



NATIONAL ASSOCIATION OF
Community Health Centers



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NACHC Study: Benefits of the 340B Drug Pricing Program for Health Centers

May 2011



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Background

The 340B Drug Pricing Program (340B program) was created in 1992 to provide discounts on outpatient prescription drugs to select safety net providers, including among others, Federally Qualified Health Centers, which include centers receiving grant funds under Section 330 of the Public Health Service (PHS) Act and look-a-like health centers.¹ The program promotes: 1) access to affordable medications, 2) efficient business practices, 3) outcomes-driven pharmacy services, and 4) quality assurance.² The intent of the program is to permit covered entities “to stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services.”³

The 340B program was developed in response to unintended consequences stemming from the Medicaid Drug Rebate program that began in 1990. Under that program, drug manufacturers were required to enter into a rebate agreement with the U.S. Department of Health and Human Services (HHS) to provide drugs to state Medicaid programs. The required rebate was based on the drug manufacturers’ “best price,” and thus, manufacturers had little incentive to reduce their prices in non-Medicaid markets because doing so could lead to larger rebates in the Medicaid market. As a result of the rebate program, non-Medicaid patients may have been charged higher rates than they otherwise would have been charged. From the federal and state governments’ point of view, this was not productive because savings to the Medicaid program were offset by higher costs to other providers.⁴ To address this situation, Congress established the 340B program, requiring drug manufacturers to enter into a pharmaceutical pricing agreement with HHS to provide discounts to certain safety net providers.

Under the 340B program, drug manufacturers that participate in the Medicaid Drug Rebate program must also provide a reduced 340B price for covered outpatient drugs to select safety net providers, referred to in the 340B statute as “covered entities”, that choose to participate in the program. The 340B discount is the same discount that manufacturers are required to provide to state Medicaid agencies. The 340B Program is administered by the Office of Pharmacy Affairs (OPA) in the Health Resources and Services Administration (HRSA).⁵

¹ Section 602 of the Veterans Health Care Act of 1992 (P.L. 102-585) codified as section 340B of the Public Health Service Act. Initial federal regulations, 57 Fed. Reg. 27289 (May 7, 1993).

² Pharmacy Services Support Center. *The 340B integrity and quality leading practice achievement peer-to-peer program*. Retrieved November 12, 2010. Available at <http://pssc.aphanet.org/documents/P2POnePager20100716.pdf>.

³ H.R. Rep. No. 102-384(II), at 12 (1992)

⁴ Safety Net Hospitals for Pharmaceutical Access. (2008). *An overview of the section 340B drug discount program*. Available at http://www.snhpa.org/public/340b_overview.cfm.

⁵ For a more detailed explanation of the 340B Drug Discount program and issues related to health center participation in this program, see NACHC’s recently-issued “Understanding the 340B Program: A primer for health centers” (May, 2011).

NACHC's Recent Study of Health Center Participation in the 340B Program

The Affordable Care Act instructed the Government Accounting Office (GAO) to submit a report to Congress that examines individuals served by covered entities (including FQHCs) under the 340B program and to make recommendations to Congress relating to the program.⁶ NACHC determined to try to gauge the use and value of the 340B program to health centers and to provide GAO with the results of its study.

Accordingly, in mid-February 2011, NACHC staff sent out a list of questions electronically on the use and value of the 340B program to a sampling of 722 health centers. These centers were selected as Section 330 grantee/health centers that self identified as participating in 340B in the 2007 Uniformed Data System (UDS). Participants were additionally identified by their CFO listing in the NACHC membership database. A total of 535 unique health center⁷ CFO email addresses were generated from the larger sampling. Health center CFOs were contacted via email to participate in the online study on their use of 340B in their health centers. A total of 191 centers responded to some of the questions in the study and 175 health centers fully completed the question set, thereby providing a 32.7% response rate⁸.

Findings from the Study

Respondents are closely split in the method chosen to operate 340B drug dispensing. A total of 46.9% of health centers utilize their own internal outpatient pharmacy with 49.1% contracting with outside community pharmacies. Health centers that participated in the study included a broad range in stages of implementation of their 340B programs and the amount spent on drug purchases. Specific health center participation appears to be influenced a great deal by its patient population size and need. The response range on expenditures peaked at \$6,000,000 and was as low as \$0⁹.

Consensus from responding health centers indicated that 340B has been very useful to the operation of their organization. When asked to rate the importance of 340B on a scale of 1-5 (Question 3 in the study), 96% of all respondents checked off a ranking of 4 or 5. Approximately 93% of responders believe 340B provides increased access to prescription drugs for their patients (Question 6). In response to how access to prescription drugs has benefited their patients (Question 6a), the top four responses were:

- Enhances the health centers ability to serve the uninsured or underinsured – 98.8%
- Helps us maintain an adequate supply of inventory to meet patient demand – 64.6%
- Increases the total number of patients served by our pharmacy department – 60.2%
- Avoids restrictive formularies and otherwise increases the choices of drugs and certain devices available to patients - 55.3%

⁶ Section 7103 of P. L. 111-148

⁷ This represents inclusion of 52% of all federally funded health centers as of 2009 UDS data.

⁸ This rate is calculated from the 191 initial respondents. The remaining rates and figures will be based on the 175 whom continued with the survey. The Questionnaire can be found in Appendix B of this paper.

⁹ Follow-up indicated health centers with \$0 in expenditures were in the planning stages of their 340B program.

In the answer option labeled “Other” for Question 6a, the majority of responses indicate increased patient compliance of prescription drug usage helped improve overall patient health outcomes. A total of 92% of respondents indicated these benefits were made possible through their ability to reduce prescription drug prices. Further explanation of these savings is found in Figure 1 below.

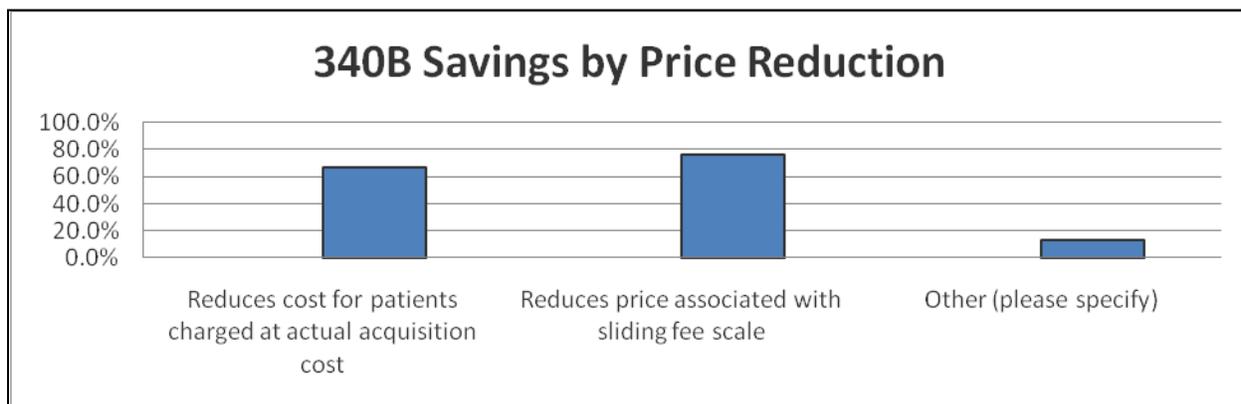


Figure 1: Question 7a – Methods to reduce 340B drug costs for patients

Health center participation in the 340B program also results in an increase in the ability of the center to provide enhanced pharmaceutical and non-pharmaceutical services. About 50% responded affirmatively that pharmaceutical-related services were enhanced and 60% of health centers indicated increased capacity in a variety of other areas. The top four services were:

- Enhancing existing departments and programs – 85.4%
- Offset losses from other departments – 71.8%
- Provide/take advantage of better technology – 62.1%
- Hire more experienced or in-demand staff – 51.5%

The opportunity for cost savings and service enhancement has been the experience for a vast majority of the responding health centers. Although the majority shows significant savings and benefits under the 340B program, a few responders indicate that they experienced less favorable outcomes. These health centers are finding it difficult to manage their costs or are unable to provide other comprehensive programs and savings other than their cost savings to patients. Respondents were queried on the estimated cost increase they would incur if their drug purchases were made at non-340B prices. **An astounding 70% of respondents indicated their costs would increase by a minimum of 41%** (See Figure 2).

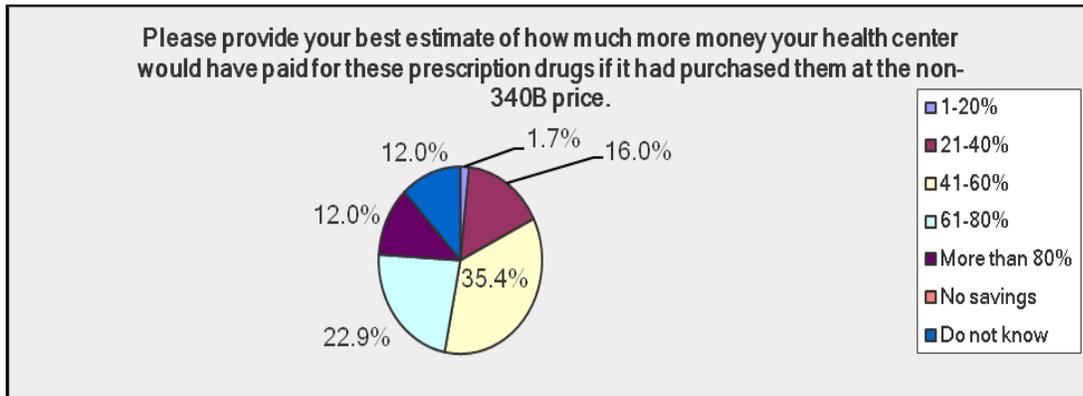
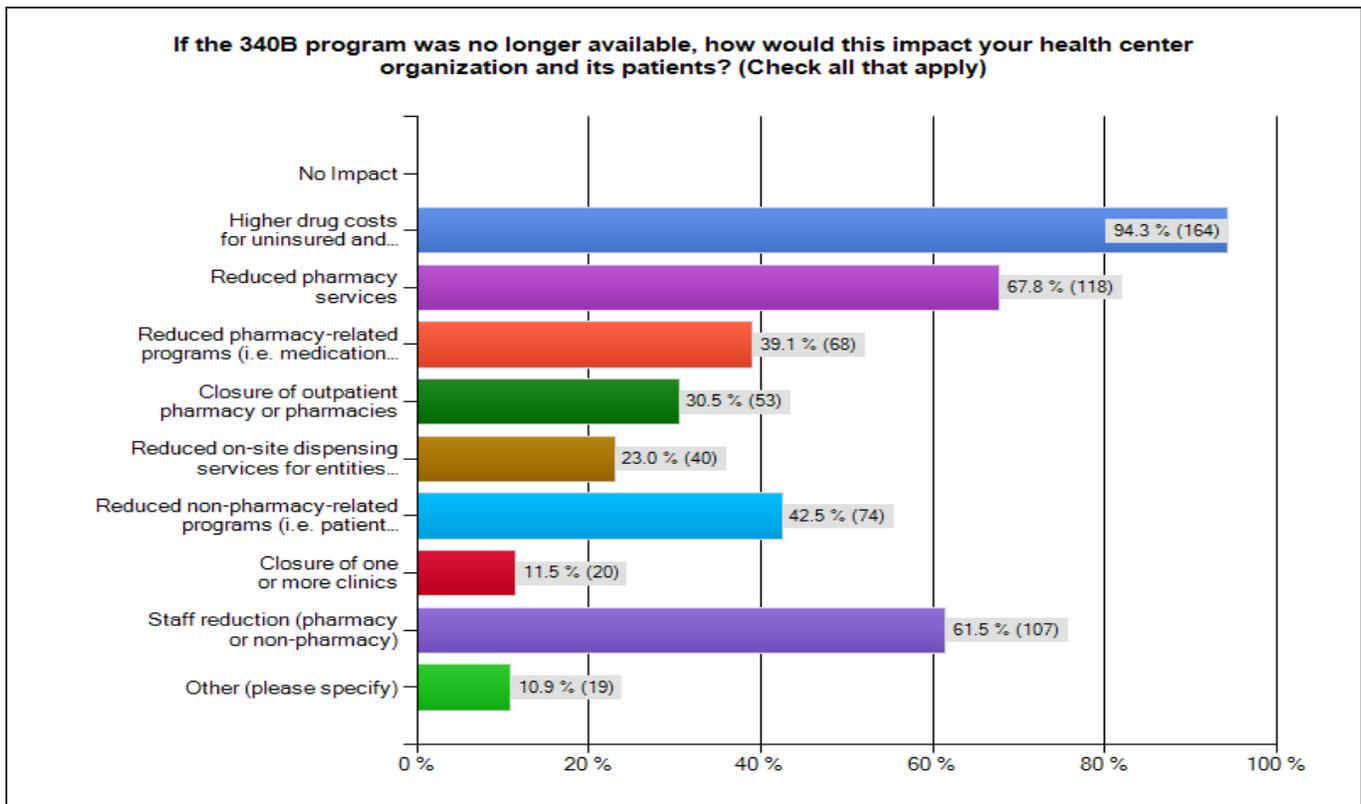


Figure 2: Question #5 – Price Increase without 340B

Not one health center indicated they would not experience a cost increase if their prescription drugs were not purchased at 340B prices. The more telling evidence to the importance of 340B to health centers is the impact on patients should 340B no longer be available (See Figure 3). The responses provided to that inquiry suggest that a wide range of services and patient benefits would no longer be available. Specifically, some health centers expressed concern that a loss of 340B drugs could impact patient health outcomes, reduce medical visits¹⁰, reduce health center revenues and reduce access to prescription drugs to patients living in certain rural areas. Other related outcomes can be found in the responses to Question 10 below.

Figure 3: Question 10 – Impact of loss of 340B program



Conclusion

Additional health center comments in response to the 340B study questions are attached (See Appendix A). Support and enthusiasm for the 340B program is almost uniformly expressed in these responses. Responding health centers strongly believe 340B is vital to their health center operations and a key element to the improved health of the patients they serve.

Appendix A

Usage Responses to Question #12
#12) Is there anything else not asked but relevant to the importance of the 340B program to your health center organization? If so, please describe.
Response Text
We have a very large uninsured/underinsured SFS population. We are moving forward with setting up our 340B program again because it will have a huge impact on our patients and the ability for them to stay compliant with their medications.
This is an integral part of our services that we offer our patients through RX management at lower costs
2010 (12 month) date: Pharmacy Rent Income \$1,572,114 340B Pharmaceutical Purchases (\$886,813) 340B Consultant to Manage Program (\$60,488) Net Income \$624,813!!!
The 340B program in our organization is an essential component to the health and well-being of patients in 3 counties [State name deleted]. The revenue from the program helps to support all other facets of the 3 primary care clinics in the 3 counties. The cost savings is also passed on to our patients through the sliding fee scale and is critical to medication access for many people. This program is a cost-effective means to provide high quality healthcare and access to necessary medication to all persons.
Medications are a critical component to the disease management of our patients. Fortunately many needed medications are available in generic form, but not all. That is where we rely on the 340b program.
It's good. It works.
WE NEED THE 340B PROGRAM FOR EXPANDING SERVICES FOR THE INCREASE IN DEMAND FOR SERVICES

During 2011, [Health center name deleted] will be expanding the 340B program to our other clinics (in addition to the mail order service currently used by our HIV patients). In late 2009, we opened an OB clinic (expensive service line relative to the primary care clinics) and the profits from the 340B program will help ([health center name deleted] maintain critical Ob-Gyn services in our service area.

Our centers could not provide the current variety of medications and services without the 340B program.

The 340B program provides significant discount on pharmaceuticals. These discount prices provide cost savings to our organization supporting programs and staff that function to fulfill our mission with medical, dental, behavioral health, pharmaceutical and support services to our underserved population. Loss of the 340B program would create a catastrophic impact on our organization and our patients whose health care is dependent on us and benefit from the services supported by 340B.

The 340B program helps insure that all patients have access to pharmacy services locally; otherwise closest town is [Town name deleted] which is 40 miles away.

As a FQHC the 340B program is absolutely essential in order to operate as the safety net provider in our communities.

Our goal is to have a patient centered medical home. The contracted 340b pharmacy is the way to our own pharmacy. The continued 340b pricing will then make that pharmacy viable. The result is a complete connection between the PCP and pharmacist. Our patients then can afford the drugs they need and take them safely and efficiently reducing drug interactions and duplications and unnecessary expense.

The 340B program is extremely important to us because it enables our patients to purchase their medications at an affordable price and encourages adherence to their medical treatment plans.

Our patients heavily rely on our onsite pharmacy. Their access to affordable prescription medication is excellent because of it, and therefore, successful clinical outcomes are achieved. Our patients **MUST HAVE ACCESS TO AFFORDABLE MEDICATION.**

As we transition to a patient centered medical home model of care the ability to dispense meds on site to persons living with chronic diseases is critical to ensuring that their care is optimally managed.

Appendix B



Health Center 340B Drug Discount Usage

Contact Information:

Name

Job Title:

Organization:

UDS Number:

Address:

City/Town:

State:

Zip:

Email Address:

Phone Number:

1. Does your health center participate in the 340B program?

- Yes
- No → END OF SURVEY
- Do not know → END OF SURVEY

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

- Has its own outpatient pharmacy or pharmacies
- Has one or more contract pharmacies
- Physician dispensing of drugs (including nurse practitioner, pharmacist, etc.)

3. 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 health center organization.

Not Important [1...2...3...4...5] Critically Important

4. Please provide your best estimate of how much your health center organization spent on drug purchases for patients of the health center during your most recent fiscal year.

Note: If your organization has not yet participated for a full year, please provide a full-fiscal year projected spending estimate.

\$_____

5. Please provide your best estimate of how much more money your health center organization would have paid for these prescription drugs if it had purchased them at the non-340B price. *Note: If your organization has not yet participated for a full fiscal year, please provide a projected estimate.*

- 1-20%
- 21-40%
- 41-60%
- 61-80%
- more than 80%
- No savings
- Do not know

6. Does your health center organization use 340B savings to increase patient access to prescription drugs?

- Yes
- No (Please skip to question 7)

6a. 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 available to patients
- Increases the total number of patients served by our pharmacy department
- Enhances the health center’s ability to serve the uninsured or underinsured
- Extends pharmacy hours
- Other, please specify: _____

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

- Yes
- No (Please skip to question 8)

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

- Reduces cost for patients charged at actual acquisition cost
- Reduces price associated with sliding fee scale
- Other, please specify: _____

8. Does your health center organization use 340B savings to increase available pharmaceutical-related 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 9)

8a. If Yes, please describe.

9. Does your health center organization 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 10)

9a. If Yes, please check all that apply.

- Create new departments/programs
- Enhance existing departments/programs
- Offset losses from other departments
- Hire more experienced or in-demand staff
- Provide/take advantage of better technology
- Educational initiatives
- Other, please specify: _____

9b. If there is more detail to your response or if savings are used in a way not listed above, please discuss.

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

- No Impact
- 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)
- Other, please specify: _____

10a. If there is more detail to your response or if the impact on your health center organization was not listed above, please discuss.

11. Has your health center 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 12)

11a. 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.

12. Is there anything else not asked but relevant to the importance of the 340B program to your health center organization? If so, please describe.

Thank you for your input!