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The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities

Final Report

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CHAPTER I

INTRODUCTION

The rapid increase in the price of prescription drugs over the past decade has affected Medicaid programs and other safety-net providers even more severely than private payers for several reasons. First, Medicaid recipients and other low-income persons are more likely to suffer from illness, injury, and chronic disease and are thus more likely to take regular prescription drugs than those in the general population. Second, some of the most expensive medications—antipsychotics and HIV anti-retrovirals—are used by groups of people who may rely disproportionately on public sources for those medications. Third, the low (typically under $1) Medicaid copayments for prescription drugs limit the ability of payers to manage demand for high-cost drugs through higher patient payments.

Section 340B of the Public Health Services Act requires manufacturers that receive reimbursement from Medicaid to furnish drugs for outpatient use to certain Public Health Service (PHS) grantees and other entities at the same discounts as those provided to state Medicaid programs under the Omnibus Budget Reconciliation Act of 1990 (OBRA 1990). The Pharmacy Affairs Branch (PAB) of the Bureau of Primary Health Care at the Health Resources and Services Administration (HRSA) administers the discount program known as the 340B Drug Pricing Program. Participating entities receive discounts of not less than 15.1 percent on brand-name drugs and 11 percent on generic drugs. Table I.1 lists the types of entities eligible for 340B discounts.

An earlier report (Schmitz, Quinn, and Williams 2003) summarized the results of interviews with representatives of professional organizations, state government officials, representatives of pharmaceutical companies, and other persons closely associated with the 340B program. The interviews identified several common themes:

- **Providers supported PAB but considered it understaffed**. Most respondents reported that PAB staff members were helpful and honest. At the same time, many said that they felt the office lacked sufficient staffing to undertake new initiatives and consequently spent most of their time "putting out fires."

- **Many providers claimed that they do not fully understand the 340B program**. Most representatives of provider associations asserted that the

program was difficult to understand. Such claims may have less to do with the inherent complexity of the program than with the absence of any unified source of information.

- **Providers wanted more and better 340B pricing information**. Most of the provider representatives expressed annoyance with the difficulty of obtaining current 340B pricing information. No 340B price list is available to participants or potential participants. While eligible entities can submit written requests to PAB for 340B price quotes, they view the process as cumbersome and inefficient.

- **Manufacturers expressed qualified support for the program**. Manufacturers' representatives generally supported the 340B program and, like providers, had a generally positive opinion of PAB. They did complain that the database of participating entities, used to verify eligibility for 340B pricing, often contained incorrect or outdated contact information.

Table I.1 Entities Eligible to Participate in the PHS 340b Drug Pricing Program

Type of Entity
Disproportionate share hospitals
Family planning projects
Community health centers
Federally Qualified Health Center Look-Alikes (FQHCLA)
Migrant health centers
Section 340S school-based programs
Health centers for residents of public housing
Health centers for the homeless
Tribal contract clinics
State-operated AIDS drug assistance programs (ADAPs)
Black lung clinics
Comprehensive hemophilia diagnostic treatment centers
Native Hawaiian health centers
Urban Indian organizations
Entities receiving assistance under the Ryan White Care Act
Sexually transmitted disease (STD) clinics
Tuberculosis (TB) clinics
Special projects of national significance (SPNS) [These projects, funded by the HIV/AIDS Bureau of HRSA, support innovative models of care for underserved populations diagnosed with HIV infection.]

Source: PL 102-585 Section 602. Consult this source for a more precise definition of eligible entities.

HRSA provides assistance to eligible entities through the Pharmacy Services Support Center (PSSC). The Center was established through a September 2002 contract between HRSA and the American Pharmacists Association to facilitate comprehensive pharmacy

services for patients who receive care at HRSA grantee and 340B-eligible health care delivery sites. The PSSC provides information and assistance to help eligible sites optimize the value of the 340B Program by increasing their patients' access to affordable drugs and comprehensive pharmacy services.

This report studies providers eligible to purchase prescription drugs under the 340B Drug Pricing Program. It describes the results of a survey of participating and nonparticipating providers conducted between October 2003 and March 2004. The survey questionnaire elicited information about the responding entity's dollar volume of drug purchases, knowledge of and satisfaction with the 340B program, extent of program savings, and allocation of the savings. Chapter II describes the survey approach, the sampling frame, and survey sample and presents response rates by entity type. Chapter III provides a description of sampled entities in terms of their pharmacy volume and dispensing arrangements. Chapter IV examines information sources used by eligible entities as well as entities' satisfaction with the program. Chapter V presents the distribution of payment sources and prescription drug use and provides estimates of program savings. Chapter VI summarizes the conclusions.

As this report was nearly complete, the Office of the Inspector General released two reports on the 340B program (U.S. Department of Health and Human Services 2004a; 2004b). The Inspector General's report is directed at a different issue from the one treated here. Our goal is to describe participating entities, estimate the volume of pharmacy expenditure and 340B saving, and entities' use of and satisfaction with the savings. The Inspector General's report aims to understand whether drug prices charged to 340B participants are correct. In one respect, however, the reports agree. Like the Inspector General, we found the database of eligible entities to be inaccurate in many respects and recommend that HRSA update information on a regular basis.

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CHAPTER II

SURVEY METHODOLOGY

The PHS 340B Drug Pricing Program Survey was conducted for the Pharmacy Affairs Branch (PAB) of HRSA's Bureau of Primary Health Care as part of its effort to improve outreach, communication, and services to all entities eligible for 340B pricing. The survey targeted organizations currently participating in the program as well as those eligible but not participating.

THE SURVEY SAMPLE

Approximately 10,500 clinics, programs, and disproportionate share hospitals have enrolled in the 340B Drug Pricing Program. The PAB maintains a database of eligible entities and program participants. The list is updated quarterly and is available on PAB's Web site, allowing manufacturers to verify a provider's enrollment.[1] While the database contains information on all 340B participants, it does not include all nonparticipants, and so is an incomplete enumeration of eligible entities.

The sampling frame for the survey (that is, the set of entities from which the survey sample was selected) was the fall 2003 version of the PAB entity database. The frame was stratified into 20 entity-type groups (10 for participating entities and 10 for nonparticipating entities). MPR selected a sample of 1,004 programs by entity-type group to achieve approximately equal precision of estimates by type.[2] Table II.1 shows the total database and sample size for participating and nonparticipating entities in each group. We combined some less common entity types to create a set of 10 survey groups from the 18 entity types listed in Table I.1. We combined Federally Qualified Health Center Look-Alikes with Community Health Centers; Migrant Health Centers with Clinics for the Homeless; Ryan White Title I and Title II programs; and Urban Indian with Tribal Contract Centers. Finally, we combined Public Housing Clinics, School-Based Programs, Black Lung Clinics, Native Hawaiian

[1] The files, in text or Microsoft Access format, appear at http://bphc.hrsa.gov/opa/downld.htm.

[2] The sample included 1,000 entities selected with equal probability within the 20 groups. An additional 4 entities (Alternative Methods Demonstration Programs) were added at the request of PAB. Since the 4 cases were purposefully selected, they were assigned a sampling weight of zero.

programs, and Special Projects of National Significance (SPNS) into a single "other" category.

Table II.1. Survey Sample

Entity	Participating		Not Participating	
	Frame Count	Sample	Frame Count	Initial Sample
All Entities	10,559	570	1,379	430
Disproportionate Share Hospitals	555	67	100	45
Family Planning Clinics	5,255	74	31	24
Community/Federally Qualified HC	1,764	72	443	63
Hemophilia Clinics	69	39	103	45
Migrant/Homeless Clinics	353	63	82	41
HIV Clinics	132	50	182	54
Ryan White Title I and II	152	52	79	40
STD/TB Clinics	2,123	72	253	58
HIS FQHCs/Urban Indian Grantees	108	47	88	42
Other Entities*	48	34	18	18

*Other Entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

SURVEY DESIGN AND PRETESTING

In cooperation with PAB, MPR developed a self-administered mail survey to serve as the data collection tool. We chose mail-based data collection for its convenience in consulting records on site and for its cost-effectiveness. The survey instrument was based on a questionnaire used in a 1998 survey conducted by MPR. We updated the questionnaire to address PAB's current issues and concerns. It elicited information about characteristics of an eligible entity, its pharmacy arrangements, prescription volume, estimated savings on prescription drugs attributable to the 340B program, and awareness of and satisfaction with the drug pricing program. The survey questionnaire appears in Appendix A.

MPR pretested the instrument with nine eligible entities selected at random from the OPA database. We sought a mix of facility type and participation status. Ultimately, seven of the nine pretest respondents were 340B program participants.

To the extent possible, the pretest replicated procedures for the main study; that is, we sent survey packets, including materials planned for the main study, to pretest sample members. The primary exception to pretest data collection procedures was that we called pretest entities in advance of the mailing to identify the most appropriate survey respondent and to gain advance cooperation. The turnaround time for completing surveys was also shorter for the pretest than for the main study.

SURVEY IMPLEMENTATION

The initial survey mailing to sampled entities took place in late October 2003 and included a cover letter on MPR letterhead, questionnaire, and prepaid return envelope. We followed the initial mailing with a reminder postcard to all nonresponding entities in mid-November, with a fax broadcast in early December to 488 entities for which a fax number was available, and with a full second mailing to nonresponders, using HRSA letterhead, at the end of December. All survey materials included contact information for the project officer at PAB and a toll-free number at which to reach the Mathematica survey director. We routinely remailed survey packets as we learned of new addresses.

In addition to the multiple attempts at establishing contact, PAB enlisted the help of membership organizations, such as the Public Hospital Pharmacy Coalition and the Hemophilia Alliance, to appeal to their members to respond to the surveys. These organizations sent general emails to their membership to encourage completion if they were contacted.

However, the organizations' efforts combined to yield only 231 completed surveys, making it necessary to modify the data collection strategy. The modified strategy, a telephone component, was added to the design in mid-January, about half way through the data collection period, and concluded in late March. Respondents to the telephone component could participate by faxing or mailing their completed survey to MPR or by completing the survey during a telephone interview.

The telephone interview required minor modifications to the design of the self-administered survey. Executive interviewers from MPR's Princeton Survey Operations Center were trained to administer the survey by telephone and to negotiate their way through complex organizational structures to identify the appropriate survey respondent. MPR received more than half (58 percent) of the completed surveys after the telephone data collection effort began.

SURVEY OUTCOMES

Overall, 558 entities completed the survey. Response rates differed sharply by program participation status. We received 69 percent (384) of the completed surveys from participating entities compared with only 31 percent (174) from nonparticipants.

Invalid address information on the PAB database of eligible entities appeared to be a major source of nonresponse. We submitted requests to MPR's locating department to search for new addresses for 347 entities. In addition, we requested of PAB update lists of entities for which mail was returned.[3] Of the 413 entities that did not respond, 229 (55 percent) did not have a correct address listing on the PAB database.

[3] There is some overlap between cases sent to PAB and cases sent to locating. Cases for which PAB could provide updates were not sent to MPR's locating department.

While both participating and nonparticipating entities were included in early locating efforts, resource constraints dictated a shift in focus to the 340B participants. PAB instructed MPR to concentrate its locating and telephone data collection resources on program participants, PAB's primary group of interest. In addition, the PAB database almost exclusively comprised participating programs. This disparate effort, along with participating agencies' likely inclination to respond, directly affected the differential response rates for participating and nonparticipating entities.

The overall response rate among participating entities was 66.5 percent (64.9 percent completed and 1.7 percent closed). For nonparticipating entities, the response rate was only 48.4 percent (43.7 percent completed and 4.8 percent closed). The proportion with a final status of "wrong address" was over twice as high among nonparticipating as participating entities.

MPR defined four final status codes for the survey:

Complete	Entity responded to the survey.
Closed	Entity is no longer in operation.
Wrong address	Address on HRSA entity database was incorrect, with no updated information available from PAB. Entity did not complete survey.
Refused/no response	An address was obtained on the entity from the HRSA entity database, MPR's locating efforts, or PAB. Entity did not complete survey.

Table II.2 displays the survey response rate by entity type for 340B participants and nonparticipants. The response rate was computed as:

Response Rate = (Complete + Closed)/(Complete + Closed + Wrong Address + Refused or No Response)

WEIGHTING SURVEY RESPONSES

We weighted responses to compensate for differential rates of selection and response across the 10 sample strata. The weight for each entity is equal to the product of the reciprocals of that entity's probability of selection within the sampling groups and probability of response. The four added entities were assigned a final weight of zero because PAB purposefully selected them.

The weighted mean of survey responses results in a mean for which each entity in the PAB database receives equal weight. The reader should bear in mind that means computed across all groups will be strongly affected by responses of family planning, STD, and TB clinics, which represent about 70 percent of all eligible entities. The weighted total of survey responses represents an estimate of the total for all eligible entities in the PAB database.

TABLE II.2. Final Survey Status by Entity Type

	All	Dispro-portionate Share Hospitals	Family Planning Clinics	Community/ Federally Qualified HC	Hemophilia Treatment Centers	Migrant/ Homeless Clinics	HIV Clinics	Ryan White Title I and II	STD/TB Clinics	Tribal Contract/ Urban Indian Health Centers	Other Entities
Participant											
All	574	68	74	75	39	63	50	52	72	47	34
Complete	384	51	49	49	31	43	36	37	42	27	19
Closed	10	0	2	1	0	0	0	0	0	2	5
Wrong address	88	5	10	11	4	12	8	12	16	8	2
Refused	92	12	13	14	4	8	6	3	14	10	8
Nonparticipant											
All	430	45	24	63	45	41	54	40	58	42	18
Complete	174	10	2	25	12	19	35	19	29	18	5
Closed	20	5	1	5	2	1	0	1	1	1	3
Wrong Address	141	24	4	26	16	18	11	14	14	10	4
Refused	95	6	17	7	15	3	8	6	14	13	6

Other Entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

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CHAPTER III

CHARACTERISTICS OF ELIGIBLE ENTITIES

Anecdotal evidence suggests that participation in the 340B program is far from random. In particular, small providers with low pharmacy volume and limited staff are generally considered least likely to participate.

This chapter briefly compares the characteristics of entities that do and do not participate in the 340B program. It is important to note that the sample sizes reported in the tables appearing in this chapter and in Chapters IV and V, will vary due to item nonresponse. Entities that returned the questionnaire did not always respond to every question. The reported sample sizes for each table refer to the total number of valid responses for the relevant item.

The comparison of survey responses of participating and nonparticipating entities, reported in this chapter and others to follow, are intended to indicate differences in characteristics of all entities that do and do not participate in the 340B Program and, in some cases, to suggest possible effects of the program on expenses for prescription drugs. Readers should bear in mind, however, that nonparticipating entities that appear in the HRSA 340B Database may or may not be representative of *all* nonparticipating entities. Therefore the comparisons reported here do not necessarily reflect differences in the overall population of participating and nonparticipating entities.

PARTICIPATION IN THE 340B PROGRAM

The survey questionnaire asked respondents whether they currently participate in the 340B Drug Pricing Program. Table III.1 presents responses by participation status as obtained from the PAB Database of Eligible Entities. Agreement between survey respondents and the participation indicator appearing on the PAB database was lower than expected. Over 35 percent of those listed on the database as participants reported that they did not participate in the program. Furthermore, 39 percent of those listed on the database as nonparticipants claimed that they did participate in the program. Overall agreement between the two sources was only 65 percent, slightly lower than the 71.7 percent agreement estimated by Cook et al. (1999) using a similar survey conducted in 1997.

TABLE III.1. Participation In 340b: Self-Report Versus Administrative Data

Participation Status According to PAB Database	Reported Participation Status					
	Participant		Nonparticipant		No Response	
	N	Percent	N	Percent	N	Percent
Participant	244	63.5	136	35.4	4	1.1
Non-Participant	68	39.1	105	60.3	1	0.6
Total	312	55.9	241	43.1	5	1.0

Percent agreement = 63.1%.

Some lack of agreement is to be expected. At present, a portion of the entities listed as participants on the PAB database might well not participate in the program. With no mechanism for disenrolling from the 340B program, entities that enroll in the program but decide later not to use the 340B discounts are carried on the database as participants, even if they have not made use of discount prices for many years. The participation rate implied by the participation indicator on the PAB database is therefore an upper bound on the proportion of entities actually receiving discounts at any time under the 340B program.

Explaining why 39 percent of the nonparticipating entities in the sample responded that they did participate in the 340B program is more difficult. Lacking any natural explanation for such a high level of disagreement, we are left to speculate that respondents might have confused the 340B program with some other set of negotiated discounts. Still more likely, perhaps, is that some respondents associated with organizations that embrace more than one eligible entity (for example, a community health center with a black lung clinic and a Ryan White Title III HIV clinic) may not have been aware that one particular entity did not participate in the program if others did participate.

This report follows Cook et al. (1999) and relies on the respondent's indication as the measure of program participation.

When nonparticipating entities were asked why they had not enrolled in the program, most cited the absence of an on-site pharmacy, as shown in Table III.2. Hemophilia treatment centers and community health centers were especially likely to cite high start-up costs in joining the program. Among reasons provided by those respondents who selected the "Other" category were low pharmacy volume, lack of knowledge about the program, and the perception that the program is complicated or difficult to understand.

PHARMACY VOLUME AND COST

Survey respondents were asked to provide the annual dollar volume of prescription drugs purchased by the sampled entity. Responses were far higher than expected, implying total annual pharmacy expenditures by all eligible entities of about $28 billion. This figure is

greater than total Medicaid spending on prescription drugs in 2000, estimated by Baugh et al. (2004) at $20.5 billion. While we can only speculate about the source of the overestimate, we suspect that many respondents reported pharmacy spending not for the sampled entity, but rather for the entire organization with which the entity is associated. Approximately two-thirds of respondents who answered both Question 4 ("What is your best estimate of total outpatient drug purchases by your organization during your most recently completed fiscal year?") and Question 6b ("What is the annual dollar volume of prescription drugs purchased by the entity listed on the label?") gave identical answers to both questions. In some cases where entities are freestanding, we expected identical responses, but many entities are associated with a larger, related organization and share that organization's pharmacy. In these cases, the answer to Question 6b ought to be a dollar amount much lower than the amount reported in Question 4.

In an effort to correct some of the apparent duplicate reporting, we grouped together all entities in the PAB database whose identifiers indicated that they belong to a common organization. We assigned entities to the same group if their identifiers differed by only a terminal letter (e.g., CH10177A and CH10177B) or by only an entity prefix (e.g., CH010220 and HO010220). In all cases in which a survey respondent both (1) provided the same answer to questions 4 and 6b *and* (2) was identified as part of a group of linked entities as described above, we set pharmacy spending by the entity equal to the survey response to question 6b divided by the number of entities in the group. This recalculation produced the results shown in Table III.3.

The mean values for pharmacy expenditures shown in the table remain far higher than expected. The 843 HRSA grantees (primarily community health centers) represented in the 2002 National Rollup Summary of the Uniform Data System (Health Resources and Services Administration 2004) reported total pharmacy costs of $272.2 million in calendar year 2002, resulting in an estimated mean per grantee of $323,000, far lower than the mean of $2 million for community health centers that appears in Table III.3. The most likely reason is that many entities that belonged to, and reported spending for, a larger organization were not identified by the process described just above. The PAB database does contain numerous instances in which entities with entirely different identifiers nevertheless list the same contact person and telephone number. This appears to occur most frequently for STD, TB, and family planning clinics and for Ryan White Title II providers. Moreover, some respondents may have reported spending for a larger organization, some part of which is not eligible to participate in the 340B program and so does not appear on the PAB database.

These circumstances offer little hope for estimating an unbiased mean for pharmacy expenditures and force us to adopt a different strategy–that of estimating a lower bound on mean and aggregate expenditures by entity type. If no more than half of all respondents of each type overstated their pharmacy spending, then the sample median will be estimated reliably. Furthermore, when the distribution of values is skewed to the right, as is the case with virtually all health care spending, the sample median can be shown to be less than the sample mean. Therefore, median spending in each entity category reported in Table III.3 can be regarded as a lower bound for the true value of mean pharmacy expenditures. In addition, the sample median multiplied by the number of entities in the population constitutes a lower

bound for total spending by all entities in a given category. This is the source of the lower bound on total spending shown in the table.

Entities that participate in the 340B program spend far more on prescription drugs than nonparticipating entities. The median pharmacy expenditure reported in Table III.3 was greater among participants than among nonparticipants for all but one of the entity types shown in the table. The lower bound on aggregate spending for all participating entities was $2.5 billion, more than 10 times the $194 million among nonparticipating entities in the database.

Table III.4 shows little evidence of a systematic difference in prescription costs between participating and nonparticipating entities. While the overall median cost per prescription was about $5 (or 26 percent) lower for participating entities, the same was not consistently true across entity types. Even though it may be tempting to use the difference in prescription costs as a measure of 340B savings, such an estimate would ignore possible differences in the nature and mix of medications prescribed and thus could prove highly misleading.

As expected, the typical prescription amounts for family planning, STD, and TB clinics tended to be low compared with those of the HIV and Ryan White providers. The particularly high value for cost per prescription at hemophilia treatment centers surely reflects both the high cost of clotting factor concentrate and the uncertain definition of "prescription" for these providers.

DISPENSING ARRANGEMENTS

Participating entities were more likely to rely on pharmacy services through an on-site pharmacy and less likely to use contracted pharmacies and provider dispensing than were nonparticipating entities (see Tables III.5a and III.5b). With the exception of family planning, STD, and TB clinics, every entity type among the participating providers was more likely to use an on-site pharmacy than any other method. By contrast, arrangements among nonparticipating providers showed greater variation. No single arrangement dominated for nonparticipants, and over 20 percent did not provide pharmacy services.

TABLE III.2. Reasons for Nonparticipation in the 340B Program

		No on-Site Pharmacy	High Startup Cost	Other
	N	Percent		
All	151	50.4	12.3	60.4
Disproportionate share hospitals	10	19.0	5.2	72.4
Family planning clinics	17	45.5	12.4	58.7
Community/federally qualified HC	18	50.4	29.7	64.9
Hemophilia treatment centers	7	17.1	47.8	60.7
Migrant/homeless clinics	14	51.6	6.5	71.0
HIV clinics	18	48.7	13.4	53.8
Ryan White Title I and II	6	63.8	0.0	54.3
STD/TB clinics	38	66.4	0.0	58.9
Tribal contract/urban Indian health centers	18	35.3	7.6	68.9
Other entities	5	87.9	12.1	39.4

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

TABLE III.3 Annual Pharmacy Expenditure by Entity Type and PHS 340B Participation Status

	Participant				Non-Participant			
	N	Mean (Dollars)	Median (Dollars)	Lower Bound of Total Expenditure (Millions of Dollars)	N	Mean (Dollars)	Median (Dollars)	Lower Bound of Total Expenditure (Millions of Dollars)
All	268	2,043,547	147,000	2,457	122	197,327	25,000	194
Disproportionate Share Hospitals	44	5,672,759	2,000,000	1,110	11	2,365,735	900,000	90
Family Planning Clinics	13	312,449	60,000	315	15	37,665	39,939	1
Community /Federally Qualified HC	34	2,046,674	171,429	302	14	99,839	18,182	8
Hemophilia Treatment Centers	23	6,202,565	3,785,625	261	5	1,163,615	600,000	62
Migrant/Homeless Clinics	37	699,951	180,000	64	13	19,533	19,623	2
HIV Clinics	28	569,762	130,000	17	14	523,101	30,000	5
Ryan White Title I and II	39	14,874,934	1,700,000	258	9	228,691	60,000	5
STD/TB Clinics	19	667,161	45,533	97	18	80,340	6,000	2
Tribal Contract/Urban Indian Health Centers	16	485,163	250,000	27	20	1,247,016	200,000	18
Other Entities	15	662,389	108,250	5	3	180,016	108,490	2

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

Mean expenditure per entity is biased upward. See text.

TABLE III.4. Cost per Prescription for Participating and Non-Participating Providers by Entity Type

	Participant			Non-Participant		
	N	Mean Dollars	Median Dollars	N	Mean Dollars	Median Dollars
All	254	133	14	105	179	19
Disproportionate Share Hospitals	42	148	36	7	1,337	59
Family Planning Clinics	13	11	11	15	51	24
Community /Federally Qualified HC	33	56	11	13	18.3	8
Hemophilia Treatment Centers	18	6,303	2,400	4	18,489	30,000
Migrant/Homeless Clinics	37	86	10	12	9	7
HIV Clinics	25	108	63	11	133	38
Ryan White Title I and II	37	249	65	9	96	48
STD/TB Clinics	18	28	17	13	44	8
Tribal Contract/Urban Indian Health Centers	16	19	16	18	33	21
Other Entities	15	23	11	3	25	20

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

TABLE III.5a. Dispensing Arrangements by Entity Type and Participation Status (Participant)

	N	On-Site Pharmacy	Contracted Pharmacy	Mail-Order Pharmacy	Provider Dispensing	Rebate	Other
		Percent					
All	310	48.7	19.5	6.2	36.5	0.2	15.6
Disproportionate share hospitals	47	100.0	9.0	10.4	8.1	0.0	2.3
Family planning clinics	22	31.8	13.6	4.6	45.5	0.0	13.6
Community/federally qualified HC	38	54.9	29.7	6.5	34.2	0.0	20.0
Hemophilia treatment centers	23	60.2	29.0	3.6	10.9	0.0	7.2
Migrant/homeless clinics	41	69.4	20.8	6.9	25.0	0.0	9.7
HIV clinics	38	53.3	48.6	8.7	21.3	0.0	17.3
Ryan White Title I and II	44	49.7	29.7	9.1	13.6	4.6	15.8
STD/TB clinics	25	43.6	18.2	6.4	46.4	0.0	24.6
Tribal contract/urban Indian health centers	17	77.1	22.9	11.4	28.6	0.0	5.7
Other entities	15	73.2	27.6	0.0	13.8	7.3	21.1

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

TABLE III.5b. Dispensing Arrangements by Entity Type and Participation Status (Non-Participant)

	N	On-Site Pharmacy	Contracted Pharmacy	Mail-Order Pharmacy	Provider Dispensing	Rebate	Other
		Percent					
All	239	21.6	22.5	5.1	43.0	2.0	21.2
Disproportionate share hospitals	14	86.2	0.0	0.0	0.0	0.0	8.6
Family planning clinics	26	25.6	12.4	4.1	57.9	4.1	16.5
Community/federally qualified HC	34	5.8	33.3	1.7	17.5	0.0	29.2
Hemophilia treatment centers	17	45.8	12.2	12.2	18.7	0.0	2.8
Migrant/homeless clinics	21	9.1	42.4	0.0	45.5	3.0	45.5
HIV clinics	33	19.6	13.1	11.7	16.5	0.0	27.8
Ryan White Title I and II	12	24.8	50.5	8.5	16.3	8.5	24.8
STD/TB clinics	46	17.0	32.8	8.2	44.4	0.0	24.0
Tribal contract/urban Indian health centers	28	42.2	35.9	7.8	14.1	0.0	14.1
Other entities	8	12.1	27.3	13.7	12.1	0.0	24.2

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

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CHAPTER IV

INFORMATION AND SATISFACTION

This chapter summarizes the surveyed entities' understanding of and satisfaction with the program. The data come from section B of the questionnaire. Given that use of information by entities is highly individualized, the results presented in this chapter are not weighted to the total population of eligible entities.

UNDERSTANDING OF THE PROGRAM

When asked how well they understand the program (Question 12), 87 percent of participants in the drug pricing program responded that they understand the program "well" or "well enough to use, but still have questions" while only 17 percent of nonparticipants responded similarly (see Table IV.1).

Stratifying by entity type among nonparticipants reveals that community health centers/federally qualified health centers and comprehensive hemophilia diagnostic treatment centers are the only entity categories in which over 50 percent of the respondents understand the program at least well enough to use it (see Table IV.1). In contrast, all entity categories among participants had a majority of respondents who understand the program "well" or "well enough to use, but still have questions."

Though less than 20 percent of nonparticipant entities who had an annual prescription drug purchase of less than $5 million understand the program well enough to use it, 55 percent of nonparticipant entities who had an annual prescription drug purchase over $5 million understand the program well enough to use it (see Table IV.2).[1] Among participants, over 80 percent understand the program at least well enough to use it regardless of annual prescription drug expenditure level.

[1] See Chapter III for a caution on the measurement of prescription drug purchases.

SOURCES OF INFORMATION

Respondents stated that they commonly use the federal grant program (27 percent), manufacturers/wholesalers (26 percent), and professional associates (22 percent) as sources of information (Question 11) about the 340B program (see Table IV.3). Another 20 and 13 percent of entities cited the PAB staff or Web site and the HRSA field office, respectively, as sources of information. Only 8 percent mentioned journal or news articles. In the "other" category, entities frequently said that the Public Hospital Pharmacy Coalition was a source of information about the drug pricing program.

As for entity type category, we note that over 60 percent of disproportionate share hospitals and comprehensive hemophilia diagnostic treatment centers cited professional organizations as a source of information (see Table IV.3). At least 30 percent of respondents in all entity categories except family planning clinics, sexually transmitted disease/tuberculosis clinics, and urban Indian/tribal contract health centers listed the PAB staff and Web site as a source of information.

Twenty-seven percent of surveyed entities had never heard of the drug pricing program. Interestingly, family planning clinics (32 percent), sexually transmitted disease/tuberculosis clinics (48 percent), and urban Indian/tribal contract health centers (41 percent) had the highest proportion of respondents who had never heard of the 340B program. Of the entities that said that they heard never heard of the program, 93 percent reported annual prescription drug expenditures in the lowest tercile (less than $2.5 million) (results not shown), and 93 percent were nonparticipants (results not shown).

Lack of knowledge about the 340B program among survey respondents could partially explain the 27 percent who had not heard of the program. The survey was mailed to the person listed on the PAB database as the 340B contact for the entity; however, in many cases, that contact person had left the organization before the receipt of the survey. Thus, it is possible that the actual survey respondent did not have either knowledge of or sufficient familiarity with the 340B program to answer the questions accurately.

INTERACTION WITH PAB

Overall, 24 and 31 percent of entities responded that they had called PAB for information/technical assistance (Question 13) and accessed the PAB Web site (Question 15), respectively (see Table IV.4). Over 70 percent of disproportionate share hospitals had done both. More than 30 percent of all other entity categories except for family planning clinics, sexually transmitted disease/tuberculosis clinics, and urban Indian/tribal contract health centers had called PAB and accessed its Web site. The low interaction rate for family planning clinics, sexually transmitted disease/tuberculosis clinics, and urban Indian/tribal contract health centers is not surprising in that many of them had reported that they had never heard of the 340B program.

Over 85 percent of respondents were satisfied with the organization, usefulness of information, and clarity of the Web site (Question 17abc) (see Table IV.5). Disproportionate share hospitals, migrant health centers, HIV clinics, and sexually transmitted

disease/tuberculosis clinics expressed no dissatisfaction with the organization, usefulness of information, or clarity of the Web site. Eighteen percent of family planning clinics reported dissatisfaction with all three measures of the Web site while 18 percent of community health centers/federally qualified health centers communicated dissatisfaction with the clarity of information.

Analyzing satisfaction with the PAB Web site by entities' purpose of use (Question 16) demonstrates over 80 percent satisfaction with the organization, usefulness of information, and clarity for all purposes of use. Seventeen and 11 percent expressed dissatisfaction with the organization of the Web site for registration and verifying eligibility, respectively. Another 11 percent communicated dissatisfaction with the clarity of information when they used the Web site for program guideline information.

When PAB staff were contacted by telephone for information or technical assistance, over 85 percent of survey respondents categorized accessibility of staff, staff's ability to answer questions, and staff's timeliness of response (Question 14 a, b, c) as "good," "very good," or "excellent" (see Table IV.7). None of the disproportionate share hospitals, family planning clinics, community health centers/federally qualified health centers, comprehensive hemophilia diagnostic centers, migrant health centers, or Ryan White care act entities rated the accessibility of staff as poor. The highest percentage of dissatisfaction occurred among urban Indian/tribal contract health centers; over a quarter of these entities rated accessibility of staff, staff's ability to answer questions, and staff's timeliness of response as fair or poor.

When asked how PAB could help entities take advantage of the 340B program (Question 19), respondents most frequently cited presentations at professional meetings (51 percent) and written materials (52 percent) (see Table IV.8). Over 40 percent of entities also said that technical assistance to individuals or groups and site visits to individual entities or groups would improve their ability to take advantage of the program. Only 15.8 mentioned an improved Web site as potentially helpful. In the "other" category, a pricing list and step-by-step guide to participation in the drug pricing program as ways in which PAB could help entities take advantage of the program.

TABLE IV.1a. Understanding of the 340B Program by Entity Type and Participation

		Participant			
		Well	Can Use, But Still Have Questions	Only Slightly	Not at All
	N	Percent			
All	312	39.1	46.7	10.9	0.3
Disproportionate share hospitals	47	55.3	42.6	2.1	0.0
Family planning clinics	22	45.5	40.9	13.6	0.0
Community/federally qualified HC	39	35.9	53.8	10.3	0.0
Hemophilia treatment centers	24	41.7	58.3	0.0	0.0
Migrant/homeless clinics	41	43.9	48.8	7.3	0.0
HIV clinics	38	42.1	52.6	5.3	0.0
Ryan White Title I and II	44	31.8	54.6	13.6	0.0
STD/TB clinics	25	20.0	48.0	28.0	4.0
Tribal contract/urban Indian health centers	17	29.4	52.9	17.7	0.0
Other entities	15	26.7	40.0	33.3	0.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

TABLE IV.1b. Understanding of the 340B Program by Entity Type and Participation Status (Non-Participant)

		Non-Participant			
		Well	Can use, but still have questions	Only slightly	Not at all
	N	Percent			
All	235	9.8	19.6	30.2	40.4
Disproportionate share hospitals	13	0.0	53.8	30.8	15.4
Family planning clinics	25	0.0	4.0	16.0	80.0
Community/federally qualified HC	33	12.1	27.3	36.4	24.2
Hemophilia treatment centers	18	22.2	50.0	11.1	16.7
Migrant/homeless clinics	21	23.8	23.8	38.1	14.3
HIV clinics	33	15.1	27.3	36.4	21.2
Ryan White Title I and II	12	8.4	0.0	58.3	33.3
STD/TB clinics	45	4.5	2.2	31.1	62.2
Tribal contract/urban Indian health centers	27	7.4	11.1	14.8	66.7
Other entities	8	0.0	25.0	50.0	25.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

TABLE IV.2a. Understanding of the 340B Program by Annual Dollar Amount of Prescription Drug Purchases and Participation

		Participant			
		Well	Can Use, But Still Have Questions	Only Slightly	Not at All
	N	Percent			
All	267	38.6	51.3	10.1	0.0
<$2,500,000	198	36.9	51.0	12.1	0.0
$2,500,000 - $5,000,000	24	50.0	50.0	0.0	0.0
>$5,000,000	45	40.0	53.3	6.7	0.0

TABLE IV.2b. Understanding of the 340B Program by Annual Dollar Amount of Prescription Drug Purchases and Participation (Non-Participant)

		Non-Participant			
		Well	Can Use, But Still Have Questions	Only Slightly	Not at All
	N	Percent			
ALL	120	10.0	21.7	28.3	40.0
<$2,500,000	111	9.9	21.6	27.9	40.6
$2,500,000 - $5,000,000	4	0.0	0.0	25.0	75.0
>$5,000,000	5	20.0	40.0	40.0	0.0

Table IV.3. Sources of Information by Entity Type

		Sources of Information									
		PAB Staff or Website	HRSA Field Office	Federal Grant Program	Professional Organization	Manufacturer or Wholesaler	Other Health Care Facilities	Professional Associates	Journal or News Article	Other	Have Not Heard of PHS 340B Program
	N	Percent									
All	554	32.1	20.2	24.9	26.2	25.5	22.2	27.6	9.8	19.7	16.4
Disproportionate share hospitals	60	58.3	11.7	3.3	61.7	23.3	25.0	41.7	11.7	38.3	1.7
Family planning clinics	49	12.2	6.1	32.7	18.4	24.5	8.2	18.4	6.1	18.4	30.6
Community/federally qualified HC	74	29.7	33.8	29.7	31.1	29.7	29.7	27.0	8.1	14.9	10.8
Hemophilia treatment centers	43	46.5	11.6	37.2	51.2	27.9	37.2	55.8	11.6	11.6	7.0
Migrant/homeless clinics	61	27.9	27.9	31.2	27.9	36.1	34.4	29.5	14.8	14.8	4.9
HIV clinics	71	46.5	32.4	32.4	22.5	19.7	28.2	22.5	4.2	18.3	9.9
Ryan White Title I and II	56	41.1	35.7	32.1	8.9	21.4	12.5	25.0	7.1	28.6	3.6
STD/TB clinics	71	7.0	2.8	15.5	7.0	19.7	5.6	21.1	15.5	18.3	43.7
Tribal contract/urban Indian health centers	45	22.2	6.7	6.7	13.3	31.1	20.0	15.6	8.9	11.1	37.8
Other entities	24	29.2	29.2	33.3	20.8	20.8	20.8	20.8	8.3	20.8	16.7

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Table IV.4. Contacts with PAB by Entity Type

	Called PAB for Information/ Technical Assistance			Accessed PAB Website		
		Yes	No		Yes	No
	N	Percent		N	Percent	
All	555	34.9	65.1	554	41.9	58.1
Disproportionate share hospitals	60	68.3	31.7	60	73.3	26.7
Family planning clinics	49	14.3	85.7	49	22.5	77.5
Community/federally qualified HC	74	31.1	68.9	73	38.4	61.6
Hemophilia treatment centers	43	44.2	55.8	43	48.8	51.2
Migrant/homeless clinics	62	43.6	56.4	62	54.8	45.2
HIV clinics	71	36.6	63.4	71	47.9	52.1
Ryan White Title I and II	56	44.6	55.4	56	51.8	48.2
STD/TB clinics	71	14.1	85.9	71	14.1	85.9
Tribal contract/urban Indian health centers	45	17.8	82.2	45	20.0	80.0
Other entities	24	33.3	66.7	24	50.0	50.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

TABLE IV.5. Satisfaction with PAB Website by Entity Type

	Organization				Usefulness of Information				Clarity of Information			
		Very Satisfied	Somewhat Satisfied	Not at All Satisfied		Very Satisfied	Somewhat Satisfied	Not at All Satisfied		Very Satisfied	Somewhat Satisfied	Not at All Satisfied
	N	Percent			N	Percent			N	Percent		
All	227	47.1	49.3	3.5	226	53.5	43.8	2.7	228	44.3	50.9	4.8
Disproportionate share hospitals	43	55.8	44.2	0.0	43	69.8	30.2	0.0	43	58.1	41.9	0.0
Family planning clinics	11	27.3	54.5	18.2	11	27.3	54.5	18.2	11	27.3	54.5	18.2
Community/federally qualified HC	29	37.9	58.6	3.5	29	48.3	44.8	6.9	29	34.5	48.3	17.2
Hemophilia treatment centers	21	52.4	42.9	4.7	21	66.7	28.6	4.7	21	47.6	47.6	4.8
Migrant/homeless clinics	34	50.0	50.0	0.0	34	47.1	52.9	0.0	34	44.1	55.9	0.0
HIV clinics	33	51.5	48.5	0.0	34	50.0	50.0	0.0	34	50.0	50.0	0.0
Ryan White Title I and II	25	32.0	56.0	12.0	25	48.0	52.0	0.0	25	32.0	60.0	8.0
STD/TB clinics	10	60.0	40.0	0.0	10	40.0	60.0	0.0	10	40.0	60.0	0.0
Tribal contract/urban Indian health clinics	9	55.6	44.4	0.0	9	55.6	33.3	11.1	9	66.7	22.2	11.1
Other entities	12	41.7	50.0	8.3	10	60.0	40.0	0.0	12	25.0	75.0	0.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Table IV.6. Satisfaction with PAB Website by Purpose of Use

	Organization				Usefulness of Information				Clarity of Information			
		Very Satisfied	Somewhat Satisfied	Not at All Satisfied		Very Satisfied	Somewhat Satisfied	Not at All Satisfied		Very Satisfied	Somewhat Satisfied	Not at All Satisfied
	N	Percent			N	Percent			N	Percent		
All	227	47.1	49.4	3.5	226	53.5	43.8	2.7	228	44.3	50.9	4.8
Verify eligibility	227	53.7	42.6	3.7	226	61.0	37.5	1.5	228	53.7	44.1	2.2
Registration	227	46.8	49.3	3.9	226	56.0	42.7	1.3	228	45.5	50.6	3.9
Federal Register notices	227	44.1	50.8	5.1	226	50.9	49.1	0.0	228	44.1	55.9	0.0
What's New? information	227	52.9	47.1	0.0	226	61.2	37.8	1.0	228	50.5	45.7	3.8
Program guidelines	227	54.4	42.9	2.7	226	62.3	34.9	2.8	228	48.7	46.6	4.7
Contracted pharmacy forms	227	56.5	38.7	4.8	226	64.5	35.5	0.0	228	51.6	46.8	1.6
Downloads	227	57.6	39.4	3.0	226	74.2	25.8	0.0	228	62.1	36.4	1.5
Entity lookup	227	59.0	39.8	1.2	226	65.1	34.9	0.0	228	55.4	44.6	0.0
Other	227	41.2	52.9	5.9	226	29.4	70.6	0.0	228	23.5	76.5	0.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Table IV.7. Satisfaction with PAB Response to Telephone Inquiries by Entity Type

	Accessibility of Staff						Ability to Answer Questions/Solve Problems						Timeliness of Response/Assistance					
		Excellent	Very Good	Good	Fair	Poor		Excellent	Very Good	Good	Fair	Poor		Excellent	Very Good	Good	Fair	Poor
	N	Percent					N	Percent					N	Percent				
All	193	36.3	34.7	17.6	7.8	3.6	193	35.2	33.7	19.2	7.8	4.1	193	31.1	35.7	22.8	7.3	3.1
Disproportionate share hospitals	41	43.9	31.7	17.1	7.3	0.0	41	41.4	39.1	14.6	0.0	4.9	41	24.4	48.8	19.5	4.9	2.4
Family planning clinics	7	28.6	42.8	14.3	14.3	0.0	7	28.6	42.8	14.3	14.3	0.0	7	42.8	28.6	14.3	14.3	0.0
Community/federally qualified HC	23	26.1	39.1	21.7	13.1	0.0	23	34.8	21.7	26.1	17.4	0.0	23	30.4	34.8	17.4	17.4	0.0
Hemophilia treatment centers	19	57.9	36.8	0.0	5.3	0.0	19	42.1	47.3	5.3	0.0	5.3	19	42.1	47.3	5.3	5.3	0.0
Migrant/homeless clinics	27	37.1	29.6	25.9	7.4	0.0	27	44.5	25.9	22.2	7.4	0.0	27	33.3	37.1	29.6	0.0	0.0
HIV clinics	26	34.6	34.6	15.4	3.9	11.5	26	23.1	46.1	15.4	7.7	7.7	26	30.8	26.9	26.9	7.7	7.7
Ryan White Title I and II	25	20.0	44.0	28.0	8.0	0.0	25	16.0	44.0	28.0	12.0	0.0	25	16.0	40.0	36.0	8.0	0.0
STD/TB clinics	10	50.0	20.0	20.0	0.0	10.0	10	60.0	0.0	20.0	20.0	0.0	10	60.0	20.0	10.0	10.0	0.0
Tribal contract/urban Indian health centers	8	37.5	12.5	12.5	25.0	12.5	8	37.5	12.5	25.0	12.5	12.5	8	37.5	0.0	37.5	12.5	12.5
Other entities	7	14.3	57.1	0.0	0.0	28.6	7	28.6	14.2	28.6	0.0	28.6	7	28.6	14.2	28.6	0.0	28.6

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Table IV.8. Methods to Help Entities Take Advantage of 340B Drug Pricing Program by Entity Type

	N	Improve Website	Presentations at Professional Meetings	Technical Assistance to Individuals/ Small Groups	Site Visits to Individual Entities or Groups	Telephone Consultations	Written Material	Other
		Percent						
All	526	15.8	51.0	43.2	45.3	38.4	51.7	22.4
Disproportionate share hospitals	59	28.8	64.4	47.5	50.9	44.1	47.5	28.8
Family planning clinics	49	8.2	40.8	36.7	34.7	34.7	53.1	26.5
Community/federally qualified HC	68	17.7	55.9	50.0	51.5	41.2	55.9	22.1
Hemophilia treatment centers	38	15.8	57.9	52.6	47.4	36.8	39.5	18.4
Migrant/homeless clinics	59	15.3	49.2	55.9	57.6	40.7	55.9	22.0
HIV clinics	69	13.0	44.9	40.6	42.0	37.7	40.6	26.1
Ryan White Title I and II	55	20.0	45.5	34.6	34.6	38.2	61.8	18.2
STD/TB clinics	63	6.4	57.1	33.3	46.0	39.7	58.7	20.6
Tribal contract/urban Indian health centers	43	9.3	34.9	34.9	30.2	30.2	44.2	20.9
Other entities	23	30.4	60.9	47.8	60.9	34.8	60.9	13.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

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CHAPTER V

PAYER MIX, PRESCRIPTION DRUG USE, AND PROGRAM SAVINGS

Participants in the 340B program serve disparate populations with widely different needs for prescription drugs. Most patients of eligible entities have low incomes or suffer from conditions (such as HIV or hemophilia) whose treatment costs are extremely high.

This chapter first describes participating entities in terms of their payer mix, method of charging uninsured patients for care, and their charge structure for prescription drugs.

PAYER MIX AND DRUG PRICING

More than half of entities in every category received at least some payment from Medicaid (results not shown). With the exception of STD/TB, family planning, and Ryan White providers, most received some payment from private insurance as well. By contrast, only among hemophilia treatment centers and disproportionate share hospitals did more than half of providers receive any payments from Medicare.

Table V.1 displays the weighted share of payments by entity type for providers enrolled in the 340B program. Most entity types rely heavily on self-payment, private insurance, or both for a significant portion of their prescription drug payment. Approximately half or more of the outpatient drug expenditures of family planning clinics, STD/TB clinics, and Ryan White providers were paid by state/local indigency programs or other sources, primarily federal grants and funds provided directly under the Ryan White Care Act. In no instance was either Medicare or Medicaid the principal payer for outpatient drugs for any entity.

The most common method of computing a charge for prescription drugs was acquisition cost plus dispensing fee, as Table V.2 shows. While a substantial portion of entities selected "Other" as a method, many described a variant of cost-plus-dispensing-fee in their written response; many others selecting the same category stated that they did not charge for drugs or that the visit included drug charges. Hemophilia treatment centers and Ryan White entities, two providers associated with particularly expensive prescription drugs,

were more likely than any other entity type to employ markdowns in their charge structure for drugs.

Most safety-net providers treat a large number of uninsured patients and so must create a procedure for charging those with limited means. Table V.3 shows the approach to charging uninsured patients for prescription drugs among 340B participants. Most charged for drugs under a sliding fee based on the patient's income. A much smaller proportion used a price list for drugs or made no provision for special pricing ("full charge"). Among those who selected "Other" as a category, many stated that they charged a flat fee, usually $4 to $6 per prescription, or did not charge for drugs.

ESTIMATES OF PROGRAM SAVINGS

Estimating the actual savings on prescription drugs among 340B participants is extremely difficult and subject to substantial uncertainty. The proper measure of savings is not the discount from average manufacturer price (AMP) codified in the Public Health Service Act but rather the difference between the price paid by participants and the price participants would have paid had they not participated. Many providers, especially those who have been enrolled in the program for several years, may be unable to formulate an accurate estimate of the amount they would pay for drugs in the absence of the program. Nonetheless, participants' self-reported estimates are probably the best available means of gauging the savings on prescription drugs as a result of program participation. Figure V.1 shows the distribution of reported percentage savings on prescription drugs by 340B participants. Reported savings were remarkably high, with well over half of all respondents saving more than 30 percent on prescription drugs as a result of program participation.

Table V.4 displays estimated savings by entity type. We calculated estimates by setting the reported percentage savings of each reporting entity equal to the midpoint of the categories shown in Figure V.1. We assigned entities that reported saving more than 30 percent a savings of 35 percent. To estimate the typical dollar value of the savings, the percentage savings for each respondent was multiplied by the respondent's reported prescription drug expenditure. Table V.4 reports the median of these amounts by entity type. We calculated a lower bound for total program savings in the same manner employed for constructing the bound for total pharmacy expenditure in Chapter III. Specifically, we multiplied median estimated savings by entity type by the number of entities of each type in the population of participating entities.[1]

Reported percentage savings were similar across entity types, typically between 24 and 27 percent. The lowest percentage savings, 19 percent, were reported by hemophilia treatment centers; the highest were reported by STD and TB clinics at 31 percent. Despite the low percentage savings reported by hemophilia centers, the median dollar savings by

[1] Because some respondents did not provide information on estimated saving, the sample size for the calculations underlying Table V.4 is smaller than the total number of respondents.

these entities, $785,000, was higher than that of any other entity type. The lowest reported median savings occurred among STD and TB clinics, at $15,400 per year.

Total savings on outpatient prescription drugs by all participating entities was estimated to be at least $661 million. Disproportionate share hospitals, family planning clinics, and community health centers accounted for about three-quarters of this total.

PRESCRIPTION DRUG USE AND PROGRAM SAVINGS

Respondents were asked to report the three therapeutic categories accounting for the largest share of outpatient drug purchases. As Table V.5 shows, entity types showed substantial variation in the categories of drug purchased. The most commonly purchased drugs overall included antibiotics, contraceptives, and diabetes medications.[2] Certain providers, such as hemophilia treatment centers, HIV clinics, and Ryan White providers, were particularly likely to purchase more specialized medications, such as clotting factor concentrate and anti-retroviral medication.

For each category they listed, respondents were asked to estimate the dollar value of savings attributable to 340B participation. Table V.6 displays the median estimated savings by therapeutic category. Savings were particularly high–$200,000 or more–for HIV anti-retrovirals, clotting factor concentrate, and chemotherapy medications. It is important to note that while antibiotics were more frequently reported than any other class of drug, savings in this category were relatively low–about $3,250 per year. Given that respondents were asked to estimate savings by therapeutic category only for those categories that account for the greatest expenditures, the reported amounts should not be regarded as typical but rather as upper bounds of the expected savings in each category.

THE PRIME VENDOR PROGRAM

In 1999, HRSA selected Bergen Brunswig Drug Company (now Amerisource Bergen) as prime vendor for the 340B program. The primary goal of the prime vendor was to negotiate prices below the 340B ceiling based on the buying power of entities enrolled in the program. Table V.7 shows the proportion of 340B participants who reported that they were enrolled in the prime vendor program. The table also shows reported 340B savings (in percent) separately for those enrolled and not enrolled in the prime vendor program. Overall, less than one-quarter of 340B participants reported that they were enrolled in the prime vendor program. Enrollment in the program was just 3 percent among hemophilia treatment centers and 11 percent among disproportionate share hospitals but over 40 percent among community health centers and other entities.

[2] Bear in mind that these proportions are weighted by the number of entities in the sampling frame, not by volume of purchases. The responses of family planning, STD, and TB clinics will have disproportionate influence on the reported numbers. Because respondents reported up to three therapeutic categories, values may sum to more than 100.

The table shows no systematic evidence of a difference in 340B savings for entities that do and do not participate in the prime vendor program. It is important to emphasize that differences in 340B savings between participants and nonparticipants cannot be regarded as an estimate of the savings attributable to enrollment in the prime vendor program because the alternative prices faced by those who enrolled in the program may have been markedly different from the prices paid by those who did not enroll. The absence of any clear indication that entities enrolled in the prime vendor program paid lower prices for drugs is nonetheless consistent with claims made by some 340B participants that the prime vendor did not succeed in negotiating substantial discounts.

An earlier report (Schmitz, Quinn, and Williams 2003) noted widespread dissatisfaction with the prime vendor. Many of the providers and advocates interviewed felt that the prime vendor's service was poor and that it devoted little effort to negotiating subceiling prices for members. To address these perceived problems, Amerisource Bergen awarded a subcontract in June, 2003 to HealthCare Purchasing Partners International (HPPI). Under the subcontract, HPPI manages the prime vendor program and works to expand the program's accessibility for covered entities. HPPI has expanded the number of pharmacy distributors and covered entities participating in the program by using its expertise in developing efficient distribution networks, securing sub-340B discounts on multisource and branded pharmaceuticals, and developing many discounted services offerings for participants of the program. The new program under HPPI enables a covered entity to participate in the program by using its existing drug distributor and maintaining any independently negotiated sub-340B discounts on outpatient drugs. Many of the previous barriers to covered entities joining the Prime Vendor Program have been removed with HPPI's management of the program.

The current prime vendor contract expires in September, 2004. On May 24, 2004, HRSA issued a solicitation seeking an organization to serve as prime vendor from September, 2004 to September 2006, with options to extend the period to 2009. The new contract will require the prime vendor to provide negotiating services "with the purpose of providing all member entities the most advantageous sub-ceiling prices." The contract will also require HRSA and the prime vendor to agree on explicit standards of performance for customer service, drug distribution, and price negotiation.

USE OF 340B SAVINGS

The legislation creating the 340B program does not require participating entities to use the savings resulting from their participation in any specified way. All entities are free to allocate savings in whatever manner they choose. Table V.8 displays the allocation of 340B savings as estimated by respondents from each entity. Allocations differed dramatically by entity type. Entities that focused on a specific aspect of health or disease–family planning, STD, TB, and HIV clinics and Ryan White grantees–all devoted the largest share of savings to increasing the number of patients receiving care. Community health centers and migrant health centers were most likely to devote a significant portion of the savings to reducing the price of medication for their patients. Entities with the highest median spending on prescription drugs--disproportionate share hospitals and hemophilia treatment centers--devoted the greatest share of their savings to offsetting losses from providing pharmacy

services at less than cost. Tribal contract and urban Indian health centers also devoted the greatest share of their savings to the same purpose. With the exception of hemophilia treatment centers, no entities devoted a significant share of savings to reducing the price of medication to third parties.

In addition to their varied allocation of 340B savings, many entities altered the manner in which they charged for outpatient drugs after entering the program. Figure V.2 shows the proportion of entities that reported changing their method for pricing drugs since entering the 340B program. Community health centers and hemophilia treatment centers were more likely to change their pricing method than any other entity type. Family planning, STD, and TB clinics, which tend to dispense low-cost drugs such as contraceptives and antibiotics, were least likely to change their pricing method.

PROGRAM OPERATION AND PARTICIPANT SATISFACTION

Perhaps the greatest annoyance reported by 340B participants during telephone interviews conducted for a previous report (Schmitz, Quinn, and Williams 2003) was the difficulty in ascertaining the current 340B prices for prescription drugs. The absence of an official 340B price list forces providers to rely on distributors for information about current 340B prices–a situation that many providers find untenable.

Table V.9 shows the proportion of respondents who experienced two commonly reported problems. About 13 percent of respondents said that drug wholesalers or manufacturers either would not or could not furnish information about 340B prices. HIV clinics and disproportionate share hospitals were especially likely to report the same problem. A higher proportion–nearly one-quarter–of respondents said that they had difficulty in obtaining quarterly changes in 340B prices from their wholesaler or from a drug manufacturer. Disproportionate share hospitals, migrant health centers, and HIV clinics most frequently reported this problem.

Despite problems, the overall level of satisfaction with 340B prices was extraordinarily high, as Table V.10 shows. The proportion of respondents who said that they were “very satisfied” or “somewhat satisfied” with 340B savings (reported in the table as “satisfied) was never less than 88 percent and exceeded 97 percent for 6 of the 10 entity categories in the survey.

Table V.1. Payer Mix by Entity Type

		Payer					
		Self-pay	Private Insurance	Medicaid	Medicare	State/Local Indigency Program	Other
	N	Percent of Outpatient Drug Expenditure					
All	286	26.7	8.6	21.0	2.2	21.0	19.4
Disproportionate share hospitals	45	19.7	25.7	20.0	8.6	18.1	7.9
Family planning clinics	17	23.9	3.3	24.1	0.0	20.9	27.8
Community/federally qualified HC	34	51.7	12.6	20.0	2.4	6.0	7.4
Hemophilia treatment centers	22	4.5	48.0	18.3	21.8	7.3	0.0
Migrant/homeless clinics	41	31.7	6.2	24.4	1.9	20.6	15.1
HIV clinics	33	28.0	10.4	21.3	3.3	23.9	13.0
Ryan White Title I and II	42	15.2	6.6	15.9	1.3	22.5	37.3
STD/TB clinics	22	8.2	0.9	16.0	1.3	43.5	24.0
Tribal contract/urban Indian health centers	16	13.5	37.2	21.6	2.1	7.3	18.3
Other entities	14	36.3	12.8	25.7	2.9	8.2	14.1

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

TABLE V.2. Charge Structure by Entity Type

		Charge Structure					
		Wholesaler Acquisition Cost + Markup + Dispensing Fee	Medication Acquisition Cost + Dispensing Fee	Medication Acquisition Cost + % Markup + Dispensing Fee	Average Wholesale Price + % Markup + Dispensing Fee	Average Wholesale Price - % Markdown + Dispensing Fee	Other
	N	Percent of Participants					
All	297	8.3	30.5	3.1	6.2	5.6	46.3
Disproportionate share hospitals	47	0.0	32.9	11.2	9.0	14.0	32.9
Family planning clinics	22	9.1	22.7	0.0	4.6	4.5	59.1
Community/federally qualified HC	36	15.2	44.8	3.5	4.8	4.8	26.9
Hemophilia treatment centers	23	10.9	7.2	14.5	7.2	24.0	36.2
Migrant/homeless clinics	40	7.0	60.6	8.5	7.0	7.0	9.9
HIV clinics	36	0.0	42.4	8.1	2.4	7.1	40.0
Ryan White Title I and II	41	2.5	29.3	11.9	4.8	21.9	29.6
STD/TB clinics	23	5.8	18.5	0.0	11.6	0.0	64.1
Tribal contract/urban indian health centers	15	0.0	54.8	6.5	0.0	0.0	38.7
Other entities	14	14.8	57.4	20.9	0.0	0.0	6.9

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

Table V.3. Method of Charge for Uninsured Patients

		Method of Charge for Uninsured Patients			
		Financial Assessment with Sliding Fee/ Discount Based on Income	Price List	Full Charge	Other
	N	Percent of Participants			
All	294	50.0	6.8	9.9	33.3
Disproportionate share hospitals	45	40.0	0.0	17.8	42.2
Family planning clinics	21	81.0	0.0	0.0	19.0
Community/federally qualified HC	36	66.7	11.1	8.3	13.9
Hemophilia treatment centers	22	27.3	13.6	22.7	36.4
Migrant/homeless clinics	40	60.0	12.5	10.0	17.5
HIV clinics	36	55.6	11.1	5.5	27.8
Ryan White Title I and II	41	39.0	4.9	7.3	48.8
STD/TB Clinics	23	43.5	0.0	4.3	52.2
Tribal contract/urban Indian health centers	16	6.3	6.3	6.3	81.1
Other entities	14	78.6	7.1	14.3	0.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

Figure V.1. Distribution of Percent Saving

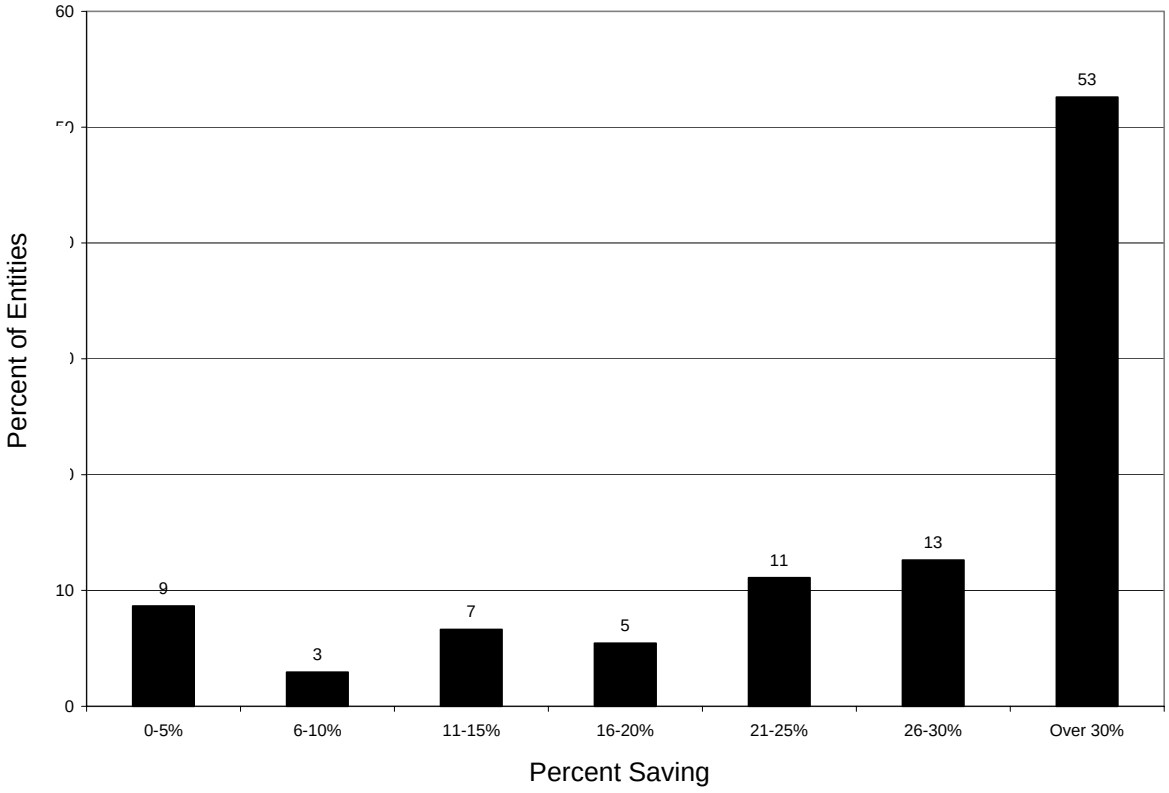

Table V.4. Estimated 340B Savings by Entity Type

	Estimated Saving Per 340B Participant			
	N	Mean Percent Saved	Median Saving (Dollars)	Lower Bound of Total Saving (Millions of Dollars)
All	249	26	26,250	661.4
Disproportionate share hospitals	44	27	616,000	341.9
Family planning clinics	13	24	18,545	97.5
Community/federally qualified HC	30	28	37,333	65.9
Hemophilia treatment centers	20	19	785,000	54.2
Migrant/homeless clinics	36	28	50,400	17.8
HIV clinics	27	26	45,500	6.0
Ryan White Title I and II	34	23	240,000	36.5
STD/TB clinics	17	31	15,400	32.7
Tribal contract/urban indian health centers	15	27	67,200	7.3
Other entities	13	24	37,888	1.8

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

TABLE V.5. Most Commonly Reported Therapeutic Category by Entity Type

	Entity Type										
	All	Disproportionate Share Hospitals	Family Planning Clinics	Community /Federally Qualified HC	Hemophilia Treatment Centers	Migrant/ Homeless Clinics	HIV Clinics	Ryan White Title I and II	STD/TB Clinics	Tribal Contract/ Urban Indian Health Center	Other Entities
	N=293	N=44	N=24	N=33	N=22	N=39	N=31	N=44	N=25	N=17	N=14
Allergy/antihistamine	2.7	0.0	0.0	3.9	0.0	1.5	3.9	0.0	10.9	0.0	13.9
Analgesics	10.2	9.6	12.5	9.2	0.0	11.8	12.0	9.0	5.5	11.4	13.9
Antibiotics/ Anti-infectives	56.1	25.8	62.5	36.9	16.2	38.2	55.2	65.8	82.7	18.6	64.4
Antidepressants/ Anti-anxiety	13.3	43.5	8.3	13.1	24.8	13.4	37.1	34.3	0.9	48.5	14.8
Anti-hypertensives	24.4	26.3	0.0	81.5	0.0	67.8	23.5	20.1	18.2	35.7	51.3
Anti-ulcerants	3.1	24.4	0.0	0.0	12.4	8.8	5.4	2.3	0.0	22.9	7.0
Arthritis/ anti-inflammatory	4.3	7.2	0.0	15.3	0.0	5.9	5.4	9.2	0.0	22.9	7.0
Asthma medications	4.5	9.6	0.0	9.2	0.0	17.7	0.0	2.21	5.5	11.4	28.7
Chemotherapy medications	3.5	37.3	0.0	0.0	12.4	0.0	3.9	4.6	0.0	0.0	0.0
Cholesterol control agents	13.1	26.3	0.0	43.1	19.9	32.4	21.3	15.9	0.0	41.4	13.9
Clotting factor concentrate	2.9	2.4	4.2	0.0	67.6	1.5	3.9	0.0	0.0	0.0	0.0
Contraceptives	48.9	0.0	95.8	1.5	0.0	5.9	2.7	4.5	33.6	5.7	13.9
Diabetes medications	26.9	14.4	4.2	82.4	0.0	72.1	9.3	24.6	22.7	75.7	43.5
HIV antiretrovirals	12.5	31.1	4.2	0.0	7.5	10.3	69.5	75.4	19.1	5.7	20.9
Osteoporosis drugs	0.2	0.0	0.0	0.0	0.0	2.9	0.0	0.0	0.0	0.0	0.0
Steroids	1.1	0.0	0.0	3.9	0.0	4.4	6.6	2.3	0.0	0.0	0.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

TABLE V.6. Estimated Saving by Therapeutic Category

	N	Median
Allergy/antihistamine	2	25,000
Analgesics	19	1,500
Antibiotics/anti-infectives	91	3,250
Antidepressants/anti-anxiety	54	25,000
Anti-hypertensives	59	12,000
Anti-ulcerants	21	53,250
Arthritis/Anti-inflammatorys	18	2,400
Asthma medications	15	10,080
Chemotherapy medications	18	200,000
Cholesterol control agents	43	12,500
Clotting factor concentrate	16	287,081
Contraceptives	24	10,000
Diabetes medications	62	7,837
HIV antiretrovirals	60	254,451
Osteoporosis drugs	1	12,000
Steroids	3	33,840

Table V.7. The Prime Vendor Program: Participation and Saving by Entity Type

			340B Saving by Prime Vendor Enrollment			
	N	Percent Participating	N	Enrolled Saving (%)	N	Not Enrolled Saving (%)
All	306	23	69	26	211	27
Disproportionate share hospitals	47	11	6	29	40	26
Family planning clinics	23	17	3	18	18	26
Community/federally qualified HC	37	45	14	29	19	27
Hemophilia treatment centers	24	3	1	23	20	19
Migrant/homeless clinics	41	39	15	27	25	29
HIV clinics	35	30	10	21	22	28
Ryan White Title I and II	43	14	6	21	32	24
STD/TB clinics	35	16	3	35	18	31
Tribal contract/urban Indian health centers	16	30	5	30	10	24
Other entities	15	47	6	26	7	21

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

TABLE V.8. Use of Saving by Entity Type

		Distribution of Saving					
		Increase Quantity/Variety of Drugs Available	Increase Number of Patients Cared For	Increase Services Available	Reduce Medication Price to Patients	Reduce Medication Price to Third Parties	Offset Losses from Providing Pharmacy Services at Less than Cost
	N	Mean %	Mean %	Mean %	Mean %	Mean %	Mean %
All	285	19.5	30.1	12.3	19.8	2.9	15.3
Disproportionate share hospitals	46	8.0	24.4	9.5	10.4	4.3	43.3
Family planning clinics	20	18.6	34.8	10.9	18.5	3.4	14.0
Community/federally qualified HC	36	18.5	19.9	18.4	31.5	0.4	11.6
Hemophilia treatment centers	19	1.3	10.1	20.4	18.8	20.2	29.2
Migrant/homeless clinics	41	21.8	23.9	13.0	26.2	2.0	10.5
HIV clinics	34	14.8	29.6	14.7	19.0	6.3	15.6
Ryan White Title I and II	40	18.7	48.4	14.0	10.3	3.3	5.0
STD/TB clinics	19	32.5	37.0	7.4	12.9	2.9	7.4
Tribal contract/urban Indian health centers	15	28.9	7.7	14.3	14.4	5.1	29.7
Other entities	15	12.6	31.1	15.1	20.0	0.3	17.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

Figure V.2. Proportion of Entities That Changed Pricing Method Since Participating in the 340B Program

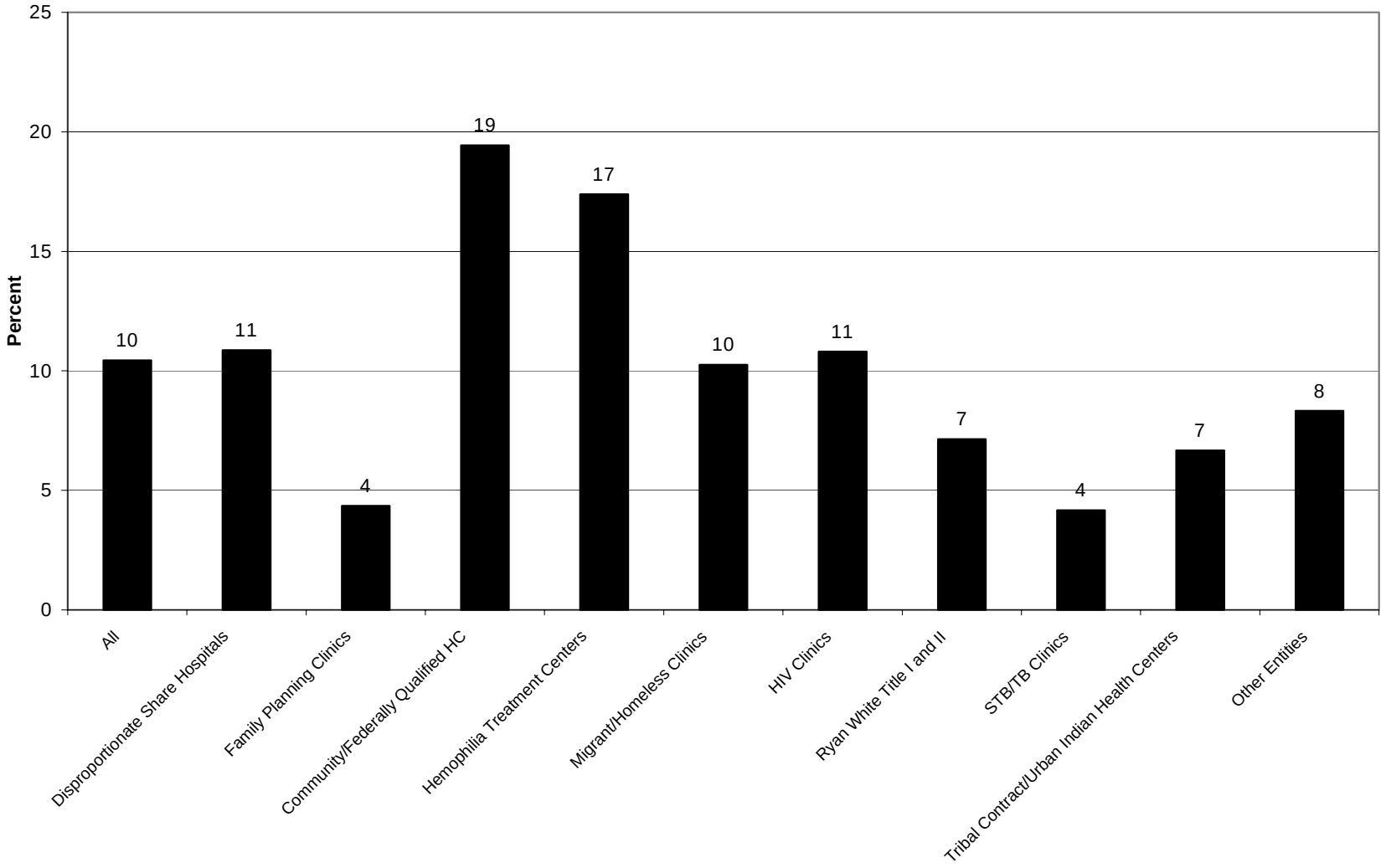

Table V.9. Reported Problems Obtaining Price Information by Entity Type

	Wholesaler/ Manufacturer Unwilling or Unable to Provide Information		Difficulty Obtaining Quarterly Price Changes from Wholesaler/ Manufacturer	
	N	Percent	N	Percent
All	298	12.8	295	23.1
Disproportionate share hospitals	46	17.5	47	44.1
Family planning clinics	21	14.3	21	19.1
Community/federally qualified HC	35	14.1	35	25.2
Hemophilia treatment centers	24	9.7	24	3.2
Migrant/homeless clinics	40	14.3	40	31.4
HIV clinics	35	18.2	34	29.6
Ryan White Title I and II	42	12.0	41	24.3
STD/TB clinics	25	5.5	24	18.3
Tribal contract/urban Indian health centers	15	0.0	15	0.0
Other entities	15	6.5	14	7.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

Table V.10. Satisfaction with Saving by Entity Type

		Satisfied	Dissatisfied
	N	Percent	
All	305	98.8	1.2
Disproportionate share hospitals	47	100.0	0.0
Family planning clinics	22	100.0	0.0
Community/federally qualified HC	35	96.5	3.5
Hemophilia treatment centers	23	96.4	3.6
Migrant/homeless clinics	41	97.2	2.8
HIV clinics	38	97.7	2.3
Ryan White Title I and II	43	97.6	2.4
STD/TB Clinics	25	100.0	0.0
Tribal contract/urban Indian health centers	17	88.6	11.4
Other entities	14	93.0	7.0

Note: Other entities include Section 340S School Health Programs, Black Lung Clinics, Health Centers for the Homeless, Public Housing Clinics, and Special Projects of National Significance (SPNS).

Values are weighted by the reciprocal of the probability of selection.

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CHAPTER VI

CONCLUSION

The evidence from MPR's survey of provider attitudes and experiences with the 340B Drug Pricing Program suggests that the program has been successful insofar as it has led to significant savings and a high level of satisfaction for its enrollees. If the program did not exist, it is quite likely that providers would serve fewer patients, would charge their patients higher prices for prescription drugs, and would incur greater losses. Total outpatient expenditures on prescription drugs by eligible entities is at least $2.65 billion per year. Total saving was estimated to be at least $661 million, or 27 percent of total outpatient drug expenditure. The actual proportion of revenue saved may well be higher still. More than half of all respondents chose the highest category for percent saved—"more than 30 percent." In estimating 340B savings, we assigned entities that selected this category a saving of 35 percent, probably a conservative estimate.

The program itself requires that participating providers pay no more than average manufacturer price (AMP) minus 15.1 percent for brand-name drugs and AMP minus 11 percent for generic drugs. The fact that our estimates indicate that savings substantially exceed these amounts implies that most providers believe they would pay more than AMP for prescription drugs in the absence of the program. However, we cannot verify this inference because AMP values, computed by the Centers for Medicare and Medicaid Services (CMS), are considered confidential.

Using estimates based on responses from participating entities to approximate the magnitude of savings brought about by the 340B program is admittedly problematic. Response errors could be substantial, especially for entities that have been enrolled for several years or more. But there is no reasonable alternative to a survey-based approach. The actual value of the saving for each entity depends on prices that the entity would pay in the absence of the program—a quantity nearly impossible to estimate in any way other than by asking. Entities do appear to be pleased with the saving. More than 98 percent of entities declared themselves to be "very satisfied" or "somewhat satisfied" with discounts they received through the program.

Limitations in the PAB Database of Eligible Entities hampered both the survey and the data analysis. Addresses in the database were incorrect for more than one-third of entities in the survey sample. In addition, thirty entities had closed. While some of the still-existing entities were eventually located, over half of the entities that did not respond to the survey

did not have a correct address in the database. Furthermore, some entities that appear either to share the same pharmacy or to be administered by the same organization (because their telephone numbers or contact person are the same) appear on the database as completely distinct entities, whose connection cannot be ascertained through their database identifier. The inability to link related entities made it difficult, if not impossible, to determine the unit for which expenditure and saving estimates were reported.

We recognize HRSA's commitment to minimizing the reporting burden on its grantees and on 340B participants. Nonetheless, we were surprised by the level of inaccuracy in the database. It clearly reduced the precision of the survey estimates and must surely interfere with the effective administration of the program. We therefore add one recommendation to the three included in an earlier report to HRSA (Schmitz, Quinn, and Williams, 2003). (The survey results give us no reason to alter these recommendations.)

The three earlier recommendations were: (1) that HRSA write a comprehensive guide to the 340B program so that authoritative information about program participation and requirements is available in a single document, (2) that HRSA should attempt to enhance the Prime Vendor program by pointing out the benefits of formularies and coordinated purchasing, and (3) that HRSA find some way to make information about current 340B ceiling prices available to participating entities.

To these, we add an additional recommendation: that HRSA should regularly update the PAB database of eligible entities to ensure its accuracy. To achieve this goal, we recommend that HRSA require all participating entities to verify, on an annual basis, their participation in the program, their address and telephone number, and the name of a contact person. While we recognize that it is a more difficult and time-consuming task, we also recommend that HRSA make additional efforts to identify and link entities that operate under the same organizational or administrative umbrella. This would provide HRSA with a useful understanding of the population of participating entities and their relationships with one another. Over time, these changes, combined with administrative reports such as the HRSA Uniform Data System, might allow HRSA to monitor the volume of pharmacy expenditure and to approximate 340B saving using regularly available data.

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APPENDIX A

PSH 340B DRUG PRICING PROGRAM SURVEY

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OMB Approval No.: 0915-0279
Expiration Date: 09/30/2004

PHS 340B DRUG PRICING PROGRAM SURVEY

PHARMACY AFFAIRS BRANCH (PAB)
HEALTH RESOURCES AND SERVICES ADMINISTRATION (HRSA)
BUREAU OF PRIMARY HEALTH CARE (BPHC)

[AVERY LABEL #5162 HERE]

Your facility is eligible to buy outpatient drugs at a discount under Section 340B of the Public Health Services Act. This law is administered by the Pharmacy Affairs Branch within the Health Resources and Services Administration.

In order to improve services to you, the Pharmacy Affairs Branch has contracted with Mathematica Policy Research to conduct this survey of eligible entities. Please fill out this customer satisfaction survey and send your completed questionnaire back to Mathematica. **PLEASE COMPLETE THE QUESTIONNAIRE EVEN IF YOU ARE NOT BUYING UNDER THE SECTION 340B PROGRAM.** Your responses, or your choice not to participate in the survey, will have no effect on your eligibility to receive discounted drug prices. Neither the identity of the respondents nor their specific responses will be available to the Pharmacy Affairs Branch. The contact information below will be used to contact you in the event we need to clarify any of your responses. Organizations that respond to the survey may request a copy of the project Final Report (in Adobe Acrobat format) by providing an email address below. This email address will not be used for any other purpose.

Completed by: _____ Title: _____

Facility Name: _____

Address: _____

Telephone: (|___|___|___|)-|___|___|___|-|___|___|___|___| Email Address (Optional): _____
Area Code Number

Date of Completion: |___|___| / |___|___| / |___|___|___|___|
Month Day Year

RETURN INSTRUCTIONS

Please return your completed survey in the pre-paid envelope provided. If you've misplaced the envelope, please send your survey by mail or fax as directed below.

Mathematica Policy Research, Inc. (8916-440)
P.O. Box 2393
Princeton, New Jersey 08543-2393
Attn: Julita Milliner-Waddell
(609)-799-0005 (fax)

PUBLIC BURDEN STATEMENT

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this project is 0915-0279. Public reporting burden for the applicant for this collection of information is estimated to average 45 minutes, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to HRSA Reports Clearance Officer, 5600 Fishers Lane, Room 14-45, Rockville, Maryland, 20857.

SECTION A

The first questions are about specific health care services that you provide and the volume of prescription drugs used in those programs.

1. Which of the following federal designation(s) are held by your organization?

(Note that all listed designations are eligible for Section 340B pricing.)

MARK (X) ALL THAT APPLY

1 ☐ Disproportionate Share Hospital
2 ☐ Community Health Center (sec. 330)
3 ☐ Migrant Health Center (sec. 329)
4 ☐ Public Housing Clinic
5 ☐ Health Care for the Homeless
6 ☐ Federally Qualified Health Center Look-Alike
7 ☐ Comprehensive Hemophilia Diagnostic Treatment Center
8 ☐ Family Planning Clinic
9 ☐ Ryan White Care Act (Title I - IV)
10 ☐ Black Lung Clinic
11 ☐ Native Hawaiian Health Center
12 ☐ Urban Indian Organization
13 ☐ FQHC 638 (tribal contractor) Self Determination
14 ☐ Sexually Transmitted Disease Clinic
15 ☐ Tuberculosis Clinic
16 ☐ School-Based Program
17 ☐ Special Project of National Significance (SPNS)
18 ☐ Other *(SPECIFY)*

_____

_____

_____

2. How are pharmacy services currently provided by your facility or program?

MARK (X) ALL THAT APPLY

1 ☐ On-site pharmacy
2 ☐ Contracted pharmacy services
3 ☐ Mail-order pharmacy
4 ☐ Provider dispensing
5 ☐ Rebate
6 ☐ Other *(SPECIFY)*

_____

_____

7 ☐ Does not provide pharmacy services → **SKIP TO Q.9**

3. What is your annual *outpatient* prescription volume for all types of pharmacy services checked in Question 2?

_____ PRESCRIPTIONS

4. What is your best estimate of the total outpatient drug purchases by your organization during your most recently completed fiscal year?

$ _____
TOTAL PURCHASES

in fiscal year ending:

		/				
Month			Year			

5. What percent of these outpatient drug purchases would you say was accounted for by patients of the entities checked in Question 1?

			%

Your answers to all remaining questions should apply *only* to the entity type printed on the label on the cover of this questionnaire. For example, if you are a disproportionate share hospital which also contains a hemophilia treatment center, and the label on the cover says "hemophilia treatment center," answers to all remaining questions should pertain only to the hemophilia treatment center.

6a. What is the annual outpatient prescription volume by the entity listed on the label?

_____ **[ANNUAL OUTPATIENT PRESCRIPTION VOLUME]**

6b. What is the annual dollar amount of prescription drugs purchased by the entity listed on the label?

$ _____ **[ANNUAL AMOUNT OF PRESCRIPTION DRUG PURCHASES]**

6c. What percent of total outpatient prescription purchases by your facility or clinic are accounted for by the entity listed on the label?

			%

[PRESCRIPTIONS PURCHASED BY SELECTED ENTITY]

7. How are you currently paid for *outpatient services* covered by Medicaid?

MARK (X) ONE RESPONSE ONLY

1 ☐ Rate per visit under Medicaid prospective payment

2 ☐ Reasonable cost per visit

3 ☐ Fee for service

4 ☐ Other *(SPECIFY)*

_____

5 ☐ Does not provide services covered by Medicaid → **SKIP TO Q.9**

8. How are you currently paid for *prescription drugs* covered by Medicaid?

MARK (X) ONE RESPONSE ONLY

1 ☐ Included in Medicaid per-visit rate

2 ☐ Included in all-inclusive reasonable cost rate

3 ☐ Carved out of all-inclusive rate and paid separately

4 ☐ Fee for service

5 ☐ Other *(SPECIFY)*

_____

SECTION B

The following questions are about information that you have received about the PHS 340B Drug Pricing Program.

9. Are you aware of the HRSA Alternative Methods Demonstration Projects?

1 ☐ Yes

0 ☐ No → **SKIP TO Q.11**

10. How did you learn about the HRSA Alternative Methods Demonstration Projects?

MARK (X) ALL THAT APPLY

1 ☐ Pharmacy Affairs Branch (PAB) Website

2 ☐ HRSA Field Office

3 ☐ Discussion with another health center

4 ☐ Newsletter

5 ☐ Any national trade association or professional meeting

6 ☐ HHS press release

7 ☐ Other *(SPECIFY)*

_____

11. What have been your sources of information about the PHS 340B Drug Pricing Program?

MARK (X) ALL THAT APPLY

1 ☐ PAB Staff or Website
2 ☐ HRSA Field Office
3 ☐ Federal Grant Program
4 ☐ Professional Organization
5 ☐ Manufacturer or Wholesaler
6 ☐ Other Health Care Facilities
7 ☐ Professional Associates
8 ☐ Journal or News Article
9 ☐ Other *(SPECIFY)*

_____

_____

10 ☐ Have not heard of PHS 340B Program

12. How would you describe your understanding of the program?

1 ☐ Understand well
2 ☐ Understand well enough to use but still have questions
3 ☐ Understand only slightly
4 ☐ Do not understand at all

13. Have you ever called the Pharmacy Affairs Branch for information or technical assistance?

1 ☐ Yes
0 ☐ No → **SKIP TO Q.15**

14. How would you rate the following aspects of their response?

MARK (X) ONE RESPONSE FOR EACH

	EXCELLENT	VERY GOOD	GOOD	FAIR	POOR
a. Accessibility of staff	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐
b. Ability to answer your questions/ solve your problem	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐
c. Timeliness of response/ assistance	5 ☐	4 ☐	3 ☐	2 ☐	1 ☐

15. Have you ever accessed the PAB Website (http://bphc.hrsa.gov/opa)?

1 ☐ Yes
0 ☐ No → **SKIP TO Q.18**

16. For what purposes have you used the website?

MARK (X) ALL THAT APPLY

1 ☐ Verify eligibility in the program
2 ☐ Registration
3 ☐ *Federal Register* notices
4 ☐ *What's New?* Information
5 ☐ Program Guidelines
6 ☐ Contracted pharmacy forms
7 ☐ Downloads
8 ☐ Entity lookup
9 ☐ Other *(SPECIFY)*

_____

17. How satisfied are you with the following aspects of the website?

MARK (X) ONE RESPONSE FOR EACH

	VERY SATISFIED	SOMEWHAT SATISFIED	NOT AT ALL SATISFIED
a. Organization...	3 ☐	2 ☐	1 ☐
b. Usefulness of the information.....	3 ☐	2 ☐	1 ☐
c. Clarity of information.....	3 ☐	2 ☐	1 ☐

SECTION C

The remaining questions are about your experience with the PHS 340B Drug Pricing Program.

18. Are you currently participating in the PHS 340B Drug Pricing Program?

1 ☐ Yes

0 ☐ No

19. What could the Pharmacy Affairs Branch (PAB) do to help more organizations like yours take advantage of the 340B Drug Pricing Program?

MARK (X) ALL THAT APPLY

1 ☐ Improve website

2 ☐ Presentations at professional meetings

3 ☐ Technical assistance to individuals or small groups of entities

4 ☐ Site visits to individual entities or groups

5 ☐ Telephone consultations

6 ☐ Written materials

7 ☐ Other *(SPECIFY)*

_____

_____

_____

IF YOU ARE PARTICIPATING IN THE PHS 340B PROGRAM, SKIP TO Q.21

20. Why isn't your organization currently participating in the 340B Drug Pricing Program?

MARK (X) ALL THAT APPLY

1 ☐ No on-site outpatient pharmacy services

2 ☐ Would decrease Medicaid reimbursement

3 ☐ Preventing drug diversions is too difficult

4 ☐ Quarterly price change is too difficult to verify

5 ☐ Difficulties resulting from GPO withdrawal

6 ☐ Would lose nominal pricing

7 ☐ Start-up costs are too high

8 ☐ Problems with manufacturers or wholesalers

9 ☐ Other *(SPECIFY)*

_____

_____

END OF SURVEY FOR THOSE NOT PARTICIPATING IN THE PROGRAM. PLEASE RETURN YOUR COMPLETED SURVEY IN THE ENVELOPE PROVIDED. THANK YOU.

21. How are you accessing PHS 340B prices?

MARK (X) ALL THAT APPLY

1 ☐ On-site pharmacy

2 ☐ Contracted pharmacy services

3 ☐ Mail-order pharmacy

4 ☐ Provider dispensing

5 ☐ Rebate

6 ☐ Other *(SPECIFY)*

_____

_____

22. What percentage of your outpatient drugs are paid for by each of the following sources? (MUST TOTAL 100%)

1 ☐ Self-pay (uninsured or underinsured) ___ %

2 ☐ Private insurance ___ %

3 ☐ Medicaid ___ %

4 ☐ Medicare ___ %

5 ☐ State/local indigency program ___ %

6 ☐ Other *(SPECIFY)* ___ %

_____

_____

TOTAL 1 0 0 %

23a. What method did you use to develop your charge structure for drugs?

MARK (X) ONE RESPONSE ONLY

1 ☐ Wholesale Acquisition Cost plus some percent (markup) plus dispensing fee **(INDICATE PERCENTAGE MARKUP)** ___ %

2 ☐ Medication Acquisition Cost + dispensing fee

3 ☐ Medication Acquisition Cost plus some percent (markup) plus a dispensing fee **(INDICATE PERCENTAGE MARKUP)** ___ %

4 ☐ Average Wholesale Price plus some percent (markup) plus a dispensing fee **(INDICATE PERCENTAGE MARKUP)** ___ %

5 ☐ Average Wholesale Price minus some percent (markdown) plus a dispensing fee **(INDICATE PERCENTAGE MARKDOWN)** ___ %

6 ☐ Other *(SPECIFY)*

_____

_____

_____

23b. What method do you now use for charging drugs for *self-pay (uninsured) patients*?

MARK (X) ONE RESPONSE ONLY

1 ☐ Financial assessment with sliding fee or discount based on income

2 ☐ Price list

3 ☐ Full charge

4 ☐ Other *(SPECIFY)*

_____

_____

24. Considering the answers checked in Questions 23a and 23b, have you changed your pricing method since you began participating in the PHS 340B Program?

1 ☐ Yes

0 ☐ No → **SKIP TO Q.26**

25a. What method did you use to develop your charge structure for drugs *prior to participating in the PHS 340B Program*?

MARK (X) ONE RESPONSE ONLY

1 ☐ Wholesale Acquisition Cost plus some percent (markup) plus dispensing fee **(INDICATE PERCENTAGE MARKUP)** ___ %

2 ☐ Medication Acquisition Cost + dispensing fee

3 ☐ Medication Acquisition Cost plus some percent (markup) plus a dispensing fee **(INDICATE PERCENTAGE MARKUP)** ___ %

4 ☐ Average Wholesale Price plus some percent (markup) plus a dispensing fee **(INDICATE PERCENTAGE MARKUP)** ___ %

5 ☐ Average Wholesale Price minus some percent (markdown) plus a dispensing fee **(INDICATE PERCENTAGE MARKDOWN)** ___ %

6 ☐ Other *(SPECIFY)*

_____

_____

_____

25b. What method did you use to charge *self-pay (uninsured) patients* for drugs prior to participating in the PHS 340B Program?

MARK (X) ONE RESPONSE ONLY

1 ☐ Financial assessment with sliding fee or discount based on income
2 ☐ Price list
3 ☐ Full charge
4 ☐ Other *(SPECIFY)*

_____

_____

26. During the last 3 months, what was the estimated range of savings on total drug purchases to the entity type on the label as a result of PHS 340B pricing? Please estimate as best you can, the percentage difference between what you pay for drugs and what you would pay in the absence of the program.

1 ☐ 0 – 5%
2 ☐ 6 – 10%
3 ☐ 11 – 15%
4 ☐ 16 – 20%
5 ☐ 21 – 25%
6 ☐ 26 – 30%
7 ☐ over 30%

27. Please provide the information requested in Columns A, B, C, and D below.

Column A: Specify the three therapeutic drug categories that account for the greatest share of purchases by the entity identified on the label of the questionnaire. Use numbers (1-16) from the drug category list.
Column B: Estimate annual purchases for outpatient use for each of the three categories.
Column C: Estimate the percent of this drug in total outpatient drug expenses.
Column D: Estimate your total 340B saving on the drug category.

Therapeutic Drug Categories

1. Allergy/Antihistamines
2. Analgesics
3. Antibiotics/Anti-infectives
4. Antidepressants/Anti-anxiety
5. Anti-hypertensives
6. Anti-ulcerants
7. Arthritis/Anti-inflammatory medications
8. Asthma Medications
9. Chemotherapy Medications
10. Cholesterol Control Agents
11. Clotting Factor Concentrate
12. Contraceptives
13. Diabetes Medications
14. HIV Antiretrovirals
15. Osteoporosis Drugs
16. Steroids

Column A Category # (from list)	Column B Dollar Volume	Column C % of Overall Volume	Column D Estimated 340B Saving
1. _____	$_____	_____%	$_____
2. _____	$_____	_____%	$_____
3. _____	$_____	_____%	$_____

28. How satisfied are you with the discount you receive from the PHS 340B Program?

1 ☐ Very satisfied
2 ☐ Somewhat satisfied
3 ☐ Somewhat dissatisfied
4 ☐ Very dissatisfied

29. Please indicate how the savings from the PHS 340B Program are distributed by entering a percent of savings for each category below. If you are unable to categorize how savings are used, please indicate how you *would* allocate any additional savings on prescription drugs. Please account for 100% of the savings.

Increase the quantity/ variety of drugs available		%
Increase the number of patients cared for		%
Increase services available at the facility		%
Reduce medication price to the patient		%
Reduce medication price to third parties		%
Offset losses from providing pharmacy services at less than full compensation		%
Other *(SPECIFY)* _____ _____		
TOTAL	**1 0 0**	%

29a. Do the allocations shown in Question 29 represent actual 340B savings, or preferred allocation of additional savings?

MARK (X) ONE RESPONSE ONLY

1 ☐ Actual 340B savings, or

2 ☐ Preferred allocation of additional savings

30. Have any wholesalers or manufacturers been unwilling or unable to provide you with 340B drug pricing information?

1 ☐ Yes → **PLEASE EXPLAIN BELOW**

0 ☐ No

_____

_____

_____

_____

31. Have you had difficulty obtaining quarterly price changes from wholesalers or manufacturers in a timely manner?

1 ☐ Yes → **PLEASE EXPLAIN BELOW**

0 ☐ No

_____

_____

_____

32. Do you currently participate in the HRSA Prime Vendor Program with Amerisource Bergen?

1 ☐ Yes

0 ☐ No → **SKIP TO Q.35**

33. Has Amerisource Bergen been your wholesaler since your enrollment in the 340B program?

1 ☐ Yes

0 ☐ No → **PLEASE EXPLAIN YOUR SWITCH TO AMERISOURCE BERGEN BELOW**

_____

_____

_____

34. Please comment briefly on the Prime Vendor Program—specifically, how could the Prime Vendor Program be improved?

_____

_____

_____

35. (ANSWER THIS QUESTION ONLY IF YOU ANSWERED "NO" TO Q.32.)
Why have you not enrolled in the Prime Vendor Program?

_____

_____

_____

THANK YOU FOR COMPLETING THIS SURVEY.
PLEASE RETURN YOUR SURVEY IN THE PRE-PAID ENVELOPE PROVIDED.