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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Jury Indicts Director of Program Utilizing 340B Discounts

Physician Charged With Illegally Distributing Discounted Drugs

IN THIS ISSUE

A federal grand jury has issued an indictment charging the director of a controversial program that worked closely with a 340B entity in Aliquippa, PA with illegally distributing 340B-discounted drugs without a wholesaler's license.

If found guilty, Physician Medicine Assist Program (PMAP) Director Dr. Joseph Rudolph could face up to ten years in jail or $250,000 in fines, depending on the seriousness of the offense and prior criminal history, if any, of the defendant, according to the U.S. Attorney's Office for the Western District of Pennsylvania.

> ***"The oncology centers that received these drugs had no relationship with Aliquippa Community Hospital or with its patients."***
>
> **Mary Beth Buchanan**
> **U.S. Attorney**

The one-count indictment, filed on January 3, specifically alleges that, from January 2004 to August 2005, Dr. Rudolph purchased 340B-priced drugs from pharmaceutical manufacturers and illegally distributed these drugs through the PMAP program—which was affiliated with Aliquippa Community Hospital (ACH) in Aliquippa, PA—to oncology clinics around the country.

"Federal law prohibits the wholesale distribution of prescription medications without a license," the U.S. Attorney said in a news release. "The indictment alleges that Dr. Rudolph was distributing these medications without such a license."

The indictment states that this behavior is a violation of the Prescription Drug and Marketing Act, which governs the marketing and distribution of prescription drugs in interstate commerce.

In addition to this alleged violation, U.S. Attorney Mary Beth Buchanan says that the indictment also charges Dr. Rudolph with violating the terms of the 340B program.

"[This behavior] completely undermines the purpose of the 340B program," Buchanan told *The Monitor*, adding that the oncology clinics that purchased the drugs from the PMAP program "had no relationship with Aliquippa Community Hospital or with its patients."

Dr. Rudolph is currently free on bond awaiting his arraignment, according to Buchanan. At the arraignment—scheduled for January 24—he will be presented with the government's evidence and may then file any procedural motions before his trial.

"An indictment is only a charge and is not evidence of guilt," Buchanan's office said in a statement. "A defendant is presumed innocent and is entitled to a fair trial at which the government must prove guilt

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Budget Bill Would Bring Major Changes in Medicaid Pharmacy Law

Along with specific changes to the 340B and Medicaid drug rebate programs, the budget reconciliation bill that is currently being considered by Congress includes a number of other measures that could affect the way that 340B providers and pharmaceutical manufacturers do business.

Last month, both the House of Representatives and U.S. Senate passed a compromise budget bill that includes prescription drug proposals made by both chambers. However, due to a procedural issue raised by Democrats on the Senate floor, the bill was ordered back to the House for a second vote.

The bill, which was narrowly approved by the House in a 212-206 vote last month, is expected to pass once a vote is held, despite efforts by some Democrats to garner Congressional support to defeat the legislation.

The House will reconvene on January 31 and is tentatively scheduled to vote on the measure on February 1.

As reported in the December issue of *The Monitor*, the compromise bill includes a number of provisions that would directly impact the 340B community. In particular, the bill would allow freestanding children's hospitals to participate in the program and change the way that manufacturers are required to calculate Medicaid rebates and 340B prices for drugs with "authorized generics" (The Monitor, December 2005).

However, a closer look at the bill reveals that there are a number of additional measures that could have an impact on 340B stakeholders and the relationship between the program and the rest of the pharmaceutical market.

Medicaid Pharmacy Reforms

Perhaps the most controversial pharmacy measures in the bill relate to changes in the Medicaid reimbursement system. As reported last month in *The Monitor*, the bill would eliminate the Average Wholesale Price (AWP)-based reimbursement system and create a new benchmark based on Average Manufacturer Price (AMP). The bill would also allow states greater flexibility in determining co-pays and cost sharing (*The Monitor*, December 2005).

The compromise budget bill must be passed by the House for a second time.

The retail and chain drug store industries have raised significant concerns about whether they will be able to continue serving Medicaid patients in light of these payment reductions.

The bill would also increase the maximum cost-sharing amounts that states are allowed to charge for various services. For instance, one measure would allow states to maintain preferred drug lists and increase current cost-sharing amounts for Medicaid patients who purchase drugs that are considered "non-preferred."

Specifically, the ceiling for state-imposed cost-sharing amounts would remain the same for individuals in families with incomes at or below 150% of the federal poverty level (FPL), while the ceiling would rise to 20% of the cost of the drug for those in families above 150% of the FPL.

Similarly, one section of the bill would permit states to impose a higher cost-sharing burden for non-emergency services performed in emergency rooms.

These options would be available to state governments as of January 1, 2007.

Greater Transparency of Pricing

The bill also includes significant measures that would increase the transparency of pricing information for both

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Budget Bill Could Lead to Changes in Nominal Pricing, More Lawsuits

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states and the general public.

Currently, a manufacturer is required to report the AMP and best price of any drugs covered by Medicaid to the Centers for Medicare and Medicaid Services (CMS) on a regular basis.

This information is considered confidential "except for the purpose of carrying out the requirements of Medicaid rebates" or unless the data is requested by certain government agencies for an investigation.

The compromise budget bill takes a number of steps to increase the accuracy and availability of this information. First, the bill would require manufacturers to report their AMP and best price data to CMS on a monthly basis and allow states to access this data for all covered outpatient drugs.

In addition, the Secretary of the Department of Health and Human Services (HHS) would be required to disclose AMP data on a website that is accessible to the public, which would be updated by the agency on a quarterly basis.

This provision would make AMP available to the public for the first time and could provide the 340B community with a tool for assessing whether they have been overcharged.

Because 340B prices cannot exceed a minimum discount off of AMP—15.1% for brand name drugs and 11% for generics—publicly available AMP data would allow covered entities to determine the maximum price that they could be charged by manufacturers under the 340B program. (Best price data would not be available to the public.)

Nominal Pricing Under Fire

Included in the bill is a provision that would discourage manufacturers from offering drugs to its private customers at nominal prices by requiring manufacturers to include these prices in their best price calculations.

As a result, manufacturers would be forced to either cease offering these deep discounts to private purchasers or make these prices available to the Medicaid and 340B programs.

Under current law, manufacturers are permitted to offer discounts of 90% or more off of a drug's AMP to any purchasers without disclosing these sales to the government or making these prices available to Medicaid. This provision, passed in 1990, was designed to encourage manufacturers to offer deep discounts to charitable organizations.

However, nominal pricing has come under scrutiny from the federal government over the last few years in light of accusations that manufacturers have offered these discounts to certain private purchasers—including hospitals, health maintenance organizations (HMO), and others—in exchange for guaranteed market share. In fact, according to press accounts, GlaxoSmithKline and Merck have both been involved in legal actions this year related to nominal pricing

The budget bill would provide the public with access to AMP data for the first time and could threaten nominal pricing for private purchasers.

As a result, the bill seeks to reign in nominal pricing to ensure that it is only exempt from best price and AMP for those entities that serve as safety net providers. In particular, the budget bill's proposed limitations on nominal pricing exempts four groups from the best price reporting requirement, including 340B entities and three other safety net groups.

Since 340B facilities already receive best price and AMP exemptions, it is unclear whether the new 340B exemption for nominal pricing is intended to apply to a wider range of drugs than those currently covered.

New State Whistleblower Laws Likely

The bill also includes a proposal—from the Senate's budget bill—designed to encourage states to develop their own qui tam laws, which would allow these states to file Medicaid rebate fraud suits brought by corporate "whistleblowers."

Under the federal False Claims Act, whistleblowers are entitled to a percentage—between 15% and 30%—of any settlement between the federal government and a manufacturer that has allegedly committed rebate fraud. However, only 13 states and the District of Columbia currently have their own qui tam laws on the books that whistleblowers to receive a share of the state settlement amounts as well.

If passed, the bill would create financial incentives for states to pass their own whistleblower laws if they are not already on the books. The reasoning behind this provision is that these incentives will encourage potential whistleblowers to expose cases of Medicaid rebate fraud and lead states to be more vigilant in combating fraud and abuse.

According to press reports, officials from the Department of Justice (DOJ) have expressed concerns about this measure because it could lead to cases being filed before the federal government has had an opportunity to fully investigate charges of fraud.

Nonetheless, if these measures are successful in increasing the number of Medicaid rebate fraud lawsuits filed by states, 340B covered entities could potentially see more refunds for alleged 340B overcharges.

Over the past few years, 340B entities have consistently received additional refunds in federal settlements related to misrepresentations of a drug's best price and AMP information.

In fact, a U.S. Attorney told *The Monitor* in November that the DOJ has pursued and will continue to pursue 340B recoveries in all such cases (*The Monitor,* November 2005).

IN FOCUS

340B ENTITIES GRAPPLE WITH MEDICARE PART D

Part D Benefit Launched Amidst Some Confusion

The Medicare Part D program—the first comprehensive prescription drug benefit available to Medicare beneficiaries—was officially launched this month as federal officials began to take stock of their enrollment efforts and plan for the program's future.

According to various reports, reaction to the implementation of the new benefit has been mixed. Pharmacists have expressed frustration with the accessibility of both Medicare representatives and the Part D plans, though some believe that the computer glitches and long waits to reach Medicare by phone are simply growing pains.

"The number is occasionally busy, and once you can get through you are easily on hold in queue for 15 minutes," says Lucy Wells, Assistant Director of the Kentucky Clinic Pharmacy at the University of Kentucky, referring to Medicare's help line for pharmacists. "But you do get to talk to someone who can give you helpful information."

There have also been further delays because some enrollees have not yet received their confirmation letters or ID cards from their respective plans, either of which can be used as proof of enrollment. In these cases, pharmacies have been forced to manually research the status of these "last-minute" Part D enrollees.

Earlier this month, the Centers for Medicare and Medicaid Services (CMS) issued a letter to Part D plans calling for immediate improvements in a number of areas including customer service and communication with their network pharmacies.

The agency has also convened a series of conference calls for pharmacists treating Part D enrollees. The purpose of the calls is to discuss implementation of the program and to assist pharmacists with new procedures for processing prescriptions for Medicare Part D beneficiaries.

The CMS website also features a document that outlines how pharmacists should address a number of "What If" scenarios that could arise.

After hearing complaints from Medicare beneficiaries and pharmacies, President Bush issued a directive that requires Part D plans to take "immediate steps" to ensure that low-income enrollees do not pay more than $2 for generic drugs and $5 for brand names.

Medicare Part D Enrollment
(as of Jan. 13, 2006)

Stand-Alone plans:	***3.6 million***
Dual Eligibles:	***6.2 million***
Medicare Advantage:	***4.7 million***
Retiree Coverage:	***5.9 million***
Federal Retirees:	***3.1 million***

Source: CMS

Meanwhile, a number of states have also stepped up to offer assistance to enrollees that are having difficulty utilizing their drug plans. For instance, Vermont Governor Jim Douglas (R) has said that his state will pay drug claims for low-income residents until the problems in the Part D program are fixed.

Similar steps have also been taken by governors and state legislatures in Massachusetts, Connecticut, North Dakota, New Hampshire, and other states.

Yet beyond these logistical issues, pharmacists have also reported a significant amount of confusion among new enrollees. Some of this confusion can perhaps be explained by the composition of the 21 million individuals currently enrolled in the program.

The three largest groups of Part D participants—"dual eligibles," retirees whose employers receive a subsidy from Medicare, and Medicare Advantage (MA) patients—are composed of individuals who have not actively enrolled in stand-alone Part D plans, which means that they may not be as knowledgeable about their coverage as those who have voluntarily selected a stand-alone plan.

According to the Centers for Medicare and Medicaid Services (CMS), the largest group of enrollees is the "dual eligible" population, which is made up of individuals who are transitioning from Medicaid to Medicare drug coverage. CMS began assigning these individuals to Part D plans on November 15.

Pharmacists and advocacy groups expressed concern before the program was launched that these individuals may not be aware of the plans to which they have been assigned, a prediction that appears to be playing out in pharmacies.

"With rare exception, the dual eligibles have no idea which plan they have been auto-enrolled in," says Wells. "However, these patients overwhelmingly know that Medicare is paying for their prescriptions."

According to Wells, many of the dual eligibles utilizing her pharmacy claim that they did not receive a letter assigning them to a plan or did not keep that information.

This issue has been further complicated by reports that CMS and Part D plans have failed in some cases to prop-

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IN FOCUS
THE FUTURE OF RX PATIENT ASSISTANCE PROGRAMS

PAP Programs Consider Ways to Continue Helping Medicare Beneficiaries

As low-income Medicare beneficiaries begin to receive coverage under the new Medicare Part D drug benefit, some pharmaceutical manufacturers are looking for ways to continue offering assistance to this population through their patient assistance programs (PAP) without running afoul of various federal fraud and abuse laws.

On November 7, the U.S. Department of Health and Human Services Office of Inspector General (OIG) issued a Special Advisory Bulletin to manufacturers that explains the ways in which PAP programs will have to be altered in order to continue providing assistance to Part D enrollees.

The guidance also offers potential models that manufacturers can utilize in the future and assures PAPs that they may continue to provide assistance to Medicare beneficiaries that do not receive drug coverage under Part D. (For more on the guidance, see *The Monitor*, November 2005.)

Although the guidance provides manufacturers with a certain degree of flexibility in operating their PAPs, questions still remain about the future of PAPs and how manufacturers will adjust their programs to continuing providing assistance to Medicare beneficiaries both within and outside of Part D.

To that end, a group of nine national and regional organizations representing providers that care for the low-income population sent letters to 14 manufacturers on January 4 asking them to continue providing assistance to Medicare beneficiaries not enrolled in Part D and to explore ways to assist Part D enrollees.

The group—which includes the Association of Clinicians for the Uninsured, the National Association of Free Clinics, Free Clinics of the Great Lakes Region, the Public Hospital Pharmacy Coalition, MedBank of Maryland, , Senior PHARMAssist, Medicine for People in Need, Volunteers in Health Care, and the National Association of Community Health Centers—specifically asks manufacturers to continue providing assistance to non-Part D beneficiaries at least until the end of the Part D initial enrollment period.

According to the letter, this step would allow seniors to continue receiving assistance while they evaluate their options under Part D.

The letter further encourages the manufacturers to explore the options suggested by OIG for continuing to assist Part D enrollees that do not qualify for low-income subsidies or other forms of additional assistance.

Some manufacturers have agreed to continue offering PAP assistance to Medicare beneficiaries not enrolled in Part D.

"Although the OIG has raised concerns with *today's* manufacturer PAPs assisting Part D enrollees, we are encouraged that the OIG has laid out several ways in which manufacturers can restructure their PAPs to assist Part D enrollees while complying with federal fraud and abuse laws," the letter states.

Manufacturers Respond to Guidance

Following the November guidance, a number of manufacturers have already agreed to continue providing assistance to Medicare beneficiaries not participating in Part D while encouraging these individuals to enroll in the program.

For instance, the AstraZeneca Foundation PAP has launched a campaign to educate its PAP patients about the Part D program while continuing to provide free drugs to non-enrollees until the expiration of the open enrollment period, which ends on May 15.

"We are trying to educate the patient population about their options in Medicare," says Sean Dougherty, AstraZeneca's Senior Director of Medicare Strategy and PAPs.

Dougherty says that AstraZeneca has offered assistance in enrolling for low-income subsidies, developed a help line dedicated entirely to Medicare questions, and issued mailings to PAP beneficiaries outlining their options in the Part D program.

"The majority of our patients qualify for the low-income subsidy," says Dougherty, adding that Part D coverage will be more valuable to these patients than their drug-specific PAPs. "Patient assistance is not a long term solution for these individuals."

Eli Lilly has taken a similar approach with its Lilly Cares Program. Individuals participating in Lilly Cares will be eligible to receive free drugs through the program until May 1 unless they choose to enroll in a Part D plan, according to a letter sent by Eli Lilly to patient advocates.

With an eye towards the long term future, Dougherty says that AstraZeneca is looking at ways to provide assistance to Part D enrollees currently enrolled in their PAPs who do not qualify for low-income subsidies.

In particular, AstraZeneca has been in discussions with other manufacturers about collaborating on an effort to provide assistance for low-income patients in the "donut hole," the range of spending where Part D enrollees are responsible for 100% of their drug costs.

"That gap in coverage is our key concern," says Dougherty, adding that his organization will also begin to look at other populations that may need drug assistance.

U.S. Attorney Charges PMAP Director With Illegal Distribution of 340B Drugs

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beyond a reasonable doubt."

According to the indictment, the particular drugs in question include Procrit, Vidaza, Gemzar, Taxotere, Anzement, Epogen, Avastin, Herceptin, Rituxan, Aranesp, Neulasta, Neupogen, and Zometa.

The investigation that led to the indictment was jointly conducted by the Federal Bureau of Investigation (FBI), the Department of Health and Human Services Office of Inspector General (OIG), and special agents of the Food and Drug Administration (FDA), according to the U.S. Attorney. Details of the investigation are not available.

The PMAP Program

The PMAP program—administered jointly by Dr. Rudolph and Family Professional Center, PC—has been operating in Pittsburgh since 2001, at which point the program obtained its drugs through a Canadian distributor. According to the PMAP website, the program assists patients in "obtaining free, low cost, or discounted medications."

In a 2002 interview with *Physician's News Digest*, Dr. Rudolph—who has run for a number of political offices in Pennsylvania including U.S. Congress, state Senate, and county council—said that he founded the program as a way to assist particular individuals with accessing affordable drugs.

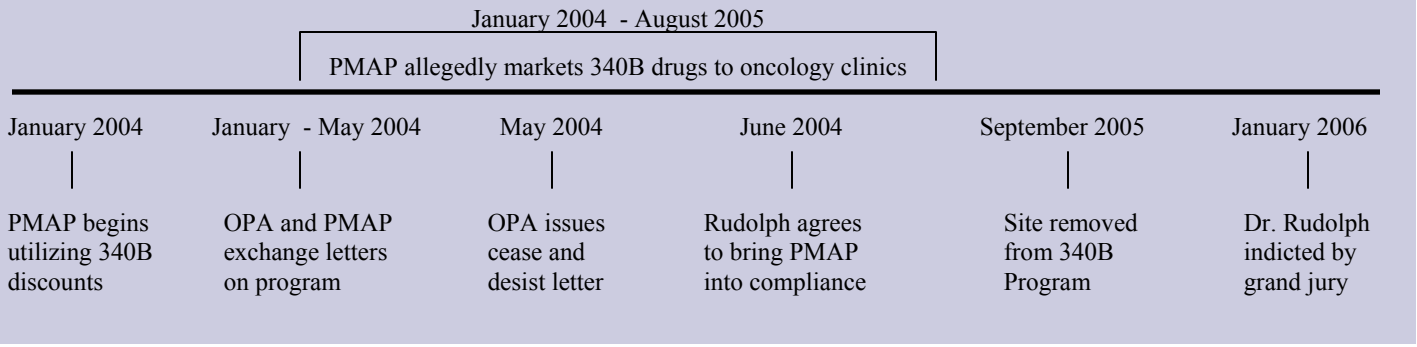
that were ordered by the physician and then "send the patient's order to a wholesaler in Canada."

In January 2004, the PMAP program ended its relationship with its Canadian supplier and began distributing discounted drugs purchased through the 340B program, according to the U.S. Attorney.

In fact, Dr. Rudolph told the *Pittsburgh Post-Gazette* in March 2004 that he was altering his program to focus on helping individuals find discounted drugs in the United States through various programs.

Under this new initiative, the PMAP program first affiliated itself with ACH, a registered 340B facility.

A History of PMAP and 340B



The PMAP program was run out of a disproportionate share hospital (DSH) site called ACH Oncology Centers, which was listed in the Office of Pharmacy Affairs (OPA) database as having entered the 340B program in January 2004 as part of the ACH system.

As reported in *The Monitor*, this particular site was deemed ineligible for the program by OPA in September 2005, at which point the site was listed in the OPA database as "not participating." OPA Director Jim Mitchell told *The Monitor* at the time that the site was removed because it was not listed on ACH's Medicare cost report (see *The Monitor*, September 2005).

"There are three primary groups that we deal with: those who do not have insurance, those who do not have full coverage under their insurance program such as a Medicare HMO, and those who are underinsured," Dr. Rudolph said in the interview.

He also described the process by which the program operated in its infancy. According to Rudolph, patients who applied for the program were required to have each of their prescriptions approved by their family physician before participating in PMAP.

Once an individual was approved to participate, Rudolph said that he would make any changes to the prescriptions

Under the new program, individuals who received permission from their primary healthcare providers were eligible to pay a $30 fee in exchange for a "pharmacological consultation" with a PMAP doctor. Following this consultation, the PMAP program would dispense 340B-discounted drugs to these patients through Family Professional Care, PC.

According to correspondence between OPA and PMAP, the program distributed 340B-discounted drugs to patients both within Pennsylvania and in other states. The *Post-Gazette* reported in June 2004 that the PMAP program had delivered medications to 38 patients

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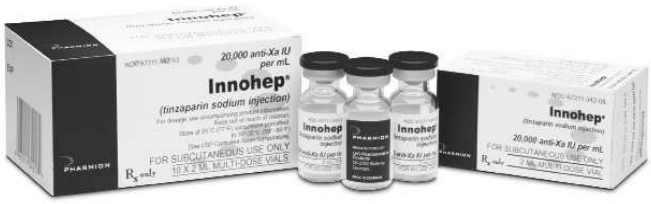

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340B Hospital Group Reacts to Indictment

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in South Dakota following pharmacological consultations performed over the telephone.

The PMAP program's new efforts first attracted the attention of OPA when the *Post-Gazette* and others published a number of articles on the 340B and PMAP programs, prompting OPA Director Jim Mitchell to contact Dr. Rudolph directly to seek more information on the program.

After months of correspondence between OPA and PMAP, in which Dr. Rudolph argued that his program was consistent with the 340B program' requirements, OPA Director Jim Mitchell issued a letter to ACH CEO Anthony Puorro on May 27, 2004 ordering the hospital to "cease and desist" the PMAP program's 340B-related activities and to bring the program into compliance with the 340B program's patient definition guidelines (For more on this correspondence, see *The Monitor,* July 2004).

Dr. Rudolph agreed to take steps to bring his program into compliance with the 340B program, though he raised hackles once again in 2005 when he allegedly began proposing contracts to freestanding cancer clinics offering access to 340B drugs (For more, see *The Monitor*, September 2005).

It was at this point that federal officials began to step up their investigation of the PMAP program, and the ACH Oncology Centers were removed from the 340B program just months later.

The Public Hospital Pharmacy Coalition (PHPC), an organization that represents most of the disproportionate share hospitals in the 340B program but does not include ACH, has repeatedly raised concerns over possible misuse of the program by PMAP and has expressed those concerns in letters to the Health Resources and Services Administration (HRSA).

"PHPC and its member hospitals take seriously the anti-diversion requirements of the 340B program and believe this is an isolated case," says PHPC General Counsel William von Oehsen. "We will continue to work closely with the government to ensure that the program is not undermined."

According to von Oehsen, PHPC has published detailed principles for complying with the 340B definition of patient, recommended that government guidance be clarified, and ramped up its educational efforts in an effort to ensure that its hospitals do not expose themselves to the possibility of violating the 340B program guidelines.

Neither Dr. Rudolph nor ACH CEO Anthony Puorro returned requests for comments for this story.

Federal Government Working to Address Confusion in Medicare Part D

erly notify pharmacies as to which enrollees are eligible for subsidies.

To address this problem, CMS has taken steps to ensure that these individuals continue to receive their current drug coverage for a limited amount of time until they have enrolled in a plan that suits them. (For more on these efforts, see *The Monitor*, November 2005.)

The second largest group of program participants is composed of retirees who will benefit from an employer subsidy, under which the federal government will provide additional funds to support the existing coverage that individuals receive under their private retirement benefits package.

The third major class of enrollees, according to CMS, includes those who will receive Medicare drug coverage through MA plans. Many of these individuals were enrolled in these plans before the introduction of the Part D benefit. There are currently more than five million of these individuals, including approximately 600,000 dual eligibles, according to CMS.

That leaves approximately 3.6 million Medicare beneficiaries who have voluntarily chosen to enroll in standalone plans as of January 13, according to CMS. The agency predicts that additional beneficiaries will be enrolled by the end of January as CMS moves towards its goal of enrolling 28-30 million beneficiaries by the end of this year.

"Interest in the drug coverage is strong, and these numbers do show that people are getting questions answered and making decisions," said Secretary of Health and Human Services Michael Leavitt.

> ***"With rare exception, the dual eligibles have no idea which plan they have been auto-enrolled in."***
>
> **Lucy Wells**
> **University of Kentucky**

Final Subsidy Rule Released

The Social Security Administration (SSA) released its final rule on the eligibility requirements for Part D subsidies on December 30 amidst reports that a majority of applicants have failed to qualify for this extra help.

The final rule codifies the criteria for determining whether Medicare beneficiaries are eligible for "extra help" under the Part D program. These subsidies are designed to assist individuals that meet both income and assets tests and who are not dual eligibles.

The subsidies can be used to help cover the cost of the premiums, copayments, and deductibles required of these individuals. (For a detailed look at the low-income subsidies, see *The Monitor*, December 2004.)

The final rule, which is based on proposed guidelines released in March, was published in the December 30 issue of the *Federal Register*.

The rule states that beneficiaries must be enrolled in a Part D plan by the end of the enrollment period—May 15, 2006—in order to qualify for these subsidies. SSA plans to review the eligibility status of all individuals receiving extra help within the first year of enrollment to ensure that they are indeed eligible for the subsidies they receive.

According to data provided by SSA, the agency has received 4.1 million applications for low-income subsidies. With 87% of the applications reviewed, only 1.1 million individuals have been approved for the extra help. The remaining 2.5 million were rejected by SSA because they failed the income and/or assets test.

Manufacturers Seek to Dismiss 340B Class Action Lawsuit

A group of pharmaceutical manufacturers is seeking to dismiss a lawsuit brought by Santa Clara County which claims that these manufacturers have overcharged California's public hospitals and community health centers (CHC) for drugs purchased under the 340B program.

The suit, which was recently removed from California State Superior Court in Alameda County to the United States District Court in the Northern District of California in San Francisco, was originally filed in August 2005.

Santa Clara filed the case as a putative class action seeking to represent all cities and counties in California that support 340B facilities.

In its complaint, Santa Clara seeks a court-ordered "accounting" of the defendants' 340B prices based on the results of two reports released by the U.S. Department of Health and Human Services Office of Inspector General (OIG) in March 2003 and June 2004.

The plaintiff also contends that the defendant manufacturers violated a state consumer protection law by not providing the county's facilities with appropriate 340B pricing. Santa Clara's state law claim is the first of its kind to be made in 340B litigation (see *The Monitor*, September 2005).

Specifically, the complaint asks the court to order an accounting of the manufacturers' 340B prices to determine the extent of overcharges. If overcharges are identified, the complaint further asks that the court award damages of two to three times the amount of actual damages sustained by Santa Clara and the other cities and counties that operate 340B entities in California.

On January 3, the defendants filed a motion to dismiss the lawsuit, arguing against both the appropriateness of ordering an accounting of manufacturer pricing data and the state law claim raised by the plaintiff.

The defendants' motion argues that the June 2004 OIG report—which estimated $41.1 million in overcharges for a single month—did not identify individual manufacturers as having overcharged 340B entities and therefore provides no basis for a legal claim against the defendants.

"The June 2004 report mentions no specific manufacturer, no specific drug, and no specific California 340B entity (or any entity)," the motion states.

The motion further points out that the June 2004 report was withdrawn by OIG after acknowledging that there were a number of problems with the underlying data used to determine the overcharge estimates.

Since that time, OIG has announced its intention to release a report later this year that will effectively replace the June 2004 report and explore potential causes of any overcharges that are discovered.

> ***"This is a court that looks forward to getting to the merits of the case and getting to them quickly."***
>
> **Jacqueline Mottek**
> **Lerach Coughlin, LLP**

"OIG has stated that until it sorts out the data issues that caused the withdrawal of the June 2004 report, it cannot even determine *if* there have been overcharges in the 340B program," the motion contends.

The defendants further argue that because the 340B program is governed by federal law, the state law claim made by the plaintiff does not apply. Accordingly, the manufacturers argue that the investigations currently being conducted by HHS must be allowed to be pursued to their completion.

"The federal government created the discount program, the federal government governs all terms of participation in the 340B program, the federal government exclusively controls oversight of the discounting scheme, and the federal government administers the penalties for 340B program violations," the motion states.

The motion further argues that the particular state law in question—the Unfair Competition Law (UCL)—is not applicable in this case because the plaintiff does not qualify as a "person" under that law.

In addressing the plaintiff's call for an accounting, the arguments made by the defendants are similar to those raised by defendants in a suit filed in federal court in Alabama in 2004. (The motion to dismiss filed in the Alabama suit was denied by a federal judge in September. For more information on this suit, see *The Monitor*, October 2005).

The defendants argue that the plaintiffs are not entitled to an accounting—which would require disclosure of confidential manufacturer pricing information by each defendant—simply to determine whether overcharges have occurred in the first place.

In addition to the motion to dismiss filed on behalf of all the defendants, GlaxoSmithKline (GSK) filed a supplemental motion that advances an additional legal theory.

According to the GSK claim, the statute of limitations—the amount of time that a plaintiff has to file a complaint after an alleged injury has occurred—has already expired on the plaintiff's claims related to the OIG's reports on best price violations.

Jacqueline Mottek, an attorney representing Santa Clara in the case, calls the defendants' motion "particularly weak" and says that she is confident the judge will deny the motion to dismiss in its entirety and allow the case to move forward to the discovery phase.

"This is a court that looks forward to getting to the merits of the case and getting to them quickly," she says. "That's exactly what I think will happen."

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