Supporting Statement – Part A
Medicare Health Plan Denial Notices: NDMC / NDP
CMS-10003 / OMB approval #0938-0829

A. Background

The Centers for Medicare & Medicaid Services requests a revision of two Office of Management and Budget (OMB) -approved collections: The Notice of Denial of Medical Coverage (NDMC) and the Notice of Denial of Payment (NDP). Both notices are due to expire on August 31, 2010. The OMB previously approved these notices (OMB approval #0938-0829).

Medicare health plans, including Medicare Advantage plans, cost plans, and Health Care Prepayment Plans (HCPPs), are required to issue the NDMC and NDP 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. All Medicare health plans are required to use these standardized notices. A description of the notices follows:

CMS-10003-NDMC

Medicare health plans provide an NDMC to enrollees upon denial, in whole or in part, of an enrollee's coverage request. This denial may be subject to a series of administrative review levels, involving defined steps and timeframes. The NDMC was developed to ensure Medicare enrollees have access to information needed to navigate the Medicare beneficiary appeals process. The NDMC meets requirements for both Medicare's standard and expedited appeals processes.

CMS-10003-NDP

Medicare health plans provide an NDP to enrollees upon denial, in whole or in part, of payment for a service or item that the enrollee received. This denial may be subject to a series of administrative review levels, involving defined steps and timeframes. The NDP was developed to ensure Medicare enrollees have access to information needed to navigate the Medicare beneficiary appeals process. The NDP meets requirements for Medicare's standard appeals process.

B. Justification

1. Need and Legal Basis

Section 1852(g)(1)(B) of the Social Security Act, as amended by Section 4001 of the Balanced Budget Act of 1997, requires Medicare health plans to provide determinations to deny coverage (i.e., medical service or payment) in writing and to include a statement in understandable language of the reasons for the denial and a description of the applicable reconsideration and appeals processes. The NDP and NDMC were

developed to comply with the statute. Regulatory authority for the NDMC and NDP are found at 42 CFR 422.568, and 42 CFR 417.600(b). Also, 42 CFR 417.840 applies certain Subpart M notice and appeal rules to cost plans and HCPPs.

Additionally, CMS recently published a final rule with comment, "Medicare Program; Medicare Advantage and Prescription Drug Benefit Programs: Negotiated Pricing and Remaining Revisions," which added language to 42 CFR 422.578 and 42 CFR 422.582. This rule permits a physician providing treatment to an enrollee, upon providing notice to the enrollee, to request a standard reconsideration of a pre-service request for reconsideration on the enrollee's behalf (Federal Register 74:7 (January 12, 2009)
p. 1542).

2. Information Users

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.

These notices are not available for completion electronically; information is not being collected. Medicare health plans are required to provide these notices to Medicare enrollees upon denial of a service or payment request. The notices inform individuals of the denial and of their Medicare appeal rights. The notices do not require a signature from respondents. Thus, the question of CMS accepting electronic signatures is not applicable. These notices cannot be made electronic since plans are required by law to deliver written notices to Medicare health plan enrollees. Therefore, CMS has no plans to employ electronic delivery/collection techniques in the future.

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. Thus, there are no opportunities for less frequent collection.

7. Special Circumstances

The NDMC and NDP are 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.

8. Federal Register/Outside Consultation

A 60-day Federal Register notice was published on April 30, 2010. No comments were received.

9. Payments/Gifts to Respondents

Not applicable.

10. Confidentiality

Personally identifiable information contained in the notices is protected by the Privacy Act and 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)

For the 740 Medicare health plans, the total hour burden for this collection is **194,728** hours, or **263.15** hours per plan. (Source: CMS Statistics: http://www.cms.hhs.gov/ResearchGenInfo/02_CMSStatistics.asp.)

The total burden in dollars for this collection is **$5,623,744.64** (based on a GS 12 step-1 salary at an hourly rate of **$28.88**), or **$7,599.65** per plan.

We calculated the burden estimates as follows:

According to an October 2009 Memorandum Report, the HHS Office of Inspector General found that 3,196,469 organization determinations (97.8%) of the 3.2 million service-related organization determinations Medicare plans processed from October 1 to December 31, 2007 were fully favorable to beneficiaries. That is, plans denied, in whole or in part, only 73,023 (2.2%) of all service-related organization determinations. (Source: OIG Memorandum Report: "Beneficiary Appeals in Medicare Advantage," October 22, 2009, OEI-01-08-00280, pp. 8-9: http://oig.hhs.gov/oei/reports/oei-01-08-

00280.pdf.)

Separately, data reported by CMS' Part C independent review entity, Maximus, suggest that about 25% of Medicare health plan appeals are service-related and approximately 75% of appeals are payment-related. (Source: Fact Sheet: Part C Reconsideration Appeals Data - 2008. Maximus Federal Services. http://www.cms.hhs.gov/MMCAG/05_IRE.asp#TopOfPage.)

If 73,023 represents the 25% of service-related denials for one quarter in 2007, we assume Medicare health plans over the course of a year issue 292,092 (73,023 multiplied by 4) service-related denials, or NDMCs. And we estimate plans annually issue approximately 876,276 NDPs in response to payment-related requests (73,023 multiplied by 3 equals 219,069; 219,069 multiplied by 4 equals 876,276).

These data suggest plans annually issue a total of approximately **1,168,368** denial notices to 10,894,000 Medicare enrollees. We derived the universe of all denials (payment and pre-service) of 1,168,368 by assuming the 292,092 of annual service-related denials represents 25% of all organization determinations, based on the Part C IRE's data.

Accounting for the 740 Medicare health plans nationwide, on average, each Medicare health plan, over the course of a year, is responsible for issuing approximately 1,578.88 denial notices (1,168,368 divided by 740). The corresponding annual rate of notices per enrollee is about 0.11 (1,168,368 notices divided by 10,894,000 enrollees).

We continue to estimate that plan administrative staff spend, on average, between 6.3 to 15 minutes per NDP or NDMC. While plans now have had several years of experience with these notice requirements, time may be required to research the basis of the denial and mail notices to enrollees. Therefore, we estimate (using a 10 minute time limit) the total burden of these notices as 194,728 hours (10 minutes multiplied by 1,168,368 notices divided by 60 minutes), or 263.15 hours per plan (194,728 hours divided by 740 plans).

The hour burden estimates for each type of notice are:

NDP:	197.36 hours per plan
NDMC:	65.79 hours per plan

The total wage burden for this process is $5,623,744.64, based on a GS 12 Step 1 salary at an hourly rate of $28.88 (194,728 hours multiplied by 28.88), or $7,599.65 per plan ($5,623,744.64 divided by 740).

> Note: This OIG evaluation, which is national in scope, analyzed data on service-related organization determinations made from October 1, 2007 to December 31, 2007. To obtain data, the OIG drew a stratified random sample of 105 MA contracts from the universe of 505 MA contracts in the 50

States and the District of Columbia as of October 2007. The 105 MA contracts were then requested to provide data on the total number of organization determinations that were favorable and adverse.

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 increase in burden is, in part, due to the increase in the numbers of Medicare health plans and Medicare health plan enrollees. Since 2005, the number of Medicare plans has increased from 454 to 740, and the number of enrollees has risen from 7.3 million to 10.9 million.

Additionally, we adjusted our methodology for estimating the total number of Medicare health plan denial notices based on a new HHS OIG evaluation of the Medicare appeals program. (Source: OIG Memorandum Report: "Beneficiary Appeals in Medicare Advantage," October 22, 2009, OEI-01-08-00280, pp. 8-9: http://oig.hhs.gov/oei/reports/oei-01-08-00280.pdf.) The October 2009 OIG report includes an analysis of actual, plan-level, service-related denial data for the last quarter of 2007.

Also, there was a substantive change to the form and instructions. For additional information, refer to the crosswalk document.

Previously, CMS estimated Medicare health plans disseminated approximately 88,000 denial notices per year. This 88,000 estimate was based on the assumption that in 2005 the Part C independent review entity (IRE) adjudicated 22,032 service/payment denials issued by the plans. On appeal, plans generally reverse their denials 75% of the time. Thus, we determined the probable universe of NDP and NDMCs in 2005 was about 88,000.

Now, based on the OIG's recent study, we estimate Medicare health plans issue 292,000 service-related denial per year. Using data from Maximus, CMS' Part C appeals contractor / IRE, we applied the IRE's breakdown between service and payment denials (25% service and 75% payment) to plan-level appeals. Applying this 25% (22,032) and 75% (88,000) breakdown, we derived the total universe of 1,168,368 denials.

Given the availability of actual, plan-level denial data, we now estimate a total hour burden of **194,728** hours, or **263.15** hours per plan. Previously, we estimated a total

hour burden of **26,284.5** hours, or **57.90** hours per plan.

Likewise, where we previously estimated a total dollar burden of **$697,384.86** or **$1,536.09** per plan, we now estimate a total dollar burden of **$5,623,744.64** or **$7,599.65** per plan.

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 I-83 is requested.