

**Justification for Emergency PRA Clearance
Applications for
Prescription Drug Plans, Medicare Advantage Organizations and Cost Plans to
Provide Part D Benefits**

The Centers for Beneficiary Choices (CBC) is requesting that the Paperwork Reduction Act (PRA) package for the clearance of a group of Part D applications, for the purpose of public reporting on www.medicare.gov, be processed under 5 CFR 1320.13 for emergency clearance. This package contains updated applications for new Part D contracts and applications for Part D service area expansions for the following types of plans: Prescription Drug Plans (PDPs), Medicare Advantage Organizations (MAOs), Cost Plans, and Employer Group Plans.

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) established a program to offer prescription drug benefits to Medicare enrollees through Prescription Drug Plans, Medicare Advantage Organizations, and Cost Plans, and Employer Group Plans. The Medicare Prescription Drug Benefit program is codified in section 1860D of the Social Security Act (the Act). Section 101 of the MMA amended Title XVIII of the Social Security Act by re-designating Part D as Part E and inserting a Part D, which establishes the Voluntary Prescription Drug Benefit Program (hereinafter referred to as "Part D"). Prior to the 2008 contract year for the Part D program the industry must have an appropriate amount of time to respond to the solicitation and CMS must have sufficient time to review and approve organizations that qualify for a Part D contract or service area expansion.

We request this Paperwork Reduction Act clearance under an emergency approval process to accommodate the statutorily mandated timelines under the MMA and to allow sufficient time to automate the Part D applications, thereby reducing overall burden to Applicants. The MMA requires the Part D sponsors offering Part D benefits for January 2008 are contracted with CMS for their approved service area with open enrollment beginning on November 15, 2007. Further the MMA requires the submission of Part D benefit bids from applicant organizations by the first Monday in June of 2007 (June 4).

The applications for new contracts and for service area expansions have been updated to reference CMS guidance that was developed and released throughout 2006 in order to expand the frame of reference that an applicant might look to in developing the application. In addition, the applications were streamlined to incorporate the Pharmacy Access Instructions into the overall applications creating only one document. These applications do not represent substantively new material for Applicants relative to the prior Part D applications. Lastly, the instructions for completing the applications have been revised to reflect the submission of the application electronically.

Meeting the timeline for the Part D benefit represents a challenge for new entrants. CMS has developed a schedule for release, comment and approval of the application that supports the challenging industry timeline and the CMS automation of the Part D applications. CMS must determine qualified applicants prior to the first Monday in June

of 2007 (June 4). Key dates for the application process are provided in the following table. These applications will be announced and posted on www.Medicare.gov for public comment on November 13, 2006. In addition, their availability for comment will be made public through the Part D User Group and through release to the various trade associations that represent the Part D industry.

APPLICATION REVIEW PROCESS	
Date	Milestone
November 13, 2006	Draft applications posted by CMS for industry comment.
November 20, 2006	Comments due to CMS on draft applications.
December 1, 2006	<ol style="list-style-type: none"> 1. Submit notice of intent to apply to CMS 2. Request HPMS Access 3. Request CMS User ID and Password
January 14, 2007	Final version of applications posted by CMS
March 12, 2007	Applications due
May/June 2007	CMS sends Part D contract eligibility determination to Applicants, based on review of application. Applicant's bids must still be negotiated in a separate process.