Legal Backgrounder

Washington Legal Foundation
Advocate for freedom and justice®
2009 Massachusetts Ave., NW
Washington, D.C. 20036
202.588.0302

Vol. 18 No. 45 October 17, 2003

ACCURATE DRUG PRICE REPORTING: A MODEST PROPOSAL

by

Grant Bagley
John Bentivoglio
Rosemary Maxwell

Charging drug manufacturers with "fraudulent" price reporting has become a cottage industry. While these charges have never been proven in court, they generated over $766 million in settlements just in the past year. Since last October, allegations that manufacturers inaccurately reported the "Best Price" used in calculating Medicaid rebates, the Average Wholesale Price (AWP) used in calculating Medicare and Medicaid reimbursement rates, or other pricing figures produced settlements of $257 million (Bayer), $87 million (GlaxoSmithKline), $49 million (Pfizer), $18.5 million (Dey), and $355 million (AstraZeneca).

Numerous lawsuits alleging "inflated" AWPs and/or overstated Best Prices, brought both by States and private groups, are currently pending; widely-reported Federal investigations in Boston and Philadelphia also include scrutiny of AWP and Best Price issues; and the Department of Health and Human Services Office of Inspector General (OIG) recently warned that it considers manufacturers "responsible for ensuring the integrity of data they generate that is used for government reimbursement purposes."[1] Congress, having conducted an exhaustive investigation of the "inflated AWP" issue in 1999-2000, launched a new investigation in June focusing on the same topic. And recent proposals to adopt *new* pricing measures that manufacturers would be required to report to the Government could produce a second generation of fraud theories, accompanied by a new wave of investigations, lawsuits, and settlements.

Clearly there is a problem associated with drug price reporting. But there is little evidence that the problem is fraud by drug manufacturers — or that the solution is more investigations, more litigation, or more price reporting obligations.

[1] 68 Fed. Reg. 23731, 23734 (May 5, 2003).

Grant Bagley, **John Bentivoglio**, and **Rosemary Maxwell** are members of the healthcare and pharmaceutical regulatory practice in the Washington, D.C. office of the law firm Arnold & Porter.

Charges that a drug manufacturer defrauded Medicare or Medicaid (or other Government programs, private insurers, or patients) can be based on the alleged inaccuracy of various pricing benchmarks. The pricing landscape is increasingly cluttered with candidates. Established and emerging drug pricing benchmarks include the following:

- ***AMP and Best Price***: Medicaid rebates for generic drugs are 11% of their Average Manufacturer Price (AMP), while the rebate formula for branded drugs involves both AMP and Best Price. Manufacturers must report these figures to the Centers for Medicare and Medicaid Services (CMS) each quarter. Allegedly overstated Best Prices (which could reduce a manufacturer's rebate payments) have typically been the focus of scrutiny, but at least two investigations (the recently-launched congressional pricing probe, and an SEC investigation of King Pharmaceuticals) include AMPs as well.

- ***AWP***: AWP, the eye of the hurricane, affects Medicare and Medicaid payments to providers. Medicare-covered drugs are now reimbursed at 95% of AWP (at least usually), and most State Medicaid programs also base reimbursement on discounted AWP formulas. AWPs are published by private price reporting services, sometimes using suggested AWPs from manufacturers. Today, most large manufacturers do not report suggested AWPs to the price reporting services.

- ***WAC***: A few State Medicaid programs have reimbursement formulas based on Wholesale Acquisition Cost (WAC), and the price reporting services (which do not disclose how they generate AWPs) are often assumed to derive AWPs by marking up the WACs reported by manufacturers. The theory that allegedly inflated WACs resulted in the price reporting services generating inflated AWPs is the basis for a suit against a major pharmaceutical manufacturer filed in February by the New York State Attorney General.

- ***Federal Ceiling Price and Non-FAMP***: Manufacturers must sell branded drugs to four Federal agencies (the Department of Veterans' Affairs, the Defense Department, the Public Health Service, and the Coast Guard) at or below a Federal Ceiling Price, which is derived mainly from the non-federal AMP (non-FAMP) for the drug. Manufacturers must report non-FAMPs to the Department of Veterans' Affairs on a quarterly basis, and Federal Ceiling Prices annually. To date, these pricing measures have yet to generate reported lawsuits or investigations.

- ***ASP***: The Average Sales Price (ASP) was created in a 2001 Corporate Integrity Agreement (CIA) between Bayer and the OIG. Bayer must report the ASP for certain drugs each quarter, so as to allow State Medicaid programs to use the ASP in setting reimbursement rates. Two additional companies (TAP Pharmaceuticals and AstraZeneca) now have CIAs with ASP-reporting obligations. ASP may also become part of the Medicare prescription drug legislation now in conference; under the House bill, payment for drugs now covered by Medicare would be based on ASP or a competitive bidding model.[2] CMS, which published a proposal for revamping Medicare's payment system administratively in mid-August,[3] also identified ASP plus competitive bidding as one of four alternatives under consideration. CMS stated that "[m]anufacturers would be required to report the ASP to us on a quarterly basis," without explaining its authority to impose this new reporting obligation.[4]

- ***WAMP***: The Widely Available Market Price (WAMP), the newest pricing figure, is also featured in the

[2] H.R. 1, § 303.

[3] 68 Fed. Reg. 50428 (Aug. 20, 2003).

[4] 68 Fed. Reg. at 50436. Remarkably, CMS also estimated that it would take a manufacturer one hour per drug to meet this new reporting burden each quarter. *Id*. at 50442.

  ISBN 1056 3059

CMS proposal.[5] Under two of the alternatives in the proposal, Medicare payment for new drugs or drugs coming off patent would initially be based on WAMP data reported by manufacturers. CMS would compel manufacturers to submit this data by denying a new drug the HCPCS code necessary for Medicare billing purposes (or, for drugs coming off patent, taking away the existing code) if they failed to do so. The proposal warns that "[i]f we suspect that a manufacturer has knowingly supplied misleading pricing information to generate or maintain a 'spread' between Medicare payment and the [WAMP], we will refer the matter to the OIG."[6] Similarly, under the Senate version of the Medicare drug bill, payments would generally equal 85% of the April 1, 2003 AWP, but for new drugs manufacturers would be required to report data on prices routinely available in the market.[7]

Why payment rates and Medicaid rebates cannot be based on one or two well-defined pricing benchmarks is unclear. But the proliferation of pricing measures — and the pattern of Government agencies failing to provide adequate guidance (or any guidance) on how they define these measures — are the key drivers of the fraud charges now facing manufacturers, and the key obstacles thwarting greater "accuracy" in pricing calculations.

AWP exemplifies this problem. Congress set Medicare drug payments at 95% of AWP in 1997, and Medicare and Medicaid payment formulas had already been based on AWP long before that. For decades, AWP was undefined but commonly understood as a "sticker price" with little connection to market prices. As early as 1975, a predecessor agency to CMS noted that AWP was "frequently inflated" and should not be equated with the estimated acquisition cost for a drug.[8] As explained by CMS (then HCFA) in 1998, AWP "is not a true discounted price" and "does not reflect the cost to the physician or supplier furnishing the drug to the Medicare beneficiary."[9] But even as CMS and State Medicaid agencies began to grumble about AWPs being "inaccurate" and to intimate that they should be "reformed" in some manner, they *still failed to define the term* or otherwise to announce new ground rules. As CMS acknowledged in August of 2003, AWP "is not defined in law or regulation."[10]

Similarly, lack of guidance has been a longstanding problem in the Medicaid rebate arena. The Medicaid rebate statute was passed in 1990. In 1992, the OIG pointed out that manufacturers lacked the guidance necessary to calculate AMPs correctly, and CMS (then HCFA) stated that it would clarify these issues in a future regulation.[11]

---

[5] The proposal describes WAMP as "the price that a prudent physician or prudent supplier would pay when purchasing the drug from common sources," stating that it "would not be a list price that is commonly discounted" but "the purchase price net of discounts, rebates, and price concessions routinely available to prudent purchasers." 68 Fed. Reg. at 50433.

[6] 68 Fed. Reg. at 50433.

[7] S.1, § 432. As in the CMS proposal, failure to report this data would result in the denial of a HCPCS code.

[8] *State of Louisiana v. United States Dept. of Health and Human Services*, 905 F.2d 877, 880 (5th Cir. 1990) (quoting 40 Fed. Reg. 34518 (Aug. 15, 1975)).

[9] Program Memorandum No. AB-97-25 (Jan. 1998). *See also*, *e.g.*, Office of Inspector General, OEI-03-97-00290, EXCESSIVE MEDICARE PAYMENTS FOR PRESCRIPTION DRUGS 10 (Dec. 1997) ("published AWPs . . . bear little or no resemblance to actual wholesale prices"); Office of Inspector General, A-06-95-00065, REVIEW OF PHARMACY ACQUISITION COSTS FOR DRUGS REIMBURSED UNDER THE MEDICAID PRESCRIPTION DRUG PROGRAM OF THE FLORIDA AGENCY FOR HEALTH CARE ADMINISTRATION 1 (Aug. 1996) ("OIG issued a report in 1984 which stated that, on average, pharmacies purchased drugs for 15.9 percent below AWP"); Office of Inspector General, A-06-97-00052, NEED TO ESTABLISH CONNECTION BETWEEN MEDICAID DRUG REBATES AND REIMBURSEMENT FOR MEDICAID DRUGS 5 (May 1998) ("[t]he drug industry currently treats AWP as a published list price rather than a true wholesale price"); Office of Inspector General, OEI-05-99-00611, COST CONTAINMENT OF MEDICAID HIV/AIDS DRUG EXPENDITURES 6 (July 2001) ("[b]oth the WAC and the AWP operate as suggested list prices and are typically not what is paid"); United States General Accounting Office, GAO-02-531T, MEDICARE OUTPATIENT DRUGS: PROGRAM PAYMENTS SHOULD BETTER REFLECT MARKET PRICES 2, 5 (Mar. 14, 2002) (noting that "there are no requirements or conventions that AWP reflect the price of any actual sale of drugs" and that "AWP is not defined in law or regulation").

[10] 68 Fed. Reg. at 50429. Oddly, CMS just recently proposed to define AWP, at a point when it has had authority for two years now to revise Medicare's drug payment methodology and jettison AWP altogether. Under its August proposal, CMS would "define AWP to be the [WAMP]," and would then pay for drugs at 100% of the newly-defined "AWP" instead of 95%. 68 Fed. Reg. at 50433.

[11] Office of Inspector General, A-06-91-00092, MEDICAID DRUG REBATES: THE HEALTH CARE FINANCING ADMINISTRATION

Proposed regulations were issued in 1995 but never finalized.

As things stand today, thirteen years after enactment of the Medicaid rebate statute, no implementing regulations exist to help manufacturers answer the questions that continually arise about AMP and Best Price calculations. To take just one example: are discounts to patients supposed to be reflected in Best Price? This issue (unlike most of the questions manufacturers confront in calculating Medicaid rebates) is actually discussed in two sources of guidance: an October 22, 2002 letter from CMS Administrator Scully to one of the manufacturers offering the Together Rx discount card; and a June 24, 2002 letter from Mr. Scully to the Pharmaceutical Research and Manufacturers Association (PhRMA). (These documents were obtained from InsideHealthPolicy.com, a paid subscription service, and PhRMA; requests to CMS were unsuccessful.) While PhRMA and the Together Rx companies have helped to obtain useful guidance on this specific issue, the point is that manufacturers deserve clear and easily-accessible guidance on all of the various ambiguities plaguing Medicaid rebate calculations: there is no reason why basic information on how to comply with the law should remain shrouded in mystery. Fraud charges are powerful weapons — but weapons that should be reserved for purposeful violations of *known* legal standards. If the goal is to improve Medicaid rebate calculations and promote compliance with the law, an old-fashioned approach like published regulations would have considerably more effect.

FDA Commissioner Mark McClellan, in a recent speech on enforcement strategy, articulated a principle that applies equally to the price-reporting arena — clarity is a simple and cost-effective compliance tool:

> We don't have the luxury of enough resources to play 'gotcha.' Instead, clarity and effective communication can get more companies into compliance at a low cost.[12]

Cost-effectiveness aside, basic principles of fairness call for providing manufacturers with clear ground rules. Adopting clear rules should be the first order of business in the price-reporting field. Until this occurs until, for example, a complicated statute passed thirteen years ago has implementing regulations — it makes little sense to adopt *new* price reporting obligations. As a policy matter, there is no apparent reason why the Government even needs additional pricing data from manufacturers; the recent CMS proposal notes a wide variety of sources CMS could tap to obtain data on drug prices, including many sources better positioned than manufacturers to furnish data on prices paid by the providers that bill Medicare. And without a proven commitment to providing the information drug manufacturers need to understand *existing* price-reporting requirements; added requirements will only expose manufacturers to a second generation of fraud investigations and lawsuits, without contributing in any way to better reimbursement policies.

NEEDS TO PROVIDE ADDITIONAL GUIDANCE TO DRUG MANUFACTURERS TO BETTER IMPLEMENT THE PROGRAM (Nov. 1992).

[12] *FDA Enforcement Priorities Include Guidance on Detailing and Kickbacks*, THE PINK SHEET, Aug. 11, 2003.