

Supporting Statement – Part A

Final Peer Review Organizations Sanction and Supporting Regulations (CMS-R-65)

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 Quality Improvement Organization may require documentation from the entity providing the care to ensure that the practitioner or other person is meeting the obligations imposed by section 1156(a) of the Act. (42 CFR 1004.10(c)).

It is the responsibility of the Quality Improvement Organization to identify violations when conducting individual case reviews (e.g., beneficiary complaints, general quality of care, utilization, etc.). 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 Quality Improvement Organizations (QIO) will ensure 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 of Health and Human Services (HHS) determines the obligations as stated by this section are not met.

These sanctions are recommended to the Secretary by the QIOs, who have been contracted responsibilities to determine whether practitioners and other persons are complying with their obligations under the statute. Based upon the QIO recommendations, the HHS 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 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.

The QIO must report the findings to CMS. If the violation(s) identified have not been resolved, the QIO must submit a report and its recommendation to the OIG Office of Counsel. The QIO report must include at least the following information:

- Identification of the practitioner or other person and, when applicable, the name of the director, administrator, or owner of the entity involved;
- The type of health care services involved;
- A description of each failure to comply with an obligation, including specific dates, places, circumstances, and other relevant facts;
- Pertinent documentary evidence;
- Copies of written correspondence, including reports of conversations with the practitioner or other person about the violation and, if applicable, a copy of the verbatim transcript of the meeting with the practitioner or other person;
- The QIO's finding that an obligation under §1156(a) of the Act has been violated, that the violation is substantial and has occurred in a substantial number of cases, or is gross and flagrant;
- A case-by-case analysis and evaluation of any additional information provided by the practitioner or other person in response to the QIO's initial finding;
- A copy of the CAP that the QIO developed and documentation of the results of the plan;
- The number of admissions by the practitioner or other person the QIO reviewed during the period in which the violation(s) was identified;
- The professional qualifications of QIO reviewers; and
- The QIO sanction recommendation.

The QIO's recommendation to OIG must be based on documentation of the type of offense involved, the severity of the offense, the deterrent value of the recommended sanction, a consideration of the practitioner's or other person's previous sanction record, the availability of alternative sources of services in the community, and any other factors that it considers relevant such as the duration of the problem. (See 42 CFR §1004.90.)

QIO Recommendation Report Requirements:

If OIG decides that a violation of an obligation has occurred, it determines the

appropriate sanction by considering the:

- *QIO's recommendation;*
- *Type of offense;*
- *Severity of the offense;*
- *Practitioner's or other person's previous sanction record;*
- *Availability of alternative sources of services in the community;*
- *Any prior problems the Medicare or State health care programs have had with the practitioner or other person; and*
- *Any other matters relevant to the particular case.*

(See 42 CFR §1004.100(d).)

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

QIO provisions are more flexible in terms of data gathering. The QIOs are free to take advantage of any technological advances they find appropriate to their needs. CMS has updated its regulations so that providers are required to "send secure transmission of an electronic version of medical information, if available, subject to the QIO's ability to support receipt and transmission of the electronic version" (42 CFR 476.78). Section 1156(b)(1) of the Social Security Act Provides any organization to submit recommendation regarding potential sanction when quality standards have been violated. Information is sent to OIG through postal mail.

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

9. Payments/ 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 18 national cases per three-year contract period for which serious violations are identified without resolution.

For each case that is not resolved, the QIOs attempts to correct the situation before it takes further action. In each instance, the QIOs thoroughly reviews all data in their possession from both the medical and legal standpoint and prepares a complete written notice that 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 encouraged to use the provided templates of a model notice.

The notice shall 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. The Bureau of Labor Statistics was utilized to determine reasonable rates for physicians and legal staff. The [physician](#) and [legal staff](#) is estimated at \$200.00 per hour. The secretarial support is estimated at a comparative GS-5 (step 1) rate of \$18.83 per hour.

The costs have been computed as follows:

226 hours for physician and legal staff time at \$200/hr	=	\$ 200.00 <u>x 226</u> \$ 45,200.00
multiplied by 18 sanctions per yr		<u>x 18</u>
	=	\$ 813,600.00 annually
36 hours of secretarial time at \$18.83/hr		\$ 18.83 <u>x 36</u> \$ 677.88
multiplied by 18 sanctions per yr contract period		<u>x 18</u>
	=	\$ 12,201.84 annually
TOTAL COSTS		
\$825,802 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 approximately one case per contract period - 40 hours.

Legal Staff time: Estimate of 8 hours per notice for an approximately one case per contract period - 8 hours.

Secretarial time: Estimate of 8 hours per notice for an approximately one 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 approximately one case per contract period - 40 hours.

Legal Staff time: Estimate of 10 hours per notice for an approximately one case per contract period - 10 hours.

Secretarial time: Estimate of 10 hours per notice for an approximately one 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 approximately one case per contract period - 60 hours.
Legal Staff time:	Estimate of 20 hours per notice for an approximately one case per contract period - 20 hours.
Secretarial time:	Estimate of 10 hours per notice for an approximately one 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 approximately one case per contract period – 40 hours.
Legal Staff time:	Estimate of 8 hours per notice for an approximately one case per contract period – 8 hours.
Secretarial time:	Estimate of 8 hours per notice for an approximately one 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 18 sanctions		
per 3-yr contract period		<u> x 18 </u>
TOTAL BURDEN		4,716 hours per year

The above cost is associated with Physician, Legal and Secretarial time per notice 1 case per contract period with an estimation of 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

There were no substantial changes in the level of sanctions in the past three years. Therefore, we assume the sanction will remain 18 within a three-year contract period. We assume that the burden level will remain unchanged. The hourly rate for secretary equivalent GS 5-1 increased from \$17.53 to \$18.83 hourly reflecting a change in cost of living and inflation over time.

16. Publication and Tabulation Dates

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

17. OMB Expiration Date

The expiration date is listed in the PRA disclosure statement which is located on the footer of the last page of the QIO notice template. The expiration date is posted next to the OMB control number.