The Nuts and Bolts of Medicare Part D
February 22, 2007

Understanding Medicare and Medicaid: Fundamentals and Issues for the New Congress

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Medicare Drug Benefit Group
Part D History

- E-prescribing and the Prescription Drug Program; Final Rule published on November 7, 2005.
- Medicare Part D Data NPRM published on October 18, 2006.
- Tax Relief and Health Care Act of 2006 (Sec. 202(b) Payment for Administration of Part D Vaccines) was signed into law on December 20, 2006.
Part D Eligibility and Enrollment Process
Eligibility

➢ To join a Medicare Drug Plan, individuals must:
  – Be entitled to Medicare Part A and/or enrolled in Part B
  – Reside in Plan’s service area

➢ Individuals living outside the U.S. and Territories or are incarcerated are not eligible
Enrollment into Part D Plans

- Coverage is not automatic
  - Except people who qualify for extra help (LIS)
- People entitled to Medicare on February 1, 2006, or later have a 7-month period to enroll.
- Annual enrollment period (AEP) is from November 15 through December 31.
  - Beneficiaries not receiving extra help can switch plans during this period
  - Do nothing and rollover into current plan.
- Full Benefit Dual Eligibles (FBDE) can switch plans during any month (effective the 1st of the following month).
What is the Low Income Subsidy (LIS)?

- Provides people with limited income and resources extra help with their Medicare prescription drug plan costs, including their premium, deductible and cost sharing.
- A person must enroll in a Medicare drug plan such as a PDP, MA-PD, or PACE to receive this assistance.
- CMS is working with States to identify FBDEs prospectively and autoenroll them into Part D plans prior to their effective date.
# How Do People Qualify for LIS?

<table>
<thead>
<tr>
<th>People with Medicare and Medicaid benefits</th>
<th>Basis</th>
<th>Data Source</th>
<th>Changes During the Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medicaid benefits</td>
<td>Automatically qualify</td>
<td>State files</td>
<td>Deemed for a full calendar year</td>
</tr>
<tr>
<td>• Full Medicaid benefits</td>
<td></td>
<td></td>
<td>Generally only change LIS level if favorable to beneficiary</td>
</tr>
<tr>
<td>• Medicare Savings Program</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SSI benefits</td>
<td></td>
<td>SSA</td>
<td></td>
</tr>
<tr>
<td>Limited income and resources</td>
<td>Must apply</td>
<td>SSA (most) or states</td>
<td>Subsidy changing events may impact status mid-year (both favorable and unfavorable changes)</td>
</tr>
</tbody>
</table>
Starting August 2006, CMS began redetermining eligibility for calendar year 2007
- Full-benefit dual eligibles
- Medicare Savings Program participants
- SSI recipients

Changes become effective January 1, 2007

Those currently eligible still qualify through December 31, 2006
- Even if don’t automatically qualify for 2007
Late Enrollment

- On January 9, 2007 CMS announced the elimination of the 2007 late enrollment penalty for any beneficiary eligible for the low income subsidy for a Part D plan even if they failed to sign up by the program’s initial deadline.

- Most people will have to pay a penalty if they wait to enroll
  - Additional 1% of base premium for every month they were eligible but not enrolled
  - For as long as they are enrolled in a Medicare prescription drug plan

- Unless they have other coverage that, on average, is at least as good as Medicare prescription drug coverage

- Possible examples of creditable coverage
  - Some group health plans (GHP), VA coverage, & Military coverage including TRICARE
Plan Offerings and Analysis
Standard Benefit 2007

- **Total Spending**: $265
- **Deductible**: $265
  - **Beneficiary Liability**: $265
  - **Direct Subsidy/Beneficiary Premium**: $798.75
  - **Medicare Pays Reinsurance**: 80% Reinsurance
- **Coverage Gap**:
  - **75% Plan Pays**: $2400
  - **25% Coinsurance**: $798.75
  - **Direct Subsidy/Beneficiary Premium**: $3850 TrOOP
- **Catastrophic Coverage**:
  - **15% Plan Pays**: $5451.25
  - **5% Coinsurance**

- **Approximate Out-of-Pocket**: 95%
### Annual Adjustments for Standard Benefit in 2007

<table>
<thead>
<tr>
<th>Benefit Parameters</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deductible</td>
<td>$250</td>
<td>$265</td>
</tr>
<tr>
<td>Initial Coverage Limit</td>
<td>$2250</td>
<td>$2400</td>
</tr>
<tr>
<td>Out-of-Pocket Threshold</td>
<td>$3600</td>
<td>$3850</td>
</tr>
<tr>
<td>Total Covered Drug Spend at OOP Threshold</td>
<td>$5100</td>
<td>$5451.25</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>LIS Copayments</th>
<th>2006</th>
<th>2007</th>
</tr>
</thead>
<tbody>
<tr>
<td>Institutionalized</td>
<td>$0</td>
<td>$0</td>
</tr>
<tr>
<td>Up to or at 100% FPL</td>
<td>$1/$3</td>
<td>$1/$3.10</td>
</tr>
<tr>
<td>Other LIS</td>
<td>$2/$5</td>
<td>$2.15/$5.35</td>
</tr>
</tbody>
</table>
Other Coverage Structures

- Plans may offer more than standard coverage
  - “Tiered” copayments or coinsurance common
  - Lower deductible
  - Change the coverage gap
    - Different dollar amount where the person begins to pay 100%
  - Provide coverage in the gap

- Many of the plan options in 2007 are “enhanced” plans that offer additional benefits beyond Medicare’s standard drug coverage.
## CY07 Benefit Type Analysis

<table>
<thead>
<tr>
<th>Benefit Type</th>
<th>% of PDP Plans</th>
<th>Change from 2006</th>
<th>% of MA-PD Plans</th>
<th>Change from 2006</th>
</tr>
</thead>
<tbody>
<tr>
<td>Defined Std. Benefit</td>
<td>12.1%</td>
<td>+2.8%</td>
<td>5.1%</td>
<td>-2.4%</td>
</tr>
<tr>
<td>Actuarially Equivalent Std.</td>
<td>13.4%</td>
<td>-8.3%</td>
<td>2.1%</td>
<td>-5.2%</td>
</tr>
<tr>
<td>Basic Alternative</td>
<td>27.2%</td>
<td>+0.5%</td>
<td>18.1%</td>
<td>-2.6%</td>
</tr>
<tr>
<td>Enhanced Alternative</td>
<td>47.3%</td>
<td>+5.0%</td>
<td>74.7%</td>
<td>+10.2%</td>
</tr>
<tr>
<td>Totals</td>
<td>100%</td>
<td>-</td>
<td>100%</td>
<td>-</td>
</tr>
</tbody>
</table>
## Part D Contract Summary

<table>
<thead>
<tr>
<th>Contract Type</th>
<th>2006</th>
<th></th>
<th>2007</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Contracts</td>
<td>Plans</td>
<td>Contracts</td>
<td>Plans</td>
</tr>
<tr>
<td>PDP</td>
<td>91</td>
<td>1,446</td>
<td>91</td>
<td>1,920</td>
</tr>
<tr>
<td>MA-PD</td>
<td>469</td>
<td>1,491</td>
<td>549</td>
<td>1,715</td>
</tr>
<tr>
<td>Totals</td>
<td>560</td>
<td>2,937</td>
<td>640</td>
<td>3,635</td>
</tr>
</tbody>
</table>

Excludes Employer Only Plans
Every state has at least one plan option with a premium less than $20 per month; at least one plan available with no deductible; and several plans available with coverage of generic drugs in the coverage gap.

On average, premiums increased less than $8 over 2006 and in several states the average premiums decreased.

Beneficiaries have access to between 27 and 41 plans with no deductibles in 2007 (an increase of 3 to 13 plans per state from 2006).

In every state, the majority of plans offer mail-order pharmacy services.
The number of PDP sponsors ranges from 20 to 29 per state which represents an increase over 2006 of 4 to 9 sponsors per state.

The number of PDP plans offered by these sponsors ranges from 45 to 66, representing an increase of 7 to 18 plans compared to 2006.

In general, the largest increase in plans was seen for those offering enhanced coverage.

In 2007, there are between 4 and 12 additional enhanced plans offered in each state.

Enhanced plans represent between 44% to 50% of plans offered in each state.
Maximize opportunity for retirees to continue receiving high quality drug coverage they have received in the past

Encourage plan sponsors to continue offering some form of drug coverage

Provide as much flexibility to plan sponsors as possible

Encourage plan sponsors to communicate early and repeatedly with retirees about how their coverage will work with Medicare

Implement through electronic information systems

Protect fiscal integrity of the program
Provide drug coverage that takes the place of Part D and receive 28% federal tax free Retiree Drug Subsidy (RDS)

Provide separate, stand-alone drug plan to supplement Medicare drug coverage

Sponsor customized Part D group coverage by directly contracting with Medicare or contracting with a Medicare PDP or MA-PD (requires waivers of Medicare requirements)
  – Can also offer customized MA-only + RDS coverage

Pay part or all of retirees’ Medicare drug premium

Different options for different groups (mix and match)
Formulary Highlights
What is a Part D Drug?

- Rx Only
- Drugs approved by FDA for safety and efficacy as described in §1927(k)(2)
- Biologicals as described in §1927(k)(2)
- Insulin and medical supplies associated with the injection of insulin
- Vaccines
- Used for “Medically Accepted Indications”
Drug Exclusions

- A drug in which coverage is available under Parts A or B as it is prescribed and dispensed or administered to an individual
- Drugs when used for anorexia, weight loss, or weight gain
- Drugs when used to promote fertility
- Drugs when used for cosmetic purposes or hair growth
- Drug when used for symptomatic relief of cough and colds
- Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations
- Nonprescription drugs, barbiturates, and benzodiazepines
A formulary is the list of drugs that a Medicare Prescription Drug Plan covers without granting an exception. Formularies help to contain costs.

General requirement: The formulary must include at least two drugs in each therapeutic category and class of covered Part D drugs.

Represents a floor rather than an absolute standard.

Utilization Tools: Prior Authorization, Step Therapy, and Quantity Limits.
Roles of U.S. Pharmacopeia (USP) and CMS

- USP Developed a model set of guidelines for drug categories and classes that represent:
  - A framework that may be used for the development of prescription drug plan formularies.
  - A benchmark for the start of CMS review process.
- USP updates the models annually.
- CMS is responsible for beneficiary protection.
- CMS will review formularies to ensure the adequacy of the benefit offered, regardless of whether plans adopt the model guidelines.
6 Classes of Clinical Concern

- All formularies must include "all or substantially all" drugs from the following classes:
  - Anticonvulsant, antidepressant, antineoplastic, antipsychotic, antiretroviral, and immunosuppressant
- New drugs within these classes must undergo an expedited P&T committee review
- Utilization management (UM) restrictions are not applicable to enrollees currently taking the medications
- UM is not generally permitted for HIV drugs
Formulary Review: Approach

- Part D formularies are reviewed to prevent discrimination against beneficiaries by age, disease, or setting (e.g. long-term care)
- Ensure the inclusion of a broad distribution of therapeutic categories and classes
- Utilize reasonable benchmarks to check that drug lists are robust
- Review tiering and utilization management strategies
- Identify potential outliers at each review step for further CMS investigation
- Obtain reasonable clinical justification when outliers appear to create access problems
Positive changes / enhancements can be made at any time upon notifying CMS.

Negative changes are generally limited to types of changes consistent with current best practices (for example, changing the tiering of a brand drug upon availability of a new generic equivalent).

Enrollees previously taking the affected drug are exempt from the negative change.

Drug deletions, increases in cost sharing or UM tools must be communicated to beneficiaries, providers, and CMS at least 60 days in advance.

All negative formulary changes must be approved by CMS prior to implementation.
# Characteristics of 2007 Formularies

## USP Model Analysis

<table>
<thead>
<tr>
<th># of Formularies</th>
<th>% of Formularies</th>
<th>% of Plans</th>
</tr>
</thead>
<tbody>
<tr>
<td>232</td>
<td>60%</td>
<td>78%</td>
</tr>
</tbody>
</table>

## Formulary Edit Analysis

<table>
<thead>
<tr>
<th>Type</th>
<th># of Formularies</th>
<th>% of Formularies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Specialty Tier</td>
<td>288</td>
<td>74.42%</td>
</tr>
<tr>
<td>Step Therapy</td>
<td>269</td>
<td>69.51%</td>
</tr>
<tr>
<td>Quantity Limit</td>
<td>381</td>
<td>98.45%</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>380</td>
<td>98.19%</td>
</tr>
<tr>
<td>Total Formularies</td>
<td>387</td>
<td></td>
</tr>
</tbody>
</table>
Enrollment Data
# Final 2006 Part D Enrollment

<table>
<thead>
<tr>
<th>Enrollment Category</th>
<th>#</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stand-Alone Prescription Drug Plan</td>
<td>10.98M</td>
</tr>
<tr>
<td>Medicare Advantage with Prescription Drugs</td>
<td>6.65M</td>
</tr>
<tr>
<td>Medicare-Medicaid (Automatically Enrolled)</td>
<td>6.27</td>
</tr>
<tr>
<td>Medicare Retiree Drug Subsidy</td>
<td>6.94M</td>
</tr>
<tr>
<td>Estimated Federal Retirees (Tricare, FEHB)</td>
<td>3.33M</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>34.17M</strong></td>
</tr>
<tr>
<td>Additional Sources of Creditable Coverage</td>
<td>4.86M</td>
</tr>
</tbody>
</table>

Data as of 01.16.07
Enrollment by Benefit Type

Data as of Jan07
Analysis excludes FBDE & LIS
Enrollment by Premium Category

Data as of Jan07
Analysis excludes FBDE & LIS
Grievances and Appeals
Grievances and Appeals Overview

- Modeled after the Medicare Advantage Processes
- **Differences**
  - Shorter adjudication timeframes
  - No adjudication timeframe extensions
  - Adverse redeterminations are not automatically forwarded to the IRE/Part D QIC (unless plan fails to meet timeframe)
- **Standardized Notices**
  - Pharmacy Notice
  - Coverage Denial Notice
- **Safeguards**
  - Plan sponsors cannot require additional exception requests for refills for the remainder of the plan year.
  - Plan sponsors must provide 60 days notice for mid-year formulary changes
Representatives
- May be authorized or appointed
- May request coverage determinations and appeals on behalf of the enrollee
- Not required for all interactions with a plan
Grievances and Appeals

- **Coverage Determinations**
  - Initial decision about the benefits an enrollee is entitled to receive or the amount, if any, that an enrollee is required to pay for a benefit

- **Adjudication Timeframes:**
  - Standard determinations: 72 hours
  - Expedited determinations: 24 hours
  - If a plan fails to meet these timeframes it must forward the enrollee’s request to Part D QIC
Grievances and Appeals Cont.

- **Tiering Exception**
  - Allows enrollees to obtain a non-preferred drug at more favorable cost-sharing terms applicable to drugs in the preferred tier

- **Formulary Exception**
  - Ensures that Part D enrollees have access to medically necessary Part D drugs that are not included on a plan’s formulary
  - Includes exceptions to cost utilization management tools
Final Thoughts
Next Steps - The 2008 Process:
Medicare Prescription Drug Benefit

Goals for 2008:

- Improve the overall quality of our plans.
- To enhance the information available to beneficiaries on plan quality and effectiveness.
- To meaningful problems in transitioning beneficiaries from one plan to another.
Additional Resources
For More Part D Information

www.cms.hhs.gov/PrescriptionDrugCovGenIn/01/01_Overview.asp
- Enrollment Data
- Performance Data
- Information for Pharmaceutical Manufacturers and Physicians
- Part D Regulations

www.cms.hhs.gov/PrescriptionDrugCovContra/01_Overview.asp
- Formulary Guidance
- Marketing Guidance
- Reporting Requirements
- Enrollment Guidance
- Coordination of Benefits Guidance
- Other Part D Related Guidance

www.cms.hhs.gov/DrugCoverageClaimsData/01_Overview.asp
- Prescription Drug Event (PDE) Information
- Risk Adjustment Information
Grievances and Appeals Resources

- Enrollment and Appeals Guidance Page
  [http://www.cms.hhs.gov/PrescriptionDrugCovContra/06_RxContracting_EnrollmentAppeals.asp](http://www.cms.hhs.gov/PrescriptionDrugCovContra/06_RxContracting_EnrollmentAppeals.asp)

- List of exceptions and appeals contacts at plans and the provider communication form:
  [http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp#TopOfPage](http://www.cms.hhs.gov/PrescriptionDrugCovGenIn/04_Formulary.asp#TopOfPage)

- “How to File a Complaint, Coverage Determination, or Appeal”:
  [http://www.medicare.gov/Publications/Pubs/pdf/11112.pdf](http://www.medicare.gov/Publications/Pubs/pdf/11112.pdf)
2007 Premium Analysis

Percentage of Plans

Premium Amount

<table>
<thead>
<tr>
<th>$0</th>
<th>$0.01 to $9.99</th>
<th>$10.00 to $19.99</th>
<th>$20.00 to $29.99</th>
<th>$30.00 to $39.99</th>
<th>$40.00 to $49.99</th>
<th>$50.00 or more</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>PDP</td>
<td>MA-PD</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Based on data as of Jan07
2007 Gap Coverage Analysis

Based on data as of Jan07
2006 vs. 2007 Formularies (PDP)

2006 vs. 2007 Formularies (MA-PD)

Average Percent of Reference NDCs with Prior Authorization
Average Percent of Reference NDCs with Step Therapy
Average Percent of Reference NDCs with Quantity Limits

Transition Process
Transition to Formulary Drugs in 2007

- **Transition is a process, not a time period**

- **Plans must establish transition processes for:**
  - New plan enrollees with 1/1/07 start date
  - Newly Medicare-eligible plan enrollees joining anytime in 2007
  - Transfers from other Part D plans (e.g., FBDEs) joining anytime in 2007

- **Transition applies to:**
  - Non-formulary drugs
  - Formulary drugs with UM requirements
Elements of Transition Process

- **Temporary Transition fills**
  - During the first 90 days after enrollment
  - One-time, 30-day fill at retail

- **Edits only if they can be resolved at POS**

- **Public notice of transition process (e.g., enrollment materials, websites)**
Enrollment by Deductible Category

Data as of Jan07
Analysis excludes FBDE & LIS
Data as of Jan07
Analysis excludes FBDE & LIS
Enrollment by Number of Generic Drugs on Formulary

Data as of Jan07
Analysis excludes FBDE & LIS

Note: Drugs on formularies are considered at the generic entity level
 Appeals Process

Request for a Coverage Determination

Standard Process
72 hour time limit

MA-PD/PDP Redetermination
7 day time limit

60 days to file

Expedited Process
24 hour time limit

MA-PD/PDP Redetermination
72 hour time limit

60 days to file

IRE Reconsideration
7 day time limit

60 days to file

IRE Reconsideration
72 hour time limit

See next slide

Coverage Determination

First Level of Appeal

Second Level of Appeal
See previous slide

ALJ
AIC=> $110
No statutory time limit for processing

60 days to file

Medicare Appeals Council
No statutory time limit for processing

60 days to file

Federal District Court
AIC=> $1,090

60 days to file

Third Level of Appeal

Fourth Level of Appeal

Final Appeal Level
Performance Measures
As Dr. Mark McClellan has said, “Consumers need and want more useful information to get better care at a lower cost”.

CMS wants to ensure that beneficiaries receive the best prescription drug coverage available and that they have the data necessary to make the most informed decision about plan selection.
There are currently five domain areas for performance measures:

- Telephone Customer Service
- Complaints
- Appeals
- Information Sharing with Pharmacists
- Drug Pricing
Telephone Customer Service

- Part D Plan Sponsor’s call centers received weekly survey phone calls to track the length of time to reach a live customer service representative.
- CMS has secured a new contractor to survey call centers in 2007 on a quarterly basis.
- RTI is serving as CMS’ contractor.
Customer Service (Wait Time)

Star Analysis

Percentage of Plans

Based on data as of Nov. 15, 2006

0.0% 20.0% 40.0% 60.0% 80.0% 100.0%

Customer Service 3 Stars
Pharmacist Support 2 Stars
Customer Service 1 Star
Pharmacist Support

PDP Measure MA-PD
Complaints

Measures:

- Benefits/access complaints per 1,000 enrollees
- Enrollment/disenrollment complaints per 1,000 enrollees
- Pricing/other co-insurance complaints per 1,000 enrollees
- Other complaints per 1,000 enrollees
Based on data as of Nov. 15, 2006
MA-PD Complaints (per 1000 enrollees)
Star Analysis

Based on data as of Nov. 15, 2006
Appeals

➤ Measures:
  – Rate per 10,000 Enrollees in which a Plan Did Not Make a Timely Appeals Decision
  – Percent of Cases Where the Independent Review Entity Agreed with a Plan's Decision
Appeals Star Analysis

Based on data as of Nov. 15, 2006
Information Sharing with Pharmacists

Measure:

– Percent of Current Members with Complete Enrollment Records Available to Pharmacists

• Represents the completeness of 4Rx data for current enrollees
Info Sharing (Data Systems) Star Analysis

Based on data as of Nov. 15, 2006
Measures:

– Percent of Plan’s Updates Available on Medicare Prescription Drug Plan Finder
– Percent of Drugs on Medicare Prescription Drug Plan Finder with Displayed Price Increases
Drug Pricing Star Analysis

Based on data as of Nov. 15, 2006
Telephone Customer Service
– All PDPs received 3 stars for both customers service measures

Complaints
– For the 4 complaint measures, the range of PDPs with 3 stars is from 70% to 90%

Appeals
– For the 2 appeals measures, approximately 90% of PDPs have 3 stars

Information Sharing with Pharmacists
– 89% of PDPs met the standard for complete 4Rx data and received 3 stars

Drug Pricing
– All PDPs met the standard for percent of plan updates available on the Plan Finder and received 3 stars
– 92% of PDPs received 3 stars for having a low percent of drugs on the Plan Finder with displayed price increases
MA-PD Performance Summary

- **Telephone Customer Service**
  - All contracts that had data reported, with the exception of one MA-PD received 3 stars for both customer service measures.

- **Complaints**
  - For the four complaint measures, the range of PDPs with 3 stars is from 84% to 89%.

- **Appeals**
  - For both appeals measures, approximately 90% of MA-PDs have 3 stars.

- **Information Sharing with Pharmacists**
  - 80% of MA-PDs met the standard for complete 4Rx data and received 3 stars.

- **Drug Pricing**
  - All but one MA-PD met the standard for percent of plan updates available on the Plan Finder and received 3 stars.
  - 90% of MA-PDs received 3 stars for having a low percent of drugs on the Plan Finder with displayed price increases.
Data for each measure will be monitored on an ongoing basis.

Contracts not meeting standards may receive warning letters or face further corrective action.