

Policy Updates: Medicare Part D and Pharmaceutical Pricing

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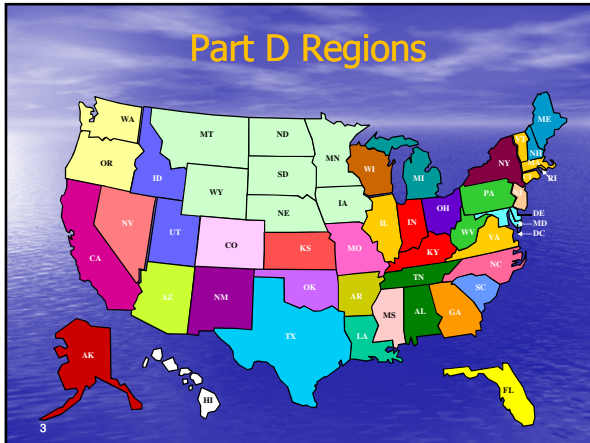
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Presentation Outline

- **Medicare Part D Update**
 - 2008 Transition in Florida
 - Evaluating 2006 and 2007
 - Evolving Benefits, Remaining Obstacles
 - Implications
- **Pharmaceutical Pricing**
 - The demise of Average Wholesale Price (AWP)
 - Average Sales Price (ASP) and Medicare Part B
 - Average Manufacturer Price (AMP) and Medicaid
 - Impact on senior care pharmacists
- **Q & A**

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Part D Regions



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2008 Part D Transition

National Perspective – Plan Sponsors

- 17 sponsors offering plans nationwide
- New: Sterling Ins. & Universal American
- Exited Market: Express Scripts & NMHC

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2008 Part D Transition

National Perspective - Premiums

- National average monthly premium is \$25 (40% lower than projection)
- 90% of beneficiaries have access to 2008 plan with a lower premium
- All beneficiaries have access to 1 or more plans with a premium <\$20

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2008 Part D Transition

National Perspective - Formularies

- 8 of top 10 plans reduced their formularies
 - Overall, 26% decrease (2,892 to 2,134)
- Almost 90% of plans use 4-tier formulary
- Significant cost-sharing for:
 - Tier 2 (preferred brands)
 - Tier 4 (specialty and biologics)

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2008 Part D Transition

National Perspective – LIS / Dual Eligibles

- 1.6 million re-assigned to new plans
- National plans
 - United lost 650,000
 - Humana lost 500,000

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Florida Perspective

2008 Part D Changes

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2008 Part D Transition

Florida Perspective – Plan Options

58 Prescription Drug Plans
281 Medicare Advantage Plans
106 Medicare Special Needs Plan

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Florida Perspective – LIS / Duals

8 options in '08, increase from '07

- Health Net
- RxAmerica
- UniCare
- Pennsylvania Life Insurance Company
- Member Health
- WellCare
- First Health Part D
- Quality Health Plans

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Florida Perspective – Special Needs Plans

- Type of MA-PD tailored to duals, institutionalized or those with severe chronic conditions
- 106 SNPs operate in FL in '08
- Only 7 with Institutional Care
 - Evercare Plan
 - MD Medicare Choice (4 options)
 - Universal IP (2 options)
- Jan 2008: Moratorium on new SNPs

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Evaluating 2006 and 2007 Part D

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Evaluating 2006 and 2007 Part D

- Cost Savings
 - Lower than projections
 - Further cost savings
- Utilization – generics a focus
- Access – concerns remain
- Plan performance
 - Beneficiary satisfaction
 - Reconciliation

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Plan Reconciliation for 2006

- Plans reimbursed 80 % of catastrophic cost
- Subsidies for monthly premium payments
- Risk Corridor – if cost more/less than expected
 - Plan pays/keep if cost 2.5% +/- of expected
- 2006 reconciliation = \$4 billion

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Evolving Benefits, Remaining Obstacles

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Medicare Part D and LTC

- Designed on commercial model for ambulatory patients
- LTC 5% of Part D population
- Friction with Part D and LTC
 - Clinical
 - Regulatory
 - Operational

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The Paradox:

Quality and efficiency in LTC achieved through consistency and uniformity.

The number of Part D plans, and the wide variability from plan to plan, create challenges in LTC setting.

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New changes for 2008

- Beneficiary protection during transition
- Assisting with beneficiary plan selection
- Home infusion delivery
- Plan rating for MA and PDPs
 - Customer service
 - Troubleshooting
 - Chronic condition management

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Policy Developments: Part D

Recent Adjustments - Prior authorizations

- PA facilitated by LTC pharmacy/pharmacist
- Top 5 PDPs internal policy (not required)
- Exclusivity to certain pharmacies?
- Awareness by prescribers and pharmacists?

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Policy Developments: Part D

2009 Changes - Prior authorizations

- 2009 bids - plans must detail PA processes within framework determined by CMS
- Required deadlines (summer 08)
- Disclosure via plan website
- Beneficiary can compare "apples to apples" on CMS Plan Finder website - Oct 2008

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Regulatory Changes for 2009

- Proposed rule - Plan Bidding for LIS
 - Plans choose when submitting bids if they will charge LIS a zero premium if plan's bid does not fall below the regional benchmark
 - Applies to regions where <5 sponsor organizations fall below the benchmark
- CMS objective - mitigate the disruption of plan switching during 2008-09 transition
- First time Part D would allow plan to apply premium differently to LIS / non-LIS

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Congressional "Fixes" for Part D

- Cost-sharing protection for LIS
 - caps out-of-pocket spending to 2.5% of income
- Eliminates cost-sharing for duals receiving care under HCBS waiver
- Plan switching
 - Mid-year changes allowed if formulary change adversely impacts beneficiaries
 - Allows change for up to 90-day period following notification of LIS status change

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Congressional "Fixes" for Part D

- Intelligent assignment for duals
 - eliminates random assignments
- Removes exclusion of benzodiazepines
- Codifies protection of 6 classes of drugs
 - Anti-convulsants
 - Anti-neoplastics
 - Anti-retrovirals
 - Anti-depressants
 - Anti-psychotics
 - Immunosuppressants

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Part D and Part B

- Part B / Part D Coordination
- Over 600 meds can be paid either way, depending upon diagnosis, etc.
- MMA requires Part D to pay only after Part A or B pays first
- Logistical/operational challenges
- 2008 Change: vaccine coverage and administration

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Medication Therapy Management (MTM)

"Any symptom in an elderly patient should be considered a drug side effect until proved otherwise."

Gurwitz J, Monane M, Monane S, Avorn J. Polypharmacy. In: Morris JN, Lipsitz LA, Murphy K, Bellville-Taylor P, eds. Quality Care in the Nursing Home. St. Louis, MO: Mosby-Year Book; 1997:13-25.

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Medication Therapy Management (MTM)

- Plans slow to respond
- Which professionals will seize the opportunity?
- Market-based approach

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Part D Implications

2008 Transition Brings

- Greater choices, more plans
- Dual Eligible / LIS disruption
 - Re-assignment (400K)
 - Choosers (100K)
- Congress - minor Part D reform in 2008
- CMS – reform implemented prior to 2009 bidding

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Pharmaceutical Pricing: Navigating the Changes

Outline

- Context of pricing changes
- Sorting out the acronyms
- The demise of AWP
- ASP and Medicare Part B
- The "new" AMP
- Implications of changing landscape

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Context of Pharmaceutical Pricing Changes

- **Policy goals of government**
 - Consistency
 - Transparency
 - Control
- **Pharmacies / Physicians**
 - Adequate payment for product and services
- **Manufacturers**
 - Access to markets and clarity on reporting requirements
- **Consumers**
 - Lowest cost and access

Pricing Acronyms

- AWP = **Average Wholesale Price**
- ASP = **Average Sales Price**
- AMP = **Average Manufacturer Price**

- FUL = **Federal Upper Limit**
- MAC = **Maximum Allowable Cost**
- WAC = **Wholesale Acquisition Price**
- EAC = **Estimated Acquisition Price**

The Demise of AWP

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AWP = **Average Wholesale Price**

- **Definition:** Published (blue book, red book) suggested wholesale price.
- **Used for:** Pharmacies use as cost basis for pricing prescriptions
- **Government programs:**
 - Still widely used, but trend is toward eliminating this benchmark.
 - AWP no longer used for Part B meds (replaced by ASP) and may no longer be used for FUL (replaced by new AMP)

Changes with AWP

Legal Action

- First DataBank – MediSpan legal settlement
- Court ruling against manufacturers

Gov't Action

- Part B drugs
- Medicaid multi-source drugs

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Legal Action # 1

First DataBank - MediSpan Settlement

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First DataBank (FDB) Medi-Span Settlement

- October 2006, FDB announced it would settle claims that it fraudulently inflated AWP's
- Case of New England Carpenters Health Benefits Fund v. First DataBank Inc., D. Mass., No. 1:05-CV-11148
- Settlement preliminary approval by judge in May 2007
- Proposed settlement rejected by judge in ³⁶January 2008

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FDB Settlement

- Plaintiffs are employee welfare benefit plans and associations
- Allege FDB and McKesson engaged in a scheme to fraudulently inflate AWP

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Allegations

- FDB did not systematically survey wholesalers but typically set AWP by applying markup to the drug's WAC
- WAC is a price established by manufacturers to offer the product to wholesalers and specialty distributors.
- FDB and McKesson allegedly conspired to raise the WAC-to-AWP markup for all drugs to a uniform 25%

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FDB Settlement

- Settlement requires FDB to lower the AWP it publishes for thousands of NDCs so that each drug's WAC-to-AWP markup is no greater than 20%.
- FDB will cease publishing AWP information (within 2 years)
- UPDATE: Court rejected settlement. Back to the drawing board, new settlement should not adversely impact pharmacies

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Legal Action # 2

Litigation Against Manufacturers

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Litigation Against Manufacturers

- Many suits against manufacturers since late 2001
 - Follow TAP's \$875 million settlement with DOJ and States
- Allege that manufacturers reported artificially high AWP's resulting in inflated reimbursements by payors.
- Two related class action suits pending in AZ and NJ courts.
- Other actions by state attorneys general are pending
- All federal class actions combined in MDL 1456 before Judge Saris in D. Mass.

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Federal Court Ruling

- AstraZeneca, Bristol-Myers Squibb and Schering-Plough were found guilty
 - over-inflating the published price
 - selling at a steep discount to prescribers
 - encouraging doctors to claim full reimbursement from Medicare and pension funds
- Judge Saris' June 2007 ruling based on use of AWP on Part B drugs.

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Federal Court Ruling

"Spread" is difference between a drug's AWP and its ASP
30% "speed limit"

- "Spreads" always under 30% are not sufficiently "egregious" to impose liability

"Mega-spreads"

- Potential for liability when spread exceeds 30%.
- Liability likely whenever spreads are routinely over 100%.
- With "mega-spreads," no need to show "proactive spread marketing or increase in the published AWP."
- "Price manipulation" alone can constitute sufficient basis for liability

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Implications of Legal Actions

FDB Settlement

- Future publications of AWP
- Gov't and private payors that use AWP will need to find a substitute pricing benchmark
- Manufacturers with contracts based on AWP will need to transition those contracts to another reference price

Litigation Against Manufacturers

- Navigating "30% speed limit" and "mega-spreads"
- Safe Harbor?

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ASP and Part B Drugs

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ASP for Part B Drugs

AWP was the benchmark prior to 2005

Congress and Medicaid Fraud Unit Taskforces uncovered abuses with AWP benchmark

Medicare Modernization Act of 2003

- ASP becomes new benchmark
- Competitive Acquisition Program (CAP) for Part B drugs and biologicals

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ASP = Average Sales Price

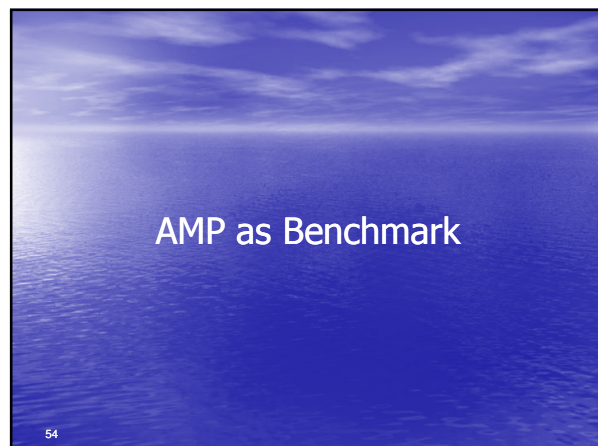
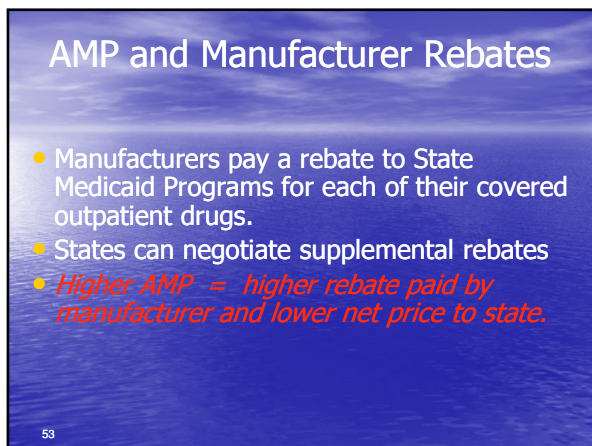
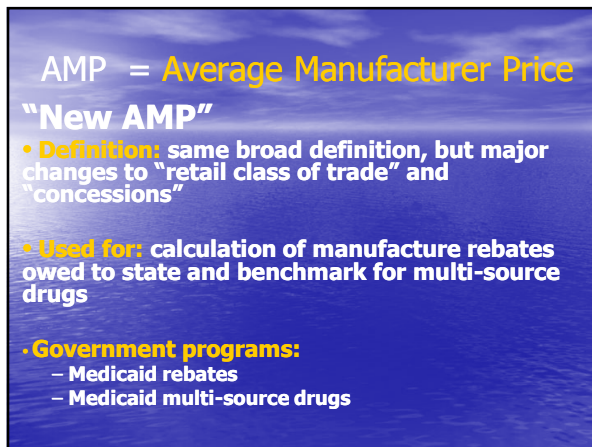
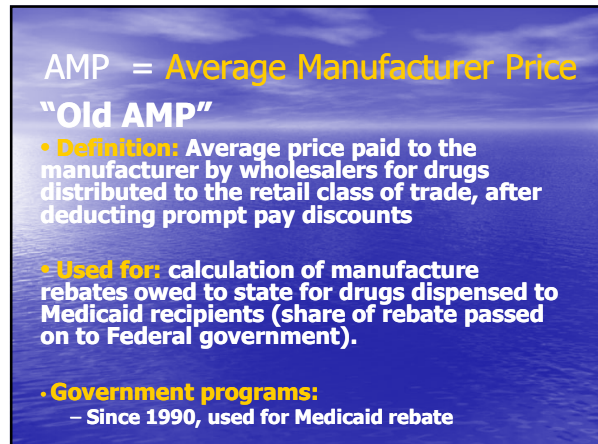
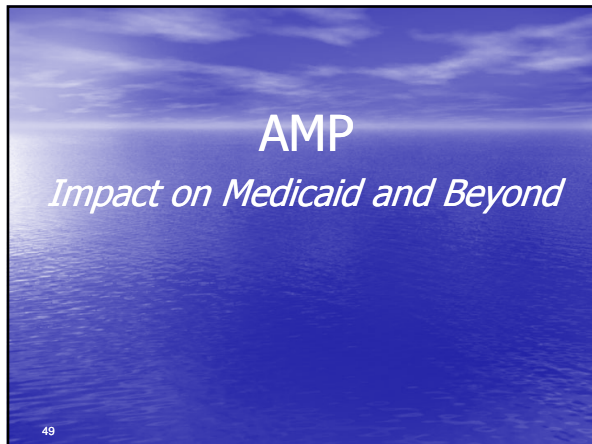
- **Used for: Part B drugs (replaced AWP in 2005)**
Payment based on product only, not special packaging, labeling or identifiers.
- **Government programs:**
 - Part B is ASP +6%
 - ASP updated quarterly
 - ASP compared to widely available market prices (WAMP) by Office of Inspector General. WAMP may be adopted on a drug-specific basis if found to be lower.

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ASP – Current Status

- Physicians choose from:
 - Buy and bill at ASP+6%
 - CAP enrollment, frees them from buy and bill
- CAP sole vendor is BioScrip, paid at ASP+4.1%
 - Implication: Gov't and beneficiaries "save" on every drug dispensed under CAP
- Potential Changes
 - Mandatory physician enrollment
 - Change to ASP calculation and/or multiplier

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AMP as Benchmark

- States were to begin using AMP to set reimbursement for Medicaid multi-source drugs (replaces AWP)
- Court intervention stopped policy
- Extended legal battle expected

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AMP as Benchmark

- Legal Arguments by Pharmacies
 - Definition of “multi-source drugs”
 - Calculation of AMP
 - Public disclosure of AMPs via government website

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Pharmaceutical Pricing Trends

- **BROAD TREND** - Benchmark established in statute and monitored by government
- AWP going away... WAC may also phase out
- ASP working in Part B reimbursement
- AMP pricing
 - uniform reporting, public disclosure
 - commercial market implications
- Push for generics
- Untangling product reimbursement from payment for pharmaceutical care services (medication therapy management)

Thank you!!

Questions?

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