

**Supporting Statement – Part A**  
**Notice of Denial of Medical Coverage (or Payment) - NDMCP**  
**CMS-10003, OMB 0938-0829**

**Background**

Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue the Notice of Denial of Medical Coverage (or Payment) (NDMCP) when a request for either a medical service or payment is denied, in whole or in part. Additionally, the notices inform Medicare enrollees of their right to file an appeal, outlining the steps and timeframes for filing. All Medicare health plans are required to use these standardized notices. In 2013, Medicaid appeal rights were integrated into form CMS-10003 for beneficiaries who are eligible for Medicare and full Medicaid benefits under a State Medicaid plan. These appeal rights are provided in instances where a Medicare health plan enrollee receives full benefits under a State Medical Assistance (Medicaid) program being managed by the plan and the plan denies a service or item that is also subject to Medicaid appeal rights. As a result of integrating Medicare Advantage and Medicaid appeal rights for the 2013 package, this notice is commonly referred to as the Integrated Denial Notice (IDN).

The Centers for Medicare & Medicaid Services (CMS) requests a revision of this collections (CMS-10003), which is due to expire on January 31, 2020. The OMB has previously approved these notices (OMB approval #0938-0829). The revised notice and accompanying instructions that are the subject of this PRA package includes the following changes:

- Removal of language related to State Fair Hearings to comply with the change in Medicaid managed care rules at 42 CFR 438.402(c)(1)(i), effective 2017, that all Medicaid managed care denials must now first have a plan-level review before a State Fair Hearing can be requested.
- Updates to comply with the Medicare Advantage final rule, published May 23, 2019, Federal Register, 84 FR 23832, effective January 1, 2020, regarding the change in timeframes for Medicare Advantage appeals related to Part B drugs.
- Removing the option to delete sections related to expedited payment requests (if applicable); plans are to leave all language regarding fast appeals. Text has been added to the notice informing enrollees they do not have a right to request an expedited appeal if they are asking to be paid back for an item or service already received (42 CFR §422.570(a)).
- The addition of language in the instructions that “applicable integrated plans” should follow notification requirements under final rule published April 16, 2019, Federal Register, 84 FR 15680, and amended May 23, 2019, Federal Register, 84 FR 23832, effective January 1, 2021.
- The addition of instructions for MA-PDs to enter text in the free text field “why did we deny your request?” when they have determined that the requested drug being denied is covered under Part D.

## **A. Justification**

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

Section 1852(g)(1)(B) of the Social Security Act (the Act) requires Medicare health plans to provide enrollees with a written notice in understandable language of the reasons for the denial and a description of the applicable appeals processes.

Regulatory authority for this notice is set forth in Subpart M of Part 422 at 42 CFR 422.568, 422.572, 417.600(b), and 417.840.

Section 1932 of the Act sets forth requirements for Medicaid managed care plans, including beneficiary protections related to appealing a denial of coverage or payment. Section 1902(a)(3) of the SSA requires State plans to provide for a fair hearing before the State agency to any individual whose claim for medical assistance under the plan is denied or not acted upon promptly. The Medicaid managed care appeals regulations are set forth in Subpart F of Part 438, Title 42 of the Code of Federal Regulations (CFR). Rules on the content of the written denial notice can be found at 42 CFR 438.404. Related requirements on the information a Medicaid managed care plan must provide to enrollees related to grievances, appeals and fair hearing procedures can be found at 42 CFR 438.10(g)(1). A State may provide for greater appeal protections under its Medicaid State plan.

### **2. Information Users**

Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue form CMS-10003 to Medicare Advantage plan enrollees when a request for either a medical service or payment is denied in whole or in part. The notice explains to the enrollee why the plan denied the service or payment and informs Medicare enrollees of their appeal rights.

In addition this notice is also used, as appropriate, to explain Medicaid appeal rights to full dual eligible individuals enrolled in a Medicare health plan that is also managing the individual's Medicaid benefits. To that end, the revised notice contains bracketed text the plan will insert if the denial notice is being delivered to an enrollee who is a full dual eligible. The text in square brackets "[ ]" reflects the Federal protections for Medicaid managed care enrollees. Since a State may offer additional protections, there is also free-text space for inclusion of any State-specific protections that exceed the Federal protections.

CMS will not use these notices to collect and analyze data on Medicare health plan appeals.

### **3. Use of Information Technology**

The notice is available for completion electronically, however, the notice must be delivered in writing unless an enrollee opts in to receive this notification via electronic means. Currently, there is no data available to determine how many Medicare

Advantage enrollees have chosen to receive notifications electronically and CMS has no current plans to rely on electronic delivery of this notice. The notice does not require a signature from respondents, so the question of CMS accepting electronic signatures is not applicable.

#### **4. Duplication of Efforts**

This information collection does not duplicate any other effort and the information cannot be obtained from any other source.

#### **5. Small Businesses**

There is no significant impact on small businesses. The notices inform 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 notice to enrollees whenever requests for items/services or payment are denied by Medicare. Thus, there are no opportunities for less frequent collection.

#### **7. Special Circumstances**

The Notice of Denial of Medical Coverage (or Payment) is issued by 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 notice:

- 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 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

- 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 (84 FR 14383) 4/10/2019. During this 60-day comment period, CMS received four comments that resulted in minor revisions to the notice and instructions. CMS has responded to these comments in a separate document.

The 30-day notice published in the Federal Register (84 FR 32926) 07/10/2019. No comments were received during the comment period.

## **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 notice 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 notices. 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 Estimate (Total Hours and Wages)**

### *Background*

The number of respondents for this collection is based on June 2019 CMS Medicare Advantage/Part D Contract and Enrollment Data which indicate that there are 733 Medicare health plans (excluding stand-alone prescription drug plans). Source: June 2019 Monthly Contract Summary Report:

<https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/MCRAdvPartDENrolData/Downloads/2019/June/Monthly-Summary-Report-2019-06.zip>

The most current CMS validated plan reported data is for 2016 and indicated a 9.0% denial rate (44,634,284 denials issued out of a total of 498,366,788

organization determinations), which is slightly higher than the 8.3% and 8.4% denial rate contained in the 2014 and 2015 data, respectively. While higher, we believe these three data sets are still consistent with respect to the rate at which plans are denying organization determination requests.

*Wage Estimates*

To derive average costs, we used data from 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](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.

*Burden Estimates*

We estimate it will take about 6 minutes to complete the notice for Medicare services that have been denied. We recognize that completion of the notice will take slightly longer in instances where the plan has to populate information on the enrollee's Medicaid benefits and rights. We are retaining our previous estimate that it will take plans an average of 10 minutes (0.1666 hours) to complete the denial notice.

Based on data reported to CMS by Medicare health plans, there were 44,634,284 adverse and partially favorable decisions issued in 2016. As explained more fully below these plan reported data are over-inclusive for purposes of estimating the number of IDNs that will be issued. The IDN is only issued when there is enrollee liability.

Because the total universe of adverse decisions (44,634,284) includes contract provider claims where there is no enrollee liability (and the IDN is not issued), the burden estimate for this PRA package only accounts for instances where an adverse decision is made on an enrollee or non-contract provider request (instances when the IDN is issued). We estimate that the IDN will be issued in 21% of the total volume of adverse decisions.

Prior to 2012, plans were instructed to report adverse determinations issued to non- contract providers only, as well as adverse decisions issued directly to enrollees.

Beginning in 2012, plans were instructed to report all determinations for both contract and non-contract providers (in addition to decisions issued directly to enrollees). This change to the reporting requirements resulted in a substantial increase in the total number of adverse and partially favorable organization determinations. However, for the purposes of this PRA package, we acknowledge an IDN is not required to be issued for contract provider claims where there is no enrollee liability. Based on our previous burden estimate in 2011 where the data set only included non-contract provider and enrollee requests, we believe it is reasonable to estimate that about 79% of all adverse decisions under the new reporting requirements are attributed to contract provider claims where an IDN would not be issued. Therefore, we estimate that 21% of the 2016 universe for adverse or partially favorable decisions are non-contract provider and enrollee requests, yielding an estimate of 9,373,200 (44,634,284 determinations x 0.21) IDNs that will be issued.

The total annual hourly burden for this collection is 1,561,575 hours (0.1666 hours x 9,373,200 notices) or 2130 hours per plan.

The total estimated annual cost for this collection is \$58,715,220 (1,561,575 hours x \$37.60/hr) or \$80,102 per plan.

CMS does not have Medicaid data on the rate at which services are denied for only dual eligibles in the managed care setting. However, since the integrated version of this notice will be provided to individuals who are eligible for Medicare and full Medicaid benefits (full duals), we believe these burden estimates adequately account for this population and inclusion of Medicaid appeals information materially does not affect the burden estimate with respect to the total number of denial notices that will be issued by health plans.

### **13. Capital Costs**

There are no capital costs.

### **14. Cost to the Federal Government**

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

### **15. Changes to Burden**

Changes made to the notice and instructions include removal of language related to State Fair Hearings, removal of the option to delete sections related to expedited payment requests, and updates to conform to proposed rules for Medicare Advantage plans and applicable integrated plans for dual eligible enrollees as published in the Federal Register, effective 2019 and 2020. These changes did not have an effect on burden.

The slight increase in burden is, in part, due to the increase in the numbers of Medicare health plan enrollees and total number of organization determinations. Since 2014, the number of enrollees has risen from 16.2 million to 18.3 million and the total number of organization determinations increased from 405,455,838 to 498,366,788.

This slight increase in the numbers of Medicare health plan enrollees and total number of organization determinations has increased when an IDN is issued for enrollee liability. We estimate that 21% of the 2016 universe for adverse or partially favorable decisions are non-contract provider and enrollee requests, yielding an estimate of 9,373,200. This estimate has increased from the previously approved 7,050,602.

Also, the hourly rate used in the previous package has changed. As indicated, we are changing our employee hourly wage estimates to reflect data from the U.S. Bureau of Labor Statistics' May 2018 National Occupational Employment and Wage Estimates and adjusting the hourly wage estimates by a factor of 100 percent.

The annual hourly burden associated with this collection is estimated to be 1,561,575 hours. The annual hourly burden in the 2017 submission for this collection was 1,174,630 hours, resulting in an increase in the burden. CMS believes these adjusted burden estimates, drawn from the most current and reliable data available (2016 plan reported data) are appropriate for the purpose of developing the burden estimates for the IDN (CMS-10003).

We are excluding the revised Spanish version from this iteration since we believe that the best use of our limited translation resources is to wait until after OMB approves the revised notice (in English) before translating that notice into another language.

#### **16. Publication / Tabulation Dates**

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

#### **17. Expiration Date**

CMS will display the expiration date.

#### **18. Certification Statement**

No exception to any section of the 83i is requested.

#### **B. Collection of Information Employing Statistical Methods**

N/A