



Analysis of the Effectiveness of Title X Family Planning Providers' Use of the 340B Drug Pricing Program

Final Report

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Executive Summary

A. Background

The Title X program plays a unique role in the health of Americans. It serves approximately 5 million women and men and provides a range of contraceptive, health screening, and sexually transmitted disease (STD) prevention and treatment services. To help safety-net providers – including those supported by Title X – continue to serve clients amid increasing health care costs, the federal government has implemented cost-saving mechanisms and programs. One such effort, the 340B Drug Pricing Program, was created through the Veterans Health Care Act of 1992 and codified as Section 340B of the Public Health Service Act. This law requires that manufacturers provide outpatient drugs at a discounted price to certain federal grantees, including Title X-supported entities.¹ The program is run by the federal Office of Pharmacy Affairs of the Health Resources and Services Administration (OPA/HRSA), which also funds the Pharmacy Services Support Center (PSSC), a free technical assistance service. Many providers use their savings to serve more clients, offset losses, reduce prescription drug prices to patients, and increase the scope of services offered.

Additional discounts on some products are negotiated through 340B's Prime Vendor Program, which leverages public health entities' collective purchasing power to negotiate sub-340B discounts. The program, run by an organization called Apexus, also works to improve drug distribution for providers and to negotiate discounts on pharmacy-related services. The actual prices charged under both 340B and Prime Vendor programs are considered proprietary and are not made available to non-participating entities.

B. Purpose and Methodology

The Office of Family Planning (OFP) within the Office of Population Affairs (OPA), in the U.S. Department of Health and Human Services, contracted with The Lewin Group and the Guttmacher Institute to better understand the facilitators and barriers, as well as benefits and drawbacks, to Title X providers' participation in the 340B and Prime Vendor programs. The study aimed to help OPA/OFP understand the many issues contributing to Title X providers' experiences using these programs, along with alternative methods available for achieving pharmaceutical discounts.

The research was conducted in two phases. First, a review of the relevant literature was performed to gain an understanding of the programs' basic rules and approaches, and any existing research on them. Beyond the literature, this phase also included discussions with representatives from 340B and Prime Vendor, OFP central office and regional office staff², national organizations representing family planning providers, and a family planning cooperative purchasing program serving Title X-supported providers nationwide. The second

¹ <ftp://ftp.hrsa.gov/bphc/pdf/opa/FR05071993b.pdf>.

² The delegation of authority for the Title X Family Planning Services Program is to the Regional Health Administrator (RHA) in each of the ten Public Health Service (PHS) Regions. The RHA is responsible for the award and administration of regional family planning service grants, and for oversight and monitoring program performance of the family planning service program in the region.

major phase of the research comprised in-depth discussions with grantee and delegate agencies around the country currently receiving Title X funds.

The main findings of the paper are described below.

C. Main Findings

This study identified numerous positive aspects in Title X–supported providers’ experiences with the 340B and Prime Vendor programs. A large portion, if not all, are enrolled in 340B, and an increasing number are enrolled in Prime Vendor. This report also notes a number of challenges reported by informants, including a lack of consistently available information about the programs. These challenges were, in some cases, identified as leading to misinformation and an ensuing unwillingness to take full advantage of the programs.

1. *Use of 340B, Prime Vendor, and Other Purchasing Programs*

Near universal use of 340B; use of Prime Vendor program increasing. All of the providers with whom the study team spoke are enrolled in the 340B program. Informants indicated that although 340B participation has long been widespread, it essentially became required in 2006, after a change in federal law ended providers’ access to very low (“nominal”) drug prices unless they were enrolled in 340B. (That law was again changed in 2009, after this study was completed, to provide non-340B family planning providers with access to nominal drug prices.)

Further, a substantial and increasing number of grantees and delegates are aware of and signed up for the Prime Vendor program (including about two-thirds of informants), and Title X-supported providers account for nearly half of Prime Vendor’s enrollment (although they represent a much smaller proportion of the program’s purchasing volume). Although several enrollees reported that they were not purchasing any products for which the program had secured a discount, most of those enrolled were purchasing at least a few pharmaceuticals through Prime Vendor.

Use of other purchasing programs widespread; few providers use 340B and Prime Vendor exclusively. A majority of the study informants do not use 340B on its own, but rather use it in collaboration with other purchasing arrangements or contracts that offer lower costs, conveniences, or both. Roughly half of informants were enrolled in the Family Planning Cooperative Purchasing Program (FPCPP) – a Title X-specific purchasing program established in the early 1990s by the California Family Health Council – but few saw the program today as a central source of drug discounts. In contrast, informants indicated that the pharmaceutical contracts negotiated by Planned Parenthood Federation of America (PPFA) – contracts specific to family planning providers’ needs and open only to PPFA affiliates – were superior to any other option. Both programs were seen as important sources of information and of discounts on non-pharmaceutical supplies and services. Only a few informants indicated that negotiation by state agencies was a fruitful source of drug discounts, although in those few cases, the discounts negotiated were strong ones. Multistate negotiation was not widely seen as valuable either for contraceptive supplies, because the contracts negotiated through the existing programs are above the 340B prices.

Cost savings and stability top priorities. Informants’ top priorities in their use of the various drug purchasing programs were cost savings and the stability of drug prices. However,

informants reported struggling in terms of the time, resources, and information they needed to invest in order to identify the best discounts and ensure that they are receiving all of the discounts to which they are entitled. In general, informants saw the 340B discounts as a bare minimum of what they needed to provide care for their clients. They valued Prime Vendor, PPFA and other programs for deeper discounts and longer contracts but viewed them as having limitations, such as Prime Vendor's failure as yet to secure contracts with Ortho-McNeil, which manufactures many of the contraceptive products that Title X providers purchase most.

2. Awareness of 340B, Prime Vendor, and Other Purchasing Programs

Providers desire additional, easily accessible information. Informants differ on the scope of information about purchasing and drug prices they needed in order to run their programs effectively. Most agree, however, that they need more information than they have now. Ideally, that information should be easily accessible; tailored to their particular needs as Title X–supported providers; and communicated in a straight-forward, non-technical manner.

This research found that Title X–supported providers do not have a single, trusted, central source of information about drug purchasing programs, or how to choose among them for any given drug. The informants generally agreed that OFP central office and regional office staff do not currently serve that function, an assessment with which Federal staff agreed in focus group discussions. Informants reported getting information from a patchwork of other sources, including the various drug purchasing programs. The FPCPP and PPFA were both viewed as especially valuable; both were reported to communicate with their membership through a wide variety of media, and both are focused on the issues important to family planning providers. For those same reasons, other affiliate organizations, such as the National Family Planning and Reproductive Health Association (NFPRHA), were viewed as equally important to many informants. Informants reported that grantees themselves are a good source of information for their delegates.

Many informants praised the drug purchasing programs' websites, emails, newsletters and customer service. Others called for introductory information packets or tutorials that were simply written and tailored to the Title X–supported enrollees. They also called for clear explanations of program rules that specifically addressed intersections of Title X and long-standing arrangements such as FPCPP and the PPFA discounts.

Absence of public information about prices impedes full use of programs. Informants consistently expressed frustration with the unique problems of the pharmaceutical marketplace, including the lack of publicly available pricing information or any standards for comparison. Informants reported piecing together information from drug purchasing arrangements, distributors and manufacturers, including on-line price lists, regular newsletters and phone contact with vendors. This information is rarely available far enough in advance to provide for adequate budgeting, and providers have no means of verifying its accuracy.

3. *Barriers to Maximizing Use of Drug Purchasing Programs*

Although this research found that most – if not all – Title X grantees participate in 340B, and many in Prime Vendor, discussions also revealed that they have faced a number of obstacles to using the drug discount programs to the fullest extent.

Providers seek deeper discounts on more products. Informants report increasing satisfaction with the products available from 340B and Prime Vendor. But most informants also indicated needing additional products that are not currently available, and assumed that new and deeper discounts and longer-term contracts for the products that Title X-supported providers want would require more purchasing power – for example, more Title X-supported providers signed up for and purchasing drugs through Prime Vendor.

Complexities in the enrollment process. Some cited 340B’s quarterly enrollment policy, which can result in up to a three-month delay in enrolling a new clinic if an entity misses a deadline or makes a mistake during the enrollment process, as one factor standing in the way of easy enrollment. Others mentioned that the Prime Vendor application asks for a Drug Enforcement Agency (DEA) identification number – something that many family planning providers do not have since they do not prescribe controlled substances. Although applicants are not required to supply a DEA number, the directions do not state this either way, and the resulting perception that they are required to leads informants to see this as evidence of Prime Vendor’s not having tailored their documents to the Title X community.

Title X providers seek increased targeted outreach and information. Many informants praised recent steps taken by the 340B and Prime Vendor programs to reach out to Title X-supported providers and encourage enrollment; of particular note was a Title X advisory group set up by Prime Vendor to identify ways to bolster the program’s usefulness for family planning providers. Nevertheless, informants expressed mixed opinions about the type and quality of information coming from OPA/HRSA, PSSC and Apexus, including their websites, written materials, presentations and marketing. The most commonly voiced concern was that the 340B and Prime Vendor programs had not developed marketing materials that spoke sufficiently to Title X-specific issues and populations in plain language.

Challenges common with pricing. Title X-supported providers face many ongoing problems in making purchases of pharmaceutical products. A key issue is the volatility and shifting of drug prices, which creates uncertainty for providers’ budgets, patients, and inventories. Informants commonly cited an unpredictable but seemingly accelerating upward trend in prices, particularly in the 340B program, where prices change quarterly. Although sometimes the volatile prices lead to substantial discounts for providers – including one-cent pricing (called “penny-a-pack”) for some drugs – informants typically saw limited options for taking advantage of these discounts, because of restrictions on these sales by vendors, including both formal restrictions (e.g., setting monthly quotas for each customer) and informal ones (e.g., placing a customer’s order on backorder). Smaller informants often cited additional problems of minimum-order and prepayment requirements. Many informants, particularly those that prefer to provide long-term supplies of contraceptives to their patients, cited the problem of short expiration dates. Several informants asserted that many of these problems could be avoided through assertive conversations with drug vendors.

Pricing challenges affect clients, budgets and inventory. Informants generally felt constrained in their ability to take full advantage of available discounts if it meant clients would need to switch between methods or specific pills; changes in contraceptive regimens could lead to negative side-effects, reduce method effectiveness, and harm provider-client relations. Others saw these problems as easily addressed with a good pharmacist (who could identify bioequivalent products for patients) and thoughtful communication with clients. By contrast, informants – especially government agencies and providers with a high proportion of poor, uninsured clients – consistently reported that shifting prices and other logistical challenges negatively affected their budgets and affected clients’ options, or make it difficult for them to maintain an adequate and accurate inventory. Further, informants’ interpretation varied widely about different inventory tracking requirements under the rules of various programs, including 340B, Prime Vendor, Title X and Medicaid – another indication that the parameters of the programs are not well understood.

As noted above, some informants saw these challenges as important but solvable at the level of individual Title X-supported providers. Others, however, argued for greater intervention by the federal government.

4. Drug Purchasing and Medicaid Reimbursement

Medicaid an important revenue source. To avoid the cost-saving measures described above, informants reported ways of seeking greater revenues. Several had succeeded in securing additional federal or state funding (including no-cost drugs for STD treatment through the Infertility Prevention Program³), or private-sector grants and donations (including manufacturers’ patient assistance programs). However, third-party reimbursement, which for this population is almost always Medicaid, was the most important source of revenue reported by informants, and maximizing this revenue is challenging.

The relative importance of Medicaid to informants appeared to depend on the scope of their state’s Medicaid program, which is determined largely by the program’s eligibility standards, both in terms of income and immigration status. This is true both for Medicaid overall and for the family planning expansion programs that have been established over the past 15 years in about half the states. Those informants in some states with Medicaid expansion programs reported that the expansions substantially eased the challenges presented by rising drug prices. Nevertheless, many informants reported as daunting the intricacies of Medicaid reimbursement, including avoiding duplicate discounts, negotiating with managed care plans, delayed payments, and maintaining appropriate inventories. On all of these issues, informants suggested that clearer and more specifically tailored guidance would be helpful.

5. Consequences of Rising Costs

Additional cost savings sought by informants out of necessity. Informants consistently reported that the discounts under 340B, Prime Vendor and other drug purchasing programs do not entirely compensate for the rising program costs including those of pharmaceuticals and supplies. Informants described numerous approaches outside of utilizing drug discount

³ The Infertility Prevention Program (IPP) is a CDC-administered program which focuses on chlamydia and gonorrhea screening, treatment, prevention, and control through coordination of a number of health care programs. The IPP has been in place since 1992.

programs to achieving cost savings and maximizing revenue, demonstrating the degree to which drug purchasing issues are intertwined with broader issues of reimbursement, revenues and budgets. They also show how 340B, Prime Vendor and Title X are linked with a host of other federal, state and private programs, most notably Medicaid.

All of the informants have given considerable thought to the cost pressures facing their organizations and have sought ways to achieve cost savings on pharmaceuticals. One commonly reported tactic was to limit the list of contraceptive drugs and devices offered at their clinics (commonly referred to as a formulary). Contraceptive devices such as the IUD and implant (with their high up-front costs) and brand-name products such as Yasmin and Seasonale were cited as especially problematic and were often excluded from clinics' formularies or ordered only in small quantities. Another tactic – in some ways an opposite one – was to “chase” discounts and thereby frequently change the provider’s formulary. However, many informants were reluctant to take such measures because of the potential effects on patients, budgets and inventories discussed above. Informants also debated the merits of “scripting out” their clients, requiring them to fill a prescription at a drug store or on-line pharmacy. This practice saves Title X-supported providers money since they no longer have to use their own funds to purchase drugs, but it imposes significant burdens on clients, particularly lower-income ones. Different informants reported receiving varying answers from regional office staff regarding when scripting out is allowed under Title X.

Chapter I. Introduction

A. Background

The Title X program plays a unique role in the health of Americans. It serves approximately 5 million women and men and provides a range of contraceptive, health screening, and sexually transmitted disease (STD) prevention and treatment services. In 2006, the program helped provide contraceptive services to 27 percent of U.S. women in need of subsidized care.⁴ In 2004, Title X-supported providers helped women avoid nearly one million unintended pregnancies, and saved taxpayers \$4.02 for every dollar spent.⁵

Title X-supported providers have faced challenges in recent years in serving their current base of clients in the context of inflation, rising health care costs and the advent of new reproductive health technology and medication (e.g., the new contraceptive implant, ring and patch).⁶ Congress appropriated \$300 million for Title X in FY 2008. One calculation shows that in order to account for general and medical inflation, Title X would have had to have been funded at \$787 million for FY 2008 to match the FY 1980 funding levels.⁷ The rising cost of contraceptives and other pharmaceutical supplies is a major factor in the financial equation. For instance, a small-scale, 2002 investigation by the Guttmacher Institute found a 58 percent increase in the cost per client over six years.⁸ In this environment, steps to help Title X providers maximize existing funding are critical to their ability to serve their clients.

The 340B Drug Pricing Program is one federal program designed to reduce the amount Title X and other safety net entities spend on drugs amid these increasing costs.^{9,10} The 340B Drug Pricing Program was created through the Veterans Health Care Act of 1992 and codified as Section 340B of the Public Health Service Act. This law requires that manufacturers provide outpatient drugs at a discounted price to certain statutorily defined covered entities, often referred to as safety net health care providers¹¹ Ultimately, 340B discounts result in cost savings to participating entities. Many use their savings to serve more patients, offset losses, reduce prescription drug prices to patients, and increase the scope of services offered.¹² Title X family planning providers are one such type of entity.

In order to receive drug discounts through the 340B program, entities must enroll with the Office of Pharmacy Affairs of the Health Resources and Services Administration (OPA/HRSA)

⁴ Gold RB et al., *Next Steps for America's Family Planning Program: Leveraging the Potential of Medicaid and Title X in an Evolving Health Care System*, New York: Guttmacher Institute, 2009

⁵ Frost JJ, Finer LB and Tapales A, The impact of publicly funded family planning clinic services on unintended pregnancies and government cost savings, *Journal of Health Care for the Poor and Underserved*, 2008, 19(3):777-795.

⁶ National Family Planning & Reproductive Health Association. (2007). Title X(ten) National Family Planning Program.

⁷ Unpublished tabulations by the Guttmacher Institute, 2009.

⁸ <http://www.guttmacher.org/pubs/tgr/05/5/gr050506.html>.

⁹ <http://www.guttmacher.org/pubs/tgr/05/5/gr050506.html>.

¹⁰ <ftp://ftp.hrsa.gov/bphc/pdf/opa/FR05071993b.pdf>.

¹¹ <ftp://ftp.hrsa.gov/bphc/pdf/opa/FR05071993b.pdf>.

¹² Richardson, Katheryne. (April 2004). Implementing a Comprehensive 340B Contracted Pharmacy Service. Prepared for Medpin.

within the U.S. Department of Health and Human Services (DHHS). There are approximately 15,000 eligible entities, of which about 80 percent participate in the 340B program. In addition to Title X providers, these eligible entities include (but are not limited to) federally qualified health centers (FQHCs), Ryan White programs, and sexually transmitted disease (STD)/TB programs.

Additional discounts on some products are negotiated through 340B's Prime Vendor Program. Since 2004, this program has been operated by HealthCare Purchasing Partners International, which in July 2007 changed its name to Apexus. Prime Vendor leverages public health entities' collective purchasing power to negotiate sub-340B prices. The program also works to improve drug distribution for clinics and to negotiate discounts on pharmacy-related services. The actual prices charged under both programs are considered proprietary and are not made available to the public.

The 2006 passage of the Deficit Reduction Act (DRA), which was intended to cut costs for the federal government and made significant changes to the federal Medicaid program, brought greater attention to these programs. Prior to the DRA, many safety-net providers, including Title X and non-Title X-funded family planning clinics, had long been able to secure "nominal" prices (defined as any price less than 10 percent of the average manufacturer price) from drug manufacturers, regardless of whether they were participating in the 340B program. Under the DRA, however, manufacturers could only offer "nominal prices" to some entities – including any entity participating in 340B – without affecting the rebates they must offer to the entire Medicaid program.¹³ Effectively, this made enrolling in the 340B program a prerequisite for family planning providers seeking major drug discounts.

The law was again changed in 2009¹⁴ to include many non-340B family planning providers among the list of entities to which manufacturers were allowed to offer nominal prices. That change occurred after this study was conducted, thus its affect on availability of drug discounts is not reflected in this report.

B. Study Goals and Methodology

The Office of Family Planning (OFP) within the Office of Population Affairs, DHHS, contracted with The Lewin Group and the Guttmacher Institute to better understand the benefits and drawbacks to Title X providers' participation in the 340B and Prime Vendor programs. Through a literature review and discussions with a range of key informants, the study was designed to illuminate the obstacles and facilitators to Title X providers' knowledge, understanding and use of the 340B and Prime Vendor programs, as well as alternative sources of drug discounts.

The project team, in collaboration with OPA/OFP, identified key research topics to explore the effectiveness of Title X-supported providers' use of the 340B and Prime Vendor programs. These were:

- ▶ Provider awareness of 340B and Prime Vendor programs

¹³ <http://edocket.access.gpo.gov/2007/pdf/07-3356.pdf>.

¹⁴ http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=111_cong_bills&docid=f:h1105enr.txt.pdf

- ▶ Provider use of 340B, Prime Vendor and other purchasing programs
- ▶ Barriers to use of the programs
- ▶ Relationship between purchasing programs and Medicaid
- ▶ Consequences of rising costs

These study questions shaped the study methodology. The project involved two key tasks:

- ▶ A systematic review of the literature and targeted background discussions on the factors influencing Title X providers' participation in the 340B and Prime Vendor programs and other drug purchasing arrangements.
- ▶ In-depth discussions with a range of Title X–supported providers (e.g., different agency types, sizes, client characteristics, geography) and other key informants (e.g., 340B and Prime Vendor program personnel, staff from alternative drug purchasing structures).

Literature review and initial discussions. The project team first conducted a literature review of the 340B drug pricing program and the Prime Vendor program. The team searched academic literature through PubMed using a combination of key terms and phrases such as: 340B, Prime Vendor, Title X, family planning clinics, drug discount, and drug pricing. The team found very little published literature in PubMed or other peer-review journal databases. The same key terms and phrases were used to search for grey literature (i.e., literature produced by government, academia, and business but not controlled by commercial publishers, such as government reports, masters and doctoral theses, conference proceedings, and other official reports not published commercially) on 340B and Prime Vendor.

After reviewing the limited available literature, the team supplemented the information gathered with targeted discussions with experts who could provide a basic understanding of the programs. The discussions began with focus groups of regional office staff to ascertain their understanding of the programs, guidance they provide to family planning providers, questions they field from providers, and their perceptions of barriers to and facilitators of participation in the 340B and Prime Vendor programs. The team also spoke with OFP central office staff, representatives of the 340B and Prime Vendor programs, the National Family Planning and Reproductive Health Association (NFPRHA), Planned Parenthood Federation of America (PPFA), the Family Planning Cooperative Purchasing Program (FPCPP), as well as a limited number of Title X providers.

Key Informants. The second phase of the research consisted of in-depth discussions with 40 informants: 24 grantee and 16 delegate agencies receiving Title X funds. The team formulated a general discussion guide that operationalized the key research questions. Discussions explored topics such as informants' use of 340B, Prime Vendor, and other purchasing arrangements; cost saving tactics; pharmaceutical formulary; and record keeping and administration practices. While most discussions followed the same general topics, the specifics of each varied widely depending on the entity's organizational structure and individual experiences with drug purchasing programs.

The family planning entities that served as informants for this study were chosen through a two-step process. First, the research team, in collaboration with OFP central office and regional

office staff, identified criteria for selecting a diverse set of Title X grantees and delegates for in-depth discussions. These criteria are described in *Exhibit 1*.

Exhibit 1: Categories of Informants - Discussions During Phases I and II

PHASE I - BACKGROUND DISCUSSIONS	
Representatives of Federal Agencies	
340B and Prime Vendor Program	Representatives of the 340B and Prime Vendor programs discussed issues pertaining to the administration of the program, the degree of technical assistance that is offered to participants, and the degree to which the representatives have interacted with Title X entities.
Regional Office Staff	Focus groups of regional office staff were conducted to ascertain their understanding of the programs, guidance they provide to family planning providers, questions they field from the providers, and their perceptions of barriers to and facilitators of participation in the 340B and Prime Vendor programs.
Provider Associations	
National Family Planning and Reproductive Health Association	NFPRHA staff members were interviewed to discuss their understanding of grantees' experiences grantees with the 340B and Prime Vendor Programs, and the type of assistance to Title X entities who participate in these programs.
Planned Parent Federation of America	PPFA national staff were interviewed regarding their perception of the benefits of the programs for their affiliates.
Purchasing Program	
Family Planning Cooperative Purchasing Program	FPCPP staff members were asked questions pertaining to their purchasing program, which requires that members also belong to the 340B program.

PHASE II - IN-DEPTH DISCUSSIONS WITH KEY INFORMANTS, LISTED BY CATEGORY <i>(Categories are not mutually exclusive)</i>		
Category	Description	Number of Informants
Category: Location		
Title X Region	All 10 regions	Spoke with grantees and delegates in all 10 regions, with an average of 4 informants per region. Informants represented 20 states and territories.
Urban, rural, or mixed location	Predominant population served is urban, rural, or mixed urban and rural populations	12 urban-based informants 5 rural-based informants 23 informants that served both
Medicaid waiver	Whether grantee is in a state with a Medicaid waiver	18 informants in states with an income-based waiver 22 informants in states with no waiver or a limited waiver
Characteristic	Definition	Number of Grantees/Delegates
Category: Type of Agency		
Planned Parenthood Affiliate	Agencies part of the Planned Parenthood Federation of America	6 informants
Government agency	State, regional, and county health departments	14 informants (8 have no clinics under direct control)
Other non-profit	Family planning councils, federally qualified health centers (FQHCs), community action programs, and other such non-profit entities	20 informants
Category: Organizational Structure		
Purchasing method	Whether grantee organization uses centralized or non-centralized purchasing for delegates.	13 grantees performed some degree of centralized purchasing for their delegates 11 grantees performed no centralized purchasing (includes 7 of the 8 state agencies and all 4 family planning councils that provide no direct patient care).

OPA/OFP central office and regional office staff then identified potential informants and provided information on each criterion. Using that information as a starting point, the team created a target list of Title X grantees with whom to talk that was balanced by region, type and size of grantee, and other characteristics.¹⁵

Delegates were identified through grantees. At the end of each grantee discussion the team asked for suggestions of delegate agencies under their grant that could serve as additional informants. Delegate agencies were then selected from these recommendations, again seeking to balance the list of informants by their characteristics.

Once all of the grantee and delegate discussions were completed, data were organized into a spreadsheet with columns that corresponded to each interview topic and reviewed for recurring themes as well as unique findings that stood out from the rest of the data. The resulting qualitative analysis forms the basis of this final report.

C. Research Limitations

The main findings of this research highlight that while 340B participation is nearly universal among Title X-supported providers, and Prime Vendor participation is increasing, a number of challenges still inhibit making optimal use of the drug discounts. However, a few potential limitations to these findings should be highlighted.

In order to obtain a comprehensive picture of Title X-supported providers' experiences with 340B and Prime Vendor, the research included conversations with Title X-funded entities from across the country working in a variety drug purchasing contexts. However, although sound research principles were employed, this study did not use a nationally representative sample. While the main findings of this research represent issues faced by a majority of the informants, their generalizability cannot be guaranteed.

Furthermore, the findings in this study must be considered in the context of the main finding: that there is a lack of consistent, accurate information available regarding drug purchasing programs, which seems to have resulted in misinformation. In a few noticeable cases informants' statements regarding the programs were inaccurate. Therefore, while some informants reported problems that hampered their use of the programs, the problems stemmed from a lack of understanding over how the programs work, rather than actual issues with program administration. Therefore, though these obstacles were very real to the informants, and resulted, in some cases, in their not taking full advantage of, or not participating at all in the drug purchasing programs, these obstacles may have been based on misperception or misinformation.

D. Structure of Report

Following the introduction, the report is divided into the following sections:

¹⁵ In addition to the criteria included in the table, the research team and OPA/OFP also considered agency size, whether a new director had recently joined the staff, and whether entity serves a large immigrant population as factors in securing a variety of experiences and viewpoints, but does not have exact counts of the number of informants who met those criteria.

- ▶ **Chapter II: 340B and Prime Vendor Program Background.** This chapter provides background on the two drug discount programs, discusses some of the specific rules involved in participating in these programs, and outlines the programs' primary benefits and restrictions. It draws largely on the literature review phase of this study.
- ▶ **Chapter III: Use of 340B, Prime Vendor, and Other Purchasing Programs.** This chapter describes the multiple avenues through which informants report purchasing pharmaceuticals and other supplies. This includes the 340B and Prime Vendor programs, as well as alternative purchasing programs. The chapter also addresses the extent of informants' participation in each type of program.
- ▶ **Chapter IV: Awareness of 340B, Prime Vendor, and Other Purchasing Programs.** This chapter discusses providers' awareness of drug purchasing programs and discounts. Specifically, it reports on informants' use of a patchwork of sources to gather information about programs, recent communication efforts on the part of 340B and Prime Vendor, and informants' understanding of the various purchasing programs and the levels of discounts they provide.
- ▶ **Chapter V: Barriers to Maximizing Use of Drug Purchasing Programs.** This chapter discusses the numerous challenges faced by informants as they strive to make the most of 340B, Prime Vendor, and other purchasing arrangements. The barriers deal with all of the varied aspects of drug purchasing, such as learning about purchasing options, setting up a purchasing system, and adapting to changes in prices and discounts.
- ▶ **Chapter VI: Drug Purchasing and Medicaid Reimbursement.** This chapter describes how reimbursement for pharmaceuticals works under states' Medicaid programs and the challenges informants encounter.
- ▶ **Chapter VII: Consequences of Rising Costs.** This chapter describes challenges faced by informants in serving their clients in the context of inflation and rising health care costs. It also includes information on steps informants are taking to deal with these rising costs, which include, but are not limited to, the cost of medications. Informants reported reducing formularies, finding additional drug-related savings, scripting out prescriptions, finding other savings, and raising new revenue.
- ▶ **Chapter VIII: Conclusion.** The final chapter summarizes the key study findings and posits possible next steps for OPA/OFP.

In addition, in the Appendices, the report includes a number of features intended to guide readers through the main findings of the research. These include graphics that illustrate some of the fundamental components of drug purchasing, as well as case studies that describe how typical grantees and delegates might make decisions related to use of 340B and Prime Vendor and cost savings, in general. Also included at the end of the report is a resource list that provides websites that may be referenced by current and future users of the drug purchasing programs. The resource list includes links to all citations in this paper, previous research on these topics, as well as links to the programs' registration applications.

Chapter II. 340B and Prime Vendor Program Background

This chapter provides background information on the 340B and Prime Vendor programs, as well as information on particular complexities within the programs: how the 340B program's ceiling prices are set, and two key restrictions on drug purchasing through both programs. This chapter draws primarily on the literature review phase of this study.

A. The 340B Program

In order to receive drug discounts through the 340B program, entities must enroll in the program through OPA/HRSA. There are approximately 15,000 eligible entities, of which about 80 percent participate in the 340B program. As noted above, these eligible entities include Title X family planning clinics, FQHCs, hemophilia treatment centers, Ryan White programs, STD/TB programs, urban/638 tribal programs, and certain disproportionate share hospitals. Key issues related to 340B, and potential sources of confusion for family planning entities, include calculations of the ceiling price and restrictions on who can receive 340B-discounted drugs.

Enrollment in the 340B program is not automatic. Rather, Title X providers must submit an enrollment form to OPA/HRSA (found on the agency's website¹⁶) indicating their intent to participate in the program.

The enrollment form is a single page (see the Resources section in the Appendix for a website link to the form). Required elements include the covered entity's name and address; contact information for the person filling out the application; the Title X grant ID number; and two questions to prevent Medicaid duplicate discounts. Once OPA/HRSA receives the enrollment form, the provider is added to the official database of participating entities each quarter. Updates to add or make changes to entities are made quarterly: January 1, April 1, July 1, and October 1. Forms must be submitted one month prior to the scheduled update.¹⁷ Entities enrolled in the 340B program must inform manufacturers and drug wholesalers that they are participating in 340B in order to receive 340B prices. Once manufacturers and wholesalers verify an entity's enrollment via a public database maintained on OPA/HRSA's website, they then must make 340B prices available to that entity.

B. Prime Vendor Program

340B-enrolled entities may also enroll through a separate application process in the Prime Vendor program to receive additional cost savings.¹⁸ The Prime Vendor program was established as part of the original 340B legislation with the intention of using market forces to generate more substantial discounts than Congress imposed legislatively. The program is free and voluntary to entities that are already participating in the 340B program. The Prime Vendor program aims to improve access to affordable medications for covered entities and their patients by:

¹⁶ <ftp://ftp.hrsa.gov/bphc/pdf/opa/FPPrgmReg.pdf>.

¹⁷ Richardson, Katheryne. (April 2004). *The Bridge to 340B Comprehensive Pharmacy Services Solutions in Underserved Populations*. Prepared for Medpin.

¹⁸ 340B Prime Vendor Program FAQs. Retrieved December 5, 2007 from https://www.340bpvp.com/public/faq/faq_general.asp

- ▶ Negotiating sub-340B pricing on pharmaceuticals;
- ▶ Establishing distribution solutions and networks that improve access to affordable medications; and
- ▶ Providing other value-added products and services (see below).¹⁹

The program is administered by Apexus through a contract with OPA/HRSA and is meant to serve as the prime vendor for all 340B-participating entities. Apexus is tasked with negotiating sub-ceiling pharmaceutical prices for 340B entities, using as leverage the collective purchasing potential of its enrollees. Prime Vendor also provides covered entities with other services and supports. These include discounts for some products not covered by 340B (e.g., vaccines and medical devices), computer support, and pharmacy management consultation and drug information.²⁰

As is the case for 340B ceiling prices, Prime Vendor-negotiated prices are not publicly available. Instead, only Prime Vendor-enrolled entities, as well as the drug distributors that work with the program, have access to the price lists.

To register for the Prime Vendor program, entities must first enroll in the 340B program. Entities can then enroll in Prime Vendor through a separate participation agreement and application form (see the Appendix).²¹ There are no fees or costs to join the program.²²

C. 340B Price Ceiling

A 2004 study provided a lower-bound estimate of \$97.5 million in savings to family planning providers through their participation in 340B.²³ In that report, clinics reported that they used their savings to expand their client base, increase clients' contraceptive options and reduce client charges. Although the 340B program provides access to lower-cost drugs, it is not without its difficulties. The same report found that some providers did not understand the 340B program and were frustrated with the lack of information on current pricing for available drugs. In addition, it did not find evidence of savings under the previous Prime Vendor program; the reorganized Prime Vendor program, as administered by Apexus, has not yet been evaluated in this manner.

The 340B price is considered a "ceiling price," meaning it is the highest price a participating entity may be charged for a specific drug. The ceiling price is calculated using a formula that is defined by statute. In some cases, the ceiling price it can require manufacturers to provide a

¹⁹ https://www.340bpvp.com/public/faq/faq_general.asp#Q3.

²⁰ Richardson, Katheryne. The Public Health Service (PHS) Section 340B Drug Pricing Program In Basic Language. http://pssc.aphanet.org/pdfs/340b_handbook.pdf

²¹ https://www.340bpvp.com/public/participation/340b_agreement.pdf.

²² 340B Prime Vendor Program FAQ's. Retrieved December 5, 2007 from https://www.340bpvp.com/public/faq/faq_general.asp.

²³ Schmitz, R., S. Limpa-Amara, J. Milliner-Waddell and F. Potter. (2004). The PHS 340B Drug Pricing Program: Results of a Survey of Eligible Entities. Mathematica Policy Research, Inc.

specific drug at a price of one cent per unit (“penny-a-pack” pricing).²⁴ The formula used to calculate the 340B ceiling price is publicly available²⁵ (see text box on next page).

How the 340B Ceiling Price is Calculated

There are a number of factors that go into the calculation of the 340B ceiling price, including type of drug (generic, over-the-counter and brand-name) and whether the drug price has risen faster than inflation. Below is a “tutorial” on how the 340B ceiling price is calculated.

For *generic and over-the-counter drugs*, the 340B ceiling price is the average manufacturer price (AMP), or the average price paid by wholesalers that service retail pharmacies, **minus 11%**.

For *brand-name* (“single source”) prescription drugs, the formula is more complicated. The ceiling is the lower of:

- ▶ the “best price” – the lowest price available to any private-sector entity – or
- ▶ the AMP **minus 15.1%**

The following four examples illustrate how the factors influencing pricing may work in practice. (Note that because key components of the calculations— AMP and best prices—are considered proprietary, a provider is unlikely to be able to make these calculations on its own.)

These examples are for illustrative purposes only:

Drug A: A generic oral contraceptive. List price for a one-month supply is \$20. AMP, as calculated by the manufacturer, is \$16 for that drug. The 340B price ceiling will be AMP minus 11%, or \$14.24. That amounts to 71.2% of the list price.

Drug B: A brand-name oral contraceptive. List price is \$50 for a one-month supply. AMP is calculated at \$35. AMP minus 15.1% = \$29.72. The manufacturer’s best price is \$30, a price it offered to a large private-sector purchaser. The 340 ceiling price is the lower of the two numbers (best price or AMP minus 15.1%). In this case, it is the AMP-based price: \$29.72. That amounts to 59.4% of the list price.

Additional discounts are added if the drug’s AMP has risen faster than inflation. If that additional discount would result in a number below zero, the price ceiling is instead set at one cent (\$.01).

Drug C: A second brand-name oral contraceptive. List price is \$55 for a one-month supply. AMP is calculated at \$45. Current AMP minus 15.1% = \$38.21. The manufacturer’s best price is \$37. Normally, the 340B price ceiling would be the lower of the two: \$37. However, the original AMP of the drug, when it was introduced in the mid-1990s, was \$34, adjusting for inflation. The manufacturer must offer an additional discount, equal to the difference between the current AMP and the inflation-adjusted “baseline” AMP: \$45 minus \$34 = \$11. With that additional discount, the final ceiling price is \$26. That amounts to 47.3% of the list price.

Drug D: A third brand-name oral contraceptive. List price is \$45 for a one-month supply. AMP is calculated at \$40. Current AMP minus 15.1% = \$33.96. The manufacturer’s best price is \$25. The price of this drug, too, has risen faster than inflation: Its baseline AMP was \$16, adjusted for inflation. The additional, inflation-induced discount is \$45 minus \$16 = \$29. Subtracting that additional discount from the best price would result in a number less than zero. As a result, the manufacturer must offer the drug to 340B-eligible entities for one cent.

Manufacturers can and do offer prices below the 340B price ceiling to 340B-enrolled entities, including many Title X providers.

²⁴ Richardson, Katheryne. (April 2004). Implementing a Comprehensive 340B Contracted Pharmacy Service. Prepared for Medpin.

²⁵ The formula is included in the “Calculation of the Drug Price” section of the following Federal Register notice: <ftp://ftp.hrsa.gov/bphc/pdf/opa/FR05071993a.pdf>.

How the 340B Ceiling Price is Calculated (Cont'd)

The 340B ceiling price for each drug is recalculated by manufacturers on a quarterly basis. Manufacturers may lower a drug's price (below the ceiling) in the middle of a quarter, but may not raise a drug's price until the beginning of the next quarter.

The formula includes the "average manufacturer price" (AMP), which is the average price paid by wholesalers that service retail pharmacies, and the "best price" for a given drug, which is the lowest price available to any private-sector entity (with certain exclusions, such as "nominal" prices offered to 340B-enrolled entities), some components of which have been considered proprietary by pharmaceutical companies and is therefore not public. As noted further in the report, informants cite this fact as contributing to the challenges associated with estimating prices. The Deficit Reduction Act of 2005 required CMS to begin publishing a list of AMPs on a public website. However, this requirement was suspended due to a lawsuit brought by the National Association of Chain Drug Stores (NACDS) *et al* over using the AMP to calculate pharmacy reimbursement.^{26,27}

In general, 340B ceiling prices are estimated to be almost half of the list price retail customers pay.²⁸ The Congressional Budget Office (CBO) also compared the 340B price to other federal programs offering discounted drugs, such as Medicaid, the Department of Defense TRICARE pharmaceutical program, and the Department of Veterans Affairs pharmaceutical prime vendor program. The CBO analyzed the prices paid to manufacturers under these federal programs compared to the AWP, or average wholesale price--the suggested list price. The 340B ceiling price is, on average, 51 percent of the list price (AWP).²⁹

However, research has shown that it is not easy to determine whether 340B offers the best prices. Several organizations, including the Government Accountability Office (GAO) and the DHHS Office of Inspector General (OIG), have explored a variety of issues related to the use of 340B. OIG's latest report in February 2007 highlighted the oversight of drug prices for several federal programs, including the 340B program.³⁰ The report identified findings from an earlier OIG paper that OPA/HRSA's calculation of some 340B prices were inaccurate and that OPA/HRSA did not confirm prices calculated by the manufacturers. GAO has also found that OPA/HRSA does not routinely compare prices paid by eligible entities. Both GAO and the OIG

²⁶ National Association of Chain Drug Stores v. Leavitt, United States District Court for the District of Columbia, Dec. 19, 2007, Civil Action No. 1:07cv02017 (RCL).

²⁷ The rule was suspended when a court found, amid other stipulations, that a rule requiring public disclosure of the AMP violated the Administrative Procedure Act.

<http://www.cms.hhs.gov/DeficitReductionAct/Downloads/AMPPIOrder.pdf>

²⁸ Hoadley, Jack. (May 9, 2007). The Prescription Drug Safety Net: Access to Pharmaceuticals for the Uninsured. National Health Policy Forum. Retrieved December 10, 2007.

²⁹ Prices for Brand-Name Drugs Under Selected Federal Programs. (June 2005). Congressional Budget Office.

³⁰ Other programs include the Medicaid drug rebate program and the Medicaid Part D program.

found that many entities paid prices for drugs higher than the 340B price, resulting in overpayments by almost \$4 million.³¹

D. 340B Restrictions

There are two key restrictions related to purchasing drugs through the 340B and Prime Vendor programs. First, an entity may not sell the discounted drugs to anyone other than a patient of the participating entity. For this purpose, a “definition of a patient” was established (see text box). Specifically, all users of 340B- or Prime Vendor-purchased drugs must be patients of the covered entity, and drugs purchased through the program may only be given to patients receiving healthcare services within the scope of the approved Title X project. Entities could inadvertently serve individuals who are not patients in several ways. The location where services are provided could be at issue: For example, a family planning agency with multiple clinic locations might attempt to purchase contraceptive drugs for all of its locations through the 340B program, despite the fact that only a few of its clinics receive Title X funding and are eligible to receive 340B prices. Similarly, the scope of services provided could be at issue: A county health department, for example, eligible for 340B only because it receives Title X funds, might attempt to purchase drugs through the 340B program for activities outside of the scope of its approved Title X project – for example, prenatal care, a service that is supported by other sources of funding.

Definition of a Patient

According to the Office of Pharmacy Affairs, “an individual is a ‘patient’ of a covered entity only if:

- ▶ the covered entity has established a relationship with the individual, such that the covered entity maintains records of the individual's health care; and
- ▶ the individual receives health care services from a health care professional who is either employed by the covered entity or provides health care under contractual or other arrangements (e.g., referral for consultation) such that responsibility for the care provided remains with the covered entity; and
- ▶ the individual receives a health care service or range of services from the covered entity which is consistent with the service or range of services for which grant funding or Federally-qualified health center look-alike status has been provided to the entity. Disproportionate share hospitals are exempt from this requirement.

An individual will not be considered a ‘patient’ of the entity for purposes of 340B if the only health care service received by the individual from the covered entity is the dispensing of a drug or drugs for subsequent self- administration or administration in the home setting.”³²

A revised, more detailed definition was proposed by OPA/HRSA in January 2007 but has not been finalized.³³

³¹ Oversight of Drug Pricing in Federal Programs. (February 9, 2007). United States Government Accountability Office.

The second restriction requires 340B entities to have a process in place that avoids a duplicate discount for Medicaid patients: in other words, to avoid a situation in which the entity obtains a drug at a discounted price via the 340B program and the state Medicaid agency later receives a Medicaid rebate from the manufacturer for the same drug. Providers have a few options to ensure that a duplicate discount does not occur; see Chapter VI for a full discussion of these options and the challenges they create.

³² <http://www.hrsa.gov/opa/patientdefinition.htm>.

³³ <ftp://ftp.hrsa.gov/bphc/pdf/opa/frn011207va.pdf>.

Chapter III. Use of 340B, Prime Vendor and Other Purchasing Programs

As the two government-sponsored drug discount programs available to Title X-supported providers, the 340B and Prime Vendor programs are the foci of this project. For several informants, these two programs – and for a few, the 340B program alone – were sufficient to meet their pharmaceutical needs. However, Title X grantees and delegates participating in the 340B and Prime Vendor programs are not legally restricted from seeking additional discounts on prescription drugs, and these two programs are among a large array of available options, several of which predate 340B and have been widely used historically within the Title X program. Indeed, most informants in this study reported using additional purchasing arrangements, either as their primary option or as part of a more complicated patchwork of drug purchasing.

This chapter lays out the project's findings on the extent of 340B and Prime Vendor participation among Title X grantees and delegates. It also describes several additional purchasing arrangements – via the FPCPP, PPFA, state governments and multistate cooperatives, and additional arrangements targeted to FQHCs (including those participating in Title X) – and discusses rates of participation and use of those arrangements. The chapter draws equally on the literature review and discussion phases of the study.

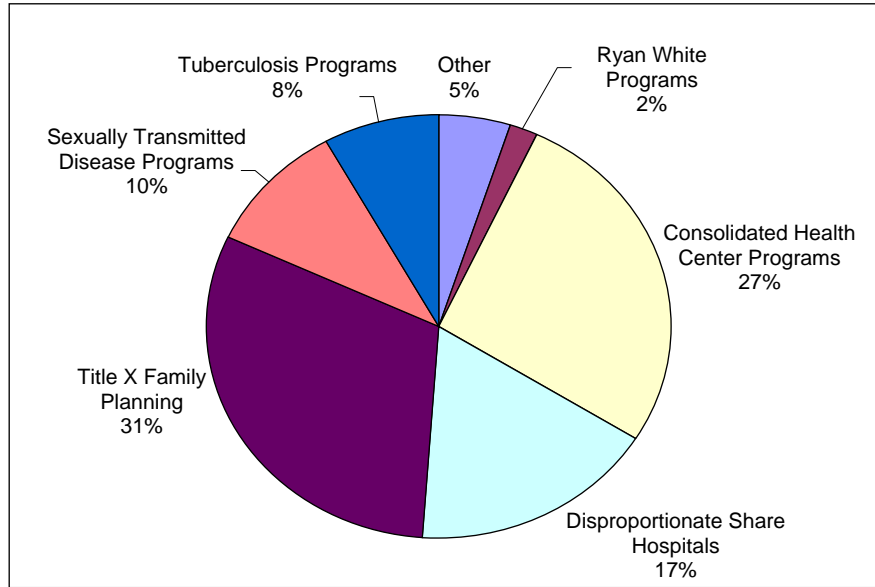
A. 340B Program

According to statistics from OPA/HRSA, about 4,000 of the 4,400 Title X family planning clinics – over 90 percent – participate in 340B. However, the actual percentage of Title X family planning sites participating in the program may be closer to 100 percent, since some grantees and clinics that purchase centrally for their service sites may not be registering these sites separately with the program. The research team found all of the informants that provide direct client services were signed up for the program, and the provider associations contacted as part of the literature review phase of this study also agreed that participation is, for all practical purposes, mandatory for entities that want to save money on drug purchases.

As a percentage of the 340B program, Title X family planning clinics make up about 30 percent of the approximately 13,300 participating entities (Figure 1), the highest percentage of any participating group.³⁴

³⁴ Retrieved December 3, 2008 from ftp://ftp.hrsa.gov/bphc/pdf/opa/Stats_2008_QTR_4.pdf, as of October 1, 2008.

Figure 1: 340B Participating Entities



Source: OPA/HRSA

There has not always been near universal participation in 340B by Title X family planning clinics. Many family planning clinics and other safety-net providers had, for decades, secured “nominal” prices directly from drug manufacturers, regardless of whether they were participating in or even eligible for 340B. This changed in 2006 with the passage of the DRA. Under the DRA and the regulations implementing it, manufacturers were only allowed to offer nominal prices to a small list of entities, including 340B-enrolled entities, without affecting the rebate they must offer to the entire Medicaid program.³⁵ This effectively made enrolling in the 340B program a necessity for family planning clinics. A number of this study’s informants reported that they joined the 340B program since 2006 specifically for this reason. One PPFA affiliate reported that the main reason they accept Title X funding is to maintain eligibility for 340B. As noted above, the 2009 changes to the law were enacted after this study was conducted, and it is not certain whether enrollment in 340B will remain universal, now that some family planning clinics may obtain nominally priced drugs without 340B membership.

B. Prime Vendor Program

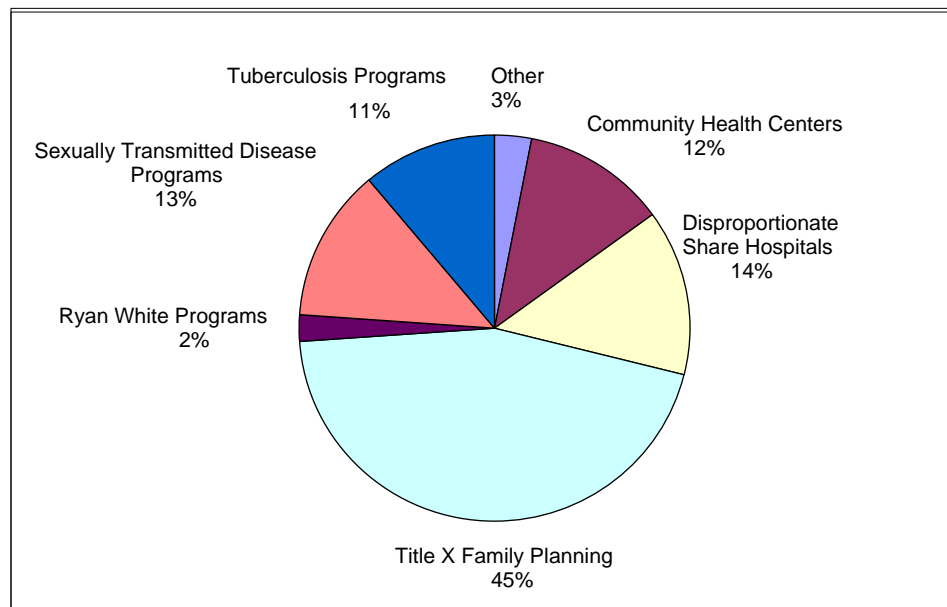
Statistics from OPA/HRSA indicate that of the 4,400 Title X family planning clinics, about 2,200, or almost half, are registered with the Prime Vendor Program. However, as with participation in the 340B program, grantees and clinics may purchase from Prime Vendor centrally for their service sites. Thus, the total number of Title X sites participating in Prime Vendor may be higher than the number listed by OPA/HRSA. As with 340B, Title X family planning clinics compose the greatest portion of Prime Vendor sites. This fact was confirmed by this study, in which significantly more than half of the study informants (about 65 percent) stated that they

³⁵ <http://edocket.access.gpo.gov/2007/pdf/07-3356.pdf>.

are registered for Prime Vendor. As a percentage of the approximately 4,800 entities participating in Prime Vendor, Title X family planning clinics constitute about 45 percent (Figure 2).

According to study informants, recent outreach to the Title X family planning community by Prime Vendor has increased participation in that program. Originally focusing on disproportionate share hospitals, Prime Vendor recently established a family planning clinic advisory council, and invited local and national representatives of the Title X community to participate. The council seeks ways to improve Title X family planning clinics' participation and satisfaction with the Prime Vendor program. For instance, one informant on the council reported that they have discussed new contracts that the Prime Vendor staff is attempting to obtain. This gave the informant and her organization a positive outlook on Prime Vendor's future benefits.

Figure 2: Prime Vendor Program Participating Entities



Source: OPA/HRSA

C. Family Planning Cooperative Purchasing Program

The Family Planning Cooperative Purchasing Program (FPCPP), founded and run by the California Family Health Council (a Title X grantee), is open to all Title X-supported providers. Founded in the early 1990s, the program now serves roughly 3,000 Title X agencies and clinics in almost every state.³⁶ As of 2008, there is an annual membership fee of \$199, imposed to replace a Title X grant that ended. (A parallel program, started in 2001, serves nonprofit entities that do not receive Title X funding.) FPCPP negotiates prices that are at or below the 340B ceiling for a limited number of pharmaceuticals, as well as for office supply products, lab

³⁶ Retrieved January 23, 2008 from <http://www.fcpp.org/>

services, diagnostic tests, condoms and other medical and surgical supplies. The program maintains a price list on a secured area of its website, as well as a regular, public blog³⁷ to provide updates on the program and on sexual and reproductive health issues more broadly.

Outside of 340B and Prime Vendor, FPCPP was the purchasing arrangement most frequently cited by study informants, with roughly half indicating that they were members. In a few cases, informants stated that they had been an FPCPP member until the membership fee was imposed in 2008. Several additional informants indicated that they were uncertain whether they were FPCPP members, and confusion over the program appeared to be common. For example, one informant reported that it joined 340B and FPCPP at the same time and ordered all of its drugs through FPCPP—even those for which FPCPP had not negotiated sub-340B-ceiling prices; thus, the informant did not distinguish between 340B and FPCPP.

D. Planned Parenthood Federation of America

PPFA is the most prominent example of a nonprofit organization that has successfully negotiated directly with manufacturers for discounts on contraceptive supplies, doing so on behalf of its affiliates across the country. Informants reported that they believe manufacturers have agreed to such discounts for several decades because of PPFA's ability to offer large and consistent volumes of purchases. PPFA also has contracts with several major distributors of medical and office supplies. All six of the study informants that are PPFA affiliates reported relying primarily on PPFA-negotiated prices, and several grantees with PPFA affiliates as delegates confirmed that those delegates also relied on the PPFA-negotiated prices.

The DRA made negotiating directly with manufacturers somewhat more challenging for PPFA and similar organizations that have a mix of members—some eligible for 340B and others not eligible for the program. Informants indicated that PPFA was required to negotiate two separate prices: one price (which may be nominal) for 340B-enrolled entities and another price (which may *not* be nominal) for entities not eligible or not enrolled in the 340B program. Presumably, this situation may have been resolved by the 2009 changes to the law around nominal drug pricing.

E. State Purchasing Arrangements

In recent years, state and local governments—on their own or as part of multistate groups—have authorized bulk-purchasing programs as a means of securing lower prices for pharmaceuticals.³⁸ State-level negotiations for contraceptive supplies appear to have been successful in at least a few cases, with one government-agency informant reporting that it was consistently able to negotiate prices superior to those under the Prime Vendor program by making use of the state's combined purchasing power.

More common than state-level negotiation was participation in the Minnesota Multi-state Contracting Alliance for Pharmacy (MMCAP), which was created in 1985.³⁹ The program is managed by the State of Minnesota and guided by an advisory board elected by representatives

³⁷ The blog can be found at <http://cfhcweblog.typepad.com/fpcpp/>

³⁸ National Conference of State Legislatures, *Pharmaceutical Bulk Purchasing: Multi-state and Inter-agency Plans*, 2008 edition, <https://www.ncsl.org/programs/health/bulkrx.htm>.

³⁹ <http://www.mmcap.org>.

of the 45 participating states; it is funded through an administrative fee added to purchases through the program. Every participating state selects one of three distributors to work with exclusively. Individual government facilities sign up through their state's central contact, completing an application form and membership agreement that, among other things, prohibits the resale of any purchased drugs or supplies.⁴⁰ MMCAP negotiates contracts with dozens of drug manufacturers, as well as companies supplying vaccines, condoms, nutritional supplements and medical supplies. Despite the program's substantial membership, only four informants – all of which were state health agencies – reported using MMCAP to purchase contraceptive supplies; several informants indicated that MMCAP prices are always above the 340B ceiling, because the alliance does not negotiate separate, sub-ceiling prices for those participants also enrolled in 340B.

F. Group Purchasing Arrangements for Federally Qualified Health Centers

Several other group purchasing arrangements are targeted to FQHCs and other safety-net providers that have a broad primary-care focus. This target group includes many Title X-supported entities that have a mission broader than family planning and are typically eligible for 340B not only through Title X but also through the sec. 330 Health Centers program that funds FQHCs. These programs typically negotiate contracts not only for contraceptive supplies but also for other pharmaceuticals, medical supplies, office supplies and lab work. One informant reported that it relied on Council Connections, a group purchasing program founded in 1979 by community health centers and today includes 500 non-profit member organizations with 2,400 service sites, including family planning clinics.⁴¹ Two other informants reported relying on smaller consortiums, limited to specific metropolitan areas. Another group purchasing program identified during the literature review phase of this study is the 340Better program, run by the Texas Association of Community Health Centers (TACHC) and Cardinal Health, a major distributor;⁴² none of the study informants reported using this program.

⁴⁰ <http://www.mmd.admin.state.mn.us/mmcap/pdf/MMCAP%20Membership%20Application%20--121407.pdf>.

⁴¹ <http://www.councilconnections.com>

⁴² Retrieved January 23, 2008 from http://www.tachc.org/Programs/Group_Purchasing/Overview.asp

Chapter IV. Awareness of 340B, Prime Vendor and Other Purchasing Programs

This chapter focuses on providers' awareness of drug purchasing programs and discounts. Specifically, it reports on informants' use of a patchwork of sources to gather information about programs, recent communication efforts on the part of 340B and Prime Vendor, and informants' understanding of the various purchasing programs and the levels of discounts they provide.

A. Sources of Information Regarding Purchasing Arrangements

The following sub-sections describe sources of information about the 340B and Prime Vendor programs, and other purchasing programs mentioned by informants. The informants discussed their knowledge of these sources as well as some of the shortcomings of each, suggesting potential areas for clarification by OPA/HRSA or OPA/OFP.

The 340B and Prime Vendor Programs. The various purchasing programs themselves were considered by many informants to be valuable sources of information. Guidance is available on the websites of the 340B and the Prime Vendor programs,⁴³ and several informants praised these sites, particularly for providing information about issues such as duplicate discounts and the definition of a patient. Additionally, several informants said that they relied on emails and newsletters sent out by both programs. The programs also present at numerous conferences each year, including two annual conferences focused on 340B.

A few informants noted that they found program staff to be helpful and responsive over the telephone as well. A few cited "poor customer service" and responses in bureaucratic language that was difficult to understand.

Discussions with informants revealed that many providers do not know about or use a key program resource supported: the Pharmacy Services Support Center (PSSC).⁴⁴ The PSSC is operated by the American Pharmacists Association and funded by OPA/HRSA. In addition to its toll-free phone line, the PSSC offers free, on-site technical assistance to Title X providers.

Although providers noted the variety of information available through various program sources, some identified seemingly contradictory information from OPA/HRSA regarding such issues as the extent to which centralized purchasing by a Title X entity for its local clinics is allowed. Conversations with OPA/OFP central office and regional office staff echoed these concerns. Another informant reported that they did not know whether their satellite clinics (for example, clinics held at a social services office one day a week) should be enrolled in the 340B program and had been trying to find an answer to this question for almost two months. They were not able to find an answer to their question on the program's website, and did not find the 340B program manual helpful.

Alternate Purchasing Programs. PFFA-affiliated informants indicated that the federation is a valuable source of information not only about its own contracts but about 340B. For example, PFFA offers a primer on the 340B program to all of its affiliates and provides guidance to

⁴³ The following is the website for the 340B program: <http://www.hrsa.gov/opa/>; The following is the website for PVP: <http://www.hrsa.gov/opa/primevendor.htm>

⁴⁴ <http://pssc.aphanet.org/>.

affiliates about 340B when one has specific questions or needs extra assistance choosing the optimal avenue through which to purchase drugs. The federation also provides its affiliates with legal analyses about ambiguous program rules. Among the universe of informants for this study, PPFA-affiliated informants generally seemed more satisfied with the available 340B information than non-PPFA informants. Perhaps due to this additional guidance and information, the PPFA affiliates seemed to have a firmer grasp of the 340B program than the other discussants.

The FPCPP was also cited by several informants as a useful source of information about drug purchasing. The co-op communicates with its members through monthly email updates, a quarterly newsletter, telephone calls and a regularly updated, public blog. The blog, in particular, was cited by program staff as a recruitment aid for FPCPP. While several informants stated that they participated in FPCPP primarily as an information resource, another informant noted that the website is not “user-friendly.”

OPA/OFP Staff. OPA/OFP central office and regional office staff are another potential sources of information regarding the 340B and Prime Vendor programs. Moreover, each regional office has training staff. One area the research team probed was the extent to which OPA/OFP staff and trainers inform Title X providers about the 340B and Prime Vendor programs and are resources for questions. Neither OPA/OFP staff nor providers described OPA/OFP as a major source of information on 340B, Prime Vendor, or other purchasing programs.

The informants noted that they occasionally seek guidance or clarification regarding 340B and Prime Vendor from OPA/OFP central office or regional office staff. Information about both programs has traditionally been provided on an ad hoc, as requested, basis, rather than through formal trainings or other mechanisms. Although OPA/OFP provides information about drug purchasing programs at annual conferences, regional staff noted that in-depth training by the regional training providers has not been provided on this topic.

Only a handful of informants reported speaking with regional office staff about drug purchasing programs generally and 340B and Prime Vendor specifically. Regional office staff agreed that they receive few such inquiries, and reported having little exposure themselves to complete, accurate, or consistent information about the programs. As a result, they typically refer the providers to OPA/HRSA. One informant reported being wrongly informed by a regional staff person about 340B eligibility, noting that they were once told that they did not receive enough Title X money to be eligible (in fact, any Title X service site is eligible).

Other Sources. Almost all of the informants noted that they looked for information about 340B and Prime Vendor specifically, and drug purchasing programs more generally, from sources beyond the official program sources and OPA/OFP. The most frequently mentioned source of information was the National Family Planning and Reproductive Health Association (NFPRHA). A number cited NFPRHA conferences, emails and conference calls as the first place they heard about the 340B and Prime Vendor programs and as a key source of continuing information. NFPRHA recently posted an updated 340B program fact sheet on its website.⁴⁵ One informant, similarly, mentioned the National Association of Community Health Centers as an information source. Finally, Title X delegates commonly described their grantees as their

⁴⁵ http://www.nfprha.org/main/family_planning.cfm?Category=Fact_Sheets&Section=Main.

most important information source, both as a conduit for the federal government and, in many cases, as a resource in its own right. State agencies and family planning councils that serve as grantees without directly providing care often see the provision of information as one of their primary roles, and most of those grantees reported strong understanding of their delegates' options.

The study team also identified a number of other publicly available sources that provide information on the 340B and Prime Vendor programs. These resources include "The Bridge to 340B Comprehensive Pharmacy Solutions in Underserved Populations," and "Implementing a Comprehensive 340B Contracted Pharmacy Service," both from Medicine for People in Need (Medpin) and written by PSSC staff (see the Resources list in the Appendix). These materials are available to entities at no charge, and provide a step-by-step guide to enrolling in the 340B program and include various models for participating in the 340B program. Discussions with informants suggest that these resources are not widely known or used.

B. Communication and Marketing by Programs

Representatives of the 340B and Prime Vendor programs have made efforts in recent years to communicate with Title X providers and market the programs to them. Informants report that 340B and Prime Vendor's outreach to the Title X community has affected informants' knowledge of and participation in their programs. In some cases, Title X providers may simply not have heard about a given drug purchasing arrangement, or may not know enough about it to understand that it would be beneficial to learn more. This was the case for several informants regarding the Prime Vendor program, with one asking "What's the catch? It seems almost too good to be true."

To improve program knowledge and limit misunderstandings, both the 340B and Prime Vendor programs have conducted targeted outreach to the Title X family planning community to disseminate information and encourage enrollment. Staff from both programs report attending increasing numbers of provider conferences to make the case for enrollment, and several informants reported having benefited from information shared in those forums. These steps were cited by informants as having increased understanding of the two programs and having encouraged participation. Informants did not make similar observations about other purchasing arrangements, and those participating in other arrangements generally had been for many years.

The Prime Vendor program also launched a Title X advisor group, which aimed to provide feedback on contracting strategies that meet the unique needs of Title X-supported providers. Most informants, however, were not aware of the advisory group, and those that were aware of it had mixed opinions. Several informants were members of the group, and most expressed appreciation for Apexus's efforts to make the program more relevant for Title X providers. For instance, they appreciated its push for more contracts with manufacturers of contraceptive supplies and attempts for more price stability. Other informants (including several participating in the group) were less enthusiastic about the advisory group's work, seeing it as designed primarily as a public relations tactic. However, members of the advisory group were consistently among the most informed about the 340B and Prime Vendor programs, including understanding 340B price-ceiling calculations.

C. Awareness of the Extent of Drug Discounts

Generally, drug prices are only available to members of the given program. Non-members, thus, do not have access as the price lists are not publicly available, and informants' awareness of the extent of drug discounts through competing programs is in many ways limited. (These challenges of transparency are described in detail in Chapter V.)

Informants reported relying on on-line price lists from Prime Vendor, FPCPP, PPFA and other group purchasing arrangements to which they belong. Prime Vendor staff noted their price list was one of the program's most advantageous features, noting that pharmaceutical manufacturers are wary about making their prices public and appreciate the website's security features. Some informants also noticed recent changes to the Prime Vendor list that organizes drugs by category, making it easier to compare among contraceptive products. While complaints over the Prime Vendor price list were minor, a few said that the Prime Vendor list does not clearly indicate distributors' fees, so they paid more than they expected.

Informants also rely on information from distributors. Some informants were satisfied working with a single distributor (most often R&S Northeast), and received consolidated price lists from that vendor that, they said, took into account all of their available discounts (including 340B, MMCAP and others).

Without access to manufacturers' proprietary pricing information, informants report that they must rely almost exclusively on the costs reported by their drug purchasing programs, without any way to confirm that these prices are correct. Only a few informants reported comparing the prices quoted by distributors or manufacturers with independent sources of price information. For instance, one consults a paid, on-line service (the Red Book⁴⁶) to look up a drug's AWP, a second relies on knowledge consultants to conduct contract negotiations, and a third compares prices with a local pharmacy to confirm that they are receiving real discounts.

The informants that were most confident that they were obtaining the best prices were those with staff members who are able to devote large amounts of time to seeking discounts. One informant, for example, described a routine of regular phone contact with competing distributors to compare prices. Through these calls, the informant had established a strong enough relationship with key vendors that they will actually recommend their competitors for certain purchases.

In terms of which drug purchasing programs offer the best prices, few informants, other than smaller ones with limited drug purchasing needs, reported being so completely satisfied with the 340B ceiling prices that they saw no need to seek deeper discounts. While all informants noted that they used the program, only a handful used it exclusively.

In many instances, providers obtained better prices through the Prime Vendor program. Numerous informants, for example, praised recent Prime Vendor contracts for two newer contraceptive methods, the vaginal ring (NuvaRing) and the contraceptive implant (Implanon), both manufactured by Organon. However, many clinics do not offer these methods, both because of price (e.g., even with the Prime Vendor discount, the ring is several times more

⁴⁶ <http://clinical.thomsonhealthcare.com/products/redbook/>

expensive than many oral contraceptives) and because of staffing requirements (e.g., inserting and removing the implant requires special training). A few informants touted new Prime Vendor contracts with Watson Pharmaceuticals for their generic oral contraceptives.

Although some informants praised Prime Vendor as their best source of discounts, others asserted that the program provides few worthwhile drug discounts. Some of the variation in perception may be based on outdated information, as grantees and delegates who are not currently Prime Vendor members had, in many cases, made that decision to leave the program before Apexus revamped it. Prime Vendor has also made an attempt in recent years to make the program more useful for Title X–supported providers (e.g., the advisory group). In other cases, varied opinions about Prime Vendor may stem in part from differences in the specific set of drugs that informants purchase. While newer drugs and devices may be offered at a deep discount, some providers noted that generic oral contraceptives offered through Prime Vendor were more expensive than the brand-name ones available at 340B ceiling prices from Ortho-McNeil, and they wondered why Prime Vendor has not secured sub-ceiling discounts from Ortho-McNeil.⁴⁷

Although informants are prohibited by contract from providing any specific pricing information, those with knowledge of PPFA’s prices for contraceptive supplies were unequivocal in reporting that these prices are substantially below the 340B ceiling prices and nearly always lower than Prime Vendor prices or any other sub-340B-ceiling price. Informants with historical knowledge of the PPFA contracts report that it has been increasingly difficult in recent years – even before the DRA – to secure deep discounts from manufacturers and that PPFA, like much of the Title X system, has become heavily dependent on discounts from a single manufacturer (Ortho-McNeil). Nevertheless, it was evident in this study that PPFA affiliates are under less cost pressure than many of their peers.

Few cited other purchasing programs as their best source of pharmaceuticals. During the 1990s, FPCPP was a major, valued source of discounts on pharmaceuticals. Today, however, the program has only a few sub-340B-ceiling drug contracts, and few informants rely on it for this purpose. FPCPP staff assert that manufacturers are increasingly hesitant to negotiate nominal prices, in part because of confusion over what is allowed under the DRA. MMCAP, as well, is not considered valuable as a source of discounts for Title X–supported providers, as its prices are rarely or never (depending on the account) lower than the 340B ceiling prices. Instead, providers described FPCPP as a good source for non-pharmaceutical supplies – including diagnostic tests; health education materials; information technology; and medical, office and janitorial supplies. Several informants praised the program’s contracts for condoms.

⁴⁷ Ortho-McNeil produces the most popular oral contraceptives in the country, including Ortho Tri Cyclen Lo and Ortho Tri Cyclen, as well as the contraceptive patch, Ortho Evra. It has long provided many of its products at nominal prices to family planning clinics, and many informants reported relying heavily on these products. Major increases to Ortho-McNeil prices – temporarily in 2006 and again in 2008 – have been of serious concern to family planning providers.

Chapter V. Barriers to Maximizing Use of Drug Purchasing Programs

Although informants reported high levels of awareness and use of 340B, Prime Vendor and other purchasing arrangements, they also reported numerous challenges to making the most of these discount programs. Some of these challenges were specific to individual programs, while others applied to all of their available drug purchasing options and to the pharmaceutical marketplace as a whole. This chapter details these challenges, including those related to learning about purchasing options, enrolling in purchasing programs, setting up a purchasing system, keeping abreast of current prices, adapting to changes in prices and discounts, maintaining an annual budget, and keeping a proper inventory.

A. Learning About Purchasing Options

As noted above, information about pricing is not readily available and makes comparison shopping difficult. This absence of such an information resource – regarding issues ranging from how to join, to whether they are eligible, to what the rules are and whether they might inadvertently break them – creates confusion for Title X-supported providers about the available programs. In some cases, this can lead to a loss of interest in joining. It can also lead to misperceptions and misinformation about the programs.

Questions abound regarding the drug purchasing programs. Although most informants asserted that they felt adequately informed about major program rules, some were concerned that they may not entirely understand complicated issues such as the definition of a patient and duplicate discounting. Others expressed concerns that new staff members were unsure where to turn for information, a sentiment confirmed by those informants who were themselves new to their positions. Several conversations illuminated cases in which informants were making drug discount program selections based on falsehoods about the programs. Lack of understanding of the programs occurred even at the most fundamental levels: Numerous informants reported, for example, that they or their colleagues are not always able to distinguish between the 340B and Prime Vendor programs. Some thought they were the same program. Some were unclear which programs they used.

For instance, a medium-sized family planning agency stated that “We are not sure what [drug purchasing] programs we are using since we order our drugs through a wholesaler.” Another informant, a state grantee, reported “I always felt that clear, basic print material that was readily available and you got as soon as you contacted them [the 340B program] would have helped. Because then I could have referenced that and framed my questions better.” A third informant, a PPFA affiliate, simply stated of 340B, “The program was so confusing that for awhile we did not understand it at all.” Another informant stated that her organization has not signed up for Prime Vendor because it does not fully understand the program. The informant worried that if it signs up for Prime Vendor, it would restrict the provider’s ability to participate in other purchasing programs.

Providers reported being unsure where to turn if they had questions about 340B and Prime Vendor. A few providers admitted they are wary of contacting a source in the federal government, be it OPA/HRSA or OPA/OFP, for fear that inadvertently violating a program rule could result in being reported for an infraction.

B. Enrolling in Purchasing Programs

Although 340B and Prime Vendor have made considerable efforts to streamline their enrollment process, informants report logistical problems related to initiating and maintaining their enrollment.

Informants had few criticisms about enrollment in 340B, praising the program's on-line registration and recertification process. A few did state that it was difficult to take advantage of the programs with the sometimes three-month delay created by the program's quarterly enrollment process. In addition, some informants described the rules requiring each individual service site to enroll in order to receive discounted drugs as burdensome, explaining that a one-page form can become tedious when it has to be filled out for multiple sites. Similarly, providers that are eligible for 340B under multiple programs (e.g., one that is both a FQHC and receives Title X funding) must register multiple times. Changes to the entity's name or address must be reported immediately, and the 340B program requires that this information be checked annually by regional offices, and in turn, by providers. The process is perceived as even more onerous to providers.

Informants expressed frustration with having to sign up separately for Prime Vendor and 340B. Several informants also cited confusion over the different identification numbers that must be included in the Prime Vendor application. For instance, many family planning providers do not have a Drug Enforcement Agency (DEA) identification number, since they do not prescribe controlled substances. However, the form does not make it clear that providing this number is optional, and therefore leaves many informants confused.

C. Establishing a Purchasing System

The 340B program requires that manufacturers provide drugs at a discounted price; it is not a channel through which drugs can be purchased. Thus, providers must make decisions as to whether to purchase directly from a manufacturer or use one or more distributors, then navigate the complicated web of manufacturers and distributors to make their purchases. This was cited by some informants as one of the many challenges to purchasing drugs for their clients. (Other programs may be more directive. MMCAP, for example, requires participating entities to conduct their purchases under the program through a single distributor of their choice, simplifying this process but also limiting their options.)

Typically, a distributor is slightly more expensive, because of the distribution fees that it charges to cover its expenses (and make a profit). A distributor provides certain advantages, however, such as one-stop shopping and easier comparisons among different manufacturers' products. Informants with the most limited drug formularies (i.e., the list of drugs purchased by the entity) were particularly likely to report purchasing exclusively or almost exclusively from manufacturers directly, as the advantages of a distributor are less valuable in such cases.

Also, informants reported that different drugs have different rules for purchasing. For example, some drugs and devices can only be purchased at discount prices – or at all – directly from the manufacturer, rather than through a distributor. One example given was the hormonal IUD Mirena, which informants reported they must purchase directly from its manufacturer.⁴⁸

⁴⁸ This could not be confirmed by Lewin researchers, but was mentioned by several informants.

Another was Implanon, which is only sold through a single distributor, so that the company can better ensure that the method is only inserted by clinicians that have received special training.

A related issue is that of centralization, in terms of purchasing, shipping, inventory, and storage. Many grantees and delegates negotiate and purchase drugs on behalf of their individual clinic locations, taking advantage of economies of scale. But centralized purchasing does not mean necessarily that the supplies are shipped to that central location. Several informants did indicate that distributors generally prefer to ship to a central site; indeed, some smaller sites have limited hours and may not always be open to receive shipments. On the other hand, some manufactures will not ship to central sites, for fear that the product will be diverted to providers who do not have special training or who are ineligible for 340B-related discounts. One informant found that manufacturers were refusing to ship drugs at two different prices (340B and non-340B) to the same location, and had to secure a second address for its one warehouse. Grantees and delegates that have drugs shipped to a single location still may not store those drugs centrally or keep a central inventory, instead shipping large batches to local sites on a regular basis or working on a “just in time” basis to minimize storage costs.

D. Availability of Pricing Information

One of the most compelling findings of this research was that although cost savings are the main purpose of the 340B and Prime Vendor programs, only a handful of informants reported that they had more than a vague sense of how much money they are saving by participating in purchasing arrangements. Informants noted that a number of factors make assessing price savings difficult, but primarily they boil down to a lack of transparency.

Although they often enroll in multiple drug purchasing programs and therefore have access to some amount of price information through their membership, informants report that even with ample staff resources, a cost comparison is difficult to conduct properly for numerous reasons: factors that make up the final price are considered proprietary by manufacturers and cannot be shared; manufacturers and distributors provide vastly different prices to different customers; frequent price changes make for a moving target; bioequivalency among different categories of contraceptives – which allows one product can be substituted for another without any medical effect on a patient – adds another layer of complexity; and, finally, there is no clear baseline price against which discounted prices should be compared.

Few informants, moreover, report that they have the resources to even attempt such a thorough comparison. Rather, virtually all of the informants noted that obtaining price information can be time-consuming and frustrating. None of these price lists on their own was seen as ideal, and newsletters highlighting new contracts or price changes were mentioned as valuable supplements. Even then, the information from these sources has limited meaningfulness for budgeting purposes: Only a few informants reported that they found out about price changes before they are rolled out, and others stated that they learn about changes only after they attempt to place an order, a process that causes administrative and budgeting hassles.

More generally, informants displayed varying experiences with and levels of understanding of drug pricing. All but a handful admitted to finding the 340B price ceilings confusing, both in concept (what is a ceiling? when do manufacturers sell below that ceiling?) and in execution (how is the ceiling calculated? why does it change quarterly?). Although many were

comfortable assuming that the government was ensuring that manufacturers provided the required discounts, several expressed a desire for more information, worried that oversight is lacking and asserted that prices should be made public to allow for greater accountability.

Lack of pricing transparency was also reported by some informants as creating its own vicious circle with regard to Prime Vendor: Prime Vendor asserts that it will be able to negotiate lower prices for the drugs that Title X providers want if more Title X providers join the program; meanwhile, many Title X-supported providers do not want to sign up until they are guaranteed better prices. Indeed, several informants reported having signed up specifically to help break this cycle. However, some informants asserted that an entity cannot know unless they sign up whether doing so will reap financial benefits, as non-members do not have access to pricing information.

E. Changes in Prices and Discounts

One of the most common areas of concern among providers was the volatility and unpredictability of drug prices—especially the quarterly shifts in the 340B ceiling prices. Overall, the consensus among informants was that prices are trending upward and that this trend may be accelerating.

The 340B ceiling prices are recalculated every quarter, and the new prices are changed without much or any prior notice. Virtually every informant cited these quarterly shifts as one of the primary disadvantages of 340B (although some mistakenly associated the shifts with Prime Vendor and FPCPP). Prime Vendor, PPFA and FPCPP have all worked to secure longer-term contracts—in some cases, multi-year contracts—with drug vendors, and both the program staff themselves and the grantees and delegates who rely on these programs cite the longer contracts as a primary advantage. This stability is valued because it insulates providers against sudden price spikes, makes annual budgeting easier and frees up considerable staff time. Informants commonly placed additional long-term contracts near the top of their wish lists.

Informants were quick to note that some of the price changes are favorable to them, most notably when the formula requires manufacturers to offer a given drug at only a few cents per cycle. However, most informants are reluctant to purchase these minimally priced drugs for fear that the price will soon increase again to an unaffordable price and they will be unable to continue to provide the drug to patients.

Manufacturers forced to offer penny-a-pack pricing may also choose to ration the distribution of the given product, in order to make sure that they can meet the demand of their regular customers and prevent hoarding. In such cases, the manufacturer, with guidance from OPA/HRSA, will set purchase limits for each customer based on their recent purchasing history. For example, Bayer HealthCare Pharmaceuticals announced such a policy in September 2008 when its fourth-quarter price for Yasmin dropped to one cent per cycle.⁴⁹ Many informants noted that the injectable Depo-Provera was in the midst of a similar sales restriction. Several informants agreed that such limits were justified, although some asserted that manufacturers' methodologies for setting purchase limits are sometimes flawed and have forced them to purchase month-to-month. Even without this type of formal restriction, manufacturers or

⁴⁹ <http://www.hrsa.gov/opa/bayerletter.htm>

distributors can prevent providers from taking full advantage of discounts by placing products on backorder until a new quarter. They then charge the provider at the new, higher price.

With the exception of these “fire sales,” caps on orders were not considered a major problem for almost any of the study’s informants. Some smaller informants, however, said that minimum orders were a problem. One informant asserted that most of the distributors participating in the Prime Vendor program, in particular, would prefer to work with hospitals and use minimum orders to weed out smaller providers. Another informant asserted that minimum requirements were a major factor in their decision to use centralized shipping, as that arrangement allowed their smaller clinics to pool their purchasing volume. Distributors may also require prepayment for specific drugs or devices, which can be a major discouragement for non-profits with limited resources; one informant found that distributors will stop such requirements if confronted.

A final related difficulty reported commonly by informants is receiving drugs with short expiration dates. This is particularly problematic for family planning clinics that provide their clients with several months’ or a full year’s supply of contraceptives. Adding to the problem, one informant explained that oral contraceptives typically expire (according to their labels) in 24 months, compared with 60 months for other types of drugs. All told, it means that many clinics have a limited window for storing contraceptive supplies and need to be careful in their purchases. Several informants asserted that they address this issue by talking with their distributor before they make any purchase, to verify the expiration dates on the drugs currently in the distributor’s stock; if the dates are too short, they will limit their order and try again later. Other informants accused manufacturers of lowering their prices in order to dump their stock of soon-to-be-expired drugs.

1. Maintaining a Budget

Informants were consistent in reporting that shifting prices and other logistical problems had a significant, negative effect on their budgets. Many reported that they were skeptical of new discounts for fear they will not last, because of the staff costs of continually searching for better prices and because they have little room in their budgets (or their storerooms) to stock up on sale items. The quarterly changes in the 340B price ceilings were cited as especially problematic, because they made it impossible to accurately craft an annual budget. Even a \$0.50 change in the price of a contraceptive product could have real budgetary implications when that product is used by tens of thousands of clients each year.

State and county agencies – which have strict budgetary procedures to follow and few opportunities to raise new revenue mid-year – were particularly concerned about this problem. To address it, many use very conservative budget estimates. For example, one county-level informant assumes that the price of each drug for the coming year will equal its highest price from any point in the prior year; even then, however, the agency sometimes goes over budget and will need to “beg” the state for additional money. One state-level informant, instead, uses the MMCAP prices – which are above the 340B ceiling – as a guide to the maximum amount a drug will cost for the coming year. That same informant noted that there is nothing built into the budget to account for new clients who seek services during an economic downturn, something that is currently threatening government budgets at all levels.

The degree to which these shifts affect a provider's budget seems to depend in large part on the composition of their clientele. One informant, for example, reported that 70 percent of clients have incomes below the poverty level and are therefore fully subsidized by the clinic, and almost none has Medicaid or private insurance coverage. Every change in price, therefore, has a strong effect on clinic finances, and the agency has been unable to afford many newer contraceptive methods. In contrast, one informant from a state with a large Medicaid family planning expansion reported that they were only marginally affected by changes in contraceptive pricing, because the vast majority of their patients have coverage through Medicaid and the program reimburses the provider in full for contraceptive supplies. While the program does have a reimbursement ceiling for supplies, so far actual prices have not approached that ceiling. Medicaid reimbursement issues are covered in more detail in Chapter VI.

These budgetary issues might also have an effect on patients' cost sharing. Under Title X, clients above the poverty level are assessed a fee based on a percentage of the average cost of patient care, with those above 250 percent of poverty required to pay the full cost. Two informants reported their confusion over how often they should adjust their sliding fee scale to account for changing drug prices. They fretted that adjusting the fee scale each quarter – or however often drug prices shift – would be a huge burden on staff and could negatively affect their relationships with clients.

2. *Tracking Inventory*

All participating providers must maintain accurate records of their drug purchasing to ensure they are not violating the above-mentioned restrictions. This can be complicated because an entity may need to keep separate electronic (or in some states, physical) inventories of each drug at every price at which it has been purchased, and keep track of every drug given to every patient. That way, it can prove that a drug it purchased at the 340B-discounted prices was given to an eligible patient. An audit may be conducted by the manufacturer or by the federal government, and if providers do not comply with the requirements, they may be obliged to refund the manufacturer.⁵⁰ The PSSC, a free technical assistance service funded by OPA/HRSA, helps providers with these issues.⁵¹

Many informants also noted the challenges created by the 340B program's quarterly shifting prices and other logistical issues on their ability to maintain an inventory of pharmaceutical supplies. Informants differed widely in their inventory systems, using everything from sophisticated electronic systems to simple, hand-written notebooks. Larger informants, as would be expected, were more likely to report using computer-based systems; one informant noted that many of the nation's largest PPFA affiliates had banded together to purchase a single system.

For some informants, the most troubling inventory issues were related to ensuring that they have an adequate inventory on hand at all times to supply all of their service sites. One large grantee with dozens of delegates and clinics reported that maximum orders are a problem

⁵⁰ Richardson, Katheryne. (April 2004). Implementing a Comprehensive 340B Contracted Pharmacy Service. Prepared for Medpin.

⁵¹ For additional information about the PSSC, go to <http://pssc.aphanet.org/>.

under many purchasing arrangements. If they cannot supply their entire network with a particular drug from a given distributor, they will offer an alternative. They do make exceptions, such as when they are testing a new product, in which case they may supply the drug to a small number of provider sites.

Informants had different options as to how shifting prices affected their inventory practices. For many – particularly those that have many clients with Medicaid or private insurance coverage – it has meant keeping separate inventories based on the price of a drug, so that they can appropriately bill for the cost of the drugs provided to each patient. Some informants believe they are obligated to track the price of each drug provided to each client, with one noting that it had to submit invoices to the state Medicaid agency and to several private insurers. Other informants, instead, reported that they average prices over the course of a quarter or a year. One state agency, for example, purchases and stores drugs centrally, with delegate agencies then ordering on an as needed basis. Delegate agencies are charged at an average price based on the past year’s prices, a process that streamlines inventory and minimizes the negative effects of shifting prices on the delegate agencies.

Informants noted that Title X rules and auditors also encouraged strict inventory practices in order to perform accurate cost analyses and to set the sliding fee scale for client cost sharing. A few informants said they had received pressure through Title X to match up drug prices by client, but that their inventory systems were not at a level of sophistication where they could do so, and it was not formally required. One informant noted that even the Title X auditors were confused by what inventory practices are required, with one auditor asserting that agencies needed to maintain physically separate stocks of drugs (as opposed to inventories separated via record systems). (The project team’s discussions with OPA/OFP staff and OPA/HRSA indicate this is incorrect.)

One area where Title X rules are clear is that entities that provide abortion services must maintain “firewalls” to keep those clients separate from their Title X projects, including in their inventory systems. This is also required under 340B rules regarding the definition of a patient, although the lines there are not always clear: One informant noted that they were in discussion with their grantee about how to handle contraceptive care to post-abortion patients, and another questioned how to draw a distinct line between their family planning and prenatal clients.

Chapter VI. Drug Purchasing and Medicaid Reimbursement

The key questions for this study focused exclusively on issues related to purchasing drugs, never directly addressing the revenue side of providers' operations. Yet, the literature review phase of this study pointed to the issue of avoiding duplicate discounts for Medicaid clients as a major source of confusion and complexity for Title X-supported providers. In the discussion phase of the study, informants echoed that concern, and more broadly cited the interaction between drug purchasing and Medicaid reimbursement as resulting in substantial complications in running other aspects of their programs, as noted in Chapter V. Although the degree to which informants rely on Medicaid reimbursement varies considerably, almost all of them reported having at least some clients on Medicaid and having made attempts to receive reimbursement from that program. These problems, therefore, were nearly universal among the sample.

This chapter describes the options that providers have for avoiding the problem of duplicate discounts. It then details what informants reported as common challenges – largely related to result of state, federal, and corporate paperwork – for making use of these various options, including their affects on revenue flow, staff time, budgeting, and inventory.

A. Reimbursement for Pharmaceuticals

As described earlier, entities participating in the 340B program are required to take steps to avoid a duplicate discount for Medicaid patients – i.e., a situation in which the provider obtains a drug at a 340B-discounted price and, later, the state receives a Medicaid rebate from the manufacturer for the same drug. OPA/HRSA describes two primary options for avoiding duplicate discounts.

One option is to purchase discounted drugs for Medicaid patients through the 340B program while ensuring that the state's Medicaid agency knows not to seek a Medicaid rebate. Under this option, the provider would be limited to billing Medicaid at the acquisition cost of the drug plus a small dispensing fee (set by each state's Medicaid agency, typically in the range of \$2 to \$6).^{52,53} To ensure that the state does not seek a rebate, the provider must inform OPA/HRSA on its 340B application form that it will be billing Medicaid for drugs purchased via the 340B program. OPA/HRSA maintains a Medicaid Exclusion File that identifies those entities that are purchasing drugs via 340B for their Medicaid patients and grantees may update this information as necessary. State Medicaid agencies use this file to help ensure that Medicaid rebates are not paid on drugs that were purchased under the 340B program.⁵⁴ Because the state-set dispensing fees are typically low and may not adequately cover a provider's administrative expenses, some providers may actually lose money under this option.⁵⁵

A second option is for providers to “carve out” Medicaid patients; that is, purchase drugs for Medicaid patients outside of the 340B program and instead receive standard, state-set Medicaid

⁵² <ftp://ftp.hrsa.gov/bphc/pdf/opa/FR05071993b.pdf>.

⁵³ <http://www.kff.org/medicaid/benefits/service.jsp?gr=off&nt=on&so=0&tg=0&yr=3&cat=5&sv=32>.

⁵⁴ A tutorial on the Medicaid Exclusion file is available on line at <http://www.hrsa.gov/opa/medicaidexclusion.htm>.

⁵⁵ <http://www.hrsa.gov/opa/medicaidexclusion.htm>.

reimbursement rates for those drugs. In this case, the provider must ensure that it is not included on OPA/HRSA's Medicaid Exclusion File so that the state Medicaid agency will know to seek a rebate. If the Medicaid Exclusion File is incorrect, it could mean that the state may receive a double discount or no discount at all. In either case, the provider may be liable for refunding the manufacturer or the state. The following text box provides examples of provider options.

Whether to "Carve out" Medicaid Patients

Example 1: The provider carves out Medicaid patients. The provider is in a state in which the applicable dispensing fee for a family planning clinic is \$3 per prescription (as determined by the state Medicaid agency). The provider calculates that its true dispensing cost, including staff time, storage, inventory and other administrative requirements, is \$5 per prescription, or \$2 dollars higher than what Medicaid will reimburse. So, if the 340B price for a one month supply of oral contraceptives is \$20, the Medicaid agency will reimburse the provider \$23. However, it costs the provider \$25 to dispense this method. Thus, the provider would lose money for each client served.

If the same drug is not purchased through the 340B program, the state Medicaid program would reimburse the provider at a set reimbursement rate (often based on the drug's list price minus a set percentage plus the dispensing fee). The provider is in a state in which the reimbursement rate for this method, as set by the state Medicaid agency, is \$35. The provider investigates the non-340B prices of this oral contraceptive and finds that it can be purchased for \$30. Thus, the Medicaid reimbursement more than covers the provider's cost. The provider, therefore, chooses to "carve out" its Medicaid patients, purchasing drugs for them at non-340B prices.

Example 2: The provider does not carve out Medicaid patients. The provider is in a state in which the applicable dispensing fee for a clinic is \$5 per prescription. A provider calculates its dispensing costs are \$4 per prescription. This provider would not need to carve out its patients, because it is not losing money through the 340B program.

Still, the provider should gauge its options. Investigating prices in the marketplace, the provider finds that, except for its 340B-related discounts, the best prices it can find for contraceptive supplies are, on average, several dollars above the state Medicaid agency reimbursement rates, and it would lose money for each Medicaid patient it did carve out. The clinic, therefore, chooses to purchase at 340B-discounted prices for all its patients.

According to the informants, the dispensing fees and standard reimbursement rates set by each state are the most important factors in determining which of the two options is preferable. How these rates are set varies across states. One family planning council, for example, reported that each of their delegate agencies set its own dispensing fee, based roughly on their true costs of serving clients. Another informant reported that it had negotiated an appropriate dispensing fee with its state Medicaid agency. Others said that the state agency set these fees without negotiation, or that the state legislature was involved in setting fees. Informants in one state noted that their state Medicaid agency would prefer that they choose the carve-out option, because it would reduce the state's administrative burden and reportedly would save the state money.

These two options are not, however, the only ones available to Title X-supported providers for avoiding the problem of duplicate discounts under 340B. In many states, Medicaid – either the state agency or a Medicaid managed care (MMC) plan – reimburses family planning providers at a single rate for a bundle of services – e.g., at one rate for an initial family planning visit and

at another rate for a subsequent annual visit. Typically, this “bundled” or “global” rate includes the cost of oral contraceptives (as well as an examination, counseling, diagnostic tests, etc.). In such cases, the provider may purchase drugs at the best price available to them and will receive the bundled rate; the state, in such cases, will not seek a rebate from the manufacturer, so there is no risk of duplicate discounts. (Some other methods of contraception may be excluded from the bundled rate, and in those cases, providers receive additional reimbursement, generally at cost plus a dispensing fee.) FQHCs have their own, special bundled reimbursement rates under Medicaid, and are paid on a per-visit basis. This applies to all of the services FQHCs provide to patients, family planning and otherwise.

Many informants also discussed the option of “scripting out” — i.e., not dispensing a method on site, but instead writing a prescription for the client to fill at a local or mail-order pharmacy. In such cases, Medicaid will reimburse the pharmacy and will receive a rebate from the manufacturer; the family planning clinic, meanwhile, will avoid having to purchase the drug at all. This option avoids the issue of duplicate discounts entirely, leaving providers with no risk of violating 340B rules. It also is a way for providers to save money. Informants varied widely in their interpretation of when they may use this option for patients under their Title X projects, and in the guidance they reported receiving from regional office staff. This option is discussed in more detail in Chapter VII.

B. Common Challenges

From informants’ perspectives, none of these reimbursement arrangements is ideal. For example, informants report that bundled rates are often left unchanged by the state for years — in several cases, not since the early 1990s — in terms of both the rate itself (so that it is not even adjusted for inflation) and the services and methods included within the bundle. Several informants stated that they successfully pushed for newer methods to be reimbursed in addition to the bundled rate as a way to counteract both problems. Yet, it can take years for some states to add a reimbursement code to their fee schedules for a new contraceptive method, forcing family planning providers either to not offer the method, to find other sources of reimbursement or to essentially give the new method away to their clients. This is a daunting prospect, considering the high cost of many newer methods, such as the hormonal IUD or implant.

MMC poses unique problems for family planning providers that make the entire process of drug purchasing more difficult. Several informants discussed the fact that — in order to avoid duplicate discounts by making use of global fees or carving out their Medicaid clients — they had to negotiate reimbursement fee schedules for each MMC plan in the state. Even if these negotiations are successful, they are time- and labor-intensive. If the negotiations are unsuccessful, clinics should still be allowed to serve Medicaid clients and receive reimbursement at a fee-for-service rate. This is the result of the special requirement under Medicaid law that allows even those patients assigned to an MMC plan to see any willing family planning provider, regardless of whether it is a part of the plan’s network of providers. However, several informants reported the layers of paperwork made this unfeasible. One informant reported that the state instead does the negotiation with the MMC plans, but the fee schedules are not complete, and they are provided no guidance in identifying the appropriate fees for services and items that are not listed. In addition, one informant reported that local MMC plans were requiring that clients be scripted out for their contraceptive supplies. While

MMC plans view this as a way to save themselves money, doing so can drive away clients and may compromise care, since there is no way to ensure that clients follow through with having their prescriptions filled. Another informant stated that MMC plans want providers to dispense generic drugs to their clients. The MMC plan does not realize that brand-name drugs are often less expensive for 340B-eligible entities. The informant has attempted to persuade their state Medicaid office to intervene in this situation, but to no avail. Several informants noted that these issues in dealing with MMC plans hold true for private insurance plans as well.

Many informants mentioned paperwork in discussing Medicaid reimbursement. One reported that their state only allowed them to dispense three months of contraceptive supplies at one time. Another reported that the state took an especially long time to process reimbursement for anything beyond their global fee (e.g., for an IUD). Indeed, informants frequently mentioned reimbursement delays as challenges they faced with Medicaid and Medicaid waiver programs. Compared to a grant like Title X, which is available upfront, the after-the-fact reimbursement provided by Medicaid can be problematic for clinics, requiring them to rely on other revenue to purchase supplies up front. A couple of informants reported that the combination of red tape and delayed reimbursement sometimes led them to cover the costs of some Medicaid-enrolled patients with other funds. Several informants cited this after-the-fact reimbursement as an especially important downside within their state's Medicaid family planning expansion. This is particularly true for states that scaled back their traditional, up-front grants to family planning clinics when they implemented their waiver programs.

When asked, few informants expressed confidence in their understanding of the Medicaid carve-out option. For many of them the issue is irrelevant because they have bundled rates or they script out their Medicaid clients. Nevertheless, the consensus among informants was that additional clarification would be helpful in order not to violate federal law and to help them choose the most fiscally sound reimbursement method.

Finally, several informants worried about the intersection among shifting prices, inventory tracking and Medicaid reimbursement. Informants carving out their Medicaid patients understood that it meant purchasing drugs at two different prices, maintaining two different inventories of drugs (one for most of its patients, purchased at 340B-discounted prices; and one for Medicaid patients, purchased without that discount), and matching up each patient with the correct drug. Those that were using 340B for their Medicaid clients knew that they needed to bill the state at the cost of the drug, plus a dispensing fee. However, some expressed uncertainty over the precision required under 340B rules. One informant, for example, reported that their state Medicaid agency has started asking them about their purchase prices, and they were concerned that they would be required to update their reimbursement rate every time prices change, rather than averaging the prices over the course of a quarter or a year. Another informant referred to such a requirement as an "administrative nightmare."

Chapter VII. Consequences of Rising Costs

Almost every informant in this study described challenges in serving their clients in the context of inflation and rising health care costs, including, but not limited to the cost of medications. They asserted that the discounts they receive through 340B, Prime Vendor and other drug purchasing programs, while welcome, are simply not large enough to address these rising costs.

Many informants referred to Ortho-McNeil drastically raising prices of many of its contraceptive products in the summer of 2006, only to back down several months later under public pressure, as having a significant and negative effect on their finances and ability to serve clients. As this study was underway, Ortho-McNeil announced another increase in contraceptive prices, this time promising to spread the increase over several quarters and providing clinics with time to prepare. Despite this advance notice, many informants had not heard about the shift, and few had concrete plans in place for addressing the increase in prices. Nevertheless, informants reported a number of tactics for addressing the shortcomings of the various drug discount programs – seeking other ways of saving money on their drug purchases, finding additional, non-drug savings, and locating new sources of revenue.

A. Reducing Formularies

Despite the savings associated with participation in 340B, Prime Vendor and other drug purchasing programs, most informants reported having to take additional steps to curb their drug-related costs. One common tactic was to restrict the number of contraceptive drugs and devices offered at their clinics. For some clinics, this meant offering only three or four types of oral contraceptives, along with the injectable and perhaps one or two other methods. Other, larger informants thought of a 15-product formulary as limited in comparison to what they had offered a few years earlier. Several informants noted that they relied primarily on only a few specific pills, but commonly stocked small quantities of other oral contraceptives for patients who respond poorly to the standard ones.

Contraceptive devices and brand-name oral contraceptives stood out as especially problematic. Devices such as the hormonal IUD and implant were deemed unaffordable by many informants, despite their long-term cost-effectiveness, as were shorter-term devices such as the contraceptive patch and ring. Similarly, numerous informants mentioned heavily advertised oral contraceptives such as Yazmin and Seasonale as both in demand by clients and unaffordable to clinics; as one informant said, “our client education can’t compete with their marketing.” In the case of Seasonale, several informants reported that they choose to provide clients with a longer supply of generic oral contraceptives, so that clients can skip the placebo pills and obtain Seasonale’s feature of only four periods per year. Several other informants noted that they had limited options in restricting their formulary because of the cultural preferences of their clientele. For example, one informant serving a large population of Asian immigrants reported that many of their clients were opposed to the use of hormonal contraception, preferring the copper IUD instead.

Several informants said that they changed their formulary reluctantly, and only after much internal debate and analysis. One state agency, for example, reported that it had recently revised its formulary based on the recommendations of a medical advisory council; that council “started pretty much from scratch” to look at all of their possible contraceptive options, and

obtained “buy in” from the state’s clinicians. Shifting between bioequivalent drugs is easier for clinicians and clients, but even that option is limited. For example, many family planning clinics attempted to switch to generic products in 2006, in response to the increase in Ortho-McNeil prices, but were stymied by limitations in companies’ manufacturing capacity.

B. Finding Additional Drug-Related Savings

Another tactic, reported by a smaller number of informants, amounted to “chasing” discounts. For some, that simply meant building a relationship with multiple distributors, to take advantage of small differences in prices among these vendors. For others, that meant taking maximum advantage of sales and other price shifts by changing which contraceptives they offer to clients. One informant referred to this a “gambling game,” in which they attempted to predict prices and make purchasing decisions – which drugs to buy and how much to buy at one time – accordingly. Another informant, a large grantee, reported using a computerized inventory system that enables them to predict how many drugs they will prescribe in a 12-month period; using this information, they can make better use of this tactic by purchasing in large volume.

Many informants reported feeling constrained in their ability to seek out the deepest discounts on contraceptive supplies because it may require them to force patients to switch from one pill formula to another or from method to method. Informants were especially wary of taking advantage of “fire sales” to introduce an entirely new product to their formulary, not wanting their clients to become attached to a method that may not be affordable a quarter or two later.

Some informants worried about side-effects and method effectiveness, since women tolerate methods differently, and it can sometimes take many tries before a woman finds a specific pill or other method that is right for her. They noted that having to switch a patient from her choice because it has become unaffordable to the clinic could be detrimental to her health and to her ability to practice contraception effectively. Several informants extolled the virtues of their staff pharmacists, whose expertise allows them to identify comparable drugs, so that the entity can adapt to price increases in a way that minimizes the health consequences for clients and avoids pulling the client in for another visit merely to change her prescription.

Informants noted that they also worry about patients’ reaction to being told they must switch to a different product. Some informants found that their patients were emotionally wedded to their specific contraceptive, and even changes in packaging or in the color and shape of a pill caused concern and confusion. They also were concerned that patients would have trouble understanding and following a new product’s label, and that they would feel as if they are receiving substandard service; a few informants reported that patients were increasingly brand-conscious, arriving for their clinic visit convinced by direct-to-consumer advertising that they needed one specific product. Many other informants played down these concerns, asserting that most patients’ apprehensions and grievances could be addressed effectively by a careful and thoughtful explanation from a clinician, particularly when switching between bioequivalent products.

C. Scripting Out

Informants appeared to be especially conflicted over the practice of “scripting out” – a tactic that, by allowing providers to purchase fewer drugs, can provide substantial cost savings. First,

they differed over the circumstances in which they believe Title X–supported clinics are allowed to write their clients a prescription, rather than dispensing a contraceptive method on site; and different informants reported different responses from regional office staff on the issue. Several informants thought that this practice was simply not allowed under Title X. Others asserted that it was only allowed if a client had a medical need for a drug not offered on site. Yet other informants believed that they could script out to any client upon request, so long as the clinic offered the product on site as well. Finally, a few informants asserted that they scripted out all of their clients with Medicaid or private insurance coverage. One such informant reported that Medicaid will not allow them to dispense contraceptives on site, because they do not have an in-house pharmacist.

Informants cited numerous benefits and drawbacks of scripting out when allowed, primarily involving issues related to patient access. Several noted that the cost of purchasing a drug at a retail or mail-order pharmacy – even the \$9 generic drugs available at major chain drug stores – is simply too high for many of their lower-income clients. Even if it were allowed, it would subvert the intent of Title X’s sliding fee scale, under which the poorest clients receive care free of charge. They also expressed concern about undermining the one-stop-shopping aspect of Title X, because many low-income clients rely on public transportation and have restrictive work and home schedules. Clients in small towns may also have confidentiality concerns about going to their local pharmacy, and those in rural areas often face few local options. In addition, one informant reported that nurses are not allowed to write prescriptions in their state.

On the other hand, one informant reported what they saw as a growing comfort on the part of their regional office staff with scripting out, specifically for clients in rural areas so that they do not have to travel a long distance merely to obtain a refill. Others saw benefits for higher-income clients when their co-payment at a drug store would be lower than the clinic’s fee under Title X. Another noted that in their state, in-house dispensing was made difficult by record-keeping and other administrative requirements. Several FQHCs reported that they regularly wrote prescriptions for their primary care clients. For these entities it is not feasible to have a fully stocked in-house pharmacy. They also have financial incentives for scripting out because of the flat per-visit fees they receive from Medicaid and private insurers. However, contraceptive supplies were often an exception to this practice.

D. Finding Other Savings

One long-standing grantee noted that the price of pharmaceuticals is more volatile than anything else in their system, making it both imperative and difficult to compensate for increasing drug prices by finding other types of savings. Most informants reported that they seek discounts on other types of supplies, including gowns, gloves, and needles, along with office and janitorial products and utility bills. A few informants noted that there is more competition among vendors of these supplies, which gives clinics more leverage to secure discounts.

Several informants reported finding ways to take advantage of economies of scale. For example, one state family planning program was bulk purchasing medical gloves for the entire state health department. Other informants bought in bulk for their own purposes, purchasing large stores of supplies when items go on sale. PPFA affiliates, as noted above, sometimes take advantage of discounts negotiated by the federation on non-contraceptive supplies, or by

smaller, regional joint projects. One informant, for example, reported that a group of large PFFA affiliates had jointly purchased a new electronic health records system at a substantial volume discount; moreover, the group had established a center to standardize the reporting and data analysis under this new system, a set-up that was also expected to provide cost savings.

Few informants admitted to having more drastic contingency plans for rising prices. Several suggested that they may have to reduce the size of their staff, leaving empty positions unfilled, or otherwise cut back on staff and clinic hours. One state agency reported that some of its county clinics had already eliminated their in-house pharmacists. Another informant said that it might stop providing contraceptive supplies to its partner clinics; it noted that those clinics would probably refer their clients to the informant's own clinics, although many clients would be unable to travel the additional distance. Already, many family planning clinics are cutting down on the number of contraceptive cycles they provide at a single visit.

Raising client fees is typically seen as a last resort, particularly given the current economic climate. Yet while informants universally reported wanting to avoid shifting the burden to their patients, some said this might become unavoidable.

E. Raising New Revenue

In addition to seeking savings, informants are also seeking ways to increase their revenue without raising their client fees. One potential source is government grant funding. Other informants – particularly state health agencies – reported seeking additional state-level appropriations, with mixed results. Numerous informants noted that they received drugs for STD treatment from their state at no cost through the Infertility Prevention Program.

Informants also highlighted the importance of private-sector grants and donations. Several PFFA affiliates, for example, reported that they typically run a deficit each year and turn to private foundations and individual donors to cover their costs. One family planning council, similarly, said that it had a grant from a private foundation to support care for some of its uninsured patients. More commonly mentioned were the patient assistance programs set up by several drug manufacturers, through which a clinic can receive products such as the hormonal IUD or the HPV vaccine at no cost for low-income, uninsured clients. Several informants noted that these programs often have monthly limits, leading them to schedule IUD insertions early each month. Informants also cited as challenging the fact that the programs require the clinic to have invested in a supply of the drug or device up front; the manufacturer will then provide replacements for supplies used for eligible patients.

As expected, the most discussed form of revenue was third-party reimbursement generally and Medicaid specifically. The degree to which informants reported relying on Medicaid reimbursement depended in large part on the design of each states' Medicaid program. Those in states with income-based family planning waiver programs or in states that have high income eligibility ceilings for broader Medicaid (for instance, covering everyone in the state below the poverty level) often reported that two-thirds or more of their clients (and of their revenue) came from Medicaid. Those in states with limited or no waiver programs and with low-income ceilings for Medicaid (e.g., less than half the poverty level for parents and no coverage at all for childless adults) typically reported far lower rates of Medicaid participation among their clients. Many informants serving large numbers of immigrant clients also reported

low rates of Medicaid participation, as the federal government prohibits Medicaid coverage – including under waiver programs – for legal immigrants within their first five years of residency and for immigrants in the country illegally. (A 2009 law allows states to enroll recent immigrant children and pregnant women.) This problem was particularly common with urban-based informants. Several inner-city informants reported that, despite their state’s Medicaid waiver program, most of their clients were ineligible for coverage because of their immigration status.

Informants were mixed in their opinions about the effectiveness of the Medicaid waivers. Informants in four states with long-standing income-based waivers were unabashed in their praise, with one describing the waiver as “one of the best things to happen in [their state] in years” – both for its impact on women’s access to services and for the degree to which it has eased clinics’ cost pressures. Other informants in those states reported that waiver funds had allowed them to expand their client base, while freeing up Title X funding to support outreach, education and infrastructure. Several noted that cost-based reimbursement under the waivers was especially useful, as it negated the impact of rising drug prices for those Medicaid clients. (They did not see it as a disincentive to seek out savings, both because they need to worry about their non-Medicaid patients and because they see themselves as responsible partners in the waiver programs.) In several other states with waiver programs, however, informants reported facing significant administrative barriers that limited their ability to use these programs effectively; one informant noted that the waiver program in their state was new, and that they expected things to improve.

Chapter VIII. Conclusion

This study, undertaken for OPA/OFP, sought to provide a better understanding of the benefits, drawbacks, facilitators, and barriers to Title X-supported providers' participation in the 340B and Prime Vendor programs. It aimed to help OPA/OFP understand Title X-supported providers' experiences with these programs, and the factors in their decisions to employ alternative ways for achieving pharmaceutical discounts. Although this research discovered high levels of participation in the 340B and Prime Vendor programs, it also uncovered the nuanced, dynamic and complicated context in which they attempt to maximize use of 340B and other drug purchasing programs.

This section briefly summarizes the report's findings, and explores possible next steps for enabling Title X-supported providers to make the best use of drug discounts programs.

Overall, the report's informants cited numerous positive aspects of their experiences with both programs, but also a number of ongoing obstacles to maximizing savings on pharmaceuticals. Conversations with study informants illuminated the immense thought and time that grantees devote to drug purchasing, which has significant implications for how Title X programs are operated.

Findings. The findings include:

Use of 340B, Prime Vendor, and Other Purchasing Programs

- ▶ Participation in 340B was universal among Title X providers in the study sample; data from the Office of Pharmacy Affairs/Health Resources and Services Administration indicates participation is almost universal among Title X providers generally.
- ▶ Participation in the Prime Vendor program is increasing. About half of the study sample is enrolled, which align with data from OPA/HRSA.
- ▶ Providers use other purchasing programs in tandem with 340B and Prime Vendor. These include PPFA's purchasing program, the FPCPP and the MMCAP. Often the discounts offered by the alternate programs are superior to those available through 340B and Prime Vendor.
- ▶ Cost savings and stability are top priorities in determining which drug purchasing program to use.

Awareness of 340B, Prime Vendor, and Other Purchasing Programs

- ▶ Providers seek additional, easily accessible information on drug purchasing programs.
- ▶ The absence of information creates confusion, leads to misinformation, and impedes greater use of the programs.

Barriers to Maximizing Use of Drug Purchasing Programs

- ▶ Family planning providers seek larger discounts on a wider variety of products than either program offers.

- ▶ The enrollment process can be complex and confusing; providers are unsure where to turn for information and guidance.
- ▶ Additional and targeted information and outreach by the drug purchasing programs is desired.
- ▶ Price shifting creates difficulties for providers in terms of inventory and budgeting. Providers are concerned about the effect of changing formularies on patients.

Drug Purchasing and Medicaid Reimbursement

- ▶ Medicaid is an important revenue source. However, providers need to be cognizant of the interaction between Medicaid and drug purchasing programs and take steps to avoid double billing.

Consequences of Rising Costs

- ▶ To address rising health care costs, providers seek additional cost savings through reductions in formularies and scripting out.

Next Steps. A number of the findings of this research center around information-related challenges articulated by many informants. These challenges are all related to a lack of consistently available information regarding the programs, and the misinformation and misperceptions that result that may ultimately lead to lower usage of both programs. Conversations with key informants indicated a desire for information – both generally about the programs and targeted specifically to the Title X community. Informants were invited to think about tools and information that would help them navigate and use the 340B and Prime Vendor programs more effectively. The resulting “wish list” suggests some future steps that could help Title X providers maximize their use of these drug purchasing arrangements. Suggested beginning steps from informants included:

- ▶ More attention at national Title X family planning conferences
- ▶ Standardized training information and guidelines for Title X grantees and delegates
- ▶ Alerts about relevant changes to 340B and Prime Vendor
- ▶ Grantee/ delegate feedback about promising practices (e.g., some type of “community of learning” where providers can share information)

Based on the research, technical assistance targeted on the following issues may also be helpful:

- ▶ Where to find the most complete and best information about the 340B and Prime Vendor programs (including the PSSC); where to find answers
- ▶ How to budget in a constantly changing drug purchasing marketplace
- ▶ How to speak to clients about changing formularies
- ▶ How best to work with Medicaid – including how to maintain an accurate listing on the Medicaid Exclusion File
- ▶ Identifying other cost saving mechanisms

Appendix A: Resource List

Resource Type	Source	Description	Website
Purchasing Program Websites	340B Program website	This website, maintained by the Health Resources and Services Administration (HRSA) within the U.S. Department of Health and Human Services, provides an introduction to the Office of Pharmacy Affairs and the 340B Program. It contains valuable information for 340B participants including updates on the 340B database, legal resources including the definition of a patient and registration forms; and a glossary of pharmacy-related terms. It also contains a link to the Medicaid Exclusion File, which enables participants to avoid obtaining double discounts on drugs (described in greater detail below).	http://www.hrsa.gov/opa/
	Prime Vendor Program website	This website, accessible via the 340B website, is maintained by Apexus, the contracted organization responsible for securing sub-340B ceiling prices for the Prime Vendor Program. The PVP website provides general information on the PVP program for the public, including recent news and upcoming PVP-related events, frequently asked questions, and instructions for program participation. The website is also equipped with a 340B/PVP tutorial that enables program participants to understand both programs and how they can use them to optimize cost savings. Finally, the website has a participant log-in section with information geared solely towards current program participants.	http://www.hrsa.gov/opa/primevendor.htm
	Family Planning Cooperative Purchasing Program (FPCPP) website	The FPCPP, a purchasing cooperative for participants of the 340B program, provides information geared specifically to 340B and family planning entities. The FPCPP website provides information on how the program operates, how to become a member, updates on research in the family planning and reproductive health fields, links to vendors from which FPCPP members receive discounts, and links to newsletters and outside agencies involved in family planning.	http://fpcpp.org/
	Minnesota Multistate Contracting Alliance for Pharmacy website	MMCAP is a purchasing cooperative for which 340B entities are eligible. The MMCAP website provides information on the program's administration and how it accomplishes cost savings for its clients. It also includes information on eligibility and the vendors that provide different types of medical supplies to program participants. In addition, there is a log-in section for participants to monitor contract release documents.	http://mmcap.org/

Resource Type	Source	Description	Website
Forms	340B enrollment form	Potential participants must complete this form in order to register in the 340B Program. The form has detailed instructions for completion as well as essential information on program participation that should be reviewed carefully before enrolling.	ftp://ftp.hrsa.gov/bphc/pdf/opa/FPPrgmReg.pdf
Additional On-line Information on 340B/Prime Vendor and Drug Purchasing	Kaiser Family Foundation, "Medicaid Prescription Drug Benefits by State"	This website provides information on each state's Medicaid benefits for prescription drugs. Each state's benefits vary along the following categories: whether or not they provide Medicaid benefits for prescription drugs, whether a copayment is required, whether prior approval is required, coverage limitations, reimbursement methodology, and populations covered. Title X entities may use these categories to determine the extent to which their prescription drug costs will be covered by Medicaid, and therefore what percentage of their overall budget will need to be spent towards paying prescription drug costs for low-income clients.	http://www.kff.org/medicaid/benefits/service.jsp?gr=off&nt=on&so=0&tg=0&yr=3&cat=5&sv=32
	Medicaid Exclusion Tutorial and Medicaid Exclusion File Basics	This website provides guidance on the Medicaid Exclusion File (MEF), which prevents entities from receiving discounts from both 340B and Medicaid reimbursement, so-called "double discounts." It includes information key to 340B grantees, such as how data is gathered for the MEF, what determines whether an entity will be included in the MEF, and how an entity should proceed if it uses Medicaid reimbursement for some clients but not for others.	http://www.hrsa.gov/opa/medicaidexclusion.htm
	HRSA Pharmacy Services Support Center (PSSC)	The PSSC website provides information, education, and policy analysis to help 340B participants maximize their use of the program. The main goal of the website is to support participants towards providing clinically and cost effective pharmacy services that improve medication use and advance patient care. The website's "About the 340B Program" provides additional information on how the program functions and answers questions such as which entities are eligible to participate in the program.	http://pssc.aphanet.org/
	Prime Vendor Program FAQ/Resources	The FAQs/Resources page on the PVP website provide answers to questions pertaining to program structure, implementation, registration, and other essential program components. It is a valuable resource for both current and potential program participants.	https://www.340bpvp.com/public/fag/fag_general.asp

Resource Type	Source	Description	Website
Additional On-line Information on 340B/Prime Vendor and Drug Purchasing	Federal Register Notice, "Calculation of a Drug Price"	The Federal Register provides information regarding the establishment of the 340B program. The document then provides supplemental information, including which entities are covered by the program, the certification process for participants, the formula by which the drug prices that are charged to 340B participants are calculated, and information specific to drug manufacturers.	ftp://ftp.hrsa.gov/bphc/pdf/opa/FR05071993a.pdf
	340B Database, "Statistics on 340B-Covered Entities"	The 340B database includes a document with statistics pertaining to 340B-covered entities, organized in chart form for easy reference. For instance, the second chart in the document includes information on the number of registered covered entity sites by entity type. The last chart presents similar information for Prime Vendor registered entities.	ftp://ftp.hrsa.gov/bphc/pdf/opa/Stats_2008_OTR_4.pdf
	Deficient Reduction Act Rule regarding nominal prices	This document includes information on the DRA rule stating which entities may receive nominal pricing from manufacturers. It states that under the DRA, manufacturers are now only allowed to offer a nominal price to specific entities—including any entity participating in 340B—without it affecting the rebates that manufacturers must offer to the entire Medicaid program.	http://edocket.access.gpo.gov/2007/pdf/07-3356.pdf
	National Family Planning and Reproductive Health Association (NFPRHA) fact sheets on Title X and 340B	These fact sheets provide information on 340B, such as how the 340B price is established and how the 340B prices and the steps entities should take when receiving both 340B prices and Medicaid reimbursement. The fact sheets also have information aimed specifically towards Title X entities, such as a step-by-step guide for how Title X entities may obtain drug discounts. This process includes the various means through which it may receive information updates from NFPRHA pertaining to drug discounts.	http://www.nfprha.org/images/pdf/2008%20Fact%20sheets/340B%20Program%20February%202008%20FINAL.pdf
	The Guttmacher Institute Report on Public Policy, "Nowhere But Up: Rising Costs for Title X Clinics"	This research brief discusses the three main financial challenges facing Title X entities: the increasing cost of contraceptives, the high costs of diagnostic tests, and the disparity between the percentage of Title X clients who receive Medicaid and the percentage of Title X entities' budgets that comes from Medicaid.	http://www.guttmacher.org/pubs/tgr/05/5/gr050506.pdf
	Congressional Budget Office, "Prices for Brand-Name Drugs Under	This report analyzes the prices paid to manufacturers under several federal programs compared to the average wholesaler price (AWP). The report found that the 340B ceiling price is, on average, 51 percent of the list price (AWP). The report may help Title X entities become familiar with how drug	http://www.cbo.gov/ftpdocs/64xx/doc6481/06-16-PrescriptDrug.pdf

Resource Type	Source	Description	Website
Reports/Studies	Selected Federal Programs"	prices are set, an aspect of drug purchasing with which many providers are not completely familiar.	
	Medicine for People in Need (Medpin) Report, "Implementing a Comprehensive 340B Contracted Pharmacy Service: Information and Tools for Community Pharmacists" and "The Bridge to Comprehensive 340B Pharmacy Services Solutions in Underserved Population"	These two manuals, meant to be used in concert with one another, are geared towards enabling health care entities best administer pharmacy services for their patient population. The goal of the first manual is to provide health center administrators with information and tools for pharmacy services implementation. The goal of the second manual is to equip community pharmacists with the information and tools to provide a comprehensive 340B pharmacy service under contract with a federally qualified entity. The information provided in both manuals is practical in nature and can lead to real improvements in how pharmacy services are administered in 340B eligible entities. For instance, the report provides an overview of the three most common 340B implementation options for pharmacies, and the ways in which a pharmacy services agreement may be structured.	http://pssc.aphanet.org/documents/pharmacy_001.pdf http://pssc.aphanet.org/documents/bridge-340B_001.pdf

Appendix B: Case Studies

Case Study One: Family Planning Council

- Introduction

Optimal Care Health is a large family planning council that has several dozen direct service clinics and contracted delegate sites, with the patient population divided evenly between direct and contracted sites. OCH serves a mixed urban and rural population, and currently has about 75,000 patients. Unlike many of the informants we interviewed, they do not serve a large immigrant population.

Drugs are purchased centrally at OCH for both the direct service clinics and contracted delegates. OCH collects purchase orders from its various sites and forwards these orders to the array of vendors through which it obtains drugs. Products are purchased on a monthly basis, and are either stored centrally at OCH headquarters or are shipped directly to the clinics and delegates. They charge the provider the price that OCH paid for each drug, whether the drug was sent to the provider from the central OCH location or was shipped directly to the clinic or delegate.

- Use of 340B, Prime Vendor, and Other Purchasing Programs

OCH is registered for both 340B and Prime Vendor. They find that there are only a few sub-ceiling prices that Prime Vendor has negotiated that are helpful to them, including the price of the NuvaRing. Otherwise, they use 340B for the majority of their drug purchasing. OCH also belongs to the FPCPP, which they use mainly to purchase the contraceptive Depo-Provera. OCH does not purchase drugs through MMCAP or any other state purchasing arrangement.

- Awareness of 340B, Prime Vendor, and Other Purchasing Programs

OCH is a sophisticated grantee that makes a point to remain as well-informed as possible about the various purchasing options available. They make use of the 340B and Prime Vendor websites to remain updated on those programs, and receive additional information on drug pricing through the FPCPP. They also look to the National Family Planning and Reproductive Health Association (NFPRHA) to inform them if price specials occur for certain drugs or if any other buying opportunity has become available. In fact, OCH originally signed up for Prime Vendor after repeatedly learning of the program through NFPRHA conferences. Yet OCH continues to be confused over how 340B price ceilings are established. They wrongly assume that the pharmaceutical companies negotiated with a representative from 340B, and do not know that there is a special formula set by law.

- Barriers to Maximizing Use of Drug Purchasing Programs

Until several years ago, OCH had negotiated its own long-term drug contracts, but it has not been successful recently and feels that the family planning community no longer has sufficient leverage. Referring to the pharmaceutical companies, OCH stated that “Nobody wants to be in the contraception business. Drug companies just want to come out ahead financially. They do not view any responsibility to get drugs out there to clients. We are at the mercy of the system.”

OCH has also faced administrative issues with 340B. For instance, they have faced challenges with keeping their clinics' entries in the 340B database updated over the past three years. They repeatedly updated their information, sent it to 340B, and were told that they had updated the database incorrectly. OCH has therefore taken to performing a secondary review of all of their clinics' information prior to sending it to 340B, and they are hopeful that it will need few changes this year.

Finally, quarterly price shifts have created tremendous problems for OCH. In 2007, they placed 30% of their patients on a certain oral contraceptive, Yasmin, when it was priced at one cent per cycle. The drug then increased to \$17 per cycle, and OCH was forced to switch its patients to different, less expensive brands that were not bio-equivalent. This created administrative headaches for OCH and upset patients who had become accustomed to the previous contraceptive's packaging and side effects.

- Drug Purchasing and Medicaid Reimbursement

The state in which OCH is located has a relatively new Medicaid family planning waiver and has experienced some problems in the early phases of the program. In the past, OCH received funding from multiple federal and state grants and used that money to purchase drugs centrally. Now, much of that funding has been shifted to support the waiver program and comes to clinics as after-the-fact reimbursement, requiring OCH to use other funds for their initial drug orders. In addition, OCH worries that some clinic sites will face funding shortages until they succeed in enrolling sufficient numbers of clients in the waiver program – and that they will have to adjust the grant funding they provide to delegates and clinics if some sites are more successful at enrolling clients than others.

- Consequences of Rising Costs

OCH has a limited formulary with only about three oral contraceptives and several other forms of birth control. The formulary is not uniform across their delivery area but rather varies by site. While they try to stock at least one type of oral contraceptive (e.g. monophasic, triphasic, low-dose pill) at each site, this is not always possible due to cost limitations. OCH has also tried adjusting its formulary to take advantage of discounts; the latter tactic, as noted in Chapter VII, has led to problems for clinics and patients. OCH does take advantage of sales on certain drugs where the quantity of drugs they may purchase is limited; it does so by only providing these drugs to smaller clinics and delegates. OCH does not script out its clients, except when medically necessary, and believes it would be harmful for low-income clients; however, it is concerned that if prices continue to escalate, it may have to seek permission to script out in more situations.

OCH is also keeping a close watch on Medicaid reimbursement through the new waiver program. OCH is concerned that reimbursement under Medicaid is insufficient to cover clinics' dispensing costs, and may need to renegotiate these rates with the state. Both OCH and the state are aware of the issue of duplicate discounts and are looking into which arrangement makes more financial sense for each of them. Regardless of what the state decides, OCH stated that they "will continue to do what is best for us."

Case Study Two: State Health Department

- Introduction

The Franklin State Department of Health (FDH) is a medium-sized health department in the state of Franklin with six direct clinic sites and three delegates. The clinics and delegates together serve over three quarters of the state's population, making it the largest grantee in the state. FDH is located in an urban area, with the majority of its patients residing in the same city. Their patient population has substantially increased in size over the past couple of decades, and now includes a large percentage of immigrants. FDH performs centralized purchasing on behalf of all of its direct clinic sites, stocking the drugs in a central warehouse. In contrast, its delegates perform their own drug purchasing. Franklin does not have a Medicaid family planning waiver program.

- Use of 340B, Prime Vendor, and Other Purchasing Programs

FDH has signed up all of its clinics for 340B and Prime Vendor, and has provided extensive additional assistance to one of its delegates throughout the enrollment process. FDH does not participate in FPCPP or MMCAP, mainly because, until recently, state laws requiring competitive bidding rendered it difficult to participate in these programs. FDH has not negotiated prices directly with manufacturers or distributors.

- Awareness of 340B, Prime Vendor, and Other Purchasing Programs

Until recently, FDH staff had not focused on their drug purchasing options, but due to rapidly increasing prices, the agency hired a new purchasing agent in 2008 to explore these options. This purchasing agent has brought needed information to the department and has worked to develop relationships with manufacturers and distributors. Yet there is still confusion among other staff: For instance, they are still not always able to distinguish between 340B and Prime Vendor and do not know how prices are set. At the time of the discussion, FDH was also unaware of Prime Vendor's family planning advisory council.

Further complicating FDH's drug purchasing is the fact that FDH has experienced difficulties communicating with the 340B and Prime Vendor programs when it requires assistance. For instance, at one point FDH supplied one of its delegates with drugs purchased at 340B discounts. They have been subsequently informed by 340B staff (apparently incorrectly) that this is not allowed, even though that delegate is also eligible for and enrolled in 340B. FDH has also experienced various administrative issues, such as confusion over the paperwork needed to register delegates in 340B and Prime Vendor.

- Barriers to Maximizing Use of Drug Purchasing Programs

FDH has experienced a wide range of the problems discussed in this chapter, including back-orders for drugs that are on sale, short expiration dates, and quarterly price shifts. Due to their cost, FDH is unable to offer the patch or the ring, two forms of birth control that clients have repeatedly requested.

FDH has also experienced difficulties forecasting its budget due to the unpredictability of drug prices. In order to forecast conservatively, FDH assumes that prices for the next year will match the highest prices for various drugs that occurred over the previous year; this tactic, however, cannot account for major new increases in the price of a drug. They also keep track of each order from their various clinics and investigate any orders that appear to be out of the norm.

- Drug Purchasing and Medicaid Reimbursement

Franklin is a state without a Medicaid waiver program, with low income-eligibility levels for regular Medicaid, and with a large population of immigrants who are ineligible for Medicaid at any income. Therefore, FDH receives very little reimbursement from Medicaid, a problem compounded by the fact that 70% of their clients are below the poverty level, yet many do not qualify for Medicaid. These clients must therefore receive completely subsidized care.

- Consequences of Rising Costs

Due to the low reimbursement it receives from Medicaid, the state has been examining ways it can continue to serve clients and survive as an organization. Hiring a new purchasing agent was one such tactic, and FDH believes that he will be able to obtain discounts by working with multiple distributors and taking full advantage of sales. In addition, FDH is only distributing a three-month supply of contraceptives at a time, rather than providing a year-long supply as they did in the past; this is particularly helpful in Franklin, a state that has a large transient population. Finally, the state of Franklin is pursuing a Medicaid waiver, something FDH believes is necessary for them to survive in the long term.

Case Study Three: Small Delegate Agency

- Chapter I: Introduction

The Center for Health Excellence (CHE) is an FQHC and Title X delegate serving about 10,000 patients, including a large percentage of immigrants. It is located in an urban area but serves patients who live in both urban and rural locations. CHE is located in a state with a long-standing Medicaid waiver program. The grantee under which CHE is located, a state-wide family planning council, does not perform any purchasing, but rather assists CHE by providing information and logistical support.

- Use of 340B, Prime Vendor, and Other Purchasing Programs

CHE is a member of 340B and Prime Vendor, as well as the FPCPP, which CHE uses mainly to purchase condoms. CHE is also a member of Council Connections, a group that maintains contracts with a wide variety of vendors; CHE uses this arrangement primarily for lab work and to purchase medical and office supplies. CHE does not participate in MMCAP or any other state purchasing arrangements.

In addition, as an FQHC providing both family planning services and broader primary care, CHE performs its own purchasing via both a contract pharmacy and various distributors. The contract pharmacy allows clients who must pay the full cost of their visit to purchase drugs by mail, at a better price and for more months at a time than at a local drug store; this option is primarily for non-contraceptive supplies, as CHE does dispense contraceptives on site.

- Awareness of 340B, Prime Vendor, and Other Purchasing Programs

CHE learned much of what it knows about drug purchasing arrangements from its grantee, and had high praise for that organization. It also cited Council Connections as a valuable information source. That organization has an annual members' meeting that provides an overview of all of their contracts and of drug purchasing in general. When CHE joined 340B, the Council explained how 340B could be used optimally by clinics.

Regarding drug prices, CHE relies primarily on emails from their wholesaler that includes information about prices under 340B, Prime Vendor and FPCPP; it also receives price information directly from manufacturers, such as Ortho-McNeil. However, it does not receive any regular information from Prime Vendor except for updates on when the system will be down for maintenance. CHE asserted that although Prime Vendor was helpful and communicative when they first signed up, that is no longer the case: "We can't seem to get a call back. And every time I call, I never get a live person."

- Barriers to Maximizing Use of Drug Purchasing Programs

Like many other informants, CHE feels burdened by the responsibility to monitor quarterly price shifts and ensure that they are obtaining the lowest prices each quarter. Moreover, CHE observes that certain prices are subject to change monthly, forcing CHE to monitor prices on a near constant basis. Finding the lowest price is also made difficult since there is no publicized price list for comparing prices between different distributors under Prime Vendor. In other

words, CHE only knows the prices offered by their current vendor, and can only find out the prices of a rival vendor after it has switched vendors.

CHE has also found it difficult at times to participate in the Prime Vendor program because many wholesalers with which they wished to conduct business do not see it as worthwhile to contract with small-volume clinics. They eventually found a wholesaler that was willing to accept them as a client; however, that vendor does not offer them the non-contraceptive injectable drugs they need for their primary care clients.

- Drug Purchasing and Medicaid Reimbursement

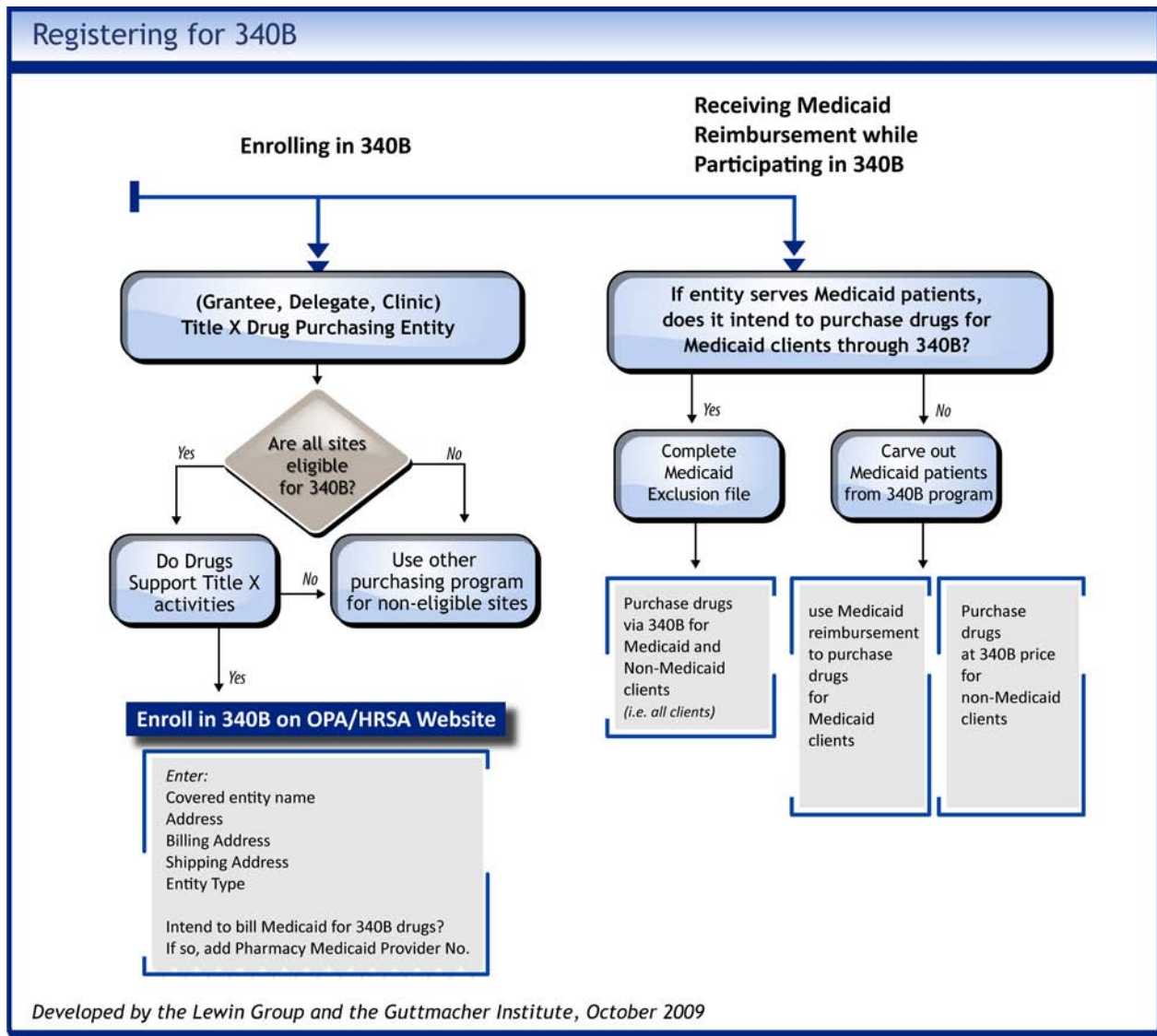
According to CHE, the state's Medicaid family planning waiver and its primary state-wide Medicaid program cover almost all of their contraceptive clients. (Medicaid covers far fewer primary care clients.) Under the waiver program, CHE is reimbursed on a fee-for-service basis at rates set by the state Medicaid agency, and those rates have been adequate to cover the provider's purchasing costs. CHE reports that it is not required to match up specific drugs and specific waiver clients, with a few exceptions, such as condoms, for which the state requires them to bill on a cost-plus-dispensing-fee basis. For clients on regular Medicaid, CHE receives a global fee, and these clients are usually scripted out for non-contraceptive drugs.

- Consequences of Rising Costs

To save money on drugs, CHE is exploring generic products; at the time of the discussion, brand-name contraceptives from Ortho-McNeil were less expensive than any of the prices for generic drugs available through Prime Vendor, FPCPP or other arrangements. However, as with many informants CHE is worried about pending Ortho-McNeil price increases and the potential impact of the state's fiscal crisis. CHE does script out non-contraceptive supplies and some contraceptives when requested by their clients, both to their contract, mail-order pharmacy and to local chain drug stores to take advantage of special \$4 and \$9 prescriptions.

In addition, CHE has been aggressive in seeking out savings for medical and office supplies, lab work and similar expenses through Council Connections and FPCPP. They have also been contacting suppliers directly and have found that they receive better deals than some other local clinics. CHE also makes extensive efforts to enroll clients in manufacturers' patient assistance programs, something that is especially helpful for primary care clients with chronic conditions.

Appendix C: 340B Registration Flowchart



Appendix D: 340B Tip Sheet

Tips on Getting Started:

Learn. Register. Obtain.

Learn

Register

How to Begin Making the Most of 340B and Prime Vendor

1. Learn about the drug discount programs. These programs provide eligible entities, including Title-X grantees and delegates, access to reduced cost pharmaceuticals.
 - a. Action Steps:
 - i. Start learning by:
 - ▶ Visiting websites for information and applications:
 - a. 340B: <http://www.hrsa.gov/opa/introduction.htm>
 - b. Prime Vendor: <https://www.340bpvp.com/public/>
 - ▶ Calling the Pharmaceutical Services Support Center: 1-888-340-2787.
 - ▶ Speaking with your regional office contact.
 - ▶ Attending presentations by 340B and Prime Vendor staff at grantee conferences.
 - ▶ Reading existing resources: Go to www.nfprha.org to see the 340B Fact Sheets under the Policy Action Center.
 - ▶ Completing the 340B/Prime Vendor online interactive tutorial: <https://www.340bpvp.com/public/gps/gps.html>
 - ii. Don't forget:
 - i. Ask questions. Tap the resources above as much as you need to. They're free, and they are there for you.
2. Register
 - a. Action Steps: The 340B and Prime Vendor programs are two distinct programs. Once you are registered for 340B, you must complete a separate form in order to register for Prime Vendor.
 - i. Begin by finding out if your "entity" (grantee, delegate, clinic) is registered with 340B. Note: some grantees register all of their service sites; others require individual sites to register on their own.
 - ii. If not, register for 340B. Begin with 340B and move on from there.
 - ▶ Go to <ftp://ftp.hrsa.gov/bphc/pdf/opa/FPPrmReg.pdf> to find the application form.
 - iii. Note whether you will be billing 340B for Medicaid clients. If so, indicate this on the Medicaid Exclusion File.
 - iv. Once you are registered for 340B, you can register for Prime Vendor! It's also free and available to Title X-funded entities enrolled in 340B. It offers sub-340B prices.

Tips on Getting Started:

Learn. Register. Obtain.

How to Begin Making the Most of 340B and Prime Vendor

- ▶ Go to <https://www.340bpvp.com/public/registration/default.aspx> to find the application form.

b. Don't forget:

- i. Pay special attention to timelines for registration. The membership list for 340B is updated quarterly so it may take a while before enrollment is official.
- ii. Know what you can get, and from where. 340B and Prime Vendor offer access to different pharmaceuticals. 340B membership, for example, does not provide access to reduced-cost devices.
- iii. 340B-purchased drugs and Prime Vendor-purchased devices can only be used for eligible patients. Check with your Regional Office to learn about the "definition of a patient," or go to <http://www.hrsa.gov/opa/patientdefinition.htm>.

Obtain

3. Obtain needed pharmaceuticals. 340B is a mechanism for guaranteeing prices. Once registered, entities must then work with distributors or manufacturers to purchase the pharmaceuticals and other supplies.

a. Action Steps:

- i. 340B is a program for obtaining discounts, not purchasing drugs. You will need to elect whether you will work with distributors or manufacturers. This may vary for different drugs and supplies and for different drug purchasing programs. Here's a starting tip:
 - ▶ Distributors are typically slightly more expensive, yet they provide one-stop shopping and easier comparison's among different manufacturers' products.
 - ▶ Purchasing directly from the manufacturer requires more administrative work and costs, but can save money for entities with limited formularies.
- ii. Talk to a pharmacist. A pharmacist can help you identify bioequivalent products that can broaden your inventory. This may also enable you to take advantage of special sales or navigate quarterly price shifts that may make some drugs unaffordable at different times.
- iii. Understand Medicaid reimbursement in your state. Participating in 340B and Prime Vendor while also receiving Medicaid reimbursement requires an extra level of paperwork to prevent "double discounts." Keep your information in the Medicaid Exclusion File up-to-date if you are using these purchasing programs for your Medicaid clients.

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Tips on Getting Started:

Learn. Register. Obtain.

Obtain

How to Begin Making the Most of 340B and Prime Vendor

- b. Don't forget:
 - i. 340B prices can shift quarterly. Make preparations in your inventory and your budget accordingly.
 - ii. Centralized purchasing for all eligible clinics is allowed, but remember, all entities and patients that receive drugs at 340B and Prime Vendor discounts must be eligible, and the drugs must be within the scope of the federal grant that makes them eligible. If you don't understand what's allowed, ask! ([See step 1](#))
 - iii. If you have questions, ask!