Federal Drug Discount and Compliance Monitor

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The Inside Source on the Public Health Service 340B Drug Discount Program

Volume 2, no. 1 **January 2005**

IN THIS ISSUE

OPA Prepares for Busy Year

Agency to Expand Staff, Step Up Enforcement Efforts as Program Grows

Following a "tipping point year" for the 340B program, Office of Pharmacy Affairs (OPA) Director Jim Mitchell says that his agency has strong support from the US Department of Health and Human Services (HHS) and plans to spend 2005 working to improve the integrity of the program.

Mitchell says that the developments of 2004, including the agency's transfer to the Health Systems Bureau (HSB) at Health Resources and Services Administration (HRSA) headquarters in Rockville, MD, reflect a renewed commitment from his superiors and will improve OPA's ability to monitor the program.

Members of the OPA Staff with HHS Deputy Secretary Claude Allen

"This was a very successful year," says Mitchell, whose agency received the Secretary's Award for Distinguished Service from the US Department of Health and Human Services (HHS)—HHS's highest honor—in July (*The Monitor*, August 2004). "We anticipate continuing success and increased resources to allow us to improve the internal and external integrity of this program."

Mitchell recently discussed his agency's plans for the upcoming year with *The Monitor*, focusing on OPA's goals for 2005.

New Staff. After several years of facing hiring freezes and reductions in the job force, OPA is on a hiring spree. The agency has already taken on three new staff members in the early part of 2005, all of whom should be officially on board within a month, says Mitchell.

The first new hire is Louis Flowers, a Lt. Commander in the United States Public Health Service (PHS) whose primary responsibility will be to set up OPA's systems for data analysis. Specifically, he will help develop and maintain systems that will allow OPA to assess selling prices and compare them to 340B ceiling prices and more effectively analyze prime vendor data provided by wholesalers and the new 340B prime vendor.

Mitchell says that Flowers will also gain exposure to the various covered entity groups by dealing directly with 340B providers. He

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Report Encourages Medicaid to Reimburse Clinical Pharmacy Services

The expansion of clinical pharmacy services for low-income patients could significantly improve outcomes for vulnerable populations and should be taken into account in Medicaid's reimbursement scheme, according to a report prepared for the Office of Pharmacy Affairs (OPA).

The report, conducted by Mathematica Policy Research, Inc., argues that clinical pharmacy services should be recognized as "a legitimate approach to care," and that the Health Resources and Services Administration (HRSA) should also "consider the value of these services in its funding decisions."

Such an approach could bring Medicaid into line with the new Medicare prescription drug benefit, which requires that all health plans that administer the new Medicare prescription drug benefit include "medication therapy management services" for its patients with multiple chronic conditions.

OPA has embraced the report's recommendations and committed itself to continuing to promote and expand Clinical Pharmacy Demonstration Project (CDPD) opportunities.

"I personally take the report's recommendations very seriously, and we plan to act on them," said OPA Director Jim Mitchell, adding that the success of medication therapy management services provided through the new Medicare drug benefit will likely determine whether a similar benefit will be considered under the Medicaid program.

The Mathematica report was designed as an evaluation of the 18 CDPDs administered by OPA beginning in 2000. Mathematica began its evaluation in September 2002.

The purpose of the CDPDs, according to the report, was to "demonstrate how access to needed pharmaceuticals, when delivered as part of comprehensive pharmacy services, makes a substantial and affordable contribution" to patients' health.

The report states that all but two of the networks that received CDPD grants implemented clinical pharmacy services or disease management programs—including physician and patient education, medication management, and reviewing charts—as part of their grant programs. In order to do so, each network partnered with a local school of pharmacy and all but one network hired at least one clinical pharmacist.

Much of the grant funding allotted to the participating networks was used to implement disease management programs for patients with diabetes. Sixteen of the 18 networks developed such programs, which often included patient consultations and outreach efforts.

The report found that patients who remained in pharmacist-run disease management programs for at least six months saw significant improvements in their health outcomes. Nearly all participating entities saw an improvement in their patients' blood pressure and other relevant measures, regardless of the differences in the programs' details.

At Siouxland Community Health Center, located in Sioux City, IA, pharmacists implemented bi-weekly consultations with their patients in order to ensure compliance with their programs and also developed innovative strategies to encourage patients to keep their appointments.

"Taken together, the evidence suggests that diabetes disease management run by a pharmacist is potentially an effective tool for improving health outcomes for health center populations with diabetes," the report states.

In the least successful cases, clinical pharmacists suffered from both an inability to reach potential patients and a lack of support from the physician staff. Many physicians were unfamiliar with clinical pharmacy services at the inception of their respective projects, the report found, though many offered their support once the program began to show positive results.

The report argues that despite the success of these demonstrations, it will most likely be difficult to sustain these

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The Monitor

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The *Federal Drug Discount and Compliance Monitor* is a national monthly newsletter that covers the legal and political issues surrounding the Public Health Service 340B drug discount program and other developments in federal drug pricing law and policy. *The Monitor* also updates subscribers on breaking news stories through e-mail alerts.

The Monitor is published by the Public Hospital Pharmacy Coalition, a non-profit organization that represents approximately 250 340B hospitals, and the law firm of Powers, Pyles, Sutter and Verville.

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Withdrawal of OIG Report Reshapes Federal Class Action Suit

A class action lawsuit filed against 22 pharmaceutical manufacturers for alleged 340B overcharges remains in play despite the decision by the government to temporarily withdraw a June 2004 report that estimated significant overpayments made by 340B entities.

The court's most recent filings by both the plaintiffs and the defendants specifically address the October 22 "Notice to the Court" announcing OIG's withdrawal of the report due to "information that puts into question the pricing data on which the June 2004 report was based."

The suit, which calls for a "full accounting" of 340B prices and the recovery of all overcharges, was first filed in the US District Court in the Middle District of Alabama in July 2004.

Prior to the report's withdrawal, the plaintiffs in the case, Central Alabama Comprehensive Health Care, Inc. (CACHC) and Health Services, Inc. (HSI), relied heavily on the report's findings as concrete evidence of their claims of improper 340B pricing.

Nevertheless, in light of the withdrawal, the plaintiffs have responded to the defendants' memorandum supporting their motion to dismiss the case (*The Monitor*, October 2004) by arguing that the withdrawal of the June report actually reinforces the need for an official accounting of the overcharges made to covered entities.

According to the plaintiffs, the fact that an experienced OIG team was unable to accurately calculate 340B prices speaks to the need for a verifiable court-ordered accounting.

"This rare regulatory 'Mulligan'—withdrawal of some aspects of a previously approved report by careful OIG investigators—underscores the allegation…that serious misreporting of indeterminate scale has been rampant in the 340B Program," the brief argues.

The brief also suggests that the withdrawal is suspect because "[t]he OIG notice was issued four months after OIG publicly released the *340B Drug Price Report* and six months after [the Office of Pharmacy Affairs (OPA)], whose performance was sharply criticized by the report, signed off on it."

OIG explained its withdrawal of the report in a memorandum to Health Resources and Services Administration (HRSA) Administrator Elizabeth Duke and Centers for Medicare and Medicaid Services (CMS) Administrator Mark McClellan in November, stating that CMS had provided OIG with data from an incorrect time period and that OIG had failed to accurately take into account the package sizes of certain drugs (*The Monitor*, November 2004).

The HHS OIG withdrew the June 2004 report in October and is currently reviewing the data on which the report was based.

The plaintiffs contend that a court-ordered accounting is still likely to uncover overcharges even though the June 2004 report is no longer publicly available, noting that the OIG memorandum asserts that, despite errors in the data underlying the June report, there remain "systemic issues that lead to price discrepancies within the 340B Drug Pricing Program."

In response to the plaintiffs' filing, the defendants' attorneys—representing 22 pharmaceutical manufacturers—filed a brief arguing that, without the report's findings, the plaintiffs lack "even an allegation of injury" that can be attributed to the defendants.

Carolyn McElroy, an attorney with the law firm of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo who is connected to the case, calls the withdrawal "one more nail in the coffin for this lawsuit," arguing that OIG's actions expose the flaws in the report's original methodology.

"The entities that have first-hand information on the pricing to 340B entities and the best reason to ensure the accuracy of the information—the manufacturers—were not contacted for price information by the OIG in the first attempt," says McElroy.

According to the defendants' brief, "Only in plaintiffs' Alice-In-Wonderland world does the withdrawal of the OIG Report make the supposition that they were injured and that the defendants violated the law *more* likely, rather than, as the record now stands, without any factual foundation."

The brief also echoes the defendants' previous argument that the court should allow OIG to conduct its own comprehensive review of the 340B program before requiring manufacturers to do so, especially in light of the report's withdrawal.

"It would be senseless, wasteful, and contrary to the statutory scheme for this Court to require defendants to finance an 'accounting' of drug pricing under the 340B Program while the OIG is working in parallel to address the same issues," the brief states, adding that audits and accountings performed by government agencies "are not only likely to materially aid the Court if further consideration of plaintiffs' allegations is ever required, but may conclusively resolve the issue in its entirety."

Parties Disagree over Right to Sue

Another major point of contention between the two sides is whether covered entities have a right to sue manufacturers for violations of the 340B law.

When filing their original motion to dismiss the case, the defendants argued that the law does not allow individual covered entities to sue manufacturers for violations of the 340B statute because the Pharmaceutical Pricing Agreements (PPA) that outline manufacturers' obligations under the program are between manufacturers and the government rather than between manufacturers and providers.

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City Seeks Covered Entity Status for State/Local Health Departments

The Detroit Department of Health and Wellness Promotion (DHWP) has launched an effort to organize health departments around the country and lobby legislators to amend the 340B law to include state and local health departments as covered entities.

According to DHWP Pharmacy Administrator Ron Coleman, health departments are excellent candidates for the 340B program because of their similarity to many other covered entities and their emphasis on care for the uninsured and underinsured.

"Why not include local health departments?" says Coleman. "Access to cheaper drugs would allow us to continue providing primary care to our uninsured patients."

The 340B law explicitly defines which types of health care providers are eligible to receive covered outpatient drugs through the 340B program, including certain disproportionate share hospitals (DSH), Indian Health Service (IHS) grantees, family planning clinics, STD and tuberculosis clinics, and Health Resources and Services Administration (HRSA) grantees such as community health centers (CHC), hemophilia treatment centers (HTC), Ryan White AIDS clinics, and federally qualified health center (FQHC) "look-alikes."

Health departments, on the other hand, may be eligible to participate if they receive grants for STD, family planning, tuberculosis, or AIDS care. In these cases, the 340B drugs can only be used if they are provided within the scope of the grant program.

Coleman says that health departments were most likely "overlooked" when the 340B law was originally drafted because legislators may not have been aware that local health departments provide primary care to patients.

"I'm not blaming anyone," says Coleman. "We just didn't know enough [at the time] to tell someone that we needed to be included."

DHWP has developed a fact sheet outlining their position, and the Department's Public Health Director has begun distributing materials to legislators both in Michigan and elsewhere. DHWP has also contacted organizations such as the American Pharmacists Association (APhA) and the American Public Health Association (APHA), as well as a number of 340B experts.

According to the fact sheet, "an amendment to the original legislation could allow a local/state Public Health Department to qualify for 340B if it provided primary care to uninsured and if it had an in house pharmacy or contracted with an outside pharmacy as is provided for in the legislation."

DHWP Pharmacy Administrator Ron Coleman

Coleman believes that there is a precedent for expansion of the law in the passage of the Medicare Modernization Act (MMA) in 2003, which included a provision allowing rural and small urban hospitals that were previously ineligible to participate in the program (*The Monitor*, July 2004).

Other groups have also called for an expansion of the 340B program to include additional classes of covered entities. For instance, the Senate Republican Task Force on the Uninsured and the National Rural Health Association (NHRA) have proposed that the program be amended to include cost-based reimbursed health care providers such as critical access hospitals. (*The Monitor*, July 2004).

Coleman says that, like small hospitals, health departments share many characteristics with providers that are currently considered covered entities.

Health departments are funded entirely by public dollars provided by the state, city, and county. In the case of DHWP, the pharmacies are funded by the county, while other sectors of the health department rely on state grants and other sources of funding. The health department also receives some free STD and family planning drugs from state programs, said Coleman.

DHWP administers four health clinics in the city of Detroit, three of which have on-site pharmacies that serve uninsured and underinsured patients exclusively. Coleman says that DPHW treats approximately 50,000 of the 250,000 uninsured individuals in the city.

Last year, DHWP's pharmacies filled 194,000 free prescriptions, according to Coleman. As a result, the city's clinics are often forced to send away Medicaid patients in order to ensure that the pharmacies have the capacity to treat the city's uninsured population.

"DSH hospitals and other covered entities are encouraged to treat insured patients. We're only able to treat the uninsured," says Coleman, adding that most health departments are probably facing the same challenges.

Nonetheless, one of the biggest obstacles for DHWP has been mobilizing and communicating with local health departments.

To do so, DPHW has hired a new employee whose primary responsibility will be to contact other local health departments and educate their directors about the 340B program.

Coleman is hopeful that an educational campaign will inspire other health departments to pursue what he considers to be a "million dollar idea." However, he recognizes that Congress will have to get involved for his initiative to gain momentum.

"It's going to take legislators to get this done," says Coleman. "But we need to provide as much information as possible."

OPA to Focus on Outreach and Compliance

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will begin by working with the community health centers (CHC), and will eventually be given the opportunity to "learn the idiosyncrasies of each of the customer groups," says Mitchell.

Flowers holds a Doctorate in Pharmacy and is currently completing a Masters program in Pharmacoeconomics at the University of Maryland.

OPA also plans to add a second Lt. Commander to its staff to assist with systems development. This new staffer, whose name has not yet been released by OPA, is currently pursuing a Masters degree in Infomatics and will help OPA to improve its database and develop its compliance program.

Mitchell says that OPA is in the process of finalizing this hiring, and should receive confirmation from the government soon.

On January 10, OPA also added an office manager to its staff, who will provide OPA with administrative support for the first time in four years. Judy McLucas previously served the HHS Office of Inspector General (OIG). Mitchell says that this hire came with a great deal of support from HSB.

Mitchell says that OPA plans to add two additional staff members this year, and the agency continues to recruit and interview candidates for these positions.

"Given the evolution of this program and HRSA's commitment to improve integrity, these positions are absolutely critical to the future of the program," says Mitchell, adding that the new hires "reflect the commitment of both HRSA and the Health Systems Bureau to this program."

Program Enforcement. OPA continues its efforts to recover 340B overcharges for a group of drugs identified in a March 2003 OIG audit (*The Monitor*, December 2004), and Mitchell says that the agency will be active on this front in the upcoming year.

"We made a commitment up front to follow up with each drug company, and we will do so," says Mitchell.

In September, HRSA issued letters to each of the drug companies identified in the audit requesting that they develop plans to refund covered entities for overcharges from fiscal year 1999 that resulted from the companies failing to include sales made to HMO repackagers in their "best price" calculations.

Mitchell says that the companies have responded to the letters, though refunds from the manufacturers have not been recovered as of yet.

Lt. Commander Louis Flowers

The Monitor has learned that OIG continues to review the data from its June 2004 report on 340B pricing, which was temporarily withdraw in October, and plans to publish a revised report later this year.

Mitchell says that OPA will continue to work with both OIG and the Department of Justice to pursue recoveries and develop studies on the 340B program.

OPA Database. One of the most pressing challenges facing OPA in the upcoming year will be improving the covered entity and manufacturer databases, says Mitchell.

OPA recently contracted with Mitretek Systems, Inc., a nonprofit scientific research and engineering corporation, to develop a "requirements assessment" of the database and offer recommendations for how it should be improved. Mitchell says that he hopes to receive the report from HRSA's Office of Information Technology shortly.

Once the Mitretek report has been reviewed by OPA staff, Mitchell says that the agency will contract with Primescape Solutions, Inc., a technology consulting firm, to implement the report's recommendations and translate them into OPA's systems.

Overall, Mitchell says that this process will take up to two years, though OPA plans to implement all incremental improvements to the database as they become operational.

Rural Hospitals. Mitchell says that OPA will commit a great deal of effort in 2005 to help rural and small urban hospitals enroll in and take advantage of the 340B program.

Rural and small urban hospitals have been joining program at a rapid rate following the passage of a provision in the Medicare Modernization Act (MMA) that revised the disproportionate share hospital (DSH) adjustment formula for these hospitals and made it possible for them to qualify for the program (*The Monitor*, July 2004).

A total of 74 rural hospitals have joined the program since this change was enacted, including 16 hospitals that entered the program on January 1 of this year, according to OPA data.

Mitchell says that OPA will continue to work with HRSA's Office of Rural Health Policy (ORHP) and the new 340B DSH hospitals to provide technical assistance on how to implement the program.

"We look forward to working with covered entity groups like the Public Hospital Pharmacy Coalition (PHPC) to get small DSH hospitals educated and to allow them to maximize use of the program," he says.

Rx Companies Unveil Drug Discount Card for Non-Senior Uninsured

A group of 10 pharmaceutical manufacturers have joined together to introduce a new drug discount card that they believe will save many non-senior uninsured individuals 25-40% on more than 275 brand name drugs and a variety of generic products.

The goal of the Together Rx Access Card program is to "help qualified individuals and families who lack prescription drug insurance to save on brand-name prescription drugs and other prescription products, as well as a wide range of generic drugs."

The program's members are Abbott, AstraZeneca, Aventis Pharmaceuticals, Bristol-Myers Squibb, GlaxoSmithKline, Johnson & Johnson Health Care Systems, Novartis, Pfizer, Takeda, and TAP Pharmaceuticals.

A number of these companies also founded the Together Rx Card for low-income Medicare enrollees, which will be phased out when the Medicare drug benefit is introduced in 2006. Questions remain as to what role pharmaceutical companies will play in helping to fill coverage gaps under the new benefit.

In addition to offering discounts on pharmaceuticals, the program will also assist beneficiaries in identifying and enrolling in manufacturer-sponsored patient assistance programs (PAP).

Enrolling in the program is free for those who meet the requisite age and income requirements. Beneficiaries will not be charged to use the card, and discounts will be calculated and applied directly at the pharmacy counter.

To be eligible, applicants must be under the age of 65 and may not be otherwise eligible for Medicare or other drug coverage. Applicants must also not exceed a household income requirements based on family size (*see table*).

Together Rx Access Card Enrollment Requirements

- **Age: less than 65**
  not otherwise eligible for Medicare or other insurance programs
- **Income: less than $30,000 for a single person**
  " " $40,000 for a family of two
  " " $50,000 for a family of three
  " " $60,000 for a family of four

Enrollment began in January, and savings are expected to be offered beginning in February. More detailed eligibility information can be found on the program's website, which is located at www.togetherrxacces.com.

Currently, the only pharmacies included in the program are those that participate in the Together Rx Card. Additional pharmacies that wish to contract with the program should contact Argus Health Systems at 1-800-522-7487. Participating pharmacies will be reimbursed by Argus, rather than by the member companies, in a manner similar to Argus's other drug insurance card programs.

A list of brand name and generic drugs available through the program is available on the program's website. The site also includes a "pharmacy locator" that can be used to identify pharmacies that participate in the program.

While the program may not be particularly helpful for large disproportionate share hospitals that have developed institutional PAPs that allow for streamlined access to free pharmaceuticals, it may prove beneficial for smaller providers.

"[This program] should provide significant support for smaller and rural hospitals," says Andrew Wilson, Director of Pharmacy Services for the Virginia Commonwealth University Health System. "It should also have some impact on other clinics and community health centers and provide an indirect benefit to safety-net hospitals."

Together Rx Access will host regional events over the next few months to introduce the card and engage third-party organizations in helping to promote it, according to Karissa Laur, Senior Manager of Corporate Relations for AstraZeneca.

Public Hospital Pharmacy Coalition

Present

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The Public Hospital Pharmacy Coalition (PHPC) and Medicine for People in Need (Medpin) invite you to attend a conference on the effect of the new Medicare Rx Benefit on safety net providers and the pharmaceutical industry. Topics to be discussed include:

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- Lessons Learned from the Medicare Rx Discount Cards
- Co-Branding 340B/Medicare Rx Plans
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- Update on 340B Inpatient Discounts
- How the New Benefit Will Affect PAPs and State Rx Programs
- Legislative Update

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CDPD Grantees Benefit from Opening On-site Pharmacies

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programs without grant funding or increased payments by third-party payers such as Medicaid.

"The current financing environment presents a major challenge to sustainability of these services, because payers do not generally pay for clinical pharmacy visits…and often at rates the pharmacists considered extremely low relative to the required effort," the report states.

The expansion of pharmacy access was also an important component of many of the CDPD grant programs, as 14 of the 18 participating networks used this strategy. More specifically, 11 out of the 35 participating health centers used a portion of their grants to establish an on-site pharmacy, while 6 developed a 340B contract pharmacy agreement with an outside organization.

The health centers that established new pharmacies filled an average of 26,500 prescriptions during the second year of their grant program. These health centers often found that their new pharmacies attracted both insured and indigent patients from their communities.

For some participants, opening a new pharmacy was the most important accomplishment of their CDPDs. The Bell Clinic at Trenton Medical Center (TMC) in Trenton, FL, for instance, was able to use their HRSA funding to build a new 340B pharmacy that attracted uninsured, privately insured, and Medicaid patients.

By the end of the second year of their CDPD, TMC's pharmacy was dispensing over 11,000 prescriptions annually and had managed to break even financially.

In addition, 11 of the participating health centers began to use or expanded their use of patient assistance programs (PAP) sponsored by pharmaceutical manufacturers, which provide free pharmaceuticals to low-income uninsured patients. On average, these entities saved $114,000 through the use of PAPs.

"It seems likely that health centers in general were becoming more savvy about the potential value of PAPs for their patients during the time period of the grant," the report states.

Mathematica also released a companion report that details the experiences of specific health care networks in developing and implementing their CDPDs. Both reports can be found at http://bphc.hrsa.gov/opa/new.htm.

Plaintiffs in Class Action Suit Seek Court-Ordered Accounting

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"[T]he express focus of Section 340B is on the drug manufacturer, not the health care provider that may participate in the program," the defendants argued. The defendants also rely on the fact that the government explicitly developed a dispute resolution procedure in 1996 through which HRSA can settle claims of improper pricing, which the defendants believe strongly implies that Congress did not intend to allow providers to privately sue manufacturers.

"There is no sound legal basis for the entities to simply ignore the program's administrative options and file private, class action lawsuits," says McElroy.

Hagens Berman, one of the primary law firms representing the plaintiffs, did not respond to *The Monitor's* request for comment by deadline. However, their brief emphasizes their contention that the government lacks both the authority and the resources to settle claims of overcharges and that judicial intervention is therefore necessary to protect 340B providers.

"[OPA] does not have the legislative, regulatory, or contractual authority to require manufacturers to reimburse the entity for overcharges if they are discovered," their brief states. "It does not have the authority to compel manufacturers to participate in its voluntary, informal dispute resolution process."

340B Program Sees Significant Growth in Latest Quarter

The 340B program experienced significant growth over the last quarter, as 391 covered entity sites and 14 pharmaceutical manufacturers joined the program between October 1, 2004 and January 1, 2005.

The total number of covered entity sites in the program has now reached 11,911, representing a net increase of 122 since October 1. This number takes into account both additions to the Office of Pharmacy Affairs (OPA) database and those entities whose memberships have been either terminated or found to be duplicated in the database.

The increase in the number of manufacturers with Pharmaceutical Pricing Agreements (PPA)—the contract between the government and a manufacturer authorizing the manufacturer to participate in the program—brings the total number of manufacturers participating in the program to 677.

Another significant development over the past quarter was the increase in contract pharmacy arrangements registered with OPA. There are currently 846 such agreements on file with OPA, representing a net increase of 82 over the last quarter.

Contract pharmacy arrangements allow covered entities that lack in-house pharmacies to contract with a single outside pharmacy to provide its patients with drugs purchased through the 340B program.

OPA began recognizing and approving contract pharmacy agreements in 1996 after community health center (CHC) groups expressed concern that many of their members were unable to support in-house pharmacies.

Each of the covered entity groups saw an increase in the number of sites participating in 340B over the last quarter. The most significant increases were seen among Health Resources and Services Administration (HRSA) grantees—consisting of CHCs, hemophilia treatment centers (HTC), and others—followed by Sexually Transmitted Disease/Tuberculosis clinics (STD/TB) and disproportionate share hospitals (DSH), of which there are now more than 1,000 sites in the program. There was also a modest increases in the number of family planning clinics enrolled in the program.

340B Enrollment Statistics as of January 1, 2005

- **Active manufacturers with signed PPAs = 677 (Oct. 1 = 663, net increase of 14)**
- **Active contracted pharmacy arrangements = 846 (Oct. 1 = 764, net increase of 82)**
- **Participating covered entities (sites) = 11,911 (Oct. 1 = 11,789, net increase of 122)**

Distribution by Entity Type

Entity type	Sites added on Jan. 1**	All Participating sites
HRSA Grantees	148	3,212
DSH Hospitals	91	1,026
STD/Tuberculosis	124	2,366
Indian Health Service	1	117
Family Planning	27	5,190
TOTAL	391	11,911

** Sites may include multiple locations operated by the same hospital or clinic.

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