Supporting Statement for the Detailed Notice and Supporting Regulations Contained in 42 CFR §§405.1206 and 422.622

INTRODUCTION

This application requests publication for a second round of public comment on the Detailed Notice of Discharge (the second notice in CMS 10066) in association with final rule CMS-4105-F, [Medicare Program; Notification of Hospital Discharge Appeal Rights.] This final rule was published on November 27, 2006 and sets forth requirements for hospitals to deliver a detailed notice to beneficiaries who request review of a discharge decision by a Quality Improvement Organization (QIO). Hospitals and Medicare Advantage (MA) organizations will be affected by this rule.

A. Background

In recent years, we have published several rules regarding hospital discharge notice policy, as well as rules regarding required notices in other provider settings when Medicare services are terminated. (See our April 5, 2006 proposed rule in the Federal Register (71 FR 17053) for a description of these rules.) Currently, at or about the time of admission, hospitals must deliver the "Important Message from Medicare" (IM) to all hospital inpatients with Medicare to explain their rights as a hospital patient, including their appeal rights at discharge. In addition, a hospital must provide a Hospital-Issued Notice of Non-coverage (HINN) to any beneficiary in original Medicare who expresses dissatisfaction with an impending hospital discharge. Similarly, MA organizations are required to provide enrollees with a notice of non-coverage, known as the Notice of Discharge and Medicare Appeal Rights (NODMAR), when a beneficiary disagrees with the discharge decision (or when the individual is not being discharged, but the organization no longer intends to cover the inpatient stay).

The <u>Weichardt v. Leavitt</u> class action lawsuit was filed in 2003 and contested the legitimacy of the hospital notice procedures. A settlement agreement was signed on October 28, 2005 whereby CMS agreed to publication of a proposed rule. On April 5, 2006, CMS published CMS-4105-P in the Federal Register (71 FR 17052) setting forth revised discharge notice requirements for hospital inpatients who have Medicare. We also published, on April 5, 2006, notices associated with the proposed notification process (CMS 10066).

In the proposed rule, we proposed requiring hospitals to deliver, prior to discharge, a standardized and largely generic notice of non-coverage to each Medicare beneficiary whose physician concurred with the discharge decision. Hospitals would also deliver a more

detailed discharge notice to patients who exercised their right to appeal the discharge.

CMS received over 500 comments on the proposed rule, the overwhelming majority of which strenuously opposed the proposed process, stating that the proposed generic notice (the first of 2 notices in collection CMS 10066) repeated much of the same information contained in the Important Message from Medicare. Therefore, as set forth in final rule, CMS-4105-F, hospitals will deliver a revised version of the Important Message from Medicare, a statutorily required notice explaining the discharge rights, in place of the generic notice. The revised IM is being submitted separately as a revision of current collection #0938-0692.

For patients who request an appeal, the hospital will deliver a more detailed notice, called the Detailed Notice of Discharge. The detailed notice is the subject of this collection, CMS 10066 – and is the second notice in the original collection CMS 10066.

An enrollee who wishes to appeal a determination by a Medicare health plan or hospital that inpatient care is no longer necessary, may request QIO review of the determination. On the date the QIO receives the enrollee's request, it must notify the plan that the enrollee has filed a request for an expedited determination. The plan in turn must deliver a detailed notice to the enrollee.

To the extent that a beneficiary exercises this right, the total estimated time it would take for Original Medicare beneficiaries to either write or call the QIO to request an expedited determination is 9,417 hours. We base this on a projection that 1 percent of inpatients, that is, 113,000 beneficiaries, will request an expedited determination. We estimate that on average, it would take 5 minutes per request. Using the same methodology, we estimate that 17,000 managed care enrollees will request an immediate review, bringing the total estimated time to 1,417 hours.

B. <u>JUSTIFICATION</u>

1. NEED AND LEGAL BASIS

The authority for the right to an expedited determination is set forth at Section 1869(c)(3)(C)(iii)(III) of the Act.

§405.1206, §422.622- When a QIO notifies a hospital or MA organization that a beneficiary/enrollee has requested an expedited determination, the hospital or MA organization must deliver a detailed notice to the beneficiary/enrollee by noon of the day after the QIO's notification.

2. INFORMATION USERS

According to the 2004 Medicare CMS Statistics booklet published by the U.S. Department of Health and Human Services, in 2003 there were 6,057 hospitals participating in Medicare that potentially would need to issue the notice. There were approximately 13 million discharges. Based on our experience with the Expedited Review process for MA and original Medicare in the non-hospital settings, we project that providers would be responsible for delivering detailed notices to approximately one percent of the 13 million Medicare beneficiaries or enrollees who request a QIO review, or 130,000 beneficiaries and enrollees per year.

3. <u>IMPROVED INFORMATION TECHNOLOGY</u>

Hospitals and MA organizations must deliver a hard copy of the detailed notice whenever beneficiaries or enrollees request a review of the discharge decision by a QIO. There is no provision for alternative uses of information technology for the detailed notice, although hospitals may store a copy of the notice electronically.

4. DUPLICATION OF SIMILAR INFORMATION

Currently, hospitals or plans issue a HINN or NODMAR when the patient disagrees with the discharge decision. Under the new process, the detailed notice will be given to patients who initiate a QIO review, instead of the HINN and NODMAR. In the vast majority of cases, a beneficiary will agree to the discharge decision and will not initiate a review. In almost all other cases, beneficiaries who disagrees with the discharge decision will initiate a QIO review (and receive a detailed notice), so that their stay can continue without liability until the QIO confirms the discharge decision or determines that the stay should continue. Only in the extremely rare instance where patients decide to remain in the hospital past the planned discharge date and do not choose to initiate a review would they be notified of liability via a traditional liability notice similar to the existing HINN or NODMAR. We are planning to revise the HINN in the near future.

Providing the same notices to all beneficiaries and enrollees who are being discharged from an inpatient hospital stay ensures that all receive consistent information about the right to request an expedited review by a QIO.

5. SMALL BUSINESS

This information collection will affect small businesses, however, the new requirements have been designed to impose as little burden as possible on these providers. The detailed notice would be delivered to beneficiaries only when they request an immediate QIO review of

the discharge decision. Our experience with expedited determinations in the non-hospital setting is that delivery of this detailed notice represents a very small (approximately 1 percent) fraction of the total number of notices delivered. To simplify the notice structure, hospitals will use a single notice for both Original Medicare beneficiaries and Medicare managed care enrollees. The rule will not have a significant impact on small rural hospitals.

6. <u>LESS FREQUENT COLLECTION</u>

Instead of providing a HINN to original Medicare beneficiaries and a NODMAR to Medicare Advantage enrollees, we would require that providers deliver the same detailed notice to all beneficiaries and enrollees who have requested immediate QIO review of a discharge decision.

7. SPECIAL CIRCUMSTANCES

The regulations at §405.1206(b) and §422.622(b) require that the detailed notice be delivered to either beneficiaries or their representatives when they request a QIO review. However, we will specify in guidance that if the request is made by a beneficiary or representative, providers will be able to provide a detailed notice prior to a request for review being filed with the QIO if they need more information to make a decision about whether to request a QIO review.

8. FEDERAL REGISTER NOTICE/OUTSIDE CONSULTATION

A 60-day Federal Register notice was published on April 5, 2006.

Information about the notice and corresponding instructions will be published in the Federal Register. The detailed notice was published in the Federal Register at the same time as the Generic Notice of Non-coverage on April 5, 2006 for a 60 day comment period. The generic notice is being replaced by a revised version of the Important Message from Medicare and is being submitted separately as a revision of a current collection (0938-0692). We considered feedback gained on the notices through that process in developing the revised detailed notice. We also took into account beneficiary comments made when the detailed notices used in the non-hospital settings for both MA and original Medicare were consumer tested.

9. PAYMENT/GIFT TO RESPONDENT

We do not plan to provide any payment or gifts to respondents.

10. CONFIDENTIALITY

We are not collecting information. The provider and QIO will maintain records of notices and decisions, but those records do not become part of a federal system of records. Therefore, this item is not applicable.

11. SENSITIVE QUESTIONS

We do not require beneficiaries to answer any sensitive questions. Therefore, this item is not applicable.

12. BURDEN ESTIMATE

Section 405.1206 Expedited determination procedures for inpatient hospital care.

Section 405.1206(b) requires any beneficiary wishing to exercise the right to an expedited determination to submit a request, in writing or by telephone, to the QIO that has an agreement with the hospital. We project that 1 percent of the 11.3 million fee-for-service beneficiaries who are discharged from inpatient hospital settings, (that is, 113,000 beneficiaries) will request an expedited determination. This estimate is based on our experience with the non-hospital expedited determination process in both original Medicare and MA, where approximately 1 percent of patients request an expedited review. However, we believe that this estimate may be high, given previous use of a standard discharge notice, the Notice of Discharge and Medicare Appeal Rights (NODMAR), in managed care settings showed an appeal rate of less than .5 percent.

Section 405.1206(e) requires hospitals to deliver a detailed notice of discharge to the beneficiary and to make available to the QIO (and to the beneficiary upon request) a copy of that notice and any necessary supporting documentation. Hospitals are presently responsible for providing the Hospital Issued Notice of Non-Coverage (HINN) when a beneficiary disagrees with a discharge. Therefore, we believe that the detailed notice will not constitute a new burden, but will essentially replace the time associated with filling out and delivering the HINN. We believe that, in addition to the time it currently takes to complete the HINN, an extra 60 minutes is sufficient for filling out and delivering the detailed notice.

Therefore, for these 113,000 cases, we estimate that it would take providers an average of 60 extra minutes to prepare the detailed termination notice and to prepare a case file for the QIO. Based on 113,000 cases, the total annual burden associated with this proposed requirement is approximately 113,000 hours.

Section 422.622 Requesting immediate QIO review of decision to discharge from inpatient hospital care.

As specified in §422.622 (e), Medicare health plans would be required under this rule to deliver a detailed notice to the enrollee and to make a copy of that notice and any necessary supporting documentation available to the QIO (and to the enrollee upon request). Plans are presently responsible for providing the Notice of Medicare Discharge and Appeal Rights (NODMAR) when an enrollee disagrees with a discharge or is being moved to a lower level of care. Therefore, we believe that the detailed notice will not constitute a new burden, but will essentially replace the time associated with filling out and delivering the NODMAR. We believe that, in addition to the time it currently takes to complete the NODMAR, an extra 60 minutes is sufficient, taking into account infrequent and first-time filers, for filling out and delivering the detailed notice.

Therefore, we estimate that it would take plans an extra 60 minutes to prepare the detailed notice and to prepare a case file for the QIO. Based on 17,000 cases, the total annual burden associated with this requirement is approximately 17,000 hours.

13. CAPITAL COSTS

There are no capital costs associated with this collection.

14. COSTS TO FEDERAL GOVERNMENT

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

15. PROGRAM OR BURDEN CHANGES

The detailed notice would be a new collection given to beneficiaries who request a QIO review of a discharge decision, and would replace issuance of the HINN or NODMAR when given to beneficiaries who disagree with a discharge decision. The increased burden was derived from comments received on CMS-4105-P and accounts for the fact that this notice will replace the existing burden associated with the HINN and NODMAR when given to a beneficiary who disagrees with a discharge decision. We believe that, in addition to the time it currently takes to complete the HINN or NODMAR, an extra 60 minutes is sufficient, taking into account infrequent and first-time filers, for filling out and delivering the detailed notice. We note that the HINN is actually a family of notices, and this detailed notice will only replace the HINN when used to inform patients of their discharge appeal rights when they disagree with a discharge decision.

16. PUBLICATION AND TABULATION DATES

These notices will be published on the Internet; however, no aggregate or individual data will be tabulated from them.

17. EXPIRATION DATE

We are not requesting exemption.

18. <u>CERTIFICATION STATEMENT</u>

There are no exceptions to the certification statement.

C. <u>COLLECTION OF INFORMATION EMPLOYING STATISTICAL</u> <u>METHODS</u>

There are no statistical methods associated with this collection.