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 renewal of two Medicare notices: the Notice of Medicare Non-Coverage (NOMNC) and the Detailed Explanation of Non-Coverage (DENC). This information collection results from the fast appeal process available to beneficiaries in Original 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 Original Medicare,
- The term "Medicare health plans" includes Medicare Advantage plans and cost plans, and
- "Beneficiaries" refers to Medicare beneficiaries in Original Medicare and "enrollees" refers to Medicare beneficiaries enrolled in Medicare health plans.

We have adjusted our burden based on more consistent NOMNC delivery as well as more accurate reporting of the number of fast appeals requested by beneficiaries and enrollees. Overall, our estimate has been adjusted by +4,941 respondents, +737,095 responses, and +177,944 hours. Our per response estimates are unchanged. See section 15 of this Supporting Statement for details.

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 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 Original Medicare, and §§422.624(b) and 422.626(e)(1) - (5) for Medicare health 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.

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 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. The NOMNC and the DENC fulfill these regulatory requirements.

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.

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

SNFs, CORFs, HHAs and hospices must deliver a hard copy of the NOMNC to beneficiaries/enrollees. 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 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 the case of an individual receiving provider services, he or she needs to decide whether the services continue to be medically necessary. (Providing the 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 other special circumstances that would require an information collection to be conducted in a manner that requires respondents to:

- Report information to the agency more often than quarterly;
- Submit more than an original and two copies of any document;
- Retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years;
- Collect data in connection with a statistical survey that is not designed to produce valid and reliable results that can be generalized to the universe of study,
- Use a statistical data classification that has not been reviewed and approved by OMB;
- Include 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
- 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 September 22, 2017 (82 FR 44416). Comments have been received and are attached to this package along with our response.

The 30-day notice published in the Federal Register on November 22, 2017 (82 FR 55612). We did not receive any 30-day comments.

9. Payments/Gifts to Respondent

Not applicable.

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 question of the enrollee.

12. Requirements and Associated Burden Estimates

In 2015, 37.8 million Medicare beneficiaries in OM requested 25,445 fast appeals. Thus, 0.067 percent of beneficiaries in OM used the fast appeal process in 2015.

In 2015, 17.8 million MA enrollees in 741 health plans requested 60,494 fast appeals. Thus, 0.339 percent of MA enrollees used the fast track appeal process in 2015.

In 2015, we estimate that providers delivered approximately 5.91 million notices to Medicare beneficiaries and health plan enrollees based on the number of persons receiving home health services and covered SNF admissions (CMS Program Statistics 2015).

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.

Wages

To derive average costs, we used data from the U.S. Bureau of Labor Statistics' May 2016 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)
Registered nurse	29-1141	34.70	34.70	69.40

*Annual Burden Estimates (*NOMNC)

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

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

Issuing the **5,991,005** NOMNCs to OM beneficiaries and health plan enrollees results in a total annualized burden of **998,501 hours** (10 min/60 x 5,991,005 NOMNCs), or 36 hours per provider (998,501 hours/**27,385 providers**).

We estimate a total labor burden of $69,295,969.40 (998,501 hr x $69.40/hr) or $11.57 per NOMNC ($69,295,969.40/ 5,991,005 NOMNCs).

*Annual Burden Estimates (*DENC)

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

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

Note that because Original Medicare providers are responsible for delivering the DENC to beneficiaries and health plans are responsible for delivering the DENC to health plan enrollees, we are breaking out the burden for the two Medicare programs. The burden breakdown is as follows:

The number of DENCs issued per year is **85,939** (25,445 by Original Medicare providers and 60,494 by health plans). This equates to .93 notices per OM provider (25,445 divided by 27,385 providers) and 82 notices per health plan (60,494 divided by 741 plans).

Issuing the OM DENCs results in an annualized burden of 31,806 hours (75 min/60 x 25,445 DENCs).

Issuing the MA DENCs results in an annualized burden of 75,618 hours (75 min/60 x 60,494 DENCs).

We estimate a total burden of **107,424 hours** (31,806 hr + 75,618 hr) at a cost of $7,455,225.60 (107,424 hr x $69.40) or $86.75 per DENC ($7,455,225.60 / 85,939 DENCs).

Burden Summary

	Respondents	Responses	Time (per response)	Time (Total)
NOMNC	27,385	5,991,005	10 min	998,501 hr
DENC	28,126	85,939	75 min	107,424
TOTAL	**55,511**	**6,076,944**	**85 min**	**1,105,925**

We also estimate a total cost of **$76,751,195** ($69,295,969.40 + $7,455,225.60)

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

There is no cost to the Federal Government for this collection.

15. Changes to Burden

An increased number of fast appeal requests is responsible for the increase in our estimated burden. Reasons for the increases have been attributed to more consistent NOMNC delivery as well as more accurate reporting of the number of fast appeals requested by beneficiaries and enrollees.

There are no changes to any of our per response burden estimates. Adjustments have been made to the following figures:

Changes to burden (Respondents)

	Currently Approved	Proposed	Difference
NOMNC	24,915	27,385	+2,470
DENC	25,655	28,126	+2,471

	Currently Approved	Proposed	Difference
TOTAL	50,570	55,511	+4,941

Changes to burden (Responses)

	Currently Approved	Proposed	Difference
NOMNC	5,314,194	5,991,005	+676,811
DENC	25,655	85,939	+60,284
TOTAL	5,339,849	6,076,944	+737,095

Changes to burden (Time)

	Currently Approved (hr)	Proposed (hr)	Difference (hr)
NOMNC	885,699	998,501	+112,802
DENC	42,232	107,424	+65,192
TOTAL	927,931	1,105,925	+177,944

With regard to cost estimates, we propose to change the source of our wage data. Specifically, our currently approved package uses OPM general schedule equivalent wages (at $32.40/hr) while this 2017 iteration uses BLS wage figures (at $69.40/hr when adjusted for fringe benefits and overhead). This amounts to an increase of $37.00/hr.

16. Publication and 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 I-83 is requested.

B. Collection of Information Employing Statistical Methods

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