Supporting Statement for the
Information Collection Requirements in HSQ-110 Acquisition, Protection, and Disclosure of Quality Improvement Organization (QIO) Information and Supporting Regulations in 42 CFR Sections 480.104, 480.105, 480.116, and 480.134
(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).

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 was October 1, 2011. Effective September 29, 1989, the QIO review areas were consolidated, reducing the number of QIOs from 54 to 53. Therefore, our estimates are based on 53 QIOs.

"§480.104 - Procedures for disclosure by a QIO.

(a)(2) 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 recipient that the information may not be redisclosed except as provided under §480.107 that limits redisclosure."

Informing the recipient that the information cannot be disclosed protects the rights of the involved parties.

"§480.105 - Notice of disclosures made by a QIO

(a) Notification of the disclosure of nonconfidential information. Except as permitted under §480.106, at least 30 calendar days before disclosure of nonconfidential information, the PRO must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to CMS or Medicare fiscal intermediaries, or to or from QIO

subcontractors, or to or from the institution), and provide the institution with a copy of the information. The institution may submit comments to the QIO that must be attached to the information disclosed if received before disclosure, or forwarded separately if received after disclosure.

(b) (1) A QIO must notify the practitioner who has treated a patient, of a request for disclosure to the patient or patient representative...

(b) (2) A QIO must notify a practitioner or institution of the QIO's intent to disclosure 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."

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.

The QIO must establish and implement procedures to provide patients, practitioners, and institutions under review with the following information-

(a) The title and address of the person responsible for maintenance of QIO information;
(b) The types of information that will be collected and maintained;
(c) The general rules governing disclosure of QIO information; and
(d) The procedures whereby patients, practitioners, and institutions may obtain access to information about themselves."

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.

(a) A QIO must verify the accuracy of its information concerning patients, practitioners, reviewers, and institutions and must permit the individual or institution to request an amendment of pertinent information that is in the possession of the QIO.

(b) If the QIO agrees with the request for amendment, the QIO must correct the information in its possession. If the information being amended has already been disclosed, the QIO must forward the amended information to the requester where it may affect decisions about a particular provider, practitioner, or case under review.

(c) If the QIO disagrees with the requester for amendment, a notation of the request, reasons for the request, and the reasons for refusal must be included with the information and attached to any disclosure of the 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 patients, 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.

3. Improved Information Technology

Since the information exchanged will be read and interpreted by people, rather than machines, it will be in hard copy. There is no advantage to use electronic media in these instances. Changes that were made in the crosswalk to CMS R-70 include editorial corrections and deletions of requirements that QIOs have already fulfilled such as creating a form letter.

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 was published on May 10, 2013.

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

The issue of confidentiality does not apply to these requirements. The requirements address the manner in which QIOs will provide general information on how the public can obtain information. The requirements do not address any substantive information about individuals.

11. Sensitive Questions

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

12. Estimate of Burden (Hours and Wages)

Section 480.104

When confidential information is disclosed, a written statement must accompany the information that informs the recipient of the limits on redisclosure. Since the QIOs

already have a form letter, there will be no administrative burden on them for that requirement. We project that there will be 53 QIOs that will be awarded a contract for the next (11th contract period (2014-2019).

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 200 disclosures notification per year. 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 2 hours to prepare the response to a specific proposed disclosure notice.

QIO Burden = 2 hours to develop letter x 200 disclosures by QIO = 400 hours

400 hours x 53 QIOs = 21,200 hours

Provider Burden = 2 hours to prepare response x 200 disclosures by QIO = 400 hours

400 hours x 53 QIOs = 21,200 hours

Total burden for this section = 42,400 hours

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 all 53 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. We estimate there will be 120 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 120 disclosures x 53 QIOs = 12,640 hours

Practitioner Burden- 109 responses x 30 minutes = 055 hours

Total burden for this section = 12,695 hours

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 all 53 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 50 disclosures each year for each QIO.

Burden = 1 hour for development of letter x 50 disclosures x 53 QIOS = 2,650 hours.

1 hour for preparation of information x 50 disclosures x 53 QIOS = 2,650 hours.

Total burden for this section

=

5,300 hours.

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. Since all 53 QIOs have already developed these procedure, there will be no administrative burden for this section.

Total burden for this section = 0 hours

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 all 53 QIOs making these notations to their copy of information. We expect 10 requests for amendment per QIO. Each notation will take approximately 30 minutes.

Burden = 53 QIOs x 10 request x 30 minutes = 265 hours

Total burden for this section

= 265 hours

TOTAL BURDEN:

Section 486.104	0 hours
Section 480.105	60,395 hours
Section 480.116	0 hours
Section 480.134	265 hours
TOTAL	60,660 hours

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

We have estimated the costs for this rule at the rate of $15.74 per hour.

Section 480.104	0 hours	=	$0
Section 480.105(a)	42,400 hours	=	$667,376.00
Section 480.105(b)(1)	12,695 hours	=	$199,819.30
Section 480.105(b)(2)	5,300 hours	=	$83,422.00
Section 480.115	0hours	=	$0
Section 480.134(c)	265 hours	=	$4,171.10
TOTAL COSTS	60, 660 hours	=	$954,788.40

15. Changes in Burden

There are no changes to the burden; however, it will appear to be a reduction in the ICRAS and ROCIS systems due to rounding issues.

16. Publication and Tabulation Dates

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

17. OMB Expiration Date

This collection of information does not lend itself to the displaying of an expiration date.

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.