Supporting Statement – Part A

Supporting Statement For Paperwork Reduction Act Submissions

~~General Instructions~~
~~A Supporting Statement, including the text of the notice to the public required by 5 CFR 1320.5(a)(I)(iv) and its actual or estimated date of publication in the Federal Register, must accompany each request for approval of a collection of information. The Supporting Statement must be prepared in the format described below, and must contain the information specified in Section A below. If an item is not applicable, provide a brief explanation. When Item 17 of the OMB Form 83-I is checked "Yes," Section C of the Supporting Statement must be completed. OMB reserves the right to require the submission of additional information with respect to any request for approval.~~

~~Specific Instructions~~

A. Background

The Peer Review Improvement Act of 1982 amended Title XI of the Social Security Act to create the Utilization and Quality Control Peer Review Organization (PRO) program which replaces the Professional Standards Review Organization (PSRO) program and streamlines peer review activities. This rule implemented those provisions of the Peer Review Improvement Act of 1982 (Title I, Part III, Subtitle C of the Tax Equity and Fiscal Responsibility Act of 1982, P.L. 97-248, as amended by the Social Security Amendments of 1983, (P.L. 98-21), the Deficit Reduction Act of 1984 (P.L. 98-369), the Consolidated Omnibus Budget Reconciliation Act of 1985 (P.L. 99-272), the Omnibus Budget Reconciliation Act (OBRA) of 1986 (P.L. 99-509), the OBRA of 1987 (P.L. 100-203) and the OBRA of 1989 (P.L. 101-239) that establish the review functions to be performed by a PRO.

NOTE: PROs have been renamed QIOs

Contracts have been signed with QIOs in all 53 areas designated by regulations published in 42 C.F.R., Chapter IV. QIOs will assure that covered care provided to Medicare patients is reasonable, medically necessary, appropriate, and of a quality that meets professionally recognized standards of care, and that inpatient services could not be more appropriately provided on an outpatient basis or in a different type facility.

B. Justification

1 . Need and Legal Basis

The information collection requirements contained in this rule that are subject to OMB review are underlined below. A short justification is included with each requirement.

Section 412.44 A hospital must have an agreement with a QIO to have the QIO review care provided to Medicare beneficiaries. Medical Review Requirements: Admissions and Quality Review

QIOs are physician sponsored organizations under contract with the Centers for Medicare and Medicaid Services (CMS), formerly the Health Care Financing Administration (HCFA) to review services received by Medicare beneficiaries in hospitals. QIOs conduct review to ensure that admissions are medically necessary, provided in the appropriate setting, and that they meet acceptable standards of quality. For each review, the hospital is required to make the appropriate records available to the QIO. If reviews are not conducted onsite, the hospital is required to provide copies of all appropriate records to the QIO within 30 days. This section requires that hospitals have memorandum of agreements (MOAs) with QIOs which outline the review process. We use this regulation and the mandates of the Social Security Act for QIO review to also require QIOs to maintain similar agreements with ambulatory surgical centers whose cases the QIO will review.

412.46 Medical Review Requirements: Physician Acknowledgement:

Since payment under the prospective payment system is based in part on each patient's principal and secondary diagnoses and major procedures performed, as evidenced by the physician's entries in the patient's medical record, physicians must complete an acknowledgement statement before he is able to submit a claim for payment of services.

The acknowledgement statement must be completed by the physician when he is either granted admitting privileges or before or at the time the physician admits his/her first patient to the facility.

Section 431.630 - Coordination of Medicaid with QIOs.

The State may contract with the QIO and must provide that the contract with the QIO -- (1) Meets the requirements of §434.6(a) of this part; (2) Includes a monitoring and evaluation plan by which the State ensures satisfactory performance by the QIO; (3) Identifies the services and providers subject to QIO review; (4) Ensures that the review activities performed by the QIO are not inconsistent with QIO review activities of Medicare services and includes a description of whether and to what extent QIO determinations will be considered conclusive for Medicaid payment purposes.

Section 476.71 - QIO review requirements.

Review of services under the QIO program can be accomplished by individual case review, and CDACS. Accordingly, QIOs must review 100% of all: 1) 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 (HINNS); 6) specific codes for assistants at cataract surgery; 7) cases referred by CMS, OIG, the managed care appeals contractor, intermediaries, carriers, or the CDACs. The scope of the review will depend on the reason for the referral.

In its review, and when appropriate, the QIO must determine: whether the quality of the services meets professionally recognized standards of health care; whether those services furnished or proposed to be furnished on an inpatient basis could, consistent with the provisions of appropriate medical care, be effectively furnished more economically on an outpatient basis or in an inpatient health care facility of a different type; validate the diagnostic and procedural information supplied by the hospital on higher weighted DRGs, (CDACS will perform the routine validation process); the completeness, adequacy and quality of hospital care provided. In the event of a HINN, a QIO may grant a period of not more than two days (grace days) for the purpose of arranging post discharge care when the provider did not know or could not reasonably be expected to have known that payment for the services(s) would not be made under the Medicare program as specified in §411.400(b)(2). The review determinations are based on information provided in the hospital medical records. TEFRA requires that CMS enter into contracts with QIOs to promote the effective, efficient and economical delivery of health care services, and to promote the quality of these services. This requirement cites what determinations a QIO must make in accordance with the terms of its contract. The contents of the contract are statutorily based and this requirement ensures that each QIO contract contains at least these minimal requirements.

Section 476.73(b) - Notification of QIO designation and implementation of review. Notification to health care facilities and the public.

As specified in its contract with CMS, the QIO must -- Provide to each health care facility scheduled to come under review, a timely written notice that specifies the date and manner in which the QIO proposes to implement review, and the information to be furnished by the facility to each Medicare beneficiary upon admission as specified in §476.78(b)(3) of this part.

Every QIO contract will: 1) specify that the QIO will notify each facility in writing of its schedule to come under review. Health care facilities need this information in order to prepare for QIO review; 2) publish, in at least one local newspaper of general circulation in the QIO area, a notice that states the date the QIO will assume review responsibilities and lists each area health care facility to be under review; 3) indicate that its plan for the review of health care services as approved in its contract with CMS is available for public inspection in the QIO's business office and give the address, telephone number and usual hours of business.

Section 476.74 General requirements for assumption of review.

The QIO contract will specify that the QIO must publish a notice announcing its assumption of review. The public, public interest groups, health planning agencies and individual physicians all

will want to know when the QIO will assume review responsibilities.

A QIO must notify the appropriate Medicare intermediary or carrier of its assumption of review in specific health care facilities no later than five working days after the day that review is assumed in the facility. This is intended to ensure a smooth and efficient start to QIO review and to assure that the existing operation of the intermediary is not interfered with. A QIO must maintain and make available for public inspection at its principal business office: copy of each agreement with Medicare intermediaries and carriers; a copy of its currently approved review plan that includes the QIO's method for implementing review; and copies of all subcontracts for the conduct of review. This section ensures that all parties who may be involved in the review process are fully informed about the QIO's review responsibilities and review procedures. Parties who may be interested in this information include intermediaries, carriers, hospitals, physicians, beneficiaries, State Medicaid agencies, and consumer groups.

Section 476.78 Responsibilities of health care facilities.

Beginning November 15, 1984, every hospital seeking payment for services provided to Medicare beneficiaries must maintain a written agreement with a QIO operating in the area in which the hospital is located. These agreements must provide for the QIO review specified in §476.71.

Health care facilities that submit Medicare claims must cooperate in the assumption and conduct of QIO review. These facilities must provide patient care data and other pertinent data to the QIO at the time the QIO is collecting review information that is required for the QIO to make its determinations. When review is performed away from the facility, the facility must photocopy and deliver to the QIO all required information within 30 days of a request. When the QIO does post-admission, pre-procedure review, the facility must provide the necessary information before the procedure is performed, unless it must be performed on an emergency basis.

This section requires that hospitals seeking Medicare reimbursement must have a written agreement with the QIO. Also, in order to carry out its review functions, the QIO must have access to the patient's medical record, test results, and other information. Section 1156 of the Act states that it is the obligation of health care facilities to assure that the care they furnish is supported by evidence of medical necessity and quality in the form and at the time required by the QIO.

Facilities are to inform Medicare beneficiaries at the time of admission, in writing, that the care for which Medicare payment is sought will be subject to QIO review and indicate the potential outcomes of that review. Furnishing this information to the patient does not constitute notice, under §405.332(a) of this chapter, that can support a finding that the beneficiary knew the services were not covered. Facilities are required to inform beneficiaries that their care may be reviewed by the QIO. This information assures that beneficiaries are aware that all the services provided may not be covered by Medicare. Hospitals are required to be responsible for assuring that the QIO reviews and approves all those cases that are subject to readmission review, before

the patient is admitted to the hospital.

2. Information Users

Section 412.44
The information in this section is needed by hospitals and to ensure that they continue receiving payment under P.P.S. This section revises the date by which a hospital must have an agreement with a QIO. The date was revised by PL. 98-369.

Section 412.46(a)(b)

The information in this section is used by CMS to hold the physician responsible for the accuracy of information contained in the medical record by attesting to its accuracy. The hospital is responsible for assuring this task is accomplished.

Section 412.46(c)

The information in this section is used by CMS to hold the physician responsible for the accuracy of information contained in the medical record by acknowledging that he/she is aware of the penalties for attesting to false information. The hospital is responsible for assuring that this task is accomplished.

Section 431.630(b)

The information in this section is used by CMS in order to assure that the State's contract with the QIO fulfills the requirements for an effective quality/utilization review program.

Section 476.71(a)(b)(c)

The information in this section is used by QIOs, intermediaries, carriers, hospitals, physicians and the public to determine the review responsibilities of QIOs.

Section 476.73(b)(1)

Health care facilities will use the information provided in the written notification to prepare for QIO review. CMS Project Officers may wish to see copies of the written notification as part of their routine monitoring.

Section 476.73(b)(2)

The information provided in this section will inform the public, intermediaries, carriers, physicians, hospitals, and consumer groups of those facilities in which the QIO will assume review and will announce that the QIO's review plans are available for public inspection. All of these parties will need this information to be prepared to cooperate with, and prepare for, the

QIO's assumption of review.

Section 476.74(b)

The intermediaries/carriers will use the data to revise their billing operations, prepare for the assumption of QIO review, or to revise existing agreements.

Section 476.74

The information provided in this section is used by any party (e.g., physicians, hospitals, and the public) interested in becoming knowledgeable on all aspects of QIO review, and in preparing themselves to cooperate with the QIO in the peer review process.

Section 476.78(a)

The QIO must have a MOA with every hospital receiving Medicare payment in order to assure efficient review of medical records.

Section 476.78(b)(2)

The information in this section will be used by QIOs in making their review determinations for payment purposes under Medicare.

Section 476.78(b)(3)

The hospital may use this data to assure that all Medicare beneficiaries are identified. The beneficiaries can use the notice to be prepared for the possibility that not all of the care they receive may be covered by Medicare.

Section 476.78(b)(5)

The information in this section is used by the intermediary to determine whether payment should be made for a procedure.

3. Use of Information Technology

This rule does not prescribe how QIOs should provide the information collection activities described in this regulation. The QIOs are free to take advantage of any technological advances they find appropriate to their needs.

4. Duplication of Efforts

These requirements do not duplicate any existing requirements.

5. Small Businesses

These requirements can be easily met by small businesses.

6. Less Frequent Collection

This information is collected as needed. If it were to be collected less frequently, QIO's would not be able to obtain the necessary data.

7. Special Circumstances

These information requirements are imposed on QIOs under contract with CMS. They will allow for the smooth and efficient implementation of QIO review activities. These requirements comply with all the general collection guidelines described in 5 C.F.R. 1320.6. There are no special circumstances related to this information collection.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice was published on January 28, 2005, attached. Consultations were not made outside the Agency; however, the public had the opportunity to comment on the proposed rule. All comments were initially addressed in the preamble to the regulation. . No comments were received for resubmission of this approval.

9. Payments/Gifts to Respondents

There are no payments or gifts associated with this collection.

10. Confidentiality

There is no information of a confidential nature associated with this request.

11. Sensitive Questions

There are no questions asked of the sensitive nature.

12. Burden Estimates (Hours & Wages)

Section 412.44 - Each QIO must establish an MOA with each hospital in its review area. The MOA is renegotiated every 3 years when the QIO contract is renewed.

6,036 acute care and specialty hospitals (times) 10 hours per MOA (5 hours each QIO/facility) (divided by 3 to annualize) = 20,120 hours per year

Section 412.46 - The QIO monitors PPS hospitals to ensure that hospitals are in compliance with the physician acknowledgement statement requirements set forth in 42 CFR 412.46. ~~Section 412.46(d)(e) - The QIO must amend higher weighted DRGs and notify the physician and hospital of all DRG errors (except technical coding errors). The burden on the QIO is in the preparation of the notice to notify the provider/practitioner of the DRG error. Bas~~Based on program experience,

we project that the QIO will request a listing of new providers granted admitting privileges from each of approximately 3500 PPS hospitals annually and will request a total of 12726 copies of physician acknowledgement statements from these hospitals. ~~find 12,000 errors per year under the 7th Scope of Work. This burden is based on common practice that the physician and/or practitioner will provide one response.~~ We project that it will take 1 hour per list and 5 minutes per copy, ~~notice~~ based on the information being readily available for generating the list and copying the statements.~~inclusion in the letter.~~

QIO Burden: 3500 ~~27,000 errors x 2~~ lists + 12726 copies of acknowledgement statements~~letters (1 physician, 1 facility)~~ x 1 hour = ~~54,000~~ 16,226 hours
Provider~~/practitioner~~ burden: 3500 ~~27,000 x 1~~lists ~~letter~~ x 1 hour = ~~27~~3,~~0~~500 hours
Provider burden: 12726 acknowledgement statements X 5 minutes= 1060.5 hours
~~54,000 + 27,000~~= 20,786.5 ~~81,000~~ Total burden hours

Section 431.630(b) - These requirements were implemented by use of the State plan preprint, and burden is reported under another OMB number (0938-0359).

Section 476.71(c) - states, "The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare fiscal intermediary (FI) or carrier if it determines that the information submitted by the hospital was incorrect." Further, the QIO must amend higher weighted DRGs and notify the physician and hospital of all DRG errors (except technical coding errors). The burden on the QIO is in the preparation of the notice to notify the provider/practitioner of the DRG error. Based on program experience, we project that the QIO will find 12,000 errors per year under the 7th Scope of Work. This burden is based on common practice that the physician and/or practitioner will provide one response. We project that it will take 1 hour per notice based on the information being readily for inclusion in the letter.

An additional ~~The~~ burden for the QIO is in the preparation of the notification to the fiscal intermediary. It is estimated that the notice takes 30 minutes to prepare. The notification may be done electronically or by regular mail. Upon QIO notification the FI must execute a payment adjustment based on QIO findings, we project the burden to be 1.5 hours per error notification.

QIO Burden: 27,000 errors x 2 letters (1 physician, 1 facility) x 1 hour = 54,000 hours
Provider/practitioner burden: 27,000 x 1 letter x 1 hour = 27,000

QIO Burden: 27,000 x .5 = 13,500

FI burden: 27,000 x 1.5 hours = 40,500 hours
Burden = 13~~5~~4,000 hours

Section 476.73(b)(1) - Each new QIO is required to develop notices to provide facilities with general information on their proposed review activity. It is estimated that a QIO could develop each notice in 2 hours. Notices will be prepared for facilities coming under review. QIOs will

develop these notices at the start of the contract period. This is a general notice of review assumption to 6,036 existing hospitals.

53 existing QIOS (times) 2 hours	=	106 hours
7 new QIOS (times) 2 hours (times) 6,036 facilities (times)	=	14 hours
5 minutes mail preparation	=	503 hours
	TOTAL	623 hours per year

Section 476.73(b)(2) - Each new QIO is required to prepare a notice listing the facilities that will be reviewed by the QIO. Each QIO will spend about 4 hours preparing this notice. This time will be spent compiling the information, having the notice typed, edited, and sent to the newspaper. Only new QIOs (estimated at 7 annually) entering the program will need to respond and, therefore, this is a one-time burden as follows:

7 QIOS (times) 1 notice (times) 4 hours = 28 hours.

Section 476.74(b) - Each new QIO will notify its intermediary and carrier during the period of its three year contract. Additionally, any new QIOs (we estimate a total of 3, are required to notify the appropriate Medicare agent (both intermediary and carrier) of its assumption of review in specific health care facilities. A new QIO will spend about 1 hour preparing each notice, while a QIO whose contract has been renewed should complete the update within ½ hour. This includes time spent compiling the list of facilities and dates, composing and editing the notices, and finally typing and distribution. Burden for this section is computed as follows:

53 existing QIOs (times) 1 notice (times) ½ hour (divided by 3 to annualize)	=	9 hours
7 new QIOS (times) 1 notice (times 1 hour)	=	7 hours
	TOTAL	16 hours

Section 476.74(c) - QIOS are required to maintain and make available for public inspection specific information. We estimate each QIO will spend no more than 1 hour yearly to comply with this requirement. There are 53 QIOS that will spend 1 hour on record maintenance, resulting in an annual burden as follows:

53 QIOS (times) 1 hour = 53 hours

Section 476.78(a) - Each QIO must have an agreement with every hospital in order to assure efficient review of medical records. There is no additional burden beyond that associated with 42 C.F.R. 412.44.

Section 476.78(b)(2) - We are seeking an extension of this requirement only; the associated burden is currently approved under OMB control number 0938-0359.

Section 476.78(b)(3) - This requirement is to inform Medicare beneficiaries that the care for which Medicare payment is sought will be subject to QIO review and to indicate the potential outcomes of that review. The requirement will be met by giving each Medicare beneficiary at the time of admission a preprinted form letter (known as the Important Message for Medicare) which explains the above requirement. The only burden on the facility is to reprint the form letter. This should take approximately 30 minutes per facility. Since the letter is presented to the beneficiary along with materials, there is no additional burden associated with distribution of this letter.

The burden is computed as follows:

6,036 facilities (times) 30 minutes
(divided by 3 to annualize) = 1,006 hours

Section 476.78(b)(5) - It requires the health care facility to assure that readmission review has been approved by the QIO. The requirement has been eliminated from QIO contracts. There is no workload burden.

Total burden for this rule:

Section 412.44	-	20,120
Section 412.46 (a)(b)	-	0
Section 412.46(c)	-	0
~~Section 412.46(d)(e)~~	~~-~~	~~81,000~~
Section 431.630 (b)	-	0
Section 476.71 (a)(b)(c)	-	~~54~~134,000
Section 476.73 (b)(1)	-	623
Section 476.73(b)(2)	-	28
Section 476.74(b)	-	16
Section 476.74(c)	-	53
Section 476.78(a)(b)(2)	-	0
Section 476.78(b)(3)	-	1,006
Section 476.78(b)(5)	-	0

TOTAL 156,846 hours

13. Capital Costs

This rule requires health care facilities to spend 1,006 hours of time complying with these requirements. An average cost to the public is $15.00 per hour. The public will spend $15,090 complying with this rule.

14. Cost to Federal Government

All Federal costs associated with this request will be incurred by CMS through their contract with QIOs. We estimate that the average salary of the QIO employee responding to these requirements to be equal to that of a GS-9 (step 4) government employee earning $7.00 per hour fringe benefits. Therefore, for this rule there are 156,846 hours of burden to the QIO at a rate of $22.13 per hour equaling $3,471,002.

15. Changes to Burden

The burden has been revised to account for a miscalculation of the burden that was included in the last submission of this information collection request.~~re are no program changes or adjustments to the burden.~~

16. Publication/Tabulation Dates

There are no tabulation or publication requirements or complex analytical techniques associated with this collection.

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date.

18. Certification Statement

There are no exceptions to the certification statement.