

Supporting Statement
for the
Information Collection Requirements in
42 CFR Sections 478.18, 478.34,
478.36, and 478.42
PRO Reconsiderations and Appeals
CMS-R-72

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 is designated in each State to ensure that care provided to Medicare patients is reasonable, medically necessary, and of a quality that meets professionally recognized standards of care. A Federal Register notice dated May 24, 2002, renamed the PROs as quality improvement organizations (QIOs).

B. Justification

1. Need and Legal Basis

This collection is mandated by 42 CFR 478.18, 478.34, 478.36, and 478.42 (as re-designated from Part 473 to Part 478 in November 14,1999). Effective August 1, 2014, the QIO review areas were consolidated, reducing the number of QIOs from 53 to 2. Therefore, the QIO estimates are based on two QIOs. The information collection requirements contained in this rule that are subject to OMB review are outlined in Item12. A short justification for each requirement is included.

2. Information Users

The requirements in this rule are on QIOs to provide information to parties who request a reconsideration review. The affected parties will use the information as guidelines for appeal rights in instances where issues are still in dispute.

The requirement for QIOs to maintain records of reconsideration information is necessary in case of a request for further appeal (hearing) or litigation. If a case is appealed, the information is forwarded to the administrative law judge of the Office of Hearings and Appeals of SSA.

3. Improved Information Technology

The information requirements in this regulation do not lend themselves to electronic exchange. They will be printed in hard-copy to be interpreted by

people, not by machines.

4. Duplication and Similar Information

These requirements do not duplicate other existing requirements.

5. Small Business

These requirements can be easily met by small businesses and individuals. The notices serve to protect the rights of parties requesting reconsiderations and hearings.

6. Less Frequent Collection

A request for reconsideration or hearing and a notice of the QIO's reconsideration determination is required one time only for each reconsideration action.

7. Special Circumstances for Information Collection

Section 478.48 of this rule requires that records be maintained until the later of 4 years of the date of the determination, or completion of litigation or until the time period for filing an appeal has passed. This section prohibits the Federal government from requiring respondents to maintain records, other than health or medical records, for more than 3 years. The Section 478.48 requirement meets this criterion since the reconsideration is a medical determination. All other sections of the regulation comply with the guidelines in 5 CFR 1320.6.

8. Federal Register and Outside Consultation

The 60-day Federal Register notice published on July 22, 2016. There were no comments.

9. Payments or Gifts

There are no payments or gifts associated with this collection.

10. Confidentiality

The record of QIO reconsideration is subject to prohibitions against disclosure of information as specified in section 1160 of the Social Security Act and applicable regulations.

11. Sensitive Questions

There are no sensitive questions associated with this information collection.

12. Estimate of Burden (Hours and Wages)

Section 478.18 - Request for reconsideration.

- (a) Beneficiaries. a beneficiary who wishes to obtain reconsideration must submit a written request to one of the following:
 - (1) The QIO or the QIO contractor that made the initial determination.
 - (2) A Social Security District Office.
 - (3) A Railroad Retirement Board Office, if the individual is a railroad retirement beneficiary.

- (b) Others. A provider, physician, or other practitioner that wishes to obtain reconsideration must submit a written request to the QIO or QIO contractor that made the initial determination.

In the event that a beneficiary, provider, physician, or other practitioner does not agree with the initial determination of a QIO or a QIO subcontractor, it is within that party's rights to request reconsideration. The requirement that it be made in writing is beneficial to both the requesting party and the QIO itself. The affected party's request must be filed within 3 calendar days of receipt of the notice of preadmission or pre-procedure denial or within 60 calendar days of the date on the notice of any other initial determination. The written request serves as proof of meeting these timeframes and cannot be disputed by the QIO. If reconsiderations were requested in any other manner, it would be up to the QIO to record when the request was received, and errors could result. The QIO also uses this written request as a tracking mechanism to ensure expedient handling of the request. After receipt of the request for reconsideration, a QIO will have a specific timeframe (3, 10 or 30 working days depending on the type of services and the issue under review) for completing the reconsideration review. After the review is completed and the determination made, the QIO must prepare a written notice and send it to the requesting party.

Section 478.18(a) - This section requires a beneficiary who wishes to obtain a reconsideration to do so in writing. We do not require a justification or any specific information to be included with the request.

Section 478.18(b) - This requirement is the same as 478.18(a) except burden in this section is on the provider or practitioner.

We estimate a beneficiary, provider, physician, or practitioner would be able to comply with this requirement in 30 minutes. Based on data collected for the period of 1 fiscal year, the burden for these sections is computed as follows:

2,414 requests (times) 30 minutes (times) once a year = 1,207
hours

Section 478.34 - Notice of a reconsidered determination.

- (a) Notice to Parties. A written notice of a QIO reconsidered determination must contain the following:
- (1) The basis for the reconsidered determination.
 - (2) A detailed rationale for the reconsidered determination.
 - (3) A statement explaining the Medicare payment consequences of the reconsidered determination.
 - (4) A statement informing the parties of their appeal rights, including the information concerning what must be included in the request for hearing, the amount in controversy, locations for submitting a request for an administrative hearing and the time period for filing a request.
- (b) Notice to Payers.
- (1) A QIO must provide written notification of its reconsidered determination to the appropriate Medicare intermediary or carrier within 30 days if the initial determination is modified or reversed.
 - (2) This notice must contain adequate information to allow the intermediary or carrier to locate the claim file. This must include the name of the beneficiary, the Health Insurance Claim Number, the name of the provider, date of admission, and dates or services for which Medicare payment will not be made.

Proper notice is part of the due process of Medicare review. The "notice to parties" explains the reconsideration determination and the parties' appeal rights. Providing this information to the affected parties at this time affords them the opportunity to file a timely request for a hearing and is a good business practice for the QIOs.

The "notice to payers" provides the Medicare intermediary or carrier with information to identify the claim file of the affected party who requested the reconsideration determination. It is necessary for the intermediary or carrier to have this information in the event that the reconsidered coverage decision is different than that in its possession (i.e., if the initial denial is changed to approval). In this instance, the information would be used by the intermediary or carrier to reimburse the affected party.

Section 478.34(a) - This requirement is on the QIO to provide a written notice to the affected parties of a reconsidered determination. To ensure the party is fully informed, we specify in this section what is to be included in each notice. Each notice will be prepared individually with information readily available to the QIO. The QIO should be able to develop each notice in about 30 minutes. Based on data collected for the period of 1 fiscal year, the burden for all two QIOs is calculated as follows:

2,414 notices (times) 30 minutes (times) once a year = 1,207 hours

Section 478.34(b) - This section requires the QIO to send the appropriate Medicare intermediary or carrier a written notice if an initial determination has been reversed or modified. We require that the notice contain adequate information to allow the intermediary or carrier to locate the claim file and act on the QIO's reversal decision. We estimate that the QIO will have the data readily available and it should only take about 10 minutes to prepare the notice. On the other hand, the intermediary or carrier will take approximately 30 minutes per claim to process the QIOs' new determinations. Based on data collected for the period of 1 fiscal year, the burden for this section is computed as follows:

300 (QIO) notices (times) 10 minutes (times) once a year = 50 hours

300 claim reopened (times) 30 minutes (times) once a year = 150 hours

Total = 200 hours

Section 478.36 - Record of reconsideration.

- (a) QIO Requirements. A QIO must maintain the record of its reconsideration until the later of the following:
- (1) Four years after the date on the notice of the QIO's reconsidered determination.
 - (2) Completion of litigation and passage of the time period for filing all appeals.
- (b) Contents of the record. The record of the reconsideration must include:
- (1) The initial determination.
 - (2) The basis for the initial determination.
 - (3) Documentation of the date of the receipt of the request for reconsideration.
 - (4) The detailed basis for the reconsidered determination.
 - (5) Evidence submitted by the parties.
 - (6) A copy of the notice of the reconsidered determination that was provided to the parties.
 - (7) Documentation of the delivery or mailing and, if appropriate, the

receipt of the notice of the reconsidered determination by the parties.

To be consistent with current Medicare practice, we are requiring QIOs to maintain the reconsideration information for at least 4 years. The "record of reconsideration" is required in the event there is a request for a hearing by an administrative law judge or if there is litigation. If a hearing is requested, the QIO forwards the reconsideration information to an administrative law judge of the Office of Hearings and Appeals in the Social Security Administration. If an issue in the reconsideration determinations is still in litigation at the end of the 4-year period, the record must be maintained until the litigation has been completed and the time period for filing all appeals has passed.

All information that we require the QIOs to maintain would be used in the event of a hearing or litigation. This information includes the basis for the initial and reconsidered determinations and proof that the QIO met all of the procedural requirements for reconsideration.

Section 478.36 - This section requires QIOs to maintain the records of its reconsideration determinations. We estimate that each QIO may spend 5 minutes a year for each reconsideration determination for files maintenance. Burden for this requirement follows:

2,414 records (times) 5 minutes per year = 201.2 hours

Section 478.42 - Submitting a request for a hearing.

- (a) Where to submit the written request. A beneficiary who wants to obtain a hearing ... must submit a written request to one of the following offices:
- (1) The office of the QIO or QIO subcontractor that made the reconsidered determination.
 - (2) Any Social Security District Office.
 - (3) Any office of the Office of Hearings and Appeals of the Social Security Administration.
 - (4) Any office of the Railroad Retirement Board, in the case of a railroad retiree.

The justification for the above section is the same as that already given for Section 478.18 on submitting a request for reconsideration. The only difference is that a request for a hearing must be postmarked within 60 days from the date on the notice of the QIO's reconsideration determination.

Section 478.42(a) - This section requires a beneficiary who wishes to

obtain an administrative hearing to do so in writing. We do not require a justification or any specific information be included with the request. Therefore, we estimate a party would be able to comply with this requirement in 10 minutes time. Based on data collected for the period of 1 fiscal year, the burden for this section is computed as follows:

42 requests (times) 10 minutes (times) once a year = 7.0 hours

Sections 478.18(a) and (b)	1,207 hours
Section 478.34(a)	1,207 hours
Section 478.34(b)	200 hours
Section 478.36	201 hours
Section 478.42(a)	<u>007hours</u>
Total	2,822 hours

Public

We are estimating costs to the public at the rate of \$13.19 per hour.

Sections 478.18(a) and (b)	1,207 hours =	\$ 15,920.33
Section 478.42(a)	007 hours =	<u>92.33</u>
Total		\$ 16,012.66

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.

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

Section 478.34(a)	1,207 hours =	\$ 18,998.18
Section 478.34(b)	200 hours =	3,148.00
Section 478.36	201 hours =	<u>3,163.74</u>
Total 1,608 hours =		\$ 25,309.92

15. Changes in Burden

Adjustments to the burden are due the correction of arithmetic errors in the last

submission the resulted in slightly higher than usual numbers of respondents, responses, and burden hours.

16. Publication and Tabulation Dates

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

17. Expiration Date

This collection does not lend itself to the displaying of an expiration date because there are no collection instruments.

18. Certification Statement

There are no exceptions to the certification statement.

C. Collection of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.