

PHARMACY REIMBURSEMENT: AWP, Medicaid and AMP

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Challenging Times

- AWP Shrinking ... And Disappearing?
- AMP Is A Flawed Replacement For AWP
- State Deficits Leading To Medicaid Cuts
- Concern And Uncertainty Surrounds Healthcare Reform

Agenda

1. AWP And The First DataBank Lawsuit
 - Impact of cutting and eliminating AWP
2. State Medicaid Reimbursement Cuts
3. AMP And The Future Of Reimbursement
 - Litigation, regulation and legislation

First DataBank AWP Litigation

What Is AWP?

- **Payors Use AWP As Benchmark For Reimbursement**
- **AWP = "Average Wholesale Price"**
 - Theory: AWP = prices pharmacies pay wholesalers
 - Reality: AWP = "Ain't What's Paid"
- **FDB And Medi-Span Publish AWP's**
 - Wholesale Acquisition Cost (WAC) plus a "markup"
 - Markups are often 120% or 125% of WAC
 - Many other markups above, below & between 120% and 125%

AWP Lawsuits

- **Many AWP Lawsuits Since 1995**
 - Payors claim manufacturers report "false" AWP's
- **FDB, Medi-Span and McKesson Sued In 2005**
 - Payors claimed improper increase of 1,442 AWP's
 - From 120% of WAC to 125% of WAC
 - Allegedly caused payors to pay more for drugs

AWP Reductions

- **FDB & Medi-Span Settlements**
 - Will cut 1,442 AWP to 120% of WAC
 - Create “data rooms” with pharmacy data for lawyers
 - Court approved settlements in March 2009
- **FDB & Medi-Span Customer Letters**
 - 7,000+ other AWP also reduced to 120% of WAC
 - Many AWP will remain *lower* than 120% of WAC

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Timing Of AWP Changes

- **AWP Reductions Start September 26, 2009**
 - Appeal seeks to halt AWP cuts before that date
- **FDB And Medi-Span Plan To Stop Publishing AWP Within 2 Years**
 - Appeal cannot halt elimination of AWP in 2 years

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Impact On Pharmacies

- **Net 4% Reduction Of AWP**
 - Most pharmacies make less than 4% net profit
- **Medicaid Reimbursement Automatically Cut**
 - 48 state use AWP for Medicaid reimbursement
 - \$68 million reduction per year if cut all AWP

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Impact On Pharmacies

- **Reduced Reimbursement By Private Payors**
 - For pharmacies that cannot renegotiate contracts
 - Affects thousands of contracts
 - Plaintiffs' expert: \$1+ billion cut for 1,442 AWP's
 - Plus another \$1+ billion for other AWP reductions?
- **NCPA Expert: 1000s Of Pharmacies May Close**
 - Up to 40% of independent pharmacies
 - Plaintiffs' expert says NCPA exaggerates ... but agrees some pharmacies will close

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Rationale For Cutting AWP's

March 17, 2009 District Court Order Held:

- Pharmacies were "unjustly enriched" when AWP's were increased in 2001-03
- Purpose of AWP reduction is to recoup "windfall" from pharmacies
- FDB and Medi-Span can cut all other AWP's

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Appeal

- Filed by NACDS, Members And Allied Associations
- **Court Cannot Intentionally Harm Pharmacies**
 - "Unjust enrichment" claims were never asserted in the lawsuit
 - Pharmacies were not parties in the lawsuit
- **Court Cannot Approve Other AWP Cuts**
 - No jurisdiction over AWP's not covered by the settlements
- **Court Cannot Approve "Data Rooms"**
 - No jurisdiction over different lawsuits involving different parties

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Status

- All Briefs Filed
- Hearing Held July 28th
- Decision Before September 26th?
- Delay Of AWP Cuts While Court Decides?

Other AWP Litigation

- AWP Reductions Spawn Subsequent Litigation
- Lawsuit Against Pharmacies
 - Payors sued certain chains for “unjust enrichment”
 - May be dismissed if McKesson settlement approved
- Potential Lawsuits By Pharmacies
 - Lowering AWP’s = “tortious interference” in pharmacy reimbursement contracts
 - Challenge Medicaid reimbursement rates

**State Medicaid
Reimbursement Cuts**

States Are Cutting Medicaid

- **Almost All States Face Budget Deficits**
 - Tax receipts decreased – service demands increased
- **Usual Response Is To Cut Medicaid**
 - In 2009, cuts proposed in CA, CO, CT, DE, FL, IN, MN, NJ, NY, NC, PA (Pace), OH, SC, UT, VT, VA, WA

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Legislative & Regulatory Efforts

- **Offset AWP Reductions**
 - “revenue neutrality” language for Medicaid
- **Oppose Rate Reductions**
 - State legislatures (oppose legislation)
 - State Medicaid Agencies (oppose regulations)
 - CMS (oppose approval of State Plan Amendments)
 - Success in IN, NY, UT, VA

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Litigation Against Medicaid Cuts

- **Federal Law Sets Reimbursement Standards**
 - Access Standard: Reimbursement rates must be “sufficient to enlist enough providers so that care and services are available under the [Medicaid] plan at least to the extent that such care and services are available to the general population....”
- **For Years Pharmacies Had No Right To Sue**
- **New Court Decisions Allow Pharmacies To Sue**
 - Argue rates insufficient to ensure pharmacies participate
 - In Western states and perhaps elsewhere

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Recent State Medicaid Lawsuits

- **Mississippi**
 - New SMAC halted due to violation of state law
- **California**
 - 10% cut halted
 - 5% cut halted
- **Washington State**
 - AWP – 20% halted
- **Delaware**
 - AWP – 15% (using Redbook)
 - Hearing on injunction August 12th

AMP: **Litigation, Regulation and Legislation**

Deficit Reduction Act

- **Cut Federal Upper Limits (FULs)**
 - FULs are caps on Medicaid payments for generics
- **FULs Will Be Based On AMP**
 - AMP = Average Manufacturer Price
 - FULs will = 250% of the lowest AMP
- **FULs Will Apply To More Generics**
- **AMPs Disclosed On Website**

AMPs Cut Medicaid Payments

- **AMP Rule Reduced AMPs**
 - CMS rule explains how to calculate AMPs
- **Result: Lower Reimbursement For Generics**
 - Reimbursement cut to 36% below cost (GAO)
 - 78% reduction in payments for generics (CMS)
 - \$21+ billion in cuts over 10 years (CMS)
 - 10-12,000 pharmacies may close (Expert)
 - Other payors may use AMP website to cut payments

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AMP Litigation

- **NACDS And NCPA Filed Lawsuit**
 - See www.NACDS.org for documents and details
- **Challenging AMP Rule**
 - AMP rule violates Social Security Act in 3 ways
- **First Argument: AMP Rule Does Not Comply With Statutory Definition Of AMP**

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Statute Defines AMP

- **Social Security Act Says AMP Only Includes:**
 1. Prices paid to manufacturers
 2. By wholesalers
 3. For covered drugs
 4. Distributed to retail pharmacies
- Section 1927: "average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade...."

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AMP Rule Definition of AMP

- **AMP Rule Violates Statute's 4 Part Test**
- **The AMP Rule Includes In AMP Calculations:**
 1. Prices not paid by wholesalers
 2. Prices not paid to manufacturers
 3. Sales of drugs not distributed to retail pharmacies
 4. Sales of drugs that are not covered by Medicaid
- **Includes Many Lower-Priced Sales**
 - Result: AMP rule lowers AMPs and reimbursement

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Examples From AMP Rule

- **Sales to Physicians**
 - Not wholesalers, not retail pharmacies, not covered
- **Direct Sales to Patients**
 - Not wholesalers, not retail pharmacies
- **Sales to Medical Outpatient Facilities**
 - Surgical centers, dialysis centers, mental health facilities, ambulatory care facilities & physician clinics
 - Not wholesalers, not retail pharmacies, not covered

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Examples From AMP Rule

- **Sales to Hospital Pharmacies and Clinics**
 - Not wholesalers, not retail pharmacies, not covered
- **Sales to Home Infusion & Home Health**
 - Not wholesalers, not retail pharmacies
- **Sales to Retail Pharmacies**
 - If not acting and licensed as wholesalers
- **Sales to Other Manufacturers**
 - If not acting and licensed as wholesalers

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Examples From AMP Rule

- **Sales to Specialty Pharmacies**
 - Not normally wholesalers, not retail pharmacies
- **Sales and Rebates to PBMs**
 - Not normally wholesalers, not paid to manufacturers
- **Sales to Mail Order Pharmacies**
 - Not normally wholesalers, not retail pharmacies

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Injunction Halts Cuts

- **Federal Court Preliminary Injunction**
 - Temporarily halts AMP rule's reimbursement cuts
 - Prevents CMS from disclosing flawed AMPs
 - No website or distribution to states
- **Injunction Saves Pharmacies \$5.5 Million Each Day**
 - Based on CMS estimate of the cuts

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The Future Of AMP: Litigation

- **Court Expected To Permanently Block AMP Rule**
 - Indicated rule violates "crystal clear" statute
- **Probably No Final Court Decision In 2009**
 - Waiting on documents & 4th "multiple source drug" definition
 - We will amend our complaint
 - 2+ months to file briefs and hold hearing
 - No deadline for final court decision
- **CMS Could Appeal**
- **Good News: Injunction Should Remain In Place**

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The Future Of AMP: Regulation

- **If We Win, CMS Must Issue New AMP Rule**
 - Somewhat better reimbursement if AMP rule is fixed
 - We can challenge revised AMP rule if it is flawed
- **Will CMS Stop Defending The AMP Rule?**
 - Obama could withdraw or revise Bush's rule
 - But that could be expensive
 - Statute would require CMS to issue a new AMP rule

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The Future Of AMP: Legislation

- **Only New Legislation Can Repeal The DRA**
- **MIPPA Delay of AMP Rule Expires October 1st**
 - But injunction remains
- **House Healthcare Reform Proposal**
 - Sets FULs at 130% of weighted average AMP
 - Amp definition revised
- **Senate Bill? House-Senate Conference? Timing?**

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Summary

- **Economy And Deficits Cause Pressure To Reduce Reimbursement**
- **AWP May Shrink And Disappear**
- **AMP Will Be Used For Reimbursement**
 - Hopefully it will be revised by courts or Congress

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Thank You!

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