

## How the Federal Government's Drug Discount Programs Could Work Better for Family Planning Centers

By Adam Sonfield

Publicly funded family planning centers have long struggled with the seemingly ever-rising cost of contraceptive supplies and other pharmaceuticals. It is true that they have also long benefited from discounts on these drugs from manufacturers eager to foster brand loyalty among young women. Yet, manufacturers appear to be retreating from these voluntary discounts, as health insurance companies push their generic competitors and direct-to-consumer advertising has emerged as a more attractive sales strategy (related article, Fall 2006, page 2).

Providers are increasingly dependent on the power of the federal government to ensure that they can acquire pharmaceuticals at prices that will not shatter their budgets. A 2009 study conducted jointly by The Lewin Group and the Guttmacher Institute found that although family planning centers do make use of the options provided by the government, they also face a wide range of problems in maximizing these discounts. That finding poses an obvious next question: What more might the federal government be able to do to help providers overcome these problems?

### The Universe of Drug Discounts

The Lewin-Guttmacher study was commissioned by the Office of Population Affairs (OPA) in the Department of Health and Human Services (DHHS) to focus on Title X-supported providers' use of two major federal drug discount programs: the 340B Drug Pricing Program and its sibling, the Prime Vendor Program. The 340B program, established by Congress in 1992, is named for a section of the Public Health Service Act and run by the federal Office of Pharmacy Affairs within the Health Resources and Services Administration

(HRSA), also a branch of DHHS. The law requires manufacturers to sell their drugs to a range of safety-net providers, including Title X-supported family planning centers and community health centers, below a certain price (called a price ceiling) calculated for each drug each fiscal quarter using a statutory formula based on private-sector prices. The companies are permitted to set their safety-net prices below that ceiling, if they so choose. Congress designed 340B to generate discounts that are equivalent to the rebates on drugs provided to state Medicaid programs, also set under federal law.

At the same time, Congress authorized a Prime Vendor Program that is tasked with leveraging the collective purchasing power of enrolled safety-net providers to negotiate discounts below the 340B price ceilings. Prime Vendor, operated for the past several years by the private company Apexus, also negotiates discounts on products not covered by 340B, including medical devices and pharmacy-related services.

According to the Lewin-Guttmacher study, which was based primarily on interviews with representatives of 40 Title X-supported entities across the country, both programs are commonly relied upon by family planning providers. Program statistics indicate that there is near-universal enrollment in 340B among Title X providers. Provider representatives asserted that although 340B participation had long been widespread, it essentially became mandatory after a 2006 change in federal law effectively prevented safety-net clinics from receiving steep discounts on drugs if they were not enrolled in 340B. (The law was changed again in 2009—after the study was con-

ducted—to let non-340B family planning centers access these “nominal” prices.) Enrollment in Prime Vendor was also common, with about two-thirds of the providers in the study participating in the program. Overall, Title X–supported providers account for roughly 30% of 340B participants and 45% of Prime Vendor participants, although they account for a considerably smaller share of the volume of drugs purchased through the programs.

The 340B and Prime Vendor programs are not the only options that safety-net providers have for securing drug discounts. Most family planning providers appear to use a range of purchasing arrangements, cobbling them together to find the best prices for the full list of drugs and devices they offer to their clients. Some larger nonprofit or government agencies—most notably, Planned Parenthood Federation of America (PPFA)—have managed to negotiate directly with manufacturers for contracts that offer lower or more stable prices than under 340B and Prime Vendor. Manufacturers agree to such discounts because of the promise of large volumes of drug purchases over many years.

Providers may also participate in private programs, such as the Family Planning Cooperative Purchasing Program, a Title X–specific program established in the early 1990s by the California Family Health Council that today encompasses about 3,000 sites across the United States. Community health centers (which are required by law under the federal Sec. 330 program to provide family planning services and also sometimes receive Title X funding) have additional purchasing programs to choose from that negotiate contracts to meet their broader, primary-care focus. Although many providers in the study were enrolled in these types of programs, few reported relying heavily on them for purchasing drugs; they did, however, find them critical for other needs, such as condoms, medical and office supplies, and lab work.

### **A Host of Problems**

Providers in the Lewin-Guttmacher study described a host of problems with the various drug purchasing programs. Some problems were

annoyances—such as excessive red-tape in the programs’ enrollment procedures—that, once identified, should be easily fixable by HRSA and Apexus. Others were beyond the scope of the purchasing programs themselves, such as quandaries about how much to centralize purchasing, shipping, inventory and storage across a family planning provider network. Yet, three clusters of problems stood out as being real dangers for many safety-net family planning providers that are realistically within the reach of the federal government to address: information about purchasing options and prices, inadequate and unusable discounts, and the intersection between drug purchasing and other aspects of administering a family planning center.

#### **Inadequate Information**

Family planning centers need a substantial amount of information to make optimal use of their available drug purchasing options. Providers need to know about the options’ particular advantages and drawbacks, their rules and restrictions, and how they may complement or conflict with each other and with government funding programs such as Title X and Medicaid. Providers also need to know about and compare the specific prices available through each option, and to learn about these prices in a timely and efficient manner. Although the staff members interviewed in the Lewin-Guttmacher study differed greatly in their knowledge, sophistication and assessment of the information available to them, one thing was clear: The information available is simply not good enough.

Part of the problem is that family planning centers do not have a single, central source of information. Instead, they piece together what they think they need to know from the various purchasing programs, drug manufacturers and distributors, outside organizations (such as the National Family Planning and Reproductive Health Association), Title X program staff, fellow Title X recipients, and even private-sector pharmacies and price guides. This disjointed method of gathering information brings with it a second hurdle: Much of the information they manage to dig up is not tailored to their specific needs and level of understanding.

The problem is further compounded by the cloak of secrecy that surrounds pharmaceutical pricing in general. Drug manufacturers consider the prices they offer to different customers to be proprietary information and have long fought efforts to make such information public. Prices may differ substantially by customer and over time, as customers gain or lose purchasing clout and negotiate more or less favorable contracts. The end result is that safety-net providers cannot easily compare prices across purchasing arrangements or competing pharmaceutical products, or swap notes with other providers to see who is most successful and why. The 340B price ceilings add an additional layer of complexity: Although the price ceiling formula itself is publicly available, the data that feed into that formula are unique to each manufacturer and never released publicly. Therefore, changes in the price ceiling cannot be predicted by providers and typically are made by manufacturers without any prior notice. All told, family planning centers must devote substantial staff time and resources to tracking down the best prices for the best mix of drugs and devices, but can never be certain that they have fully succeeded.

### Deficient Discounts

The essential point, of course, of gathering all of this information on purchasing options and prices is to identify and secure the greatest possible discounts—and thus stretch scarce public dollars as far as possible. Study participants, however, made it clear that they did not view the available discounts as being nearly as deep as needed to meet the rising challenges. Few providers appeared able to make do relying solely on the 340B price ceilings. Although those ceiling prices are, on average, about half a drug's official "list" price, they are in truth discounted, in most cases, only marginally from the actual average prices manufacturers offer in the private sector—by 11% for generic drugs. It is only when manufacturers have raised their private-sector prices rapidly that safety-net providers receive any extraordinary discounts, according to the statutory formula.

Prime Vendor exists to rectify that problem, and many of those interviewed for the study praised

the program for securing additional discounts on the contraceptive ring and implant, as well as a series of generic oral contraceptives. Drug manufacturers have no obligation to negotiate with Prime Vendor, however, and the program has not secured contracts for many of the newest and most popular brand-name contraceptives. Similarly, providers turn to groups like PFFA and the Family Planning Cooperative Purchasing Program to negotiate discounts below the 340B ceiling, with varying and seemingly diminishing degrees of success.

The other major reason that providers turn to programs like Prime Vendor is for their ability to negotiate long-term contracts. By federal law, the 340B discounts are adjusted each quarter, and manufacturers are not obligated to announce the new discounts in advance. This instability and unpredictability creates numerous problems for safety-net providers and their clients. Sudden price increases, for example, may force providers to change the list of drugs they dispense to their clients. The clients, in turn, may have to adjust to a new contraceptive drug and dosage—and potentially new side-effects—although a staff pharmacist can sometimes mitigate the problem by identifying appropriate alternatives for the family planning center to purchase. Thus, even when a contract via Prime Vendor or through PFFA has secured only a marginal discount below the 340B ceiling, providers may greatly value that the discount will be secure for one or more years, rather than only three months.

### Awkward Administration

The problems with and rules accompanying 340B and Prime Vendor may have a pronounced impact on almost every aspect of administering a family planning center. Rising and unstable prices, for example, can wreak havoc on a health center's budget, particularly if it is primarily supported by stagnant and already-inadequate government funding. Even seemingly small price increases—for example, from \$2 per pill pack to \$2.50—can add up to massive budget gaps, because so many of a family planning center's clients receive contraceptives or drugs to treat STIs. If a health center or network is wrong in its

predictions of potential price shifts, it may have to scramble midyear to find new sources of revenue (for example, by imploring a state legislature for additional funding) or else cut back in expenses (for example, by limiting clinic hours).

The drug purchasing programs, moreover, have never been designed with the peculiarities of the Title X program in mind, or vice versa. Study participants raised legitimate questions, for example, about how and how often shifting drug prices should be factored into the calculations to set their sliding-fee scale. Under that scale, clients are assessed a fee equal to a percentage of the family planning center's actual per-client costs—including the costs of drugs. Frequent recalculation of the sliding-fee scale could involve significant administrative expenses and has the potential to confuse and antagonize clients.

Similarly, 340B and Prime Vendor intersect problematically with Medicaid, a program that is increasingly central to most family planning centers' funding. On the one hand, family planning centers benefit fiscally from having high proportions of Medicaid clients, because they are operating in a state with generous eligibility standards for its overall Medicaid program or one with a Medicaid expansion specifically for family planning. Those centers benefit both because of Medicaid's legal status as an entitlement program in which services must be reimbursed for all enrolled clients, and because health centers may have the option of being reimbursed by Medicaid for their actual costs for dispensing drugs, letting them pass along the task of securing drug discounts to their state government. On the other hand, health care providers are responsible under federal law for assuring that drug manufacturers do not provide duplicate discounts—once to the provider and again to the state Medicaid agency in the form of a rebate. That poses numerous complications in maintaining and tracking their drug inventory and figuring out how to bill Medicaid. They are also forced to deal with the bureaucracy and payment delays common to state Medicaid programs and Medicaid managed care plans.

## Possible Solutions

The Lewin-Guttmacher study was not designed to look for potential solutions to the myriad problems it identified and did not include many in the final report. Nevertheless, provider representatives volunteered numerous suggestions in the course of their interviews, most of them directed at the federal government and, specifically, at how OPA could lead the way.

OPA could act on some of these suggestions on its own authority. For example, it could serve as the centralized information source that is so clearly needed by family planning centers. (Indeed, this was the most common suggestion offered.) The agency today does promote awareness of 340B and Prime Vendor, highlighting the programs, for example, at its grantee meetings. Yet, Title X-supported providers could benefit from an intensive, coordinated and ongoing information campaign about all of the available discount options; the rules that govern each option and how they can be used together; how those rules intersect with those of Title X, Medicaid and other key funding sources; the prices of specific drugs and devices, particularly when they are slated to change; and best practices identified by other family planning centers to maximize drug discounts and streamline their purchasing systems. What makes OPA uniquely situated to serve as this information hub is its unrivaled knowledge of what Title X-supported providers need and understand. Better than any other agency, OPA could pull together information that is accurate, in advance of when providers will need it, in plain language, and focused on matters that are of greatest concern specifically to family planning providers. (Undoubtedly, other groups of safety-net providers such as community health centers would need the agencies that govern their grant programs to provide a similar service.)

OPA also could take a leadership role in ensuring that Title X interacts smoothly with 340B, Medicaid and other government programs. Information is certainly a part of that, but there are some situations where more information will merely help providers understand that federal rules and regulations are not always designed to

work in concert. As but one example, the intersection of 340B's quarterly pricing shifts, Title X's sliding-fee scale and Medicaid's rules for reimbursing providers for the cost of the drugs they dispense is immensely tangled; study participants were uncertain that they were appropriately meeting the rules of all three programs in their budgeting, inventory and billing practices. OPA could take the lead to identify what is efficient and appropriate, and to work with HRSA and the Centers for Medicare and Medicaid Services to tinker with the relevant regulations if they interfere with those best practices.

Several providers suggested that OPA go several steps further to more directly secure deeper discounts for Title X-supported providers, and such steps are worth considering. For example, the agency could gather, organize and analyze purchasing data from its grantees and use its findings to demonstrate the collective purchasing clout of the Title X network to drug manufacturers that prefer to view them as individual clinics. Further, it could provide technical assistance to its providers in banding together to leverage this clout. Together, these steps could help independent and government-run family planning centers approach the bargaining effectiveness of PPSA.

Other, more certain methods of increasing the drug discounts available to safety-net providers might require congressional intervention. For example, the Title X statute governing OPA does not explicitly give the agency the authority to conduct direct negotiations with drug manufacturers to secure discounts below the 340B ceiling or more stable prices. Indeed, such negotiations, if allowed, would also require OPA to develop considerable new expertise among its staff.

Because the problems with 340B and Prime Vendor are not limited to family planning providers, however, it may make more sense for Congress to modify those programs directly. And, in fact, lawmakers had already begun that process, by including three significant provisions to update the 340B program in the massive health care reform legislation that has dominated their time over the past year. Both the House and

Senate reform bills under consideration would provide a roughly 50% increase in the discounts that manufacturers must offer under 340B (and to state Medicaid programs) for both brand-name and generic drugs. (Unfortunately, manufacturers may be able to manipulate the statutory formula by increasing their private-sector prices, and there were press reports throughout the fall that they were doing just that in anticipation that health care reform would be enacted.) In addition, the bills would expand the list of safety-net providers that are eligible for 340B; of particular note for the family planning world is the addition in the House bill of providers receiving funding through the Maternal and Child Health Block Grant, which includes some family planning providers (particularly in Texas) that do not receive Title X money. Finally, they would increase manufacturers' accountability in accurately calculating price ceilings and in offering the required discounts to providers.

Although these steps—whether enacted through health care reform or some other vehicle—would represent major progress, Congress could do still more. It could expand the list of supplies that are included within the 340B program—notably for family planning centers, by including medical devices such as the IUD. It could change the statutory requirement that 340B price ceilings are recalculated every quarter, to increase the stability of prices and enable manufacturers to provide more advance notice to their customers. It could even require manufacturers to participate in the Prime Vendor Program, to give the program more leverage in securing contracts for the drugs and devices that providers and their clients are demanding. For any of this to happen, family planning providers and the organizations that advocate on their behalf will need to make their needs public and work to make policymakers aware of their importance and scope.

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