

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

A. BACKGROUND

This is a reinstatement. 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).

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 are Quality Innovation Network-QIOs, and focus on health care quality improvement efforts.

The scope of this information collection includes that from the 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 decision to discharge or end services if beneficiaries believe that their Medicare Part A Medicare services (e.g. hospital discharge, skilled nursing home care, home health, etc.) are ending too soon. Medicare beneficiaries have the right to file a reconsideration of a BFCC-QIO appeals review determination.

This package does not have a collection instrument.

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). 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 Item 12. A short justification for each requirement is included.

2. Information Users

The requirements in regulation 42 CFR 478.16 Right to Reconsideration are on QIOs to provide information to beneficiary (or their representative), provider or

practitioner 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) and/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.

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 electronic means.

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 August 29, 2025 (90 FR 42246). We received one comment. The commenter indicated that the government has violated the

law concerning some matter involving the commenter his/her family. The comment is out of scope of the proposed information collection and therefore cannot be addressed.

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 sensitive questions associated with this information collection.

12. Estimate of Burden (Hours and Wages)

Section 478.18 - Request for reconsideration.

In the event that a beneficiary, provider, 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 affected party's request must be filed within 3 calendar days of receipt of the notice of preadmission or within 60 calendar days of the date on the notice of any other initial determination. The request must be in writing and serves as proof of meeting these timeframes and cannot be disputed by the QIO.

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, or practitioner would be able to comply with this requirement in 30 minutes. Based on previous data collected for BFCC-QIO contracts, the burden for these sections is computed as follows:

$$20,129 \text{ requests} \times .50 \text{ hours} \times \text{once a year} = 10,065 \text{ hours}$$

$$10,065 \text{ hours} \times \$44.24 = \$445,276$$

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. The adjusted hourly rate for this position is \$44.24. <https://www.dol.gov/sites/dolgov/files/VETS/files/TAP-EFCT-ParticipantGuide-5.1-J-Fillable.pdf>

Section 478.34 - Notice of a reconsidered determination.

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 Medicare Administrative Contractor (MAC) 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 MAC 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 years 1 and 2 of the five BFCC-QIO contracts, the burden for all QIOs is calculated as follows:

$$20,129 \text{ requests} \times .50 \text{ hours} \times \text{once a year} = 10,065 \text{ hours}$$

$$10,065 \text{ hours} \times \$44.24 = \$445,276$$

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 previous data collected, the burden for this section is computed as follows:

$$300 \text{ (QIO) notices} \times .1666 \text{ hours} \times 1 \text{ year} = 50 \text{ hours}$$

$$50 \text{ hours} \times \$44.24 = \$2,212$$

$$300 \text{ claim reopened} \times .50 \text{ minutes (times)} \text{ once a year} = 150 \text{ hours}$$

$$150 \text{ hours} \times \$44.24 = \$6,636$$

Section 478.36 - Record of reconsideration.

To be consistent with current Medicare practice, we are requiring QIOs to maintain the reconsideration information for at least 6 years when a QIO finds against a beneficiary. 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 6-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:

$$20,129 \text{ records} \times .0833 \text{ hours} \times 1 \text{ year} = 1,677 \text{ hours}$$

$$1,677 \text{ hours} \times \$44.24 = \$74,190$$

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 previously collected, the burden for this section is computed as follows:

$$42 \text{ requests} \times .1666 \text{ hours} \times 1 \text{ year} = 7 \text{ hours}$$

$$7 \text{ hours} \times 44.24 = \$310$$

Total Burden Table

Section	Response Time	Cost
478.18 (a)	0	0
478.18 (b)	10,065	445,276
478.34 (a)	10,065	445,276
478.34 (b)	200	8,848
478.36	1,677	74,190
478.42	7	310
Total	22,014	973,900

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
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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 did not change however, the cost did increase due to the wage rates being updated. The cost increased from \$867,791 to \$973,900.

16. Publication and Tabulation Dates

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

17. 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. Collection of Information Employing Statistical Methods

There are no statistical methods employed in this information collection.