CMS Manual System	**Department of Health & Human Services (DHHS)**
Pub 100-10 Medicare Quality Improvement Organization	**Centers for Medicare & Medicaid Services (CMS)**
Transmittal 19	**Date: May 1, 2015**

SUBJECT: QIO Manual Chapter 1 – "Background, Eligibility and Responsibilities"

I. SUMMARY OF CHANGES: The Quality Improvement Organization (QIO) Program originated with the Peer Review Improvement Act of 1982 (P.L. 97-248, §§ 141-143, 96 Stat. 324) and is authorized by Title XI Part B and Title XVIII the Social Security Act (the Act). The QIO provisions in the Act were most recently amended in 2011 by the Trade Adjustment Assistance Extension Act (P.L. 112-40, § 261, 125 Stat. 401).

The 2011 amendments apply to QIO contracts entered into or renewed on or after January 1, 2012. The Trade Adjustment Assistance Extension Act of 2011 amended 42 U.S.C. Sections 1320c–1 to 1320c–5, 1320c–7, 1320c–9, 1320c–10, 1395g, 1395k, 1395u, 1395x, 1395y, 1395cc, 1395dd, 1395ff, 1395mm, 1395pp, and 1395ww.

Revisions to the QIO Manual address the following statutory (Title II, Part B of the Act codified at 42 U.S.C. Sections 1320c through 1320c12) and regulatory changes (42 CFR Parts 475 through 480):

- Substitutes "quality improvement" and "the quality improvement organizations" in place of references to "the utilization and quality control peer review" and "peer review organizations"
- Changes criteria for the organizations entitled to contract with CMS, and provides broader authority for the Secretary to set the number and geographic scope of QIO contracts
- Changes authorities related to the functions performed by QIO contractors, the term of QIO contracts, and procedures for contract termination or renewal

Chapter 1 of the QIO Manual now includes information about eligibility, contract term, and contract renewal that were previously addressed in Chapter 2 of the QIO Manual. Chapter 2 of the QIO Manual will be rescinded.

EFFECTIVE DATE: May 1, 2015
**Unless otherwise specified, the effective date is the date of service.*
IMPLEMENTATION DATE: May 1, 2015

Disclaimer for manual changes only: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

II. CHANGES IN MANUAL INSTRUCTIONS: (N/A if manual is not updated)
R=REVISED, N=NEW, D=DELETED

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/1000/Authority
R	1/1005/QIO Program Purpose
R	1/1010/QIO Responsibilities
R	1/1015/QIO Eligibility

R/N/D	CHAPTER / SECTION / SUBSECTION / TITLE
R	1/1020/QIO Contract Term and Renewal
R	1/1025/Centers for Medicare & Medicaid Services (CMS) Role

III. FUNDING:

For Medicare Administrative Contractors (MACs):

The Medicare Administrative Contractor is hereby advised that this constitutes technical direction as defined in your contract. CMS does not construe this as a change to the MAC statement of Work. The contractor is not obliged to incur costs in excess of the amounts allotted in your contract unless and until specifically authorized by the Contracting Officer. If the contractor considers anything provided, as described above, to be outside the current scope of work, the contractor shall withhold performance on the part(s) in question and immediately notify the Contracting Officer, in writing or by e-mail, and request formal directions regarding continued performance requirements.

IV. ATTACHMENTS:

Manual Instruction

Quality Improvement Organization Manual

Chapter 1 - Background, *Eligibility*, and Responsibilities

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(*Rev. 19; 05-01-15*)

Transmittals for Chapter 1

1000 -Authority

(Rev. 19, Issued: 05-01-15, Effective: 05-01-15, Implementation: 05-01-15)

The Quality Improvement Organization (QIO) Program is authorized by Title XI Part B and Title XVIII of the Social Security Act (the Act). Citations in the Act indicate where the governing statutes for the QIO Program are codified in the United States Code (U.S.C.). Title XI Part B appears in the United States Code as 42 U.S.C. Sections1320c.-1320c-8, and Title XVIII appears in the United States Code as 42 U.S.C Sections 1395-1395ccc. The administrative entity responsible for the QIO Program is the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services. Applicable regulatory provisions for the QIO Program are in Title 42 of the Code of Federal Regulations (CFR).

The regulatory authorities and governing statutes for the QIO Program are as follows:

Title and Part	***CFR Heading***	***Relevant Sections***	***Social Security Act and U.S.C Provisions***	***Summary***
42 CFR Part 405	*Determinations, Redeterminations, Reconsiderations and Appeals under Original Medicare (Parts A and B)*	*405.900 to 990*	*Section 1869 (42 U.S.C. 1395ff)*	*Regulations governing payment of Medicare claims including procedures related to initial determination reviews performed by QIOs (See: 405.204 and 405.900-990).*
42 CFR Part 405	*Expedited Determinations and Reconsiderations of Provider Service Terminations, and Procedures for and Inpatient Hospital Discharge Reviews*	*42 CFR 405.1200 to 1208*	*Section 1869(b)(1)(F) (42 U.S.C. 1395ff(b)(1)(F))*	*Beneficiary rights to expedited determinations and hospital requests for expedited QIO review (See: 405.1200 -1208)*
42 CFR Part 412	*Prospective Payment Systems for Inpatient Hospital Services*	*412.42 to 48, 412.82 to 84, 412.508*	*Section1866(a)(1)(F) and (a)(3) (42 U.S.C. 1395cc) and 1154(a)(4) and (14) (42 U.S.C. 1320c-3(a)(4) and (14))*	*Requires hospitals to have agreements with QIOs for performance of Section 1154(a)(4) and (14) functions (See: Section 1866(a)(1)(F)). Requires hospitals to have agreements with QIOs and provides for QIO reviews of medically unnecessary inpatient hospital services (See: 412.42-48) and reviews of extended length of stay cases and high cost cases (See: 412.82-84). Requires long-term care hospitals to have an agreement with an QIO for reviews of admissions and*

Title and Part	*CFR Heading*	*Relevant Sections*	*Social Security Act and U.S.C Provisions*	*Summary*
				quality of care (See: 412.508)
42 CFR Part 422 (Subparts D and M)	*Medicare Advantage Program*	*422.153, 422.562, 422.564, and 422.622*	*Section 1852 and 1154(a)(4)(B), 1154(a)(14) (42 U.S.C. 1320c-3(a)(14))*	*Requires Medicare Advantage (MA) Plans to conduct and document performance improvement and QIOs to collect, acquire, and furnish information about MA Plans to CMS as defined in 42 CFR 475 (See: 422.153). Requires MA Plans to establish complaint, grievance, and inpatient discharge procedures for review of its services by a QIO (See: 422.562, 422.564, and 422.622)*
42 CFR Part 475	*Quality Improvement Organizations*	*475.1 to 475.107*	*Sections 1151 – 1160 of the Social Security Act (42 U.S.C.1320c – 1320c-12)*	*Specifies eligibility requirements to become a QIO selected by CMS and defines the QIO contract term*
42 CFR Part 476	*Quality Improvement Organization Review*	*476.1, 476.70 to 476.170*	*Section 1154 of the Social Security Act (42 U.S.C.1320c-3)*	*Defines the QIO functions including the scope of case review*
42 CFR Part 478	*Reconsiderations and Appeals*	*478.10 to 478.48*	*Sections 1154 and 1155 of the Social Security Act (42 U.S.C.1320c-3 and 1320c-4)*	*QIO procedures for reconsiderations or hearings related to its diagnostic coding or payment determinations*
42 CFR Part 480	*Acquisition, Protection, and Disclosure of Quality Improvement Organization Information*	*480.101 to 480.145*	*Section 1160 of the Social Security Act (42 U.S.C.1320c-9)*	*QIO confidentiality and disclosure responsibilities related to information it is authorized to collect, acquire, or generate*
42 CFR Part 482	*Conditions of Participation for Hospitals*	*482.30 and 482.21*	*Section 1861(e)(6) and 1861(k) of the Social Security Act (42 U.S.C. 1395x)*	*Requires hospitals to have a utilization review plan, which it may meet by having reviews performed by a QIO (see: 482.30).* *Requires hospitals to conduct and*

Title and Part	*CFR Heading*	*Relevant Sections*	*Social Security Act and U.S.C Provisions*	*Summary*
				document performance improvement projects and determine whether to participate in QIO cooperative projects (See: Section 482.21).
42 CFR Part 489	*Provider Agreements and Supplier Approval*	*489.20(e)and 489.24(h)*	*Sections 1866(a)(1)(F) and (a)(3) and 1867(d) of the Social Security Act (42 U.S.C. 1395cc and 42 U.S.C. 1320c-3(a)(16))*	*Requires hospitals to maintain an agreement with QIOs to allow for review of the admissions, quality, appropriateness, and diagnostic information related to inpatient services (See: 489.20(e)). Provides for QIO reviews of hospital compliance with Emergency Medical Treatment and Labor Act (See: Section 489.24 (h))*
42 CFR Part 1004	*Imposition of Sanctions on Health Care Practitioners and Providers of Health Care Services by a Quality Improvement Organization*	*1004.1 to 1004.140*	*Section 1156(a) of the Social Security Act (42 U.S.C. 1302 and 1320c-5)*	*Review, notice, and reporting procedures for QIOs to recommend a sanction to the Office of the Inspector General (OIG). QIOs are not responsible for the imposition of sanctions.*

1005 - *QIO Program* Purpose

(Rev. 19, Issued: 05-01-15, Effective: 05-01-15, Implementation: 05-01-15)

CMS contracts with QIOs to perform core functions that include case review and quality improvement. Sections 1152 and 1153(a), (b), (c), and (e) of the Social Security Act and 42 CFR Part 475.101 through 475.103 define requirements for an entity to be awarded a contract to perform QIO functions.

The case review functions of a QIO include review of healthcare services and items for which payment is made under Medicare Parts A, B, C, or D to determine whether services or items are reasonable, medically necessary, and allowable, meet professionally recognized standards of care, or in the case of inpatient care, could be provided more economically on an outpatient basis or in an inpatient facility of a different type. Generally, case reviews must be performed by a healthcare practitioner in the same professional field as the healthcare practitioner who ordered or furnished the services under review. The QIO must perform case review functions as outlined in 42 CFR Part 476 and as defined in its contract with CMS. Other chapters of this manual provide more specific guidance on the various case review functions.

Quality improvement functions may include technical assistance, data analysis, and stakeholder engagement activities that promote evidence-based healthcare practice and patient-centered care principles to improve

healthcare quality of care, improve outcomes to beneficiaries, and lower costs. The QIO must perform quality improvement functions consistent with the terms of its contract with CMS. Quality improvement functions may include, but are not limited to, the following:

- *Engaging patients, families, and care-givers with the goal of increasing patient knowledge, skill, and confidence to take an active role in managing their health and healthcare*
- *Technical assistance related to CMS quality measures across settings to help providers and practitioners meet standards*
- *An activity designed to serve as a catalyst and support for quality improvements that may relate to safety, healthcare, health, and value, and involve providers, practitioners, beneficiaries, and/or communities*

1010 -QIO Responsibilities

(Rev. 19, Issued: 05-01-15, Effective: 05-01-15, Implementation: 05-01-15)

Only those entities that hold a contract with CMS to perform as a QIO are QIOs. QIOs perform a function or functions defined in Section 1154(a) of the Social Security Act (42 U.S.C. 1320c-3(a)) in accordance with the terms that CMS defines in its QIO contracts.

QIO contracts may require performance of one or more functions governed by statute as defined in 42 U.S.C. 1320c-3(a)(1) through (18). These statutory responsibilities may include the following:

1. *Review the provision of health care services and items for which payment may be made. Involve healthcare practitioners of the type under review in such reviews. Determine through review whether services were reasonable and medically necessary, meet professionally recognized standards, and, if provided in an inpatient setting, could be provided more economically on an outpatient basis or in an inpatient facility of a different type. (42 U.S.C. 1320c-3(a)(1))*
2. *Determine, on the basis of the review described above, whether payment shall be made, provided that determinations to deny payment because the quality of care did not meet professional standards are based on criteria developed by the Secretary (42 U.S.C. 1320c-3(a)(2))*
3. *Notify the healthcare provider, patient, and the agency or organization responsible for the payment of claims of the review determination within specific parameters (42 U.S.C. 1320c-3(a)(3))*
4. *Conduct a reasonable proportion of quality of service reviews among the different cases and settings. Review both inpatient and outpatient services provided by Medicare cost plans under section 1876 pursuant to a risk-sharing contract. Maintain a beneficiary outreach program designed to apprise individuals receiving care under Medicare health plans of the QIO program. (42 U.S.C. 1320c-3(a)(4))*
5. *Consult with nurses and other professional healthcare practitioners and providers of healthcare services with respect to the organization's responsibility for the review of the professional activities of such practitioners and providers (42 U.S.C. 1320c-3(a)(5))*
6. *Apply professionally developed norms of care, diagnosis, and treatment. Provide a physician representative to meet several times a year with medical and administrative staff of each hospital whose services are reviewed by the organization. Publish not less often than annually its review findings. (42 U.S.C. 1320c-3(a)(6))*
7. *Utilize the services of persons who are practitioners of, or specialists in, the various areas it reviews, make professional inquiries, examine pertinent records, and inspect facilities in support of its reviews (42 U.S.C. 1320c-3(a)(7))*
8. *Carry out reviews to approve exceptions to the payment exclusion for assistants at surgery in a cataract operation as specified in Section 1862(a)(15) of the Social Security Act (42 U.S.C. 1320c-3(a)(8))*
9. *Collect, maintain, and permit access to information relevant to its functions and notify appropriate state boards in the event of a violation of section 1156(a) (42 U.S.C. 1320c-3(a)(9))*
10. *Coordinate activities for economical and efficient operation of the program (42 U.S.C. 1320c-3(a)(10))*
11. *Make available its facilities and resources for contracting with private and other public entities that pay for health care to provide similar review services (42 U.S.C. 1320c-3(a)(11))*

12. *Review ambulatory surgical procedures specified pursuant to section 1833(i)(1)(A) of the Social Security Act (42 U.S.C. 1320c-3(a)(12))*
13. *Review early readmission cases (42 U.S.C. 1320c-3(a)(13))*
14. *Review all written complaints from Medicare beneficiaries about the quality of services (42 U.S.C. 1320c-3(a)(14))*
15. *Perform on-site reviews (42 U.S.C. 1320c-3(a)(15))*
16. *Upon request from the Secretary or CMS pursuant to section 1867(d) of the Act, review hospital and physician performance for compliance with the Emergency Medical Treatment and Labor Act (42 U.S.C. 1320c-3(a)(16))*
17. *Offer quality improvement assistance pertaining to prescription drug therapy to providers, practitioners, and Medicare health plans (42 U.S.C. 1320c-3(a)(17))*
18. *Perform activities deemed necessary by the Secretary for purposes of improving the quality of care (42 U.S.C. 1320c-3(a)(18))*

In order to fulfill these statutory responsibilities, QIOs may perform activities that include, but are not limited to, the following:

- *Establishing methods and procedures for involvement of healthcare practitioners in performing reviews of healthcare services and investigating complaints*
- *Maintaining current knowledge of Medicare programs in order to conclusively determine whether payments must be made for services under Title XVIII of the Social Security Act*
- *Entering into Memoranda of Agreement with healthcare providers, payers, and other organizations prior to conducting Medicare case reviews in the service areas and for the types of cases it will have authority to review, and conducting outreach to inform beneficiaries about how to exercise their right to QIO reviews*
- *Establishing procedures for notifying any patient, practitioner, provider, and any organization responsible for payment to communicate with them about the QIO review determination and rights to reconsideration or appeal*
- *Planning for and maintaining sufficient staffing to assure that resources are allocated to performing reviews by duly licensed professionals for all of the different cases and settings*
- *Establishing methods for identifying cases where there is a likelihood that quality of services do not meet professionally recognized standards of care*
- *Coordinating activities and information exchanges across QIO contractors and Program stakeholders such as public and private organizations involved in healthcare delivery*
- *Publishing at least annually a report of QIO activities and findings*
- *Performing any other services to improve the quality of care for services under Title XVIII of the Social Security Act that CMS determines are appropriate for performance under QIO contract awards*
- *Maintaining procedures to continuously monitor, mitigate, or avoid any actual, potential, or apparent conflicts of interest of the QIO organization, its employees and subcontractors when performing any function of the QIO contract*

Section 1153 of the Social Security Act requires that CMS ensure there is no duplication of the functions carried out by QIOs if more than one QIO operates in the same area. QIO contractors should assist CMS and work together with other stakeholders to identify and mitigate any duplication of effort identified in their geographic or service area.

1015-*QIO Eligibility*

(Rev. 19, Issued: 05-01-15, Effective: 05-01-15, Implementation: 05-01-15)

Section 1152 of the Social Security Act and 42 CFR Part 475 provide the authority for CMS to enter into contracts with entities to perform QIO functions. In awarding such contracts, CMS complies with the Federal Acquisition Regulation (Title 48 CFR) unless the Secretary determines that a specific provision is inconsistent with the purposes of Title XI, Part B of the Social Security Act. In order to be awarded a QIO contract, an entity must meet the following qualifying requirements:

- *Have a governing body that includes at least one individual who is a representative of healthcare providers and at least one individual who is a representative of consumers (42 CFR 475.101(a))*

- *Demonstrate capability to meet the eligibility requirements and perform the activities specified by CMS in the solicitation for award of a QIO contract (42 CFR 475.101(b)(1))*
- *Demonstrate the ability to perform case reviews as set forth in 42 CFR 475.102 and/or perform quality improvement as set forth in 42 CFR 475.103 (42 CFR 475.101(b)(2)*
- *Demonstrate the ability to actively engage beneficiaries, families, and consumers in case reviews and/or quality improvement activities (42 CFR 475.101(c))*
- *Demonstrate the ability to perform QIO functions with objectivity and impartiality and in a fair and neutral manner (42 CFR 475.1010(d))*
- *Demonstrate that it is not a healthcare facility, affiliate, or payer organization. QIOs may not perform reviews of healthcare services other than the review of the quality of care (42 CFR 475.105).*

Pursuant to Section 1153(c) of the Social Security Act, the contract between CMS and a QIO must provide the right for CMS to evaluate the quality and effectiveness of the QIO in carrying out QIO functions. Further, CMS has the right to negotiate contractual performance objectives and to provide specifications or modifications based on regional or national norms for QIO contractors performing the quality improvement and case review functions.

CMS has the responsibility to determine the efficient and effective administration of the QIO Program, establish the program structure, determine the number of contracts and limitations, define the service areas, solicit for QIO services, and negotiate awards. CMS abides by the Federal Acquisition Regulation excepts when Section 1153(e) of the Social Security Act permits an exception.

1020 – *QIO Contract Term and Renewal*

(Rev. 19, Issued: 05-01-15, Effective: 05-01-15, Implementation: 05-01-15)

Beginning with contracts awarded after January 2012 and pursuant to Section 1153(c)(3) of the Social Security Act and 42 CFR 475.107 the contract between CMS and a QIO has a five-year term. Section 1153(b)(4) of the Social Security Act further grants CMS authority to renew QIO contracts for additional five-year terms of performance. CMS must assess the performance of QIO contractors in accordance with the contract and the applicable Federal Acquisition Regulations defined in Title 48 of the CFR prior to determining whether to renew a QIO contractor for an additional five-year term. Further, any CMS decision to terminate or not renew an awarded QIO contract is not subject to judicial review under the authorities provided in Section 1153(f) of the Social Security Act.

1025- *Centers for Medicare & Medicaid Services (CMS) Role*

(Rev. 19, Issued: 05-01-15, Effective: 05-01-15, Implementation: 05-01-15)

CMS was established in March 1977 to combine healthcare financing and quality *improvement* programs into a single agency. CMS is responsible for the Medicare Program, federal participation in the Medicaid Program, the Quality Improvement Organization (QIO) Program, and a variety of other health care quality *improvement* programs.

CMS's primary mission is to administer its programs in a manner that:

- Promotes the timely delivery of appropriate, quality healthcare to beneficiaries
- Ensures that beneficiaries are aware of the services for which they are eligible
- Ensures that those services are accessible and of high quality
- Promotes efficiency and quality within the total healthcare delivery system
- *Promotes the award and administration of all CMS contracts in accordance with the Federal Acquisition Regulations (48 CFR)*

Central Office Policy-making Responsibility: Overall policy-making responsibility for administration of the QIO Program is centralized in CMS's *Center for* Clinical Standards and Quality. The CMS *Central Office* is responsible for:

- Monitoring and overall administrative control of the QIO Program, including coordinating with CMS's *Office of Acquisition and Grants Management* on contracts and financial aspects
- Establishing operational policy for the QIO Program
- Developing operational instructions and official interpretations of policy for QIOs and CMS Regional Offices (ROs)

Regional Office Assistance to QIOs: *CMS Regional Offices* are responsible for assuring that QIOs meet applicable federal requirements under the provisions of their contracts *through the duties of Contracting Officer's Representatives*. The *Regional Offices*:

- Provide liaison, direction, and technical assistance to QIOs in the day-to-day management of their operations
- Interpret CMS guidelines, policies, and procedures applicable to QIO activities
- Analyze QIO budgets and spending patterns to assure that funds are economically and appropriately utilized
- Recommend the allocation of funds for conducting additional activities
- Conduct assessments of QIO operations
- Review QIO actions
- Provide feedback to each QIO