Supporting Statement for Appeal Notices and Supporting Regulations Contained in 42 CFR 422.568

A. Background

The Centers for Medicare & Medicaid Services requests an extension of two (2) OMB approved notices, the Notice of Denial of Medical Coverage (NDMC) and the Notice of Denial of Payment (NDP). Both notices are due to expire on May 1, 2007. The OMB previously approved these notices under 0938-0829 as CMS-10003-NDMC and CMS10003-NDP. The NDMC and NDP must be issued by Medicare Health plans when a request for either a medical service or payment is denied. Additionally, the notices inform beneficiaries of their right to file an appeal. All Medicare Health plans are required to use these standardized notices. Details on the specific use of each notice are as follows:

CMS-10003-NDMC

A Medicare Health plan provides the NDMC to enrollees whenever it decides to deny coverage for an enrollee's service request. This action is termed an organization determination. Adverse organization determinations may be reconsidered through a series of appeal procedures that involve defined steps and time frames. The NDMC was developed to ensure that the enrollee would have access to all of the information needed to navigate the appeals process. The NDMC meets all requirements for both the standard and expedited appeals process.

CMS-10003-NDP

A Medicare Health plan provides the NDP to enrollees whenever it denies payment for a medical service or item received. This action is also termed an organization determination. Adverse organization determinations may be reconsidered through a series of appeal procedures that involve defined steps and time frames. The NDP was developed to ensure that the enrollee would have access to all of the information needed to navigate the appeals process. The NDP meets the requirements for the standard appeals process.

B.Justification

1. Need and Legal Basis

Section 4001 of the Balanced Budget Act of 1997 (BBA) amended the Social Security Act (the Act) to add section 1852, including 1852(g)(1)(B). The Act requires plans to provide determinations to deny coverage (i.e., medical service or payment) in writing and 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 notices were

developed to comply with the statute. Specific regulatory authority for the NDMC and NDP are found at 42 CFR 422.568. Additionally, 42 CFR 417.600(b) and 417.840 apply the notice and appeal rules of subpart M to cost plans and HCPPs, to the extent applicable.

2. Information Users

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

3. <u>Improved Information Technology</u>

No data are being collected through these notices for analysis. Therefore, CMS does not use information technology to collect data.

4. <u>Duplication of Similar Information</u>

This information collection is not duplicative of another collection.

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.

6. <u>Less Frequent Collection</u>

The statute requires plans to issue written notice to enrollees whenever requests for services or payment are denied. Thus, there are no opportunities for less frequent collection.

7. Special Circumstances

The NDMC and NDP are only issued by plans when an enrollee's request for either a medical service or payment is denied.

8. <u>Federal Register Notice/Outside Consultation</u>

A 60-day Federal Register notice was published on January 26, 2007.

No outside consultation was taken regarding re-certification of the NDP and the NDMC.

9. Payments/Gifts to Respondents

Neither enrollees nor plans receive payment or gifts linked to notice distribution.

10. Confidentiality

All enrollee-specific 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 makes no assurance of confidentiality.

11. Sensitive Questions

No questions of a sensitive nature will be asked.

12. <u>Burden Estimate (Total Hours & Wages)</u>

The total hour burden for this collection is 26,284.5 hours, or 57.90 hours per plan.

The total burden in dollars for this collection is \$697,384.86, (based on a GS 12 step-1 salary at an hourly rate of \$26.53), or \$1,536.09 per plan.

We calculated the burden as follows:

Since CMS does not collect plan-level data on organization determinations, we do not have the actual number of NDMCs and NDPs that plans give out annually. However, we do know that in 2005, (the last full year for which data is available), 6,127,678 enrollees appealed 22,032 service and payment denials. Plans generally reverse their denials 75% of the time, leaving 25% of all adverse determinations (for which an NDMC or NDP was issued) subject to appeal. Thus, if the number of appeals represents approximately one-fourth of all denials, the probable universe of NDPs and NDMCs issued in 2005 by plans was approximately 88,128 and the corresponding rate of notices per enrollee is 1.44. We project that plans will continue to uphold approximately 25% of their adverse determinations. Therefore, the rate of NDPs and NDMCs issued per enrollee will continue to be approximately 1.44. Applying this rate to the current enrollment figure of 7,301,220 beneficiaries, results in 454 plans delivering 105,138 NDMCs and NDPs, or 231.58 notices per plan.

We previously estimated that plans take approximately 6.3 minutes to issue each notice. We have revised that estimate upwards to average between 6.3 to 15 minutes per NDP or NDMC, noting that, additional time may be required for research, notifications to the affected provider, and mailing the notice to the enrollee. Therefore, we estimate (using the 15 minute upper time limit) the total burden of notice delivery is 26,284.5 hours, or 57.90 hours per plan.

The total wage burden for this process is \$697,384.86, (based on a GS 12-1 salary at an hourly rate of \$26.53), or \$1,536.09 per plan.

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 Medicare Health plans.

15. Program Changes / Burden Changes

The increase in burden hours is the result of an increase in the number of Medicare Health plans and enrollees. Since 2001, the number of plans has gone up from 211 to 454, and the number of enrollees has risen to over 7.3 million. We have also increased our time estimates for preparations of either the NDP or NDMC, observing that plans may require additional time for research, notification to the affected provider, and mailing the notice to the enrollee.

16. Publication and Tabulation Dates

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

17. Expiration Date

Display of the notice expiration date is acceptable.

18. Certification Statement

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

C. Statistical Methods

No statistical methods will be employed