

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

A. Background

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 this information collection includes BFCC-QIOs for the number of Medicare beneficiary level 2 appeals. Medicare beneficiaries or their appointed representatives have the right to appeal the provider's Notice of Discharge and Medicare Appeal Rights (NODMAR) if beneficiaries believe their Medicare Part A Medicare services (e.g. hospital discharge, skilled nursing home care, home health, etc.) are ending too soon.

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 October 1, 2016, which is the beginning of the 11<sup>th</sup> SOW. These requirements listed below are not new, but we're adjusting the specifics based on redesign of the program. Therefore, our estimates are based on two QIOs.

“§480.104 - Procedures for disclosure by a QIO.

Informing the beneficiary (or representative), provider, or physician that 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 transmitting the information via the Electronic Submission of Medical Documentation System (esMD), secured fax and/or US mail.

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. These requirements comply with all general collection guidelines in 5 CFR §1320.6.

8. Federal Register and Outside Consultations

The 60-day Federal Register notice published on February 28, 2018 (83 FR 8679). There were no public comments received.

The 30-day Federal Register notice published on April 30, 2018 (83 FR 18847).

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 0.1%, or 53,850 beneficiaries would request an appeal and/or grievance disclosure report from a Medicare health plan. We then estimated it would take approximately 10 minutes (.16 hours) for a staff person to send the appeals report to these beneficiaries. In aggregate, we estimate 8,616 hours (53,850 responses per year x .16 hours/response).

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 \$17.23. The adjusted hourly rate for this position is \$34.46. We then multiplied this adjusted hourly rate (\$34.46) by the .16 hours per response estimated for reporting appeals and grievance data to arrive at \$5.60 cost per response (mailing costs.)

Last, we multiplied \$5.60 by the annual number of responses (53,850) to determine the total annual wage burden of \$301,560 per year, or \$407.00 per organization (301,560 divided by 741 Medicare health plans).

QIO Burden= 8,616 hours x \$34.46= 296,907 (response rate)  
53,850 cases x \$5.60= \$301,560 (mailing cost)

[https://www.bls.gov/oes/current/oes\\_nat.htm](https://www.bls.gov/oes/current/oes_nat.htm) (Occupation code 43-3000)

#### 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.

53,850 cases x 0.167 hours = 8,993 hours  
8,993 hours x \$34.46= \$309,897

There are two respondents (BFCC-QIOs), responding to 53,850 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 2 hours 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 53,850 disclosures notification per year. The numbers are based on the life of the current 11<sup>th</sup> SOW, which is 3 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 53,850 disclosures by QIO

5 hours x 53,850 = 269,250 hours

2 hours to develop letter x 53,850 disclosures by QIO

2 hours x 53,850 = 107,700 hours

107,700 disclosures x 2 QIOs = 215,400 disclosures

376,950 hours x \$34.46 = \$12,989,697

Total burden for this section: 376,950 hours

\$12,989,697

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 2 hours 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 11<sup>th</sup> SOW, which is 3 years. We estimate there will be 3,160 disclosures each year for each QIO. 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 3,160 disclosures x 2 QIOs = 12,640 hours

12,640 hours x \$34.46 = \$435,574

Practitioner Burden: 109 responses x 30 minutes = 55 hours

55 hours x \$34.46 = \$1,895

Total burden for this section - 12,695 hours

\$437,469

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 1,325 disclosures each year for each QIO. The numbers are based on the life of the current 11<sup>th</sup> SOW, which is 3 years.

Burden: 1 hour for development of letter x 1,325 disclosures x 2 QIOS = 2,650 hours  
 2,650 hours x \$34.46 = \$91,319  
 1 hour for research of information x 1,325 disclosures x 2 QIOS = 2,650 hours  
 2,650 hours x \$34.46 = \$91,319

Total burden for this section: 5,300 hours

\$182,638

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 (5) QIO.

Burden: 5 hours x \$34.46 = \$172

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 265 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 \$34.46 = \$9,132

TOTAL BURDEN:

We have estimated the costs for this rule at the rate of \$34.46 per hour.

Section 480.104	8993 hours	\$ 309,897
Section 480.105 (a)	376,950 hours	\$12,989,697
Section 480.105 (b) (1)	12,695 hours	\$437,469
Section 480.105 (b) (2)	5,300 hours	\$182,638

Section 480.116	5 hours	\$ 172.
Section 480.134	265 hours	\$ 9,132
<b>TOTAL</b>	<b>404,208 hours</b>	<b>\$13,929,005</b>

All costs associated with this rule will be incurred by CMS with its contracts with QIOs. (See cost estimate in #14, below).

13. Capital Costs

There are no capital costs associated with this information collection.

14. Federal Cost Estimates

The cost is covered in the normal course of federal duties.

15. Changes in Burden

The number of responses increased from 5,300 to 53,850. The burden hours increased from 60,660 to 404,208.

Section Number	Previous Burden	Current Burden	Difference Hours	Cost	Comment
§480.104	0 hrs.	8,993 hrs.	8,993	\$309,897	Based on an estimate of .1% from previous 3-year data. The calculation is a number of cases 53,850 and 10 minutes.
§480.105 (a)	42,400 hrs.	376,950 hrs.	334,550	\$12,989,697	QIO Burden of 376,950hours of work and 2 QIOs; cost added
§480.105 (b) (1)	12,695 hrs.	12,695 hrs.	0	\$437,469	No change, cost is available
§480. 105 (b) (2)	5,300 hrs.	5,300 hrs.	0	\$182,638	No change, cost is available
§480.116	0 hrs.	5 hrs.	5	\$172	Estimate of hours for QIO collection of information; cost added
§480.134	265 hrs.	265 hrs.	0	\$9,132	No change, cost is available
<b>Totals</b>	<b>60,660</b>	<b>404,208</b>	<b>343,548</b>	<b>\$13,929,005</b>	

16. Publication and Tabulation Dates



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

17. OMB Expiration Date

CMS will publish a notice in the Federal Register to inform the public of both the approval and the expiration date. In addition, the public will be able to access the expiration date on OMB's website by performing a search using the OMB control number.

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.