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Medicare Prescription Drug, Improvement, and Modernization Act of 2003

Title III – Combating Waste, Fraud, and Abuse

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U.S. Pharmaceutical Industry

$216.4 Billion

U.S. drug sales in 2003

$32 Billion

Estimated research and development investment for 2002

$445.9 Billion

Projected U.S. spending for prescription drugs in 2012

Outpatient Drugs & Biologicals

Pre-Reform Status

Part B coverage usually if:

- Not self-administered and provided incident to physician services
- Necessary for effective use of covered DME
- Certain self-administered oral cancer and anti-nausea drugs, erythropoietin, immunosuppressive drugs after a covered Medicare organ transplant, and hemophilia clotting factors

Payment generally based on 95% average wholesale price (AWP)

Outpatient Drugs & Biologicals

AWP and "Spread"

AWP designed to represent average price that wholesalers sell drugs to customers

Evidence that use of AWP leads to excess Medicare payments when AWP is inflated to influence physician prescription habits (GAO & OIG investigations)

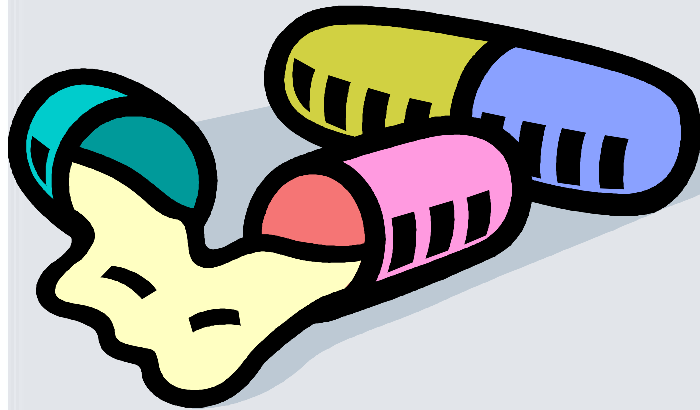
Estimated that Medicare pays in excess of $1 billion in overpayments and beneficiaries pay hundreds of millions of additional dollars in co-payments annually

Outpatient Drugs & Biologicals

AWP Reform –
Focus on Market Based Payment Structures

Outpatient Drugs & Biologicals

2004 Payment Methodology



Generally 85% of AWP determined as of 4/1/2003

DHHS may substitute a different AWP percentage based upon data submitted by manufacturer

Percentage adjustment may not fall below 80% of AWP

Outpatient Drugs & Biologicals

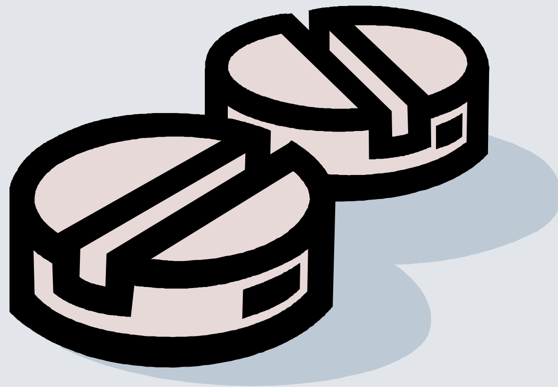
2004 Payment Methodology

Certain drugs and biologicals (i.e., Pneumococcal, influenza, and hepatitis B vaccines) are excluded

Excluded items will continue at 95% of AWP

Outpatient Drugs & Biologicals

Payment Reform



Two new sections to the Social Security Act:

2005
Average Sales Price (ASP)

2006
Competitive Acquisition Program

Outpatient Drugs & Biologicals

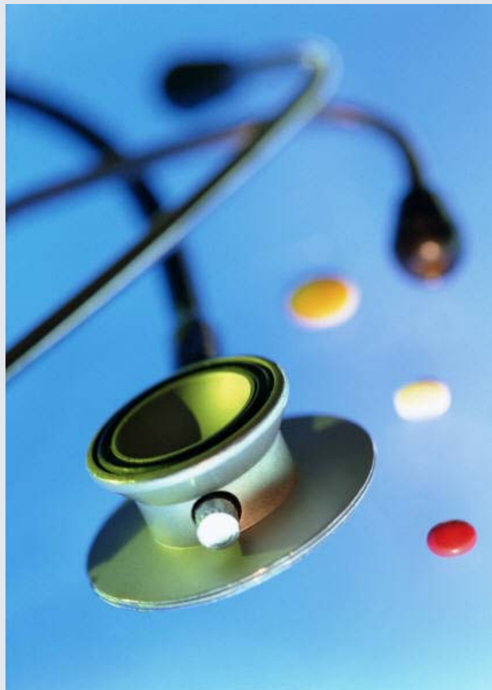
Average Sales Price (2005)

Does not apply to:

- Certain drugs and biologicals (i.e., Pneumococcal, influenza, and hepatitis B vaccines)
- Physicians who opt to participate in the competitive acquisition program

Outpatient Drugs & Biologicals

Average Sales Price (2005)



Generally:

Multiple Source Drugs

Reimbursement will be 106% of ASP

Single Source Drugs

Reimbursement will be 106% of lesser of ASP or Wholesale Acquisition Cost (WAC)

Outpatient Drugs & Biologicals

Average Sales Price (2005)

ASP determined by National Drug Code (NDC) on a quarterly basis

$$\text{ASP} = \frac{\text{Manufacturer's Total Sales}}{\text{Total Number of Units Sold Per Quarter}}$$

Outpatient Drugs & Biologicals

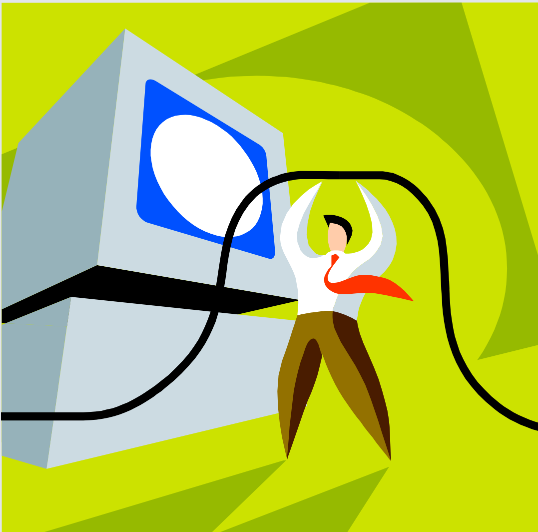
Average Sales Price (2005)

ASP calculation will account for volume discounts, prompt pay discounts, cash discounts, free goods conditioned on required purchases, chargebacks, and certain rebates

Medicaid rebates exempt from calculation

Outpatient Drugs & Biologicals

Average Sales Price (2005)



Manufacturer to submit quarterly data regarding:

- ASP
- Total number of units
- WAC
- Nominal price sales

Misrepresentation of data:

- False Claims Act exposure
- Civil monetary penalties up to $10,000 per incorrect price and for each day price was applied

Outpatient Drugs & Biologicals

Average Sales Price (2005)

OIG to compare ASP to Widely Available Market Price (WAMP) and Average Manufacturer Price (AMP)

DHHS may disregard ASP if it exceeds WAMP or AMP by a threshold percentage (5% for 2005)

Outpatient Drugs & Biologicals

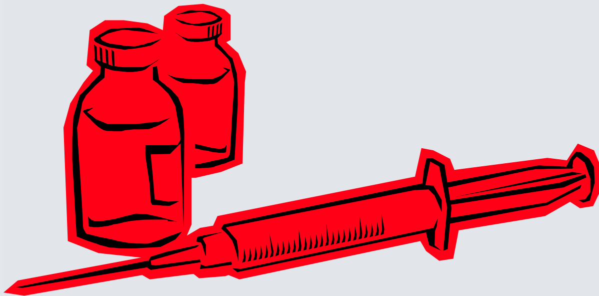
Average Sales Price (2005)

OIG to report to DHHS if ASP exceeds WAMP or AMP by threshold

If threshold exceeded – DHHS will reimburse the lesser of WAMP or 106% of AMP

Outpatient Drugs & Biologicals

Competitive Acquisition Program (2006)



Alternative to ASP reimbursement

Competitive acquisition areas established by geographic area

Outpatient Drugs & Biologicals

Competitive Acquisition Program (2006)

Physicians may voluntarily participate – annual election option

Program projected to reduce administrative and inventory costs for physicians

Program reduces physician liability since they do not take title to drugs

Outpatient Drugs & Biologicals

Competitive Acquisition Program (2006)

Competitively biddable drugs and biologicals established

Some drugs and biologicals (i.e., Pneumococcal, influenza, and hepatitis B vaccines) are excluded

Outpatient Drugs & Biologicals

Competitive Acquisition Program (2006)

Contracts awarded for term of 3 years

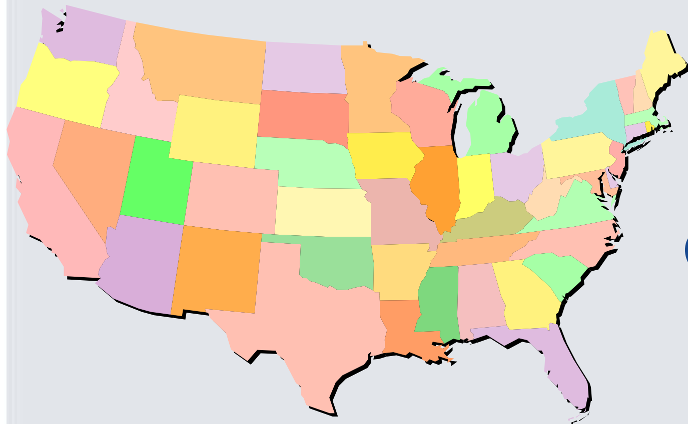
DHHS may limit contractors to no less than 2 for each drug category and area

Contractor selection criteria:

- Bid price for selected drugs and biologicals
- Bid price for distribution
- Product integrity
- Customer service
- Industry experience

Outpatient Drugs & Biologicals

Competitive Acquisition Program (2006)



Based on bidding process DHHS to establish single payment amount for each drug in the respective areas

Contractor may cover entire U.S. or selected areas

Outpatient Drugs & Biologicals

Competitive Acquisition Program (2006)

Contractor required to disclose to DHHS:

- Reasonable, net acquisition costs regularly
- Price adjustments over period of contract to reflect reasonable, net acquisition costs

Durable Medical Equipment
Quality Standards

DHHS to implement quality standards for suppliers

DHHS to designate one or more independent accreditation organizations

DHHS to establish standards for clinical conditions for payment for DME

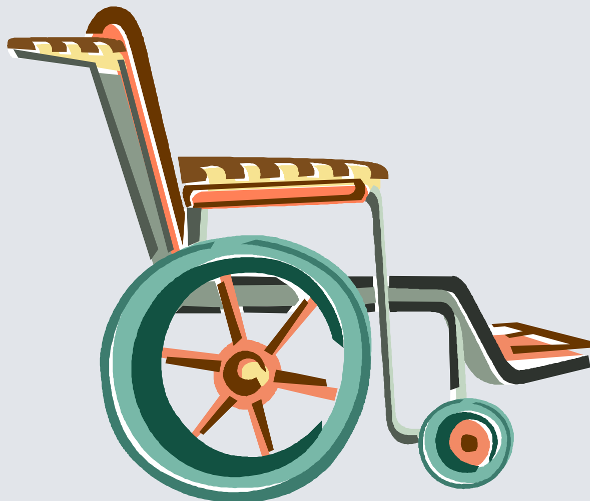
Durable Medical Equipment

Reimbursement

2004 to 2006 – 0% increase for DME, prosthetic devices and orthotics

2005 – payment reduced by percentage difference between 2002 rate and median FEHBP rate for oxygen and oxygen equipment, standard wheelchairs, nebulizers, diabetic lancets and testing strips, hospital beds and air mattresses

Durable Medical Equipment
Competitive Acquisition Programs



Competitive Acquisition Program
to replace current fee schedule for most DME

Program phased in:
- 2007 – 10 largest MSAs
- 2009 – 80 largest MSAs
- Post 2009 – most remaining areas

2009 – items not included in competitive bidding will receive CPI update

Durable Medical Equipment
Competitive Acquisition Programs

Conditions for receiving contract:

- Meet quality standards;
- Financial standards;
- Amount paid under contract less than would normally be paid; and
- Multiple suppliers available to beneficiaries

Payment based upon DHHS acceptance of competitive bids

Recovery Audit

DHHS to conduct 3 year demonstration project using recovery audit contractors

Contractors to identify and recoup Medicare overpayments

To involve 2 states amongst those with highest per-capita Medicare utilization

Recovery of overpayments does <u>not</u> preclude prosecution or further fraud and abuse actions

Final Thoughts
AWP Reform

Uncertainty will continue for manufacturers

Heightened scrutiny in fraud and abuse areas with quarterly reporting and OIG actively monitoring

How will AWP reform affect current DOJ/OIG enforcement actions?

How will AWP reform affect ongoing Congressional investigations into pricing?

Final Thoughts
OIG Role

Shift from oversight to proactive performance

Congress transferred authority from CMS and GAO to OIG

OIG responsible for monitoring the market

- Survey WAMP data
- Compare WAMP data with ASP and AMP
- Evaluate whether oncologists and hematologists are able to acquire items at 106% ASP