Supporting Statement – Part A

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

A. BACKGROUND

This is an extension package. 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 (1) the services or items are 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 (QIO) 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 QIO to identify violations when conducting individual case reviews (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 QIOs will ensure 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 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, which have been contracted with the 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 the 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 the right 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 and medically necessary and are of a quality that 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 October 4, 2024 (89 FR 80903). There were no public comments received.

The 30-day Federal Register notice published on December 20, 2024 (89 FR 104182).

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, CMS estimates that there will be 170 national cases combined between the two BFCC QIOs in the current five-year contract period (May 1, 2024-April 30, 2029) for which serious violations are identified without resolution.

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 its 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 encouraged to use the provided model notice templates.

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:

The burden is computed by each QIO in its CMS-approved budget estimate for 170 sanctions over 5 years as follows:

We have estimated costs from the BFCC QIOs from their contractual budget estimates.

Table 1. Sanctions: 5-year Contract Budget Estimates for 170 Sanctions, 34 Sanctions Annually

Labor	Hours (5 Years)	Cost (5 Years)	Hourly Rate
BFCC QIO 1: Medical Director	3,920	$624,846	$159.37

Labor	Hours (5 Years)	Cost (5 Years)	Hourly Rate
BFCC QIO 1: Director Operations	226	$13,886	$61.43
BFCC QIO 1: RN Sanctions Specialist	32,478	$1,450,110	$44.66
BFCC QIO 1: Technical Writer	153	$4,407	$28.81
BFCC QIO 1: Total	**36,777**	**$2,093,249**	**—**
BFCC QIO 2: Medical Director	243	$27, 092	$111.51
BFCC QIO 2: Sanctions Coordinator	3,506	$136,269	$38.86
BFCC QIO 2: Physician Reviewer	64	$6,712.50	$105.31
BFCC QIO 2: Other Subcontractors	130	$13,753.39	$106.25
BFCC QIO 2: Total	**3,943**	**$183,826.89**	**—**
Combined Total	**40,720**	**$2,277,075.89**	**—**

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.

See above for hourly and cost breakdown.

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.

See above for hourly and cost breakdown.

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

See above for hourly and cost breakdown.

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

See above for hourly and cost breakdown.

SUMMARY OF BURDEN

Section 1004.40(b) – 56.0 hours

Section 1004.50(g) - 55.5 hours

Section 1004.60(b) – 72.0 hours

Section 1004.70(b) & (c) – 56.0 hours

TOTAL = 239.5 hours multiplied by 34 sanctions per 5-year contract period = 8,144

TOTAL BURDEN = 8,144 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

Table 2. Sanctions: 5-Year Contract Budget Estimates for 170 Sanctions, 34 Sanctions Annually

Labor	Hours (5 Years)	Cost (5 Years)	Hourly Rate
COR x2	120	$13,610	GS 13: Step 1 $56.71
Data Scientists	60	$6,805	GS: 13 Step 1 $56.71
Division Director	60	$9,460	GS: 15 Step 1 $78.83
Total	**240**	**$29,875**	—

15. Changes in Burden

The 12th Statement of Work (SOW) Case Review Contract ended effective April 30, 2024, and a new contract was extended for another five years. During the 12th SOW the COVID 19 Pandemic significantly impacted the sanction work burden. Outside of the pandemic and due to the overall increase in case review activity volumes of all case types and new case review appeals rights. It is estimated that sanction case volumes will be 34 annually and 170 during the next five-year contract period.

Table 3. Case Review Program Sanction Volumes, 12th SOW June 8, 2019-April 30, 2024

Year	Number of Sanction Cases 12th SOW
2019	62
2020	42
2021	35
2022	34
2023	41
2024	18
Total	**232**

The burden hours increased from 4,716 to 8,144.

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.

18. Certification Statement

There is no exception to the certification.