

## WHY MEDICAID PAYS TOO MUCH FOR ITS #1 EXPENSE

### I. Introduction

Florida provides a prescription drug benefit for Medicaid beneficiaries, which is not required by federal law in order for states to participate in the Medicaid program. By choosing to offer prescription drugs to beneficiaries, the state takes advantage of receiving matching federal matching funds (in Florida, almost 60% this year).<sup>1</sup> Florida is not alone in offering such a benefit; all states provide some form of prescription drug benefit.

The impact on the Medicaid program, and consequently Florida's budget, has been increasingly burdensome. It recently became the number one expense for Medicaid, surpassing inpatient hospital care and nursing home expenses. Overall, Florida's Medicaid has grown 12% annually over the past six years on average.<sup>2</sup> State spending on prescription drugs, however, has increased by an average of 31% over the past four years.<sup>3</sup>

Currently, the Medicaid budget is almost \$15 billion dollars for fiscal year 2004-05; the budgeted expense for prescription drugs over \$2.6 billion dollars,<sup>4</sup> which covers 2.2 million beneficiaries and 38.8 million prescriptions.<sup>5</sup>

The Florida Governor's Office and various legislative committees are currently discussing transforming the entire Medicaid program in an attempt to stem the tide of Medicaid's impact on Florida's budget. Based upon the recent presentations by AHCA, there appear to be outstanding questions with respect to prescription drugs, namely whether drugs will be covered under the premium-based benefit package that would be offered by health care providers in the Governor's plan, or whether the State would reimburse the pharmacies directly, as it currently does. In fact, the Governor's website containing his proposal reform does not even mention prescription drugs.<sup>6</sup>

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<sup>1</sup><<http://aspe.os.dhhs.gov/health/fmap05.htm>>.

<sup>2</sup><<http://www.theledger.com/apps/pbcs.dll/article?AID=/20050112/NEWS/501120346/1023/LIFE02>>; <<http://www.empoweredcare.com>>.

<sup>3</sup>Mark Hollis, *Bush Plan Limits Medicaid Patients to Least Costly Prescription Drugs*, Sun-Sentinel, Jan. 26, 2005, at 1B.

<sup>4</sup><[http://www.fdhc.state.fl.us/Medicaid/deputy\\_secretary/recent\\_presentations/proposed\\_framework\\_for\\_modernization\\_012605\(senate\).pdf](http://www.fdhc.state.fl.us/Medicaid/deputy_secretary/recent_presentations/proposed_framework_for_modernization_012605(senate).pdf)>; <[http://www.fdhc.state.fl.us/Medicaid/medicaid\\_reform/docs/fl\\_medicaid\\_a\\_case\\_for\\_modernization\\_0712041.pdf](http://www.fdhc.state.fl.us/Medicaid/medicaid_reform/docs/fl_medicaid_a_case_for_modernization_0712041.pdf)>.

<sup>5</sup><[http://www.fdhc.state.fl.us/Medicaid/medicaid\\_reform/docs/workshop\\_options\\_100504.pdf](http://www.fdhc.state.fl.us/Medicaid/medicaid_reform/docs/workshop_options_100504.pdf)>.

<sup>6</sup><<http://www.empoweredcare.com>>.

While the impact of these reforms, if successful, is unclear with respect to prescription drug costs, if prescription drug expenditures are not reduced, the state will undoubtedly look to cut other necessary programs.

## II. The Current Drug Reimbursement Formula

Florida directly reimburses pharmacies for filling Medicaid prescriptions.<sup>7</sup> The federal government does not prescribe a universal method for states to reimburse pharmacies. States are generally required to reimburse based upon providers' "estimated acquisition cost," (EAC) which is defined as the cost of the drug to the pharmacies. States then get to determine a method of calculating the EAC. The state, in theory, is supposed to then reimburse the pharmacy for its cost (the EAC), and pay an additional "dispensing fee" (in Florida, currently \$4.23 for pharmacies and \$4.73 for nursing homes), which is supposed to represent the pharmacy's profit. In reality, the business partnership between the pharmacies and pharmaceutical companies do much better financially than this straightforward arrangement.

Most states, including Florida, reimburse primarily based upon published "average wholesale prices" (AWP), minus a discount. AWP, unfortunately, is not defined by state or federal law. It is an industry term of art that differs slightly from a "plain English" interpretation, which might suggest it was the mathematical average of actual prices from the manufacturer to the wholesalers.

AWP is actually the sticker price to the pharmacies, as recommended by the drug manufacturers. Drug companies primarily report AWP prices to the various trade publications (i.e., the "Red Book" and "Blue Book") which publish AWP prices for drugs.

The AWP formula is fundamentally flawed for a number of reasons. It omits an important middleman in the formula, for pharmaceuticals rarely pass directly from a drug manufacturer to the pharmacy. There are a few major pharmaceutical wholesalers in this country (the number has decreased in recent years due to larger mergers), and they play an enormous role in the drug distribution system. They resolve drug companies' issues with storage, inventory, marketing (to some extent), and distribution. It should immediately strike one as odd that manufacturers are reporting what is supposed to be a wholesale price.

Drug companies have every incentive to inflate AWP prices to artificial levels. Once the price has been inflated (and published), the drug manufacturers can then approach drug wholesalers (or pharmacies) and negotiate a much lower sales price. The attraction of this scheme soon becomes obvious: as the bogus AWP prices reportedly "rise" and the actual acquisition cost of the drug to the wholesalers goes down, the resulting profit spread to the pharmacy (who acquired its product from the wholesalers at a greatly reduced rate off of AWP) grows. The only loser in this reimbursement scheme is the state and federal governments.

Due to the apparent lack of a connection between AWP prices and what is paid anywhere in the distribution chain, it has cynically been referred to as the "Aint'-What's-Paid" price.

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<sup>7</sup><[http://www.pfizer.com/are/about\\_public/download/HQGuideBestPriceAWP.pdf](http://www.pfizer.com/are/about_public/download/HQGuideBestPriceAWP.pdf)>.

As of July 1, 2004, Florida reimburses pharmacies for Medicaid prescribed drugs at the lesser of:

- the average wholesale price (AWP) minus 15.4 percent,
- the wholesaler acquisition cost (WAC) plus 5.75 percent,
- the federal upper limit (FUL),
- the state maximum allowable cost (SMAC), or
- the usual and customary (UAC) charge billed by the provider.<sup>8</sup>

Florida used to rely more heavily on the WAC price, which is generally much lower than AWP. It is also not defined by state law, and is also an industry term-of-art, which coincides with its meaning in plain english. Florida's website for consumer health information, [www.floridastat.com](http://www.floridastat.com), defines WAC as the "average actual price wholesalers charge retail pharmacies."<sup>9</sup> This is incorrect. It is not the wholesalers' sales price, but the acquisition cost to the wholesalers (e.g., the sales price from the drug manufacturer).<sup>10</sup> Drug wholesalers then markup their price to sell to pharmacies, which explains why Medicaid reimbursement adds a percentage to this price (versus the discount on AWP pricing), covering the wholesalers' profit margin.

The FUL and SMAC reimbursement methods are similar concepts to each other, and are much favorable in terms of costs savings due to their imposition of ceiling prices. Unfortunately, these prices are only imposed by the government for certain generic drugs when there are several therapeutic equivalents of the drug available. The pricing theory is that once multiple generic entrants are on the market, the price of the drug will not be reduced by the entrance of new competitors. Therefore, the price of the drug will stabilize, and should never increase as long as the supply remains abundant. Therefore, there is no reason to pay more than \$X dollars for it.

The UAC is full retail pharmacy price, and represents a 0% savings to Medicaid.

The reality is that due to the wider availability of AWP prices, and the fact that FUL and SMAC prices are not in place for many of the more expensive drugs, AWP has become the benchmark for reimbursement for most of Florida's drugs.

AWP manipulation has been known for years. The Office of the Inspector General (OIG) of the Department of Health & Human Services (HHS), in a memorandum to the Administrator of the

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<sup>8</sup> Fla. Stat. § 409.912(39)(a)(2);  
<[http://www.fdhc.state.fl.us/Medicaid/Prescribed\\_Drug/banners.shtml](http://www.fdhc.state.fl.us/Medicaid/Prescribed_Drug/banners.shtml)>

<sup>9</sup><<http://www.floridahealthstat.com/rxcost2001.shtml>>.

<sup>10</sup>Prescription Drugs,  
<<http://207.22.102.105/medicaidbenefits/prescriptiondrugs.html#Author>>;  
<<http://www.wa.regence.com/broker/communication/2003/030606RegenceRxCostsLess.html>>.

Centers for Medicare and Medicaid Services (CMS), stated that nationally “drug acquisition cost [for generic drugs] was an average of 65.93 percent below AWP,” and recommended that CMS require States to “bring pharmacy reimbursement for generic drugs more in line with the actual acquisition cost . . .” (emphasis added). As a result, the average discount paid by States is not sufficient, and there is a “critical need for States to better control the costs of their Medicaid drug programs because expenditures are rising at a dramatic rate.” CMS agreed, and stated it will “strongly encourage States to look for an alternate basis for reimbursement . . . .”<sup>11</sup>

AHCA, on the other hand, disagrees that CMS has discouraged the use of AWP, stating as recently as last month that federal guidelines “encourage” the use of AWP.<sup>12</sup>

AWP abuses can be more severe for certain classes of drugs. TAP Pharmaceutical Products, for example, in its AWP pricing for its drug Lupron, enabled some urologists to reap as much as \$400,000 a year by prescribing the prostate cancer drug.<sup>13</sup>

Oncologists also receive free drugs in exchange for promises to buy other cancer drugs from the drug manufacturer, resulting in lower overall acquisition costs. AWP prices for cancer drugs can contain markups of 25% to over 90% than actual acquisition costs for medical providers.<sup>14</sup>

The legality of the over-inflation of AWP prices is in question, as attorneys general and private class action litigants are currently litigating a wide range of fraud, conspiracy, and antitrust allegations against drug manufacturers in various courts around the country.<sup>15</sup> Defenses raised include the fact that government has known for years that AWP was inflated, but has done nothing to stop it: in order words, yes, we lied, but the government hasn’t stopped us yet.

### III. Possible Solutions

The current reimbursement Medicaid sales has undoubtedly helped pharmaceutical companies’ bottom line: it is the most profitable industry in the United States, with profits over 5.5 times

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<sup>11</sup>Memorandum from Janet Rehnquist, Inspector General, HHS, to Thomas Scully, Administrator, CMS (Mar. 14, 2002).

<sup>12</sup><[Http://www.fdhc.state.fl.us/Medicaid/deputy\\_secretary/recent\\_presentations/medicaid\\_prescription\\_drug\\_program\\_011305.pdf](http://www.fdhc.state.fl.us/Medicaid/deputy_secretary/recent_presentations/medicaid_prescription_drug_program_011305.pdf)>; Presentation by Dep. Sec. Tom Arnold to Senate Health and Human Services Appropriations Committee, Jan. 13, 2005.

<sup>13</sup><<http://www.californiaoncology.org/gaoprotest/tribune.htm>>.

<sup>14</sup><<http://www.house.gov/stark/documents/107th/bristolletter.html>>.

<sup>15</sup>In *Re Pharm. Indust. Average Wholesale Price Litigation*, 263 F. Supp. 2d 172, 178-80 (D. Mass. 2003); <[http://www.hagens-berman.com/average\\_wholesale\\_price\\_drug\\_litigation](http://www.hagens-berman.com/average_wholesale_price_drug_litigation)>; <[http://www.ag.state.mn.us/consumer/PR/PR\\_DrugCompanyDefraud\\_9403.htm](http://www.ag.state.mn.us/consumer/PR/PR_DrugCompanyDefraud_9403.htm)>; <[http://www.ag.state.oh.us/press\\_releases/2004/press\\_release\\_20040309.htm](http://www.ag.state.oh.us/press_releases/2004/press_release_20040309.htm)>.

the median for Fortune 500 companies.<sup>16</sup>

According to the OIG, our faulty AWP reimbursement policy costs the states and federal government as much as \$470 million for the 200 generic drugs with the greatest amount of Medicaid reimbursement in 1999.<sup>17</sup>

Florida has tried to reduced its expenditures for prescription drugs in the past. Examples of cost-cutting measures include instituting co-payments for drugs, the creation of prior authorization lists (note: this isn't the same thing as a formulary), and negotiating supplemental rebates with drug manufacturers. These measures try to obtain additional cash discounts from manufacturers, curb over-prescription by doctors, and curb over-utilization by patients.

The latest current prescription drug cost-cutting measure announced by the Governor's Office (separate from the privatization proposal) does not address the method of reimbursement, but tries to curb prescribing methods of doctors by calling for restrictions on patients' access to drugs, limiting treatment to the least expensive drugs.<sup>18</sup>

While these measures do save money in the short term and may curb the successful marketing campaigns by drug manufacturers (who often spend more on marketing than research and development for new drugs), they do not resolve fundamental problems with Medicaid's reimbursement formula for drugs. Measures need to be taken to address the partnership between pharmacies (who reap excess profits through their success efforts to obtain their drugs at lower costs) and drug manufacturers (whose market shares can be driven by their inaccurate pricing schemes). If the coziness of the relationship between the two groups is in question, one need only examine the paper sack from their pharmacy upon filling her next prescription, or by the litigation against pharmacies who sell patient lists to drug companies for their direct marketing campaign.

Many solutions for reform have long been on the table.

Drug companies do have to pay a rebate to state medicaid programs for prescription drugs, but luckily for them, the rebate is not based upon a percentage of AWP. It is based upon a formula using a different concept, the average manufacturer's price, or AMP, which is defined by federal statute. AMP is the price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts.<sup>19</sup>

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<sup>16</sup><<http://www.familiesusa.org/site/DocServer/PPreport.pdf?docID=249>>.

<sup>17</sup>Memorandum from Janet Rehnquist, Inspector General, HHS, to Thomas Scully, Administrator, CMS (Mar. 14, 2002).

<sup>18</sup>Douglas C. Lyons, *Budget-cutting Can Be Way to Set Program Right*, Sun-Sentinel, Jan. 29, 2005, at 19A.

<sup>19</sup> 42 U.S.C. § 1396r-8(k)(1).

Solution 1: Tie reimbursement formulas to rebates paid by drug manufacturers. If front-end sales are tied to back-end rebates, the incentives to overinflate the spread to pharmacies is tempered by the corresponding rebate that will have to be paid.

Obstacles to this solution have been drug companies, who submit their actual pricing data to the federal and state governments. Such data is currently confidential under Florida and federal law. Drug companies claim their data contains proprietary, confidential data that if revealed or known by their competitors, would eliminate their competitiveness.

It is hard to imagine that a drug company maintains any significant competitive advantage by hiding their sales prices from their competitors. The price *is known*, however, to purchasers (primarily wholesalers). In a competitive market, economic theory states the market will respond by assigning a competitive price to the drug. If the drugs contain patents (or legal monopolies) preventing generic competition (and are thus generally brand-name drugs), they generally will not have any competition other than with other classes of drugs.

Solution 2: Use actual acquisition data, or “best prices” from the manufacturers to the pharmacies to calculate reimbursement, instead of allowing the drug manufacturers to ultimately define the benchmark price. Actual data is available, and certainly the large pharmacy chains know actual acquisition cost. Drug companies should also have this data, as it is used in the calculation of rebates they are required to pay.

Again, drug companies respond that this data should remain confidential.

Solution 3: Reform of drug reimbursement to the few drugs covered under Medicare Part B may offer another solution. Medicare had been reimbursing providers an astonishing 95% of AWP. This dropped to 85% of AWP in 2004, and then is based on a new concept in 2005: the average sale price (ASP), which is supposed to be calculated quarterly and based on the sales price of each drug, taking into account discounts, rebates, and other charges. Reimbursement will be ASP plus 6%. In 2006, a competitive bidding alternative will be created. Reporting false ASP information would constitute a violation of the Federal False Claims Act.<sup>20</sup>

#### IV. Conclusion

The federal government, who is the primary funder of Medicaid, should take the lead and establish a nationalized formula for reimbursement of drugs under Medicaid, or at least establish a regionalized formula in order to take into account remote areas of the country.

Florida should not wait for the federal government, and change its reimbursement formula immediately to stop its overpayments. Florida should reimburse pharmacies based on actual sales data rather than AWP, which has no bearing whatsoever to the actual price of drugs.

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<sup>20</sup><[http://library.lp.findlaw.com/articles/file/00010/009545/title/Subject/topic/Health\\_Drugs%20and%20Medical%20Devices/filename/health\\_2\\_3858](http://library.lp.findlaw.com/articles/file/00010/009545/title/Subject/topic/Health_Drugs%20and%20Medical%20Devices/filename/health_2_3858)>; <<http://www.abanet.org/health/esource/focus-2.html>>.

Pharmacies should be allowed to make a profit, but their profit should be confined to a fixed and/or known amount (much like patients' co-payments), which is the system currently contemplated by the current statutory scheme. The current dispensing fee may or may not be sufficient to cover this cost; regardless, Medicaid is not supposed to be a financial windfall for any health care provider. The reality is that government has no idea what the profits are. Drug companies should also be allowed to make a profit, but should not be allowed to drive market share by over-inflating data.

Nationally, the savings could be hundreds of millions of dollars, and could allow states to continue offering much needed services.