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. 4 **April 2005**

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HHS Rejects Manufacturer Proposal to Cap 340B Drug Supply

HRSA Calls Plan "Contrary to the Intent" of 340B

The Office of Pharmacy Affairs (OPA) will not approve of any effort to address drug shortages that would place a cap on the amount of discounted drugs made available to 340B covered entities, according to a letter written by OPA Director Jim Mitchell.

In response to a proposal submitted by Berlex Laboratories—which manufacturers the family planning drugs Levlen and Tri-Levlen—Mitchell wrote on February 22 that any plan that caps the amount of product available to 340B entities constitutes a violation of the 340B guidelines and could expose the manufacturer in question to potential legal penalties.

> ***"OPA is unaware of any method through which a manufacturer faced with a shortage can cap the amount of available product . . . without violating the requirements of Section 340B of the Public Health Service Act."***
>
> **Jim Mitchell**
> **Office of Pharmacy Affairs**

The Monitor obtained the correspondence between OPA and Berlex through a request made under the Freedom of Information Act (FOIA).

Mitchell's letter was drafted after Berlex claimed that a shortage of Levlen and Tri-Levlen had forced the company to consider ways of limiting the amount of the product that would be made available to various purchasers.

Berlex had proposed the following system to OPA in a letter sent in December 2004: The company would divide its market by "class of trade"—including wholesalers, health maintenance organizations (HMO), 340B covered entities, and other purchasers—and determine, based on past sales, what percentage of their products would be made available to each group per quarter.

Once any group had purchased above their allotted amount, the company would reject all subsequent purchase requests and ask that members of the class wait until the beginning of the next quarter to try ordering again.

According to the proposal, 340B entities would have been eligible to purchase 21.1% of the available stock of Levlen and 13.3% of Tri-Levlen each quarter. Furthermore, 340B entities would be required to acquire these drugs directly from the manufacturer rather than through a wholesaler.

OPA had first contacted Berlex in October 2004 after receiving notification from the company's customers that Berlex was no longer supplying Levlen and Tri-Levlen to 340B entities through wholesale distributors. Mitchell also said that other "340B entity personnel" had claimed that they were

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OPA Introduces New "Pilot Test" Database

The Office of Pharmacy Affairs (OPA) has introduced a number of changes to its online database aimed at improving the efficiency of the data and increasing the amount of information available to 340B stakeholders, according to OPA officials.

As part of this effort, OPA has launched a "pilot test" site that will serve as a model for a revamped database of covered entities, participating manufacturers, and contracted pharmacy arrangements.

The pilot test period will run until June 30, at which point the new database will begin to run concurrently with the current system for two quarters. By January 2006, the current system will no longer be available. In the meantime, the pilot test site will continue to be updated as new features are made available.

"Our goals are to improve the utility and user-friendliness of the database and begin to address some of the deficiencies identified in the June OIG report [on the covered entity database]," says OPA Director Jim Mitchell.

The most significant feature of the pilot database, according to Mitchell, is that all of the various databases will eventually be linked together. Under the current system, the databases hosted on the OPA website are freestanding and do not update themselves when changes are made to corresponding data sets.

"This is a huge jump in improving the OPA website and database," says Mitchell.

By the time the new database is complete, it will host a number of new features including a "related entities" section that will designate which entities are part of a larger system or organization. The new database will also include "ship to-bill to" information for entities that have entered into contracted pharmacy arrangements.

> ***"Our goals are to improve the utility and user-friendliness of the database and begin to address some of the deficiencies identified in the June 2004 OIG report."***
>
> **Jim Mitchell**
> **OPA Director**

Both of these features will require a great deal of manual data entry, according to Mitchell, though they will be made operational on the pilot test site as soon as they are completed.

Another function that is featured on the new database allows users to download and print a file that details all of the updates made to the database on a daily basis.

The site also includes a feedback page so that users can "participate in the finalization of the format and offer any suggestions." OPA plans to develop a user manual in the near future.

The OPA database has been under fire since the release of a report conducted by the Office of Inspector General (OIG) in June 2004 entitled "Deficiencies in the 340B Drug Discount Program's Database."

The OIG report, which was released as a companion report to a study on 340B overpayments, identified glaring errors and omissions in the OPA website's data. For instance, 38% of entities sampled by OIG were incorrectly listed as "participating" in the 340B program, while 43% of the OIG's sample were listed under incorrect addresses (*The Monitor*, July 2004).

Representatives of the pharmaceutical industry have been particularly critical of the current database, arguing that it's deficiencies make it difficult for manufacturers to determine whether purchasers are eligible for the program and verify covered entities' contact information.

One potential solution that has been proposed by various 340B stakeholders, including the Public Hospital Pharmacy Coalition (PHPC), would be to require covered entities to update their contact information on an annual basis.

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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 more than 250 340B hospitals, and the law firm of Powers, Pyles, Sutter and Verville.

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HRSA Responds to Drug Shortage Issues

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verbally informed that Berlex did not intend to honor their obligations to sell these products to covered entities under the 340B program.

In a letter to Mitchell sent in late October 2004, Berlex President and CEO Reinhard Franzen denied the claim that his company did not intend to honor their 340B contracts, stating that "[a]t no time was it Berlex's position that 340B customers were to be informed that we would no longer be honoring our legal obligations" under the program.

Franzen also explained that a shortage of both Levlen and Tri-Levlen, as well as a marked increase in demand among 340B entities, could lead Berlex to limit sales to certain groups of purchasers.

"[B]erlex takes seriously its obligations under the 340B drug pricing program and the Pharmaceutical Pricing Agreement to which we are a party...and we fully intend to honor such obligations," Franzen wrote. "Please be aware, however, that if 340B covered entities continue to place orders at recent levels, we expect to experience further shortages from time to time for the foreseeable future."

According to Franzen, 340B entities have increased their orders for Berlex products by approximately 400% since 2002.

After receiving the October letter from Mitchell, Berlex officials met with OPA to discuss possible solutions to their shortage issues. In the meantime, Berlex said that it would require 340B entities to purchase directly from Berlex on a "first in, first out" basis until a compromise could be reached.

"Not only will this allow Berlex to monitor directly orders from 340B customers to ensure they are receiving available product, but we believe our 340B customers will receive better service (e.g., they will avoid wholesaler upcharges for our products)," Berlex wrote at the time.

Following the submission of their proposal, Mitchell issued a second letter on February 22 that appeared to reject both the interim and long-term solutions proposed by Berlex.

Mitchell's letter argued that (a) the company is not permitted to cap the amount of product available to 340B entities under a "class of trade" system and that (b) requiring covered entities to purchase directly from the manufacturer while allowing other customers to purchase through a wholesaler qualified as discrimination.

In fact, Mitchell's letter stated that there is no way to limit sales to 340B entities without violating the "anti-discrimination" provision in the 340B guidelines, which clearly states that "[m]anufacturers may not single out covered entities from their other customers for restrictive conditions."

> ***"In general, a manufacturer cannot commit all available supplies of drugs to other purchasers if that contractual obligation takes priority over making those drugs available at discounted 340B prices."***
>
> **Joyce Somsak**
> **HRSA Health Systems Bureau**

"OPA is unaware of any method through which a manufacturer faced with a shortage can cap the amount of available product . . . without violating the requirements of Section 340B of the Public Health Service Act," Mitchell wrote. "When a manufacturer is faced with a shortage, it must allocate its products based on factors other than the 340B status of the customer."

Berlex, which has met with OPA officials to discuss this issue, is currently formulating a written response to Mitchell's letter and the company is confident that a mutually acceptable compromise will be reached with the federal government, a Berlex representative told *The Monitor*.

HHS Answers PHPC Letter

The issue of drug shortages was also recently addressed in a letter issued by the Health Resources and Services Administration (HRSA) to the Public Hospital Pharmacy Coalition (PHPC), an organization that represents more than 250 hospitals in the 340B program.

PHPC had written to Department of Health and Human Services (HHS) Secretary Michael Leavitt on February 17 requesting that his agency investigate pharmaceutical companies that choose not to offer their products to 340B entities due to "drug shortages" while still fulfilling their private contracts (*The Monitor*, March 2005). In particular, the letter stated that the Coalition's members had experienced difficulty acquiring intravenous immunoglobulin (IVIG) product.

In response, HRSA Health Systems Bureau (HSB) Acting Administrator Joyce Somsak wrote on behalf of HHS that the agency agrees with PHPC that this practice is "contrary to the intent of" the 340B program and that manufacturers are not permitted to discriminate against 340B entities based on their participation in the program.

"In general, a manufacturer cannot commit all available supplies of drugs to other purchasers if that contractual obligation takes priority over making those drugs available at discounted 340B prices," the letter states, adding that 340B purchasers cannot be treated differently from other purchasers simply because they are enrolled in 340B.

However, Somsak also said that HHS does not plan to clarify its regulations in order to explicitly prohibit this practice, instead suggesting that affected entities address their grievances through HRSA's dispute resolution process.

"We feel at this time that it would be premature to take the steps suggested as we feel there are sufficient safeguards for covered entities to seek redress," the letter states.

Heinz Foundation Calls For Increased State Use of 340B

Just months after the Rhode Island Health Department changed its pharmacy regulations to allow drug importation from Canada, a state-commissioned report has recommended expanded use of the 340B program as another method of lowering state drug costs.

The report, published by the Heinz Foundation, estimates that the state could achieve a net savings of up to $18.8 million over five years by purchasing pharmaceuticals for a small group of state programs and agencies through the 340B program.

"Although the 340B Program isn't a silver bullet, it can be a secret weapon in the fight to provide access to affordable prescription drugs," said Teresa Heinz, referring to 340B as the "best kept secret in Washington."

The report concludes that, despite its inherent challenges, transitioning to a 340B purchasing model is a safe and viable way to save money for the state's taxpayers while improving access to pharmaceuticals.

"[T]he State must maximize its participation in federal drug discount programs such as 340B, which offer immediate, predictable, and significant savings on prescription drugs," the report states.

According to the report, Rhode Island is an excellent candidate to pursue a 340B purchasing strategy due to the state's projected $192 million budget deficit for 2005. The state spent $2.2 billion—41% of the state budget—on healthcare in 2003, including over $200 million on outpatient drugs.

In fact, recent budget shortfalls have prompted Governor Donald Carcieri (R) to implement a "Fiscal Fitness" program aimed at decreasing costs and increasing the efficiency of state programs.

The Heinz Foundation study, conducted for the state in collaboration with Americhoice Management Services Organization, compared the purchasing data of four state agencies and programs—the Department of Corrections (DOC), the Community Medication Assistance Program (CMAP), the Rhode Island (RI) Training School, and the RI Pharmaceutical Assistance to the Elderly Program (RIPAE)—with "a recent 340B price list" compiled from various sources.

The Heinz Foundation was asked to develop the report after state officials took particular interest in 340B-related recommendations made by the Heinz Foundation in a previous report for the state, according to Jeff Lewis, President of the Heinz Foundation and former Staff Director for the late Senator John Heinz (R-PA).

> ***"Although the 340B Program isn't a silver bullet, it can be a secret weapon in the fight to provide access to affordable prescription drugs."***
>
> **Teresa Heinz**
> **The Heinz Foundation**

The initial report, which focused on coordinated contracting for prescription drugs, included a section entitled "340B Prescription Drug Pricing: Opportunities Are Available."

"The 340B portion of the initial report intrigued them enough to ask for a second report," says Lewis, adding that the state was interested in identifying programs where they could implement 340B purchasing strategies quickly.

According to the report, the programs in question have the potential to save a total of $2.77 million above costs within the first year of expanding the state's use of the 340B program, with estimated net savings of up to $4.35 million in the fifth year.

The report argues that other state agencies would also likely benefit from the 340B program, though the analysis focuses specifically on these particular programs because of the ease with which they could transfer to a 340B purchasing model.

Overall, the report estimates that by purchasing drugs through the 340B program, the four programs included in the study could save 65% off of Average Wholesale Price (AWP) and achieve significant savings off of the cost of drugs under the Medicaid program.

The RI DOC, which provides pharmaceutical services to the state's prison population, could save up to $900,000 within a year by partnering with 340B entities to provide care to their patients and purchasing their drugs through the 340B program, according to the report.

Meanwhile, the report estimates that the state's elderly prescription drug assistance program could save millions by ensuring that beneficiaries who receive care from covered entities are receiving discounted drugs and by transferring some patients' care to 340B entities. The program, which requires beneficiaries to make copays for their drugs, could potentially save up to $11.8 million over five years (excluding fixed costs) by implementing this strategy.

Lewis says that while the report focuses on specific state programs in Rhode Island, he believes that it could serve as a model for other states interested in taking advantage of the 340B program.

"I'm confident that this model is transferable to other state programs and will work effectively for other states," he says. "[The report] allows them to see what is possible."

As for Rhode Island, Lewis says that the report has been well-received by state officials and that he expects to be called to testify before the state legislature shortly. He also says that the state has begun to hold internal discussion on the report's recommendations at the agency level.

The Heinz Foundation study was released just months after the Rhode Island Health Department adopted new rules that will allow Canadian pharmacies to dispense drugs to consumers in

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340B Providers Urge Caution on Medicaid Best Price Reform

A group of six national organizations representing many of the participants in the 340B program have issued letters to committee leaders in both the House and Senate urging members to consider the unintended effects that proposed changes to the Medicaid program could have on the administration of the 340B program.

The purpose of the letter, according to Public Hospital Pharmacy Coalition (PHPC) Executive Director Ted Slafsky, is to educate members of Congress about the value of the 340B program, illustrate the connection between Medicaid and 340B, and caution lawmakers that fundamental changes to Medicaid could threaten the 340B program.

In particular, Slafsky says that PHPC and other covered entity groups are concerned about the President's proposal to eliminate best price from the Medicaid drug rebate formula and replace it with a flat rebate. Under the current system, the Medicaid and 340B programs are entitled to either a rebate/ discount off of a drug's Average Manufacturer Price (AMP) or the best price offered in the private market. (For more on the President's budget proposals, see *The Monitor*, February 2005).

"Any changes to these key Medicaid provisions would directly affect the operation of the 340B program, and such effects would likely cause confusion within the 340B community, or worse, paralyze operation of the 340B program in its entirety," the letter states.

The letter also argues that any damage done to the 340B program could potentially result in increased costs at the federal, state, and local levels because many 340B providers are financially supported by government entities.

> ***"Changes to the Medicaid drug rebate program could increase costs to federal, state and local governments if the changes inadvertently disrupt or terminate operation of the 340B program."***
>
> **Joint Letter to House and Senate Committee Leadership**

"The 340B program saves safety net providers hundreds of millions of dollars per year which, in turn, saves the federal, state and local governments that subsidize these providers," the letter states. "Accordingly, changes to the Medicaid drug rebate program could increase costs to federal, state and local governments if the changes inadvertently disrupt or terminate operation of the 340B program."

The letter, dated March 15, is signed by the National Association of Community Health Centers (NACHC), the National Association of Counties (NACO), the National Rural Health Association (NHRA), the National Association of Public Hospitals and Health Systems (NAPH), PHPC, and the Hemophilia Alliance.

The legislators targeted by the letter include the Chairmen and ranking Democrats in the committees with direct jurisdiction over the Medicaid and 340B programs, i.e. the Senate Finance Committee and the House Energy and Commerce Committee. Also receiving letters were the Chairman and ranking Democrat on the House Energy and Commerce Subcommittee on Health.

Two of the recipients—Senate Finance Chairman Charles Grassley (R-IA) and House Energy and Commerce Chairman Joe Barton (R-TX)—have been active in monitoring the 340B program in the past. Both Grassley and Barton sent letters to the Department of Health and Human Services (HHS) last year requesting that the agency step up its efforts to pursue refunds from manufacturers that the government found to have overcharged 340B entities.

CMS Appears to Change Position on "Authorized Generic" Drugs

In what appears to be a victory for the generic pharmaceutical industry, the Centers for Medicare and Medicaid Services (CMS) have publicly stated that "authorized generic" drugs should be classified as innovator multiple source drugs, meaning that they would be treated by the Medicaid drug rebate and 340B programs as brand name drugs and discounted as such.

Authorized generics, which are generic versions of brand name drugs manufactured by brand name companies and sold even while generic manufacturers have exclusive rights to the drug, are currently exempt from best price calculations because the Medicaid and 340B programs do not take best price into account when calculating rebates and discounts for generic drugs (For more on authorized generics, see *The Monitor*, November 2004).

However, in a March 18 letter to the Generic Pharmaceutical Association (GPhA), a trade association of generic drug manufacturers, CMS Administrator Mark McClellan advanced his agency's position that authorized generics should be treated as "innovator multiple source drugs," which are subject to the best price provisions in the Medicaid and 340B programs.

"It is CMS's position that such multiple source drugs marketed under a New Drug Application approved by the Food and Drug Administration should be classified as an innovator multiple source drug," the letter states.

Currently, the 340B ceiling price for an authorized generic drug is equal to the drug's Average Manufacturer Price (AMP) - 11%. If authorized generics were to be treated as innovator multiple source drugs, the ceiling price for these drugs would then be equal to the lesser of either AMP - 15% or the best price offered in the private market.

> ***"It is CMS's position that such multiple source drugs marketed under a New Drug Application approved by the FDA should be classified as an innovator multiple source drug."***
>
> **Mark McClellan**
> **CMS Administrator**

The letter also states that the agency is "currently reviewing its policy on the calculation of prices for these drugs."

GPhA has been an active opponent of the authorized generic system, which was endorsed by the Food and Drug Administration (FDA) in July 2004 as a means of increasing competition and lowering drug prices. In the past, GPhA has argued that it is inconsistent for the FDA to allow manufacturers to launch authorized generics during another company's exclusivity period while CMS treats the drug as a generic product for the purpose of Medicaid and 340B.

"The untoward result is that brand companies obtain a major windfall by not including in their CMS Best Price calculation the authorized generic product to the detriment of the federal and state government programs," according to a GPhA document outlining the organization's 2005 policy priorities.

The issue of authorized generics was also broached during a recent budget hearing featuring U.S. Department of Health and Human Services (HHS) Secretary Michael Leavitt. During the hearings, Senator Charles Schumer (D-NY) argued that authorized generics allow brand name manufacturers to "escape reporting the price" of the drug when submitting their best price data to the government.

At the time, Leavitt argued that HHS did not have the authority to change the rules that guide this issue, though he promised to address it more thoroughly at a later date in a written response (*The Monitor*, March 2005).

Heinz Foundation Report Lauds 340B

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the state, effectively making Rhode Island the first state to sanction drug importation in its regulations.

The new regulations are the result of legislation passed by the Rhode Island General Assembly calling upon the Health Department to amend the state's existing pharmacy licensure regulations to include pharmacies that are licensed in Canada.

"The Department, at this time, has determined that the requirements in Rhode Island for licensure of Canadian pharmacies should parallel the requirements for the licensure in Rhode Island of pharmacies licensed by other states," the Health Department stated in the introduction to the new pharmacy regulations.

In response to safety concerns, the Health Department argued that "the statute and regulations that govern the licensure of out-of-state pharmacies have been tested and found sufficient to protect Rhode Islanders from substandard pharmacy practice" and that these regulations are sufficient to address safety issues related to Canadian pharmacies.

The US Food and Drug Administration (FDA) has historically opposed importation due to safety concerns, but the agency has not yet stated whether they will take action against Rhode Island's new regulations.

Advocates of the 340B program, including the Heinz Foundation, view the expansion of the 340B program as another strategy for reigning in health care costs.

"Advising states on the 340B program provides them with another option for acquiring affordable pharmaceuticals," says Lewis.

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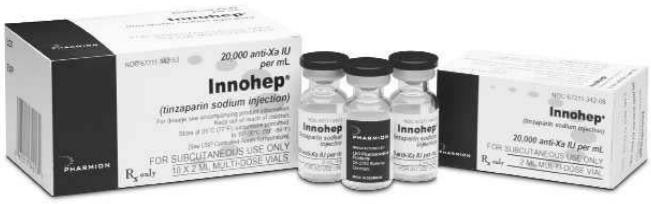

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Where Are They Now?

An Occasional Series on Former Government Officials and Policymakers Who Have Impacted the 340B Program

Former OPA Staffers Take Their Expertise Overseas

Robert "Butch" Staley and Laila Akhlaghi are quick to point out that they haven't been able to keep up with the most recent developments in the 340B program. After all, these two former Office of Pharmacy Affairs (OPA) staffers have spent much of the past year in nations such as Ghana and Namibia helping governments to acquire and distribute life-saving drugs.

"I used to eat, sleep, and breathe the 340B program," says Staley. "But now I eat, sleep, and breathe developing world programs."

Both Staley and Akhlaghi currently work in the Arlington, VA office of Management Sciences in Health (MSH), a private nonprofit organization that works to bring health care services to underserved populations in the developing world.

Yet despite their separation from the 340B program, both Staley and Akhlaghi say that their experiences at OPA have helped prepare them for the ambitious programs that they now direct overseas.

For Staley, his time at OPA seems like decades ago. He first joined the agency in 1994 after serving in the National Health Service Corps in the Northern Mariana Islands, where he helped train pharmacists and assisted them in setting up their practices.

Upon joining OPA, Staley worked with a variety of covered entity groups, which he says allowed him to take advantage of his pharmacy degree and familiarize himself with the pharmaceuticals and manufacturers that he now deals with on a daily basis.

"I was able to interact with the various players in the US drug market," he says. "I could pick up the phone and talk to any manufacturer participating in the 340B program."

After leaving OPA in 2000, Staley took a position at MSH working on a number of projects for the organization's Center for Pharmaceutical Management.

Over the last five years, Staley has worked in five countries on three continents. He has assisted the governments in countries such as Bangladesh, Albania, and Cambodia with everything from evaluating their health care programs to supervising the development of pharmacy services.

Robert "Butch" Staley

Laila Akhlaghi

In Ghana, Staley serves as the country program manager, working with the Ministry of Health and organizations such as the Christian Health Association to strengthen the country's regulatory enforcement capabilities, improve their pharmacist licensing databases, and increase the affordability and accessibility of pharmaceuticals.

He has also worked on the Lead for Health project in the Phillipines, where he has assisted government officials as they work to improve access to reproductive health drugs and related products. He has also helped to implement an HIV surveillance program and worked with a local network of drug sellers on pharmacist training.

Staley says that his schedule is unlike anything he experienced working at OPA. After returning to the states for a few days at the end of February, he left for Ghana on March 2 to resume his work there.

Unlike Staley, Akhlaghi began her career at OPA, first working as an intern while studying for her PharmD at the University of Kentucky.

Following her graduation in 2001, Akhlaghi took a full-time position at the agency, where she served primarily as the project officer for the 340B prime vendor program and as the point person for Alternative Methods Demonstrations Projects (ADMP).

Since joining MSH in 2002, Akhlaghi has worked on a number of HIV/AIDS related projects around the world. Last year, she made six trips to Namibia, where she assisted USAID-funded organizations and the Namibian Ministry of Health with the procurement of HIV/AIDS drugs.

While in Namibia, Akhlaghi was primarily responsible for helping to forecast the quantity of drugs to be purchased by the government, which she says required her to analyze "any information we could get our hands on." She has also performed similar functions in other developing nations, including Haiti, Rwanda, and Vietnam.

She is currently on a break from international travel as she helps to develop a tool that will assist MSH staff members in forecasting pharmacy need in developing nations.

Akhlaghi says that her experience at OPA began to pay dividends immediately when she left OPA to work for MSH.

"Working with the prime vendor program helped me to understand how the market works and what factors are important in negotiations," she says. She

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OPA Plans to Continue Updating Agency's Databases

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Currently, OPA relies on a number of sources in updating covered entities' contact information. Although 340B entities are responsible for informing OPA of all changes, Mitchell says that his agency is growing increasingly dependent on information from drug manufacturers, wholesalers, and the 340B prime vendor program.

In addition to creating a new pilot database, OPA has also recently added a feature to its current website that assists state Medicaid directors in excluding 340B purchases from their rebate claims, as well as a comprehensive glossary of acronyms used in the database.

The pilot database can be found on the OPA website at the following address: bphc.hrsa.gov/opa/downld.htm.

Mitchell Honored by APhA

OPA Director Jim Mitchell was honored on April 3 with the 2005 Distinguished Achievement Award in Administrative Practice from the American Pharmacists Association (APhA),

Among the organizations most prestigious honors, the award "recognizes the achievements of an individual who has made a significant contribution or sustained contributions to the provision of pharmaceutical care within administrative practice," according to APhA.

"It is a distinct honor to be given this award," says Mitchell. "I'm extremely honored and pleased to have HRSA's support in directing the program."

In his acceptance speech at the APhA Annual Meeting in Orlando, Mitchell expressed his gratitude for the work of his small staff.

"I'm being honored for the work of a lot of people," he says. "They deserve the credit."

Also receiving an award on April 3 was William Gouveia, Pharmacy Director at Tufts-New England Medical Center, a member hospital of PHPC. Gouveia received the APhA Distinguished Achievement Award in Hospital and Institutional Practice, which recognizes "an individual who has made contributions to pharmaceutical care within a hospital and institutional practice."

Former OPA Staffers Contribute to Developing Nations' Health Programs

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also believes that working with covered entities on demonstration projects familiarized her with the process of interpreting federal regulations.

OPA Director Jim Mitchell remembers both Staley and Akhlaghi as valuable members of the OPA staff and is proud of what they have accomplished since leaving the agency.

"They graduated from this program," he says. "The experience they got [at OPA] prepared them for working in the international arena."

Mitchell says that both have kept in touch with the agency since moving on and are interested in staying informed on 340B matters.

In light of recent activity at OPA, both Staley and Akhlaghi say that they are encouraged by the expansion of the agency and its move to the Health Systems Bureau (HSB).

"OPA is in a position to do some innovative work," says Staley, referring specifically to the role that clinical pharmacy demonstration projects can play in improving community pharmacy.

Akhlaghi, meanwhile, is hopeful that additional resources will allow OPA to continue to promote the 340B program.

"Hopefully these resources will help them with advocacy and letting people know about the opportunities available to them [through 340B]," she says.

9th Annual 340B Coalition Conference

On Improving Access To Pharmaceutical Care and Ensuring Compiance With Federal And State Laws

A conference designed for health care providers, the pharmaceutical industry, pharmacy service companies, and other entities concerned about providing quality pharmaceutical care to low income and vulnerable populations while ensuring compliance with drug pricing laws.

July 11-13, 2005
J.W. Marriott Hotel
Washington, DC

This event is hosted by the 340B Coalition, a group of 17 national associations that represent the thousands of health care providers and programs participating in the Public Health Service 340B drug discount program. This conference is unparalleled in providing timely information and relevant strategies for providers and industry representatives on how to provide high quality pharmaceutical care and handle various compliance issues.

You will hear from key officials from Federal and State government who administer the 340B, Medicaid drug rebate, and Veterans Affairs drug discount programs. The Office of Pharmacy Affairs will provide presentations and will be available each day to answer your questions. Topics to be discussed include:

- 340B Introductory Class
- Update on government studies on 340B program, including Inspector General reports
- Status report on efforts to recover 340B overcharges, including various legal and legislative action
- President's proposal to eliminate the best price calculation used to determine 340B and Medicaid rebate discounts and replace it with a flat rebate
- Update on the new best price exemption for inpatient pharmaceuticals
- Contract pharmacy options under 340B
- Key issues related to inventory management and patient definition
- The new Medicare drug law and its implications for 340B stakeholders
- Medicaid billing procedures used by 340B providers
- Update on the 340B prime vendor program, including new contracts with brand name companies for subceiling discounts
- Other 340B legislative and regulatory hot topics

More details about hotel reservations and agenda available at
WWW.340BCOALITION.ORG

AIDS Action; AIDS Alliance for Children, Youth and Families; Communities Advocating Emergency AIDS Relief Coalition; Hemophilia Alliance, Inc.; National Alliance of State and Territorial AIDS Directors; National Association of Community Health Centers; National Association of Counties; National Association of People with AIDS; National Association of Public Hospitals and Health Systems; National Coalition for The Homeless; National Family Planning and Reproductive Health Association; National Health Care for the Homeless; National Hemophilia Foundation; National Rural Health Association; Planned Parenthood Federation of America, Inc.; Public Hospital Pharmacy Coalition

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