Supporting Statement – Part A
Fast Appeals Notices: NOMNC/DENC
CMS-10123/10124, OMB 0938-0953

Introduction

The Centers for Medicare & Medicaid Services (CMS) requests a revision type of approval of two Medicare notices: the Notice of Medicare Non-Coverage (NOMNC)/CMS-10123 and the Detailed Explanation of Non-Coverage (DENC)/CMS-10124. This information collection results from the fast appeal process available to beneficiaries in Traditional Medicare and enrollees in Medicare health plans who receive notice that their Medicare-covered services are ending. Medicare beneficiaries and health plan enrollees are permitted by law to request that an Independent Review Entity (IRE) decide whether Medicare-coverage should continue.

For purposes of these provisions;

- The term "Medicare providers" includes skilled nursing facilities (SNFs), home health agencies (HHAs), and comprehensive outpatient rehabilitation facilities (CORFs),
- The term "Medicare providers" also includes hospice when referring to beneficiaries in Traditional Medicare,
- The term "Medicare health plans" includes Medicare Advantage (MA) plans and cost plans, and
- "Beneficiaries" refers to Medicare beneficiaries in Traditional Medicare and "enrollees" refers to Medicare beneficiaries enrolled in MA plans.

This revision contains the existing notices for extension until 12/31/2024 and updated notices with the following changes effective 1/1/2025:

- Updated language and formatting for both notices to utilize more research-based 'plain language' and formatting consistent with current CMS guidelines.
- Removal of language from the 'If you Miss the Deadline to Appeal Section' of the NOMNC that directs MA enrollees to their plan if their request is untimely.

A. Background

The purpose of the NOMNC is to help a beneficiary/enrollee decide whether to pursue a fast appeal by a Quality Improvement Organization (QIO) and informs them on how to file a request. Consistent with §§405.1200 and 422.624, SNFs, HHAs, CORFs, and hospices must provide notice to all beneficiaries/enrollees whose Medicare-covered services are ending, no later than two days in advance of the proposed termination of service. This information is conveyed to the beneficiary/enrollee via the NOMNC.

If a beneficiary/enrollee appeals the termination decision, the beneficiary/enrollee and the QIO, consistent with §§405.1200(b) and 405.1202(f) for Traditional Medicare, and §§422.624(b) and 422.626(e)(1) - (5) for MA plans, will receive a detailed explanation of the reasons services should end. This detailed explanation is provided to the beneficiary/enrollee using the DENC, the second notice included in this renewal package.

The NOMNC and the DENC must be hand delivered to beneficiaries and enrollees by providers and health plans (or to a legal representative, when appropriate.). *Thus, recipients of these notices have the opportunity to ask questions to ensure their understanding of the notices.*

The changes made to this form were completed by the CMS Office of Communications (OC) to utilize plain language in order to increase accessibility and reduce health disparities. The OC supplied the following information on how their design and language decisions used in this form are research-based.

OC recommendations are soundly based on research-based best practices in plain language and information design. Along with decades of research in cognitive science and behavioral economics, we draw from a wealth of research data specific to CMS programs. We've been conducting consumer research with the patients, caregivers, providers and partners who interact with CMS programs for more than 20 years, and we use feedback from this research to make sure our information and products are clear and easy to use. Consumer testing is ongoing, and we iteratively refine language and design standards as our audiences and their information needs evolve. We work to apply the same research-based standards across all products and channels to make sure our language, messaging and branding are consistent.

Post 1/1/2025
In addition, a small change was made to the 'If you Miss the Deadline to Appeal' section of the NOMNC. This section now has the same untimely appeal info for all who receive the notice (MA enrollees and Traditional Medicare beneficiaries). The reference to contacting a health plan was removed. This change reflects the policy in the associated regulation which further aligned the appeals process for MA and Traditional Medicare by granting untimely MA enrollees the right to an appeal and preserving the right to appeal to a QIO even if they end services early. [1] Previously, MA enrollees with untimely appeals had to appeal to their MA plan instead of the QIO and forfeited their right to appeal if they ended care before the service termination date on the NOMNC while beneficiaries in Traditional Medicare have the right to appeal untimely to the QIO and appeal even if they end services early.

B. Justification

1. Need and Legal Basis

Section 521 of the Benefits Improvement and Protection Act (**BIPA**), Pub.L. 106--554, amended section 1869 of the Social Security Act (the Act) to require significant changes to the Medicare appeals procedures. Among these changes is a requirement under section 1869(b)(1)(F) of the Act that the Secretary establish a process by which an individual may obtain an expedited

[1] Medicare Program; Contract Year 2025 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications (CMS 4205-P/ 88 FR 78476/ (§ 422.626)). Effective 1/1/2025

determination and reconsideration with respect to the termination of provider services. The NOMNC and the DENC fulfill these regulatory requirements.

- §405.1200(b) – Prior to any termination of covered service, the provider of the service must deliver valid written notice to the beneficiary of the provider's decision to terminate services.
- §405.1202(f) – When an QIO notifies a provider that a beneficiary has requested an expedited determination, the provider must send a detailed termination notice to the beneficiary by close of business of the day of the QIO's notification.

In Grijalva v. Shalala (October 17, 1996), the District Court ruled in favor of the plaintiffs and ordered the Secretary to provide notice and expedited hearings for enrollees that are denied urgently needed medical services by their HMO. Pursuant to §422.624 (b)(1), providers must deliver enrollees a 2-day advance notice of termination of services. Per requirements at §422.626(e)(1), plans must deliver detailed notices to the QIO and enrollees whenever an enrollee appeals a termination of services.

Additionally, §417.600(b) provides that cost plans must follow these same fast appeal notification procedures for their enrollees in the covered providers.

- §422.624(b) – Prior to any termination of service, the provider of the service must deliver valid written notice to the enrollee of the Medicare health plan's decision to terminate services.
- §422.626(e)(1) – When an Independent Review Entity (IRE) notifies a Medicare health plan that an enrollee has requested a fast track appeal, the Medicare health plan must send a detailed notice to the enrollee by close of business on the day of the IRE's notification.
- §417.600(b)(1) – The rights, procedures, and requirements relating to beneficiary appeals and grievances set forth in subpart M of part 422 of this chapter also apply to Medicare contracts with HMOs and CMPs under section 1876 of the Act.

The NOMNC and the DENC fulfill these regulatory requirements.

2. Information Users

Providers will deliver a NOMNC to beneficiaries/enrollees no later than two days prior to the end of Medicare-covered SNF, Home Health, CORFs and Hospice services. Beneficiaries/enrollees will use this information to determine whether they want to appeal the service termination to their QIO. If the beneficiary/enrollee decides to appeal, the Medicare provider/health plan will send the QIO and beneficiary/enrollee a DENC, detailing the rationale for the termination decision.

3. Use of Information Technology

Providers and health plans must hand deliver the NOMNC & DENC to beneficiaries. Thus, recipients of these notices have the opportunity to ask questions to ensure their understanding

of the notices. These providers must retain a copy of the signed NOMNC and may store the NOMNC electronically if electronic medical records are maintained. If a provider elects to issue an NOMNC that is viewed on an electronic screen before signing, the beneficiary/enrollee must be given the option of requesting paper rather than electronic issuance if that is what the beneficiary/enrollee prefers. Regardless of whether a paper or electronic version is issued, and whether the signature is digitally captured or manually penned, the beneficiary must be given a paper copy of the signed NOMNC.

In cases where the beneficiary has a representative who is not physically present, providers are permitted to give the NOMNC by telephone as long as a hard copy is also delivered to the representative.

4. Duplication of Efforts

The requirement that providers supply plan beneficiaries/enrollees in HHA, SNF, CORF, and hospice settings with advance notice of service terminations does not duplicate any other effort and the information cannot be obtained from any other source.

5. Small Businesses

These requirements will not adversely affect small businesses.

6. Less Frequent Collection

In instances where an individual is receiving provider services, they need to be notified timely that services will be ending. The individual needs to have time to make a decision whether the services continue to be medically necessary. Giving this information other than during the receipt of services would significantly reduce the effectiveness. In addition, providing the notice two days in advance of coverage ending decreases potential financial liability in the event the beneficiary/enrollee wants to appeal. Providing advance notices to less than 100% of all individuals who are facing service terminations would not afford all beneficiaries/enrollees equal protection of their rights.

7. Special Circumstances

There are no special circumstances to report. No statistical methods will be employed. The regulations at §405.1200(b) and §422.624(b) require that the completed NOMNCs be timely delivered to beneficiaries/enrollees or their representatives. For Medicare enrollees, providers are required to deliver the NOMNC on behalf of enrollee’s health plan. Note: CMS holds the Medicare health plan responsible for delivery of all notices, and compliance with the regulations governing this activity.

8. Federal Register Notice/Outside Consultation

The 60-day Federal Notice published in the Federal Register (89 FR 41967) on 05/14/2024.

No comments were received.

The 30-day Federal Notice published in the Federal Register (89 FR 60639) on 07/26/2024.

Outside Consultation

The changes made to this form were completed by the CMS Office of Communications (OC) to utilize plain language in order to increase accessibility and reduce health disparities. The OC supplied the following information on how their design and language decisions used in this form are research-based.

OC recommendations are soundly based on research-based best practices in plain language and information design. Along with decades of research in cognitive science and behavioral economics, we draw from a wealth of research data specific to CMS programs. We've been conducting consumer research with the patients, caregivers, providers and partners who interact with CMS programs for more than 20 years, and we use feedback from this research to make sure our information and products are clear and easy to use. Consumer testing is ongoing, and we iteratively refine language and design standards as our audiences and their information needs evolve. We work to apply the same research-based standards across all products and channels to make sure our language, messaging and branding are consistent.

9. Payments/Gifts to Respondent

No payments or gifts is provided to respondents for their participation in this collection. Providers provide the Beneficiaries/enrollees with the **CMS-10123/10124** and beneficiaries/enrollees determine whether they want to appeal the service termination to their QIO.

10. Confidentiality

Not applicable; CMS does not collect information. The provider and plan will maintain records of the notices, but those records do not become part of a federal system of records.

11. Sensitive Questions

Not applicable. We do not ask any questions of the beneficiaries/enrollees.

12. Requirements and Associated Burden Estimates

In 2023, there were 34 million Medicare beneficiaries in Traditional Medicare and they requested 47,376 fast appeals.

In 2023, there were 32 million MA enrollees in health plans and they requested 322,379 fast appeals.

In 2023, we estimate that providers delivered approximately 21 million NOMNCs to Medicare beneficiaries and health plan enrollees based on the number of home health and SNF episodes of care.[12]

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2023 National Occupational 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 and overhead (calculated at 100 percent of salary), and the adjusted hourly wage.

Labor Rate

Occupation Title	Occupation Code	Mean Hourly Wage ($/hr)	Fringe Benefit ($/hr)	Adjusted Hourly Wage ($/hr)
Healthcare Social Worker	21-1022	32.42	32.42	64.84

Annual Burden Estimates (NOMNC)

To arrive at the combined hourly and wage burden for Traditional Medicare and MA we made the following assumptions and calculations for the individual notices:

Provider staff spend **10 minutes** per NOMNC.

Issuing the 21 million NOMNCs to Traditional Medicare beneficiaries and health plan enrollees results in a total annualized burden of **3.5 million hours** (10 min/60 x 21 million), or 133 hours per provider (3.5 million hours/ 26,399 providers).

We estimate a total burden of $226,940,000 (3.5 million hours x $64.84/hours) or $10.81 per NOMNC ($226,940,000 / 21 million NOMNCs).

Annual Burden Estimates (DENC)

To arrive at the combined hourly and wage burden for Traditional Medicare and MA we made the following assumptions and calculations for the individual notices:

Provider and health plan staff spend **75 minutes** per DENC.

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[1] The data used in this report came from CMS Program Statistics for most recent years available (MA/2019, Traditional Medicare/2021).

[2] Note that the amount of Medicare business with CORFs is so small that Medicare statistical summaries do not include a separate line item for patient encounters with these facilities. Similarly, we do not have a precise estimate for of hospice discharges, but the number is considered to be an extremely small percentage of the total number of annual hospice patients. Accordingly, our analysis is necessarily limited to HHA and SNF services.

The number of DENCs issued per year is **369,755**.

Issuing the DENCs results in an annualized burden of **462,194 hours** (75 min/60 x 369,755 DENCs).

We estimate a total burden of 472,268 hours at a cost of **$29,968,659** (462,194 hours x $64.84) or $81.05 per DENC ($29,968,659 / 369,755 DENCs).

Post 1/1/2025
The estimated burden for the DENC is expected to increase once 4205-F becomes effective January 1, 2025.

Currently, there is no data collected on the volume of fast-track appeals conducted by MA plans for untimely requests. The QIO conducts appeals for beneficiaries in Traditional Medicare for untimely requests but does not formally collect data on appeals based on untimely requests from MA enrollees. Thus, the following estimates are speculative given the lack of precise data on the number of the fast-track appeals for untimely Traditional Medicare requests.

Anecdotal data from the QIOs conducting these fast-track appeals indicates that approximately 2.5 percent of all fee-for-service (Traditional Medicare) fast-track appeal requests are untimely. In the most recent year available (2/1/2023-1/31/2024, there were 322,379 MA fast-track appeals to the QIO. Thus, we estimate that approximately 8,059 fast track appeals will be shifted from MA plans to the QIO (0.025 × 322,379), and thus, a DENC will be required for these appeals.

This will raise the total annual burden estimate for the DENC to 472,305 hours (75 min/60 x 377,844 (369,755+8,089) DENCs beginning January 1, 2025.

Burden Summary

We estimate a total cost of **$256,908,659** ($226,940,000 + $29,968,659) and annual hourly burden of **3,962,194** for the NOMNC and DENC combined.

Post 1/1/2025
We estimate a total cost of **$257,564,256** ($226,940,000 + $30,624,256) and annual hourly burden of **3,972,305 (3.5 million hours +472,305 hours)** for both the NOMNC and DENC.

Form	**Respondent**	**Responses**	**Burden Hours**	**Total Cost**
NOMNC	26,399	21,000,000	3,500,000	226,940,000
DENC	26,399	377,844	472,305	30,624,256
TOTAL			**3,972,305**	**$257,564,256**

Information Collection Instruments and Instruction/Guidance Documents

- Notice of Medicare Non-Coverage (NOMNC) (CMS-10123)

- Detailed Explanation of Non-Coverage (DENC) (CMS-10124)

13. Capital Costs

There are no capital costs associated with this collection.

14. Cost to Federal Government

The cost to the Federal government is generally on a triennial basis and is associated with the preparation and release of the MCSN and includes the time it takes the employee to complete the PRA process, another employee to create a translated version, and posting the documents to CMS.gov.

The analysis and preparation of the PRA package and the subsequent release of documents is performed by CMS employees. The average salary of the employees who would be completing this task, which includes the locality pay adjustment for the area of Washington-Baltimore-Arlington, is listed in the table below. See OPM 2023 General Schedule (GS) Locality Pay Tables, https://www.opm.gov/policy-data-oversight/payleave/salaries-wages/salary-tables/pdf/2023/DCB.pdf. We estimate that on average it takes a CMS employee 24 hours to perform these activities and the triennial cost to the Federal government to be $1,588.80.

Employee	Hourly Wage	Number of Hours	Triennial Cost to Government
GS-13, step 5	$66.20	24	$1,588.80
			TOTAL: $1,588.80

15. Changes to Burden

An increased number of QIO appeal requests is responsible for the increase in our estimated burden for the DENC. Reasons for the increases have been attributed to the increasing numbers of Medicare beneficiaries and enrollees. Also, beneficiaries/enrollees and their families are becoming more knowledgeable about exercising their Medicare rights. In addition, we have improved our MA data collection efforts and can better reflect enrollee utilization of SNF and home health services, and thus, numbers of NOMNCs delivered.

16. Publication and Tabulation Dates

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

17. Expiration Date

CMS will display the expiration date on the CMS 10123/NOMNC & CMS 10123/DENC.

18. Certification Statement

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

B. Collection of Information Employing Statistical Methods

There will be no statistical method employed in this collection of information.