

Supporting Statement – Part A

Final Peer Review Organizations Sanction Regulations

A. BACKGROUND

Section 1156(a) of the Social Security Act, (the Act) provides that health care practitioners and other persons (e.g. hospitals or other health care facilities, organizations or agencies) that furnish health care services or items for which payment may be made under the Act, have obligations to ensure that the services or items are (1) Provided economically and only when, and to the extent, medically necessary, (42 CFR 1004.10(a)); (2) the care provided is of a quality that meets professionally recognized standards of health care (42 CFR 1004(b)); and (3) the care is supported by appropriate evidence of medical necessity and quality, and the reviewing QIO may require documentation from the entity providing the care (42 CFR 1004.10(c)).

The Office of the Inspector General (OIG) in 2001 submitted an OIG Audited Opinion of CMS' 2001 Financial Statement. In this audit it was estimated that approximately \$12.1 billion in improper payments were made under the Medicare Program.

It is the responsibility of the QIO to identify violations. The QIO may allow the practitioner or other person an opportunity to submit relevant information before determining that a violation has occurred. These requirements are used by the QIOs to collect the information necessary to make their determinations.

B. JUSTIFICATION

1. Need and Legal Basis

The Peer Review Improvement Act of 1982 amended Title XI of the Act to create the Utilization and Quality Control Peer Review Organization (PRO) program. QIOs will ensure that care provided to Medicare patients is reasonable, medically necessary, appropriate, and is 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 of facility.

Section 1156 of the Act imposes certain obligations upon health care practitioners and other persons who furnish or order services or items under Medicare. This section also provides for sanction actions, if the Secretary determines that the obligations as stated by this section are not met.

These sanctions are recommended to the Secretary by the QIOs that contract with the Secretary. QIOs have the responsibility to determine whether practitioners and other persons are complying with their obligations under the statute. Based upon the QIO recommendations, the Secretary is authorized by the statute, to exclude practitioners or other persons from the Medicare program, or in lieu of exclusion, the offender may be required to pay a monetary penalty as a condition of continued eligibility to receive reimbursement under the Medicare program.

2. Information Users

Sections 42 CFR 1004.40, 1004.50, and 1004.60:

Practitioners or other persons who furnish or order health care services are sent notices by a QIO when they fail to comply with their obligation as specified under Section 1156(a) of the Act. The notices contain information pertaining to the violation and the QIO's recommendations, as well as an opportunity to submit additional information or to discuss the problem with a representative of the QIO. The affected parties use this information to take corrective actions so as to avoid being excluded from the Medicare program or having a monetary penalty placed on them. These regulatory sections define the due process afforded to parties who may have violated their statutory obligations.

Section 42 CFR 1004.70:

The OIG, based on the QIO recommendation included in its report, makes the decision of whether to exclude practitioners or other parties from the Medicare program, or in lieu of exclusion, require a monetary penalty as a condition for their continued eligibility to receive reimbursement under the program. This regulatory section specifies the content of the QIO's report to OIG, thus ensuring that the QIO will provide the necessary documentation on which the OIG can base its decision.

3. Improve Information Technology

Written notices are printed in hard-copy. They do not lend themselves to electronic exchange.

4. Duplication and Similar information

The information we are requesting is different and does not duplicate any other effort.

5. Small Business

This collection does not affect small businesses.

6. Less Frequent Collection

This information is collected on occasion. If this information was collected less frequently, CMS would not be able to determine if the services provided are economically & medically necessary, and are of a quality which meets professional standards.

7. Special Circumstances

These requirements comply with all general collection guidelines in 5 CFR 1320.6. There are no frequency requirements or specified reporting requirements associated with this collection;

therefore, there are no special circumstances.

8. Federal Register and Outside Consultants

The 60-day Federal Register notice published on July 26, 2013. There were no public comments.

9. Payments or Gifts

There are no payments or gifts associated with this requirement.

10. Confidentiality

The issue of confidentiality does apply to these regulations. Any information that identifies a physician or other person is subject to the confidentiality requirement specified in Section 1160 of the Act.

11. Sensitive Questions

There are no questions asked of a sensitive nature.

12. Estimate of Burden

Based on historical data related to the Medicare program QIO sanction activity, we estimate that there will be at most 53 national cases per three year contract period for which serious violations are identified and not resolved. (This averages to 1 case per QIO per three year contract period).

For each case that is not resolved, the QIO attempts to correct the situation before it takes further action. In each instance, the QIO thoroughly reviews all data in their possession from both the medical and legal standpoint and prepares a complete written notice that is sent to the affected party. To facilitate the work of the QIOs in preparing these notices, the OIG, together with CMS, developed template notices which contain the mandatory regulatory language as well as the legal and technical requirements. The QIOs are mandated to use the template notices.

The notice must be completed by adding detailed medical information, through supporting documentation and a summary of all ongoing activity. Each notice is completed by a QIO physician and is reviewed by the legal staff to prepare it for court action, if it becomes necessary. Each notice is individually completed. The burden is computed as follows:

We have estimated secretarial costs to the QIO by comparing the QIO personnel to an equivalent GS counterpart. Salary.com was utilized to determine reasonable rates for physicians and legal staff. The physician and legal staff is estimated at \$100.00 per hour. The secretarial support is estimated at a comparative GS-5 (step 1) rate of \$16.33 per hour.

The costs have been computed as follows:

234 hours for physician and legal staff time at \$100/hr =	\$ 100.00 x 234 \$ 23,400.00
multiplied by 53 sanctions per 3 yr contract period	x 53 \$1,240,200.00 per 3 yr contract period/3 =\$413,400.00 annually

36 hours of secretarial time at \$16.33/hr	\$ 16.33 x 36 \$ 587.88
multiplied by 53 sanctions per 3 yr contract period	x 53 \$ 31,157.64 per 3 yr contract period/3 =\$10,385.88 annually

TOTAL COSTS

\$1,271,357.60 per 3 yr contract period/3
=\$423,785.86 annually

Section 1004.40(b) - This section contains the information collection requirement for QIOs to provide practitioners or other persons written notice of the identification of a violation.

Physician time:	Estimate of 40 hours per notice for an approximate total of 1 case per contract period - 40 hours
Legal Staff time:	Estimate of 8 hours per notice for an approximate total of 1 case per contract period - 8 hours
Secretarial time:	Estimate of 8 hours per notice for an approximate total of 1 case per contract period - 8 hours

Section 1004.50(g) - This section contains the information collection requirement for allowing the practitioner or other person 5 working days after the meeting to provide additional relevant information.

Physician time:	Estimate of 40 hours per notice for an approximate total of 1 case per contract period - 40 hours.
Legal Staff time:	Estimate of 10 hours per notice for an approximate total of 1 case per contract period - 10 hours.
Secretarial time:	Estimate of 10 hours per notice for an approximate total of 1 case per contract period - 10 hours.

Section 1004.60(b) - This section contains the information collection requirement for the final notice which is sent to the affected party.

- Physician time: Estimate of 60 hours per notice for an approximate total of 1 case per contract period - 60 hours.
- Legal Staff time: Estimate of 20 hours per notice for an approximate total of 1 case per contract period - 20 hours.
- Secretarial time: Estimate of 10 hours per notice for an approximate total of 1 case per contract period – 10 hours.

Section 1004.70(b)(c) - These sections contain the information collection requirements that are contained in the QIOs report to the OIG.

- Physician time: Estimate of 40 hours per notice for an approximate total of 1 case per contract period – 40 hours.
- Legal Staff time: Estimate of 8 hours per notice for an approximate total of 1 case per contract period – 8 hours.
- Secretarial time: Estimate of 8 hours per notice for an approximate total of 1 case per contract period – 8 hours.

Summary of Burden

Section 1004.40(b)	-	56 hours
Section 1004.50(g)	-	60 hours
Section 1004.60(b)	-	90 hours
Section 1004.70(b) & (c)	-	56 hours
TOTAL		262 hours
multiplied by 53 sanctions per 3 yr contract period		<u> </u> x 53
TOTAL BURDEN		13,886 hours

13. Capital Costs

There are no capital costs associated with this collection.

14. Federal Costs Estimates

All costs associated with this request will be incurred by QIOs as approved and funded by CMS

(broken out in #12, above). There are no additional costs to the Federal Government.

15. Changes in Burden

In section 1004.70(b)(C) burden hours decreased from 64 hours to 56 hours. This caused a total burden hour decrease of (8 hours X 53 sanctions) 424 hours.

16. Publication and Tabulation Dates

There are no publication and tabulation dates associated with this collection.

17. OMB Expiration Date

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