

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

Subject

The Center for Drug and Health Plan Choice (CPC) is requesting emergency approval of revisions of a currently approved collection, OMB #0938-0936 “Applications for Medicare Part D plans: PDP Plans, MA-PD Plans, Cost Plans, Pace organizations, SAE and EPOG” (CMS-10137) under 5 CFR 1320.13(a)(2)(iii). The requested change revisions include clarifying edits related to the application submission process, technical edits to reflect date changes for the 2010 contract year and new language edits related to the enactment of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA).

Background

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. Section 101 of the MMA amended Title XVIII of the Social Security Act to establish the Voluntary Prescription Drug Benefit Program (hereinafter referred to as “Part D”). On July 15, 2008, Congress—MIPPA, which contained several provisions that effect the Part D program.

Justification

CMS is in the process of publishing regulations that are intended to be released as an interim final rule with comment. Many of the provisions included in MIPPA that impact the Part D program are self-implementing, meaning these provisions will go into effect without any further regulatory clarification or changes to the Part D solicitations. Therefore, CMS is seeking an emergency PRA clearance to amend the Part D solicitations to reflect the new MIPPA requirements. As part of the revised information collection request, CMS will include language from MIPPA into the Part D solicitations from sections 171, 172 and 173. These sections amend the contractual requirements that Part D sponsors (applicants) must have with CMS and with any downstream or related entities performing Part D functions on the sponsor’s behalf. Currently CMS provides templates that contain the required language for the contracts based on the statute and regulations. While applicants do not have to use the exact CMS contract templates, they will be responsible for including the required language in the contracts upon the time they submit materials to CMS for the 2010 contract year. By including these provisions in the templates CMS is helping applicants by clearly indicating the expected contractual language. The solicitations do not represent new policy, but rather implement the provisions that will exist in the forthcoming regulations and the statute. Therefore the material being added to the solicitation will only reflect changes made by Congress to the Medicare Advantage and Prescription Drug programs. CMS does not expect that the MIPPA provisions will increase the burden hours to complete the application.

We request this emergency clearance request be approved to accommodate the new statutorily mandated provisions under the MIPPA. CMS does not want to publish the Part D solicitations ahead of the interim final rule implementing MIPPA. Ideally, CMS request that the emergency PRA package for the Part D solicitations be published in the Federal Register at the same time as the regulation (September 15, 2008). The MMA requires the Part D sponsors offering Part D benefits for January 2010 are contracted with CMS for their approved service area with open enrollment beginning on November 15, 2009. Further the MMA requires the submission of Part D benefit bids from applicant organizations by the first Monday in June of 2009 (June 1). In order to ensure appropriate due process for any applicants that may have their Part D applications denied CMS works backwards on the calendar. CMS provides applicants with approximately 45 days to complete the application and then takes about 6 weeks to review with two opportunities for the applicants to cure any deficiencies.

In addition to the new requirements mandated by MIPPA, we will also be clarifying updates were also made to the existing language of the Part D solicitations. Updates include date changes and incorporating the most current references in statute, regulation and CMS guidance above each section as appropriate. Lastly, clarifying instructions were added to more clearly articulate the application submission process through the Health Plan Management System (HPMS).

Meeting the timeline for the Part D benefit represents a challenge for new entrants. CMS has developed a schedule for release that incorporates the time needed for applicants to complete the solicitations; the time needed for CMS to properly review the applications, and the time needed to allow any applicants to work through their appeal rights by the regulatory date of July 15th. Key dates for the application process are provided in the following table.

| APPLICATION REVIEW PROCESS | |
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| Date | Milestone |
| August 15, 2008 | Submit to OSORA/PRA, OMB emergency justification request |
| August 22, 2008 | Due from OMB emergency justification request approval |
| August 29, 2008 | Final Version of Emergency package due to OSORA/PRA |
| September 15, 2008 | Emergency Federal Register notice with 30-day comment period |
| October 15, 2008 | End Emergency Federal Register notice 30-day comment period |
| December 12, 2008 | Requested date of OMB approval |
| January 6, 2009 | Final applications posted by CMS |
| February 26, 2009 | Applications due |
| May/June 2009 | 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. |