

Federal Drug Discount and Compliance Monitor



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

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Class Action Suit Adds Plaintiff and Defendants

Defendants file motion to dismiss

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A class action suit aimed at recovering 340B overcharges from a group of pharmaceutical manufacturers has been expanded to include a new plaintiff and a slew of additional defendants. Meanwhile, the original defendants have filed a motion to dismiss the suit primarily on the grounds that the claim relies on evidence that does not specifically implicate the defendants.

These two filings are the first actions taken on the matter since it was introduced in the federal District Court of the Middle District of Alabama in July.

The suit, originally filed by Central Alabama Comprehensive Healthcare, Inc., alleges that the defendants have violated their Pharmaceutical Pricing Agreements (PPA) and retained unjust enrichment as a result of overcharges for 340B covered drugs.

The claim calls for a full accounting “from each and every defendant” to determine whether their drug prices are consistent with the 340B pricing formula, as well as an injunction against future overcharges, coverage of legal fees, and “further relief as the court may deem just and proper.”

The suit was inspired by a report from the US Department of Health and Services Office of Inspector General (OIG), which estimated that covered entities had been overcharged by approximately \$41.1 million during the course of one month in 2002 (*The Monitor*, June 2004).

The complaint alleges that “based on the OIG’s report, it is all but certain that the plaintiff...has overpaid for prescription drugs manufactured by defendants,” and that these overcharges cannot be proven without the disclosure of pricing data by the manufacturers in question.

According to the amended complaint, the new plaintiff in the case is Health Services, Inc. (HSI), a Section 330(e) federally qualified health center (FQHC) with five clinics in Alabama.

The defendants added to the suit are GD Searle LLC, GlaxoSmithKline, Boehringer Ingelheim, Bristol-Myers Squibb Co., AstraZeneca US, Zeneca, Astrazeneca Pharmaceuticals LP, Schering-Plough Corporation, Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products, LP, McNeil-PPC, Inc., and Ortho-Biotech.

The following companies were already named in the suit: Aventis Pharmaceuticals, Inc., Aventis Behring LLC, Eli Lilly, Pfizer, Inc., Hoffman-La Roche, Inc., Merck & Co., Pharmacia & Upjohn, Inc., Pharmacia Corp., and Wyeth-Ayerst Laboratories, Inc.

The Central Alabama suit is the first class action suit to be filed against pharmaceutical manufacturers for alleged violations of the 340B program. On September 1, the California-based AIDS Healthcare Foundation (AHF) filed a suit accusing GlaxoSmithKline alleging overcharges of 340B providers for

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Pharmacy Affairs Begins Expansion and Prepares for Move

The Pharmacy Affairs Branch (PAB), the government agency charged with overseeing the 340B program, has officially changed its name to the Office of Pharmacy Affairs (OPA), according to a *Federal Register* notice released on September 21. The notice also states that OPA has been transferred within the Health Resources and Services Administration (HRSA) from the Bureau of Primary Health Care to the Healthcare Systems Bureau (formerly the Special Programs Bureau).

The agency's office will also be moving from Bethesda, MD to HRSA headquarters in Rockville, MD as early as November, *The Monitor* has learned.

The bureau change became official on September 13, although it was first announced at the 340B Coalition conference in July and the office has been operating within the Healthcare Systems Bureau for more than two months.

On July 12, Dennis Williams told the attendees at the 340B Conference that the move was part of a larger effort to "enhance Pharmacy Affairs' visibility and its ability to carry out our plan to improve the [340B] program."

"It has been tremendous [so far]," says OPA Chief Jim Mitchell of the move. "We have had very strong support, as well as direct access to the Associate Administrator [of the Bureau]."

The *Federal Register* notice also includes a detailed description of the roles and responsibilities of OPA, divided into four categories: (1) maximizing the value of the 340B program for covered entities, (2) supporting health centers and states as they develop programs for affordable drug benefits, (3) serving as a federal government resource on pharmacy, and (4) carrying out special projects as assigned by the Administrator of HRSA.

"The notice solidifies and strengthens our mission," says Mitchell.

In addition to its shift to the Healthcare Systems Bureau, OPA will also soon be moving its office from Bethesda, MD to the Parklawn Building in Rockville, MD, where many of HRSA's offices are currently located.

"[The move is] part of an effort to consolidate HRSA to one location and allow us to interact more efficiently," says Mitchell.

Staff Notes

As reported in *The Monitor* in August, OPA has been authorized by the Health Systems Bureau to hire a number of additional staff members.

"We have four positions that I can fill today," says Mitchell, adding that the office is in the midst of recruiting

applicants and conducting interviews.

"We are looking to hire pharmacists who understand pricing and clinical issues," says Mitchell, though he adds that applicants must also be "analysts who can communicate effectively." The specific responsibilities of each new employee have not yet been determined, but Mitchell says that the goal is to prepare "for the future, not the past."

The office is currently concentrating on recruiting pharmacists from the Public Health Service (PHS) Commissioned Corps because of the ease with which they can be transferred into the positions. However, Mitchell says that they are also considering civilians as the vacancies are formally announced by the federal government.

In addition to filling these new positions, OPA must also replace Jeff Mouakket, a Senior Program Manager at OPA who was responsible for handling Alternative Demonstration Projects. Moukket left OPA last month to serve in HRSA's Office of Program Review in Dallas, TX, where he will assist in reviewing grantee performance.

Jeanene Meyers, a former HRSA scholar and a current OPA staffer, will serve as the point person on Alternative Demonstration Projects until the office hires a replacement for Mouakket.

<p><i>The Monitor</i></p> <p>Managing Editor Jared Bloom</p> <p>Supervising Editors Ted Slafsky William von Oehsen</p>	<p>The <i>Federal Drug Discount and Compliance Monitor</i> 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. <i>The Monitor</i> also updates subscribers on breaking news stories through e-mail alerts.</p> <p><i>The Monitor</i> is published jointly by the Public Hospital Pharmacy Coalition, a non-profit organization that represents more than 200 340B hospitals, and the law firm of Powers, Pyles, Sutter and Verville.</p> <p>Federal Drug Discount and Compliance Monitor 1875 Eye St., NW, 12th Floor Washington, DC 20006 Phone: (202) 349-4244 Fax: (202) 785-1756 www.drugdiscountmonitor.com</p> <p>For information on <i>The Monitor</i>, including advertising opportunities, contact Jared Bloom at jbloom@drugdiscountmonitor.com or (202) 349-4244.</p>
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OIG Plans Follow-Up Report on 340B Overcharges

The US Department of Health and Human Services Office of Inspector General (OIG) has announced plans to complete a study in the upcoming year that will attempt to determine the causes of 340B overcharges found in a June 2004 OIG report.

The follow-up study will explore “potential reasons for price discrepancies within the Department and will provide information to pharmaceutical manufacturers, wholesalers, and covered entities to independently resolve discrepancies,” according to the HHS/OIG Fiscal Year 2005 Work Plan, which was released on October 12.

The new study is likely to include a larger sample size than the previous investigation and investigators are expected to predetermine which entities are participating in the 340B program. While the new study is not likely to be launched until March 2005, the agency has already begun to examine the data collected during the June 2004 study, which estimated that 340B entities were overcharged by approximately \$41 million during September 2002.

The June 2004 report also found that 31% of drug prices sampled were above the ceiling price and that 36 out of 37 sampled entities were overcharged at least once. HHS investigators hope that a more thorough analysis of the current

data will help the agency determine the causes for the overcharges.

In addition to the 340B study, OIG is also planning to complete a number of reports on the Medicaid Drug Rebate Program that could have an impact on the 340B program. One such report, referred to as “Medicaid Drug Rebates—Computation of AMP and Best Price,” will examine the methodology used by manufacturers to compute Medicaid “best price” and Average Manufacturer Price (AMP), the two most important figures in determining the 340B ceiling price.

The report will follow up on three past studies, which found that manufacturers did not consistently define the retail class of trade in their calculations, and will assess the efforts of the Centers for Medicare and Medicaid Services (CMS) to oversee the recalculations of AMP and best price performed by manufacturers.

“It is critical that CMS effectively oversee the recalculation process to ensure that State Medicaid programs are receiving the appropriate drug rebates,” the work plan states.

A second study, entitled “Average Manufacturer Price and Average Wholesale Price,” will examine the relationship between these two figures, though it will also “examine other Medicaid

drug rebate trends, such as the significance of the best price in the rebate amount, to determine whether drug manufacturers are circumventing the requirements of the Medicaid drug rebate legislation.”

OIG also plans to conduct an examination into whether manufacturers are accurately classifying their drugs as either brand name or generic drugs for the purpose of reimbursement. These classifications are significant because Medicaid rebates, and 340B prices, are calculated differently for generic and brand name drugs.

This study is also relevant to the 340B program because the “best price” requirement is only applicable for brand name drugs and not for generics. As a result, the classification of a brand name as a generic reduces the level of Medicaid rebates and 340B discounts.

Other proposed reports that may be relevant to 340B entities include three studies of Average Sales Price (ASP), which will be used to determine the reimbursement rates for drugs dispensed under Medicare Part B beginning in 2005, and an examination of the controls that are currently in place to prevent fraud with respect to the transitional assistance grants provided to low-income seniors under the Medicare Drug Discount Card program.

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West Virginia Government Releases Report on 340B

The West Virginia Legislative Auditor has released a report on the state's efforts to expand the 340B program, concluding that the Department of Health and Human Resources (DHHR) could save millions of dollars by enrolling more entities in the program and providing better technical assistance to potential applicants.

The report, which was presented to the state's Joint Committee of Government Operations on September 19, found that since the state created its 340B working group in April 2003, 53 federally qualified health centers (FQHC) and one disproportionate share hospital (DSH) have joined the 340B program.

This modest increase is a significant improvement considering that prior to the formation of the working group, only 8 FQHCs and 1 DSH hospital were enrolled, according to the report. Nonetheless, the report argues that the state still has its work cut out, as there are approximately 97 FQHC sites and 58 DSH hospitals (11 of which are likely to be eligible for 340B) in the state that are not in the program.

Based on estimates taken from a study by the Public Hospital Pharmacy Coalition (PHPC), the report concludes that the state could save \$3.3 million a year in Medicaid drug expenses by enrolling all 11 eligible DSH hospitals in the program. Of this total, \$825,000 would go directly to the state, while the federal government would receive the remaining \$2.4 million.

The report also estimates that FQHCs and DSH hospitals would benefit significantly from joining the 340B program. For instance, West Virginia University Hospitals reports that it has saved 10% off its entire prescription drug budget in the 18 months since it has been enrolled. According to the Bureau for Medical Services, 340B discounts average approximately 38% off of the price at which Medicaid reimburses for the state's top 25 drugs.

To encourage further enrollment, the

Legislative Auditor makes a number of recommendations aimed at improving the state's capacity to promote 340B to DSH hospitals and others that might be interested in the program but are deterred by their lack of familiarity with the program's requirements.

"Evidence suggests that DSHs may have misconceptions about 340B, still lack knowledge of the program, or may not know how to complete the application process," the report states.

The report recommends that DHHR continue to serve as a resource for entities at all stages of the application process, and notes that the 340B working group recently received a grant from the Claude Worthington Benedum Foundation to further these efforts.

"Evidence suggests that DSHs may have misconceptions about 340B, still lack knowledge of the program, or may not know how to complete the application process."

**West Virginia Legislative Auditor
September 2004**

The report also encourages DHHR to expand the types of assistance provided to potential 340B entities by offering information on how to overcome regulatory issues such as the GPO exclusion and the governmental affiliation requirement for DSH hospitals.

To further expand the reach of the program, the report recommends that the state continue to pursue an agreement with the Division of Corrections that would create a contract between DSH hospitals and prisons and allow inmates to receive drugs through the 340B program.

Currently, West Virginia's average pharmaceutical prices rank among the lowest in the nation. However, the fact that 15.2 prescriptions are dispensed per capita (the second highest demand in the nation) has led the state to seek cost containment measures over the years

including the creation of a Preferred Drug List.

It was not until 2003, however, that DHHR began looking towards the 340B program as a possible means of lowering drug costs and creating savings for the state Medicaid program. In April of that year, the state created a 340B working group made up of representatives from Medicaid, the Health Care Authority, the West Virginia Hospital Association, the West Virginia Primary Care Association, and the Division of Primary Care.

Governmental Affiliation An Obstacle

One of the major challenges facing DHHR is educating DSH hospitals on how to meet the governmental affiliation requirement in the 340B statute. The law states that in order to be eligible for the 340B program, a DSH hospital must either be government-owned or have an agreement with state or local government to provide a certain amount of indigent care.

The report states that this obstacle could "hamper DSHs from participating in the program" unless state and local governments become involved in the process.

One model offered by the report is that of Maryland, where the state has implemented a "formal referendum of agreement" by which all of the state's non-profit hospitals have agreed in writing to provide indigent care to patients regardless of their ability to pay. As a result, all of Maryland's DSH hospitals have met the governmental affiliation criteria for 340B participation.

In the case of New Jersey, the Health Resources and Services Administration (HRSA) has formally stated that all of the state's DSH hospitals have met the requirement because of "unique factual circumstances" specific to New Jersey, including the fact that these hospitals are legislatively mandated to provide inpatient and outpatient treatment to indigent patients.

Pennsylvania Government Proposes New 340B Reimbursement Model

The Pennsylvania Department of Public Welfare (DPW) has proposed a model for reimbursing covered entities for drugs purchased through the 340B program that would allow both the state Medicaid program and the provider's pharmacy to benefit from 340B discounts.

According to the proposed model, DPW would pay 340B entities at a rate that would permit the state to take an additional discount off of its net Medicaid cost for 340B drugs. This would increase the state's savings, while allowing covered entities to maintain most of the savings accrued through the 340B program.

The stated goal of the proposal is to create a pricing mechanism that will "make DPW whole, enable DPW to share in the 340B savings and incent pharmacies to become 340B entities."

The current model for reimbursement in Pennsylvania works as follows: Under the Medical Assistance Fee-for-Service (FFS) program, the state reimburses pharmacies at the Average Wholesale Price (AWP) of the drug being dispensed, minus 10%, plus a \$4 dispensing fee. The state then is legally entitled under the Medicaid rebate program to request a rebate from the manufacturer of the drug, which average about 22% of AWP.

The result of this process is that the state's net Medicaid cost for a drug is AWP - 32% (the 10% withheld from the provider + the 22% rebate paid by the manufacturer), plus \$4.

Currently, covered entities have the option of "carving out" their Medicaid drugs from the 340B program, which means that they do not purchase these drugs at 340B prices and continue to bill Medicaid at higher prices. This practice allows entities to keep all of their 340B savings rather than passing them on to the states by billing at acquisition cost.

The proposed model, announced at the end of September, seeks to create a mutually beneficial system that would make covered entities less inclined to take advantage of the "carve out" option. The new plan would allow the state to deduct an additional 2% from its net Medicaid cost, which would translate into a 2% savings for the state on each reimbursement.

This model is also acceptable to covered entities because the prices at which they purchase these drugs are estimated at AWP - 50%. Therefore, they would still be able to keep most of the savings that they receive through the program.

The proposal states that this pricing mechanism would only apply to brand name drugs. In the case of generics, the state would continue to seek manufac-

turer rebates and would reimburse 340B pharmacies under current rules. This provision would mean that covered entities could *not* purchase generic drugs through the 340B program.

Because this plan would create one payment policy for 340B drugs and one for all others, pharmacies would be required to develop two service location codes—one for 340B drugs and one for generics and non-340B brand name drugs. Similarly, pharmacies would have to separate their inventories between 340B drugs and generics/non-340B brand name drugs.

To ensure compliance with these provisions, the state would audit covered entities to ensure that they are maintaining separate inventories.

The proposal also includes a "non 'cherry-picking'" provision, which states that participating 340B entities must provide *all* brand name drugs under the 340B program, and may not "pick and choose" which drugs they want reimbursed.

Once implemented, DPW would be required to announce each year its net Medicaid cost for 340B drugs. In cases where the agency implements cost containment strategies for pharmacies, the net Medicaid cost would decrease and suppress some of the potential savings for 340B entities.

California Passes New 340B Billing Law

The California State Legislature has passed a law that will formally codify the way that some covered entities must bill Medi-Cal—the state's Medicaid agency—for their 340B eligible drugs.

The law states that community and free clinics in the 340B program must bill Medi-Cal and the Family PACT Waiver Program for any 340B "take-home" drugs at an amount equal to the lesser of either (a) the clinic's average annual actual acquisition cost for that drug plus a dispensing fee up to \$12, or (b) its "usual charge made to the general

public." In either case, these prices are not to exceed the net cost of these drugs as provided to retail pharmacies. Governor Arnold Schwarzenegger signed the bill into law on September 28.

The Planned Parenthood Affiliates of California (PPAC) have welcomed the passage of the bill. In a recent statement, PPAC thanked the Governor for his signature and celebrated the law as a way to ensure that "clinics such as Planned Parenthood will continue to provide high-quality health care services for all Californians."

As reported in *The Monitor* last month, the state legislature also passed a bill recently that would have created a drug discount program for certain providers that was similar to the 340B program (*The Monitor*, September 2004). Governor Schwarzenegger vetoed the bill on September 29.

While the Governor called the bill "a well-intentioned attempt to address the rising costs of prescription drugs," he argued that it could potentially increase costs to the state Medicaid program and other government purchasers.

340B Coalition Members Respond to Proposed Medicare Regulations

Two member organizations of the 340B Coalition have officially filed comments with the Centers for Medicaid and Medicare Services (CMS) on the proposed regulations for the Medicare Prescription Drug Benefit.

Both the Public Hospital Pharmacy Coalition (PHPC) and the National Alliance of State and Territorial AIDS Directors (NASTAD) submitted their comments to CMS Administrator Mark McClellan seeking clarification on how the new drug benefit will interact with the 340B program.

The proposed regulations were first posted in a *Federal Register* notice dated August 3, and comments were due by the end of business on October 4.

PHPC, an organization that represents nearly all of the disproportionate share hospitals (DSH) in the 340B program, focused its comments on ensuring that 340B pharmacies are not discriminated against by Prescription Drug Plan (PDP) sponsors in developing their pharmacy networks.

“340B hospitals have historically faced barriers to being included in pharmacy networks established by pharmacy benefit managers (PBMs) and managed care plans,” the comments stated. “Because the new Part D benefit will be administered in large part by PBMs and managed care organizations, we are concerned that the subtle forms of discrimination against 340B pharmacies over the past decade will be perpetuated.”

To that end, PHPC requested that CMS include in its regulations language that would encourage PDP sponsors to include 340B pharmacies in their pharmacy networks. CMS has communicated that they are making efforts to educate both PDP sponsors and the Health Resources and Services Administration (HRSA) about partnership opportunities between covered entities and sponsors with respect to the Medicare drug discount cards, which will give way to the drug benefit in 2006.

PHPC raised similar concerns over the notion of “preferred pharmacies.”

According to the regulations, PDPs are authorized to extend reductions in co-payments or coinsurance for Part D drugs to beneficiaries who purchase drugs in “preferred pharmacies.”

While PHPC supports this notion, the Coalition argued in its comments that CMS must clarify this section to ensure that the criteria used to determine which pharmacies receive “preferred” status are not impossible for 340B pharmacies to meet.

PHPC’s comments also addressed a section of the regulations which claims that “CMS does not approve a bid [to administer the drug benefit] if it finds that the design of the plan and its benefits . . . are likely to substantially discourage enrollment by certain Part D eligible individuals under the plan.”

“The intersection of the 340B program and the new Medicare Part D drug benefit both raises concerns and creates opportunities [for covered entities].”

**William von Oehsen
Public Hospital Pharmacy Coalition**

According to PHPC’s comments, this section could potentially be interpreted in a way that would discourage the “co-branded” arrangements that have been established between drug card sponsors and some 340B entities, which PHPC hopes will carry over once the drug benefit begins.

A number of DSH hospitals and federally qualified health centers (FQHC) are currently partnered with drug card sponsors such that patients of the entities are able to enroll in a card program while still receiving 340B drugs from their 340B pharmacies. However, to avoid the potential for drug diversion, these arrangements are only acceptable under the 340B statute if the card program is exclusively offered to “patients” of the covered entity.

As a result, PHPC is concerned that the language in this section could be

“construed as prohibiting the co-branded partnership model” because it may be seen as discouraging enrollment of Medicare beneficiaries who are not eligible to receive 340B drugs.

While PHPC’s comments asked for further clarification on a number of issues, the comments submitted by NASTAD were more direct in their criticism of the proposed regulations.

NASTAD, an organization that represents the public health officials who administer state HIV/AIDS care and treatment programs, directly challenged CMS’s authority to offer guidance on how states should operate their ADAP programs.

“NASTAD feels it is completely inappropriate for CMS to use these proposed regulations to comment on the mechanics of a program that is not under its purview,” wrote NASTAD Executive Director Julie Scofield.

In particular, NASTAD’s comments were critical of CMS’s recommendation that ADAPs that purchase drugs under the 340B program convert from a rebate-based model—unique among 340B entities—to a direct purchase model (*The Monitor, September 2004*).

“Direct purchase ADAPs often have additional dispensing and distribution costs that also must be considered in the total cost when comparing these two purchasing mechanisms,” Scofield wrote. “ADAPs have and will continue to use every mechanism available to receive the best prices for their HIV-related drugs, including negotiating for supplemental rebates and discounts.”

NASTAD also argued that the demographics of the population being served, as well as a state’s health care and pharmacy infrastructure, could also serve as incentives to continue using the rebate model.

NASTAD added that state HIV/AIDS programs are looking for ways to create partnerships between ADAPs and PDPs to ensure that Medicare beneficiaries living with AIDS can acquire their drugs through 340B.

Manufacturers Challenge Plaintiffs' Right to File Suit

continued from pg. 1

their AIDS/HIV treatments (*The Monitor*, September 2004). The AHF suit differs from the Central Alabama case in a number of respects, including the fact that the AHF action targets a single manufacturer.

Defendants Challenge Claim

The original defendants in the Central Alabama suit have filed a motion to dismiss the case, as well as a supporting memorandum of law, mounting a number of challenges against the plaintiffs' legal and factual theories.

With respect to the "full accounting" requested by the plaintiff, the memorandum argues that such a remedy would force manufacturers to share confidential pricing data that is only available to HHS.

"To provide Covered Entities with precisely the audit remedy that Congress has chosen to extend only to manufacturers and HHS would be contrary to congressional intent," the memorandum states.

Regarding the OIG report, the memorandum states that the report does not identify the manufacturers or the providers included in the study, nor does it claim that manufacturers should necessarily be held responsible for the overcharges.

As a result, the manufacturers argue, the claim fails to demonstrate that the plaintiffs have suffered "an actual injury in fact" that is directly attributable to any particular manufacturers.

According to the defendants, "The

crux of Plaintiff's alleged injury here is that Plaintiff believes that it *may* be among a group of Section 340B providers that, according to a non-specific OIG Report, may or may not have paid more than the ceiling price for some unknown drugs manufactured by some unidentified pharmaceutical company or companies."

The defendants also claim that the suit should be dismissed because it implies that 340B entities have "a private

alleging.

In addition, the memorandum argues that the court should not hear the case because it should first be handled by the Health Resources and Services Administration (HRSA) in accordance with the 340B statute.

HRSA offers an administrative dispute resolution process for dealing with alleged 340B violations by which HRSA appoints a committee to address charges of program violations in cases where informal negotiations are unsuccessful.

According to the *Federal Register* notice that outlines the process, HRSA has the authority to either remove violators from the program or force guilty parties to reimburse their accusers. However, some have argued that funding and staffing shortages in the Office of Pharmacy Affairs (OPA) have limited the effectiveness of this process.

In a similar vein, the legal memorandum filed by the manufacturers also points out that the OIG and HRSA plan to follow up on the findings in the June 2004 OIG report, and argues that this should be allowed to take place before such a class action is heard by the court.

Finally, the memorandum challenges the notion that covered entities can sue for breach of contract. According to the memorandum, because the PPA contract is between the government and the manufacturer, covered entities do not have the authority to sue manufacturers as "third party beneficiaries" of the agreement.

**CENTRAL ALABAMA COMPREHENSIVE HEALTHCARE, INC.,
AND HEALTH SERVICES, INC.**

v.

AVENTIS PHARMACEUTICALS, INC., ET AL.

The plaintiff's complaint calls for the following:

- An full accounting of 340B prices by every defendant;
- An injunction against future overcharges;
- Coverage of legal fees and "further relief as the court may deem just and proper."

The defendants have filed a motion to dismiss, claiming that:

- The June 2004 OIG report on the 340B program did not identify which manufacturers and providers were included in the study, and therefore specific manufacturers can not be held responsible;
- The plaintiff does not have a "private right of action" under the 340B law and may not seek compensation from manufacturers for any alleged overcharges;
- The plaintiff is not a party to the Pharmaceutical Pricing Agreement, and therefore has no authority to sue for its enforcement.

right of action," e.g. the right to seek retribution for overcharges under the 340B statute. The memorandum argues that the 340B statute does not explicitly grant this right to covered entities and that it is incorrect to infer such a right. Therefore, the defendants contend that the entities have no legal right to seek recovery of the overcharges that they are



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OIG and Texas AG Call for Disclosure of AMP

The U.S. Department of Health and Human Services Office of Inspector General (OIG) and the Texas Attorney General's Office have recently called upon pharmaceutical manufacturers to make the Average Manufacturer Price (AMP) of their drugs, a key component in the 340B pricing formula, more widely accessible.

In a September 2004 study of the drug reimbursements paid by state Medicaid agencies, the OIG argues that the Centers for Medicare and Medicaid Services (CMS) should be required to provide states with each drug's AMP in order to help ensure that all states reimburse providers at similar levels.

The report's findings indicate a failure on the part of some state Medicaid agencies to accurately determine the appropriate reimbursement rates for drugs billed to Medicaid. According to the report, the primary reason for this failure is that the states do not have enough evidence to determine how much pharmacies have spent on the drugs in question.

"State price variation results from several factors, but fundamentally stems from States' lack of access to pharmacies' true acquisition costs," the report states, arguing that states would be better equipped to estimate acquisition costs if AMP were available to them.

"Currently, average manufacturer price data may represent the most accurate drug pricing data available to CMS," according to the report.

AMP represents the average price paid to a manufacturer by wholesalers for drugs distributed to retail pharmacies. The figure is calculated based on actual sales transactions between manufacturers and wholesalers. The Congressional Budget Office estimates AMP to be about 20% less than Average Wholesale Price (AWP) for more than 200 drug products frequently purchased by Medicaid recipients.

If this recommendation were to be implemented by CMS, states would also be better equipped to estimate the ceil-

ing price allowable under the 340B program, which is defined as the lesser of a drug's AMP - 15.1% or its Medicaid "best price" for brand name drugs and AMP - 11% for generics. Other discounts may also apply for brand name drugs if a manufacturer raises the AMP of a drug faster than the rate of inflation.

While AMP data would not enable states to determine the exact ceiling price for brand name drugs, it would allow them to calculate the ceiling price for generic drugs and create a "maximum price" for brand name drugs.

In their response to the report, CMS expressed concern with the recommendation to require AMP reporting, citing "issues associated with [AMP] confidentiality." Both AMP and "best price" are confidential under Title XIX of the Social Security Act.

Average manufacturer price is equal to the average price paid to manufacturers by wholesalers for drugs distributed by retail pharmacies.

CMS has also claimed that the data in the report includes "numerous flaws" and must be corroborated with the states before CMS will be willing to respond to the OIG's findings. For example, CMS points out that the report cites the average cost of a prescription for Prilosec as more than \$3,000, while the AWP of the drug is between \$125 and \$150 per prescription.

The report, which monitored the reimbursements paid by 42 states in FY 2001 for a group of 28 drugs, found that, on average, the highest paying state paid 477%, or \$200 per prescription, more than the lowest paying state for the drugs in the sample. If all states had issued reimbursements at the same rate as the lowest paying state for each drug, the Medicaid program could have saved more than \$86 million, the report states.

The estimates in the report revealed that most states varied by drug with respect to the reimbursements they paid.

However, the report found that New York and New Jersey tended to pay the highest prices, while Texas and Michigan paid the lowest.

The AMP recommendation is one of many included in the OIG report in an effort to encourage CMS to help states improve their ability to accurately estimate the acquisition costs of pharmacies.

OIG recommends that CMS conduct further research on the factors that determine a state's drug prices, including its estimated acquisition cost formula, usual and customary charges, and maximum allowable costs. The report also suggests that CMS review state drug prices annually and provide technical assistance to those states with the highest reimbursement rates.

Texas AG May Go After AMP

On the legal front, the Texas Attorney General's Office is currently considering the option of pursuing lawsuits against manufacturers that do not disclose the AMP of their drugs in accordance with a Texas state mandate.

At a recent conference on the Medicaid Drug Rebate Program hosted by the International Institute for Research, Texas Assistant Attorney General Cynthia O'Keefe told pharmaceutical representatives to "Go back and tell your company that they need to immediately start complying with this requirement."

According to the mandate, which was adopted in April 2002, manufacturers must provide the Texas Health and Human Services Commission with AMP data for all drugs that are listed on the state's Medicaid drug formulary. The data, once submitted, can only be disclosed for enforcement purposes.

Currently, only one-third to one-half of all manufacturers have complied with the mandate, said O'Keefe, adding that the penalty for noncompliance could come in the form of a temporary or permanent injunction or a fine.

VA Agrees To Offer FSS Reporting Exemption on Generic and OTC Drugs

The Department of Veterans Affairs (VA) has agreed to allow pharmaceutical manufacturers to exclude the sale of 340B inpatient generic and over-the-counter (OTC) drugs from their Federal Supply Schedule (FSS) reporting, following a request by the Public Hospital Pharmacy Coalition (PHPC).

As a result, manufacturers may now offer 340B discounts on inpatient generic and OTC drugs without affecting the prices that they are required to provide to FSS customers.

This shift in policy comes less than three months after VA agreed to grant a voluntary exemption for brand name inpatient 340B drugs from non-Federal Average Manufacturer Price (non-FAMP) calculations.

These two developments, along with a provision in the Medicare Modernization Act (MMA) that extended the Medicaid “best price” exemption to 340B inpatient drugs, have made it less costly for manufacturers to offer 340B discounts on inpatient drugs to disproportionate share hospitals (DSH).

Currently, manufacturers are not required to offer 340B pricing on inpatient drugs, and many had argued in the past that doing so would force them to lower their prices in a number of other markets.

According to the new policy, “manufacturers who agree to sell gener-

ics and ‘OTC’ products at 340B prices to all 340B DSHs for their inpatient purposes” may exclude these sales from the reporting required by the FSS Commercial Sales Practice Sheets and the Price Reduction Clause.

Much like the non-FAMP exemption, the FSS exemption requires that manufacturers offer 340B pricing to all covered entities, and the exemption does not apply to sales at prices below the 340B ceiling price.

In order to acquire the exemption, manufacturers must first contact VA to request a “hold harmless” letter by submitting a written request declaring that they agree to sell generic and/or OTC drugs to all DSH hospitals at the 340B ceiling price.

Whether generic or OTC manufacturers will be able to select which of their drugs will receive the exemption is a question that still must be answered.

The “Dear Manufacturer Letter” that explained the non-FAMP exemption specifically stated that manufacturers could only receive an exemption if they agreed to offer 340B pricing on “either all of its commercially marketed inpatient covered drugs or specified covered drug product lines,” in which case it is necessary to extend the pricing to all marketed NDC packages of the line.

The FSS exemption letter, on the other hand, offers what seems to be a

more flexible policy for manufacturers. According to the letter, a manufacturer must declare that it has “committed itself to sell *certain* ‘OTC’ and/or generic inpatient drugs to all 340B DSHs at 340B ceiling prices” (emphasis added).

The request for a “hold harmless” letter must contain the same information that is required in requesting a non-FAMP “hold harmless” letter (*The Monitor, August 2004*). A sample request letter, as well as other related materials, can be found on the PHPC website at www.phpcrx.org/Inpatient_July04.html.

VA’s National Acquisition Center (NAC) communicated its latest change in policy on September 24 in a letter to PHPC’s William von Oehsen.

PHPC had written to VA on August 23 arguing that the agency should not treat generic and OTC drugs differently from brand name drugs with respect to the 340B program. PHPC also suggested that VA release a “Dear Manufacturer Letter” to announce the new policy.

While VA will not be announcing the policy in a “Dear Manufacturer Letter” or issuing a sample request for a “hold harmless” letter, as they did when announcing the non-FAMP exemption, VA Director of FSS Service Carole O’Brien said that the letter to PHPC was to be distributed at NAC’s October Industry Conference and that PHPC may distribute the letter as well.



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