

Supporting Statement Part A
Medicare Advantage, Section 1876 Cost Plans, and Prescription Drug Program: Notification of
Free Interpreter Services
(CMS-10802, OMB 0938-1421)

Final Marketing Provisions in 42 CFR 422.111(h)(1)(iii) and 423.128(d)(1)(iii)

Background

Pursuant to disclosure requirements set out in sections 1851(d)(2)(A) and 1860D-1(c) of the Social Security Act (the Act) and in §§ 422.111(h)(1)(iii) and 423.128(d)(1)(iii), Medicare Advantage (MA) organizations, section 1876 cost plans, and Part D sponsors must provide interpreters for non-English speaking and limited English proficient individuals. To this effect, the multi-language insert (MLI) is a standardized notification document that informs the reader that interpreter services are available in Spanish, Chinese, Tagalog, French, Vietnamese, German, Korean, Russian, Arabic, Italian, Portuguese, French Creole, Polish, Hindi, and Japanese; the 15 most common non-English languages in the United States. CMS maintains a standardized document with the statement in different languages, see Attachment A.

Beginning in 2012, the Medicare Marketing Guidelines (MMG) required plans to include the MLI with the Summary of Benefits (SB), Annual Notice of Change (ANOC)/Evidence of Coverage (EOC), and the enrollment form (most recently in section 30.5.1 of the 2017 MMG, issued on June 10, 2016). The issuance of the MLI was independent of the translation requirements for any non-English language that is the primary language of at least 5 percent of the individuals in a plan benefit package (PBP) service area, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2). In 2016, the Office for Civil Rights (OCR) created their own version of the MLI based on section 1557 of the Affordable Care Act. Because of the inherent duplication between CMS' MLI requirement and OCR's requirement, CMS issued an HPMS email on August 25, 2016, that removed the MLI requirement. OCR later vacated their requirement, leaving a gap.

In CMS 4192-F, we reinstated the MLI in both parts 422 and 423. CMS considers the materials required under §§ 422.2267(e) and 423.2267(e), including the MLI, to be vital to the beneficiary decision making process. Providing a notification for beneficiaries with limited English proficiency that translator services are available provides a clear path for this portion of the population to properly understand and access their benefits. In our February 18, 2020 (85 FR 9002) Notice for Proposed Rulemaking (CMS-4190-P; RIN 0938-AT97), CMS proposed an availability of non-English translations disclaimer. The disclaimer consists of the statement "ATTENTION: If you speak [insert language], language assistance services, free of charge, are available to you. Call 1-XXX-XXX-XXXX (TTY: 1-XXX-XXX-XXXX)." We proposed that the disclaimer be required in all non-English languages that met the 5 percent threshold for language translation under §§ 422.2267(a)(2) and 423.2267(a)(2). In addition, when applicable, we proposed the disclaimer be added to all required materials under §§ 422.2267(e) and 423.2267(e). However, we did not finalize the proposed disclaimer in our January 19, 2021 (86 FR 5864) final rule.

In our May 9, 2022 (87 FR 27704) final rule (CMS 4192-F, RIN 0938-AU30) we reinstated the

MLI and require MA organizations, section 1876 cost plans, and Part D plan sponsors to create a multi-language insert that would inform the reader, in the top fifteen languages used in the U.S., that interpreter services are available for free. The final rule requires the use of MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). The MLI must be included with all the required materials listed in §§ 422.2267(e) and 423.2267(e). In addition, plans must insert the required MLI's statement in any language when the 5 percent threshold language for a plan's service area is not currently on the standardized MLI that CMS created and is making available.

A. Justification

1. Need and Legal Basis

CMS requires MA organizations, section 1876 cost plans, and Part D sponsors to use the standardized MLI document to satisfy disclosure requirements mandated by section 1851 (d)(3) (A) of the Act and § 422.111 for MA organizations and section 1860D-1(c) of the Act and § 423.128(a)(3) for Part D sponsors.

In our May 9, 2022, rule we finalized a requirement to use the MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). We also require plans to include the required statement in any language that meets the 5 percent threshold for a plan's service area, as currently required under §§ 422.2267(a)(2) and 423.2267(a)(2) for translation of required materials, when not currently on the standardized MLI. Finally, we require the MLI to be included with all required materials listed in §§ 422.2267(e) and 423.2267(e).

The MLI cannot be modified except, as permitted in §§ 422.2267(e)(31)(i) and 423.2267(e)(33)(i), to include any language when the 5 percent threshold language of a plan's service area is not currently on the MLI. Additional inserts are not permitted.

2. Information Users

CMS requires MA organizations, section 1876 cost plans, and Part D sponsors to use the approved standardized document to ensure that correct information is disclosed to current and potential enrollees. This would inform the reader, in the top 15 languages used in the U.S., that interpreter services are available for free.

The May 9, 2022 final rule requires the use of MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). The MLI must be included with all the required materials listed in §§ 422.2267(e) and 423.2267(e). In addition, plans must insert the required statement in any language when the 5 percent threshold language for a plan's service area is not currently on the standardized MLI.

3. Use of Information Technology

MA organizations, section 1876 cost plans, and Part D sponsors will use subpart V of 42 CFR parts 422 and 423 and may use the information discussed in the Medicare Communication and Marketing Guidelines (MCMG) to comply with the requirements. MA organizations, section 1876 cost plans, and Part D sponsors are not required to upload the MLI into HPMS, unless specifically requested by CMS.

4. Duplication of Efforts

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

5. Small Businesses

The collection of information will have a minimal impact on small business since MA organizations, section 1876 cost plans, and Part D sponsors must possess an insurance license and be able to accept substantial financial risk. Generally, state statutory requirements effectively preclude small businesses from being licensed to bear risk needed to serve Medicare enrollees.

6. Less Frequent Collection

Sections 1851(d)(2)(A) and 1860D-1(c) of the Act requires CMS to collect this information to ensure compliance with applicable laws and regulations. If CMS were to collect the information less frequently, MA organizations, section 1876 cost plans, and Part D sponsors would not be providing updated, accurate information to their enrollees and potential enrollees. MA, section 1876 cost plans, and Part D plans update their contracts on a yearly cycle. If we were to collect the completed templates less frequently, we would not be doing our due diligence in maintaining oversight of plans' compliance with the applicable statute and regulation. Possible consequences include improper enrollment of beneficiaries in an MA organization, section 1876 cost plans, or Part D sponsor, the release of misleading information regarding health care coverage through an MA organization, section 1876 cost plans, or Part D sponsor to potential and/or current members, and inadequate provision of patients' rights regarding Medicare-covered services.

7. Special Circumstances

CMS requires MA organizations, section 1876 cost plans, and Part D sponsors to maintain documentation related to their CMS contracts for 10 years pursuant to statutory and regulatory requirements.

Otherwise, there are no special circumstances. More specifically, this MLI and marketing materials information collection does not do any of the following:

- Require respondents to report information to the agency more often than quarterly;
- Require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Require respondents to submit more than an original and two copies of any document;
- Require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Make use of a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Includes a pledge of confidentiality that is not supported by authority established in statute or regulation that is not supported by disclosure and data security policies that are

consistent with the pledge, or which unnecessarily impedes sharing of data with other agencies for compatible confidential use; or

- Require respondents to submit proprietary trade secret, or other confidential information unless the agency can demonstrate that it has instituted procedures to protect the information's confidentiality to the extent permitted by law.

8. Federal Register/Outside Consultation

Serving as the 60-day notice, our proposed rule (CMS-4192-P, RIN 0938-AU30) filed for public inspection on January 6, 2022, and published in the Federal Register on January 12, 2022 (87 FR 1842). We received two PRA related comments without specificity to the burden estimates, therefore we declined the comments.

Our final rule (CMS 4192-F, RIN 0938-AU30) published in the Federal Register on May 9, 2022 (87 FR 27704).

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected through these documents from MA organizations, section 1876 cost plans, and Part D sponsors is intended for public disclosure to current and potential enrollees regarding health care and prescription drug coverage choices, program rules, premiums and cost sharing of the contracting MA organizations, section 1876 cost plans, and Part D sponsors' plan offerings.

11. Sensitive Questions

There are no sensitive questions associated with this collection. Specifically, the collection does not solicit questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private.

12. Burden Estimates

CMS requires MA organizations, section 1876 cost plans, and Part D sponsors to use the standardized MLI document being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Act and § 422.111 for MA organizations, section 1876 cost plans, and section 1860D-1(c) of the Act and § 423.128(a)(3) for Part D sponsors. The MLI cannot be modified except, as permitted in §§ 422.2267(e)(31) (i) and 423.2267(e)(33)(i), to include any language when the 5 percent threshold language of a plan's service area is not currently on the MLI. Additional inserts are not permitted.

The MLI insert is not subject to the PRA since it does not constitute a "collection of information" as defined under 5 CFR 1320.3(c) of the PRA's implementing regulations. Rather, the MLI is a "public disclosure" of information originally supplied by the Federal Government to the recipient

for the purpose of "disclosure to the public" (5 CFR 1320.3(c)(2)). Consequently we are not setting out such burden.

For languages that are not on the standardized MLI §§ 422.2267(e)(31) and 423.2267(e)(33) require plans to include the required statement in any language that meets the 5 percent threshold for a plan's service area. In such cases where the MLI does not include such languages, respondents would have to use our standardized MLI as a basis for translating the insert. We are not setting out such burden since we have no reliable basis for estimating such burden. We have no basis for knowing how many languages meet the 5 percent threshold with the plans service area not how many individuals would be impacted.

Finally, we require the MLI to be included with all required materials listed in §§ 422.2267(e) and 423.2267(e). In that regard we only estimate mailing costs under section 13 of this Supporting Statement.

Information Collection Instruments and Associated Instructions

MLI CMS provides a standardized one-page document in 15 non-English languages in the U.S. informing enrollees that interpreter services are available at no cost. As noted above, the MLI insert is not subject to the PRA. It is, however, attached to this collection of information request for transparency.

13. Capital Costs

While we do not project any capital costs, our January 12, 2022 (87 FR 1842) rule (CMS-4192-P; RIN 0938-AU30) proposes non-labor costs associated with the distribution of a one-page multi-language insert under §§ 422.2267(e)(31) and 423.2267(e)(33).

This proposed provision would require that plans add in their postings or mailings of CMS required materials a one-page document written in the top 15 non-English languages in the U.S. informing enrollees that interpreter services are available at no cost. The MLI cannot be modified except to include any language when the 5 percent threshold language of a plan's service area is not currently on the MLI or if a plan wants to add a language that does not meet the 5 percent threshold.

We previously required plans to provide this document to enrollees. However, based on section 1557 of the Affordable Care Act, the Office for Civil Rights (OCR) created their own version. Because of the inherent duplication between CMS' MLI requirement and OCR's requirement, CMS issued an HPMS email on August 25, 2016, that removed the MLI requirement. OCR later vacated their requirement, leaving a gap. Consequently, we are proposing to require that MA plans, section 1876 cost plans, and Part D plan sponsors provide the one-page document.

In estimating the burden of this one-page document we assume plans have retained their templates consistent with the record retention requirements at § 422.504(e)(4). Consequently, there is no burden to create the template, as plans will either use their existing templates or a template that will be provided by CMS to new plans based on the previously created MLI without change.

The cost of placing an extra page on the plan’s webpage is incurred by plans as part of their normal course of fluctuating business activities and hence excluded from the PRA (5 CFR 1320.3(b)(2)). For those beneficiaries who request a paper copy, the proposed regulations require sending it with other CMS required materials (§§ 422.2267(e) and 423.2267(e)). We believe it is reasonable to assume that adding one page (at 0.1696 ounces) to a bulk mailing cost is de minimis and therefore does not create additional postage costs.

Similar estimates have been made in previous final rules where we identified the major burden as paper and toner. We have checked the following assumptions of cost and beneficiary interest in receiving paper copies found in the April 2018 final rule (83 FR 16695), and found them to still be reliable for the purpose of this proposed rule.

A 10-ream box (of 5,000 sheets) of paper costs approximately \$50. Hence the cost per sheet is \$50/5,000 sheets = \$0.01 per page.

Standard toner cartridges which last for about 10,000 pages also cost \$50. Hence the cost per sheet is \$50/10,000 = \$0.005 per page.

Thus, the total paper and toner cost is \$0.015 per page.

As of September 2021, there are 52 million beneficiaries enrolled in Medicare Advantage Health plans including MA PD, standalone PDP plans, and other types of plans such section 1876 cost plans.¹

Of these 52 million beneficiaries we estimate that two fifths or 20,800,000 beneficiaries (52 million beneficiaries x 0.40) will request paper copies.

It follows that the aggregate cost of providing one extra sheet of paper is \$312,000 (20,800,000 enrollees x \$0.015/sheet).

Regulation Section in Part 42 of the CFR	Item	Number of respondents	Responses per respondent	Total Responses	Total Time (hours)	Hourly Labor Cost (\$)	Total Cost First Year (\$)	Total Cost Subsequent years (\$)
422.2267(e) (31) and 423.2267(e) (33))	1 pager multi language insert	961 MA Plans and Part D Sponsors	21,644	20,800,000	0	n/a	312,000	312,000

14. Cost to Federal Government

The data for CMS employees’ hourly wages were obtained from the Office of Personnel Management 2022 General Schedule Pay Table for the Washington DC Metro area <https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2022/general-schedule>.

The annual burden to the Federal Government including the cost of CMS employees’ time is calculated to be \$7,646.70 as reflected in Table 1.

¹ <https://www.cms.gov/research-statistics-data-and-systemsstatistics-trends-and-reportsmcradvpartdenroldatamonthly/contract-summary-2021-09>

Table 1: Cost to Federal Government – MLI

Program Subject Matter Experts and staff Help/Review:	
6 GS-13 step 5: 6 x \$58.01/hr. x 20 hours	6,961.20
1 GS -14 step 5: 1 x \$68.55/hr. x 10 hours	685.50
TOTAL	7,646.70

15. Changes to Burden

This is a new collection of information request. Consequently, there are no changes.

16. Publication/Tabulation Dates

MA organizations, section 1876 cost plans, and Part D sponsors must ensure that enrollees receive the MLI along with the required documents.

17. Expiration Date

CMS does not object to displaying the expiration date.

18. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.