



## CMS Issues Draft Guidelines for 2009 Part D Contracting

The Centers for Medicare and Medicaid Services (CMS) this week issued **draft** guidance for organizations wishing to sponsor a Medicare Part D plan in 2009. Interested parties may comment on the draft guidance until January 30, 2008. Entities that wish to continue or expand an existing Part D contract, or that are seeking approval to offer a plan for the first time (e.g., sponsors of Medicare Advantage Prescription Drug Plans [MA-PDs] and Prescription Drug Plans [PDPs]), must all participate in the 2009 bidding process.

Among the new information and operational reminders contained in this lengthy document are the following topics of particular note:

- **Six Classes of Clinical Concern:** CMS will continue to require Part D plan formularies to include all or substantially all drugs in the immunosuppressant, antidepressant, antipsychotic, anticonvulsant, antiretroviral, and antineoplastic classes. Unlike in 2008, there are no prior authorization exceptions contained in the antiretroviral class for 2009.

Sponsors must provide expedited P&T committee review of new drugs or newly-approved uses of drugs in these classes that come on the market after April 21, 2008. These drugs must be added to plans' formularies at the end of 90 days.

- **New Prior Authorization Policy:** Sponsors will be required for the first time to post their approved prior authorization criteria (if any) on their Part D plan Web sites. This must be done prior to the start of the 2009 open enrollment period, which begins November 15, 2008.
- **Specialty Tiers:** If a sponsor's Part D negotiated price for a drug exceeds \$600 per month, the sponsor may include the drug on a specialty formulary tier.
- **Specialty Pharmacies:** Part D sponsors may not restrict certain Part D drugs to specialty pharmacies **unless:** 1) the FDA has restricted distribution to certain facilities or physicians OR 2) appropriate distribution of the Part D drug requires extraordinary special handling, provider coordination, or patient education that cannot be met by a network pharmacy. (The need for additional education or counseling alone does not qualify a drug for limited distribution.)
- **Preferred Pharmacies:** Sponsors may not designate certain network pharmacies as preferred without designating their other network pharmacies as non-preferred. A preferred pharmacy must offer a lower level of cost-sharing than a non-preferred pharmacy.

- **Low-Income Subsidy:** As in years past, CMS will reassign certain low-income beneficiaries who receive a full premium subsidy to different PDPs in the fall of 2008.
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- **Patient Privacy:** CMS will no longer include a patient's full name and full Health Insurance Claim Number (HICN) on correspondence from independent review entities (IREs) who handle Part D appeals and grievances, or on Medicare Summary Notices, starting January 1, 2009.

Highlights of the timeline for the 2009 bidding process include:

**March 15, 2008:** CMS to release final guidelines for 2009

**April 21, 2008:** Deadlines for plans to submit their 2009 formularies to CMS for review and approval

**May 16 – June 2, 2008:** Bidding period

**August 1, 2008:** CMS notifies PDPs whose contracts are not renewed or newly approved for 2009

**October 9, 2008:** Tentative date for CMS to display 2009 plan data and 2009 plan drug benefit info on [www.Medicare.gov](http://www.Medicare.gov)

**November 15 – December 31, 2008:** Open enrollment period for beneficiaries

**January 1, 2009:** Start of new plan year

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