# Section-by-Section of the Medicare Prescription Drug Simplification Act of 2006

This is the Medicare Prescription Drug Simplification Act (MPDSA) of 2006. This bill will amend Title XVIII of the Social Security Act.

**Benefits Simplification and Improvement:**

***Simplification***

*Sec. 101 Establishment of National Uniform Part D Benefit Packages*

- This section requires that prescription drug coverage only be offered by prescription drug plans or MA-PDPs through national uniform benefit packages established by the Secretary of Health and Human Services.

- In addition to the standard prescription drug package, established by the MMA, the Secretary will develop five national benefit packages to be offered under Medicare Part D. Of the five new benefit packages, three are basic packages that would not include medications during the coverage gap, and two are supplemental packages which include coverage of drugs during the gap. The Secretary will ensure that the actuarial value of the three basic plans is equivalent to that of standard prescription drug coverage and the actuarial value of the two supplemental packages is progressively greater than standard coverage. In addition, all of the national benefit packages will have a formulary maximum of three tiers; an additional specialty tier is permitted if it, like the other tiers, is open to exceptions.

- The Secretary will develop standardized language, nomenclature, definitions, and format to be used for the uniform benefit packages so as to facilitate comparisons. The Secretary will establish and consult with a Benefits Advisory Committee to establish the benefit packages. Benefit packages will be reviewed and updated by the Secretary no less than once every three years.

- Standard prescription drug coverage will be simplified so that coinsurance up to the initial coverage limit is set at 25 percent with no actuarially equivalent variations.

- The provisions of this section take effect January 1, 2008.

***Formulary Requirements and Improvements***

*Sec. 111 Limitation on Removal or Change of Coverage of Covered Part D Drugs*

- This section prohibits plans from removing drugs from their formularies, imposing new restrictions on drug coverage, or increasing cost-sharing for drugs - other than at the beginning of plan marketing for the next plan year. Exceptions are allowed for newly available generic drugs and other limited events. Plans will provide notice of such changes in the formulary. This provision takes effect with plan years beginning on or after January 1, 2007.
- Plans will also be required to provide notice of changes in formulary and other restrictions or limitations on coverage to each enrollee at each annual coordinated election period. This provision applies to annual election periods beginning on or after November 15, 2006.

*Sec. 112 Formulary Requirement with Respect to Certain Categories and Classes of Drugs*

- This section requires plans to continue to include on formulary all or substantially all drugs in the six currently protected classes for plan years 2007 and 2008. For plan years beginning 2009 and beyond, the Secretary may require such a policy but only through the promulgation of regulations taking into account a study by the Institute of Medicine described below.

- The Secretary will arrange for the Institute of Medicine (IOM) to conduct a study that evaluates whether drugs within certain drug categories or classes should be required on formularies of Medicare drug plans in order to protect beneficiaries from undue medical risk stemming from restricted access to certain drugs. The IOM will be asked to consider existing protections for beneficiaries, among other factors. The report is due 14 months from the date of enactment of this Act and will include guidelines for the Secretary to re-evaluate this issue on an ongoing basis.

*Sec. 113 Certainty Regarding Excluded Drugs*

- This section requires the Secretary to publish and provide notice on an annual basis a list of drugs excluded from coverage under the prescription drug program. This section takes effect with respect to plan year 2007.

*Sec. 114 Pharmacy and Therapeutic Committee Improvements*

- This section requires plans to disclose to the Secretary on an annual basis the conflicts of interest for each member of their Pharmacy and Therapeutics Committee and, upon request, to the public beginning November 1, 2006. Further, plans must disclose committee decisions and the bases for them on an annual basis beginning with plan year 2007.

***Funding Certain Costs for Administrative Improvements***

*Sec. 121 Funding Certain Costs for Administrative Improvements*

- This section authorizes up to $120,000,000 in appropriations from the Federal Supplemental Medical Insurance Trust Fund for the Centers for Medicare and Medicaid Services. Such funds must be used to provide additional grants to State Health Insurance Assistance Programs, and related programs to expand beneficiary outreach and enrollment assistance, according to priorities outlined in this section. Such funds will remain available until December 31, 2010.

**Beneficiary Protection Improvements:**

*Sec. 201 Improved plan information*

- This section will require the Secretary to post information on cost and utilization management tools that restrict coverage of drugs on plan formularies, using standard definitions and nomenclature (established in Section 202, below). Plans must also provide more specific information up front about how plan formularies work, cost-sharing requirements that apply for each drug or class of drugs, and the coverage decision process, including how to appeal. The Secretary will also standardize how plan sponsors present formulary information in writing and on the internet. This section takes effect for plan years beginning on or after January 1, 2007.

*Sec. 202 Standardized definitions for cost and utilization management tools*

- This section requires the Secretary to develop standard definitions of the cost and utilization management tools employed by drug plans. The Secretary will provide definitions in time for the 2007 plan benefit year.

*Sec. 203 Standardized enrollee notice regarding coverage determinations.*

- This section requires the Secretary to develop a standard notice for pharmacies to distribute to enrollees when a drug is not covered, when coverage is restricted, or when cost-sharing is higher than the preferred tier. The notice will explain the coverage decision and how to file a reconsideration, exception or appeal. Plans will provide information necessary for the notices and reimburse pharmacies for the cost of distribution. The Secretary will develop the notice and require distribution no later than January 1, 2007.

*Sec. 204 Standardized and simplified process for reconsiderations, exceptions, appeals*

- This section requires the Secretary to develop standard exception forms that plans will have to use in considering whether to grant an exception from plan formulary rules. The Secretary will also develop a standardized process for reconsiderations and exceptions requiring that medical decisions are based on medical criteria, the treating provider's recommendation, and the condition of the enrollee. The appeals process for non-formulary drugs will be clarified to include cases where individuals will destabilize if a drug was discontinued. These requirements will be effective no later than January 1, 2007.

*Sec. 205 Standardized marketing and licensing; State certification for licensure waiver*

- This section requires the Secretary to request the National Association of Insurance Commissioners (NAIC) to develop new marketing guidelines to restrict certain marketing practices and promote consumer protections, or to develop such guidelines if the NAIC fails to act. The Secretary will adopt these guidelines at the federal level and incorporate them into all plan contracts.

- States that adopted the NAIC requirements could enforce them for agents licensed in their state. Adopting states could also enter into agreements with the Secretary to enforce the requirements for plans sponsors.

- This section also clarifies that the Secretary's waiver of the state licensing requirements for plan sponsors is limited, applying only in cases where the sponsor has submitted a substantially complete application and allowing states to petition the Secretary to revoke the waiver in cases involving fraud or failure to meet licensing requirements. This section applies to plan years beginning January 1, 2007.

*Sec. 206 Authority to waive late enrollment penalty in certain circumstances*

- This section allows the Secretary to waive the Part D premium penalty for late enrollees or categories of enrollees in exceptional circumstances.

*Sec. 207 Integrated Application and Enrollment Processes*

- This section requires the Secretary and the Commissioner of Social Security to integrate the processes of applying for the low income subsidy and enrolling in the prescription drug benefit.

*Sec. 208 GAO study and report on cost and utilization management tools*

- This section requires the General Accounting .Office (GAO) to compare the cost and utilization management tools employed by plans under the Medicare drug benefit to those offered in the commercial sector and the Federal Employee Health Benefits program. GAO will also assess their effect on enrollees, providers, and costs, and consider the feasibility of standardizing criteria for the use of such tools across plans. The report is due September 1, 2007.

**Performance and Quality**

*Sec. 301 Requirements for Comparative Information Regarding Performance of Plans*

- This section requires the Secretary to include specific plan performance indicators in comparative plan information provided to Medicare beneficiaries and the public. In addition, enrollment and appeals information will be included in comparative information beginning with the second plan year. This section takes effect beginning with the plan year 2007.

*Sec. 302 Required Quality for Approval of Plan*

- This section requires the Secretary to consider indices of performance quality in decisions to approve plans beginning with the plan year 2007.

*Sec. 303 MedPAC Study and Report Regarding a Value-Based Purchasing Program*

- This section requires MedPAC to report options for aligning payments to plans offering Medicare prescription drug coverage with plan performance. The report is due by June 1, 2007.