*Drug Pricing Considerations*

# Medicare Prescription Drug, Improvement, and Modernization Act of 2003



July 28, 2005

# *Overview*

- Timetable and Key Changes in Drug Benefits
- Prior Law
- New Part D Benefit
- New Payment Rules for Part B Drugs
- Hospital Outpatient Drug Payment

# *Timetable for Key Changes*

- The new Medicare prescription drug benefit (Medicare "Part D") available until January 1, 2006.

- In addition, the legislation changes the payment rules for drugs currently covered by Medicare, and requires manufacturers to begin compiling new pricing data.

# *Prior Law -- Drug Coverage Under Medicare, Medicaid*

- Coverage for drugs limited to drugs administered in a physician's office and a small number of additional drugs specified by statute ( "Part B" drugs).
- Approximately 10% of Medicare beneficiaries are enrolled in managed care plans under the Medicare+Choice program (now called MedicareAdvantage); some Plans cover outpatient prescription drugs that go beyond Part B drugs.
- Medicaid, a joint federal-state program that provides health insurance to the poor, provides broad drug coverage.
- "Dual Eligibles" receive coverage for most drugs under the Medicaid program.

# New Part D Drug Benefit

- A new voluntary benefit under Medicare Part D, delivered through private risk-bearing entities under contract to HHS.
- Individuals entitled to Part A or enrolled in Part B may enroll in the new Part D benefit.
- For 2006, beneficiaries enrolling in Part D typically would pay a premium (estimated at $35/month), a $250 annual deductible, and the following co-payments:

| Prescription drug costs | Beneficiary co-pay |
|---|---|
| $ 250-2,250 | 25% |
| 2,250-3,600 | 100% |
| 3,600 and above | 5% (approx.) |

- Deductible and co-pays are indexed [to inflation].
- Additional subsidies are provided to persons with incomes below 150% of federal poverty level.

# Part D -- Covered Drugs

- "Covered Part D drugs" are defined primarily by reference to Medicaid rebate statute and include most prescription drugs, biologics, vaccines, and insulin.

- Part D drugs do not include:
  - Part B drugs
  - Drugs such as drugs for weight gain or loss, infertility, or hair growth;
  - Drugs that would not meet Medicare's "reasonable and necessary" requirements (subject to provisions for reconsideration and appeal);
  - Drugs prescribed for uses that are not "medically accepted indications" (as that term is defined in the Medicaid rebate statute); and
  - Drugs not prescribed as required under the plan or Part D.

# Part D -- Role of Private Health Plans

- The new drug benefit will be provided by private entities under contract with the Department of Health and Human Services (HHS).
- These entities will bear significant financial risk in providing the benefit and receive federal payments and enrollee premiums.
- Plans will submit bids and compete for contracts based on factors such as the coverage offered (including the deductible and other cost sharing) and the level of risk assumed.

# Part D -- Role of Private Plans (cont'd)

- Two types of prescription drug plans will be available: (1) stand-alone plans, and (2) drug coverage provided through MedicareAdvantage plans) (collectively "plans" or "plan sponsors").

- Health plans may provide supplemental coverage of reduced cost sharing or coverage of drugs excluded from Part D.

- To assure beneficiary choice, HHS must contract with at least two plans (at least one of which must be a PDP) in each geographic region.

# Part B Payments (cont'd)

- ***Payments for 2005***. Under a new payment methodology that takes effect beginning in 2005, payment for most drugs will usually depend on their Average Sales Price (ASP).

- The ASP for a drug is a quarterly figure, which basically equals the average net price at which the manufacturer sells the drug in the U.S. during that quarter. Manufacturers must report ASPs (and other data) to CMS "for calendar quarters beginning on or after January 1, 2004."

- The basic payment formula for single source drugs is the lesser of: (1) 106% of ASP; or (2) 106% of Wholesale Acquisition Cost (WAC). The basic payment formula for multiple source drugs is 106% of the volume-weighted ASP for all of the multiple source products within the same Medicare billing code.

# Part B Payments (cont'd)

- ***Payments for 2005 (cont'd).*** Payments will be lower than 106% of ASP (or 106% of the lesser of ASP or WAC) in some cases.

- The HHS OIG will conduct studies to determine the Widely Available Market Price (WAMP) -- "the price that a prudent physician or supplier would pay for the drug," taking into account "the discounts, rebates, and other price concessions routinely made available to such prudent physicians or suppliers" -- and will notify CMS if the ASP for a drug exceeds its WAMP or AMP by a threshold percentage.

- Upon receiving this notice, CMS "shall" substitute an alternative payment formula (WAMP or 103% of AMP, whichever is lower) for the basic payment formula.

# Part B Payments (cont'd)

- ***Payments for 2006 and Beyond.*** CMS will phase in a "competitive acquisition program" for certain drugs beginning in 2006.
- Certain drugs (*e.g.*, specified types of vaccines, clotting factors) are not "competitively biddable drugs." CMS may exclude additional drugs from the competitive acquisition program.
- CMS will conduct competitions to select competitive acquisition contractors, based on bid prices and certain other factors. Based on the bids it accepts, CMS will set "a single payment amount for each competitively biddable drug . . . in the area."

# *CAP for Outpatient Drugs*

- Interim final rule, 7/6/06; comments due 9/6/05
- Program begins 1/106
- Optional for physicians; election period 10/1/05 to 11/15/05
- National distribution area
- 169 Medicare Part B Drugs
- Vendor bids due 8/5/05

# *CAP*

- Bids may not include costs "related to the administration of the drug or wastage, spillage, or spoilage."
- Bids for 169 drugs evaluated as single consolidated bid; must be < weighted average of ASP+6%
- Bids for each "new drug" evaluated separately; must be < ASP+6%

# *CAP*

- Single payment amount per drug (based on median of wining bids, updated to mid-2006 by PPI); for years 2 & 3, updated based on vendor net acquisition cost data
- CMS say CAP prices must be included in ASP calculations
- “Furnish as written” option for CAP physicians; ASP-based payment applies

# OPPS: 2006 NPRM

- Published 7/25, comments due 9/16
- 3.2% market basket increase but overall impact on all hospitals is a 1.9% payment increase over 2005; proposed conversion factor ($59,350) up 4.1% over the 2005 conversion factor ($56,983)
- Continue paying separately for drugs with per day costs > $50, but seeking comments on alternative threshold for 2007
- Proposed ASP+6% (updated quarterly) for SCODs; will not use GAO survey data

# *OPPS*

- Proposes to pay selected orphan drugs ASP+6
- Proposes collecting ASP data for radiopharmaceuticals
- Proposes to add 2% to drug payments (ASP+8%) to cover pharmacy overhead costs