
CMS Manual System

Pub. 100-10 Medicare Quality Improvement Organizations

Department of Health &
Human Services (HHS)
Centers for Medicare &
Medicaid Services (CMS)

Transmittal 23

Date: December 3, 2015

SUBJECT: QIO Manual Chapter 13 – “Management”

I. SUMMARY OF CHANGES: This revision of the QIO Manual provides general updated language consistent with current program operations.

NEW/REVISED MATERIAL – December 3, 2015
December 3, 2015

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual not updated.)
(R = REVISED, N = NEW, D = DELETED) – (Only one per row)

R/N/D	Chapter/Section/Subsection/Title
R	13/Table of Contents
R	13/Internal Quality Improvement Program (IQIP)
R	13/13000/Purpose and Objectives of the Internal Quality Improvement Program (IQIP)
R	13/13010/IQIP Requirements, Control Process, and Reporting
D	13/13020/IQIP Control Process
D	13/13030/Analysis and Reporting Requirements
R	13/Documentation and Record Retention
R	13/13100/ Introduction
R	13/13110/QIO Documentation
R	13/13115/Timeframes for Retaining QIO Review Documentation
D	13/13120/ Medical Records
R	13/13125/Timeframes for Retaining Patient Medical Records
D	13/DATA Exchange Reports
D	13/13200/Purpose of Data Exchange Reports
D	13/13210/Reporting Requirements
D	13/13220/QIO/Intermediary Data Exchange Reports

III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
X	Manual Instruction
	Confidential Requirements
	One-Time Notification
	One-Time Notification – Confidential
	Recurring Update Notification

*Unless otherwise specified, the effective date is the date of service.

Quality Improvement Organization Manual

Chapter 13 - Management

Table Of Contents (Rev.23, Issued: 12-03-15)

Transmittals for Chapter 13

(New)

INTERNAL QUALITY IMPROVEMENT PROGRAM (IQIP)

- 13000 *Purpose and Objectives of the Internal Quality Improvement Program (IQIP)*
- 13010 *IQIP Requirements, Control Process, and Reporting*

DOCUMENTATION AND RECORD RETENTION

- 13110 *QIO Documentation*
- 13125 Timeframes for Retaining **Patient** Medical Records

INTERNAL QUALITY IMPROVEMENT PROGRAM (IQIP)

13000 - Purpose and Objectives of the Internal Quality *Improvement* Program (IQIP)

(Rev. 23, Issued: 12-03-15, Effective: 12-03-15, Implementation; 12- 03-15)

Each QIO must develop and maintain an Internal Quality Improvement Program (IQIP), also known as an Internal Quality Control (IQC) program or a Continuous Internal Quality Improvement Program (CIQIP), in accordance with provisions in its QIO contract. The purpose of the IQIP requirement is to support and foster an environment of continuous quality improvement within the QIO through ongoing assessment and improvement in areas that are critical for successful contract performance. The objectives of the contractual requirements for an IQIP are to:

- *Demonstrate continuous improvement in the quality of services provided by QIOs in support of the performance objectives, functions, tasks, and subtasks identified in QIO contracts*
- Develop and implement a plan that ensures all aspects of QIO activities run efficiently, comply with the contract, and are consistent with CMS's goals and objectives for the *QIO contract*
- *Document and share with CMS, other QIOs, providers, or key stakeholders, its lessons learned in carrying out its functions to help advance the quality and effectiveness of the QIO program*
- Improve the reliability, accuracy, consistency, and timeliness of data *analysis and reporting*, and case review processing and decision-making
- *Provide contract services that consider and meet the needs of customers, and result in high levels of customer satisfaction*
- *Identify opportunities to enhance internal and external customer satisfaction, including but not limited to the need for and development of additional provider, practitioner, beneficiary, or family/caregiver education regarding QIO review processes and criteria*
- Ensure the support, understanding, and participation of all beneficiaries, practitioners, providers, and other constituencies that are affected by QIO activities
- *Ensure compliance with the requirements of statutes, regulations, policy, and the QIO contracts*

13010 - IQIP Requirements, Control Process, and Reporting

(Rev. 23, Issued: 12-03-15, Effective: 12-03-15, Implementation: 12-03-15)

Every QIO shall document and implement an IQIP that encompasses the tasks, subtasks, major activities, deliverables, reporting, and contract administrative functions such as financial management defined in its contract with CMS.

IQIPs must address the following requirements, and each QIO must implement internal quality control processes that strengthen performance of the work identified in its QIO contract:

- Identify tasks, subtasks, and/or activities that are included
- *Identify measures and/or monitors of performance* for each of the tasks, subtasks, and/or activities
- *Identify* plans for how *the QIO* will meet goals and targets
- *Implement control* measures that enable *the QIO* to determine if performance is proceeding acceptably during the course of the contract to enable *the QIO to adjust course when necessary and meet intermediate and/or process goals or targets that the QIO has set for identified tasks, subtasks, and/or activities and evaluation targets specified in the contract*
- At least *quarterly*, or more often as performance indicates or as otherwise directed, use measures, results, and other information to assess whether *the QIO is* likely to

meet goals *and* targets. Analyze any causes of failure and *propose and implement* changes in the process(es) that *the QIO* believes will improve performance

- *Maintain documentation of:*
 - *Measures, thresholds, measurement timeframes*
 - *Results of measurement*
 - *Method(s) used to analyze causes of failure and results of the analysis*
 - *Proposed and selected process improvements that address the causes of failure*
 - *Implementation of improvement actions and their impact*
 - *Communication of results and actions*
- *Assess* whether improvements were successful and *make* adjustments to the process, if needed

When requested by CMS, QIOs shall report and make available documentation of *the QIO's continuous internal quality improvement process controls including* measurements, monitoring, plan, results, improvement actions, *and lessons learned* for all tasks, subtasks, and major activities.

DOCUMENTATION AND RECORD RETENTION

13100 - Introduction

(Rev. 23, Issued: 12-03-15, Effective: 12-03-15, Implementation; 12- 03-15)

QIOs shall maintain complete and accurate documentation of all *QIO* activities in a manner that ensures that:

- *QIO* activities can be validated during auditing procedures
- Documentation is available to verify performance of all *quality improvement and case review functions as defined in each QIO contract*
- Activities and documentation are handled in a manner that ensures the confidentiality of all QIO data in accordance with 42 CFR Part 480

13110 - QIO Documentation

(Rev. 23, Issued: 12-03-15, Effective: 12-03-15, Implementation; 12- 03-15)

QIOs shall maintain file records and establish internal control systems that at a minimum enable it to perform the following functions as required under the contract:

- *Provide an accurate and complete record of all in-progress and completed activities, correspondence, and analyses, including a record of times and dates, in connection with every individual case review effort*
- *Identify all individuals, roles, responsibilities, and determinations made as part of every individual case review effort*

- *Identify all quality improvement activities in-progress and completed, to include provider/practitioner improvement plans and points of contact for each quality improvement activity*
- *Furnish complete and accurate documentation to CMS and authorized third parties upon request*
- *Comply with requirements for protection of all data and records in accordance with CMS security and privacy policies (see QIO Manual Chapters 8 and 10, and 42 CFR Part 480) and procedures identified in the QIO contract*
- *Transfer to CMS, or to a successor QIO contractor as directed by CMS, any records and files, including patient medical records, necessary to perform the business functions of the QIO that are identified in the QIO contract*

Case Review Documentation Requirements

At a minimum, *QIO case* review documentation must include:

- Case identifiers (e.g., Health Insurance Claim (HIC) number)
- Determinations (outcomes) of each review (e.g., approval, denial, coding decision, quality concern)
- Medical review criteria used in the review
- Verification that appropriate review was performed
- Name and title of each reviewer who contributed to the determination (e.g., review coordinator, physician advisor)
- Dates of each review function that demonstrate compliance with review timeframes (e.g., date case was identified for review, dates records requested and received, dates review initiated and completed, dates notices issued, if applicable)
- Any referrals to other QIOs or external agencies

Denial Determinations, Diagnostic Related Group (DRG) Assignment Changes, and Confirmed Quality Concerns

If the QIO determination results in an initial or technical denial, DRG assignment change, or confirmed quality concern, *the* review documentation must also include:

- The detailed basis (e.g., all documentation already in your possession for the case) for the denial determination (including limitation on liability determinations and documentation errors), DRG assignment change, or confirmed quality concern
- A copy of the notice that was sent to all parties, identification of each party, and the date the notice was mailed or delivered
- The returned envelope and notice, if the notice was subsequently returned as undeliverable or receipt refused

Reconsideration and/or Provider Request for a Review of a QIO DRG Determination

If the QIO conducts a reconsideration *or review of the QIO DRG determination, its* review documentation must also include:

- *Documentation* of the reconsideration or review request

- The detailed basis for the reconsideration (including the limitation on liability determination) or review determination
- A copy of the reconsideration or review *determination letter* that was sent to all parties, identification of each party, and the date on which the notice was mailed or delivered
- The returned envelope and notice, if the notice was subsequently returned as undeliverable or receipt refused

Format of QIO Case Review Documentation

QIOs shall retain case review documentation in an easily retrievable format such as hard copy, *electronic file record, or as specified in its contract.*

13115 - Timeframes For Retaining QIO Review Documentation – *(Rev. 23, Issued: 12-03-15, Effective: 12-03-15, Implementation; 12- 03-15)*

Retain copies of *all case* review documentation as follows:

Approved Reviews

Retain *all* review documentation for 12 months from the date review is completed. *Approved reviews, as used in this instruction, refer to initial reviews of medical necessity, quality, or appropriateness of healthcare services conducted by a QIO review associate and/or a physician peer reviewer in which there are no confirmed issues at the completion of the reviews identified in 42 CFR 476.71.*

Negative Determinations

In accordance with regulations at 42 CFR 476.94(e), retain *all* review documentation of initial denial determinations and DRG assignment changes for *six* years from the date the services in question are furnished. In addition, retain *all* review documentation of confirmed quality concerns for *six* years from the date the services in question are furnished.

DRG Review Determinations

Retain *all* review documentation of DRG assignment change review determinations, *including re-reviews*, for *six* years from the date the services in question are furnished.

Reconsideration Determinations

In accordance with regulations at 42 CFR 478.36, retain all review documentation of reconsideration determinations for four years after the date on the notice of the QIO's reconsidered determination, or until litigation is completed and the time period for filing all appeals has passed, whichever is later.

Audits

Ensure that the documentation is readily retrievable within 10 working days for any auditing process that may be required by CMS. If an audit is conducted by CMS, retain

all review documentation for three years from the date of the audit or the *timeframes for retaining documentation* specified in this Manual, whichever is later.

13125 - Timeframes for Retaining Patient Medical Records

(Rev. 23, Issued: 12-03-15, Effective: 12-03-15, Implementation: 12-03-15)

Retain copies of patient medical records as follows:

Approved Reviews

Retain patient medical records for at least 90 days from the date review is completed.

Negative Determinations

Retain patient medical records for initial denial determinations, DRG assignment changes, and confirmed quality concerns for 12 months from the date review is completed.

Reconsideration Determinations

Retain patient medical records for at least four years after the date of the QIO reconsideration determination notice or the time period for completion of litigation and for filing all appeals whichever is the later as defined in 42 CFR 478.36.