LITIGATING AWP

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Litigation Landscape

Federal Gov’t/States/Private Class Actions

Payment Systems

- Medicare (based on 95% of AWP)
  - Medicare pays provider 80% of this amount.
  - Medicare beneficiary responsible for 20%, “co-pay.”
- Medicaid
  - Generally AWP less 5% to 10% (sole source).
  - Generally MACs tied to FULs (multi-source).
- Private
  - Insurer or Employee Health & Welfare Fund contracts with medical providers or pharmacy benefit manager to pay “based on” AWP

What is AWP?

- Long been recognized as “sticker price” and not actual retail acquisition price or wholesaler price to retail.
- Not defined by statute or regulation.
- “Ain’t What’s Paid.”

Government Knew of Divergence Between AWP and Acquisition Cost

- 1968 HEW Report
  - "wholesalers, retailers, hospitals and government agencies often pay markedly different prices for the same drug and dosage form."
  - "The *Red Book* and Blue Book do not reflect actual manufacturers' prices to wholesalers and retailers . . . . The catalog [list] price constitutes an 'umbrella' beneath which the company can maneuver against competing products."

Government Knew of Divergence Between AWP and Acquisition Cost

- 1974 HEW Federal Register Notice: "Red Book data, Blue Book data (i.e. AWP) and other standard prices . . . were frequently in excess of actual acquisition cost."
- 1977 HCFA action transmittal to States: "[T]he Department is not convinced that those states which continue to reimburse at average wholesale price or wholesale invoice cost have made a real effort to approach actual acquisition cost."

Government Knew of Divergence Between AWP and Acquisition Cost

- 1984 HHS OIG Report
  - Pharmacies purchased most drugs at an average of 15.9% below AWP, and actual prices as much as 42% below AWP.
  - AWP was not "even an adequate estimate of the prices providers are generally paying for their drugs. AWP represents a list price and does not reflect several types of discounts."

Government Knew of Divergence Between AWP and Acquisition Cost

- 1989 Senate Report
  - "There are two markets in the U.S. for most big selling prescription drugs: a price competitive market characterized by deep discounts off of list price, and a high-priced market, where retail customers, Medicare and Medicaid purchase their prescription drugs."
  - "The VA achieves an average discount of 41% off AWP for single source drugs and 67% off AWP for multiple source drugs."
  - "Hospital, HMOs and nursing homes that contract with wholesalers achieve discounts up to 99% off AWP."

Government Knew of Divergence Between AWP and Acquisition Cost

- 1992 HHS OIG Report
  - The difference between AWP and physician acquisition cost for commonly used chemotherapy drugs varied from 12% to 83%.
  - "AWP is not a reliable indicator of physician cost; indeed *Red Book* officials confirmed that AWP is not designed to reflect physicians' costs."
  - "[T]here is no single discount rate which can be applied to the AWP to provide a reasonably consistent estimate of physician's acquisition cost."

Government Knew of Divergence Between AWP and Acquisition Cost

- 1997 HHS OIG Report
  - "Medicare and its beneficiaries are making excessive payments for prescription drugs. The published AWPs that are currently being used by Medicare-contracted carriers bear little resemblance to actual wholesale prices that are available to the physician and supplier communities that bill for those drugs."

Public Knowledge

- June 1996, Barron's Article
  - "AWP: Ain't What's Paid."
- President Clinton's 12/31/97 Radio Address
  - "Sometimes the waste and abuses aren't even illegal; they're just embedded in the practices of the system. . . . [O]verpayment occur because Medicare reimburses doctors according to the published average wholesale price, the so-called sticker price for drugs. Few doctors, however, actually pay the full sticker price. In fact, some pay just one-tenth . . . ."

The Government Chose Not to Change the Payment System

- The government continues to make knowing policy decisions to tie payment to AWP.
- The government has used drug ingredient payment to address/"cross-subsidize"
  - Patient care and access issues.
  - Insufficient dispensing fees paid to pharmacies.
  - Insufficient payment to oncologists for office services and practice expenses.
  - Insufficient payments to suppliers of hemophilia products to cover shipping, storage and inventory costs.

Federal Government Regulation

- HCFA proposed AAC in the 1970s and 1980s but Congress did not implement.
- After HCFA revised Medicaid manual in 1989 to require EAC to include "significant discount" from AWP, Congress imposed moratorium on changes to State payment policies for pharmacies.
- Administration proposed AAC in 1997 and 1998; Congress chose to reimburse AWP – 5% in 1997 and made no change in 1998.

Federal Government Regulation

- Administration proposed AWP minus 17% in 1999 and 2000, but Congress did not adopt either proposal.
- Congress' and HCFA's response to DOJ activity.
  - September 2000
    - HCFA provided DOJ-compiled pricing information to Medicare carriers so information could be used in determining AWPs for Medicare reimbursement purposes.
    - HCFA, however, instructed carriers not to use data for oncology and hemophilia products because of "concern about the access to care . . . due to other Medicare payment policies associated with the provision of these drugs for the treatment of cancer and hemophilia."

Federal Government Regulation

- November 2000
  - HCFA completely reversed initial position and prohibited carriers from using *any* of the DOJ data in setting reimbursement rates.
  - HCFA required that reimbursement continue to be based on published AWPs that DOJ had determined to be "inflated."
- December 2000
  - Congress passed Medicare, Medicaid, and SCHIP Benefits Improvement Act.
  - The Act precluded HHS Secretary from "directly or indirectly decreas[ing] the rates or reimbursement . . . under the current reimbursement methodology" until the Secretary had reviewed a GAO study.
- September 2001: GAO study released
- Current
  - Medicare reimbursement still based entirely on published AWP rather than DOJ data or any other pricing point.
  - Congress debating the issue today

State Government Involvement

- 1993 GAO Report
  - Pharmacists "contended that because of insufficient dispensing fees they used excess reimbursement to cover the drugs' dispensing costs."
  - "HCFA and State Medicaid officials agreed that pharmacies must often use excess Medicaid reimbursement to cover their dispensing costs."

State Government Involvement

- OIG has audited drug payments of approximately half of the state Medicaid programs over the past 19 years.
- HCFA audited 11 Key States in 1995
  - Identified average national acquisition cost of generic products at AWP – 42.5%.
  - States made no significant change to payment formulas.

State Government Involvement

- In response to OIG audits, states defended their decision to pay more than acquisition cost
  - 1996 Florida Medicaid:
    - "Restricting reimbursement to actual acquisition cost might have the unintended effect of discouraging purchase of promotional products and eventually shifting the market to single-source products that are universally more costly. The average multi-source prescription costs Medicaid less than $11 and the average single-source product averages over $45."
    - "Florida imposes the federal upper limit price which also does not fully capture all available discounts and pharmacies may still have significant markups."

State Government Involvement

- 1996 Missouri Medicaid
  - "[I]ngredient cost is only one component to be considered in determining an appropriate pharmacy reimbursement level."
  - Noted that its dispensing fee was $4.09 in 1996, over $2.00 below the 1991 pharmacy cost to dispense.
- 1996 Virginia Medicaid
  - ". . . The acquisition cost is just one factor involved in pharmacy reimbursement policy or methodology, and with any change, consideration should be given to other factors. . ."
- 1996 Montana Medicaid
  - "[W]e currently believe that the dispensing fee is below the cost to dispense because of the cap on dispensing fees that is currently in place and has been for many years."

State Government Involvement

- In transmittal letter, the OIG expressed agreement with position
  - "We agree with the [states] that acquisition cost is just one factor to consider in evaluating Medicaid pharmacy reimbursement."

Government Enforcement

- DOJ Bayer Settlement (January 2001)
  - "The United States contends that Bayer, in a manner similar to the practices of certain other manufacturers . . . knowingly engaged in a marketing scheme whereby it set the Average Wholesale Prices ("AWPs") of the qui tam drugs at levels far higher than what the vast majority of its customers actually paid for these products when purchasing either directly from Bayer or through a wholesaler. . . ."

Government Enforcement

- Boston TAP Settlement (September 2001)
  - "The United States contends that TAP engaged in a marketing scheme where it set AWPs of Lupron at levels far higher than the majority of physician customers actually paid for the drug when purchasing either directly from TAP or or through a wholesaler or distributor."
- Guilty plea to PDMA violation is distinct

Government Enforcement

- Draft OIG Compliance Guidance (October 2002)
  - "Manipulation of the AWP to induce customers to purchase a product , coupled with the active marketing of the spread is evidence of unlawful intent necessary to to trigger the anti-kickback statute."
- State Actions
  - Minnesota, Montana, Nevada and Texas
  - Ongoing investigative activity

No Viable False Claims Act Theory

- Government can not prove "falsity"
  - Government must prove that its definition is correct and any other potential interpretation is unreasonable.
  - Government cannot meet this burden.
    - No law, regulation or other source that provides a controlling definition of AWP.
    - Clear understanding that AWP a "sticker price."
    - No support for government's position that AWP should bear a specific relationship to acquisition cost.

No Viable False Claims Act Theory

- Government cannot establish a "knowing" submission of "false" information
  - Government must prove manufacturers knew, demonstrated deliberate influence to, or recklessly disregarded a risk that they were providing misleading or incorrect information.
  - A good faith interpretation of a requirement precludes liability.
  - Given the widespread knowledge that AWP bears no relationship to acquisition cost, it will be difficult for the government to satisfy this element.

No Viable False Claims Act Theory

- Government cannot prove justifiable reliance on published AWPs
  - Government must prove that it relied upon the false information to its detriment.
  - Government cannot meet this burden.
    - For more than a decade HCFA told the states not to rely on published AWPs.
    - The federal and state governments have long known that AWPs do not even approach provider acquisition cost.
    - The federal and state governments have made knowing policy decisions to pay based on the AWP “sticker prices.”

State Attorney General Cases

- Nevada, Montana, Minnesota
- Suing As Sovereign
  - False claims under state law
  - Medicaid fraud
  - Breach of Rebate Agreement
  - Deceptive trade practices
- Suing As *Parens Patriae*
  - Medicare co-payors
  - Direct payors
- Removal Jurisdiction
- AG cases being run by class action firms

Class Action Cases

- Started in California State Court in October 2001
- Now over 25 cases against more than 25 manufactures
- MDL in District of Massachusetts (In re Pharmaceutical Industry Average Wholesale Price Litigation)
- Lupron MDL is also there
- New Complaints being filed in California State Court under Cal. Business & Professional Code §17200
  - Removal, transfer and consolidation

Two Classes

- (1) Medicare Part B Co-Payors
- (2) Private entities that contract with intermediaries, like PBMs , to pay for drugs based on AWP

Legal Theories

- RICO
  - Reporting of AWP = mail/wire fraud
  - Manufacturers are in "association-in-fact" enterprises with
    - Medical Providers
    - Publications that publish AWP
    - Pharmacy Benefit Managers
- State law consumer fraud/deceptive trade practices

Defenses

- Justiciability of Medicare Class Claims
  - Political Question
  - State Action
  - Filed Rate Doctrine
  - Preemption/Exhaustion of Administrative Remedies
- Truth on the Market
  - No fraud where AWPs are an industry term of art
  - Private payors had opportunity to engage in price discovery and negotiate
- Rico "Enterprises" are too amorphous
- Federal Pre-emption of state law claims
  - Not "consumer-oriented" activity

Current Status

- Lupron motion to dismiss sub judice
- AWP MDL motion to dismiss being briefed now
- Wait to see on forum for AG and recently-removed California state court cases