Supporting Statement Part-A

Applicable Integrated Plan Coverage Decision Letter

(CMS-10716, OMB 0938-1386)

Background

The Bipartisan Budget Act (BBA) of 2018 directed the establishment of procedures to unify Medicare and Medicaid grievance and appeals procedures to the extent feasible for dual eligible special needs plans (D-SNPs) and companion Medicaid managed care plans beginning in 2021. On April 16, 2019, CMS finalized rules (hereafter referred to as the April 2019 final rule) to implement these new statutory provisions.[1] As a result of these regulations, starting in 2021, a subset of full integrated dual special needs plans (FIDE SNPs) and highly integrated dual special needs plans (HIDE SNPs) and companion Medicaid managed care plans (i.e., applicable integrated plans) unified and updated appeals and grievance procedures, including how enrollees are notified of their appeal rights.

This information collection request is for the "Applicable Integrated Plan Coverage Decision Letter" or the "coverage decision letter", which will be issued as a result of an integrated organization determination under 42 CFR 422.631 when an applicable integrated plan reduces, stops, suspends, or denies, in whole or in part, a request for a service or item (including a Part B drug) or a request for payment of a service or item (including a Part B drug) that the enrollee has already received. "Applicable integrated plans," are defined at 42 CFR 422.561 as FIDE SNPs or HIDE SNPs and companion Medicaid managed care plans with exclusively aligned enrollment, where state policy limits the D-SNP's membership to a Medicaid managed care plan offered by the same organization. Applicable integrated plans will issue the coverage decision letter in place of the Notice of Denial of Medical Coverage (or Payment) (NDMCP) form (CMS-10003; 0938-0829) as part of requirements to unify appeals and grievance processes. All other Medicare Advantage (MA) plans will continue to use the NDMCP.

We are requesting a Revision approval by renewing this information with minor changes to the coverage decision letter to improve readability and reduce confusion. We added a contact information field under the title to allow states require plans to include this information at the top of the letter. In the second paragraph, we added an option for plans to select "changed" where they inform the enrollee they denied, reduced, stopped, suspended, or changed the service or item requested. We also added instructional language to help plans complete the section where they describe the requested service and if any part of the request was approved. Additionally, we added language plans may include for post-service cases to notify the enrollee there is no member liability. In the third paragraph, we added instructional language to help plans complete the section where they describe why they made the decision. In the section titled 'How to keep getting your <service or item> during your appeal' we bracketed the section to allow plans remove this paragraph if the decision relates to a service or item that has not been received by the enrollee under a previous authorization of the service/item.

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1 See CMS-4185-F, the "Medicare and Medicaid Programs; Policy and Technical Changes to the Medicare Advantage, Medicare Prescription Drug Benefit, Programs of All-Inclusive Care for the Elderly (PACE), Medicaid Fee-For-Service, and Medicaid Managed Care Programs for Years 2020 and 2021" final rule. Retrieved from https://www.govinfo.gov/content/pkg/FR-2019-04-16/pdf/2019-06822.pdf.

A. Justification

1. Need and Legal Basis

Sections 1859(f)(8) of the Act require development of unified grievance and appeals processes for D-SNPs, to the extent feasible. We finalized the implementation of this regulation for integrated organization determinations at § 422.631, effective January 1, 2021. This rule requires applicable integrated plans to send an enrollee a written notice of any adverse decision on an integrated organization determination using a notice that is written in plain language and contains the information detailed at § 422.631(d)(1)(iii).

2. Information Users

Applicable integrated plans as defined at § 422.561 are required to issue form CMS-10716 when a request for either a medical service or payment is denied in whole or in part after considering both the Medicare or Medicaid benefit. Applicable integrated plans issue this form to enrollees when the plan reduces, stops, suspends, or denies, in whole or in part, a request for a service or item (including a Part B drug) or a request for payment of a service or item (including a Part B drug) that the enrollee has already received. The form provides the enrollee with information regarding their right to an appeal of the applicable integrated plan's decision and the enrollee will use the instructions to navigate the appeal process.

CMS will not use form CMS-10716 to collect and analyze data on applicable integrated plan appeals.

3. Improved Information Technology

No data are being collected through this form for analysis; therefore, CMS does not use automated, electronic, mechanical, or other technological collection techniques or other forms of information technology to collect data related to these forms.

The form is available for completion electronically, however, the form must be delivered in writing unless an enrollee opts in to receive notifications via electronic means. Currently, there is no data available to determine how many applicable integrated plan enrollees have chosen to receive notifications electronically and CMS has no current plans to rely on electronic delivery of this form. The form does not require a signature from respondents, so the question of CMS accepting electronic signatures is not applicable.

4. Duplication of Similar Information

This information collection does not duplicate any other effort and the information cannot be obtained from any other source. While the purpose for the coverage decision letter is substantially similar to form CMS-10003, we are not able to combine this information collection with CMS-10003 due to potential confusion for MA plans and MA enrollees. The content of the coverage decision letter is for enrollees in a specific subset of MA plans (i.e., applicable integrated plans) and requires different instructions from form CMS-10003. Inclusion of this coverage decision letter with form CMS-10003 could result in MA plans sending the incorrect form to enrollees, potentially causing harm due to an incorrect understanding of their right to file an appeal.

5. Small Businesses

There is no significant impact on small businesses. The form informs enrollees of the right to file an appeal if a request for service or payment is denied in whole or in part.

6. Less Frequent Collection

The statute requires plans to issue written notices to enrollees whenever requests for items/services or payment are denied by Medicare or Medicaid. Thus, there are no opportunities for less frequent collection.

7. Special Circumstances

The coverage decision letter is issued by applicable integrated plans when an enrollee's request for either an item/service or payment is denied in whole or in part. There are no special circumstances to report, and no statistical methods will be employed. More specifically this form:

- Does not require respondents to report information to the agency more often than quarterly;
- Does not require respondents to prepare a written response to a collection of information in fewer than 30 days after receipt of it;
- Does not require respondents to submit more than an original and two copies of any document;
- Does not require respondents to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Is not connected with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study;
- Does not require the use of a statistical data classification that has not been reviewed and approved by OMB;
- Does not include 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
- Does not 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 Notice/Outside Consultation

The 60-day notice published in the Federal Register (88 FR 12686) on 03/01/2023.

The collection received 16 comments from advocacy organizations, state Medicaid agencies, and health plans that operate applicable integrated plans. Five commenters requested updated language to the terms service or item to be more consistent with the Medicare Advantage and Medicare-Medicaid integrated denial notice. Three commenters suggested keeping the paragraph that discusses continuation of benefits during appeal. A few commenters appreciated the updates made to the new version of the coverage decision letter to help with readability and reduce confusion. A few commenters suggested updates to the coverage decision letter that we included in the 30-day package. Responses to the comments can be found in the Summary of Comments and Responses for 60-day PRA coverage decision letter document published on the reginfo.gov website.

As a result of the comments received, we updated three sections of the coverage decision letter, updated language throughout the letter to read 'medical service/item *or* Medicare Part B drug *or* Medicaid drug,' and included a new disclaimer at the end of the document. These are minor changes to improve readability and reduce confusion.

The 30-day notice published in the Federal Register (88 FR 23429) on 6/6/2023.

9. Payments/Gifts to Respondents

This collection provides zero payments or gifts to respondents, but it does provide information on why the plan denied the service or payment and informs Medicare enrollees of their appeal rights.

10. Confidentiality

Personally identifiable information contained in the form is protected by the Privacy Act and Health Insurance Portability and Accountability Act (HIPAA) standards for plans and their providers. CMS will not collect data from the forms. Thus, CMS assurance of confidentiality is not applicable to this collection.

11. Sensitive Questions

No questions of a sensitive nature will be asked.

12. Burden Estimates

Background

The number of respondents for this collection is based on enrollment for the 112 applicable integrated plans. In January 2023, the enrollment for all applicable integrated plans is 810,377.[2]

Wage Estimates

To derive average costs, we used data form the U.S. Bureau of Labor Statistics' May 2021 National Occupation Employment and Wage Estimates for all salary estimates (http://www.bls.gov/oes/current/oes_nat.htm). In this regard, the following table presents the mean hourly wage, the cost of fringe benefits (calculated at 100 percent of salary), and the adjusted salary wage.

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly
Healthcare Support Workers	31-9099	$19.56	$19.56	$39.12

2 AIP enrollment data from the SNP Comprehensive Report January 2023 https://www.cms.gov/research-statisticsdata-and-systems/statistics-trends-and-reports/mcradvpartdenroldata/special/snp-comprehensive-report-2023-01

As indicated, we are adjusting our employee hourly wage estimates by a factor of 100 percent. This is necessarily a rough adjustment, both because fringe benefits and overhead costs vary significantly from employer to employer, and because methods of estimating these costs vary widely from study to study. Nonetheless, there is no practical alternative and we believe that doubling the hourly wage to estimate total cost is a reasonably accurate estimation method.

Burden Estimates

We estimate it will take applicable integrated plan staff about 10 minutes (0.1667 hours) to complete the coverage decision letter for denied Medicare and Medicaid services. We base this estimate on an estimate for similar form in CMS-10003.

Only a portion of plan enrollment will require an integrated organization determination. Dual eligible special needs plan reconsideration data does not drill down to show the applicable integrated plan population only. Given the similarity of population characteristics, we used the reconsideration experience for the Medicare Medicaid Plans (MMPs) participating in the Financial Alignment Initiative as a proxy for the applicable integrated plans. In 2021, 13,282 reconsiderations were resolved adversely or partially favorably to MMP enrollees. The corresponding MMP enrollment in 2021 was 435,306, which implies a rate of 30.5 reconsiderations per 1,000 in 2021. Applying the MMP reconsideration rate of 30.5 per 1,000 to the 2023 enrollment in applicable integrated plans of 810,377 results in an estimated 24,716 (810,377 x 30.5 / 1,000) service reconsiderations for applicable integrated plans in 2023.

The total annual hourly burden for this collection is 4,120 hours (0.1667 hours x 24,716 forms). The total estimated annual cost for this collection is $161,174 (4,120 hours x $39.12/hr) or $6.52 per form.

Regulatory Reference	Respondents	Total Number of Responses	Hours Per Response	Total Hours	Wages ($/hr)	Total Cost ($)
422.631	**112 AIPs**	**24,716**	**0.1667**	**4,120**	**$39.12**	**$161,174**

13. Capital Costs

There are no capital costs.

14. Cost to the 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/generalschedule/.

The annual burden to the Federal Government including the cost of CMS employees' time is calculated to be: **$6,193.**

Coverage Decision Letter Review	

Medicare MA, Medicaid CMCS and MMCO D-SNP Subject Matter Experts and staff	
Help/Review:5 GS-13 step 5: 5 x $60.83/hr. x 2 hours	$608
1 GS-13 step 5: 1 x $60.83/hr. x 80 hours	$4,866
1 GS-14 step 5: 1 x $71.88/hr. x 10 hours	$719
SUBTOTAL	$6,193

15. Program/Burden Changes

The changes to this collection will have some impact to the burden. Applicable integrated plans will need to make minor changes to three sections of the coverage decision letter, update language throughout the letter to read "medical service/item *or* Medicare Part B drug *or* Medicaid drug," and include a nondiscriminatory language disclaimer that is a new requirement on CMS notices and forms. It is estimated to take an applicable integrated plan 30 minutes to make these changes to the coverage decision letter.

The burden increase for this collection was due to the increase in the number of applicable integrated plans and enrollees. In 2021, there were 95 applicable integrated plans with 210,000 enrollees. In 2023, there are 112 applicable integrated plans with 810,377 enrollees. This caused the number of hours to increase from 116 to 4120.

The change in cost to the government increased as well. The cost to the government now includes the time of subject matter experts in CMS to update the coverage decision letter, getting feedback from internal CMS departments and creating the paperwork reduction act package.

16. Publication/Tabulation Dates

CMS does not intend to publish data related to the forms.

17. Expiration Date

CMS will display the expiration date and OMB approval number on the coverage decision letter and instructions document.

18. Certification Statement

No exception to any section of OMB Form 83-I is requested.

B. Collections of Information Employing Statistical Methods

This collection does not employ statistical methods.