

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

Background

When this PRA package was last updated in 2013, the Notice of Denial of Medicare Coverage (NDMC) was combined with the Notice of Denial of Payment (NDP). At that time, we also incorporated text to be inserted if the 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, this notice is also commonly referred to as the integrated denial notice (IDN).

The revisions to the NDMC and accompanying instructions that are the subject of this PRA package are intended to enhance the clarity and accuracy of the notice and instructions. In addition, the revisions include language informing beneficiaries of their rights under Section 504 of the Rehabilitation Act of 1973 (Section 504), by alerting the beneficiary to CMS's nondiscrimination practices and the availability of alternate forms of this notice, if needed.

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 when a request for either a medical service or payment is denied in whole or in part. The notice explains 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

No data are being collected through these notices 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 notices.

The notice is not available for completion electronically. Medicare health plans are required to provide this notice to Medicare enrollees if a service or payment request is denied to ensure that enrollees are informed of their Medicare appeal rights. In addition, health plans that have enrollees who are full dual eligibles will provide the integrated version of the notice to inform these individuals of their appeal rights under both Medicare and Medicaid. Medicare health plans are required by law to deliver written denial notices to plan enrollees. 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 on October 16, 2015 (80 FR 62534). During this 60-day comment period, CMS received comments that resulted in revisions to the notice and instructions. A summary of the comments and our response has been attached to this package.

A number of comments were regarding the inclusion of the various "Fast Appeals" sections in the notice that do not apply to denial of payment requests. CMS made

appropriate changes, allowing plans to delete these sections if the “Fast Appeal” process is a request for payment that has been denied.

CMS received several comments surrounding new language in the instructions of the Notice of Denial of Medical Coverage (or Payment) indicating when a denial notice should be sent for plans that manage both Medicare and Medicaid benefits. Some of the comments received included concerns related to:

- Unnecessary notices being delivered for services never covered by Medicare and fully covered by Medicaid.
- Members may be confused if they receive a denial notice, but services or items will be fully covered by Medicaid.
- An increase in the number of denials sent, which would in turn increase the number of appeals filed.
- Expansion of the scope and use of the notice, resulting in costly administrative burdens on plans to update programming systems to accommodate new instructions and effect Star Ratings.

As a result, CMS revised the instructions to now state:

- plans must determine if services are covered under the plan’s Medicare and/or Medicaid benefits;
- the criteria plans are to take into consideration when making that determination; and
- clarification on what circumstances the notice should be issued.

Following the 60-day comment period, an internal review of the notice was completed and CMS added additional language in the instructions to clarify what plans must include in the denial rationale.

9. Payments/Gifts to Respondents

Not applicable.

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 2014 CMS Statistics which indicate that there are 730 Medicare health plans (excluding stand-alone prescription drug plans). Source: 2011 CMS Statistics (Table I.7): http://www.cms.gov/ResearchGenInfo/02_CMSStatistics.asp

The CMS plan reported data for 2014 indicate a 8.3% denial rate (33,574,293 denials issued out of a total of 405,455,838 organization determinations), which is in alignment with the 8.1% and 8.7% denial rate contained in the 2013 and 2012 data, respectively. So, while the overall volumes CMS is using for the current estimates are significantly higher due to the use of actual plan reported data, there is consistency between the three data sets 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 2015 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	17.75	17.75	35.50

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.

The total annual hourly burden for this collection is 1,174,630 hours (0.1666 hours x 7,050,602 notices) or 1,609 hours per plan.

The total estimated annual cost for this collection is \$41,699,365 (1,174,630 hours x \$35.50/hr) or \$57,122 per plan.

CMS does not have Medicaid data on the rate at which services are denied 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

The hourly rate used in the previous 60-day 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 2015 National Occupational Employment and Wage Estimates and adjusting the hourly wage estimates by a factor of 100 percent.

Based on data reported to CMS by Medicare health plans, there were 33,574,293 adverse and partially favorable decisions issued in 2014. As explained more fully below, due to changes in CMS's Part C plan reporting requirements, 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 (33,574,293) 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.

The Centers for Medicare and Medicaid Services (CMS) established reporting requirements for Medicare Advantage Organizations (MAOs) under the authority described in 42 CFR §422.516(a) and each MAO must have an effective procedure to develop, compile, evaluate, and report to CMS. One of the data elements each MAO must report on under these reporting requirements relates to adverse organization determinations. As noted above, when an MAO issues an adverse organization

determination and there is enrollee liability, it must issue the IDN which is the subject of this PRA package. The 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.

In 2011, 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. Given this change in how plans report organization determination decisions and based on our previous burden estimate where the data set only included non-contract provider and enrollee requests (6,960,410), 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 2014 universe for adverse or partially favorable decisions are non-contract provider and enrollee requests, yielding an estimate of 7,050,602 (33,574,293 determinations x 0.21) IDNs that will be issued. This estimate is a slight increase from the 2013 data (6,960,410).

The annual hourly burden associated with this collection is estimated to be 1,174,630 hours. The annual hourly burden in the 2013 submission for this collection was 1,159,604 hours, resulting in a slight increase in the burden. CMS believes these adjusted burden estimates, drawn from the most current and reliable data available (2014 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 would like to 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