Supporting Statement Part A
Medicare Advantage and Prescription Drug Program:
Final Marketing Provisions in 42 CFR 422.111(h)(1)(iii) and 423.128(d)(1)(iii)
(CMS-10802, OMB 0938-TBD3)

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 and Part D sponsors must provide interpreters for non-English speaking and limited English proficient (LEP) 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. Consequently, we are proposing to require that MA plans and Part D plan sponsors provide the MLI.

CMS considers the materials required under §§ 422.2267(e) and 423.2267(e) 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 the Notice for Proposed Rulemaking which appeared in the **Federal Register** on February 18, 2020 (85 FR 9002), 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 five 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 the January 2021 final rule.

A. Justification

1. Need and Legal Basis

CMS requires MA organizations and Part D sponsors to use the standardized document being submitted for OMB approval to satisfy disclosure requirements mandated by section 1851 (d)(3)(A) of the Act and 42 CFR § 422.111 for MA organizations and section 1860D-1(c) of the Act and 42 CFR § 423.128(a)(3) for Part D sponsors.

We are proposing to reinstitute a requirement to use the MLI under §§ 422.2267(e)(31) and 423.2267(e)(33). Similar to the previously required version, the MLI will state "We have free interpreter services to answer any questions you may have about our health or drug plan. To get an interpreter, just call us at [1-xxx-xxx-xxxx]. Someone who speaks [language] can help you. This is a free service." in the 15 most common non-English languages in the United States. In addition, we propose to require plans to also include the required statement in any language that meets the five 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 propose to require the MLI to be included with all required materials listed in §§ 422.2267(e) and 423.2267(e).

2. Information Users

CMS requires MA organizations and Part D sponsors to use the approved standardized document to ensure that correct information is disclosed to current and potential enrollees.

3. Use of Information Technology

MA organizations and Part D sponsors will use Subpart V of 42 CFR §§ 422 and 423 and may use the information discussed in the Medicare Communication and Marketing Guidelines (MCMG) to comply with the requirements. MA organizations and Part D sponsors are not required to upload the multi-language insert 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 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

The Act/statute 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 and Part D sponsors would not be providing updated, accurate information to their enrollees and potential enrollees. MA 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 or Part D sponsor, the release of misleading information regarding health care coverage through an MA organization 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 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 statue 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 will publish in the Federal Register on January 12, 2022 (87 FR TBD). Comments are due on/by March 7, 2022.

9. Payments/Gifts to Respondents

There are no payments/gifts to respondents.

10. Confidentiality

The information collected through these documents from MA organizations 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 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

There are no labor costs. See section 13 of this Supporting Statement for our non-labor burden estimates.

13. 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.

14. Capital Costs

While we do not project any capital costs, our January 12, 2022 (87 FR TBD) rule (CMS-4192-P; RIN 0938-AU30) proposes non-labor costs associated with the creation 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.

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 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 MA PD or stand-alone PDP 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).

Collection of Information Instruments and Instruction/Guidance Documents

None (nothing in addition to the proposed rule).

15. Cost to Federal Government

The calculations for CMS employees' hourly salary 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.

Table 1: Cost to Federal Government – MLI

Medicare MA and Part D Program Subject Manner 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

16. Changes to Burden

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

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

17. Publication/Tabulation Dates

MA organizations and Part D sponsors must ensure that enrollees receive the MLI along with the required documents.

18. Expiration Date

CMS does not object to displaying the expiration date.

19. Certification Statement

There are no exceptions to the certification statement.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.