

ARNOLD & PORTER LLP

**The Medicare Prescription Drug, Improvement, and  
Modernization Act of 2003 (MMA)**

*An Update*

Grant P. Bagley, MD, JD  
grant.bagley@aporter.com  
202.942.5928

# *Overview*

- Part D Benefit
- Part B “Old or New?”
- Competitive Acquisition Program
- Drug Payment Wild Cards

## Prior Law — Drug Coverage Under Medicare and Medicaid

- **Traditional Medicare coverage for drugs:**  
Drugs administered in a physician's office and statutorily-specified drugs ("Part B" drugs)
- **Medicare+Choice program (now Medicare Advantage):**  
Outpatient prescription drug coverage beyond Part B drugs under managed care plans (less than 10% of Medicare beneficiaries), Plans not required by law to offer outpatient prescription drug coverage
- **Medicaid:**  
Joint federal-state non-entitlement program providing outpatient drug coverage for low income individuals
- **Dual Eligibles:** (individuals eligible for both Medicare and Medicaid)  
Majority of drug coverage under Medicaid program

# PART D

## Part D Benefit

- New drug benefit will be administered by private entities under contract with the Department of HHS -- Begins Jan. 1, 2006
- Entities required to bear significant financial risk and will receive federal payments and enrollee premiums
- Plans to submit bids and compete for contracts based on factors such as coverage (including the deductible and other cost sharing) and level of risk assumed
- In establishing the Part D structure, Congress embraced a private competition — not government price control — model for containing drug costs
- Beneficiary access protections
- Additional assistance for low-income beneficiaries

## Part D Benefit (cont'd)

- Each beneficiary must have choice of at least two qualifying plans in the area in which the beneficiary resides
- At least one plan must be a PDP (the other can be an MA-PDP), and PDPs are subject to an “any willing pharmacy” requirement
- No limits on the number of full-risk PDPs
- “Fallback” prescription drug plans (plan paid actual costs if access cannot otherwise be provided)
  - Subject to certain performance measures
  - Subject to competitive procurement procedures
  - National plan prohibited

## Part D Benefit Design

- All plans must offer “qualified prescription drug coverage”
- Qualified coverage = standard coverage or alternative coverage
- Alternative coverage = basic alternative coverage (alternative coverage without supplemental benefits) or enhanced alternative coverage (alternative coverage with supplemental benefits)
- PDPs must offer a basic coverage plan (standard coverage or alternative coverage without supplemental benefits) in an area in order to offer enhanced coverage
- Cost of enhanced coverage paid entirely through premiums

## Part D Benefit (cont'd)

- Monthly premium: \$35 (estimated)
- Deductible: \$250
- Coinsurance up to \$2,250 limit: 25%
- Doughnut hole: No coverage until \$3,600 in true out-of-pocket costs, regardless of coverage type  
  
Negotiated prices apply
- Cost-sharing beyond \$5,100: \$2 generics; \$5 other drugs, 5% co-insurance

## Part D Benefit (cont'd)

- PDP and MA-PDP plans must provide beneficiaries with access to “negotiated prices” regardless of whether benefits are payable
- PDPs and MA-PDPs must disclose to HHS aggregate negotiated price concessions made available and passed through in the form of lower premiums and lower subsidies
- What are negotiated prices?
  - Discounts and rebates
  - Direct or indirect subsidies
  - Direct or indirect remuneration

## Part D -- Covered Drugs

- “Covered Part D drugs” are eligible for coverage under Part D
- Covered Part D drugs (“Part D drugs”) are defined primarily by reference to Medicaid rebate statute and include most prescription drugs, biologics, vaccines, and insulin.
- Drugs must be prescribed for uses that are “medically accepted indications,” as that term is defined in the Medicaid rebate statute:
  - FDA-approved uses, and
  - off-label uses supported by citations in specified compendia (or approved for inclusion in such compendia), e.g., USP-DI

## Part D -- Coverage Does not include

- Part B drugs -- generally not covered “as so prescribed and administered under Part B”
  - Can be covered if Part B coverage unavailable
- Drugs such as drugs for weight gain or loss, infertility, hair growth, cosmetic purposes, symptomatic relief of coughs and colds, prescription vitamins and minerals (except prenatal vitamins and fluoride preparations), barbiturates, benzodiazepines

## Part D -- Coverage Does not include (con't)

- Nonprescription drugs
- Drugs that would not meet Medicare's "reasonable and necessary" requirements (subject to provisions for reconsideration and appeal);
- Drugs not prescribed for a medically accepted indication or as required under the plan or Part D.

## Relationship Between Part B and Part D Drug Coverage

- The MMA directs CMS to prepare a report analyzing whether to fold Part B drugs into the new Part D Medicare drug benefit
  - The report is due by January 1, 2005
  - Absent legislative changes, Part B drugs remain in Part B
  - In some cases, “Part B” drugs also could be “Part D” drugs
    - “Covered Part D drugs” exclude drugs for which Part B payments is available “for that individual”
    - For drugs potentially covered by Part B and Part D, Medicare Part B is essentially “primary payor” vis-à-vis Medicare Part D

## Part D Benefit — Formularies

- Two drug minimum rule -- formularies must include at least two drugs (that are not therapeutically equivalent and bioequivalent) within each therapeutic category and class of covered Part D drugs
  - Restricted access may apply
  - Exceptions:
    - if only two drugs available and one is clinically superior to the other, then one drug may be permitted
    - Exception -- plans may be required to include more than two drugs to fulfill the non-discrimination provision where additional drugs “present unique and important therapeutic advantages in terms of safety and efficacy, and their absence from the plan formulary may substantially discourage enrollment

## Part D Benefit — Formularies (cont'd)

- USP has developed model formulary guidelines including categories and classes of drugs
- Secretary may approve plan only if formulary and tiered structure are not likely to discourage enrollment of certain beneficiaries — mechanism to inhibit gaming of tiers
  - Preserves beneficiary choice
  - Prevents adverse risk selection
- Formularies developed using USP guidelines deemed to be in compliance with requirement that formulary design may not discourage enrollment (with respect to formulary category and class structure)
- CMS will review populated formularies to insure that the formulary structure does not discourage enrollment

# Part D Benefit — Formularies

- Pharmacy & Therapeutics (P&T) Committees:
  - Membership
    - Physicians and pharmacists with expertise in elderly
    - At least two members must be independent and free of conflict of interest
  - Basis for decisions
    - P&T Committee must “base clinical decisions on the strength of scientific evidence and standards of practice,... pharmacoeconomics studies, outcomes research data, and on such other information as the committee determines to be appropriate...”

## Part D Benefit — Appeals Process

- Coverage Determination (Plan level)
- Redetermination (Plan level)
- Review by IRE -- de novo and must solicit views of the prescribing physician
- ALJ review
- Medicare Appeals Council
- Federal District Court

## Part D Benefit — Exceptions

- Tiering exceptions
- Exceptions for non-formulary drugs
- Plans must define a process for requesting exceptions

## Part D Benefit — Other Plan Requirements

- Convenient access rules that are no less favorable than rules for the TRICARE Retail Pharmacy Program
- Requirements:
  - Drug utilization management
  - Quality assurance
  - Medication therapy management program
  - Program to control fraud, waste and abuse
- Pharmacies required to inform enrollee of price differential between the price to the enrollee and the lowest-cost generic drug that is therapeutically equivalent
- Issuance of a card or other technology that could be used by the enrollee to access negotiated prices for drugs

# PART B

## ***Overview -- Part B Drugs***

- Competitive Acquisition Program (CAP)
- Drug Payment Wild Cards
  - Functional Equivalence
  - Least Costly Alternative
  - Inherent Reasonableness

## **Competitive Acquisition Program (CAP) Part B Rules (2006 and Beyond)**

- Physicians complain that payment at 106% of ASP limits their ability to purchase drugs
- CAP creates a new drug distribution system -- introduces a middle man (the CAP contractor) that relieves physicians of purchasing, billing, and collecting for drugs
  - Participating physicians obtain drugs from a competitive acquisition contractor in their area, and contractor will bill Medicare (and collects beneficiary co-payments) for drugs
  - Physician neither pays for the drug nor obtains Medicare reimbursement for the drug
  - Relieves physicians of administrative costs and “hassle”
  - Removes opportunity to profit from Part B drugs

## CAP (cont'd)

- Phase-in of competitive acquisition program (CAP) for certain drugs
  - Based on all physician administered drugs
  - Based on drug category by physician specialty
    - Oncology drugs
    - Urology drugs
  - Based on a limited set of drugs
  - Geographic phase-in
- Physicians may make annual election to participate in CAP
- Reimbursement for non-participating physicians or excluded drugs is based on ASP methodology

## CAP (cont'd)

- Proposed rule limits “competitively biddable drugs” to physician administered drugs
- CMS may exclude additional drugs from the competitive acquisition program
- CMS competitions to select competitive acquisition contractors, based on bid prices and other factors, minimum two per area
- CMS will set “a single payment amount for each competitively biddable drug ... in the area” based on the accepted bids, as defined by the HCPCS code

## CAP (cont'd)

- Reimbursement for non-CAP drugs
  - Furnish as written (FAW)
    - Physicians can bill for specific drugs that are on the CAP list by HCPCS code but that are not available at the CAP price
    - CAP contractors can deny such claims if it determined that a specific drug was not medically necessary
  - CAP-participating physicians can bill non-CAP drugs
  - CAP-participating physicians can bill for drugs in non-CAP categories

# Drug Payment Wildcards

- Least Costly Alternative
- Coverage under Protocol
- Inherent Reasonableness
- Functional Equivalence

# Least Costly Alternative

- Medicare contractors pay for some drugs using a “least costly alternative” methodology – *i.e.*, if a drug is considered equivalent to a cheaper drug, it may be reimbursed at the level of the cheaper drug
- Full reimbursement usually available if more expensive drug is “medically necessary”
- Patients can sometimes elect to pay the difference and receive the more expensive drug

## Inherent Reasonableness

- Medicare also has “inherent reasonableness” authority to reduce payments for drugs (and other Medicare-covered items)
- CMS must determine that existing payments are grossly excessive

# Coverage Under Protocol

- New CMS approach to coverage for drugs and devices

# Functional Equivalence

- Used to limit payment for drugs in the hospital outpatient setting deemed “functionally equivalent”
- MMA limits the use of functional equivalence: CMS may not use the “functional equivalence” standard to determine drug payments unless it:
  - has already applied that standard to the drug before the legislation’s enactment; and
  - applies the functional equivalence standard only for purposes of determining the drug’s eligibility for hospital outpatient pass-through payments
- MMA provision does not prevent CMS from treating two drugs as identical if classified by FDA as pharmaceutically equivalent and bioequivalent

# Functional Equivalence



## For More Information

- [Www.aporter.com](http://Www.aporter.com)
- [grant\\_bagley@aporter.com](mailto:grant_bagley@aporter.com)
- [www.cms.hhs.gov](http://www.cms.hhs.gov)
- [www. MedicareForPharma.com](http://www.MedicareForPharma.com)