Supporting Statement Part A

Applicable Integrated Plan Coverage Decision Letter

(CMS-10716, OMB 0938-New)

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 will need to unify and update 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 member has already received. "Applicable integrated plans," hereinafter referred to as "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 starting in CY 2021 in place of the Notice of Denial of Medical Coverage (or Payment) (NDMCP) form (CMS-10003) as part of requirements to unify appeals and grievance processes. All other Medicare Advantage (MA) plans will continue to use the NDMCP.

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, to be applicable beginning 2021. We finalized the implementing 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

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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.

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. The document is issued to beneficiaries 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 member has already received. The form provides the beneficiary with information regarding their right to an appeal of the Applicable integrated plans decision and the beneficiary will the instructions to navigate the appeal process.

CMS will not use form CMS-10716 to collect and analyze data on Medicare health 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 purpose for the coverage decision letter is substantially similar to form CMS-10003, we are not able to combine this information collection with CMS10003 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 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 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
- 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 coverage decision letter was developed with assistance from a contractor. The contractor conducted in person interviews with beneficiaries and caregivers regarding the content and formatting of the coverage decision letter.

The 60-day notice published in the Federal Register on 10/18/2019 (84 FR 55966). We received comments from 16 organizations. The comment summaries and CMS responses are attached to this package. The comments were comprised of recommendations and suggestions to improve the readability of form CMS-10716. These comments did not necessitate changes to burden estimates in the 30-day package; however, CMS made changes to the form and form instructions in response to comments. These changes are displayed in the attached form, form instructions, and crosswalk document.

The 30-day notice published in the Federal Register on 04/15/2020 (85 FR 21009). We received 15 comments during the 30-day comment period and the responses are attached to this package. CMS made additional minor adjustments to the form and form instructions in response to comments. These changes are displayed in the attached form, form instructions, and crosswalk document.

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 a projected estimate of growth in enrollment for the estimated 37 applicable integrated plans. The 178,000 enrollment figure for contract year 2019 is projected to grow to 210,000 (178,000 x 1.177) enrollees by 2021, the first year that issuing the integrated organization determination in this package will be required.[2]

Wage Estimates

To derive average costs, we used data form the U.S. Bureau of Labor Statistics' May 2018

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 Wage ($/hr)
Healthcare Support Workers	31-9099	18.80	18.80	37.60

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.

2 Table IV.C1, "Private Health Enrollment" in 2019 Trustee Report, accessible at https://www.cms.gov/ResearchStatistics-Data-and-Systems/Statistics-Trends-andReports/ReportsTrustFunds/Downloads/TR2019.pdf

Burden Estimates

We estimate it will take about 10 minutes (0.1667 hours) to complete the coverage decision letter for Medicare and Medicaid services that have been denied. We basing this estimate on an estimate for similar form in CMS-10003.

Only a portion of plan enrollment will require an integrated organization determination. Given the similarity of population characteristics, the reconsideration experience for the Medicare Medicaid Plans (MMPs) participating in the Financial Alignment Initiative was used as a proxy for the applicable integrated plans. In 2016, MMP enrollees were impacted by 1,232 reconsiderations for services which were resolved adversely or partially favorably to the beneficiary. The corresponding MMP enrollment in 2016 was 368,841, which implies a rate of 3.3 reconsiderations per 1,000 in 2016. Applying the MMP reconsideration rate of 3.3 per 1,000 to the projected 2021 enrollment in applicable integrated plans of 210,000 results in an estimated 693 (210,000* 3.3/1,000) service reconsiderations for applicable integrated plans in 2021.

The total annual hourly burden for this collection is 116 hours (0.1666 hours x 693 forms). The total estimated annual cost for this collection is $4,362 (116 hours x $37.60/hr) or $6 per form.

13. Capital Costs

There are no capital costs.

14. Cost to the Federal Government

No costs to the Federal government are anticipated. The forms will be printed and distributed by individual Medicare health plans.

15. Program/Burden Changes

This collection is new and is not applicable to any changes in burden.

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.