Supporting Statement – Part A

Quality Improvement Organization (QIO) Assumption of Responsibilities and Supporting Regulations

A. Background

The Quality Improvement Organization (QIO) Program originated with the Peer Review Improvement Act of 1982 (P.L. 97-248, §§ 141-143, 96 Stat. 324) and is authorized by Title XI Part B and Title XVIII the Social Security Act (the Act). The QIO provisions in the Act were most recently amended in 2011 by the Trade Adjustment Assistance Extension Act (P.L. 112-40, § 261, 125 Stat. 401). The 2011 amendments apply to QIO contracts entered into or renewed on or after January 1, 2012. Revisions to the QIO Manual address the following statutory (Title II, Part B of the Act codified at 42 U.S.C. Sections 1320c through 1320c12) and regulatory changes (42 CFR Parts 475 through 480). 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 QIO. In 2011, QIOs were given broader responsibilities (P.L. 112-40), and are now required to "perform, subject to the terms of the contract, such other activities as the Secretary determines may be necessary for the purposes of improving the quality of care furnished to individuals with respect to items and services for which payment may be made under title XVIII.''

> *"Substitutes "quality improvement" and "the quality improvement organizations" in place of references to "the utilization and quality control peer review" and "peer review organizations" • Changes criteria for the organizations entitled to contract with CMS, and provides broader authority for the Secretary to set the number and geographic scope of QIO contracts • Changes authorities related to the functions performed by QIO contractors, the term of QIO contracts, and procedures for contract termination or renewal"*

B. Justification

1. Need and Legal Basis

Contracts have been signed with Beneficiary and Family Center Care (BFCC)-QIOs in their respective geographic areas (which includes all United States and Territories) designated by regulations published in 42 C.F.R., Chapter IV. BFCC-QIOs assure that covered care provided to Medicare beneficiaries is reasonable, medically necessary, appropriate, and of a quality that meets professionally recognized standards of care, and delivered in the most appropriate setting. Additionally, CMS has awarded contracts to Quality Improvement Network (QIN)-QIOs that include the goals of: promoting effective prevention and treatment of chronic disease, making care safer by reducing harm caused in the delivery of care, promoting effective communication and coordination of care, and making care more affordable.

A variety of different sections under 42 CFR specify the legal requirements and authority for the particular information collection requirements that are being submitted for OMB review and for which burden is estimated. These are:

- § 412.44 Medical review requirements: Admissions and quality review.
- § 412.46 Medical review requirements: Physician acknowledgement.
- § 431.630 Coordination of Medicaid with QIOs.
- § 476.71 QIO review requirements.
- § 476.73(b) (3) Notification of QIO designation and implementation of review. (b) *Notification to health care facilities and the public*.
- § 476.78 Responsibilities of providers and practitioners.
- §480.111 QIO access to records and information of institutions and practitioners.

2. Information Users

QIOs use complaints, medical records for reviews obtained from providers to improve the quality of care and ensure its safety, appropriateness, and affordability. The data obtained from reviews are fed back to providers to support learning and improvement activities and to beneficiaries to provide information about their quality of care. As part of QIO review functions related to appropriate billing and coding, the QIO may share information with Medicare administrative contractors to withhold or recover provider payment for care that was less than standard quality. In accordance, Medicare Administrative Contractors (MACs) are private entities under contract with CMS to process claims for Part A and Part B Medicare services in specific jurisdictions. MACs responsible for processing Medicare Part A and B claims must cooperate with the QIO for data exchange requirements necessary for the QIO to fulfill its case review requirements specified in the contract. Regulations at 42 CFR 476.80 require that each MAC have an agreement with the QIO and that terms of the Joint Operating Agreement (JOA) reflect mutually agreeable conditions necessary for data exchange requirements in recognition of the unique capabilities and requirements of each party. QIOs performing case reviews must maintain agreements with each MAC processing claims in the QIO services area(s) designated in the QIO contract. Or Section 476.78(b) (5) The information in this section is used by the MAC to determine whether payment should be made for the procedure. In addition, Clinical Data Abstraction Centers (CDAC) reviews produce general information about health care quality and patient safety that are used by the QIOs themselves for planning and implementing quality of care programs as well as by CMS and other federal agencies for program planning and implementation.

3. Use of Information Technology

Data gathered under 476.78 must be submitted electronically if available. Other 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.

4. Duplication of Efforts

These requirements do not duplicate any existing requirements.

5. Small Businesses

There are no small business impacted.

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

There are no special circumstances related to this information collection.

8. Federal Register/Outside Consultation

The 60-day Federal Register notice published on November 19, 2020 (85 FR 73720). There were no public comments.

The 30-day Federal Register notice published on February 4, 2021 (86 FR 8200).

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)

§ 412.44 Medical review requirements: Admissions and quality review.

Each QIO must establish an MOA with each hospital in its review area. The MOA is renegotiated when the QIO contract is renewed.

6,939 acute care and specialty hospitals (times) 10 hours per MOA (5 hours each QIO/facility) (divided by 3 to annualize) = 23,130 hours per year

§ 412.46 Medical review requirements: Physician acknowledgement.

The QIO monitors PPS hospitals to ensure that hospitals comply with the physician acknowledgement statement requirements set forth in 42 CFR 412.46. Based on program experience, we project that the QIO will request a listing of new providers granted admitting privileges from each of approximately 3,420 PPS hospitals annually and will find a total of 20,024 per year. We project that it will take 1 hour per list based on the information being readily available for inclusion in the letter.

QIO Burden: 20,024 errors x 2 letters (1 physician, 1 facility) x 1 hour = 40,048 hours
Provider burden: 20,024 x 1 hour = 20,024 hours

40,048 + 20,024=60,072 total burden hours

§ 431.630(b) Coordination of Medicaid with QIOs
These requirements were implemented by use of the State plan preprint, and burden is

QIO Burden: 229,880 responses × 2 reviews (QIO& CDAC reviews) × 1 hour = 459,760 hours
Provider burden: 229,880 x 1 hour = 229,880 hours

459,760 + 229,880= 689,640 total burden hours

§ 476.71(c) QIO review requirements. (c) *Other duties and functions.*
"The QIO must review at least a random sample of hospital discharges each quarter and submit new diagnostic and procedural information to the Medicare administrative contractor, fiscal intermediary, 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 HWDRG errors (except technical coding errors). The burden on the QIO is in the preparation of the notice to notify the provider/practitioner of the HWDRG error. During the 11th scope of work, there were 97,082 HWDRG coding and utilization reviews completed, of which 6,114 HWDRG errors were confirmed. Based on program history, and common practice that the physician and/or practitioner will provide one response, we project that the QIO will find 6,000 errors per year. We project that it will take 1 hour per notice based on the information being readily for inclusion in the letter.

An additional burden for the QIO is in the preparation of the notification to the MAC. 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 MAC must execute a payment adjustment based on QIO findings, we project the burden to be 1.5 hours per error notification.

QIO Burden: 6,000 errors x 2 letters (1 physician, 1 facility) x 1 hour = 12,000 hours annually
Provider/practitioner burden: 6,000 x 1 letter x 1 hour = 6,000 hours annually
QIO Burden: 6,000 x .5 = 3,000 hours
MAC burden: 6,000 x 1.5 hours = 9,000 hours

Burden = 30,000 hours annually

§ 476.73(b) (1) Notification of QIO designation and implementation of review. (b) *Notification to health care facilities and the public*.

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 6,939 existing hospitals.

Includes all United States and Territories 2 existing QIOs (times) 2 hours =		110 hours
5 new QIOs (times) 2 hours (times) =	10 hours	
6,939 facilities (times)		
5 minutes' mail preparation =	578 hours TOTAL	
	688 hours per year	

§ 476.73(b) (2) Notification of QIO designation and implementation of review. (b) *Notification to health care facilities and the public.*

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 five annually) entering the program will need to respond and, therefore, this is a one-time burden as follows:

5 QIOs (times) 1 notice (times) 4 hours = 20 hours.

§ 476.74(b) General requirements for the assumption of review.

Each new QIO will notify its MAC and carrier during the period of its contract. Additionally, any new QIOs are required to notify the appropriate Medicare Administrative Contractor (MAC) 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:

All United States and Territories 54 2 existing QIOs (times) 1 notice (times) ½ hour (divided by 3 to annualize) =	9 hours
5 new QIOS (times) 1 notice (times 1 hour) =	5 hours
TOTAL	14 hours

§ 476.74(c) General requirements for the assumption of review.

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 2 QIOs, which covers all United States, and Territories that will spend 1 hour on record maintenance, resulting in an annual burden as follows:

(All United States and Territories) 54 (2) QIOs (times) 1 hour = 54 hours

§ 476.78(a) Responsibilities of providers and practitioners.
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.

§ 476.78(b) (2) Responsibilities of providers and practitioners. (b) *Cooperation with QIOs &* §480.111 QIO access to records and information of institutions and practitioners.

We are seeking an extension of this requirement only; the associated burden is currently approved

QIO Burden: 229,880 responses × 2 reviews (QIO& CDAC reviews) × 1 hour = 459,760 hours
Provider burden: 229,880 x 1 hour = 229,880 hours

§ 476.78(b) (3) Responsibilities of providers and practitioners. (b) *Cooperation with QIOs.*
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:

6,939 facilities (times) 0.5 hours
(divided by 3 to annualize) = 1,156.5 hours

§ 476.78(b) (5) Responsibilities of providers and practitioners. (b) *Cooperation with QIOs.*
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	-	23,130
Section 412.46	-	60,072
Section 431.630 (b)	-	689,640
Section 476.71 (c)	-	30,000
Section 476.73 (b) (1)	-	688
Section 476.73(b) (2)	-	20
Section 476.74(b)	-	14
Section 476.74(c)	-	54
Section 476.78(a) (b) (2)	-	229,880
Section 476.78(b) (3)	-	1,157
Section 476.78(b) (5)	-	0

TOTAL 1,034,655 hours

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. Therefore, for this rule there are 1,034,655 hours of burden to the QIO at a rate of $*31.38 per hour equaling $32,467,474.

*Annual Rates by grade and step for federal employees are based on 2020 general schedule (GS) Based Pay Tables found on the U.S. Office of Personnel Management Website

13. Capital Costs

There are no capital costs associated with this information collection.

14. Federal Costs Estimates

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

The cost for government personnel is estimated at $32,440 annually.

Grade 9 (step 1):	$ 59,534 x 0.20 =	$11,907
Grade 13 (step 1):	$ 102,663 x 0.20 =	$20,533
Total		$32,440*

*Annual Rates by grade and step for federal employees are based on 2020 general schedule (GS) Locality Pay Tables for the Washington-Baltimore-Northern Virginia, (DC-MD-VA-WV-PA) area found on the U.S. Office of Personnel Management Website

15. Changes to Burden

Considering the 11 SOW level of effort and the number of providers and practitioners involved with the QIO activities, we do not expect a significant change between the 11th and 12th SOW activities.

16. Publication/Tabulation Dates

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

17. Expiration Date

CMS will display the expiration date on https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/.

.