Supporting Statement
For the CMS-R-50
Medical Records Review Under PPS
And Supporting Regulations
In 42 CFR 412.40-412.52

A. Background

The Social Security Amendments of 1983 authorized Peer Review Organizations, now known as Quality Improvement Organizations (QIOs) to conduct medical review of care provided to beneficiaries and reimbursed under the prospective payment system (PPS). The medical review activities are dependent on information gathering efforts on the part of acute general care PPS hospitals. It is the data gathering efforts of the hospitals for which the Centers for Medicare and Medicaid Services (CMS) is requesting Executive Office of Management and Budget approval under the Paperwork Reduction Act.

CMS has published information about the QIO program in Section 195 of the Medicare Hospital Manual. In Section 195.3, Statutory Obligations of Practitioners and Other Persons (e.g., hospitals and other facilities), we have identified the general information gathering requirement for hospitals related to QIO review. This Section specifies that hospitals must provide the QIO with necessary documentation (medical records). A copy of Section 195.3 is attached. In order that the hospitals be conversant with all QIO review procedures, CMS incorporates hospital-specific instructions into the Hospital Manual. Additionally, memoranda of understanding define the information that hospitals must provide. Finally, under the Health Care Quality Improvement Program (HCQIP), QIOs work cooperatively with the medical community in identifying projects (and the information needed to complete the projects) which will benefit Medicare beneficiaries.

QIOs are physician-sponsored organizations under contract with CMS to review services received by Medicare beneficiaries in hospitals, skilled nursing facilities (SNFs), home health agencies (HHAs) and Comprehensive Outpatient Rehabilitation Facilities (CORFs). The QIOs ensure that admissions are medically necessary, provided in the appropriate setting and meet acceptable standards of quality. For each review, the hospital is required to make the appropriate records available to the QIO. The hospital is not required to extract information from these records for these reviews or to engage in special efforts to aggregate any information for these purposes. If reviews are not conducted on site, the hospital is required to provide copies of all appropriate records to the QIO within 30 days and is reimbursed for the costs.

CMS has implemented HCQIP, aimed at promoting quality care for beneficiaries that is both effective and efficient. Quality care under HCQIP includes access to appropriate care, which has desired outcomes including consumer satisfaction.

The HCQIP is carried out locally by the QIO in each State. Each QIO will focus on the development and implementation of cooperative projects (i.e., collaborative efforts with health care providers and/or beneficiaries which result in measurable improvement in process and outcomes related to specific clinical issues) as a method for the QIO to improve the quality of care in the State, and to help beneficiaries make informed health care choices.

B. Justification

1. Need and Legal Basis

The Medicare PPS mandated by the Social Security Amendments of 1983 (Public Law 98-21), requires QIO review of medical services provided to Medicare beneficiaries. More recently, the Benefits Improvement and Protection Act of 2000 (BIPA), requires additional QIO reviews, as do Medicare Advantage regulations developed in response to the court decision in Grajalva v. Shalala. Review of services under the QIO program can be accomplished by individual case review and the Clinical Data Abstraction Centers (CDACs). Accordingly, QIOs must review, at the direction of CMS: 1) all anti-dumping referrals; 2) beneficiary complaints involving quality issues; 3) potential gross and flagrant violations of unnecessary admission concerns identified during project data collection; 4) requests from hospitals for higher-weighted DRG adjustments; 5) hospital and managed care plan issued notices of noncoverage; 6) specific codes for assistants at cataract surgery; and 7) cases referred by CMS, the Office of the Inspector General, the Department of Justice, the managed care appeals contractor, intermediaries, carriers, or the CDACs. The review determinations are based on the information provided in the hospital medical records.

The CDACs are QIO subcontractors that abstract DRG clinical data and conduct coding validations on all cases that CMS refers to the QIOs from a DRG validation random sample. The CDACs will request medical records on behalf of the QIOs and will maintain, track and report to the QIOs all photocopying and mailing costs incurred by hospitals. The CDAC may pay the hospital pass-through costs if designated by the QIO. Thus, QIOs rely on the participating hospitals to make the necessary records available for use as described in the previous section.

2. Information Uses and Users

The information that the hospitals provide (i.e., standard medical records) are reviewed by the QIOs to carry out the functions specified above in Section B.1. The use of these records meets the medical review requirements of the statute and supports Federal policy regarding reimbursement under PPS. The QIOs must assure the confidentiality of the medical information contained in the medical records they receive.

3. Improved Information Technology

This item is not applicable to these information requirements because of the nature of the use of the information. QIOs must review the original records or complete copies of the original records and not transcriptions or summarizations of the records. QIOs do accept all records in the format routinely used by the hospital. Medical records remain in paper form and are not automated at this time. Although the CDACs are used to compile the data abstracted from the paper records, the source of the data continues to be the paper medical record currently used by all hospitals.

4. Duplication and Similar Information

QIO review is the only routine review of hospital medical records conducted under Medicare. The reviewers obtain a significant amount of data associated with medical review from existing Federal operational sources to minimize the amount of information obtained from hospitals (e.g.,

billing information). The information provided to reviewers by the hospitals is unavailable form any other source.

5. Small Business

This requirement does not apply to the hospitals involved in the QIO Program.

6. Less Frequent Collection

Medical reviews are an ongoing activity in order to accurately reflect the utilization and quality characteristics of hospitals under PPS. Eliminating the sample and focusing review in the areas depicted in B.1 above limits the burden of providing large volumes of records.

7. Special Circumstances

These requirements comply with all general information collection guidelines in 5 CFR 1320.6. There are no special circumstances related to this information collection.

8. Federal Register Notice and Outside Consultation

The 60-day Federal Register notice was published on February 1, 2008.

9. Payment/Gift to Respondents

There are no payments or gifts associated with this collection.

10. Confidentiality

QIOs must maintain the confidentiality of the records obtained for this purpose as specified in regulations on this subject (Section 1160 of the Social Security Act, copy attached).

11. Sensitive Questions

There are no questions of a sensitive nature asked. Records that may or may not be considered are subject to the provisions of confidentiality discussed above.

12. Estimate of Burden (Total Hours and Wages)

Using data that was current as of December 31, 2007, we estimate the number of reviews required under the basic QIO contract and COBRA, OBRA and BIPA legislation to be as follows:

		HOURS	
		Divide by	Multiply
FY	QIO Reviews	100 Records	by 3 hours
2007	116,500	1,160	3,480
2008	116,500	1,160	3,480
2009	116,500	1,160	3,480
2010	116,500	1,160	3,480

(Includes quality of care, early discharge, HPMP, BIPA and MA [Grajalva] reviews.)

		Divide by	Multiply
FY	CDAC Reviews	100 Records	by 3 hours
2007	160,000	1,600	4,800
2008	160,000	1,600	4,800
2009	160,000	1,600	4,800
2010	160,000	1,600	4,800

FY	TOTAL HOURS	TOTAL RECORDS
2007	8,280	276,500
2008	8,280	276,500
2009	8,280	276,500
2010	8,280	276,500

13. Capital Costs

There are no capital costs.

14. Cost to Federal Government

As of April 1987, the Federal Government is required to pay PPS hospitals and other providers for the cost of photocopying and mailing medical records requested by QIOs and CDACs for review. We estimate this function will require the hospitals and other providers to spend three (3) hours to pull each 100 records. This takes into consideration manual retrieval and time loss for misplaced records. CMS reimburses the public for these costs.

WAGES AND POSTAGE

We estimate that hospitals and other providers will be required to copy 100 percent of the records reviewed. Of the 116,000 medical records received by the QIOs in 2007, 29,618 (25%) had an average of 213 pages. This is a sufficient sample to project this average for all QIO reviews. Each record copied for the CDACs contained an average of 192 pages in 2007. We expect the averages to remain close to these numbers. The law specifies a reimbursement rate of

12 cents per page for copying. This amount includes the cost of the photocopy machine, the salaries and fringe benefits of the individual(s) making the copies, supplies and overhead. In addition, we estimate the cost of postage to be $4.00 per record, when shipped by priority mail. The CDAD-bound records, while larger, will be shipped in bulk, reducing the cost per record. The estimated cost of photocopying and mailing medical records is:

QIO Reviews

	COPYING	**POSTAGE**	**TOTAL**
FY 2007	$2,977,000	$466,000	$3,443,000
FY 2008	$2,977,000	$466,000	$3,443,000
FY 2009	$2,977,000	$466,000	$3,443,000
FY 2010	$2,977,000	$466,000	$3,443,000

CDAC Reviews

	COPYING	**POSTAGE**	**TOTAL**
FY2007	$3,676,000	$557,000	$4,233,000
FY2008	$3,676,000	$557,000	$4,233,000
FY2009	$3,676,000	$557,000	$4,233,000
FY2010	$3,676,000	$557,000	$4,233,000

TOTAL COST FOR QIO AND CDAC REVIEWS

FY2007	$7,676,000
FY2008	$7,676,000
FY2009	$7,676,000
FY2010	$7,676,000

15. Program or Burden Changes

The number of medical records has decreased slightly. Expiration of some types of payment review, such as HPMP, and changes in the focus of the QIO Program have resulted in a decrease in the number of QIO reviews from 189,000 to 116,000. The CDAC reviews have been reduced to 160,000, from an average of 208,000 records reviewed annually. However, there is a small increase in cost due to more accurate page counts and increased postage. This results in a net increase of $466,000 (9.4 %) per year over the prior request.

16. Publication and Tabulation Dates

Not applicable. There are no publication and tabulation dates.

17. OMB Expiration Dates

There are no expiration dates because CMS anticipates that this program review will continue for the foreseeable future.

18. Certification Statement

Item 19 (i) of the OMB 83-I specifies that the information collection use effective and efficient statistical survey methodology. These records are not gathered for statistical purposes, but for oversight purposes.

Item 19 (j) specifies that the collection make appropriate use of information technology. Medical review cannot be conducted in any automated or computerized method. A medical reviewer must do review of each medical record and hard copies are required.

C. Collection

These records are not gathered for statistical purposes, but for oversight purposes.