

# Supporting Statement For Paperwork Reduction Act Submission

## A. Background

1. We are requesting OMB approval to reflect the information collection requirements referenced in the April 15, 2011 final rule revising the Medicare Advantage and Part D programs for calendar year 2012 (77 FR 21432-21577) (RIN 0938-AQ00). The rule revised the MA disclosure requirements in §422.111(b) by adding the authority for CMS to require MA organizations to furnish a written explanation of benefits directly to enrollees, in a manner specified by CMS and in a form easily understandable to enrollees, when benefits are provided under Part 422. The collection instrument that requires OMB approval concerns the disclosure requirements in paragraph §422.111(b)(12). The proposed information collection would require MA organizations to furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under Part 422.

2. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA), Pub. L. 110-275 was enacted on July 15, 2008. Section 103 established new statutory prohibitions and limitations for Medicare Advantage plans and Medicare prescription drug plans. On September 18, 2009 we published the Final Rule-4131F in the Federal Register (E8-21674) that set forth the provisions that would implement Section 103 of MIPPA. This rule finalized six new marketing provisions and modified the disclosure and dissemination of Part C and D information. Specifically, plans must disclose the information specified in §422.111 (b) and §423.128 (b), as specified in §422.111 (a)(3) and §423.128 (a)(3), at the time of enrollment and at least annually thereafter, 15 days before the annual coordinated election period.

3. Section 4001 of the Balanced Budget Act of 1997 (BBA) (Public Law 105-33), enacted August 5, 1997, added sections 1851 through 1859 to the Social Security Act (the Act) to establish a new Part C of the Medicare program, known as the “Medicare+Choice Program.” The BBA established section 1852(k)(2)(C)(1), requiring that each Medicare+Choice organization that offers a Medicare+Choice private fee-for-service plan shall, “provide that enrollees under the plan who are furnished services for which payment is sought under the plan are provided an appropriate explanation of benefits (consistent with that provided under parts A and B and, if applicable, under Medicare supplemental policies)...”. In the June 26, 1998 Federal Register, CMS published the Medicare + Choice Interim Final Rule, establishing the Medicare + Choice Program in accordance with the Act (63 FR 35085). This final rule set forth 42 CFR 422.216(d)(1), requiring that an “M+C organization that offers an M+C fee-for service plan must provide to plan enrollees, for each claim filed by the enrollee or the provider that furnished the service, an appropriate explanation of benefits. The explanation must include a clear statement of the enrollee’s liability for deductibles, coinsurance, copayment, and balance billing.”

4. In our April 12, 2012 final rule revising the MA and Part D programs for calendar year 2013 (77 FR 22072-22175), we made a technical revision to PFFS explanation of benefit requirement at §422.216(d)(1) to cross reference §422.111(b)(12), bringing the requirements for all MA plan types into alignment.

5. On January 28, 2005, we published Final Rule CMS-4068-F in the Federal Register, which set forth § 423.128(e), the requirements for Part D Sponsors to furnish claims information to beneficiaries (a Part D explanation of benefits), in accordance with section 1860D-(4)(a)(4) of the Act. This section requires Part D sponsors to furnish to enrollees who receive covered Part D drugs an explanation of benefits (EOB). EOBs will be required to be written in a form easily understandable to beneficiaries. Section 423.128(e) requires that the EOB includes: (1) a list of the items for which payment was made and the amount of payment for each service; (2) a notice of the individual's right to request an itemized statement; (3) the cumulative, year-to date total amount of benefits provided, in relation to— (i) The deductible for the current year, (ii) The initial coverage limit for the current year, (iii) The annual out-of-pocket threshold for the current year; (4) the cumulative, year-to date total of incurred costs to the extent practicable; (5) Include any applicable formulary changes for which Part D plans are required to provide notice as described in § 423.120(b)(5). This section also requires that the EOB be provided during any month when prescription drug benefits are provided under this part, including for covered Part D spending between the initial coverage limit described in § 423.104(d)(3) and the out-of-pocket threshold described in § 423.104(d)(5)(iii).

## **B. Justification**

### **1. Need and Legal Basis**

In accordance with authority cited above, we have long required MA private fee-for-service plans to furnish an explanation of benefits for Part C services furnished to enrollees. Some MA organizations offering other plan types have voluntarily provided EOBs to MA beneficiaries in their plans, but this has been inconsistent across the MA program in terms of format and content.

In order to provide all Medicare Advantage enrollees with consistent, clear, useful information about their medical claims, we established a requirement, in the April 2011 final rule, that MA organizations furnish directly to enrollees, in the manner specified by CMS and in a form easily understandable to such enrollees, a written explanation of benefits, when benefits are provided under Part 422. We finalized this policy based on the public comments and input we have received from beneficiaries, advocacy organizations, health plans and industry organizations. This EOB will help ensure that people in the Medicare Advantage program receive clear, timely information, as do people receiving the Medicare MSN and the Part D EOB, so that they may make confident, informed decisions about their healthcare options.

We stated that we would develop a model EOB for Part C benefits modeled after the EOB currently required for Part D enrollees at §423.128(e). After publication of the final rule in April 2011, we engaged MA organizations, industry and advocacy groups and beneficiaries in listening sessions to gather ideas and feedback. We developed models based on that input, as well as the newly redesigned and consumer tested Medicare Summary Notice and the Part D EOB. We have tested models through a small pilot program with a volunteer MA organization in CY 2012. In designing our model EOB, we considered language and design from Medicare MSN, integration of Part C and Part D EOBs, level of detail, and frequency of EOB dissemination as part of this process.

We sought additional public comments on the model EOBs that we developed through a Health Plan Management System (HPMS) memo release with a 30 day comment period. Our goal was to implement a model Part C EOB document in mid-year 2013 based on this process, and to require all MA organizations to periodically send an EOB to enrollees for Part C benefits in future years. This customized information would supplement general plan information in the ANOC and EOC documents as well as enhance the currently available information through tools such as Medicare Options Compare (MOC) and the Medicare Prescription Drug Plan Finder (MPDPF), which provide general information about plan costs. Based on public comments we received on the HPMS memo and November 26, 2012 Federal Register notice (77 FR 70445) and the revisions we made to the initial templates and guidance, we are extending the timeline for implementation to April, 2014. We intend for the Part C EOB to provide personal information to beneficiaries that would help them understand their current utilization, keep track of their out-of-pocket expenses, and to consider using other tools and resources, including MOC and MPDPF, to determine whether to select a new plan.

## 2. Information Users

Medicare Advantage (MA) organizations (formerly M+C organizations) will use the information discussed below to comply with the eligibility requirements and the MA and Part D contract requirements. CMS will use this information to ensure that correct information is disclosed to Medicare beneficiaries.

## 3. Use of Information Technology

Where feasible the collection of information covered by this regulation does involve the use of automated, electronic, mechanical, or other technological collection techniques designed to reduce burden and enhance accuracy. Specifically, Section §422.111 requires, to the extent that a MA plan has a website, annual notification through the website of written, hard copy notification sent to the beneficiaries. Section 423.128 requires that a Part D plan have mechanisms for providing specific information on a timely basis to current and prospective enrollees upon request. These mechanisms include an Internet website that includes information about the Part D plan.

4. Duplication of Efforts

The information collection requirements contained in the regulations are not duplicated through any other effort.

5. Small Businesses

Some MA organizations are considered small businesses and will be affected by this rule. They will have to comply with the disclosure requirement in the manner specified by CMS and in a form easily understandable to such enrollees as specified in 42 CFR §422.111 (b)(12). Several of the provisions of this rule, however, will minimize burden for all insurers, including small businesses.

6. Less Frequent Collection

This information is collected as needed. Some of the consequences would be information provided to enrollees that is too general for enrollees to actively and meaningfully evaluate track their utilization of services, including with respect to their plan's annual maximum out-of-pocket limit, and evaluate their plans annually with respect to plan costs, benefits, and overall value, resulting in enrollment in a plan that is not the best value for the enrollee.

7. Special Circumstances

Generally, information collections contained in the MA and Part D program occur annually or quarterly. Under the proposed 42 CFR §422.111(b)(12) disclosure requirements, the customized enrollee data must be disclosed to enrollees in the manner specified by CMS. Whether this disclosure will occur annually, quarterly or with some other frequency will be determined through the Part C EOB development and volunteer pilot process in CY 2012..

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published November 26, 2012.

CMS published a proposed rule in November 2010 for comments. After publication of the final rule in April 2011, we engaged MA organizations, industry and advocacy groups and beneficiaries in listening sessions to gather ideas and feedback. We developed models based on that input, as well as the newly redesigned and consumer tested Medicare Summary Notice and the Part D EOB. We have tested models through a small pilot program with a volunteer MA organization in CY 2012.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

Information will be kept private to the extent permitted by law. Contracted MA organizations must adhere to the HIPAA privacy rule on sharing patient health information during a change of ownership or a novation agreement.

11. Sensitive Questions

There are no sensitive questions included in this collection effort.

12. Burden Estimates (Hours & Wages)

The following material is from Section III.R, Collection of Information Requirements, contained in the preamble of the Final Rule, published April 15, 2011 (76 FR 21534-21535).

**§ 422.111(b) (12)-Claims Information:** The estimated cost/wage associated with this requirement in the initial year is  $\$34.92 \times 112,800 = \$3,938,976$ . This is based upon the hourly rate of GS 11 step 6 multiplied by the number hours of annual burden hours (112,800).

The estimated cost/wage associated with this requirement in subsequent years is  $\$34.92 \times 90,240 = \$3,151,181$ . This is based upon the hourly rate of GS 11 step 6 multiplied by the number hours of annual burden hours (90,240).

Claims Information (§ 422.111(b)(12))

We have calculated our estimate of the burden for a Part C EOB, based on the annual burden to Part D plan sponsors to furnish enrollees with an EOB for prescription drug benefits under OMB 0938-0964. MA organizations already collect enrollee utilization and cost-sharing information as part of their claims processing operations. In the first year that a Part C EOB is implemented, the burden associated with this proposed requirement would be the time and effort necessary for 564 MA organizations to complete program development and testing of an explanation of benefits when Part C benefits are provided, and to disclose (print and mail) this information to each beneficiary. Given that stand alone PDPs already produce an EOB in accordance with §423.128(e), this burden estimate includes only MA organizations. We estimate that in the first year it will require each entity 200 hours on an annual basis to disseminate the required materials, for a total annual burden of 112,800 hours. We calculate the total labor cost estimate based on the hourly rate of \$34.92 for a GS-11/step 6 analyst. This first year estimate builds from the estimated annual burden for the Part D EOB. Our revised estimate increases the number of hours organizations will need to initiate and complete program development and testing of an EOB.

In subsequent years, the burden associated with this requirement will be the time and effort necessary for about 564 MA organizations to provide an EOB when Part C benefits are provided to enrollees. We estimate that it will require each entity 160 hours on an annual basis disseminate the required materials, for a total annual burden of 90,240 hours. We

calculate the total labor cost estimate based on the hourly rate of \$34.92 for a GS-11/step 6 analyst. The decreased estimate of burden hours relative to the first year reflects the completion of program development in the first year and brings the estimated hours in line with the current estimated number of hours for the Part D EOB.

13. Capital Costs

Not applicable. The entities that will offer coverage are ongoing health organizations and should have no or minimal total capital, startup, operational or maintenance costs resulting from this collection of information.

14. Cost to Federal Government

Not applicable.

15. Changes to Burden

The changes in burden and the number of respondents are associated with the number of MA organizations that will participate for the new contract year.

16. Publication/Tabulation Dates

Generally there are no publication or tabulation dates. The schedule for the annual notices issued by CMS containing information regarding available choices for Medicare coverage is outlined in §422.64 and §423.48.

17. Expiration Date

CMS does not object to displaying the expiration date on information collection materials.

18. Certification Statement

There are no exceptions to the certification statement.