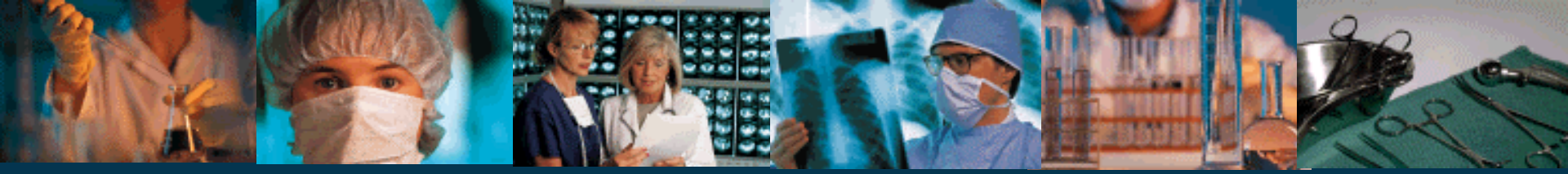

Taking a Deeper Dive: Regulatory Issues You Should Really Understand -- Reimbursement and Payment Update

ReedSmith

It's not just business. *It's personal.*℠

Presented by

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Introduction, Scope, and Overview

Overview of post-MMA coverage and payment for drugs and devices

Highlight compliance implications and challenges facing manufacturers

MMA Drug Coverage and Payment Reforms

Part B

1. HOPPS
2. RBRVS fee schedule increases
3. Drug payment reductions

Outpatient Drug Benefits

1. Section 641 “replacement drug” demonstration
2. Medicare-endorsed prescription drug discount card
3. Part D drug benefit

Medicare Part B Coverage and Payment: Hospital Outpatient Services (I)

BBA '97: All-inclusive HOPPS payment based on ambulatory payment classifications (APCs)

BBRA '99: Transitional pass-through payments

Medicare Part B Coverage and Payment: Hospital Outpatient Services (II)

Payment for newly approved drugs without pass-through codes

1. 5/28 Program Instructions
   - C9399 code for drugs approved after 1/1/04
   - Payment at 95% of AWP

Medicare Part B Coverage and Payment: Hospital Outpatient Services (III)

Separate APCs for "high cost" drugs

1. $50 threshold for "specified covered outpatient drugs" eligible for pass-throughs as of 12/31/02
2. Payment amount
   - 2004
     - Single source drugs - 88% of AWP
     - Innovator multiple source drugs - 68% of AWP
     - Noninnovator multiple source drugs 46% of AWP
   - 2005 - Single source payment decrease to 83% of AWP
   - 2006 - Payment based on GAO "average acquisition cost" surveys

MMA HOPPS Amendments: Implications and Issues

Drug classifications (S-I-N)

AWPs for new drugs

2006 average acquisition cost surveys

Effect of Part B physician payment amendments on site of care

Medicare Part B Coverage and Payment for Drugs: Background

Limited coverage of self-administered outpatient drugs

Payment historically based on AWPs

MMA: Part B Drug Payment Reforms

RBRVS fee schedule increases

2004: 85% of AWP, with exceptions

2005: ASP/WAC/WAMP/AMP

2006: Distribution and payment options

1. "Buy and bill" - ASP/WAC/WAMP/AMP
2. Competitive Acquisition Program

MMA: Part B 2004 RBRVS Fee Schedule

Increase work RVUs

Practice expense RVU adjustments based on specialty survey data

Transitional adjustments

MMA: Part B 2004 RBRVS Fee Schedule

CPT	*2003 Payment*	*2004 Payment (with transitional adjustment)*
90780 (therapeutic infusion, intravenous, 1st hour)	*$42.67*	*$117.79*
90782 (therapeutic injection, subcutatneous/intramuscular)	*$4.41*	*$24.64*
90984 (therapeutic injection, intravenous)	*$16.25*	*$49.78*
96400 (Chemotherapy administration, subcutaneous/intramuscular)	*$37.52*	*$64.07*
96408 (Chemotherapy administration, intravenous; push technique)	*$37.52*	*$154.76*
96410 (Chemotherapy administration, infusion, up to 1 hour)	*$59.22*	*$217.35*

MMA: 2004 Part B Drug Payments

Most drugs paid at 85% of AWP as of 4/1/03 (Red Book)

Exceptions

1. GAO/OIG data
2. Manufacturer-submitted data
3. Drugs to be paid at 95% of AWP
   - Blood clotting factor
   - Vaccines
   - ESRD drugs
   - IVIG
   - Infusion drugs furnished through DME
   - Drugs not reimbursed as of 4/1/03

MMA: 2005 Part B Drug Payments

Single source drugs: 106% of lesser of:

1. Average sales price (ASP)
2. Wholesale acquisition cost (WAC)

Multiple source drugs: 106% of volume-weighted ASPs of all drugs represented by multiple source billing code

Adjustments: If ASP > 105% of widely available market price (WAMP) or average manufacturer price (AMP), payment amount is WAMP or 103% of AMP

MMA: Drug Pricing Alphabet Soup

AWP

ASP

WAC

WAMP

AMP

MMA: ASP Reporting Issues

Which drugs?

Which prices and other contract terms affect ASP revenue?

To which purchasers?

12-month rolling average for "lagged" price concessions

Certification of data

Effect of erroneous data

MMA: 2006 Part B Drug Payments

"Buy and bill" approach

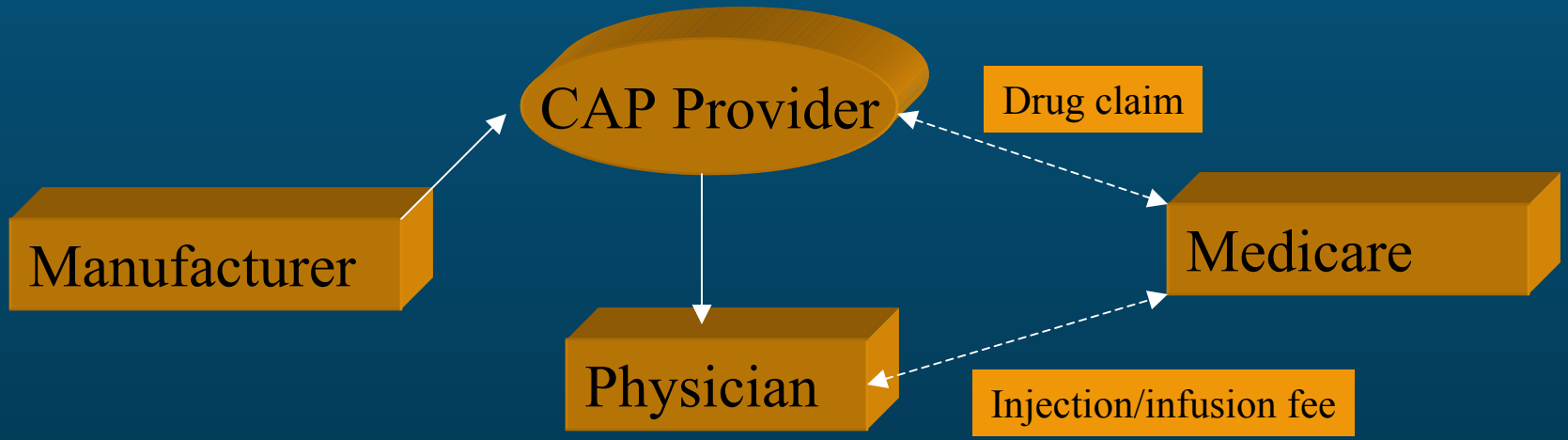
1. Physician paid under ASP/WAC/WAMP/AMP methodology

Competitive Acquisition Program (CAP)

1. HHS contracts with regional contractors to supply physicians
2. Physicians elect ASP or CAP method and select CAP contractor
3. Contractor bills Medicare for drugs and collects drug coinsurance
4. Physician bills Medicare for administration only

Medicare Part B: Traditional Model

Competitive Acquisition Program Option



MMA Part B Reforms: Implications and Issues (I)

Who will help physicians understand the MMA amendments and their implications?

Reduction of drug payments with increases in RBRVS administration payments will necessitate physician focus on operational efficiency and cost-sharing collections

Potential limitation of RBRVS adjustments in 2005 to certain specialties may inhibit introduction of office-based therapies in "new" specialties

MMA Part B Reforms: Implications and Issues (II)

Use of 4/1/03 AWP pricing data in 2004 results in anomalies for certain products

1. Regulatory responses
2. Implications of pricing responses

ASP methodology may result in losses for products that are discounted to institutions and payors but not to physicians

Absence of ASP price controls

How will OIG determine WAMP?

MMA Part B Reforms: Implications and Issues (III)

Will physicians continue to buy-and-bill or will they adopt the CAP model?

CAP contractors

1. Will they implement and manage formularies?
2. How will physicians select them?
3. Implications for contracting and pricing

Will the MMA amendments affect site-of-care decisions?

MMA Part B Reforms: Implications and Issues (IV)

Method for calculating ASP

1. Classes of trade
2. 12-month rolling average
3. Nominal pricing
4. Wholesaler/distributor prompt pay

Implications of pricing to CAPs

1. AMP, BP, NFAMP, ASP

MMA Outpatient Drug Coverage: Section 641 "Replacement Drug" Demonstration

Scope and timing

1. 2-year duration
2. 50,000 patient limit
3. $500 million limit

Delivery system

Extend Medicare coverage to self-administered drugs that "replace" Part B covered drugs

Potentially affected therapeutic areas

On-label use limitation

“Replacement Drug” Demonstration: Issues and Implications

Which drugs will be covered?

Patient enrollment

Donut hole

MMA Outpatient Drug Coverage: Prescription Drug Discount Cards

Build on prior administration efforts to implement cash card

Transitional measure to provide enrollees with discounted pricing prior to Part D benefit

Duration: 6/04-12/05

Prescription Drug Discount Cards: Eligibility

General

1. Medicare beneficiaries enrolled in Part A or B are eligible
2. No drug coverage through Medicaid

Transitional assistance for low-income individuals

1. Up to 135% of poverty level
2. $600 per year

Prescription Drug Discount Cards: Negotiated Pricing

Card sponsors must obtain discounted prices from manufacturers and pharmacies and "pass a share" of such concessions to enrollees

Formularies permitted

1. Must offer a discounted price on at least one product in 209 different therapeutic categories
2. At least 55% of the 209 therapeutic categories must include a negotiated price on a generic drug

Disclosure to CMS of aggregate price concessions and enrollee pass-through percentage

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Best price exemption

Prescription Drug Discount Cards: Issues and Implications (I)

Program philosophy

1. Charitable v. commercial
2. Card sponsors: "practice" for Part D/loss leader v. active benefit management

Contracting issues

1. Pass-through/structure/timing of price concessions
2. Administration fees
3. Nondiversion/eligible utilization

Prescription Drug Discount Cards: Issues and Implications (II)

Compliance issues

1. Transitional assistance triggers fraud and abuse rules
2. Price reporting implications (AMP, NFAMP, FSS, ASP)
3. Card sponsor patient recruitment

Medicare Part D

Part D: Overview

Scheduled to begin January 1, 2006

Optional comprehensive outpatient drug benefit

Administration through PDPs and MA-PDPs

Part D: Benefit Design

Annual deductible is $250

Plan covers 75% of drug costs from $251 to $2,250

Beneficiary responsible for OOP drug costs between $2,251 - $3,600

Drug costs over $3,600 covered with nominal cost sharing of the greater of:

1. $2 generic/multiple-source drug; or
2. $5 all other drugs.

Part D: Enrollment

Premium and cost-sharing subsidies for low income individuals

Plans may offer supplemental prescription drug coverage

Part D: Plan Sponsors

Secretary will establish regions

Minimum 2 plans per region - 1 PDP

Limited risk plans and fallback plans

Part D: Financial Support

Risk corridors

Equalizes risk among plans

Risk Corridor = specified % above and below target amount used to adjust Part D payments to Plans.

Part D: Formularies and Negotiated Pricing

Optional formularies

1. P&T committee
2. Tiered cost-sharing permitted
3. Must include at least one drug from each class defined by USP
4. May only be revised annually
5. Beneficiary appeals

Negotiated Prices

1. Beneficiaries must have access, even if in donut hole
2. BP exemption
3. Aggregate reporting to HHS

Part D: Quality Assurance

Medication therapy management program

Electronic prescription drug program

Part D: State Issues

Dual eligibles automatically enrolled

No Medicaid cost sharing

State Pharmaceutical Transition Commission

Part D Coverage: Implications and Issues (I)

Consumer perspective

1. Demand
2. Backlash?

Plan participation interest

Increased formulary contracting/formulary management activities…but how much?

Part D Coverage: Implications and Issues (II)

Electronic prescribing may push therapy management to "point of prescribing"

Compliance

1. Discount structures/safe harbors
2. Compliance Program Guidance
3. Pricing
   - Impact on AMP, ASP, NFAMP calculations

Medical Devices: Expanded Competitive Bidding

Clinical laboratory tests

Blood glucose meters and testing supplies

Enteral nutrients and pumps

Competitive Bidding Limitations

Designated areas

Phase in

Multiple suppliers

Physician can prescribe particular brand within a code to avoid adverse medical outcomes

Conclusions/Question and Answer