Supporting Statement
HSQ-110 Acquisition, Protection, and Disclosure of Quality Improvement Organization (QIO) Information and Supporting Regulations
(CMS-R-70)

A. Background

This is a reinstatement package. 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. Under this program, a PRO was designated in each State to ensure that covered care provided to Medicare patients is reasonable, medically necessary, appropriate, and of a quality that meets professionally accepted standards of care. A Federal Notice dated May 24, 2002, renamed the PROs as Quality Improvement Organizations (QIOs).

Beneficiary and Family-Centered Care-Quality Improvement Organization (BFCC-QIO) Contracts have been signed with QIOs for their respective geographic areas (which includes all United States & Territories). The second type of QIOs and Quality Innovation Network-QIOs focus on health care quality improvement efforts.

The scope of information collection by the BFCC-QIOs includes the number of Medicare beneficiaries with expedited appeals, reconsideration appeals and Beneficiary Complaint cases which are then reported into the CMS System of Record. Medicare beneficiaries or their appointed representatives have the right to appeal the provider's decision to discharge or end services if beneficiaries believe their Medicare Part A Medicare services (e.g. hospital discharge, skilled nursing home care, home health, etc.) are ending too soon. They also have the right to file a Beneficiary Complaint case when they have concerns about the quality of care they received.

In regard to standardized forms or collection instruments, CMS does not require the BFCC-QIOs to fill out or complete forms therefore, this package does not have a collection instrument. However, CMS does require the BFCC-QIOs to report case information into the CMS System of Record and retain this same information in their proprietary systems.

B. Justification

1. Need and Legal Basis

The information collection requirements for which we are seeking OMB approval are contained in 42 CFR § § 480.104, 480.105, 480.116, and 480.134. The effective date of sections quoted below will be May 1, 2019, which is the beginning of the current contract. Therefore, our estimates are based on two QIOs.

"§480.104 - Procedures for disclosure by a QIO.

Informing the beneficiary (or representative), provider, or physician the information cannot be disclosed protects the rights of the involved parties. Notifications can be sent via US Mail, Secure email and/or Fax.

"§480.105 - Notice of disclosures made by a QIO

These notices along with the copy of information to be disclosed enable providers and practitioners to review the data that is to be disclosed and to determine if it is accurate and complete. If the providers or practitioners have any comments or additions, they submit them to the QIO and in turn, the QIO attaches them to the information being disclosed. This disclosure requirement protects providers and practitioners from the disclosure of incorrect or incomplete information.

"§480.116 - Notice to individuals and institutions under review.

To protect the rights of individuals and providers, QIOs will give a notice to providers and/or individuals, which will contain a description of the type of data QIOs will be collecting, maintaining, and disclosing about them. The QIO will also give the title and address of the QIO employee whom is responsible for maintenance of this data so that the individual or provider will know whom to contact at the QIO. This requirement ensures that the public will be fully informed about the type of information the QIO maintains on them.

"§480.134 - Verification and amendment of QIO information.

The QIO must verify all data it possesses is accurate. If an individual or provider reviews this data and requests that the information be amended and the QIO disagrees, the QIO must document the file accordingly. The QIO will make a notation of the request, reasons for the request, and reasons for refusal and will include this information along with any disclosure of the information. This requirement protects the rights of the individual or provider by allowing their request for amendment to become part of the record and by requiring the QIO to put in writing its reason for denying the request.

2. Information Users

The information provided in these notices is used by the beneficiaries (or their representative), practitioners and providers to: obtain access to the data maintained and collected on them by the QIOs; add additional data or make changes to existing QIO data; and reflect in the QIO's record the reasons for the QIO's disagreeing with an individual's or provider's request for amendment.

CMS analyzes the data via monthly, quarterly, and ad hoc reports to (1) ensure the QIOs are meeting the metrics outlined in the contract (2) identify innovation for better quality of care for beneficiaries, reduce costs and reduce patient harm by looking at trends in

either particular states, geographical regions, and/or particular hospitals.

3. Improved Information Technology

We make use of information technology by allowing the transmission of medical records to the QIO via the Electronic Submission of Medical Documentation System (esMD), secured fax and/or US mail. Also the CMS System of Record for case review is the Quality Management and Review System (QMARS) which allows for electronic processing and storage of case information.

4. Duplication and Similar Information

These requirements do not duplicate any other CMS requirements.

5. Small Business

Small business and individuals can easily meet these requirements. Therefore, they do not have a significant economic impact on small businesses.

6. Less Frequent Collection

There are no frequency requirements associated with this requirement. QIOs will provide the information as needed. Less frequent collection would prevent CMS from obtaining the necessary data.

7. Special Circumstances for Information Collection

There are no special circumstances associated with this collection.

8. Federal Register and Outside Consultations

The 60-day Federal Register notice published on August 29, 2025 (90 FR 42246). There were no public comments received.

The 30-day Federal Register notice published on November 21, 2025 (90 FR 52675).

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

A QIO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative in accordance with the requirements and exceptions to the requirements for disclosure specified under § 480.132.

A QIO must notify a practitioner or institution of the QIO's intent to disclose information on the practitioner or institution to an investigative or licensing agency (§§ 480.137 and 480.138) except for cases specified in § 480.106 involving fraud or abuse or imminent danger to individuals or the public health. The practitioner or institution must be notified and provided a copy of the information to be disclosed at least 30 calendar days before the QIO discloses the identifying information. The QIO must forward with the information any comments submitted by the practitioner or institution in response to the QIO notice if received before disclosure, or forwarded separately if received after disclosure.

Disclosure of confidential information made under the authority of this subpart, except as provided in § 480.106, must be accompanied by a written statement informing the beneficiary that the information may not be redisclosed except as provided under § 480.107 that limits redisclosure.

https://www.law.cornell.edu/cfr/text/42/480.105

11. Sensitive Questions

There are no questions of the sensitive nature associated with this collection.

12. Estimate of Burden (Hours and Wages)

We estimated that approximately 50,000 beneficiaries would request an appeal and/or grievance disclosure report, based on the previous year's request. We then estimated it would take approximately 10 minutes (.167 hours) for a staff person to send the appeals report to these beneficiaries. In aggregate, we estimate 8, 333 hours (50,000 responses x .167 hours).

We determined the average hourly rate for the individual responsible for collecting and formatting the appeals information. The professional and analytical skills required to perform this function are similar to those of office and administrative support occupations with an hourly salary of $22.12. To account for fringe benefits and overhead costs, the adjusted hourly rate for this position is $44.24. We then multiplied this adjusted hourly rate ($44.24) by the .167 hours per response estimated for reporting appeals and grievance data to arrive at $7.08 cost per response (mailing costs). Hourly salary rate was obtained from the U.S. Bureau of Labor Statistics for 2024 accessible at https://www.bls.gov/ooh/office-and-administrative-support/secretaries-and-administrative-assistants.htm

Last, we multiplied $7.08 by the annual number of responses (50,000) to determine the total annual wage burden of $354,000 per year.

Burden Table

Task	Number of Forms	Time per form (minutes)	Total Time (minutes)	Total Hours
Completing Complaint Form	50,000	10	500,000	8,333

QIO Burden= 8,333 hours x $44.24= 368,652 (response rate)
50,000 cases x $7.08= $354,000 (mailing cost)

Section 480.104

When confidential information is disclosed, a written statement must accompany the information that informs the recipient of the limits on redisclosure. The burden associated with this requirement is the time and effort to complete this documentation. The burden also includes writing, typing, or dictating the face-to-face documentation and signing/dating the documentation. In this regard, we estimated 10 minutes for each encounter.

50,000 cases x 0.167 hours = 8,350 hours
8,350 hours x $44.24= $369,404

There are two respondents (BFCC-QIOs), responding to 50,000 cases.

Section 480.105(a)

As a result, of a request from an external source or upon the QIO's own motion, the QIOs must notify providers of the intent to disclose information about them and provide a copy of the information being disclosed. The providers have 30 calendar days to submit written comments prior to the information disclosure by the QIO. The notification will presumably be a letter for each proposed disclosure developed by each QIO. The burden to the QIOs is the time to develop the letter that contains the proposed information disclosure. We estimate that it will take a QIO approximately 1 hour each to complete the individual letter. This estimate is based on the information being readily available for inclusion in the letter. We project that a QIO will send out approximately 68,500 disclosures notification per year. The numbers are based on the life of the current 13th SOW, which is 5 years. In addition, the burden to the providers is the time to prepare the response to the individual proposed QIO disclosure. Based on program experience, all providers respond to the QIO proposed disclosure notices. We estimate that it takes a provider about 3 hours to prepare the response to a specific proposed disclosure notice.

QIO Burden =
3 hours to investigate and 2 hours to verify document x 68,500 disclosures by QIO
5 hours x 68,500= 342,500 hours

2 hours to develop letter x 68,500 disclosures by QIO
2 hours x 68,500 =137,000 hours

137,000 disclosures x 2 QIOs = 274,000 disclosures

501,900 hours x $44.24= $21,213,080

Total burden for this section: 479,500 hours
$22,204,056

Section 480.105(b)(1)

The QIOs must notify the practitioner who has treated a patient of a request for disclosure to the patient or patient's representative before they disclose the requested information. The notification will be a letter prepared on a case-by-case basis. Burden to the two QIOs will be the time to prepare the notification that includes the information being disclosed. We estimate it would take each QIO 5 minutes to develop the notification letter. This estimate is based on the information being readily available for inclusion in the letter. The numbers are based on the life of the current 13th SOW, which is 5 years. We estimate there will be 2,757 disclosures each year for both QIO's. In addition, burden to the practitioner will be the time to respond to the QIO notification. We project that 90 % (109) of the practitioners will respond to such notification requests. We estimate it would take about 30 minutes to prepare the response to the QIO notification.

QIO Burden: 2 hours per letter x 2,757 disclosures = 5,514 hours
5,514 hours x $44.24 = $243,939

Practitioner Burden: 109 responses x 30 minutes = 55 hours
55 hours x $44.24= $2,433

Total burden for this section - 5,569 hours
$246,372

Section 480.105(b)(2)

The QIOs must notify practitioners or providers of the intent to disclose information about them to an investigative or licensing agency and provide copies of the information being disclosed. No response is expected from the recipients.

The notification will be a letter prepared on a case-by-case basis. Burden to the two QIOs will be the time to prepare a notification letter and the time to prepare the

information. We estimate it would take each QIO 1 hour to develop a letter of notification, and 1 hour to prepare the information being disclosed. We estimate there will be 2757 disclosures each year for both QIO's. The numbers are based on the life of the current 13th SOW, which is 5 years.

Burden: 1 hour for development of letter x 2,757 disclosures = 2,757 hours
2,757 hours x $44.24 = $121,970
1 hour for research of information x 2,757 disclosures = 2,757 hours
2,757 hours x $44.24 = $121,970

Total burden for this section: 5,514 hours
$243,940

Section 480.116

The QIOs must establish and implement procedures to provide information about QIO information collection and maintenance to patients, practitioners, and providers coming under review.

Burden estimate is for the time necessary to initially develop these procedures. We anticipate one (1) hour to develop and document these procedures per each (2) QIO.

Burden: 1 hour x $44.24 = $44.24

Section 480.134

When a QIO receives a request for amendment of information in its possession and the amendment is refused, the QIO must make a notation and keep it with its copy of the information as well as the reasons for refusing the request. The notification must be disclosed with any disclosure of the information. Burden is based on two QIOs making these notations to their copy of information. We expect ? requests for amendment per QIO. Each notation will take approximately 30 minutes.

Burden: 2 QIOs x 265 requests x 30 minutes = 265 hours
265 hours x $44.24 = $11,724

TOTAL BURDEN:

We have estimated the costs for this rule at the rate of $44.24 per hour.

Section	Response Time (hours)	Cost
480.104	8,350	$369,404
480.105 (a)	501,900	$22,204,056
480.105 (b)(1)	5,569	$246,373
480.105 (b)(2)	5,514	$243,940
480.116	1	$45
480.134	265	$11,724
Total	521,599	$23,075,542

13. Capital Costs

There are no capital costs associated with this information collection.

14. Federal Cost Estimates

All Federal costs associated with this rule will be incurred by CMS through their contracts with QIOs.
The cost for government personnel is estimated at $62,066 annually.

Grade 13 (step 10):$ 155,164 x 0.20 = $31,033
Grade 13 (step 10):$ 155,164 x 0.20 = $31,033
Total $62,066*

*Annual Rates by grade and step for federal employees are based on 2020 general schedule (GS) Locality Pay Tables for the Boston-Worcester-Providence (MA-RI-NH-CT-ME-VT) area found on the U.S. Office of Personnel Management Website

15. Changes in Burden

The burden hours changed, and the cost increased due to wage rates being updated. The burden hours increased from 404,208 to 521,599. The costs increased from $16 million to $23 million.

16. Publication and Tabulation Dates

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

17. OMB Expiration Date

.The public can access expiration date information through: Federal Register notices

at federalregister.gov or OMB's website at reginfo.gov using the OMB control number search function.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collections of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.