimbursement for general, non-pharmacy care. According to Donald Davies, Pharmacy Government Programs, Indiana University Health, Indianapolis, IN, 340B savings “enable us to cover Medicare/Medicaid reimbursement shortfalls for inpatient services.”

“The main purpose of our 340B savings is to help with the operations of the entire hospital. Our DSH % is [greater than] 28% so we serve a lot of poor patients. Our payer mix is weighted significantly toward Medical Assistance and Medicare…[i]n general, these don’t cover our costs. The savings from the 340B

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Respondents described 340B program savings as essential to providing comprehensive patient care in line with their mission to serve those most in need.

SNHPA members serve a high number of Medicaid, uninsured and underinsured patients. Serving those that are most in need is the underlying mission of these hospitals and clinics. Several of the respondents provided testimonials that 340B savings enables them to reduce charges and provide uncompensated care to hospital patients. Ms. Walker of St. Francis Hospital in Wheaton, Milwaukee, WI, also said that 340B “increases our ability to provide free care for indigent patients.” In essence, the savings gleaned from participation in 340B help to offset the high cost of drugs, thus allowing these hospitals to serve those greatest in need.

“Our Health System provided about $180,000,000 in free care last year via the ER and non-compensated hospital service along with clinic provided services. We could never provide these services to the residents of Detroit without the 340B program. We would have to turn the patients away.” - Daniel Kus, VP, Pharmacy Services, Henry Ford Health System, Bingham Farms, MI

According to Mark Milburn, Director, Jewish Hospital & St. Mary’s Healthcare, Louisville, KY, “Without access to the 340B drug discount program we would be severely limited in our ability to provide care for uninsured and underinsured individuals at this level. The loss of the 340B benefit would result in a complete change in the provision of pharmacy services at JHSMH and the loss of programs that greatly serve our community and state.”

The savings from the 340B program are also seen as essential to the operations of safety net hospitals in rural areas. Florette Redmond, Director of Pharmacy, Franklin Memorial Hospital, Farmington, ME stated that “[W]e are a sole community hospital located in a rural area with many under-insured or uninsured patients. Loss of the 340B program would be another threat to the viability of the hospital.”

98 percent of respondents reported that eliminating 340B savings would adversely impact the organization and its patients

Nearly all of the survey respondents stated that their organizations and patients would be negatively impacted if the 340B program were no longer available. The 340B program, though structured as a provider benefit, ultimately provides a benefit for patients. Moreover, it is an efficient way to benefit patients because it helps finance comprehensive pharmacy services which saves tax dollars by avoiding unnecessary emergency room care or hospital admission.

Hospitals reported on a number of adverse effects that would stem from losing 340B savings. At the top of the list, 77 percent of respondents stated that without 340B, the uninsured and underinsured patients that receive services at their organizations would see higher drug costs. Gene Rhea of Duke University Medical Center in Durham, NC, said, “A reduction in the scope of our program would have a significant impact on our organization and force us to significantly reduce care provided for uninsured and underinsured patients.”

Many other respondents (74 percent) also indicated that if the savings from 340B were no longer available, the pharmacy departments would suffer through staff reduction. According to Val Hallman, Director of
Pharmacy Administration, Grady Health System, Atlanta, GA, “[t]he pharmacy is currently at ‘break even’ level. Any cut in funding will result in reduction in staffing and services and probable closing of one or more pharmacies.” Ramesh Patel, Director of Pharmacy Services at Swedish Covenant Hospital in Chicago, IL added, “Without 340B help, our outpatient pharmacy would not be able to survive!” Rounding out the top three, 72 percent of respondents reported that eliminating 340B would reduce pharmacy services, such as patient counseling and education. This last category suggests that, although 340B savings can be used to support general hospital administration, it is not at the expense of the services provided through the pharmacy department.

Chart 3, below, illustrates how eliminating the 340B program would impact organizations and their patients.

II: 340B PROGRAM SAVINGS REDUCE THE COST OF PHARMACEUTICALS TO VULNERABLE PATIENTS

The 340B program allows pharmacies to reduce the upfront costs of inventory to the hospital, which can translate into reduced costs for patients. Over half of survey respondents own one or more outpatient pharmacy that routinely fills prescriptions for low-income patients of the hospital as separate from the care provided by the hospital. Within the outpatient pharmacy setting, respondents noted multiple ways in which a hospital reduces the price of prescription drugs paid by patients, such as providing nominally priced drugs, reducing co-pays, or reducing drug charges based on a sliding fee scale.

In contrast, hospitals without a separate outpatient pharmacy typically dispense outpatient drugs to low-income patients as part of their visits and may classify these transactions within the broader category of charity care. Simply put, the cost of the prescriptions can be a separate charge when dispensed by the outpatient pharmacy, as opposed to when it is grouped together in an all-inclusive rate by the hospital. Because the “charity care” provided by these hospitals is at no or nominal cost to the patient, hospitals may not perceive the savings afforded through 340B as reducing the “price” of a drug; instead, it appears that these hospitals see the savings as valuable in offsetting the overall cost of providing “charity care.”

According to the National Association of Public Hospitals and Health Systems (NAPH), the approximately 140 safety net hospitals in their organization provide about 20 percent of all uncompensated hospital care in the
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US, even though they represent only two percent of all US hospitals. Virtually all of NAPH’s membership overlaps with SNHPA’s membership; as such, similar levels of uncompensated care would likely apply.

To demonstrate that an institution’s participation in 340B demonstrably and directly benefits the hospital’s indigent patients, SNHPA recommends that its member hospitals formally affirm their commitment to provide and expand access to pharmaceutical care for vulnerable patients consistent with the goals of the 340B program. SNHPA recommends that member hospitals have in place a charity care policy that specifically addresses their use of the 340B program in the outpatient pharmacy arena.

74 percent of respondents with an outpatient pharmacy reported using 340B savings to reduce the price of prescription drugs paid by patients

Nearly three-fourths of respondents that own or operate an outpatient pharmacy credited 340B savings for reducing the price of medications paid by patients. Craig Harvey, Pharmacy Director for Regions Hospital in St. Paul, MN, said, “340B provides the opportunity to provide medications to patients in need who are unable to pay retail price. In some cases, medications are provided at no charge to the patient to prevent subsequent hospitalization.”

Chart 4 provides a breakdown of the variety of mechanisms used by respondents that own an outpatient pharmacy to reduce prices paid by patients.

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**Chart 4: If your organization owns 1 or more outpatient pharmacies, does it use 340B savings to reduce the price of prescription drugs paid by patients?**

- Yes: 74%
- No: 26%

**In which ways are patient prices reduced?**

- Allows uninsured patients to receive prescription drugs at no or reduced cost: 86%
- Eliminates or reduces co-payments: 40%
- Reduces prices associated with sliding fee scale: 36%

*Notes: Percentages do not add to 100 percent because respondents could select more than one option.*
Of the twenty-six percent of respondents that did not report using 340B savings to reduce the cost of drugs to patients, 88 percent answered that they use 340B savings in one of the other categories provided: maintaining broader hospital operations, increasing patient access, and providing increased pharmacy services. 86 percent of respondents that use 340B in their outpatient pharmacies to reduce the price of prescriptions for patients reported that 340B savings allows uninsured patients to receive prescription drugs at little to no cost.

The majority of responding hospitals that use 340B in their outpatient pharmacies use the savings accessed through the program to provide drugs to uninsured patients at no or reduced costs. According to Frank Barnes, Pharmacy Business Manager, University of North Carolina Hospitals, Chapel Hill, NC, accessing savings from the 340B program “[a]llows us to afford giving free or highly-discounted drugs to many patients who otherwise could not afford them. 71%-75% of our outpatient pharmacy patients are completely indigent.” Finally, Val Hallman, Director of Pharmacy Administration, Grady Health System, Atlanta, GA said, “340B is critical to continued operations of our outpatient pharmacies. The Grady Health system provides more than 625,000 prescriptions a year to uninsured patients.”

Forty percent of respondents that use 340B in their outpatient pharmacies to reduce the price of prescriptions for patients use 340B savings to cover patient co-payments.

Of the respondents with an outpatient pharmacy, 40 percent reported that the savings from 340B help to reduce patient co-payments. Unlike other discount mechanisms that are focused on patients who have no insurance, reducing patient co-payments also benefits those patients that may be underinsured, an issue that impacted an estimated 25 million adults in the country in 2007, up 60 percent from 2003.7

Reductions in co-payments made available through 340B savings benefit those covered by public insurance programs, namely Medicaid and Medicare. Many Medicaid and Medicare beneficiaries experience difficulty with their drug co-payments; the safety net hospitals who serve them have responded by waiving or reducing the co-pay. Of course, such co-pay waivers and reductions must comply with federal anti-kickback laws. For example, per the Medicare Modernization Act of 2003, which created the Medicare Part D program, as long as pharmacies adhere to rules prohibiting advertisement of the waiver or reduction of cost-sharing amounts for Part D beneficiaries, they are in compliance with the anti-kickback statute. The Health Resources and Services Administration (HRSA), which oversees the 340B program, has clarified that, provided 340B pharmacies follow these rules, waivers and reductions paid for by pharmacies will count toward a beneficiary’s true out of pocket expenses.8

Responsibility for co-payments is a particularly critical issue for those patients on multiple medications, as the burden on the patient increases with the complexity of the drug regimen. The 6 million very sick and low-income patients, who were previously classified as “dual eligible” and now receive drug benefits through Part D, use at least 10 more prescription drugs than non-dual eligible beneficiaries.9 Michael Bonck, Manager, Pharmaceutical Services, Franciscan Health System, Tacoma, WA explained that the 340B program “[r]educes co-pays for the dual eligible Medicare/Medicaid patients as our state is no longer paying co-pays for them.”

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Respondents also indicated that the 340B program helps reduce the co-payments for Medicare beneficiaries obtaining pharmaceuticals through Part B. Medicare beneficiaries receiving physician-administered drugs are responsible for 20 percent of the cost of the drug. Because many of the drugs covered by Part B are very expensive chemotherapy or other physician-administered products, co-payments can be a financial hardship for many patients. For patients seen in an outpatient oncology clinic, 340B can help reduce the overall percentage that patients covered by Medicare Part B are liable for.

More than two-thirds of respondents report using 340B savings to offset low pharmacy reimbursement

More than two-thirds (68 percent) of survey respondents rely on the 340B program to offset low pharmacy reimbursement from commercially under-insured, Medicaid or Medicare patients. In many cases, the amounts that Medicaid and Medicare reimburse for pharmacy services do not adequately cover costs. One advantage that the 340B program offers its participants is a lower acquisition cost relative to the reimbursement limits set by the state or federal government. As such, the 340B program helps sustain uninterrupted access and service to these patients by closing the gap on their cost and the price reimbursed. Because patients covered by public insurance programs make up the majority of these hospitals’ patient populations, making up the difference through the advantages that the 340B program offers is vital to the continuity of operations.

Chart 5 breaks down the payers for which respondents use 340B savings to offset low pharmacy reimbursements.
Again, just because an entity did not report using 340B savings for this purpose does not detract from the importance of the program to the entities. In fact, of the 32 percent of respondents that did not report using 340B savings to offset low pharmacy reimbursement, 84 percent answered that they use 340B savings in one of the other categories provided: maintaining broader hospital operations, increasing patient access, and providing increased pharmacy services. Out of the respondents that use 340B savings to offset low pharmacy reimbursement, 93 percent use the savings to offset low payment from Medicaid.

As stated above, the reimbursement from state Medicaid agencies may not always cover costs. According to Ms. Hallman of Grady Health System, “Medicaid reimbursement is set at actual acquisition cost plus a low dispensing fee. This reimbursement does not cover our costs.”

The challenge that 340B hospitals face with low Medicaid reimbursement is anticipated to grow as safety net hospitals begin to serve a disproportionate share of newly eligible Medicaid beneficiaries under health care reform. To implement health care reform, the federal government will rely heavily upon Medicaid to expand insurance coverage. According to the Congressional Budget Office (CBO), PPACA will increase Medicaid and Children’s Health Insurance Program (CHIP) coverage by 16 million by 2019. With regard to 340B drugs, the problem of low Medicaid reimbursement for 340B drugs is exacerbated because, in many instances, state Medicaid programs require providers to bill their 340B drugs to Medicaid at acquisition cost plus a small dispensing fee, which does not come close to covering the costs of comprehensive pharmacy services, including drug preparation, counseling, and administrative overhead. The Medicaid reimbursement gap poses a significant financial challenge to 340B providers because they treat a disproportionate share of Medicaid enrollees. Faced with this reality, safety net providers will continue to be dependent on reduced drug costs to offset the losses incurred in treating the uninsured, the underinsured, and the Medicaid population.

Out of the respondents that use savings to offset low pharmacy reimbursement, 84 percent use it to offset low payment from Medicare.

In addition to covering costs of low Medicaid reimbursement, 84 percent of respondents communicated a similar issue with the extent that Medicare reimburses for Part B services. According to Terry Kirkpatrick, Director of Pharmacy Services, Saint Mary’s Health Care, Grand Rapids, MI, “CMS reimbursement for J-coded chemotherapy outpatient medications is below our acquisition cost for almost half of billings. 340B savings on non-Medicaid drug costs is critical to the financial viability of outpatient chemotherapy treatment.”

Out of the respondents that use savings to offset low pharmacy reimbursement, 59 percent use it to offset low payment from commercial payers.

The issue of insufficient reimbursement is not limited to public payers. In fact, 59 percent of respondents expressed similar concerns with the adequacy of payment from commercial insurance. 340B covered entities rely on savings from commercial payer reimbursement to achieve overall savings from the 340B program. HRSA recognizes that the 340B program generates additional resources for safety net hospitals by lowering drug acquisition costs and maintaining revenue from health insurance reimbursements. HRSA explains, “If the covered entities were not able to access resources freed up by the drug discounts when they . . . bill private health insurance, their programs would receive no assistance from the enactment of section 340B and there would be no incentive for them to become covered entities.”

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It is anticipated that low reimbursement from commercial payers will only increase after the implementation of state-based health insurance exchanges mandated by health care reform in 2014. The CBO estimates that by 2019, approximately 24 million people will purchase health insurance through the state health exchanges. These 24 million people are more likely to be in poorer health than those who currently have private health insurance. Sixteen million of these individuals would be uninsured, if not for the federal subsidies they will receive to purchase coverage through the exchanges. As many policy experts anticipate shortages of primary care providers for this new population of insured individuals, safety net providers will take the lead in providing care for them. These hospitals will continue to rely upon reduced drug costs to deal with this significant population of unhealthy individuals.\(^{11}\)

**III: 340B PROGRAM SAVINGS INCREASE ACCESS TO AND QUALITY OF PHARMACEUTICAL SERVICES FOR VULNERABLE PATIENTS**

A high priority for 340B hospitals' pharmacy departments is the quality of the service being delivered to patients. The Institute of Medicine’s (IOM) 2006 report, *Preventing Medication Errors*, recognizes the importance that pharmacists and pharmacy services play in the health care system’s strategies to reduce adverse reactions and other negative outcomes stemming from medication errors.\(^{12}\) Interestingly, the IOM’s proposed solutions for reducing medication error and improving patient safety include patient counseling and education, medication therapy management programs focused on high risk patients, and medication reconciliation across continuity of care points—all items mentioned by survey respondents as made possible by the savings from 340B.

75 percent of respondents reported using 340B savings to increase patient access to prescription drugs

Patient access to prescription drugs can broadly be defined as the ability to obtain prescription drugs when needed. More specifically, the term “access” can relate to the affordability or the availability of medications. Three-fourths of survey respondents affirmed that 340B program savings helped to increase patient access to prescription drugs.

Of the 75 percent of survey respondents that confirmed the 340B program helps increase patient access, 93 percent use 340B savings to enhance the pharmacy department’s or clinic’s ability to serve the uninsured or underinsured. In other words, 340B savings helps to aid patient access to medications, in spite of whether they can afford their prescriptions. In fact, multiple respondents mentioned the connection between the 340B program and the ability to adequately provide medications to their patients. Philip Rioux, Director of Pharmacy for Central Maine Medical Center in Lewiston, ME, said that 340B, “[e]nables us to have more resources to serve more patients, including those who are uninsured or underinsured.” Michael Magee, Director of Pharmacy for St. Joseph’s Hospitals in Tampa, FL, added that 340B, “[h]elps provide greater access to those underserved patients by offsetting the high cost of pharmaceuticals to our DSH.”

On the following page, Chart 6 depicts the number of ways in which the 75 percent of survey respondents categorize how they utilize 340B savings to increase patient access to prescription drugs.

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Of the 25 percent of respondents that did not report using 340B savings to increase patient access, 75 percent answered that they use 340B savings in one of the other categories provided: maintaining broader hospital operations, increasing patient access, and providing increased pharmacy services.

Respondents also rely on 340B savings to serve more patients, maintain sufficient supply to meet patient demand and offer an adequately staffed outpatient pharmacy.

For respondents that report using 340B savings to increase pharmacy access, 71 percent responded that 340B savings increases the total number of patients served by the pharmacy department. Specifically, Paul Carrier, Director of Pharmacy for Tift Regional Medical Center in Tifton, GA, said, “[o]ur hospital provides services regardless of a patient’s ability to pay. Without the 340B program, we would not be able to provide some of those services for uninsured patients and still remain financially viable.”

Furthermore, 67 percent responded that 340B savings help maintain an adequate supply of inventory to meet patient demand. One of the important benefits of the 340B program is the ability to acquire inventory at a reduced upfront cost, which helps these facilities manage cash flow. A lower cost at the point of purchase can mean that a hospital’s supply meets patient demand.
Sixty-four percent of responding organizations use 340B savings to maintain an outpatient pharmacy and keep it properly staffed. To many hospitals, access to medications is equated with having outpatient pharmacies in the community so that patients do not have to travel/return to the hospital to pick up prescriptions. According to Amy Gutierrez, Chief Pharmacy Officer and Director of Pharmacy Affairs, Los Angeles County Department of Health Services, Los Angeles, CA, “340B savings allows our organization to maintain operations at 18 outpatient pharmacies, allowing increased access to uninsured patients with no other options.”

To some respondents, 340B savings enable them to offer specialized pharmacy programs such as chemotherapy or infusion therapy that they otherwise could not afford to provide.

Several respondents indicated the importance of 340B savings with regard to the ability of the hospital to offer chemotherapy or infusion therapy. David Pearson, Pharmacy Director, Kadlec Regional Medical Center, Richland, WA, said, “Without the 340B program, our hospital based outpatient chemotherapy infusion service would most likely be discontinued or sharply curtailed.” Scott Butler, 340B Program Coordinator, Mercy Health Partners, Muskegen, WI, added that the 340B program “[e]nables us to serve uninsured patients in the chemotherapy arena. We write off hundreds of thousands of dollars yearly due to uninsured patients.”

In the case of some respondents, 340B program savings are directly linked to preserving their role as the sole providers of these expensive therapies within their communities. According to Terry Kirkpatrick, Director of Pharmacy Service, Saint Mary’s Health Care, Grand Rapids, MI, “We have the only comprehensive cancer treatment center in our region. The program would be thrown into financial loss on most outpatient business without 340B and this would threaten the viability of the entire program. Many jobs would be in jeopardy and countless patients would need to travel long distances for proper treatment if the program becomes financially non-viable.”

Over half of responding organizations reported using 340B savings to support cost-effective and patient-focused pharmacy services

54 percent of all respondents stated that they use savings from 340B to provide enhanced pharmacy services, such as medication therapy management (MTM), patient assistance programs, and disease management programs.

Of the 46 percent of respondents that did not report using 340B savings to support cost-effective and patient-focused pharmacy services, 88 percent answered that they use 340B savings in one of the other categories provided: maintaining broader hospital operations, increasing patient access, and providing increased pharmacy services.

Forty-three respondents connect the savings from 340B to the ability to implement a medication therapy management program.

Forty-three survey respondents credit 340B savings to the implementation and continuation of a medication therapy management (MTM) program. MTM programs are designed to reduce adverse drug reactions, drug interactions, ineffective therapy and treatment failures by increasing patient education, counseling, and medication review by a pharmacist. An analysis of an MTM program designed for city employees in Ashville, NC, known as the Asheville Project, found that the MTM resulted in cost savings by reducing unnecessary services and sick days for participants. The value of MTM was further confirmed by researchers at the University of Minnesota who found that MTM services administered in the state resulted in a 31 percent
reduction in total health expenditures per patient, from $11,965 to $8,197, and a 14 percent increase in
meeting patient’s goals. The savings exceeded the cost of MTM services by more than 12 to 1.13

Respondents indicated that they are using 340B savings to implement MTM programs in an effort to improve
patient care and reduce overall health costs. For example, Mr. Patel of Swedish Covenant Hospital, Chicago,
IL, stated, “We have started [a] medication therapy treatment clinic to assist patients and reduce adverse
drug events & drug cost[s] to [the] health system.” Donald Davies, Pharmacy Government Programs, Indiana
University Health, Indianapolis, IN, added, “We have several MTM [programs]; including HIV clinics, dialysis,
and transplant. We have been able to add clinic pharmacists to work with discharge patients group that
pose a higher risk of hospital readmission.”

Seven survey respondents specifically mentioned providing anti-coagulation clinics as part of their MTM
programs. An anti-coagulation clinic helps patients monitor and manage medications used to prevent blood
clots, namely warfarin (also known as Coumadin ® or Jantoven ®). Because of potentially fatal side effects,
patients on warfarin must be closely monitored. Anti-coagulation clinics have been shown to improve patient
outcomes by reducing adverse events and decreasing use of hospital and medical services.14

In addition to improving patient outcomes and reducing hospital costs, increased use of MTM programs can
reduce healthcare costs for Medicare and Medicaid patients, as well as commercially insured patients.
According to Mr. Barnes of University of North Carolina Hospitals, “[340B] has allowed us to greatly enhance
our counseling and MTM, which in turn reduces Emergency Department visits and thus saves money for
Medicaid and Medicare.”

Use of 340B savings to implement MTM programs is also helping respondents meet finance requirements to
become accountable care organizations (ACOs) and meet other performance objectives. An ACO is an
organization of health care providers that agrees to be accountable for the quality, cost, and overall care of
patients. Under the new health reform law, beginning January 1, 2012, Medicare will contract with ACOs as
part of the Medicare Shared Savings Program. Under this program, Medicare will provide increased
payments to ACOs that meet certain quality performance standards. Given the success of MTM programs to
improve health outcomes, organizations may look to expanding or providing new MTM services as one
method to help meet performance standards. As Mr. Davies of Indiana University Health wrote, “340B
affects the bottom line that is helping us create an ACO per PPACA recommendations.”

MTM programs can include the process of medication reconciliation, which is now required as part of Joint
Commission on Accreditation of Healthcare Organizations’ (JCAHO) patient safety goals.15 Medication
reconciliation is the process of comparing a patient’s prescription to all the medications that the patient has
been taking. The object of medication reconciliation is to prevent omissions, duplications, dosing errors, and
drug interactions. Respondents noted that they use 340B savings to complete medication reconciliation.
According to Ryan Majchrzak, Clinical Economics Specialist, Bayhealth Medical Center, Dover, DE, “We are
currently using the 340B savings as a means to get FTEs approved for pharmacist-conducted medication
reconciliation at our hospital in order to fulfill the new JCAHO patient safety goal.”

13 Isetts BJ, Schondelmeyer SW, Artz MB, et al. Clinical and economic outcomes of medication therapy management services:
15 http://www.jointcommission.org/npsg_reconciling_medications/
A number of respondents (43) also reported using 340B savings to maximize the benefits and savings of patient assistance programs (PAP).

Forty-three respondents also reported using 340B savings to maximize benefits and savings of PAPs. Offered by pharmaceutical manufacturers for certain drugs, PAPs provide free or highly discounted drugs to patients who cannot afford the cost of medications. Because each manufacturer has its own eligibility and documentation requirements, accessing PAPs can be difficult to navigate, and it is not unusual for organizations to spend significant staff time and resources helping patients access and enroll in these programs. Although administering a PAP at the pharmacy level can be costly to the organization, maximizing these programs can help stretch scarce resources even further. In particular, PAPs can be useful for offsetting the cost of expensive medications for chronic conditions.

Val Hallman, Director Pharmacy Administration, Grady Health System, Atlanta, GA, explained, “we utilize patient assistance analyst positions to allow us to maximize patient assistance program applications.” Melissa Maeker, Director of Pharmacy, University of Texas Health Science Center at Tyler, Tyler, TX, added that accessing 340B savings “allows us to adequately staff with pharmacists so that we have time to counsel each new patient as well as provide a technician to assist patients maximizing use of patient assistance programs.”

Savings from 340B “enables us to utilize consulting services that help us to maximize our use of Prescription Assistance Programs. This helps our patients to gain access to drugs that they couldn’t otherwise afford for maintenance of chronic health conditions, thereby reducing readmission rates due to relapse of these conditions.” - Ryan Majchrzak, Clinical Economics Specialist, Bayhealth Medical Center, Dover, DE

Thirteen respondents specifically mentioned that they have implemented a disease management program with 340B program savings.

According to Karl Hoffpauir, Director of Pharmacy, LSU, Walter O. Moss Regional Medical Center, Lake Charles, LA, his organization has implemented a “very effective disease management program as a result of 340B program.”

Disease management (DM) programs seek to improve quality of care and reduce health care costs through better monitoring and education, coordination of care among providers and settings, and use of best medical practices. DM programs often focus on chronic conditions, such as diabetes, chronic heart failure, and asthma. Because spending on the 30 percent of people with chronic disease, over $1.5 trillion, accounts for more than 75 percent of health spending in the United States, successful DM programs are viewed enthusiastically as one potential avenue for significant cost reduction.

Research also shows that DM programs—especially information technology enabled DM programs—improves patient satisfaction, decreases patient hospitalization, and decreases the cost of treating referred patients for

the entire health care system. One DM program for patients with congestive heart failure saw improved medication dosing and decreased hospitalization, but also saved the health system a median of $8,571 per patient per year.

Respondents also included improvements to technology as another key example of how 340B savings improve pharmacy services.

Select respondents reported that the savings from 340B are used toward upgrades in technology that, in turn, improve the delivery and safety of pharmacy services. Enhancing technology interventions has been shown to help considerably reduce medication errors and notable yield cost savings to health systems. As Madelline Collazo, Director of Pharmacy Services, Singing River Health System, Pascagoula, MS, stated, “We were able to purchase automation that allows us to use the pharmacist on clinical functions more effectively.”

Health information technology in the pharmacy department is particularly useful in the management of patients with chronic conditions and complex medical records. Studies have shown that improved technology can improve patient outcomes and control costs.

IV: OTHER ISSUES FACING SURVEY RESPONDENTS

In addition to collecting data on the many benefits that the 340B program offers its participants, the survey solicited information on the extent to which hospitals experienced difficulty in obtaining drugs at the 340B price. Further, many respondents volunteered feedback on two other issues that the survey did not explicitly inquire about: first, the inability to access 340B discounts on inpatient drugs, and, second, on the challenges of the orphan drug exclusion for entities made eligible by PPACA.

40 percent of respondents reported difficulty obtaining covered outpatient drugs at the 340B price

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A persistent challenge faced by 340B hospitals has been difficulty in obtaining certain products at the 340B price. In 2006, a SNHPA survey specifically examined the availability of intravenous immunoglobulin (IVIG) at the discounted price and found that the “incidence of unavailability of IVIG product at 340B pricing levels does not correspond with unavailability of product supply, and frequently IVIG is available for purchase, but just not at discounted, 340B prices.” Given the extent of survey responses, it appears that issues with obtaining IVIG and the blood plasma protein, albumin, at the 340B price remain.

Forty percent of survey respondents reported continued issues with shortages of certain drug products. Although the extent to which these issues are ongoing or resolved is based on the individual respondent, the response indicates there is an issue of 340B hospitals not being able to obtain products at the 340B price.

Moreover, some institutions reported that the sale of IVIG at the 340B price is contingent on whether the hospital will also use the product on the inpatient side. This is of particular concern as HRSA program guidelines on the 340B program prohibit manufacturers from requiring covered entities to agree to any such conditions in exchange for the 340B price.22

Although ten respondents specifically mentioned challenges in obtaining albumin, by far the primary issue—reported by 71 respondents—was access to IVIG at the 340B price. Christopher Day, Director of Pharmacy, Blue Ridge Regional Hospital, Spruce Pine, NC, stated, “Some companies have a 340B ‘allotment’ for specific products (i.e. IVIG).” According to Michael Molby, Director of Pharmacy Services, CaroMont Health, Gastonia, NC, “We are often unable to obtain the total quantity of IVIG that we are entitled to purchase.” Terry Kirkpatrick, Director of Pharmacy Services, Saint Mary’s Health Care, Grand Rapids, MI, added, “Until about 18 months ago, we could not get IV Immune Globulin at 340B pricing, but could get any amount we needed at a non-340B price.”

Isabell Pacheco, Manager, Harris County Hospital District, Houston, TX contributed, “HCHD has had problems accessing drugs at 340B pricing as a result of backorders and shortages, in addition to IVIG and Coagulation products…At times, HCHD is able to obtain drugs directly [through] alternate sources such as direct from manufacturers or compounding pharmacies. Access problems affect our patients in several areas, namely the risk of medical errors due to dosing or frequency of administration when forced by a shortage to use alternative drugs. In worse cases, there is no access to the drug at all or delay in therapy. On average, HCHD spends over $495,000 annually due to access issues.”

Over the past year, the entire US health care system has been plagued with shortages of a variety of products due to issues with raw materials, changes in the number of manufacturers, or supply-chain issues; however, the issue reported by the respondents in this survey is different. The hospitals argue that while shortages of drugs exist for a variety of reasons, a shortage based on the price is unfair. Not only does it directly impact the availability and quality of patient care, as demonstrated in the quote above, it also places unnecessary stress on the institution’s bottom line in a substantial way.

Support for an extension of the 340B program to inpatient drugs remains strong

Data collected from the hospitals on the total outpatient and inpatient expenditures showed that, interestingly, in over half of the cases (51 percent), the amount reported for inpatient spending exceeded outpatient spending. Because 340B pricing is not statutorily available for inpatient drugs, more than half of the hospitals that responded to this survey do not have access to the benefits of 340B discounts for the majority of their drug purchases.23

Extending the 340B program to inpatient drugs can expand taxpayer savings and, according to survey respondents, eliminate the administrative burden associated with maintaining separate inpatient and outpatient inventories. In 2008, the University of Minnesota’s PRIME Institute found that an extension of the 340B discount to inpatient purchases for all eligible DSHs would save between $1.1 billion and 1.9 billion in 2007. Expanding the 340B program to the inpatient setting would also save the federal government. According to discussions with SNHPA, congressional staff informed them that an inpatient extension would save $1.2 billion for the federal government over 10 years, as projected by the Congressional Budget Office. Though the survey did not seek to solicit input on the issue of extending 340B to inpatient purchases, a number of hospitals mentioned it as an important issue.

“The 340B program should be available for discharge and in-patient use,” commented Alexander Melchert, Director of Pharmacy, New York Hospital Queens, Flushing, NY. Peter Pascale, Director of Pharmacy, Saint Vincent Health Center, Erie PA, added, “We qualify for the program based upon meeting DSH criteria, which is based upon inpatient population. It is frustrating that we cannot get the 340B pricing extended to the inpatient drug use.”

Other comments related to the lost opportunity and administrative burden that such a segregation creates for these hospitals. According to Terry R. Clark, Director of Pharmacy, Kittitas Valley Community Hospital, Ellensburg, WA, “It is a real burden not being able to use [340B] for inpatients. It reduces the benefit of the program greatly. Currently we lose about 25% of our savings to administrative cost to meet these requirements.” Tim Wolters, Director of Reimbursement, Citizens Memorial Hospital, Bolivar, MO, echoes the sentiment, saying, “It would be very beneficial to extend the 340B program to inpatient drugs, relieving an administrative burden and providing more resources to treat the uninsured and offset Medicare and Medicaid losses.”

The orphan drug exclusion is an obstacle for newly-eligible hospitals

PPACA extended 340B eligibility to four new entity types, including critical access hospitals (CAHs), sole-community hospitals, rural referral centers, and certain free-standing cancer centers. Though participation in the 340B program should be seen as a positive step toward cost containment for these organizations, a provision added as an amendment to PPACA greatly diminishes the financial benefit that Congress intended for the program to provide its participants. One week following the passage of PPACA, the President signed into law congressional language that excluded the 340B discount for drugs designated by the Food and Drug Administration (FDA) as “orphan drugs” for the new entities. Orphan drugs are among the most costly products on the market and, consequently, represent a significant share of a hospital’s pharmacy budget. Furthermore, orphan drugs are often used for non-orphan indications that reach a much broader patient population.

23 According to SNHPA, there are some cases where manufacturers voluntarily offer the 340B price for inpatient purchases.
As a result of carving out savings on these high-cost and high-use drugs, this exclusion translates into a missed opportunity for savings, according to a number of respondents. Once again, though this survey did not ask questions about the impact of this policy, select respondents included comments that indicate the concern with this policy. For example, Lois F. Leister, Director of Pharmacy, Mendocino Coast District Hospital, Fort Bragg, CA, stated that "[a]s a CAH hospital, we are not able to purchase orphan drugs through 340B - Unfortunately, because we have an active oncology service in our rural community, this greatly effects our ability to have cost savings." Reid Horning, Pharmacy Manager, New Ulm Medical Center, New Ulm, MN, added that "[o]rphan drugs should not be excluded from 340B. There are enough other advantages of orphan drug status to offset the discount requirements of 340B entities."

In the fall of 2010, SNHPA partnered with the National Rural Health Association (NRHA) to assess the full impact of the orphan drug exclusion on newly eligible hospitals by surveying rural entities that are now eligible for the 340B program. As of October 2010, of 140 covered entities surveyed, 96 percent said repeal of the orphan drug exclusion was either “very important” or “important.” Of those organizations concerned about the orphan drug exclusion, nearly 22 percent said the exclusion may cause them to not participate in the 340B program.

**SUMMARY**

This report demonstrates the value of the 340B program to hospital systems in meeting the needs of their low-income, uninsured and underinsured patient populations while stretching tax dollars. Safety net hospitals have been using their program savings to provide, improve and expand services in innovative and cost-effective ways and will continue to rely on the program post-health care reform. As indicated by the survey respondents, without the 340B program, many safety net hospitals would have to limit services or even close their pharmacy doors. As a result, patients would lose access to health care and communities would suffer.

Because of their unique experience and expertise in meeting the demands of low-income patients, 340B providers are well equipped to treat individuals who will receive coverage through programs established by health care reform. Even after health care reform is fully implemented, there will still be tens of millions of patients who are uninsured, underinsured, or otherwise need continued access to affordable medications and comprehensive pharmacy services from their safety-net providers. The 340B program and our nation’s 340B hospitals will be essential in meeting the goals of expanding access to affordable health care.
Appendix A: Detailed Methodology
DETAILED METHODOLOGY

Scope
This purpose of this analysis is to demonstrate the value of the 340B program to hospital systems in meeting the needs of their low-income, uninsured and underinsured patient populations. When completing our analysis, we relied on self-reported survey responses. We did not independently verify information reported by survey respondents.

Data Collection
We developed a 13-question electronic survey. The survey was divided into three main parts. The first part focused on demographic characteristics, including type of hospital, number of hospitals, and methods of dispensing outpatient drugs. The second part focused on spending and savings estimates, including estimates of outpatient spending, inpatient spending, and 340B savings. The third part focused on the different ways organizations may use 340B savings, such as increasing access, reducing prices, providing additional pharmacy services, and maintaining broader organization operations.

The survey included both closed and open ended questions. Within each of the three sections, survey respondents were provided the opportunity to provide additional detail through open-ended responses.

The complete survey is included in Appendix B.

Population
For the purposes of this study, we surveyed the entire population of 632 hospitals that were SNHPA members at the time. Prior to administering the survey, we reviewed SNHPA’s membership list and grouped member hospitals by health system. SNHPA’s member hospitals have a multitude of unique organizational structures, where some member hospitals are independent while others are part of a larger health system. Further, there are varying levels of centralization within hospital systems.

To ensure the survey appropriately reflected the unique organizational structure of hospitals and health systems, we allowed SNHPA members to respond to the survey in the way that made the most sense to their organization. In other words, some surveys were completed for one individual SNHPA member while other surveys were completed for multiple SNHPA members.

Survey Administration
We administered the survey by email in February 2011, with a final deadline of March 4. To follow-up with non-respondents, we sent out two reminder emails to contacts at member hospitals without a completed survey.

Email addresses were obtained from SNHPA’s membership list. Because SNHPA’s membership list often has multiple contacts for each member hospital, survey respondents were instructed to coordinate with coworkers and limit responses to one response per member hospital. Additionally, survey instructions provided contacts with the option of responding on behalf of the larger, overall health system, instead of individual member hospitals, when appropriate.

Prior to our analysis, we reviewed survey responses to identify any instances where more than one survey was submitted on behalf of a member hospital. We identified instances where a survey was completed on behalf of the individual member hospital and the larger health system, including the member hospital. In these instances, we included only the survey response completed for the larger health system in our analysis. We
also identified instances where a survey was completed by more than one contact at an individual hospital. In these instances, we included only the most recently completed survey in our analysis.

Response Rate
After eliminating duplicates at both the individual and organizational level, we received 298 survey responses. These surveys represented 381 SNHPA members, for a response rate of 60.3 percent. Of these 298 responses, 8 were from organizations that stated that they do not participate in the 340B program. Because this analysis is focused on the use of 340B savings by participating organizations, we excluded these eight responses from our analysis, leaving 290 responses.

In total, the 290 survey responses represent 433 individual hospitals. Most survey responses (79 percent) are for only one hospital and 19 percent are for a larger health system. The remaining 2 percent are for networks of health clinics. Many health systems include 340B eligible clinics as well as hospitals. While some respondents included their clinics within the response for their hospital(s), others responded separately. Because respondents were allowed to respond in the way that made the most sense to their organization, separate responses for networks of clinics were included within the analysis.

Prior to our analysis, we reviewed basic characteristics of SNHPA’s membership to determine if responses represent a broad cross-section of 340B participants. Our review confirmed that respondents varied in size, outpatient drug spending, type and geographic location. The “Diversity of Respondents” section at the end of this appendix provides additional demographic information on respondents.

Analysis
When analyzing survey responses, we used the survey response as the unit of analysis. We believe that by allowing organizations to self-select how they responded (i.e. as an individual hospital or a health system), we are able to best represent how respondents see themselves, and, in particular we do not overweight responses regarding use of 340B savings towards larger or more centralized organizations. Additionally, we did not weight survey responses by number of hospitals because responses could include information on associated clinics as well as the hospitals. As a result, it is not possible to parse out the hospital-only information that would be required to weight survey responses by number of hospitals.

Quantitative Analysis
We analyzed closed-ended survey responses to calculate overall estimates of 340B savings and to determine how respondents are using savings within their organization. We analyzed survey responses based on demographic information provided by respondents, including size, hospital type, outpatient pharmacy spending, methods of dispensing outpatient drugs, and estimated savings rates.

To calculate the percentage of savings associated with participating in the 340B program, we divided the dollar estimate of savings by the sum of the total estimated outpatient spending and the dollar estimate of savings provided by the respondent. This calculates the percentage estimated to be saved based on the amount that would have been spent had the organization not participated in the 340B program.

When analyzing closed-ended survey responses, we excluded any survey responses that did not have a response to the question from our analysis. Table 2, below, provides rates of non-response by survey question.
Some of the responses to question #8 deserve special attention. Question #8 asks whether the organization uses 340B savings to reduce drug prices to patients. If respondents checked “yes,” they were given the option to elaborate by selecting from a list of multiple-choice statements. It was included in the survey because it mirrors questions that can be found in earlier 340B studies. In retrospect, however, our survey should have been more specific about the kind of outpatient drugs to which the statement applies.

Hospital drugs that are dispensed by a hospital outpatient pharmacy are billed differently than hospital drugs administered or dispensed as part of a hospital outpatient visit or procedure. The latter category of drugs, sometimes referred to as physician-administered or clinic-administered drugs, are generally billed through the hospital’s cost report (on the UB-04 form) whereas the former group of drugs are billed by the pharmacy under a pharmacy-specific billing number. Pharmacy billing systems are designed to bill different parties at different rates, so it is more likely that hospitals are able to reduce the price of drugs for some patients.

The same is not true for physician-administered drugs. Most hospital chargemasters can only accommodate billing at one rate. So a hospital would not be able to bill one patient at a reduced price, without billing every patient and their payers at the same rate. For this reason, hospitals generally bill their physician-administered drugs at a standard rate that is known as the “usual and customary” rate.

It is worth noting that, just because hospitals generally bill their physician-administered drugs at usual and customary rates, this does not mean that patients are necessarily paying at those rates. It is not uncommon for hospitals to reduce what they actually collect on those drugs, or to forgo collecting payment altogether. In this case, the hospital considers the lost revenue as bad debt or charity care. But regardless of how it is characterized, the patient benefits by not having to pay full price for the drug or not having to pay at all.
To better reflect these operational issues, we post-stratified the responses to distinguish between respondents with and without outpatient pharmacies and focused our analysis on respondents that reported owning or operating at least one outpatient pharmacy.

**Qualitative Analysis**

For open-ended responses provided by respondents, we systematically grouped responses into categories based on our qualitative analysis of key words or phrases. After completing our initial phase of categorization, we performed text analysis by conducting word searches within open-ended responses to ensure the responses were appropriately characterized. In addition, we cross-referenced open-ended responses with closed-ended surveys to confirm the internal validity of survey responses.

We sought permission to use the quotes included in the report from each of the respondents. If respondents provided clarification to their quotes during this follow-up, we included the revised quote.

**Diversity of Respondents**

We reviewed basic characteristics of SNHPA’s membership to determine if responses represent a broad cross-section of 340B participants. Our review confirmed that respondents varied in size, outpatient drug spending, type and geographic location. Respondents were located in 45 states and the District of Columbia.

Respondents covered all six eligible hospital types, including newly eligible entities. However, most responding organizations (83 percent) represent at least one disproportionate share hospital (DSH). Given that DSHs make up the majority of eligible hospitals, it is expected that most respondents represent at least one DSH.

Twelve percent of respondents include at least one associated 340B eligible clinic as part of the organization. The number of clinics ranged from 1 to 20. Types of clinics varied and included federally-qualified health centers (FQHC), FQHC-look alikes, consolidated health centers, hemophilia treatment centers, and Ryan White clinics to name a few.

The size of respondents varied, with 23 small organizations having 25 or fewer total hospital beds and 21 large organizations having greater than 1,000 hospital beds. On average, respondents reported 497 hospital beds, with more than half of respondents having more than 340 hospital beds.

Within the survey responses, there are varying levels of outpatient drug spending. On average, respondents reported almost $12 million total outpatient drug spending. However, the range of spending varied greatly from $100,000 to $120 million. More than half of respondents reported total outpatient spending of more than $5 million.
Appendix B: SNHPA Member Survey
The purpose of this survey is to provide information on both the direct and indirect ways in which the 340B drug discount program benefits your organization, its patients and your community. Please submit responses by Friday, March 4. If you have questions at any point, please contact Mike Hess at mike.hess@snhpa.org or 202-552-5869 and we will be happy to help you.

If your organization has ever conducted any internal evaluations of the value of 340B, such as a report to the CFO or your Board, and if your organization is able to share the evaluation with us, we would be very interested in receiving a copy. Please email the document to Jeff Davis at jeff.davis@snhpa.org.

Please note that to ensure that the survey reaches the appropriate contact, this survey may have been sent to more than one person at your institution if we had multiple contacts in our database. You should confer with your colleagues before completing the survey to ensure that each institution submits only one response. Please also note that you have the option of responding as individual hospitals or as a system if appropriate. To avoid duplicates if submitting as a system, please make sure the individual hospitals in your system do not answer the survey as well.

**Contact Information**

Name: 
Job Title: 
Organization: 
Address: 
City/Town: 
State: 
Zip: 
Email Address: 
Phone Number: 

**1. Does your organization participate in the 340B Drug Discount Program?**

- [ ] Yes
- [ ] No (you need not complete the rest of the survey)

**2. Please indicate what kind(s) of 340B covered entity your organization is by entering the quantity of each entity type for which you are responding.** For example, if responding for an individual Disproportionate Share Hospital, place a 1 in the box next to DSH; if responding for a health system with two DSHs and one children’s hospital, place a 2 in the box next to DSH and a 1 in the box next to the children’s hospital, etc. All subsequent responses should pertain to the total sum of the entities indicated here.
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<th>Hospital Entity Types</th>
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<td>Health Centers for Residents of Public Housing</td>
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<td>FQHC 638 (tribal contractor) Self Determination</td>
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340B Utilization Survey

Other Entity Types

Comprehensive Hemophilia Diagnostic Treatment Center

Family Planning Clinic

Ryan White Care Act Grantee (non-ADAP)

Ryan White Care Act ADAP Direct Purchase

Ryan White Care Act ADAP Rebate Option

Black Lung Clinic

Urban Indian Organization

Sexually Transmitted Diseases Clinic

Tuberculosis Clinic

Native Hawaiian Health Center

2a. If your organization is a hospital(s), how many census beds do you have?

3. Please indicate how your organization participates in the 340B program. (Check all that apply)

- Owns one or more outpatient pharmacies
- Has one or more contract pharmacies
- Physician dispensing of drugs (including nurse practitioner, pharmacist, etc.)
- It is a hospital and uses its acute care or inpatient pharmacy to prepare outpatient medications

4. Please provide your best estimate of how much your organization spent on drug purchases in the last year.

4a. Total dollars spent on outpatient drugs
   4a.1. Percent (%) for pharmacy-dispensed drugs
   4a.2. Percent (%) for drugs administered or dispensed during outpatient visits

Note: 4a.1 and 4a.2 should add up to 100% of your response to 4a

4b. Total dollars spent on inpatient drugs
5. Please provide your best estimate of the dollar amount that your organization saved over the last year by participating in the 340B program.

Savings in dollars: $________________________

Note: Savings are the difference between the cost of drugs purchased at the 340B price and what they would have been purchased at the non-340B price. If your organization has not yet participated for a full year, please provide a projected savings estimate.

Note: Please report savings for only those entities indicated in question #2.

6. On a scale of 1-5, with 1 being Not Important and 5 being Critically Important, please rate the importance of the 340B program to the operation of your organization.

<table>
<thead>
<tr>
<th>Rating</th>
<th>Not Important</th>
<th>Important</th>
<th>Critically important</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

7. Does your organization use 340B savings to increase patient access to prescription drugs?

☐ Yes

☐ No (Please skip to question 8)

7a. If Yes, please check all that apply.

☐ Enables us to provide an outpatient pharmacy and keep it properly staffed

☐ Helps us maintain an adequate supply of inventory to meet patient demand

☐ Reduces patient wait times

☐ Avoids restrictive formularies and otherwise increases the choices of drugs and certain devices available to patients

☐ Increases the total number of patients served by our pharmacy department

☐ Enhances the pharmacy department’s or clinic’s ability to serve the uninsured or underinsured

☐ Allows on-site clinic dispensing instead of relying on commercial pharmacies

☐ Extends pharmacy hours
7b. If there is more detail to your response or if savings are used in a way not listed above, please discuss.

8. Does your organization use 340B savings to reduce the price for prescription drugs paid by patients?

- Yes
- No (Please skip to question 9)

8a. If Yes, please check all that apply.
- Allows uninsured patients to receive prescription drugs at no or reduced cost
- Reduces cost for patients charged at actual acquisition cost
- Reduces price associated with sliding fee scale
- Eliminates or reduces co-pays for Medicaid patients
- Eliminates or reduces co-pays for Medicare patients
- Eliminates or reduces co-pays for commercially insured patients

8b. If there is more detail to your response or if savings are used in a way not listed above, please discuss.

9. Does your organization use 340B savings to increase available pharmaceutical services, such as counseling, medication therapy management, disease management, translation services, utilization of patient assistance programs, etc., provided by the pharmacy?

- Yes
- No (Please skip to question 10)

9a. If Yes, please describe.
10. Does your institution use 340B savings to maintain the broader operations of your organization, beyond the pharmaceutical services referenced in question 9?

☐ Yes
☐ No (Please skip to question 11)

10a. If Yes, please check all that apply.

☐ Capital improvements to the organization
☐ Create new departments/programs
☐ Enhance existing departments/programs
☐ Offset losses from other departments
☐ Offset lost revenue as a result of low pharmacy reimbursement from Medicaid
☐ Offset lost revenue as a result of low pharmacy reimbursement from Medicare
☐ Offset lost revenue as a result of low pharmacy reimbursement from commercial payers
☐ Hire more experienced or in-demand staff
☐ Provide/take advantage of better technology
☐ Educational initiatives

10b. If there is more detail to your response or if savings are used in a way not listed above, please discuss.

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11. If the 340B program was no longer available, how would this impact your organization and its patients? (Check all that apply)

☐ Higher drug costs for uninsured and underinsured patients
☐ Reduced pharmacy services
☐ Reduced pharmacy-related programs (i.e. medication therapy management, disease management, etc.)
☐ Closure of outpatient pharmacy or pharmacies
☐ Reduced on-site dispensing services for entities without pharmacies
☐ Reduced non-pharmacy-related programs (i.e. patient outreach, education)
☐ Closure of one or more clinics
☐ Staff reduction (pharmacy or non-pharmacy)
☐ No Impact

11a. If there is more detail to your response or if the impact on your organization was not listed above, please discuss.


12. Has your organization experienced difficulty obtaining covered drugs at the 340B price that may have been available at a non-340B price during the same timeframe? For example, have you been told a product was unavailable at the 340B price, but available at another, non-340B price?

☐ Yes
☐ No (Please skip to question 13)

12a. If yes, please describe the situation to the best of your ability, including the drugs and timeframe for which you had difficulty obtaining the 340B price.


13. Is there anything else not asked, but relevant to the importance of the 340B program to your organization?


Thank you for your input!

In addition to this survey, we are looking for covered entities that are willing to work with us to estimate how much they save their Medicaid programs as a result of their participation in the 340B program. This project may involve completing a follow-up survey or participating in a phone interview. Is your organization willing to participate?

- [ ] Yes
- [ ] No

To complete the survey, please click the Done button below.