

# Quality Improvement Organization Manual

## Chapter 5 - Quality of Care Review

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Note: This chapter is not a substitute for the underlying law. The QIO is responsible for complying with applicable statutes and regulations, as well as the supporting instruction in the manual chapter.

## **5000 – Introduction to Quality of Care Reviews** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

This Chapter provides instructions and guidance for the Beneficiary and Family Centered Care Quality Improvement Organizations (QIOs) to follow in conducting Quality of Care Reviews and for the Quality Innovation Network (QINs) in assisting providers and practitioners in improving the quality of health care through Quality Improvement Initiatives (QIIs). The phrase “quality health care” refers to the degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge.

A Quality of Care Review focuses on whether the quality of services provided to beneficiaries is consistent with professionally recognized standards of health care. In conducting a Quality of Care Review, the QIO is responsible for reviewing actual care and services to determine where the provided care and services fall within the range of professionally recognized standards of health care.

**NOTE:** In the course of conducting a Quality of Care review, if a QIO identifies an issue requiring a different type of review, the QIO must follow the relevant regulations and supporting QIO Manual Chapter instructions specific to that review activity.

## **5010 – Authority for Conducting Quality of Care Reviews** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The statutory and regulatory authority to conduct Quality of Care Reviews is as follows:

§1862(g) of the Social Security Act (the Act) requires that the Secretary enter into contracts with QIOs for the purpose of promoting the effective, efficient, and economical delivery of health care services and of promoting the quality of services of the type for which payment may be made under title XVIII.

§1154(a) (1) (B) of the Act requires that a QIO conduct review to determine whether the quality of services meets professionally recognized standards of health care.

§1154(a)(14) of the Act requires that QIOs conduct appropriate reviews of all written complaints, submitted by beneficiaries or beneficiaries’ representatives, about the quality of services not meeting professionally recognized standards of health care.

§1154(a)(4)(A) of the Act requires that each QIO provide that a reasonable proportion of its activities involve reviewing the quality of services under paragraph (a)(1)(B) and that a QIO reasonably allocates such activities among the different cases and settings (including post-acute care settings, ambulatory settings, and health maintenance organizations).

42 CFR §476.71(a) (2) requires a QIO to determine whether the quality of services meets professionally recognized standards of health care. This is accomplished through the resolution of oral beneficiary complaints, written beneficiary complaints, or the completion of general quality of care reviews.

42 CFR §476.71(a) (5) requires the QIO to determine the completeness, adequacy, and quality of hospital care.

42 CFR §476.71(d) requires the QIO to carry out the responsibilities specified in Subpart C of part 1004 related to investigations and referral for sanctions of providers and practitioners who violate statutory obligations under § 1156 of the Act.

42 CFR §476.110 allows the QIO to use immediate advocacy, when the complaint meets certain criteria, to resolve oral beneficiary complaints obtained within 6 months of the date from which the care giving rise to the complaint occurred.

42 CFR §476.120 requires the QIO to conduct a review based on written beneficiary complaints when the care concerning the complaint occurred no more than 3 years from the date when the care giving rise to the complaint occurred, and explains when the QIO can complete a General Quality of Care Review for certain oral beneficiary complaints.

42 CFR §476.130 explains the QIO's role in reviewing beneficiary complaints, including the scope of the QIO review, medical record requests, types of QIO decisions, and applicable time frames.

42 CFR §476.140 provides the beneficiary and the providers/practitioners with the right to request a reconsideration by the QIO of the initial decision with regard to a complaint , including applicable time frames and issuance of the QIO's final decision, for complaints filed after July 31, 2014.

42 CFR §476.150 explains the procedures applicable to abandoned beneficiary complaints and for reopening reviews.

42 CFR §476.160 explains the General Quality of Care Review procedures, including applicable time frames, scope of the QIO review, medical record requests, and issuance of the QIO's written initial determination.

42 CFR §476.170 explains requirements for the General Quality of Care reconsideration process and issuance of the QIO's final decision.

## **5015 – Organization of Chapter**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The chapter is organized based on the two types of Quality of Care Reviews that QIOs conduct; Beneficiary Complaint Reviews are addressed first (See §§5025-5065), followed by General Quality of Care Reviews. (See §§5100-5125.)

**NOTE:** All references to a beneficiary in this chapter also include the beneficiary representative, unless otherwise indicated.

### Review Type and Description

1. Beneficiary Quality of Care Complaints – Reviews initiated because a beneficiary or the

beneficiary's representative has complained (referred to as Beneficiary Complaint Review) about the quality of care rendered to a Medicare beneficiary

2. General Quality of Care Reviews – Reviews conducted because the QIO has independently identified a potential quality issue or has been referred a quality issue from another entity (referred to as General Quality of Care Review)

#### Sources for Reviews

##### A. Beneficiary Complaint Review Sources

1. A written complaint filed by a beneficiary
2. A oral complaint by a beneficiary where the beneficiary agrees to participate in Immediate Advocacy

##### B. General Quality of Care Reviews Sources

1. Concerns Identified during Other Review Activities: A Quality of Care review conducted when a potential quality of care concern(s) is identified during the course of any other review activity, such as medical necessity reviews, expedited discharge appeals, Emergency Medical Treatment and Labor Act (EMTALA) reviews.
2. When a beneficiary raises a concern, but the beneficiary declines to submit a formal written complaint, and the QIO makes a preliminary determination that the complaint involves a potential gross and flagrant, substantial, or significant quality of care concern, such complaint may be processed as a General Quality of Care Review. For purposes of 42 CFR §476.120(a)(1) and this provision, an anonymous complaint, even if received in writing, is not a “written complaint” sufficient to trigger the beneficiary complaint procedures outlined in 42 CFR §476.130.
3. Referrals include a Quality of Care Review conducted in response to referrals from other entities (e.g., Medicare Administrative Contractors, State-based organizations, the Office of Inspector General, the Office for Civil Rights), including anonymous referrals.
4. Tracking and Trending is a Quality of Care review conducted as a result of tracking and trending or other analysis of data.

#### **Stages of Review by Type**

##### **Beneficiary Complaint Reviews**

The process steps for this review are separated into four stages to facilitate identification of roles and steps associated with various aspects of the process:

- Stage 1: Intake Stage;
- Stage 2: Quality of Care Review Stage;
- Stage 3: Opportunity for Discussion Stage; and

Stage 4: Reconsideration Stage.

**NOTE:** The Social Security Act §1154(a)(14) requires that QIOs conduct an “appropriate review of all written complaints” from Medicare beneficiaries alleging that the quality of services they received did not meet professionally recognized standards of care. For Beneficiary Complaints, the process instructions include a QIO’s authority to offer Immediate Advocacy (See §5035) during the Intake Stage if a written complaint has not yet been received. QIOs may also offer at their discretion a Post-Peer Review alternative dispute resolution process, called Post-Review Advocacy (See §5065), for complaints submitted in writing that Peer Reviewers determine contain no significant quality of care concerns.

### **General Quality of Care Reviews**

The process steps for this review are separated into these three stages to facilitate identification of roles and steps associated with various aspects of the process:

- Stage 1: Intake Stage;
- Stage 2: Quality of Care Review Stage; and
- Stage 3: Reconsideration Stage.

### **5020 – Definitions Related to Quality of Care Reviews (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

**Appointed Representative:** An individual appointed by a beneficiary to represent the beneficiary in the Beneficiary Complaint Review process. See 42 CFR §476.1.

**Authorized Representative:** An individual authorized, under State or other applicable law, to act on behalf of a beneficiary. The authorized representative will have all of the rights and responsibilities of a beneficiary throughout the processing of a Beneficiary Complaint. See 42 CFR §476.1.

**Beneficiary Complaint:** A complaint by a beneficiary or a beneficiary’s representative alleging that the quality of services received by the beneficiary did not meet professionally recognized standards of care. A complaint may consist of one or more quality of care concerns. See 42 CFR §476.1.

**Beneficiary Complaint Review:** A review conducted by a QIO in response to the receipt of a written beneficiary complaint to determine whether the quality of Medicare-covered services provided to the beneficiary was consistent with professionally recognized standards of health care. See 42 CFR §476.1.

**Beneficiary Representative:** An individual identified as an authorized or appointed representative of a beneficiary. See 42 CFR §476.1.

**Corrective Action Plan:** A written plan for correcting poor care that is gross and flagrant or is a substantial violation in a substantial number of cases. See §1156 of the Act, 42 CFR §1004.60, and CMS Publication 100-10, Quality Improvement Organization Manual, Chapter 9, Sanction and Abuse Issues.



**Criteria:** Predetermined elements of health care, developed by health professionals relying on professional expertise, prior experience, and the professional literature, with which aspects of the quality, medical necessity, and appropriateness of a health care service may be compared. See 42 CFR §476.1.

**General Quality of Care Review:** A review conducted by a QIO to determine whether the quality of Medicare-covered services provided to a Medicare beneficiary was consistent with professionally recognized standards of health care. A general quality of care review may be carried out as a result of a referral to the QIO or a QIO's identification of a potential concern during the course of another review activity or through the analysis of data. See 42 CFR §476.1.

**Gross and Flagrant Violation:** A violation of an obligation resulting from inappropriate or unnecessary services, services that do not meet recognized professional standards of care, or services that are not supported by evidence of medical necessity or quality as required by the QIO. The violation must have occurred in one or more instances that present an imminent danger to the health, safety, or well-being of a program patient or place the program patient unnecessarily in high-risk situations. See 42 CFR §476.1.

**Health Care Service or Services:** Services or items for which payment may be made (in whole or in part) under the Medicare or State health care programs. (QIOs review only those services for which payment may be made (in whole or in part) under Medicare.) See 42 CFR §1004.1(b).

**Immediate Advocacy:** An informal alternative dispute resolution process used to quickly resolve an oral complaint a Medicare beneficiary or his/her representative has regarding the quality of Medicare-covered health care received. This process involves a QIO representative's direct contact with the practitioner and/or provider. See 42 CFR §476.1.

**Initial Determination Peer Reviewer:** A practitioner reviewer who makes the interim and final initial determinations in the Quality of Care Review process.

**Medicare Health Plan(s):** For purpose of this Chapter, a collective reference to Medicare Part C Health Plans, Medicare Part D Drug Plans, Cost Plans under section 1876 of the Act, and Health Care Prepayment Plans (HCPPs) under §1833 of the Act.

**Norm:** A pattern of performance in the delivery of health care services that is typical for a specified group. See 42 CFR §476.1.

**Pattern of Care:** Care under question has been demonstrated in more than three instances each of which involved different admissions. See 42 CFR §1004.1(b) Definitions.

**Peer Review:** A review by health care practitioners of services ordered or furnished by other practitioners in the same professional field. See 42 CFR §476.1.

**Peer Reviewer:** A reviewer who is either a physician or other practitioner who matches, as closely as possible, the variables of licensure, specialty, and practice setting of the physician or practitioner under review. The Initial Determination Peer Reviewer and Reconsideration Peer Reviewer must meet the requirements of this definition. See §1154(c) of the Act and 42 CFR

§476.98(a) (1) and (b) for additional criteria. In cases in which there is no peer match available, the QIO may use another physician reviewer without the same expertise. See 42 CFR §476.98(a) (2).

**Physician:** A doctor of medicine or osteopathy, a doctor of dental surgery or dental medicine, a doctor of podiatry, a doctor of optometry, or a chiropractor, as described in §1861(r) of the Act; an intern, resident, or Federal Government employee authorized under State or Federal law to practice as a doctor; and an individual licensed to practice as a doctor as described in this definition in any territory or commonwealth of the United States of America. See 42 CFR § 476.1.

**Practitioner:** An individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients.

**Provider:** A health care facility, institution, or organization, including but not limited to a hospital, involved in the delivery of health care services for which payment may be made in whole or in part. See 42 CFR §476.1.

**Health care practitioners other than physicians:** Refers to health professionals who do not hold a doctor of medicine or doctor of osteopathy degree but who meet all applicable State or Federal requirements for practice of their professions and are in active practice. See 42 CFR §§476.1 and 480.101(b).

**Quality of Care:** The degree to which health care services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. (Definition adopted from The Institute of Medicine).

**Quality of Care Concern:** A concern that care provided did not meet a professionally recognized standard of health care. A general quality of care review or a beneficiary complaint review may cover a single or multiple concerns. See 42 CFR §476.1.

**Quality of Care Review:** A review conducted by a QIO to determine whether the quality of Medicare-covered services provided to beneficiaries was consistent with professionally recognized standards of health care. A Quality of Care Review can be either a Beneficiary Complaint Review or a General Quality of Care Review. See 42 CFR § 476.

**Quality Improvement Initiative:** Any formal activity plan designed to serve as a catalyst and support for quality improvement that uses proven methodologies to achieve these improvements. The improvements may relate to safety, health care, health, and value, and involve providers, practitioners, beneficiaries, and/or communities.

**Reconsideration:** For written beneficiary complaints, reconsideration is the additional review performed by the QIO when requested by the beneficiary and/or the practitioner/provider when any of the parties is not pleased with the outcome of the QIO's Final Determination. See 42 CFR §476.140(a). For General Quality of Care reviews, reconsideration is the additional review conducted by the QIO when requested by the provider and/or practitioner when he/she is not pleased with the outcome of the Initial Determination. See 42 CFR §476.170(a).

**Reconsideration Peer Reviewer:** A Peer Reviewer who conducts the reconsideration segment of a Quality of Care Review.

**Significant Quality of Care Concern:** A determination by a QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

**Standards:** Professionally developed expressions of the range of acceptable variation from a norm or criterion. See 42 CFR §476.1.

**Substantial Violation in a Substantial Number of Cases:** A pattern of providing care that is inappropriate, unnecessary, does not meet recognized professional standards of care, **or** is not supported by the necessary documentation of care as required by the QIO. See 42 CFR §1004.1(b), Definitions.

## **5025 –Beneficiary Complaint Review Overview** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

This guidance and instruction addresses the processes in completing reviews of Beneficiary Complaints.

**NOTE:** The intake person(s) refers to qualified staff as designated by a QIO. The job title may differ within each QIO and duties may be split among different QIO staff.

The guidance covers:

2. Initial intake of information that a QIO Staff Member obtains from a beneficiary. (See §§5030-5030.2). The initial intake of information includes the QIO's determination about the type of review to be conducted—i.e., whether the complaint is appropriate for Immediate Advocacy, and if not, whether the complaint should be processed as a Beneficiary Complaint Review.
3. Immediate Advocacy process to be followed for complaints for which Immediate Advocacy has been offered and accepted. (See §§5035-5035.5.)
4. Beneficiary Complaint process and review instructions. (See §§5040-5055.7.)

### **5025.1 – Eligibility for Beneficiary Complaint Review** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

For a complaint to be eligible for a Beneficiary Complaint Review (see §§5040 – 5055.7), ALL of the following requirements must be met.

The complaint must:

1. Relate to the quality of care received by a beneficiary, regardless of whether the

beneficiary or Medicare paid for the care, but for which payment may otherwise be made under title XVIII;

2. Be written (includes email, facsimile, or hard-copy submission); and
3. Express concern about the quality of care received.

**NOTE:** See §5040.4 (Beneficiary Complaint: Complaints Not Submitted in Writing) for oral complaints.

### **5030 – Beneficiary Complaint Intake – Stage One** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

QIOs may become aware of a potential beneficiary complaint through a phone call or correspondence, including the receipt of a complaint by regular mail, email, or facsimile. The QIO is responsible for ensuring that enough information is obtained from the beneficiary to complete the review, whether Immediate Advocacy or a Beneficiary Complaint Review.

It is anticipated that, in most instances, a beneficiary's initial contact with a QIO about a potential complaint will be made by phone. QIOs may also be referred calls from 1-800 Medicare. For calls to 1-800 Medicare, once the beneficiary indicates, through answering a series of questions, that the call is regarding a complaint related to the quality of care received, the beneficiary is transferred to the appropriate QIO.

CMS developed the Medicare Quality of Care Complaint Form, CMS-10287 (Complaint Form), for beneficiaries to use in submitting a complaint (See Appendix 5-1.1) (See §§5040.1-5040.3 of this Chapter for information about the use of the Complaint Form.)

When a request for information from or on behalf of a beneficiary is received, the QIO must follow 42 CFR §480.132; the QIO must disclose the information to a person whom the beneficiary has identified as his/her representative or has been designated by State law. Under 42 CFR §480.132(c), if the beneficiary has not and is not able to designate a representative and State law has not designated a representative, the QIO determines who is responsible for the beneficiary and makes disclosure to that person.

A beneficiary representative is either appointed by the beneficiary or authorized under applicable law. See 42 CFR §476.1. In situations where the representative does not have any evidence of his/her status, the QIO should inform the representative of the availability of the Appointment of Representative Form. The QIO can either provide the representative with a copy of the form directly or instruct them that they may obtain a copy of the form directly by visiting the CMS forms web page. See Appendix 5-1.2 or visit <http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf>.

CMS expects QIOs to concurrently enter any information received into the CMS-designated case review system (See §5030.4) so that it is readily accessible to pertinent staff.

#### **5030.1 – Scope of Complaint** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

In obtaining information from the beneficiary about the nature or scope of the complaint, the QIO must focus on the episode of care to which the complaint pertains. The beneficiary is not required to identify all specific aspects of the medical care received during the episode in describing the complaint, nor is the beneficiary required to specifically state that the practitioner and/or provider did not “meet professionally recognized standards of care.”

The QIO should not unnecessarily narrow the focus of the scope of a review based on a beneficiary’s statements about why care was problematic because most beneficiaries are not health care practitioners or providers, and thus they do not have sufficient knowledge and/or experience to render such judgments about the care received.

In addition, as the expert in conducting Quality of Care Reviews, a QIO should not focus solely on a beneficiary’s assumptions and/or conclusions about the care received. The beneficiary’s assumptions and/or conclusions may be misleading or not relate to the actual problem encountered. For instance, a beneficiary’s statement about a single problematic aspect associated with an episode of care (e.g., the wait time in the emergency room was too long) or why the beneficiary believes the care did not meet professionally recognized standards of care (e.g., the physician should have ordered a specific test based on the beneficiary’s health condition) may not be the reason the beneficiary received poor care or received appropriate care but experienced a negative outcome.

The following examples are designed to assist QIOs in taking the appropriate approach during review of a Beneficiary Complaint:

- **EXAMPLE 1:** A beneficiary’s spouse contacts the QIO and complains about the care the beneficiary received while in the hospital. In discussing the concerns, the spouse specifically mentions the length of time the beneficiary waited in the emergency room before the beneficiary was admitted. The spouse also mentions that the beneficiary might have received the incorrect medication during the hospital stay.
  - In this scenario, the scope of the QIO’s review is not limited to the wait time in the emergency room and the medication provided to the beneficiary. A QIO’s review should include ALL care the hospital provided to the beneficiary, from arrival in the emergency room through the conclusion of the hospital stay. A QIO must convey information about any Quality of Care Concern for which care did not meet professionally recognized standards of care related to the beneficiary’s hospital stay as well as the QIO’s conclusions about the specific concerns the spouse mentioned (emergency room wait and medication error) in the complaint, even if the standard of care was met for these issues.
- **EXAMPLE 2:** A beneficiary contacts the QIO to complain about medication, which was requested but never received, during a 6-hour stay in a hospital. The beneficiary ultimately left the hospital without receiving medication. During the QIO’s review, the QIO confirms the beneficiary’s description but in addition, the QIO determines that the beneficiary was in a lock-down unit of a psychiatric hospital and should not have been allowed to leave. In this scenario, the scope of the QIO’s review is not limited to the

failure to receive the medication requested.

- The QIO's review should include ALL care provided to the beneficiary by the psychiatric hospital, including the failure to properly lock down the facility, which resulted in the beneficiary being able to leave. The QIO must convey information about any Quality of Care Concern for which care did not meet professionally recognized standards of care related to the hospital stay (failure to properly lock down the facility) as well as the QIO's conclusions about the specific items the beneficiary mentioned (failure to receive requested medication and the length of wait time).
- **EXAMPLE 3:** A beneficiary representative called to complain that an elderly beneficiary who was a relative, had told the representative that the wrong antibiotic medication was given during a recent hospitalization for pneumonia. Through chart review, the QIO discovered that the antibiotic medication was correct and administered timely, but the beneficiary had received an overdose of anti-seizure medication during the same episode of care.
  - The QIO's review must include a review of ALL care provided to the beneficiary during the episode. The QIO must convey information about any Quality of Care Concern for which care did not meet professionally recognized standards of care (i.e. the overdose of the anti-seizure medication) as well as the QIO's conclusions about the specific item the beneficiary representative mentioned (wrong antibiotic medication), even where the QIO's review demonstrates that the standard of care was met for the antibiotic medication.

### **5030.2 – Initial Information Collection**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

After receiving a call from a beneficiary or during the review of a complaint received via correspondence, the QIO should collect and record basic information about the potential complaint in the CMS-designated case review system on an ongoing basis during the course of a review, including completion of the initial contact.

In addition, the QIO must determine whether the complaint is eligible for Immediate Advocacy, or if Peer Review as part of a Beneficiary Complaint Review (under 476.130), or a General Quality of Care Review (under 42 CFR §476.160)) is required during the initial call or contact with the beneficiary.

**NOTE:** Written beneficiary complaints are not eligible for Immediate Advocacy. These steps apply only to telephonic or face-to-face encounters with a beneficiary who is making or has made a complaint about a quality of care concern.

To meet the deadlines and timeframes imposed by 42 CFR §476 for Quality of Care Reviews, QIOs should respond to messages received after normal business hours by close of the next business day.

The following list contains information deemed necessary for the completion of intake process of a beneficiary complaint. The QIO should attempt to collect this information during the initial contact from the beneficiary. Much of the information might already be accessible using the CMS-designated case review system. (See §5030.4.) If specific information is not readily available, the QIO should ensure appropriate follow-up is completed to obtain the information from the beneficiary.

The following information is the minimum necessary for the QIO to perform the initial screening of a beneficiary complaint and must be collected. The QIO should obtain or note the following information:

1. The beneficiary's name, age, date of birth, sex, Healthcare insurance identification number, and race/ethnicity (if willing to provide).
2. The beneficiary's phone number, address, and email address.
3. The name of the caller if other than the beneficiary, including phone number, address, and email address; this person should be e.g. the beneficiary representative.

**NOTE:** If the caller is other than the beneficiary (e.g., beneficiary representative) the QIO must obtain a completed Authorization of Representative Form included in Appendix 5-1.2), prior to continuing with specifics about health care issues and the detailed complaint.

4. The date and time the complaint was received.
5. General information about the health care issue(s) surrounding the complaint. The focus of the information collected must be on the general circumstances related to the episode of care. The beneficiary's assumptions and/or conclusions about the care received, including statements regarding a single problematic aspect associated with an episode of care or why the beneficiary believes the care did not meet professionally recognized standards of care, are not necessary to process the complaint.

**NOTE:** QIOs should avoid narrowly focusing the scope of a review based on the beneficiary's statements about why care was problematic because most beneficiaries are not health care practitioners or providers, and thus they are not likely to have sufficient knowledge and/or experience to render such judgments about the care received. See §5030.1, "Scope of Complaint" for additional instructions regarding the nature of the complaint.

6. The QIO must request the beneficiary's permission to disclose to the practitioner/provider the beneficiary's name and the reason for any medical information requested and document the beneficiary's response. A QIO is required to inform the practitioner and/or provider that the medical information is being requested due to a beneficiary complaint. See 42 CFR §476.130(b) (2).

**NOTE –** The QIO must explain to the beneficiary that if he/she chooses not to disclose his/her name as part of the complaint process, the complaint may be processed as a General

Quality of Care Review, if the QIO deems appropriate. (See §5100 General Quality of Care Review.)

Any additional information that may be helpful in processing the complaint should also be documented in the CMS case review system -- e.g., notes related to the conversation with the beneficiary, any discussions with internal staff about the complaint.

In order to properly conduct screening, the QIO must be able to identify the following from the information the beneficiary provides in the complaint:

1. The State in which the complaint originates.

**NOTE:** The QIO for the area that includes the State in which the care was received is the QIO that has authority to conduct the review.

2. The name of the practitioner(s) or provider(s) who is/are the subject of the complaint.
3. The setting in which the care that is the subject of the complaint took place/originates— e.g., during a physician’s office visit, hospital admission, skilled nursing facility stay, or other.
4. Whether the beneficiary:
  - Has been discharged from the facility or is no longer receiving services;
  - Is still in the facility or is still receiving the services in question; and
  - Intends to file a written complaint.
5. The overall severity of the Quality of Care Concerns involved in the complaint to determine whether Immediate Advocacy can be offered and if any concern could be deemed “gross and flagrant,” “substantial,” or “significant.” (See §5035). The QIO staff member who identifies the potential “gross and flagrant”, “substantial”, or “significant” concern should consult with the QIO as needed in making such determinations.

If any concerns the beneficiary raised could be designated “gross and flagrant,” “substantial,” or “significant,” the complaint is NOT eligible for Immediate Advocacy. See §5035 for information and process requirements for Immediate Advocacy. The QIO may consult with the QIO as needed in making such determinations.

The QIO is responsible for coordination and implementation of the medical record review process through the application of established written criteria based on typical patterns of practice in the QIO area, or use of national criteria where appropriate. See 42 CFR §476.100 (c)(1). The QIO assesses medical necessity, appropriate level of care and quality of services provided. The QIO is responsible for timely and accurate completion of all medical record review including data entry into the CMS-designated case review system in accordance with CMS contract requirements.



Any additional information that may be helpful in processing the complaint should also be collected and documented (e.g., notes related to the conversation, any discussions with internal staff about the complaint).

In situations where the beneficiary states that he/she may cause harm to self or others or where the beneficiary indicates other patients may be at risk of potential harm, the QIO should immediately contact the QIO to discuss the circumstances.

The beneficiary must provide permission to disclose to the practitioner/provider the beneficiary's name and the reason for any medical information requested. A QIO is required to inform the practitioner and/or provider that the medical information is being requested due to a beneficiary complaint. See 42 CFR §476.130(b)(2).

The QIO is expected to explain to the beneficiary that if he/she chooses not to disclose his/her name as part of the complaint process, the complaint may be processed as a General Quality of Care Review, if the QIO deems appropriate. (See §5100 General Quality of Care Review.)

**NOTE:** Once a written complaint is received, Immediate Advocacy may not be offered.

**NOTE:** If it is determined at any point during the intake of a complaint that the matter is not within the QIO's review responsibility (e.g., inappropriate referral for a billing issue, the matter occurred outside the QIO's service area), but is the responsibility of another CMS component or contractor such as the Medicare Administrative Contractor (MAC), the caller should be provided with sufficient information to contact the appropriate entity. The QIO may offer to refer the matter to the other entity after obtaining the beneficiary's oral agreement (Written consent is not required).

- Alternatively, if it is determined that the call is not a Beneficiary Complaint but does relate to an issue for which the QIO is responsible (e.g., an expedited discharge appeal), the QIO must follow the procedures in place for those types of reviews.

### **5030.3 – Initial Offer of Review**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

After collecting the above information from the beneficiary, the QIO must:

1. Briefly review the information collected, including the concern(s) raised by the beneficiary, and ask the beneficiary if he/she has any additional information to provide.
2. Determine whether Immediate Advocacy could be used to resolve the complaint (See §5035) or if the complaint should be reviewed in accordance with the Peer Review process (See §5040 for Beneficiary Complaint Review and §§5100-5125 for General Quality of Care Reviews.)
  - a. In making this determination, the QIO should consider the information collected (See §5030.2) from the beneficiary, including the Scope of the Complaint. (See §5030.1.)
3. If the complaint is deemed ELIGIBLE for Immediate Advocacy, the QIO must discuss

the availability of Immediate Advocacy with the beneficiary and provide the beneficiary with the opportunity to ask questions about Immediate Advocacy in general.

4. If the complaint is deemed INELIGIBLE for Immediate Advocacy, the QIO must explain the Beneficiary Complaint Review Peer Review process, including the need for a written complaint, and ask the beneficiary whether he/she has any questions about the process in general.
5. The QIO should also provide information about the Beneficiary Satisfaction Survey and ask the beneficiary if he/she would like to participate in the Survey.
6. The QIO should also provide information about the Beneficiary Satisfaction Survey and ask the beneficiary if he/she would like to participate in the Survey.
7. End the call by letting the beneficiary know the immediate next steps depending on whether the beneficiary elects to pursue the complaint through Immediate Advocacy or through the Peer Review process. For the Peer Review process, this includes informing the beneficiary that the QIO will call once the signed Complaint form is received. The QIO should contact beneficiaries within one (1) business day of receiving the signed Complaint form.

#### **5030.4 – Use of CMS-Designated Case Review System (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

QIOs have an obligation under §1154(a)(9) of the Act to collect and maintain all information that is necessary to perform their functions. In order to ensure that information is maintained and available to CMS (see 42 CFR 480.130), QIOs are required under their contracts to use the CMS-designated case review system to record all data/information collected for all written and oral complaints, including complaints handled through the Immediate Advocacy process. This applies to any information the beneficiary provides during the initial intake of the complaint, including a thorough description of the complaint, any notes obtained during the intake process or other individuals involved in processing the complaint, and the names of staff inputting information in the CMS-designated case review system. This data collection process is designed to help resolve any questions that may arise about a specific complaint and ensures that all pertinent information related to a complaint is uniformly recorded and centrally located in the CMS-designated case review system.

Any oral communication between the QIO, the beneficiary, the QIO, and the practitioner and/or providers should be documented in the CMS-designated case review system. For Beneficiary Complaints, oral communication information should be documented in the CMS-designated case review system. In addition, CMS will use the documentation in the system to review and ensure that QIO work in this area is consistent with the applicable law and that beneficiaries, providers, and practitioners are provided the review and reconsideration rights to which they are entitled.

For complaints deemed appropriate for Immediate Advocacy, the following information should be collected and entered in the CMS-designated case review system:

- Date that consent is obtained from the parties to participate in the Immediate Advocacy

process;

- Pertinent parts of the conversation between the QIO and the beneficiary during the Immediate Advocacy process; and
- Date of phone conversation that led to discontinuation of the Immediate Advocacy process and the outcome of the Immediate Advocacy process.

For written Beneficiary Complaints, the following information should be collected and entered in the CMS-designated case review system:

- Date(s) the QIO requests medical records or other pertinent information from the practitioner/provider by phone, in writing, fax, or CMS approved method for secure file transfer in order to conduct a Peer Review;
- Pertinent parts of the phone (or in-person) conversation between the QIO and the practitioner and/or provider when the QIO orally communicated their Interim Initial Determination;
- QIO's phone (or in-person) conversation with the beneficiary and the practitioner/provider when the QIO orally communicated the QIO's Final Initial Determination;
- Date the beneficiary and practitioner/provider exercised his/her right to request a reconsideration by notifying the QIO orally;
- Date of the phone call (or in-person conversation) and pertinent content of the oral communication when the QIO notified the beneficiary and practitioner/provider of the QIO's Final Decision;
- Date of the oral conversation between the QIO and the beneficiary when the QIO informed the beneficiary of his/her right to resubmit a written complaint after the complaint has been abandoned; **and**
- Date the beneficiary orally contacted the QIO about a complaint when the beneficiary does not submit a written Complaint Form by calendar day 31 or advises the QIO during the initial discussion that s/he will not submit a written complaint. (See §5210.2.)

For Abandoned Complaints:

If the QIO could not complete its review because the beneficiary failed to participate or comply with the complaint review process, then the date of the notice from the QIO to the beneficiary and the practitioner/provider informing the parties the complaint has been abandoned, including the reason why the QIO believes the complaint has been abandoned, should be documented. Such notice may be oral or in writing.

For abandoned complaints that the QIO subsequently refers for a General Quality of Care Review, refer to §§5100 -5120 for further instructions:

NOTE: Use of the CMS-designated case review system is designed to facilitate the resolution of any questions that may arise about a specific complaint and ensures that all pertinent information related to a complaint is uniformly recorded and centrally located in the CMS-designated case review system.

### **5035 –Immediate Advocacy**

**(Rev.28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Based on the nature of the concern(s) the beneficiary raised during the Intake Stage, the QIO may recommend the use of Immediate Advocacy.

Immediate Advocacy is an informal process the QIO uses to quickly resolve an oral complaint. The QIO should summarize the steps in the Immediate Advocacy process for the beneficiary and obtain the beneficiary’s oral consent to participate in Immediate Advocacy before proceeding. In this process, the QIO makes immediate/direct contact with the practitioner and/or provider. Immediate Advocacy is a voluntary process. The QIO must also obtain oral consent to participate from the practitioner/provider.

NOTE: A beneficiary, practitioner, provider, or the QIO may discontinue Immediate Advocacy at any time. (See §5035.5).

NOTE: The use of Immediate Advocacy is not appropriate for situations where the beneficiary does not want his/her identity disclosed to the practitioner and/or provider.

#### **5035.1 – Objectives of Immediate Advocacy**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The objectives of Immediate Advocacy are to:

- Provide flexibility in resolving complaints in situations when the traditional Peer Review process alone is likely not going to reach complete resolution—for example, if the complaint includes issues that would not be documented in the medical information, or the specific time constraints related to the complaint render the Peer Review process and review of the medical information inappropriate.
- Increase beneficiary, practitioner, and/or provider satisfaction throughout the process by resolving complaints in a more expeditious and effective fashion.
- Resolve complaints in a more cost-effective manner.

#### **5035.2 – Eligibility for Immediate Advocacy**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

A QIO may offer Immediate Advocacy to the beneficiary prior to obtaining a written beneficiary

complaint when the following criteria are met:

1. After initially screening the complaint, the QIO determines the complaint was received within six (6) months from the date of service on which the care occurred concerning the complaints and:

- a. The beneficiary complains about a matter that is unrelated to the clinical quality of health care itself but relates to items and/or services that accompany or are incidental to the medical care and are provided by a practitioner and/or provider (e.g., beneficiary in search of or needing an intervention for resources and/or services covered by Medicare, such as a wheelchair that was not delivered, a beneficiary concerned about the quality of communication with their practitioner and/or provider); or
- b. The beneficiary complains about a matter that, while related to the clinical quality of health care the beneficiary received, does not rise to the level of being a “gross and flagrant,” “substantial,” or “serious or urgent” quality of care concern. This may include situations where the QIO determines that the medical information will most likely not contain evidence related to the complaint.

**NOTE:** A complaint is not eligible for Immediate Advocacy when the beneficiary has multiple concerns and the QIO determines that at least one of the concerns is “gross and flagrant,” “substantial,” or “significant.”

2. The beneficiary AGREES to the disclosure of his/her name. See 42 CFR §476.110 (a)(3).

3. All parties orally consent to the use of Immediate Advocacy. See 42 CFR §476.110 (a)(4).

4. All parties agree to the limitations on redisclosure; namely, all communications, written and oral, exchanged during the Immediate Advocacy process must not be redisclosed without the written consent of all parties. (See 42 CFR §§476.110 (c) and 480.107)

The following examples of complaints are appropriate for Immediate Advocacy:

- The beneficiary complains that the practitioner spoke to him/her in a rude manner or otherwise did not treat him/her respectfully.
- The beneficiary contacts the QIO about his/her failure to receive a motorized scooter or wheelchair.
- The beneficiary is concerned that he/she received a different colored pill than expected and would like the QIO to call the facility to find out what drug was given.

### **5035.3 – Practitioner/Provider Consent to Participate in Immediate Advocacy (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The provider and/or practitioner must also consent to Immediate Advocacy and the conditions on

redisclosure. Therefore, the QIO must:

1. Contact the practitioner and/or provider to obtain oral consent to participate in Immediate Advocacy
2. Inform the provider/practitioner of the receipt of a complaint and the beneficiary's desire to pursue resolution of the complaint through Immediate Advocacy; and
3. Convey sufficient information regarding the nature of the complaint to enable the practitioner/provider to make an informed decision about agreeing to participate in Immediate Advocacy.

Immediate Advocacy is designed to be a faster resolution process, therefore the QIO should contact the practitioner and/or provider immediately after the beneficiary consents to Immediate Advocacy.

Upon obtaining the practitioner/provider's oral consent to participate in Immediate Advocacy, the QIO should follow the Immediate Advocacy procedures in §5035.4 to resolve the complaint.

If the practitioner/provider opts NOT to participate in the Immediate Advocacy process, the QIO must immediately contact the beneficiary and give him/her the opportunity to file his/her complaint in writing. (See §5040 Beneficiary Complaint Review.)

**Practitioner/Provider is Unavailable:** In some circumstances, the practitioner/provider may be unavailable for a period of time after the beneficiary consents to the use of Immediate Advocacy. In these situations, the QIO should contact the beneficiary to explain the circumstances and discuss the available options. Immediate Advocacy should not extend beyond 10 days from the initial effort to contact the practitioner/provider.

### **5035.4 – Immediate Advocacy Procedures (Rev.28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Once oral consent is obtained for all parties, the QIO may either use conference call/three-way call or make a call on behalf of the beneficiary to obtain resolution of the beneficiary's oral complaint. The focus of the call should be to provide a quick and amicable resolution of these complaints within a short time frame, such as within two (2) business days.

**NOTE:** With the agreement to use Immediate Advocacy, a Peer Review is NOT performed. In addition, medical information should not be requested from the practitioner/provider.

**Practitioner and/or Provider is Unavailable/ Becomes Unavailable** –In these situations, the QIO should contact the beneficiary to explain the circumstances and discuss options. In no instance should the use of Immediate Advocacy extend beyond 10 days from the initial contact with the practitioner and/or provider.

Within one (1) business day following the completion of Immediate Advocacy, the QIO should update the CMS-designated case review system in accordance with the QIO contract to reflect

resolution of the complaint through the use of Immediate Advocacy and close the case accordingly.

While the goal of Immediate Advocacy is to informally and quickly resolve the beneficiary's complaint, in certain instances the beneficiary might remain dissatisfied after completion of Immediate Advocacy. Should this occur, the QIO must advise the beneficiary of his/her right to file a written complaint. The QIO should also consider whether a Quality Improvement Initiative should be pursued in accordance with §5125.

### **5035.5 – Discontinuation of Immediate Advocacy** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Procedures and Requirements for Discontinuation.

If, at any point, the Immediate Advocacy process is terminated or discontinued, the QIO must:

- Inform the beneficiary of his/her right to file a written complaint in accordance with §5040, Beneficiary Complaint Review; and
- Notify all parties that the Immediate Advocacy process has been discontinued

Reasons for Discontinuation include the following:

- The beneficiary expresses his/her desire to stop pursuing a complaint through the Immediate Advocacy process;
- The QIO becomes aware of additional information that would render the complaint ineligible for Immediate Advocacy; or
- The provider and/or practitioner revokes consent to participate in Immediate Advocacy.

### **5040 – Beneficiary Complaint Review Protocols** **(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

These are the key decision points in determining whether to proceed with a Beneficiary Complaint and/or a General Quality of Care Review upon completion of the Intake Process:

- Immediate Advocacy was appropriate, but the beneficiary expressed the intent to file a written complaint.
- Immediate Advocacy was not appropriate, and the beneficiary expressed the intent to file a written complaint.
- Immediate Advocacy is not appropriate because an oral beneficiary complaint involved at least one concern that is significant, substantial, or gross and flagrant, and the beneficiary does not wish to submit the oral complaint in writing. When a QIO receives an oral complaint, where it finds concern(s) that may be significant, the QIO is authorized to perform a General Quality of Care Review of the services related to that concern. (See

§5100 General Quality of Care Reviews).

- Neither Immediate Advocacy nor the written beneficiary complaint processes are available options because the beneficiary wishes to remain anonymous. Oral and written complaints where the beneficiary wishes to remain anonymous can be processed at General Quality of Care Reviews if a quality of care concern is at least a significant one or if the QIO deems a General Quality of Care Review appropriate under 42 CFR §476.160. (See §5100 General Quality of Care Reviews).

## **5040.1 – Beneficiary Complaint: Preparing and Forwarding the Medicare Quality of Care Complaint Form**

*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

After ending the intake call described in §5030.2, the QIO should immediately input basic information obtained during the phone call into the Medicare Quality of Care Complaint Form, except in situations where the beneficiary has requested that the form be emailed or in situations where the beneficiary expressed desire to complete the form himself or herself.

**NOTE:** A QIO must protect confidential information under 42 CFR §480. Confidential information communicated between the QIO and the beneficiary must only be transmitted via a secure electronic submission to ensure appropriate protection of the information. Confidential information includes Personally Identifiable Information (PII) and information that would be Protected Health Information (PHI) under the HIPAA Privacy and Security Rules (45 CFR Parts 160 and 164) if the information is from a covered entity (health plan or health care provider) or if the QIO were a covered entity.

A QIO is prohibited from using any independently developed complaint forms. A QIO may only use the official Medicare Quality of Care Complaint Form (CMS 10287).

The QIO may direct the beneficiary to the QIO's website or the CMS forms web page to obtain a copy of the Medicare Quality of Care Complaint Form. To assist the beneficiary in completing the Medicare Quality of Care Complaint Form, the QIO should pre-fill the following sections of the form with the information provided by the beneficiary before mailing or faxing it to the beneficiary:

1. The beneficiary's name;
2. The beneficiary's Medicare *beneficiary identifier*;
3. The beneficiary's sex and age (if known);
4. The beneficiary's race/ethnicity (if the respondent is willing to provide it);



5. The name of the beneficiary's authorized representative (if someone other than the beneficiary will be the contact);
6. The pertinent contact information, including street address and phone numbers for either the beneficiary or representative; and
7. A brief description of the complaint following the requirements of §5030.1.

**NOTE:** The QIO can send the beneficiary complaint form by mail, fax, or email from the time the information is collected.

**NOTE:** When the beneficiary requests the form to be sent via email, the QIO must not pre-fill the form in order to assure confidentiality. When sending the complaint form by fax, the QIO should ensure that the beneficiary is aware that the fax is being sent and that it will contain confidential information. The QIO must comply with requests from the beneficiary to not pre-fill the complaint form.

Prohibition against Forwarding Additional Information: The Medicare Quality of Care Complaint Form and the Appointment of Representative Form are the only forms identified by CMS for use in the Beneficiary Complaint Review process. The QIO may forward a cover letter explaining the complaint process and any instructions for the complaint process. The QIO should not forward any additional information to the beneficiary. The QIO may only mail, fax, or email the Medicare Quality of Care Complaint Form and the Appointment of Representative Form (Appendix 5-1.2), if applicable (See the discussion of this Appointment Form in the note below).

For a copy of the Medicare Quality of Care Complaint Form, see Appendix 5-1.1, "Medicare Quality of Care Complaint Form and Instructions" or visit <http://www.cms.hhs.gov/cmsforms/downloads/cms10287.pdf>.

For a copy of the Appointment of Representative form, see Appendix 5-1.2, or visit <http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf>.

**NOTE:** When a Beneficiary Representative contacts the QIO to file a complaint on behalf of a beneficiary, the QIO must question the beneficiary representative about his/her status as a "representative" of the beneficiary in order to establish that the representative has the authority to file a complaint and to receive confidential information.

Return of Completed Medicare Quality of Care Complaint Form and/or the Appointment of Representative Form:

- In situations where the beneficiary or beneficiary representative requests to return the completed forms by email to the QIO's email address, the beneficiary must be advised that while returning the completed form by email is an option, the QIO is not responsible for the privacy of the beneficiary's private health information and that doing so may not offer adequate security for protected health information.

**NOTE:** Emailed forms or facsimiles are deemed "written" for purposes of receipt of a signed written beneficiary complaint. (See §5040.3.)

**5040.2 – Beneficiary Complaint: Follow-up – Return of Signed Medicare Quality of Care Complaint Form**  
(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

If the signed Complaint Form is not received within fourteen (14) calendar days of the date of the mailing, faxing, or emailing of the form, the QIO should follow up with the beneficiary. The QIO should determine if the beneficiary still intends to file a written complaint. The QIO should do this no later than calendar day fifteen (15) or the next business day following the 15<sup>th</sup> day after the date the Complaint Form was forwarded.

Upon contact, if the beneficiary continues to indicate a desire to file a written complaint, the QIO should work with the beneficiary to determine any additional steps necessary to ensure return of a signed Medicare Quality of Care Complaint Form, including forwarding another Medicare Quality of Care Complaint Form.

If the beneficiary no longer intends to file a written complaint or after additional follow-up the beneficiary fails to comply with the beneficiary review process and does not submit the signed Medicare Quality of Care Complaint Form by calendar day thirty (30), then the QIO may follow instructions provided in § 5040.4 (Beneficiary Complaints: Complaints Not Submitted in Writing) and Section 5040.5 (Beneficiary Complaint: Abandoned Complaints and Reopening Rights). If the beneficiary is advised that the case will be considered abandoned and closed, the beneficiary may submit the signed Medicare Quality of Care Complaint Form at any time if he/she chooses to submit a written complaint to initiate the compliant review process.

**5040.3 –Beneficiary Complaint: Receipt of a Signed Beneficiary Complaint Form**  
(Rev.28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

Upon receiving the signed Medicare Quality of Care Complaint Form, the QIO should date-stamp the form and scan the form, original envelope, and/or facsimile or email and upload them to the CMS-designated case review system, so that the information is available for the appropriate QIO within one (1) business day.

The QIO prepares the Beneficiary Quality of Care Complaint Initial Acknowledgement Letter to the Beneficiary (Appendix 5-2). The letter should be sent within one (1) business day from the date the QIO receives the signed Medicare Quality of Care Complaint Form.

The original envelope, facsimile, or email from the beneficiary indicating the postmark/ date received should be kept with the original signed Medicare Quality of Care Complaint Form and the date of receipt in QIO records. Emailed forms or facsimiles are deemed “written.”

**5040.4 – Beneficiary Complaint: Complaints Not Submitted in Writing (i.e. Oral Complaints)**  
(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

In instances when a beneficiary contacts the QIO about a complaint but does not submit a signed Complaint Form by calendar day thirty-one (31) or advises the QIO during the initial discussion

that he/she will not submit a written complaint, the QIO should:

1. Close the case as a “beneficiary complaint” in the CMS-designated case review system.
2. Identify if any Significant Quality of Care concern(s) is present, and if so, determine if a General Quality of Care review is appropriate under 42 CFR §476.160 in accordance with §1154(a)(1)(B) and the procedures in §5050, “Beneficiary Complaint: Quality of Care Review Stage-One.”, A Significant Quality of Care Concern is defined as:
  - A determination by a QIO that the quality of care provided to a Medicare beneficiary did not meet the standard of care and, while not a gross and flagrant or substantial violation of the standard, represents a noticeable departure from the standard that could reasonably be expected to have a negative impact on the health of a beneficiary.

The following activities should occur where there exist Significant Quality of Care Concern(s) arising out of an oral beneficiary complaint:

1. The QIO collects sufficient information to complete a General Quality of Care Review.
2. The QIO considers the concern(s) the beneficiary identified in an oral complaint to be at least significant. Violations that are gross and flagrant or a substantial violation in a substantial number of cases also meets this standard.

Should the QIO determine that the matter involves a significant concern and the QIO has sufficient information to complete its review, the QIO may immediately request the medical information and begin the quality of care review (See §42 CFR 476.130 for guidance, and Manual §5050 for instruction).

**NOTE:** Because oral complaints are not processed as written beneficiary complaints, the beneficiary shall not receive the results of the review. As such, the disclosure processes detailed in §5060.2, “Beneficiary Complaint: Preparation of Reconsideration Disclosure Package,” and §5060.3, “Beneficiary Complaint: QIO’s Final Decision, Preparing and Mailing Letter to Beneficiary,” are not applicable. If the beneficiary nonetheless requests information, refer to 42 CFR §480.132.

## **5040.5- Beneficiary Complaint: Abandoned Complaints and Reopening Rights**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO may determine that a written beneficiary complaint or the Immediate Advocacy process has been abandoned if a Medicare beneficiary fails to participate in or comply with the requirements of the Beneficiary Complaint Review process or Immediate Advocacy process and the QIO does not have enough information to complete its review. If the beneficiary no longer intends to file a written complaint, or after additional follow-up, the beneficiary fails to participate, the QIO may determine that the case has been abandoned.

When a QIO determines a written complaint has been abandoned, the QIO must:

1. Inform the parties by phone that the complaint review will be discontinued and document the date of the call in the case review notes.
2. Inform the beneficiary of his/her right to resubmit a written complaint in accordance with the procedures in 42 CFR §§476.120 and 476.150(b).
3. A QIO may reopen a Medicare beneficiary complaint review using the same procedure (time period) a QIO would use for reopening initial denial determinations and changes as a result of diagnosis-related group (DRG) validation, as described in 42 CFR §476.96 (See 42 CFR § 476.150). A QIO may reopen a beneficiary complaint review within one (1) year of the date the original complaint was submitted.

When a QIO determines the immediate advocacy process has been abandoned, the QIO must:

1. Inform the parties by phone that immediate advocacy has been discontinued and document the date of the call in the case review notes.
2. Inform the Medicare beneficiary of his/her right to submit a written complaint in accordance with the procedures in 42 CFR §§476.120.

### **5045 – Beneficiary Complaint: Preparing the Beneficiary Complaint Folder (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO is responsible for preparing the official Beneficiary Complaint File for maintenance at the QIO, either by hard copy or via the CMS-designated review system document storage, if and when available. CMS expects that the QIO will perform this function. A duplicate hard copy of the file or access to an approved secure electronic system, when available and approved by CMS, may be required for use by an off-site Peer Reviewer. (See §5050.3 for information related to the Peer Review process.)(See §5045.4 for more detailed information about the content and organization of the folder.)

#### **5045.1 – Beneficiary Complaint: Forwarding the Complaint to the QIO (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The Beneficiary Complaint is identified as awaiting review in the CMS-designated case review system once the intake process and subsequent entry into the system is completed. Once the Beneficiary Complaint is identified as awaiting review, the QIO:

1. Reviews the Medicare Quality of Care Complaint Form and information in the CMS-designated case review system to ensure that he/she understands the specific concern(s) involved. This includes those instances when multiple concerns have been raised, whether the concerns relate to a single complaint or multiple complaints.
2. Contacts the beneficiary to orally acknowledge receipt of the complaint, CMS expects within one (1) business day of receiving the complaint.

During the discussion with the beneficiary, the QIO should obtain additional information (if necessary) and describe/explain the following to the beneficiary:

1. The complaint process to the beneficiary in more detail;
2. His or her role;
3. The Initial Determination Peer Reviewer's role;
4. The Peer Review process in general; and
5. The anticipated time frames related to the resolution of the review.

If the QIO is unable to reach the beneficiary by phone, the QIO should follow up with the beneficiary within five (5) business days from the date of the initial call attempts. The QIO should initiate the review immediately, even in those instances when the beneficiary cannot be immediately contacted, unless information necessary for completing the review is still needed.

If the QIO is unable to reach the beneficiary by phone, he/she should contact the beneficiary by letter, advising the beneficiary that a review cannot be conducted until the necessary information is received.

**NOTE:** If the QIO is unable to collect the additional information from the beneficiary by calendar day thirty (30), contact the beneficiary on calendar day thirty-one (31)(or the next business day) and advise the beneficiary that the case will be closed.

### **5045.2 – Beneficiary Complaint: Requesting Medical Information (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO determines the date(s) of the episode(s) of care concerning the beneficiary complaint to ensure that the complaint is eligible for Beneficiary Complaint Review. Under §476.120, a beneficiary complaint must be filed within 3 years of the episode of care out of which the complaint arises.

If the complaint has been timely filed, the QIO should request medical information as soon as the written complaint is received with sufficient information to identify the practitioner and/or provider. (See §5030.2.) Timely requests should happen no later than one (1) business day after receipt of the complaint (See - Medical Record Request Key Process).

Upon request by a QIO, a practitioner and/or provider must deliver all medical information requested within fourteen (14) calendar days of the request.

**NOTE:** The QIO may request the provider submit the information sooner than fourteen (14) days if there is a preliminary determination that the complaint involves a potential gross and flagrant or substantial quality of care concern as specified in Part 1004 of the Act, and circumstances warrant earlier receipt of the medical information. See 42 CFR §476.130 (b)(1).

For significant complaints, the QIO should request medical information as soon as sufficient information has been obtained to identify the pertinent practitioners and providers. For details about a QIO's right to request medical information, see 42 CFR §476.78(b)(2), "Review

Responsibilities of Quality Improvement Organizations – Responsibilities of Health Care Facilities,” and 42 CFR §480.111(a), “QIO Access to Records and Information of Institutions and Practitioners.”

Practitioners/Providers must be informed that they are expected to provide information within the fourteen (14)-calendar-day timeframe, that the request is the result of a beneficiary’s complaint, and of the right to discuss the QIO’s interim initial determination. The QIO must also request the name of a contact person to ensure timely completion of any discussion.

Failure to Provide the Medical Record Requested:

The following paragraphs describe when a Medicare Health Plan or the practitioner/provider is responsible for the medical record submission and the steps the QIO must take for CMS to investigate or take enforcement action as a result of the failure to provide information when the requested medical information is not received.

In situations in which a practitioner/provider fails to submit medical information within the required fourteen (14)-calendar-day time frame, the practitioner/provider may be subject to a denial of payment under 42 CFR §476.90.

In some situations where either a practitioner and/or provider fails to submit medical information within the required fourteen (14)-calendar-day time frame, the QIO should advise the practitioner and/or provider that, based on §1156(a)(3), sanctions may be initiated because of the failure to support the provision of items or services with evidence of medical necessity and quality as may be required. (See Manual Chapter 9, “Sanction, Emergency Medical Treatment and Labor Act (EMTALA), and Fraud and Abuse” for information on initiating a sanction process).

**NOTE:** Upon receiving the beneficiary’s medical information at any step, follow the instructions as outlined in §5045.4, “Beneficiary Complaint: Review and Preparation of Medical Information.”

### **Medical Record Request - Key Process Steps**

CMS expects the QIO to complete the following steps in requesting medical records and information:

**Step 1:** Request the medical information within one (1) business day of receiving the written complaint.

The QIO may contact the practitioner and/or provider by phone and follow up with a facsimile or mailed letter. CMS expects the letter clearly indicate the specific date on which the medical information was first requested since this date will be used to determine when a claim denial shall be issued for a practitioner/provider. See §5045.3 for information about issuing a claim denial.

A QIO may contact either/both the Medical Records Department or the QIO liaison based on procedures established with a practitioner and/or provider.

A QIO may obtain the medical information from the practitioner and/or provider via facsimile, hard copy, or a secure electronic method when available. The QIO should remain aware of its responsibility to protect confidentiality of information at all times when arranging to receive medical information.

**Step 2:** A QIO should follow up as necessary to ensure adherence to the requested submission deadline—i.e., fourteen (14) calendar days from request or earlier in those circumstances where the QIO made a preliminary determination that the complaint involved a potential gross and flagrant or substantial quality of care concern.

Before making contact, the QIO should verify that:

1. The QIO has not previously requested and received the medical information by conducting a search in the CMS-designated case review system.
2. The date the medical record is due for receipt by the QIO is correct. The timeframe can vary in cases where a potential gross and flagrant quality of care concern is identified.

**Step 3:** If the medical information is NOT received from the practitioner/provider by calendar day fourteen (14) or other date designated by the QIO, contact the practitioner's/provider's senior leadership and notify the provider of the consequences for failure to provide documents under 42 CFR §476.90.

If the medical information is NOT received from a practitioner/provider by calendar day fourteen (14) or other date designated by the QIO, contact and remind the practitioner/provider, under §1156(a)(3), items or services provided by or ordered by practitioners/providers must be supported by evidence of medical necessity and quality, in such form and fashion and at such time as may reasonably be required by a QIO in the exercise of its duties and responsibilities. The QIO should point out that any unreasonable delay in providing medical information could lead to sanctions under §1156(b).

**Step 4:** CMS expects and best practices support that the QIO contact the CMS COR when a practitioner/provider has failed to submit a medical record within the designated timeframes.

In addition to contacting the practitioner/provider, the QIO should immediately contact the COR and provide sufficient information so that the COR is prepared to contact the practitioner and/or provider. The QIO should also follow up with the COR to advise if/when the medical information is received.

The COR will call the Medical Records Department, the QIO liaison, and/or senior leadership, and convey the responsibilities associated with the request for the medical information on the next business day after calendar day fourteen (14) (or the next business day after the date established by the QIO when there's been a preliminary determination by the QIO of potential gross and flagrant or substantial quality of care concern).

The COR will assess the willingness to comply with the request for medical information and explain the potential repercussions of failure to provide the medical information, including:

- Issuing a claim denial;
- Notifying the Division of Medicare Health Plans Operations; and
- Potential for the QIO to conduct additional reviews.

**NOTE:** The COR will advise the contact that if the medical information is not received within the next calendar day, a claim denial shall be carried out for any claim associated with the care described in the complaint.

**Step 5:** If the medical information is not received from a provider by the next business day following calendar day fourteen (14) (or the next business day after the date established by the QIO), proceed in accordance with §5045.3, “Beneficiary Complaint: Issuing a Claim Denial.”

**NOTE:** In instances where the QIO completes a claim denial in accordance with §5045.3 the provider is still required to comply with its responsibility to forward the medical information to the QIO for them to complete the Quality of Care Review.

For practitioners and providers, a COR may recommend additional action depending on the particular facts of the situation (e.g., recommending that the QIO conduct additional Quality of Care Reviews on other patients for whom similar claims have been submitted for payment by the practitioner and/or provider).

In instances where the requested medical information is not received within thirty (30) calendar days from the date of request, the beneficiary is still entitled to notice of the outcome of the review under §476.130(d); however, the specific information should be tailored to the situation rather than listing the information identified in §476.130(d). The beneficiary must be advised in writing and provided with the following information:

- The QIO is unable to complete the review as a result of the practitioner’s and/or provider’s failure to submit the medical information.
- For complaints related to practitioners and/or providers: CMS has initiated action to deny Medicare payment to the provider for the services surrounding the care referenced in the beneficiary’s complaint.
- Based on §1156(a)(3), sanctions may be initiated against a practitioner and/or provider for failing to support the items or services they have provided with evidence of the quality of the items or services.

In instances where the medical information is received within the next thirty (30) calendar days, the beneficiary should be contacted and advised that the review will be completed.

**5045.3 – Beneficiary Complaint: Issuing a Claim Denial**  
**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**



A QIO will deny a provider's claim in situations where the QIO has requested information from a provider and, despite sufficient notice and a reasonable amount of time to respond, the provider fails to forward the requested information. See 42 CFR §476.90.

**NOTE:** Before processing a claim denial, the QIO should coordinate with the appropriate CMS COR.

If the requested medical information is received before the claim denial is finalized, the QIO must stop the denial and complete the review. If the medical information is received after the claim denial has been finalized, payment must be re-instituted. The QIO must then comply with §476.130 and complete the review.

### **5045.4 – Beneficiary Complaint: Reviewing and Preparing Medical Information**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Receipt of Medical Record Documentation/Information: Upon receiving the medical record documentation, the QIO should immediately date-stamp the form and scan the form, original envelope, and/or facsimile or email. These documents should be uploaded to the CMS-designated case review system (unless received electronically) within one (1) business day.

The QIO must file the original envelope with the medical record documentation in a hard copy file or as a scan of the documents for storage in an electronic file.

Medical Documentation Completeness and Organization: The QIO ensures all information in the medical information is complete, appropriately organized, and legible.

If the medical documentation in the medical record is incomplete or illegible (poor copy), the QIO may contact the practitioner and/or provider by phone and allow an additional five (5) calendar days for submission of the documentation necessary to complete the medical information needed for review.

**NOTE:** QIOs must follow the procedures for issuing claims denials in §5045.3 when complete medical record documentation is not received in accordance with the fourteen (14) calendar-day timeframe.

The QIO should verify that the medical record documentation received for each medical record request contains the major documentation components. Examples include but are not limited to the following:

1. Emergency Room Record/Admission Record;
2. History and Physical;
3. Consultations;
4. Practitioner Orders;

5. Practitioner Progress Notes;
6. Nursing Notes;
7. Ancillary (e.g., laboratory reports, X-rays, medication administration record, treatment);
8. Miscellaneous; and
9. Discharge Summary.

**NOTE:** QIOs are authorized to upload medical record documentation received directly into the CMS-designated system or into a secure electronic system that CMS otherwise designates or approves. The documentation should be uploaded within one (1) business day of receiving the medical information.

If the QIO staff member preparing the case for review and/or Physician Peer Reviewer(s) determine that handwritten information in the medical information cannot be deciphered, the QIO may contact the provider and/or practitioner and request a typed/transcribed portion of the problem sections of the medical information.

A QIO should make every effort to limit the amount of typed/transcribed information requested. Failure to comply with a request for typed/transcribed information shall be treated as a failure to provide the medical information **if** the missing information precludes the completion of the review. QIOs must follow the procedures in §5045.3 for processing a claim denial when applicable.

### **5050 – Beneficiary Complaint: Quality of Care Review – Stage Two (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

A QIO initiates the Quality of Care Review for Beneficiary Complaint Reviews by conducting a preliminary review of the written complaint and each of the Quality of Care Concerns.

For instances when the beneficiary raises multiple concerns that are potentially unrelated, the QIO shall determine whether the QIO will process the concerns as a single complaint with multiple concerns or as multiple complaints. In making this determination, the QIO should consider the following:

- Number of episodes of care;
- Total number of concerns;
- Relationship or inter-relatedness of the concerns;
- Time frames associated with the concerns;
- Impact of different practitioner and/or provider involvement in each of the concerns;

- Health care issues related to each of the concerns;
- Beneficiary’s own statements about the relationship between the concerns; and
- Other factors deemed relevant as identified by the QIO.

The importance of a particular criterion may be different for different complaints, and the QIO should consider the totality of the circumstances.

Consultation with other QIO personnel who have been involved or reviewed the materials is recommended when appropriate for making the determination to separate complaints that have been uploaded into the CMS-designated case review system as a single complaint.

If a decision is made to process concerns as separate complaints, notice of the QIO determination under §476.130(d) must include the rationale for that decision. Further, the rationale must be included in the CMS-designated case review system files.

**5050.1 – Beneficiary Complaint: New Concerns Raised by the Beneficiary**  
**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

As a result of the QIO’s broad focus in assessing the scope of the complaint, the QIO should rarely become aware of new Quality of Care Concerns after the complaint has entered the Quality of Care Review Stage. See Scope of Complaint, §5030.1.

New issues/concerns may be added to the original complaint if the Interim Initial Determination step has not been completed.

**NOTE:** In the rare event that a beneficiary raises a new issue/concern(s) after completion of the Interim Initial Determination (See §5050.4), the new issue/concern is processed as a separate/new complaint.

**5050.2 – Beneficiary Complaint: Preparing the Quality Review Decision (QRD) Form**  
**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Once a determination is made about the number of complaints and the specific Quality of Care Concern(s) to be addressed during the review, a Quality Review Decision (QRD) Form must be prepared for each complaint (See Appendix 5-1.3, “Quality Review Decision (QRD) Form”). The QRD Form is the only form authorized for documenting the concerns addressed in a Beneficiary Complaint Review.

CMS created the QRD Form to better account for the multiple individuals involved in reviewing a beneficiary complaint and to ensure information related to every beneficiary complaint—and in particular, every quality of care concern—is maintained in an organized, detailed, and consistent fashion throughout the review process.

Using the CMS-designated case review system, the QIO:

1. Prepares a QRD Form that sets out each individual concern; and
2. Forwards the package to the Initial Determination Peer Reviewer as soon as possible following receipt of the medical information.

In addition, the QIO completes the following steps for each concern:

1. Evaluates the beneficiary complaint and each Quality of Care Concern in accordance with §5030.1, Scope of Complaint.
2. Evaluates the quality of care with regard to the admission diagnosis and treatment plan established for the beneficiary, if applicable.
3. Evaluates the quality of care for any blatant issues (e.g. Never Events identified as hospital acquired conditions that could have been reasonably prevented through the application of evidence-based guidelines) (See National Coverage Determination (NCD) made as part of CR 6405).
4. Researches evidence-based practices related to each Quality of Care Concern(s) while considering the definition of Quality Care, including reference to relevant norms and criteria. If no quality of care standard(s) exists, then the QIO will use available norms, best practices, and established guidelines and recommend a potential quality of care standard(s). In completing this step, the QIO must thoroughly research all available information, including the following:
  - Nurse screening criteria (e.g., InterQual, Milliman); and
  - Generally available resources, including information available via Internet searches.
5. Complete an assessment section for EACH Quality of Care Concern in the complaint and/or identified.
6. Evaluate additional information pertinent to the case, but unrelated to the standard(s) of care. This may include:
  - CMS-available information, including Web-based resources (e.g., Nursing Home and Hospital Compare); and
  - State-based resources, including Web-based literature/information as well as practitioner-specific information related to license revocations and referrals to the State medical conduct organizations.
7. Research all available data, at a minimum of three (3) years from the date of service, to determine whether the QIO has received similar complaints on the same practitioner and/or provider and/or if other potential concerns related to the same practitioner/provider are identifiable.

8. Prepare the package for forwarding to the Initial Determination Peer Reviewer.

### **5050.3 – Beneficiary Complaint: Receipt and Review by the Initial Determination Peer Reviewer**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO mails or sends the package via a secure electronic method to the Initial Determination Peer Reviewer immediately after receiving the Medical Record documentation.

Once the Peer Reviewer receives the medical record documentation, he/she should immediately initiate the review.

The Peer Reviewer must review the Quality of Care Concern(s) identified by the beneficiary and any additional concern(s) identified by the QIO.

After the Peer Reviewer receives all the medical record documentation, the QIO has ten (10) calendar days to ensure that the Initial Determination Peer Reviewer completes the following steps:

1. Completes the review;
2. Notifies the practitioner and/or provider of the Initial Determination Peer Reviewer's Interim Initial Determination; and
3. Notifies the practitioner/provider of the opportunity to discuss the Determination. (See 42 CFR 476.130(c).)

**NOTE:** The QIO is responsible for ensuring that the Interim Initial Determination is completed within ten (10) calendar-days of receipt of the medical information.

This includes the following:

Peer Reviewer renders an Interim Initial Determination

The practitioner/provider is notified of the Interim Initial Determination and is provided with the opportunity to discuss, within the required ten (10)-calendar-day time frame (See §5050.3.) The discussion must occur within seven (7) calendar days of the notice to the practitioner/provider.

#### **Initial Determination Peer Review Approach**

For Individual Concerns – The Peer Reviewer evaluates the standard(s) that the QIO identified on the QRD Form and checks off the appropriate box indicating whether he/she concurs or does not concur with the standard(s) of care as delineated by the QIO.

- If the Peer Reviewer identifies quality of care concerns not raised by the beneficiary or identified by the QIO, the Peer Reviewer must indicate this and identify pertinent

research describing the standard of care he/she used to identify and evaluate the concern.

- If the Peer Reviewer determines that the standard(s) that the QIO identified for a specific concern(s) is incorrect or not appropriately thorough, the Peer Reviewer must identify the correct standard(s) and provide an explanation about the change.
- For instances when the Peer Reviewer determines that the standard(s) is incorrect, the Peer Reviewer must include a rationale, with references to relevant literature/research and/or medical information supporting his/her decision on the appropriate standard(s) of care in the QRD Form.

The Peer Reviewer then applies the standard(s) of care to the specific facts of the case and the Quality of Care Concern(s) at issue. The Peer Reviewer evaluates the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. For a complete and adequate peer review, CMS expects each Peer Reviewer to:

1. Evaluate whether the quality of care standard for each identified concern is met based on the facts of the case and directly link his/her decisions to elements contained in the evidence-based standard(s), or in the absence of evidence-based standards of care, will use available norms, best practices, and established guidelines.
2. Assess the responsibility of the individual identified by the beneficiary to determine if the individual identified is different from the individual who is responsible for the standard(s) not being met.
3. Consider any historical data pertinent to the concern as provided by the QIO, and highlight specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are or are not met.

**NOTE:** The Peer Reviewer should also include any other information that the reviewer deems relevant to the Interim Initial Determination.

If the Peer Reviewer concludes that there are extenuating circumstances to consider (e.g., emergent circumstances or exceptional complexity), the Peer Reviewer must thoroughly explain these and how they are relevant to the Interim Initial Determination.

After completing the Rationale/Justification portion for each concern on the QRD Form, the Peer Reviewer must identify (and document), by checking off the appropriate box, whether the standard(s) of care was met or was not met for each concern. This decision/determination must be based on the analysis and justification.

If the Peer Reviewer determines that the standard of care was not met for a concern, the Peer Reviewer must also check off the appropriate box indicating whether any of the following findings is also present:

1. The care grossly and flagrantly violated the practitioner/provider's obligation to provide care, in one or more instances, that is of a quality that meets the professionally recognized standards.

2. The care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standards.
3. The care failed to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standards.
4. The care was not a substantial failure of a quality that meets the professionally recognized standards, but was a significant concern.
5. The care did not meet the standard of care, but was less than a substantial violation of the obligation to provide care that is of a quality that meets the professionally recognized standard.

The Initial Determination Peer Reviewer must complete the review of the medical information, completely and accurately fill out the QRD Form to document the determination review thoroughly, and return the review package to the QIO in the agreed upon timeframes.

The Peer Reviewer must sign and date the QRD Form and indicate the amount of time spent reviewing the complaint. Except in circumstances when the Peer Reviewer conducts the review on the QIO premises or electronically through a secure site, the reviewer may maintain a signed copy of the completed QRD Form and additional copies of notes in a secure location. These may be maintained by the Peer Reviewer to facilitate any additional review necessary based on the receipt of additional information during the Opportunity for Discussion Stage.

#### **5050.4 – Beneficiary Complaint: QIO Review of Interim Initial Peer Review Determination**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Immediately upon receipt of the Beneficiary Complaint folder from the Initial Determination Peer Reviewer, the QIO must ensure all necessary information is returned and the QRD Form has been signed.

A QIO may use its discretion in providing a specific number of calendar days for review of the package to ensure the Peer Reviewer:

1. Rendered a decision on all quality of care concerns;
2. Adhered to the correct format in providing comments; and
3. Provided a rationale for conclusions that is clear, cogent and based on the available information and applicable standard of care.

However, a QIO is required to have the Initial Determination Peer Review completed and the practitioner and/or provider notified of the Peer Reviewer's Interim Initial Determination within ten (10) calendar days after the Peer Reviewer receives all medical information.

**NOTE:** Additional procedures are applicable if the Initial Determination Peer Reviewer has:

1. Identified a concern(s) as either gross and flagrant, or the care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standards of health care as required by §1156(a) of the Act.
  - The QIO must initiate sanction proceedings in accordance with IOM Chapter 9.
2. Determined that the standard(s) of care was not met for any one or more of the concerns, and the concerns are not sanctionable.

The QIO must provide notice and an opportunity for discussion to the practitioner and/or provider. See the procedures detailed in §5055, “Beneficiary Complaint: Opportunity for Discussion - Stage Three.”

### **5055 – Beneficiary Complaint: Opportunity for Discussion – Stage Three (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

In accordance with §1154(a)(14) of the Act, before a QIO concludes that the quality of services does not meet professionally recognized standards of health care, the QIO must give the practitioner and/or provider reasonable notice and opportunity to discuss the concerns found.

#### **5055.1 – Beneficiary Complaint: Notification of Opportunity for Discussion (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

If, after reviewing the Interim Initial Peer Review Determination package, the QIO determines that the Peer Reviewer has identified a concern(s) for which the standard(s) of care was not met, the practitioner and/or provider must be offered the opportunity to discuss the concern(s). The QIO must make the effort of an offer, by telephone to the practitioner/provider to discuss the interim initial determination with the QIO in those situations where the peer reviewer determines that the quality of services does not meet professionally recognized standards of care for any concern in the complaint. The QIO should document the date on which the offer was first made to the practitioner and/or provider, and this may include sending to the practitioner and/or provider a facsimile or letter describing the specific concern(s) at issue.

**NOTE:** A QIO must allow a practitioner to use a representative to respond to the Opportunity for Discussion. (See Appendix 5-3, “Interim Determination Letter for Practitioners or Providers”).

In offering the discussion opportunity, the QIO shall make every effort to discuss the Initial Determination Peer Reviewer’s interim determination as expeditiously as possible. The time frame for obtaining a response from the practitioner and/or provider shall not extend beyond seven (7) calendar days from the date the offer was originally made. In rare circumstances (e.g., the practitioner is unavailable [out of the country] for the entire seven (7)-day period), the QIO may provide additional time to respond to the offer of a discussion or submission of a written response to the interim initial determination. The additional time should not exceed seven (7) calendar days.



The practitioner and/or provider may submit a written response to the opportunity for discussion in lieu of a phone call within seven (7) calendar days of receiving the initial offer of an opportunity for discussion.

- If a practitioner and/or provider requests to submit a written statement as their opportunity for discussion in addition to having a phone call, the QIO may accept both the written response and phone call discussion with the practitioner and/or provider based on the complexity of the case.

### **5055.2 – Beneficiary Complaint: Oral or Written Response by Practitioner/Provider - Opportunity for Discussion** (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

#### **Personnel**

The offer of the Opportunity for Discussion can be made by the QIO, the Initial Determination Peer Reviewer, or the Medical Director, depending on the QIO's established practice. However, the QIO should participate in discussions between the Initial Determination Peer Reviewer and the practitioner/provider to handle any administrative questions or issues that arise during this discussion. For complex cases, it is recommended that the Medical Director participate.

#### **Processing Responses**

**Oral Responses:** The QIO must prepare a summary of any oral response submitted to document that the discussion occurred. During the oral discussion, the practitioner and/or provider should be advised of the need to focus on the specific element(s) of the standard(s) of care or the care provided to the beneficiary that is being disputed in the Initial Determination Peer Reviewer's Interim Determination.

**Written Responses:** The practitioner and/or provider should be advised of the need to focus on the Initial Determination Peer Reviewer's conclusions related to specific elements of the standard(s) of care. Written statements submitted for the Opportunity for Discussion must be sent to the QIO for processing and properly documenting the review file for the Peer Reviewer.

### **5055.3 – Beneficiary Complaint: Prohibition on Submission of New/Additional Medical Information** (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

The submission of new and/or additional medical information does not occur in response to the offer of the Opportunity for Discussion because the Reconsideration process (42 CFR §476.140 (a)(3)) provides an opportunity to submit additional information.

**NOTE:** In instances when the practitioner and/or provider requests to submit new and/or additional medical information, the QIO should advise the practitioner and/or provider of his/her right to request a reconsideration and that any new and/or additional medical information can be considered during the reconsideration process. CMS considers it a basic premise of fairness that beneficiaries, practitioners and/or providers are notified of the ability to file a request for reconsideration in connection with complaints filed after July 31, 2014.

## **5055.4 – Beneficiary Complaint: Reviewing Response Submitted during Opportunity for Discussion**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

A Final Initial Determination must be completed within three (3) business days of the discussion with the practitioner/provider and/or receipt of written statement(s). The review process must take place and be completed in an appropriate timeframe. The QIO reviews the summary of any oral response that the practitioner and/or provider has submitted, or the written Opportunity for Discussion response, in light of the quality of care concern(s) raised during the Initial Determination Peer Review. For both oral and written responses, the QIO must make every effort to highlight/summarize the specific facts the practitioner and/or provider provided during the discussion in relationship to particular elements of the standard(s) of care that could alter the Initial Determination Peer Reviewer's Interim decision. (As noted in §5055.3, facts provided during the discussion stage cannot include new medical information). The QIO must also describe any information/rationale provided by the practitioner and/or provider that appears to be unrelated to the standard(s) of care.

The QIO shall forward the information, along with specific issues identified in the response, to the Initial Determination Peer Reviewer for consideration as soon as possible after completing an oral discussion and/or receiving the written response. This ensures that the QIO adheres to the three (3)-business-day (from the date of response) timeframe for notifying the beneficiary and the practitioner and/or provider by telephone of its Final Initial Determination.

**NOTE:** The QIO should ensure that the same Peer Reviewer renders both the Interim and/or Final Initial Determinations, unless rare circumstances exist (e.g., the Interim Initial Determination Peer Reviewer is unavailable due to serious illness).

In most instances, the QIO will not be required to mail the Initial Determination Peer Reviewer the entire Beneficiary Complaint file but the Peer Reviewer should be provided with information necessary from the file to complete the Final Initial Determination. The following are best practices for completing the review process:

1. The Peer Reviewer uses the copy of the QRD Form from the Interim Initial Determination in evaluating the information the practitioner and/or provider supplied to the QIO during the Opportunity for Discussion.
2. Additional materials are usually unnecessary in situations where the practitioner and/or provider conveyed information orally directly to the Peer Reviewer.
3. The QIO and the Peer Reviewer coordinate to ensure all pertinent information is considered in the Final Initial Determination.
4. After making the Final Initial Determination, the Initial Determination Peer Reviewer re-signs the QRD Form and sends it back to the QIO. The signed form may also be faxed to expedite review.

The QIO must ensure that the beneficiary and the practitioner and/or provider are informed by phone of the Peer Reviewer's Final Initial Determination, regardless of the findings about

whether the standard(s) of care were met or not met, no later than three (3) business days after the completion of its review. (See §5055.6.)

- The QIO must also issue a Final Initial Determination letter to the parties within five (5) calendar days after the QIO completes its review. (See §5055.6.)

**NOTE:** The time frame for completing review includes the Initial Determination Peer Reviewer's review as well as any additional review the QIO conducts after the peer review is complete (e.g., quality assurance of the Final Initial Determination letter).

### **5055.5 – Beneficiary Complaint: No Response to Opportunity for Discussion (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

If no response is received regarding the offer of the Opportunity for Discussion within seven (7) calendar days or the practitioner/provider agrees with findings, the Interim Initial Determination becomes the Final Initial Determination.

The Initial Determination Peer Reviewer need not sign the QRD Form again to denote this result; however, the QIO will note on the QRD Form that no response was received.

### **5055.6 – Beneficiary Complaint: Preparing the Final Determination Letter to Practitioners/Providers and Beneficiaries (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO shall follow the procedures in this Section for preparing the QIO's Final Determination Letters (Appendix 5-4.1 and 5-4.2).

Upon receiving the QRD Form, the QIO prepares the Final Determination Letter to Practitioners/Providers (Appendix 5-4.1) and Beneficiaries (Appendix 5-4.2) conveying the decision to the practitioner and/or provider, and advising the practitioner and/or provider and the beneficiary of the right to request a reconsideration within three (3) calendar days.

The QIO should:

- No later than 3 business days after completion of the review or end of the discussion period notify (by telephone) the beneficiary and the practitioner/provider of the Final Initial Determination and of the right to request a reconsideration of the QIO's Final Initial Determination; and
- Mail the Final Determination Letter to Practitioners/Providers (Appendix 5-4.1) and to the beneficiary (Appendix 5-4.2) within five (5) calendar days of completion of the review.

**NOTE:** If the determination is provided by telephone on the third business day and the fifth calendar day falls on the same day, the letter should be mailed by 12:00 noon on the next business day. See 42 CFR §476.130(d) (2).

The written notice to providers and practitioners must include:

- A statement for each concern that care did or did not meet the standard of care;
- The standard identified by the QIO for each of the concerns; and
- A summary of the specific facts that the QIO determines are pertinent to its findings, including references to medical information and, if held, the discussion with the involved practitioner and/or provider.

For all complaints involving providers or practitioners, the letter to the beneficiary (Appendix 5-4.2) shall include at least ALL of the following:

1. A statement for each quality of care concern identified in the original written complaint and whether care did or did not meet the standard of care.

**NOTE:** This does not include other quality of care concerns identified by the QIO during the course of review.

2. A statement defining the standard of care that the QIO identified for each quality of care concern raised by the beneficiary.

3. A statement of the facts describing how the practitioner/provider did or did not meet the standard of care. The statement of facts should relate only to the facts that were essential in determining whether a practitioner and/or provider met professionally recognized standards of care.

In the Final Initial Determination Letter for complaints filed after July 31, 2014, a QIO must also inform the beneficiary if the QIO receives a request for reconsideration from any of the parties, the results of the QIO's Final Initial Determination could change.

The QIO should also inform the beneficiary that if/when a reconsideration is requested and reviewed, the beneficiary will receive a QIO Final Decision letter (See Appendix 5-5.2 Reconsideration Determination Letter to the Beneficiary) at a later date (See §5060.3 for issuance of the QIOs Final Decision).

### **5055.7 – Beneficiary Complaint: Failure to Respond to the Final Initial Determination and Right to Reconsideration** (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

For instances when a practitioner/provider and the beneficiary fail to request a reconsideration following notification by phone and receipt of the QIO's Final Interim Determination (Appendix 5-4.1) and the Final Determination Letter to Beneficiary (Appendix 5-4.2) within the three (3) calendar-day period, the QIO shall follow the procedures in §5060.4, "Beneficiary Complaint: Procedures for Closing a Complaint Review" for closing as a completed case in the CMS-designated case review system.

**NOTE:** The QIO may pursue, or recommend to the appropriate Quality Innovation Network -

Quality Improvement Organization (QIN –QIO), in accordance with §5125 if deemed appropriate.

### **5055.8 – Beneficiary Complaint: Responsibility to Protect Information and Destruction of Materials**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

As specified at 42 CFR 480.115, the QIO is responsible for protecting information and must implement reasonable security measures to ensure the integrity of information and prevent unauthorized access. See Manual Chapter 10 for additional information.

No later than thirty (30) calendar days after the Initial Determination Peer Reviewer renders his/her final decision, all hard copies of materials that pertain to the specific beneficiary complaint in his/her possession must be destroyed in compliance with QIO security procedures. The QIO will maintain the original documentation at its facility.

### **5060 – Beneficiary Complaint: Reconsideration – Stage Four**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

For complaints filed after July 31, 2014, a Medicare beneficiary or practitioner and/or provider may request a reconsideration, in writing or by phone, within three (3) calendar days following initial oral notification of the QIO's Final Initial Determination. A beneficiary, provider, or practitioner who is dissatisfied with the QIO's Final Initial Determination may request reconsideration.

**NOTE:** The Beneficiary Complaint Reconsideration Procedures (See 42 CFR §476.140) replace the Retrospective Beneficiary Complaint Re-review Process (§5250) and Concurrent Beneficiary Complaint Re-review process (§5350) provided in Manual Chapter 5 Quality of Care Revision-17, dated 04/06/12.

**NOTE:** §§5250 and 5350 of Manual Chapter 5 Revision – 17 dated 04/06/12 - apply to Beneficiary Complaints filed before July 31, 2014, (the date after which reconsideration rights apply pursuant to 42 CFR §476.140). (A practitioner and/or provider may request a Re-review, in accordance with Manual Chapter 5 (§§5252 and 5350) Revision-17, dated 04/06/12.)

The beneficiary and/or the practitioner and/or provider may request reconsideration within three (3) calendar days of receipt of the Final Initial Determination Letter to Practitioners/ Providers (Appendix 5-4.1 and Appendix 5-4.2).

The QIO's Final Decision shall be issued to the beneficiary and practitioner and/or provider no later than five (5) calendar days after the request for a reconsideration, or if later, five (5) calendar days after receiving any medical or other records needed for the reconsideration. See 42 CFR§ 476.140.

**NOTE:** The timeframe for completion of review starts when additional information is received from all parties. If additional information is not received within seven (7) calendar days of the beneficiary or provider's request for reconsideration, the QIO should proceed with the reconsideration with the information that is available.

Upon receiving a reconsideration request, the following information must be forwarded to the reconsideration Peer Reviewer so that a reconsideration review can be completed:

1. Beneficiary Complaint folder/file
2. Quality Review Decision (QRD) Form;
3. All Medical information received;
4. Final Determination Letter to Practitioners/Providers and Beneficiaries (Appendix 5-4.1 and 5-3.2) (See §5060.3). If the Initial Determination was orally communicated to the beneficiary, the QIO should include a brief summary of the conversation;
5. Interim Initial Determination Letter for Providers/Practitioners (Appendix 5-3);
6. Information received related to the offer of the Opportunity for Discussion Stage; and
7. Any new evidence submitted in requesting the reconsideration.

The package with the above information should be forwarded to the Reconsideration Peer Reviewer within one (1) business day of receiving the request for reconsideration. (See §5060.1). Reconsideration reviews must be completed within five (5) calendar days after receipt of the request for reconsideration or receipt of any medical or additional information or other records needed for the reconsideration if applicable.

When a practitioner/provider fails to request a reconsideration [in cases where the concern(s) from the original beneficiary complaint are confirmed quality of care concern(s)] within three (3) calendar days following the practitioner and/or provider's oral or written receipt of the QIO's Final Initial Determination, the QIO will prepare and send the Final Determination Letter to the Beneficiary/Beneficiary Representative (Appendix 5-4.2). This mailing is to occur no later than five (5) calendar days after the expiration of the reconsideration period.

The QIO may notify the beneficiary and the practitioner/ provider of its Final Decision by phone. However, the QIO must follow up by issuing a written notice to the parties by 12:00 noon on the next calendar day. See 42 CFR §476.140(b).

### **5060.1 – Beneficiary Complaint: Reconsideration Peer Reviewer (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

To fulfill the practitioner/provider and/or beneficiary's right to reconsideration, and to provide all parties with an impartial and independent reconsideration of peer review, the Reconsideration Peer Reviewer should be different from the Peer Reviewer who conducted the Interim Initial and Final Initial Determinations. In making his/her determination, the Reconsideration Peer Reviewer shall review all information forwarded by the QIO. The Peer Reviewer shall use the QRD Form (Appendix 5-1.3) to render a determination(s).

The Reconsideration Peer Reviewer receives the package from the QIO and initiates the

reconsideration.

In order to be an effective and fair review [See §476.130(b)(1)] provided upon request for a reconsideration, the Reconsideration Peer Reviewer **must** review each Quality of Care Concern identified in the complaint **and** any additional concerns identified by the QIO or the Initial Determination Peer Reviewer during the review of the medical information. The Reconsideration Peer Reviewer should also document the reconsideration review by completing the QRD Form for each concern. The process is as follows:

1. The Reconsideration Peer Reviewer evaluates the standard(s) that the QIO and the Initial Determination Peer Reviewer identified for each Quality of Care Concern on the QRD Form.
2. The Reconsideration Peer Reviewer checks off the appropriate box indicating whether he/she concurs or does not concur with the standard(s) of care for each Quality of Care Concern as delineated by the QIO and the Initial Determination Peer Reviewer.
3. If the Reconsideration Peer Reviewer determines that the standard(s) identified by the QIO staff member who prepared the case for review and/or Initial Determination Peer Reviewer for a specific concern(s) is incorrect or not appropriately thorough, he/she must identify the correct standard(s) and provide an explanation of the change.
4. For instances when the Reconsideration Peer Reviewer determines that the standard(s) is incorrect, he/she should include references to relevant literature/ research supporting his/her decision on the appropriate standard(s) of care and consult with the Medical Director to obtain the Medical Director's concurrence on the standard to be used in evaluating the concern(s).

**NOTE:** The QIO staff member who prepared the case for peer review should be included in this consultation with the Medical Director.

#### Reconsideration Peer Reviewer Rationale/Justification

Upon determining the standard(s) of care to be used, the Reconsideration Peer Reviewer then applies the standard(s) of care to the specific facts of the case and the quality of care concern(s) at issue. The Reconsideration Peer Reviewer evaluates the information contained in the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. CMS expects that each Reconsideration Peer Reviewer will:

1. Directly link his/her decisions to elements contained in the evidence-based standard(s), or in the absence of evidence-based standards of care, will use available norms, best practices, and established guidelines when deciding whether quality of care for each identified concern is met based on the facts of the case.
2. Assess the responsibility of the individual identified by the beneficiary if that individual is different from the individual who is responsible for the standard(s) that were not met.

To conduct a complete and adequate reconsideration, CMS expects the Reconsideration Peer

Reviewer to:

1. Consider any historical data pertinent to the concern(s) that the QIO provided.
2. Highlight specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care that are or are not met.
3. Include any other information the Reconsideration Peer Reviewer deems relevant to his/her Reconsideration Determination.

If the Reconsideration Peer Reviewer, in his/her determination, concludes that there are extenuating circumstances to take into consideration (e.g., emergent circumstances or exceptional complexity), the Rationale/Justification section of the QRD Form must contain an explanation of these circumstances including relevance, in order to be complete.

After completing the Rationale/Justification portion for each concern on the QRD Form, the Reconsideration Peer Reviewer must identify (and document), by checking off the appropriate box, whether the standard(s) of care was met or not met for each concern. This decision/determination must be based on the analysis and justification.

If the Reconsideration Peer Reviewer determines that the standard(s) of care was not met, he/she must also check off the appropriate quality of care determination box indicating whether:

1. The care grossly and flagrantly violated the practitioner/provider's obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care in one or more instances.
2. The care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care.
3. The care failed to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care.
4. The care did not meet the standard of care, but was less than a substantial violation of the obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care (i.e. It was either significant or non-significant).

The QIO must ensure the Reconsideration Peer Reviewer completes his/her review of the medical information/package completely and accurately, adheres strictly to the requirements of the QRD Form to document the review thoroughly, and returns the review package to the QIO in the appropriate timeframe. The QIO may orally notify the beneficiary and practitioner/provider of its Final Decision within five (5) calendar days after the request for reconsideration or if later, five (5) days after receipt of any medical information needed to complete the reconsideration review.

**NOTE:** If the QIO initially notifies the parties orally, it must follow up with a letter by 12:00 noon of the next calendar day. (See Appendix 5-5.1 and 5-5.2)



The Reconsideration Peer Reviewer must sign and date the QRD Form and indicate the amount of time spent reviewing the concern(s). An electronic signature is acceptable when and if the feature is available through the CMS-designated or otherwise approved review system.

**NOTE:** If the Reconsideration Peer Reviewer has identified one or more concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standards of health care as required by §1156(a) of the Act, the QIO must initiate sanction proceedings in accordance with Manual Chapter 9.

### **5060.2 – Beneficiary Complaint: Preparing the Reconsideration Package (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO receives the package from the Reconsideration Peer Reviewer and examines it to ensure all necessary information was returned.

The QIO identifies the Reconsideration Decision on the QRD Form and prepares the following:

1. Beneficiary Quality of Care Complaint – Reconsideration Determination Letter to Practitioners and Providers (See Appendix 5-5.1); and
2. Beneficiary Quality of Care Complaint: Reconsideration Determination Letter to Beneficiary (Appendix 5-5.2).

**NOTE:** The QIO may copy the language used previously, unless substantial changes have been made.

### **5060.3 – Beneficiary Complaint: QIO’s Final Decision, Preparing, and Mailing the Letter to Providers and/or Practitioners and the Beneficiary (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO must provide notice to the beneficiary and the provider/practitioner of the reconsidered determination as soon as it is complete [i.e. within five (5) calendar days of receiving the request for reconsideration and the records for the review]. The initial notice may be done by telephone but written notice must be provided by noon the next calendar day.

A QIO is NOT required to obtain consent from the practitioner and/or provider to disclose to the beneficiary the QIO’s Reconsideration Determination, the standard(s) of care at issue, whether or not the standard(s) was met, and the specific facts pertinent to the QIO in making that decision.

A QIO is required to give written notice as well to the practitioner and/or provider. CMS recommends that this be done by providing a copy of the Letter to Beneficiary – Beneficiary Quality of Care Complaint: Reconsideration Determination Letter to Beneficiary (Appendix 5-4.2)

A QIO shall follow the procedures in this section for preparing the QIO’s Reconsideration Determination Letters (Appendix 5-4.1 and 5-4.2). For all complaints involving practitioners or

providers, the letter to the beneficiary (Appendix 5-4.2) shall include ALL of the following:

1. A statement for each quality of care concern identified where care did or did not meet the standard of care.
2. A statement defining the standard of care that the QIO identified for each quality of care concern.
3. A statement of the facts describing how the practitioner and/or provider did or did not meet the standard of care.
  - The statement of facts should relate only to the facts that were essential in determining whether a provider and/or practitioner met professionally recognized standards of care.
4. A statement that this constitutes the QIO's final decision on the complaint, that no further rights are available, and there is no appeal right to the beneficiary for the applicable standard(s) of care.

The QIO shall prepare and mail the Beneficiary Quality of Care Complaint: Reconsideration Determination Letter to the practitioner/provider (Appendix 5-5.1) and the Beneficiary Quality of Care Complaint: Reconsideration Determination Letter to Beneficiary (Appendix 5-5.2).

A QIO shall follow the procedures in §5060.4, "Beneficiary Complaint: Procedures for Closing a Complaint Review" for closing the case in the CMS-designated case review system.

A QIO may refer the practitioner/provider for, Quality Improvement Initiatives in accordance with §5125 if deemed appropriate.

#### **5060.4 – Beneficiary Complaint: Procedures for Closing a Complaint Review (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO must denote in the CMS-designated or otherwise approved case review system that the beneficiary complaint is completed and closed. The QIO may determine that Post-Review Advocacy, a post-peer review alternative dispute resolution process, should be made available to the beneficiary. (See §5065).

The QIO must place all final documents in the Beneficiary Complaint folder/file and maintain this hard copy or electronic file in accordance with Manual Chapter 13.

The QIO may pursue Quality Improvement Initiatives in accordance with §5125 or Post-Review Advocacy in accordance with §5065, if deemed appropriate.

#### **5060.5 – Beneficiary Complaint: Responsibility to Protect Information and Destruction of Materials**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

As specified at 42 CFR §480.115, a QIO is responsible for protecting information and must implement reasonable security measures to ensure the integrity of information and prevent

unauthorized access (See Manual Chapter 10 for additional information).

The Initial Determination Peer Reviewer must follow the established QIO policy and procedures that apply to security measures for protecting QIO electronic data and confidential information.

### **5065 – Post-Review Advocacy**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Post-Review Advocacy is an informal process that a QIO may use to resolve a continuing concern of the beneficiary after the QIO has completed the formal Peer Review process. It entails the QIO directly contacting the Practitioner and/or Provider to discuss the beneficiaries' continuing concerns.

In situations where a Beneficiary Complaint Review was completed and no significant quality of care concern was found, a QIO may voluntarily offer an additional opportunity for the beneficiary and practitioner and/or provider to resolve their dispute through Post-Review Advocacy. This alternative dispute resolution process can be used after the Peer Review process is completed, but it is not required.

A QIO should summarize what Post-Review Advocacy entails for the beneficiary and obtain both the beneficiary's and provider and/or practitioner's oral consent to participate in Post-Review Advocacy before proceeding.

A beneficiary may discontinue Post-Review Advocacy at any time during the process. See §5065.5 for additional information about discontinuing Post-Review Advocacy.

Before offering the use of Post-Review Advocacy, the QIO should consider other factors that may affect the successful use of such an advocacy approach, including, but not limited to the:

- Ability of involved parties to articulate their own needs and interests;
- Desire for a direct, indirect, or immediate response;
- Physical or mental barriers to participation by any party;
- Desire for an opportunity to ask questions face-to-face or through another person;
- Level of comfort in addressing conflict directly or indirectly;
- Special needs of participating parties/ability of family and friends to participate in a meaningful way;
- Proximity of parties and ability to meet; and
- Complexity of the case (i.e., multiple settings, length of list of concerns).

Post-Review Advocacy should not be used in cases where Immediate Advocacy was attempted,

followed by the beneficiary ultimately filing a written complaint because an informal process has already failed.

### **5065.1 – Objectives of Post-Review Advocacy**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The objectives of Post-Review Advocacy are to:

1. Provide QIOs flexibility in resolving complaints in situations when the traditional peer review process did not result in an acceptable resolution of the beneficiary's concerns (e.g., the QIO completed the peer review but found no Quality of Care violation).
2. Increase beneficiary, practitioner, and/or provider satisfaction throughout the process by resolving complaints that would have otherwise not been resolved to the beneficiary's satisfaction.

### **5065.2 – Eligibility for Post-Review Advocacy**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

A QIO should consider offering Post-Review Advocacy to a beneficiary in situations when:

1. The beneficiary conveys that he/she still has concerns about aspects of the care provided, and the QIO determines that the concerns do not relate to the clinical quality of health care itself. The concern relates to items and/or services that accompany or are incidental to the medical care; or
2. The beneficiary conveys that he/she still has concerns about aspects of the care received, but while the care is related to the clinical quality of health care received, it does not rise to the level of being a "gross and flagrant," "substantial," "serious or urgent," or even a significant Quality of Care Concern. This may include situations where the QIO determines that the medical information did not contain evidence related to the beneficiary's original complaint.

The following complaints are examples of when Post-Review Advocacy is appropriate:

- The beneficiary complains that the practitioner spoke to him/her in a rude manner or otherwise did not treat him/her respectfully.
- The beneficiary contacts the QIO about his/her failure to receive a motorized scooter or wheelchair.
- The beneficiary is concerned that he/she received a different colored pill than expected and would like the QIO to find out what drug was given.

### **5065.3 – Practitioner/Provider Consent to Participate in Post-Review Advocacy**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Immediately upon obtaining the beneficiary's oral consent to participate in Post-Review Advocacy, the practitioner/provider should be contacted to obtain oral consent to participate.

The QIO should ensure the practitioner/provider has received notice of the resolution of the original complaint and the beneficiary's desire to continue pursuing resolution of the complaint through Post-Review Advocacy.

The QIO should convey sufficient information about the nature of the continuing complaint to enable the practitioner/provider to make an informed decision about agreeing to participate in Post-Review Advocacy.

Upon obtaining the practitioner/provider's oral consent to participate in Post-Review Advocacy, the QIO should follow the Post-Review Advocacy procedures in §5065.4 to resolve the concerns.

If the practitioner and/or provider decide not to participate in the Post-Review Advocacy process, the QIO should immediately contact the beneficiary and inform him/her of the practitioner and/or provider's decision not to participate. The QIO should inform the beneficiary that the QIO's review of the matter has ended.

#### **5065.4 – Post-Review Advocacy Procedures**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Once a QIO has obtained oral consent from all parties, the QIO may either use a conference call/three-way call or make a call on behalf of the beneficiary to resolve the beneficiary's concerns. The focus should be on providing a quick and amicable resolution of the concerns within a short time frame—usually within eight (8) hours to two (2) business days.

In some circumstances, the practitioner/provider may be unavailable for a period of time after the beneficiary consents to the use of Post-Review Advocacy. In these situations, the QIO should contact the beneficiary to explain the circumstances. The use of Post-Review Advocacy should not extend beyond ten (10) days from the beneficiary's consent.

If Post-Review Advocacy is carried out for any Beneficiary Complaint, the QIO must document its work by updating the CMS-designated case review system to describe how Post-Review Advocacy occurred and resolution of the complaint. After the Post-Review Advocacy has completed, the QIO must close the case accordingly.

#### **5065.5 – Discontinuation of Post-Review Advocacy**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

If, at any point, a beneficiary expresses a desire to stop pursuing concerns through the Post-Review Advocacy process, the QIO should inform the beneficiary that the QIO's role in the review of a complaint will end and that the case will be closed. Post-Review Advocacy can only be successful when all parties participate.

**NOTE:** The QIO may refer the practitioner/provider for, Quality Improvement Initiatives in accordance with §5600 if deemed appropriate.

## **5070 – Quality of Care Reviews – General**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The following sections provide instructions for QIOs to follow in reviewing quality of care concerns received and/or identified from sources other than Beneficiary Complaints. (See 42 CFR §476.160. These sources include:

1. **Concerns Identified during Other Review Activities:** Quality of Care reviews conducted when a potential quality of care concern(s) is identified during any other review activity (e.g., medical necessity reviews, expedited discharge appeals, Emergency Medical Treatment and Labor Act (EMTALA) reviews. See § 5075, “Concerns Identified during Other Review Activities.”
2. **Referrals:** Quality of care reviews conducted in response to referrals from other entities (e.g., contractors, state-based organizations, the Office of Inspector General, the Office for Civil Rights), and anonymous referrals. See §5080, “Source – Anonymous Beneficiary” and §5085, “Referrals.”
3. **Tracking and Trending:** Quality of Care reviews conducted as a result of tracking and trending of data. See §5095, “Tracking and Trending of Data.”  
The process instructions are identical for reviews that originate from sources other than Beneficiary Complaints (i.e., Concerns Identified during Other Review Activities, Referrals, or Tracking and Trending). (See §§5100-5100.4.) Unlike Beneficiary Complaint Reviews, where the instructions are divided into four stages, General Quality of Care Review is grouped into three stages to help identify roles and steps associated with various aspects of the process.

The General Quality of Care Review stages are as follows:

Stage One: Intake

Stage Two: Quality of Care Review

Stage Three: Reconsideration

## **5075 – Concerns Identified During Other Review Activities**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

QIOs may identify potential Quality of Care Concerns while conducting any other review (e.g., appeal, medical necessity/utilization, higher-weighted DRG, EMTALA). When a potential Quality of Care Concern is identified, the QIO must conduct a General Quality of Care Review. (See §5100.)

## **5080 – General Quality of Care Review: Source – Anonymous Beneficiary**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

If a beneficiary wishes to remain anonymous, the QIO must process the complaint as a General

Quality of Care Review if the QIO believes the concerns warrant review. (See §5100, 42 CFR §§476.120(a)(2), and 476.160(a)(1)(i)).

For General Quality of Care Reviews conducted as a result of a beneficiary complaint or referral, the beneficiary should be informed that the QIO will NOT inform the practitioner/provider:

1. Of the source of the referral for the Review; and
2. That the QIO is requesting medical records as a result of a beneficiary complaint/referral.

For General Quality of Care Reviews conducted as a result of a beneficiary complaint or referral, the QIO should inform the beneficiary that she/he will NOT be informed of the results of the General Quality of Care Review.

If the individual making the complaint is identifiable as a beneficiary or beneficiary representative, the QIO is able to initiate direct contact with the beneficiary or beneficiary representative. If the beneficiary does NOT wish to remain anonymous, the QIO shall process the case in accordance with the Beneficiary Complaint Review procedures. (See §5040).

A QIO should make every effort to keep the beneficiary's name confidential during the review process if a General Quality of Care Review is initiated. This includes taking steps that will not alert the practitioner/provider to this specific beneficiary. For example:

- If additional medical records are needed from the practitioner/provider to complete other case reviews, the medical request for all records should be issued at the same time. This will minimize the practitioner's ability to ascertain the name of the particular beneficiary that initiated the Quality of Care Review by the QIO.

**NOTE:** The QIO should inform the beneficiary of the possibility the practitioner/provider could ascertain the name of the beneficiary during the General Quality of Care Review process based on the nature of and the specific facts surrounding the beneficiary's complaint.

### **5085 – General Quality of Care Review: Referrals (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Medicare Administrative Contractors (MACs), Medicare health plans (MHPs), State Medicaid survey and certification agencies (SSA), other CMS contractors, and CMS staff may also refer cases involving potential Quality of Care Concerns to QIOs.

Before conducting a General Quality of Care Review for these types of referrals, the QIO should contact the CMS COR before proceeding with the review.

Only the Request for QIO Review Form (See Appendix 5-8) is authorized for use when an agency or entity refers a potential Quality of Care Concern to a QIO. The QIO should send a copy of the request to the designated COR upon receipt. The QIO may proceed with conducting a General Quality of Care Review in accordance with §§5100-5110.

**NOTE:** At the COR's discretion, additional information may be requested from the referring agency/entity when the request involves an extensive number of General Quality of Care Reviews.

The QIO should conduct General Quality of Care Reviews on all referrals when sufficient information is conveyed to complete the review. When a potential quality of care concern, that is a potential gross and flagrant violation or a substantial violation in a substantial number of cases (more than three) is referred, the QIO must conduct a General Quality of Care Review. (See §§5100-5115.3)

### **5085.1 – Referrals from Other Federal Government Organizations (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

When a QIO receives a referral or request for review for potential Quality of Care Concerns from Federal Government organizations outside of the Centers for Medicare & Medicaid Services (e.g., the Office of Inspector General, the Department of Justice [DOJ], or the Office for Civil Rights), the QIO should provide a copy to the appropriate CMS COR. When a potential Quality of Care concern is referred to the QIO, the requestor will use the authorized QIO Case Review Referral Request Form. (See Appendix 5-8.) Upon receiving any referred potential Quality of Care Concerns, the QIO must follow the process requirements set forth in §5100, "Quality of Care Reviews – General." When a potential Quality of Care Concern is referred, the QIO must conduct a General Quality of Care Review. (See §§5100-5115.3.)

### **5090 – Overlap of Review Authority (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

QIOs may receive referrals of potential Quality of Care Concern(s) from other sources, agencies, or entities (e.g. other QIOs, public or private review organizations, Medicare contractors such as MACs), when the referring source or entity identifies what may be a quality concern related to Medicare services while conducting a review based on its jurisdictional requirements [See §476.160(a)].

Pursuant to 42 CFR §476.104, QIOs must work with these organizations to ensure any necessary coordination. QIOs are responsible for ensuring that organizations, including contractors, have clearly defined direction about the types of cases that warrant referral to the QIO.

### **5095 – Tracking and Trending of Data (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

QIOs must conduct analyses of data from all review types to identify potential Quality of Care Concerns in accordance with the contract requirements.

Data analyses may be conducted within and/or across provider settings in accordance with contract requirements. In addition, QIOs must make every attempt to identify Quality of Care Concerns related to health disparities issues, including racial, ethnic, or socioeconomic indicators.



**NOTE:** When a potential Quality of Care Concern is identified through data analysis, a QIO should conduct a General Quality of Care Review. (See 42 CFR §476.160(a)(1)(iii) and §§5100-5115.3 of Manual Chapter 5.)

## **5100 – General Quality of Care Review**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The following instructions describe the steps when the QIO reviews quality of care concerns received and/or identified from sources other than Beneficiary Complaints (i.e., Concerns identified during other review activities, referrals, or tracking and trending).

### **5110 – General Quality of Care Review: Preparing the General Quality of Care Review Folder: Intake – Stage One**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

**NOTE:** The QIO referenced in this section refers to a qualified staff member as a QIO designates. The job title may differ within each QIO.

A QIO is responsible for preparing the General Quality of Care Review folder/file. Should a copy of the folder/file be needed (e.g., for use by an off-site Peer Reviewer), a duplicate copy of the folder/file may be prepared. CMS expects that the folder/file will be forwarded to the QIO within one (1) business day of receiving a referral or identifying a potential Quality of Care Concern as a result of tracking and/or trending of data.

In instances where a Quality of Care Concern is identified during other review activities, the QIO will prepare/organize the information necessary to enable the Quality of Care Review to be completed in addition to the original review activity. For example:

In completing an expedited discharge appeal review, the Peer Reviewer identifies a Quality of Care Concern. A QIO should establish procedures to enable the Reviewer who identified the Quality of Care Concern to complete the Quality of Care Review.

#### **5110.1 – General Quality of Care Review: Review of Folder by the QIO**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO should review the General Quality of Care Review information in the folder/file as well as the information in the CMS-designated case review system to ensure that he/she understands the specific concern(s) involved and identifies the necessary medical records to be requested.

#### **5110.2 – General Quality of Care Review: Requesting Medical Information**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The following steps do not apply to instances where the QIO already possesses medical information (e.g. records in connection with another review activity). The instructions and guidance here are written to apply to requests for medical information in response to General Quality of Care Reviews conducted as a result of referrals and/or tracking and trending of data.

## TIMELINE:

Practitioners and/or providers are obligated to forward all required information within fourteen (14) calendar days of the request from a QIO. See 42 CFR §476.160(b). A QIO may request the medical information from the practitioner and/or provider sooner than the fourteen (14)-calendar day time frame, if the QIO determines the review involves a potential gross and flagrant or substantial violation of the quality of care and circumstances warrant earlier receipt of the information. If the QIO makes a preliminary determination that the review involves a potential gross and flagrant violation or a substantial quality of care concern as specified in Part 1004 of the Act, and circumstances warrant earlier receipt of the medical information, the QIO should document the determination and the reason for it.

Medicare health plans (MHPs) are responsible for submitting medical information absent a specific delegation to the provider. Should a MHP fail to submit medical information as requested within the prescribed fourteen (14)-calendar-day timeframe (or at an earlier date as applicable, the matter should also be referred to the pertinent CMS COR for CMS to take action to secure compliance by the Medicare health plan. When a provider has been specifically delegated the responsibility to submit medical information, the COR will collaborate with the Division of Medicare Health Plan Operations (DMHPO) about any options that may be pursued in light of the provider's Medicare Provider Agreement.

In situations where a practitioner and/or provider fails to submit medical information within the required time frame, the practitioner and/or provider may be subject to a denial of payment under 42 CFR §476.90. In some situations, where either a practitioner or provider fails to submit medical information within the required timeframe, the QIO should advise the practitioner or provider that, based on §1156(a)(3), sanctions may be initiated because of the failure to support the provision of items or services with evidence of the medical necessity for and quality of the items or services.

**NOTE:** Upon receiving medical information at any step, follow the instructions as outlined in §5110.4, "General Quality Review: Review and Preparation of Medical Information."

CMS expects the QIO to complete the following steps in requesting medical information consistent with 42 CFR 476.160(b):

**Step 1:** Request the medical information within one (1) business day after receiving the referral or identifying a potential quality of care concern as a result of tracking and/or trending of data.

The QIO may contact the practitioner and/or provider by phone and follow up with a facsimile or mailed letter. If a letter is sent, the letter must clearly indicate the specific date on which the medical information was first requested, because this date will be used to determine when a claim denial shall be issued. See §5110.3 for information about a claim denial. Even if a letter is not sent, the QIO must document the date and time of the request.

**NOTE:** The date of the letter may be used if it corresponds to the date of the first request. The QIO must advise a practitioner and/or provider of the requirement to submit the requested medical information within fourteen applicable time frame.

A QIO may contact either/both the Medical Records Department or the QIO liaison based on procedures that have been established with the practitioner and/or provider.

**Step 2:** The QIO should follow up as necessary to ensure adherence to the fourteen (14) calendar-day submission deadline - i.e. fourteen (14) calendar days from request or the earlier in those circumstances where the QIO made a preliminary determination that the review involved a potential gross and flagrant or substantial quality of care concern.

Before making contact to follow up on the request for information and documents, the QIO should verify the following information:

1. The QIO has not previously requested and received the medical information by conducting a search in the CMS-designated case review system.
2. The date the medical record is due for receipt by the QIO is correct. The timeframe can vary in cases where a potential gross and flagrant quality of care concern is identified.

If the medical information is not received from the practitioner and/or provider by calendar day fourteen (14) or other date the QIO designates, the QIO will notify the practitioner and/or provider of potential for denial of the applicable claim(s) under 42 CFR §476.90; **and**

Remind the practitioner/provider that , under §1156(a)(3), items or services provided by or ordered by practitioners must be supported by evidence of medical necessity and quality, in such form and fashion and at such time as may reasonably be required by a QIO in the exercise of its duties and responsibilities. The QIO should point out that any unreasonable delay in providing medical information could lead to sanctions under §1156(b).

This step is meant to furnish a practitioner and/or provider with adequate notice to correct any problems associated with submitting medical information, and to help the practitioner and/or provider avoid potential penalties or claims denials.

**Step 3:** In addition to contacting the provider /practitioner, the QIO should immediately contact the COR and provide sufficient information so that the COR is prepared to contact the practitioner and/or provider. The QIO should also follow up with the COR to advise him/her if/when the medical information is received.

**Step 4:** On the next business day after the deadline for the delivery of the medical information requested by the QIO, the COR may call the Medical Records Department, the QIO liaison, and/or senior leadership, and convey the responsibilities associated with the request for the medical information.

The COR may assess the willingness of the practitioner/provider to comply with the request for medical information and explain the potential repercussions of failure to provide the medical information, including:

- A claim denial;
- For Medicare health and drug plans, notifying the Division of Medicare Health Plan Operations; and

- Referral to the OIG.

**NOTE:** The COR advises that if the medical information is not received within the next calendar day, a claim denial shall be carried out for any claim associated with the quality of care concern identified.

**Step 5:** If the medical information is not received from a practitioner and/or provider within thirty (30) calendar day of the QIO request, the QIO must proceed in accordance with §5110.3, “General Quality Review: Issuing a Claim Denial.”

**NOTE:** In instances when the QIO completes a claim denial, the practitioner and/or provider is still required to comply with its responsibility to forward the medical information to the QIO to complete the quality of care review.

For providers and practitioners, a COR may recommend additional action depending on the particular facts of the situation (e.g., recommending that the QIO conduct additional Quality of Care Reviews on other patients for whom the practitioner and/or provider has submitted similar claims for payment).

### **5110.3 – General Quality of Care Review: Issuing a Claim Denial** (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

A QIO is authorized to deny a practitioner and/or provider’s claim in situations where the QIO has requested information from a practitioner and/or provider and, despite sufficient notice and a reasonable amount of time to respond, the practitioner and/or provider fails to forward the requested information. (See 42 CFR §§476.103(2)(b) and 476.90(b)).

**NOTE:** Before processing a claim denial, the QIO should coordinate with the appropriate CMS COR.

If the requested medical information is received before the claim denial is finalized, the QIO must stop the denial and complete the review. If the medical information is received after the claim denial has been finalized, payment must be re-instituted. The QIO should complete the review.

### **5110.4 – General Quality of Care Review: Reviewing and Preparing Medical Information** (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

Upon receiving the medical record documentation, the QIO should immediately date-stamp the form and scan the form, original envelope, and/or facsimile, or email and upload them to the CMS-designated case review system (unless received electronically).

The QIO should file the original envelope with the medical record documentation. The QIO should also ensure that all information in the medical information is complete, appropriately organized, and legible.

If the medical documentation in the medical record is incomplete or illegible (poor copy), the QIO may contact the practitioner and/or provider by phone and allow an additional five (5) calendar days for submission of the documentation necessary to complete the medical review process.

**NOTE:** QIOs should follow the procedures for issuing a claim denial in §5110.3 when complete medical information is not received in accordance with the timeline identified in §5110.2 (See Appendix 5-10, “General Quality of Care Review - Best Practices”)

The QIO should verify that the medical information record documentation received for each medical request contains the major documentation components, particularly those relevant to the quality of care concern. Examples include but are not limited to the following:

1. Emergency Room Record/Admission Record;
2. History and Physical;
3. Consultations;
4. Practitioner Orders;
5. Practitioner Progress Notes;
6. Nursing Notes;
7. Ancillary (e.g., laboratory Reports, X-rays, medication administration record, treatment administration record)
8. Discharge Summary.

**NOTE:** QIOs are authorized to upload medical record documentation received directly into the CMS-designated system or other secure electronic system(s) CMS approves. The documentation should be uploaded within one (1) business day of receiving the medical information.

For General Quality of Care Reviews, the following communication information should be documented in the CMS-designated case review system:

- Date on which a QIO requests medical records from a practitioner and/or provider by phone, in writing, fax, or CMS approved method for secure file transfer.
- Date on which a practitioner and/or provider contacts the QIO (in writing, by phone or in person) to request a reconsideration.
- Date and pertinent parts of the conversation when the QIO notifies the practitioner and/or provider of the QIO’s Final Decision, which must occur within five (5) calendar days after the request for reconsideration or receipt of the medical or other records needed for the reconsideration. (**NOTE:** If the QIO orally contacts the practitioner/provider about

this decision, the QIO must send the practitioner/provider a written notice by 12:00 noon of the next calendar day.)

Use of the CMS-designated case review system is designed to facilitate the resolution of any questions that may arise about a specific complaint and ensures that all pertinent information related to a complaint is uniformly recorded and centrally located in the CMS-designated case review system.

If the QIO or Peer Reviewer determines that handwritten information in the medical information cannot be deciphered, the QIO may contact the facility and request a typed/transcribed portion of the problem sections of the medical information.

The QIO should make every effort to limit the amount of typed/transcribed information requested. Failure to comply with a request for typed/transcribed information shall be treated as a failure to provide the medical information if the missing information precludes the completion of the review.

The Initial Determination Peer Reviewer may be consulted before determining to pursue a claim denial. QIOs must follow the procedures in §5110.3 for processing these denials.

### **5115 – General Quality of Care Review: Quality of Care Review – Stage Two (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO may also identify potential Quality of Care concerns or cases for Quality of Care Reviews while carrying out the QIO's work responsibilities related to other review activities. Additional case(s) appropriate for Quality of Care Reviews may also be identified as a result of tracking and trending of data.

Regardless of the referral source for a Quality of Care Review, the QIO initiates the review by conducting a preliminary review of each quality of care concern(s) identified.

#### **5115.1 – General Quality of Care Review: Preparing the Quality Review Decision (QRD) Form (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Once a determination is made about the specific concern(s) to be addressed, the QIO should prepare a QRD Form containing all potential concerns that have been identified (See Appendix 5-1.3 "Quality Review Decision (QRD) Form."). The QRD Form is the only form authorized for identifying, documenting, and summarizing the quality of care concerns addressed in the review.

The QRD Form is designed to account for the multiple individuals involved in a Quality of Care review and to ensure that information related to every Quality of Care Concern is maintained in an organized, detailed, and consistent fashion throughout the review process.

Pursuant to the QIO contract, the QIO uses the CMS-designated case review system to prepare a QRD Form that sets out each individual concern and forwards the review materials and associated medical information to the Initial Determination Peer Reviewer within three (3)

business days of receiving the medical information. In completing the QRD Form, the QIO should do each of the following:

1. Identify each Quality of Care Concern;
2. Identify the quality of care with regard to the admission diagnosis and treatment plan established for the beneficiary, if applicable;
3. Research evidence-based practices related to each Quality of Care Concern(s), while considering the definition of Quality Care, including reference to relevant norms and criteria. If no quality of care standard(s) exists, then the QIO will use available norms, best practices, and established guidelines, to recommend a potential quality of care standard(s). In order to identify all applicable criteria and norms to be applied pursuant to §476.100, the QIO must thoroughly research all available information, including:
  - Nurse screening criteria (e.g., InterQual, Milliman, etc.);
  - Generally available resources, including information available via Internet searches;
4. Complete an Assessment section for each Quality of Care Concern;
5. Evaluate additional information pertinent to the case, but unrelated to the standard(s) of care. This evaluation may include:
  - CMS-available information, including web-based resources (e.g., Nursing Home and Hospital Compare);
  - State-based resources, including web-based literature and information as well as practitioner-specific information related to license revocations and referrals to the State medical conduct organizations;
6. Research all available data, a minimum of three (3) years from the date of service, to determine whether similar complaints have been received on the same practitioner and/or provider and/or if other potential concerns related to the same practitioner and/or provider are identifiable; and
7. Utilize the medical information received to prepare the information needed to complete the review and forward it to the Initial Determination Peer Reviewer.

## **5115.2 – General Quality of Care Review: Receipt and Review by the Initial Determination Peer Reviewer**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO mails or sends the materials to be reviewed and the QRD Form via a secure electronic method to the Initial Determination Peer Reviewer immediately after receiving the Medical Record documentation.

Once the Peer Reviewer receives the medical record documentation, the review should be initiated immediately.

The Peer Reviewer evaluates the standard(s) that the QIO identified for each concern on the QRD Form and checks off the appropriate box indicating whether he/she concurs or does not concur with the identified standard(s) of care. If the Peer Reviewer identifies new Quality of Care Concerns, the Peer Reviewer must identify and document the concern(s), as well as the specific standard(s) of care for each concern, and include pertinent research supporting the standard of care he/she used to evaluate each concern on the QRD form.

If the Initial Determination Peer Reviewer determines that the standard(s) identified by the QIO for a specific concern(s) is incorrect or not thorough, he/she identifies the correct standard(s) and provides an explanation of the change, including references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care.

The Initial Determination Peer Reviewer then applies the standard(s) of care to the specific facts of the case and the Quality of Care Concern(s) at issue. The Peer Reviewer evaluates the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care.

The Peer Reviewer must evaluate whether the quality of care standard for each identified concern is met based on the facts of the case and directly link his/her decisions to elements contained in the evidence-based standard(s), or in the absence of evidence-based standards of care, using available norms, best practices, and established guidelines consistent with §476.100.

The Peer Reviewer also assesses the individual who is responsible for any standard(s) not met. The Peer Reviewer addresses the following in the documentation of the Review:

- Any historical data pertinent to the concern(s) provided by the QIO, highlighting specific evidence from the review of the medical information and demonstrating specific elements within the standard(s) of care that are met or not met;
- Any other information relevant to the Initial Determination; and
- Extenuating circumstances taken (or not) into consideration (e.g., emergent circumstances or exceptional complexity).

**NOTE:** The Peer Reviewer must be accurate and thorough in conducting and documenting the review, including a full explanation of the analysis, in order to fulfill the Review responsibility.

Upon completing the Rationale/Justification portion for each concern on the QRD Form, the Initial Determination Peer Reviewer must check off the appropriate box indicating his/her decision that the standard(s) of care was met or not met for each concern. If the Peer Reviewer determines that the standard(s) of care was not met for a concern, the Initial Determination Peer Reviewer must also check off the appropriate box indicating whether:



- The care grossly and flagrantly, in one or more instances, violated the provider's or practitioner's obligation to provide care that is of a quality that meets professionally recognized standards of health care.
- The care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care.
- The care failed to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care.
- The care did not meet the standard of care, but was less than a substantial violation of the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (i.e., it was either significant or non-significant).

The Initial Determination Peer Reviewer must complete the review of the medical information provided and complete the QRD Form (See Appendix 5-1.3). The peer reviewer must, adhere strictly to the format in the QRD Form, and return the completed QRD Form to the QIO in sufficient time that the practitioner/provider can be notified of the initial determination within ten (10) calendar days of the QIO receiving the necessary medical records.

The Peer Reviewer must sign and date the QRD Form and indicate the amount of time spent reviewing the materials.

Except in circumstances when the Peer Reviewer conducts the review on the QIO premises, the Peer Reviewer may maintain a signed copy of his/her completed QRD Form and additional notes.

### **5115.3 – General Quality of Care Review: Return of Initial Determination (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Immediately upon receiving the General Quality of Care Review folder from the Initial Determination Peer Reviewer, the QIO must ensure all necessary information has been returned and the QRD Form has been signed.

The QIO should review the QIO Form to ensure that the Peer Reviewer rendered a decision on all quality of care concerns, that the content adheres to the correct format, and that the rationale for conclusions is clear. This review should occur promptly to ensure that the mandatory timeframe for notifying the practitioner/provider is met.

The QIO must ensure that the practitioner and/or provider is notified of the Peer Reviewer's Initial Determination, in writing, within 10 calendar days from receipt of a complete medical record.

In the same letter in which the QIO informs the practitioner/provider of the Initial Determination results, the QIO must also notify the practitioner/provider of his/her right to request reconsideration for reviews initiated after July 31, 2014.

**NOTE:** If the Initial Determination Peer Reviewer has identified a concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (see §1156(a) of the Act), then the QIO must initiate sanction proceedings in accordance with Manual Chapter 9.

Once confirming that the documentation is complete for the Initial Determination Peer Reviewer's determination as to whether the standard of care was met or was not met for all concerns, the QIO should follow the procedures detailed in §5115.4, "General Quality of Care Review: Preparation of the Initial Determination Letter"

### **5115.4 – General Quality of Care Review: Preparation of the Initial Determination Letter**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Upon receiving the QRD Form, the QIO prepares the "General Quality of Care Reviews – Initial Determination Letter" (Appendix 5-6) conveying the decision to the practitioner and/or provider. The letter must be sent to the practitioner/provider such that the practitioner/provider is notified of the initial determination within ten (10) calendar days of the receipt of medical records by the QIO (See §476.160).

The letter must:

- Advise the practitioner and/or provider of the right to request a reconsideration of any review initiated after July 31, 2014, if the standard(s) of care was not met for any concern(s)
- Inform the practitioner and/or provider of the deadline for requesting a reconsideration (See §476.140); and
- Inform the practitioner and/or provider that this will be the last communication about the QIO's decision if no request for reconsideration is received.  
Note: See §5120, "General Quality of Review Reconsideration Stage Three," for information related to a practitioner's and/or provider's failure to respond to the reconsideration request.

If the practitioner and/or provider does not request reconsideration (by phone or in writing) within three (3) calendar days, then the practitioner and/or provider may not be granted a request for reconsideration. See §5120.

### **5115.5 – General Quality of Care Review: Responsibility to Protect Information and Destruction of Materials**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

As specified at 42 CFR §480.115, a QIO is responsible for protecting information and must implement reasonable security measures to ensure the integrity of information and prevent unauthorized access. See Manual Chapter 10 for additional information.

The Initial Determination Peer Reviewer must follow the established QIO policy and procedures that apply to security measures for protecting QIO electronic data and confidential information.

A QIO must maintain all medical record documentation in hard copy form or electronic files in accordance with Manual Chapter 13.

### **5120 – General Quality of Care of Care Review: Reconsideration – Stage Three (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The General Quality of Care Reconsideration procedures (see 42 CFR §476.170) replaces the Retrospective General Quality Re-review Process (§5580) and Concurrent General Quality Re-review Process (§5640) described in Manual Chapter 5 Quality of Care Revision-17, dated 04/06/12.

**NOTE:** For General Quality of Care Re-Reviews filed **before** July 31, 2014, (see 42 CFR §476.170), a practitioner and/or provider may request a Re-review, in accordance with Manual Chapter 5, (§s 5640 and 5580) Revision-17, dated 04/06/12.

For Re-reviews filed after July 31, 2014, a practitioner and/or provider may request reconsideration in accordance with §476.170.

For General Quality of Care Reviews filed after July 31, 2014, the practitioner and/or provider may request reconsideration within three (3) calendar days of receiving the QIO's Final Initial Determination (i.e. General Quality of Care Reviews: Initial Determination Letter with Right to Request Reconsideration to Practitioner and Providers - Appendix 5-6). Additional evidence may also be submitted as part of the reconsideration process.

Upon receiving a reconsideration request, the QIO must forward the General Quality of Care Review folder including the following items to the Reconsideration Peer Reviewer so that a reconsideration review can be completed:

- QRD form;
- All medical information received by the QIO;
- General Quality of Care Reviews: Initial Determination Letter with Right to Request Reconsideration to Practitioners and Providers, which conveys the decision to the practitioner and/or provider (Appendix 5-6); and
- Any new evidence submitted in requesting the reconsideration.

The folder with the above information should be forwarded to the Reconsideration Peer Reviewer as soon as possible as the reconsideration decision must be provided within 5 calendar days (See §5120.1).

#### **5120.1 – General Quality of Care Review: Reconsideration Peer Reviewer (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

For CMS to treat the reconsideration as valid and fulfilling the right to reconsideration, the Reconsideration Peer Reviewer must be different than the Peer Reviewer who conducted the Initial Determination. In making his/her determination, the Reconsideration Peer Reviewer shall review all information forwarded by the QIO.

The Reconsideration Peer Reviewer documents his/her review and determination using the QRD Form, for each Quality of Care Concern.

The Reconsideration Peer Reviewer receives the package from the QIO and initiates the reconsideration.

The Reconsideration Peer Reviewer must review each potential quality of care concern identified by the QIO and/or the Initial Determination Peer Reviewer. For each concern, the Reconsideration Peer Reviewer:

- Evaluates the standard(s) the QIO and the Initial Determination Peer Reviewer identified on the QRD Form;
- Checks off the appropriate box indicating whether he/she concurs or does not concur with the standard(s) of care as the QIO and Initial Determination Peer Reviewer delineated;
- Determines if the standard(s) identified by the QIO and/or Initial Determination Peer Reviewer identified for a specific concern(s) is incorrect or not thorough, and, when appropriate, identifies the correct standard(s) and provides an explanation of the change; and
- Includes references to relevant literature/research supporting the decision regarding the appropriate standard of care and consults with the Medical Director to obtain the Medical Director's concurrence on the standard to be used in evaluating the concern(s) in instances where the standard of care has not been met.

**NOTE:** The QIO staff member who prepared the case for the peer reviewer shall be included in this consultation.

In the rare instance when a Reconsideration Peer Reviewer identifies a new concern, the Reviewer must notify the QIO for the QIO to initiate processing of the newly identified concern at the Quality of Care Review Stage. The Reconsideration Peer Reviewer must not evaluate the concern because the matter will be eligible for review by an Initial Determination Peer Reviewer.

### **Completion of the Rationale/Justification**

Upon determining the appropriate standard of care, the Reconsideration Peer Reviewer then applies the standard of care to the specific facts of the case and the quality of care concern at issue.

The Reconsideration Peer Reviewer evaluates the medical information based on the standard as identified, including each evidenced-based element of the standard of care.

The Reconsideration Peer Reviewer must directly link his/her decisions to elements contained in the evidence-based standard), or in the absence of evidence-based standards of care, will use available norms, best practices, and established guidelines, when deciding whether quality of care for each identified concern is met based on the facts of the case. The Reconsideration Peer Reviewer also assesses the individual responsibility for the standard(s) not met.

In addition, the Reconsideration Peer Reviewer must consider any historical data pertinent to the concern(s) as provided by the QIO, highlight specific evidence from the review of the medical information demonstrating that specific elements within the standard of care are met or not met, and include any other information the Reconsideration Peer Reviewer deems relevant to his/her Reconsideration Determination.

If the Reconsideration Peer Reviewer, in his/her determination, concludes that there are extenuating circumstances to take into consideration (e.g., emergent circumstances or exceptional complexity), he/she must thoroughly explain these justifications in completing the Rationale/Justification section of the QRD Form.

The Reconsideration Peer Reviewer must complete a separate analysis for each quality concern. Upon completing the Rationale/Justification section, the Reconsideration Peer Reviewer must check off the appropriate box indicating his/her decision that the standard of care was met or not met.

If the Reconsideration Peer Reviewer determines that the standard(s) of care was not met, he/she must also check off the appropriate box indicating whether:

- The care grossly and flagrantly, in one or more instances, violated the practitioner/provider's obligation to provide care that is of a quality that meets professionally recognized standards of health care.
- The care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care.
- The care failed to substantially comply with the obligation) to provide care that is of a quality that meets the professionally recognized standard(s) of health care.
- The care did not meet the standard of care but was less than a substantial violation of the obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care (i.e., it was either significant or non-significant).

The Reconsideration Peer Reviewer must complete his/her review of the medical information, adhere strictly to the format in the QRD Form, sign and date the form, and indicate the amount of time spent completing the review.

The Reconsideration Peer Reviewer must return the package to the QIO with sufficient time to ensure the QIO is able to complete its review of the reconsideration. A QIO must notify the practitioner or the provider of the results within five (5) calendar days after the QIO received the

request for reconsideration, or within five (5) calendar days after receiving any medical information or other records needed for the QIO to complete the reconsideration.

**NOTE:** If the Reconsideration Peer Reviewer has identified a concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standards of health care as required by §1156(a), then the QIO must initiate sanction proceedings in accordance with Manual Chapter 9.

### **5120.2 – General Quality of Care Review: Preparing the Reconsideration/Final Determination Package** (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

The QIO receives the review materials and completed QRD from the reconsideration Peer Reviewer and examines it to ensure all necessary information is returned. The QIO identifies the reconsideration decision on the QRD Form and prepares the “General Quality of Care Review Final Reconsideration Letter for Practitioner/Provider” (See Appendix 5-7).

The QIO should use the language in the General Quality of Care Reviews: Initial Determination Letter unless substantial changes have been made. The QIO must notify the practitioner/provider of the QIO’s Final Determination (as summarized in the Letter) no later than five (5) calendar days after receiving the request for reconsideration, or if later, five (5) calendar days after receiving any medical or other records needed for the reconsideration.

### **5120.3 – General Quality of Care Review: Preparing and Mailing the Final Reconsideration Determination Letter** (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

In preparing the General Quality of Care Reviews: Final Reconsideration Determination Letter to Providers and Practitioners (See Appendix 5-7), the QIO must ensure the letter includes the following:

1. A statement for each quality of care concern that care did or did not meet the standard(s) of care;
2. The standard(s) that the QIO identified for each quality of care concern;
3. A specific statement conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard; and
4. A statement that this constitutes the QIO’s final decision and that no further appeal rights are available.

The QIO’s Final Decision shall be issued to the provider no later than five (5) calendar days after the request for reconsideration, or if later, five (5) calendar days after receiving any medical or other records needed for the reconsideration. See 42 CFR §476.170.

**NOTE:** The timeframe for completion starts when additional information is received from all parties. If additional information is not received within seven (7) calendar days of the offer to submit additional information, the QIO should proceed with the reconsideration with the information that is available.

#### **5120.4 – General Quality of Care Review: Procedures for Closing Review (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

The QIO must document in the CMS-designated case review system that the General Quality of Care Review is being closed by following all applicable requirements, and must place all file documents in hard copy or electronic file. A QIO may pursue Quality Improvement Initiatives in accordance with §5125 if deemed appropriate.

#### **5125 –Beneficiary and Family-Centered Care-QIO – Recommendations and Referrals for Quality Improvement Initiatives and Technical Assistance (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Pursuant to the QIO’s contract obligations, the Beneficiary and Family-Centered Care-QIO must make recommendations to Quality Innovation Network (QIN) - QIO or other CMS-designated contractor(s) for conducting quality improvement initiatives (QIIs) associated with quality of care issues. QIIs may be the result of any Beneficiary and Family-Centered Care review function and could include system-wide change QIIs and non-system-wide change QIIs.

A Quality Improvement Initiative (QII) is any formal activity designed to support quality improvement that uses proven methodologies to achieve these improvements. The improvements may relate to safety, health care, health, and value, and may involve providers, practitioners, beneficiaries, and/or communities. See 42 CFR §476.1.

A QII may consist of system-wide and/or non-system-wide changes and may be based on a single, confirmed concern or multiple confirmed concerns. Pursuant to the QIO’s contract obligations to develop and implement QIIs, QIIs must be considered for all confirmed concerns EXCEPT the following:

1. When it is determined that a practitioner(s) and/or provider(s) grossly and flagrantly failed to provide care that is of a quality that meets professionally recognized standard(s) of health care. (See §1156(a) of the Act.)
2. When the care failed in a substantial number of cases (more than three) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care. (See §1156 of the Act.)

**NOTE:** In either of the above instances, the QIO must initiate sanction proceedings in accordance with Manual Chapter 9. These proceedings will, if appropriate, involve the implementation of Corrective Action Plans.

To fulfill the contract obligations to develop and implement QIIs, QIN-QIOs must consider all aspects of the referral case. QIN-QIOs must employ data analysis techniques to identify potential opportunities to improve care. In addition, QIOs should consider the impact of changes within,

and across, settings. For example, if a practitioner provides care in more than one setting (e.g., an inpatient acute care setting and a skilled nursing facility), the QIO should use information available from all settings to determine improvements in one or all of the settings. QIOs may work with one, several, or all related practitioner(s)/provider(s) concerned to improve the level of the practitioner's/provider's performance; related practitioners/providers could include other practitioners/providers in the same setting(s) or other members of the practice setting. However, QIOs may not share information among providers without the specific consent of the practitioner(s) and/or provider(s).

**The Beneficiary and Family-Centered Care-QIOs are not responsible for conducting technical assistance with QIIs.** This responsibility falls on the Quality Innovation Network-QIOs. However, the Beneficiary and Family-Centered Care-QIOs are in a position where they can recognize major areas in need of improvement. This includes completing a quality of care review whenever a medical record is requested for utilization review—such as medical necessity, level of care, and higher-weighted DRGs (See QIO Manual Chapter 4)—in addition to quality of care reviews for beneficiary complaints and other General Quality of Care reviews. Therefore, the QIO's input is important in designing quality improvement efforts that address trends in health care delivery that require improvement. See § 5125.1 for additional information about QIO's responsibilities related to QIIs.

## **5125.1 - Quality Improvement Initiatives – Beneficiary and Family-Centered Care QIO Responsibilities**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

One of the contract responsibilities of the BFCC- QIO is to make recommendations to Quality Innovation Network QIOs or other CMS-designated contractor(s) for conducting quality improvement initiatives (QIIs) associated with quality of care issues. QIIs may be the result of any Beneficiary and Family-Centered Care-QIO function and could include system-wide change QIIs and non-system-wide change QIIs.

CMS expects that not every confirmed non-sanctionable quality of care concern will require a QII. When the Beneficiary and Family-Centered Care QIO determines that concerns can be addressed by offering advice or an alternative approach to the practitioner and/or provider, the BFCC-QIO should include that recommendation as part of their Final Determination Letter to the provider, practitioner and/or provider (See Appendix 5-4.1, 5-5.1,5-6, and 5-7 for applicable letters). When the BFCC QIO determines that the practitioner and/or provider needs technical assistance with QII, the BFCC QIO will refer to the Quality Innovation Network-QIO.

One of the BFCC-QIO's contract duties is to provide recommendations and referrals to Quality Innovation Network-QIOs or other CMS-designated contractors for technical assistance be provided to health care practitioners and providers. This obligation arises when the BFCC-QIO has concluded a beneficiary complaint review and when the Beneficiary and Family-Centered Care-QIO has done at least one of the following:

1. Identified and confirmed quality of care concern(s) exist, after completion of the final review and including reconsideration if requested, that require QII; or
2. Has been approached by a practitioner and/or provider who is requesting the QIO's



assistance.

The referral to the QIN-QIO or other CMS-designated contractor for technical assistance should occur after the notice to the beneficiary in connection with a complaint and notice to the provider that a quality of care concern has been identified; if a reconsideration is requested, the referral should occur after the reconsideration is performed.

In performing its contract responsibilities, the Beneficiary and Family-Centered Care-QIO must analyze findings from the CMS-designated case review system, other information from review activities, and information from providers to:

- Identify trends and patterns;
- Identify needs for technical assistance related to CMS quality measures across provider settings to help providers and practitioners meet standards. (An example of a CMS quality measure is a measure found in the National Hospital Inpatient Quality Measures set.); and
- Make recommendations or referrals to the Quality Innovation Network-QIO or other CMS-designated contractor for technical assistance that promotes evidence-based medical practice and patient-centered care principles to improve the quality of health care, improve outcomes to beneficiaries, and lower costs.

**NOTE:** Beneficiary and Family-Centered Care-QIO identified trends and patterns are to be addressed in coordination with the Beneficiary and Family-Centered Care National Coordinating Center (NCC) (See §5095-Tracking and Trending of Data). These types of recommendations must be provided to the Beneficiary and Family-Centered Care-NCC before being communicated to the applicable Quality Innovation Network-QIO.

## **5125.2 - Quality Improvement Initiatives – Quality Innovation Network (QIN) - QIO Responsibilities**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Pursuant to its contract, the QIN-QIO shall:

1. Accept recommendations and referrals from approved sources for technical assistance to practitioners and providers when a need is identified for QIIs based on a confirmed quality of care concern; and
2. Assist provider(s)/practitioner(s) when technical assistance is requested from the practitioner/provider or recommended by other approved sources. Approved sources for referrals and recommendations include:
  - The Beneficiary and Family-Centered Care- QIOs
  - The Quality Innovation Network National Coordinating Center (NCC)
  - Value Incentive and Quality Reporting Center (VIQRC) contractors
  - Practitioner and/or provider requests for assistance

- Others identified by CMS.

**Upon receiving a referral:**

1. The QIN-QIO shall coordinate with the requestor to analyze findings for the referral.
2. For Beneficiary and Family-Centered Care-QIO referrals, the QIN-QIO shall coordinate with the Beneficiary and Family-Centered Care-NCC to analyze findings from the CMS-designated case review system, other information from review activities, and provider performance measures to:
  - Identify trends and patterns; and
  - Identify needs for technical assistance related to CMS measures across settings to help providers and/or practitioners meet standards.
3. The QIN QIO shall provide technical assistance that addresses the specific needs the QIO has identified and promotes evidence-based medical practice and beneficiary-centered care principles to improve quality of care and outcomes to beneficiaries.
  - The QIO shall develop measurable interventions in collaboration with the applicable provider/practitioner practice, taking into account the scope of the provider/practitioner's practice. The intervention(s) should address systemic confirmed concerns.
  - The QIO shall assist health care provider(s) and/or practitioner(s), regarding how best to employ successful interventions and proven methods to improve health care quality and lower costs for the Medicare Program.

NOTE: If, during the course of a QIN-QIO's work under its contract (i.e. other tasks in the QIO Task Order), the QIN-QIO identifies problems or concerns that could affect the quality of care that Medicare beneficiaries are receiving, the QIO working with its designated practitioner shall consider the need to request that the practitioner and/or provider initiate and complete an improvement plan to correct the problem.

- If an improvement plan is warranted at the time the Quality Innovation Network - QIO requests initiation of the improvement plan, the QIO shall alert its CMS COR in writing of the request and the reason it was warranted; this involvement of the COR is pursuant to the QIO contract. A request for an improvement plan must be data based and clearly state the issue(s) that warrants improvement. The improvement plan must include the goals/objectives to be achieved, the process/measurements/tools to be used to assess the issue(s) and to measure improvement, and the timeframe for accomplishing the improvement plan, including monitoring/documenting improvement. The action to improve the quality of care described in the provider's/practitioner's plan must be sustainable.

In accordance with its contract, the QIN-QIO shall post tools and resources used in successful interventions on its Quality Innovation Network-QIO website within 30 days of COR/Government Task Lead (GTL) approval.

### **5125.2.1 – Unwillingness to Cooperate**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

In some instances, the practitioner(s) and/or provider(s) may clearly express intent not to cooperate with the QIO for Quality Improvement Initiatives. In these situations, the Quality Innovation Network-QIO should advise the practitioner(s) and/or provider(s) that the matter may be referred to the CMS COR (or to a State survey agency through the regional office). In addition, a QIO may refer the matter to other CMS contractors (e.g., Medicare Administrative Contractors), with appropriate review authority over the practitioner's and/or provider's activities or to the State Board of Licensing. The practitioner and/or provider(s) may also be subject to additional reviews focusing on identified areas of concern in appropriate situations.

**NOTE:** Failure to agree to or participate in a Quality Improvement Initiative is not justification for referral to the Office of Inspector General (OIG) for possible sanction action.

### **5125.2.2 – Developing a Quality Improvement Initiative**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

As provided in the Quality Innovation Network-QIO contract, these QIOs are to work with the practitioner(s) and/or provider(s) to develop and implement QIIs. QIOs should ensure that all QIIs are cost-effective. The results of QIIs should be reproducible without necessitating excessive time and/or monetary expenditures. A QIO should assist practitioner(s) and/or provider(s) in leveraging all opportunities for improvement. In addition, the QIO should work with both the administrative and the medical staff (e.g., a hospital quality assurance committee) when providing information and developing, implementing, and monitoring QIIs. The QIO should investigate if the practitioner/provider has been recruited into any of the QIO Learning and Action Networks (LAN) and, when appropriate, request the practitioner/provider participate in the applicable LAN.

### **5125.2.3 – Time Frames for Developing a Quality Improvement Initiative**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

In accordance with the QIO contract, the planning of a Quality Improvement Initiative must be finalized within thirty (30) calendar days of receiving the referral/recommendation/request with a QII Plan. The implementation of a QII may be delayed an additional thirty (30) calendar days after the QII Plan is completed to obtain sufficient baseline data from which improvements can be measured. The QIO shall coordinate with the referring entity to determine if periodic reviews should be conducted during the implementation of interventions to gauge whether potential improvements are being realized and sustained (See §476.104).

### **5125.2.4 – Quality Improvement Initiative Not Needed**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Under the Quality Innovation Network-QIO contracts, QIOs have the authority to pursue QIIs in all situations where quality of care concerns are confirmed but a referral for sanction or Corrective Action Plan covered in Manual Chapter 9 is not appropriate. However, there are situations where a QII may not be appropriate. For example:

- A case is referred to a Federal or State enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare program.
- The practitioner(s) and/or provider(s) provide evidence that the concern(s) is a single, isolated instance and does not effectively allow for improvement.
- The underlying concern has already been identified and action taken to correct the problem (e.g., a Medicare coder who has been making numerous errors has been retrained and is now performing well).
- The concern(s) will be resolved by a QII that has already been initiated.
- The source of the concern is a physician, and the physician has retired, expired, or moved his/her practice out of the State.

**NOTE:** When a practitioner has moved his/her practice out of State while a Quality of Care Review, Sanction Review under Part 1004, or Corrective Action Plan is pending, the QIO must forward any pertinent information to the QIO in the new State of practice. The appropriate COR must be provided with pertinent information related to the forwarding of concerns between QIOs.

### **5125.2.5 – Quality Improvement Initiative Root Cause Analysis (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

When a quality of care concern is confirmed and a referral initiated for a QII, the QIN-QIO should consult with the practitioner(s) and/or provider(s) to determine the root cause. This includes requesting that the practitioner(s) and/or provider(s) allow the QIO to review any root-cause analysis independently completed.

To conduct an adequate root cause analysis, the QIO must clearly identify the following:

- The specific quality of care concern(s) at issue;
- The type of provider (facility) or practitioner (individual) specialty involved;
- How the concern(s) has affected the patient or patient care in general;
- The impact of the concern(s) on health care operations;
- Whether any injuries or harm resulted from the concern;

- The prevalence of the concern;
- Whether the concern was linked to CMS-identified or other nationally identified health care initiatives;
- Any health care disparity issues associated with the concern(s);
- Whether the Quality Innovation Network-QIO and/or the Beneficiary and Family Centered Care-QIO has any data or information giving evidence of other instances of the same concern(s) within the same or a different provider setting(s) and with the same or a different practitioner(s);
- Whether the practitioner(s) and/or provider(s) are willing to cooperate in the Quality Improvement Initiative (**NOTE:** The failure to cooperate is not justification for initiating sanction proceedings.); and
- Current baseline data relevant to the concern(s).

When the baseline needs to be established as part of conducting an adequate root-cause analysis, the Quality Innovation Network-QIO must employ evidence-based techniques to obtain a clear snapshot of the current environment. To determine the baseline, the Quality Innovation Network-QIO must request data from the practitioner and/or provider that demonstrates other occurrences of the same or related concerns (or opportunities for the same and/or similar occurrences), including the timeframe during which the other instances occurred. Data before and after the time period when the actual concern arose should be considered. In most instances, QIOs should not request data for periods more than three (3) years before the time period when the actual concern arose.

Both quantitative data and anecdotal information may be considered; however, emphasis should be placed on obtaining quantitative data. The Quality Innovation Network-QIO should review its own data or collaborate with the Beneficiary Family Centered Care-NCC to identify prior occurrences of the same or similar concerns with the same practitioner and/or provider or other practitioners and/or providers. Baseline data will be used to measure improvement(s) resulting from specific intervention(s) implemented with the Intervention and Improvement Plan.

In conducting its analysis, a QIO should also consider any relevant information related to best practices developed or identified by the QIO or other QIOs.

### **5125.2.6 – “Stand-alone” or Isolated Concerns**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

In situations when the practitioner(s) and/or provider(s) indicates that the concern is a “stand-alone” or isolated occurrence, a QIO may request any evidence the Quality Innovation Network - QIO determines is necessary and relevant to substantiate that an issue is an isolated occurrence (e.g., two to three examples of similar situations when the same concern did not present itself). In addition, the QIO shall review its own data.

### **5125.2.7 – Intervention and Improvement Plan**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Once the Root Cause Analysis has been completed, the Quality Innovation Network-QIO develops the Intervention and Improvement Plan in consultation with the practitioner(s) and/or provider(s). The QIO identifies the intended outcome of intervention(s) and whether or not the identified outcome(s) is mutually established with the practitioner(s) and/or provider(s) as part of the Plan. An adequate Intervention and Improvement Plan lists the specific action(s) the practitioner(s) and/or provider(s) will take to correct the underlying cause of the concern(s) and identify a timeframe for initiating and completing the Intervention and Improvement Plan. During the implementation period, the Intervention and Improvement Plan should include periodic review of the specific intervention(s) against baseline data so that improvements can be monitored and any appropriate adjustments to the initiative considered.

### **5125.2.8 – Monitoring Quality Improvement Initiatives**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

At any point during the time period when interventions are being implemented, if the Quality Innovation Network-QIO, practitioner(s) and/or provider(s) determine that improvement is not being attained, the parties should meet as soon as possible to discuss possible reasons for the failure to achieve improvements and explore alternatives that may achieve the desired improvements. The parties should share data and mutually agree to the modifications to the Intervention and Improvement Plan, using the format of the original plan as described in §5125.2 (h), “Intervention and Improvement Plan.”

### **5125.2.9 – Reporting Results of System-wide Change Quality Improvement Initiatives**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

Pursuant to their contracts, Quality Innovation Network QIOs must report system-wide changes due to Quality Improvement Initiatives (QIIs) to CMS. Attribution of the improvements to the specific interventions that the QIO identified and/or in consultation with the practitioner and/or provider is an integral part System-wide Change Quality Improvement Initiatives. Documented improvement is required and is defined as any amount of quantitative improvement in a process or outcome related to the quality of care concern that is attributable to the QIO’s activity. In reporting the system-wide change under the contract, QIOs must document the problem, define interventions as implemented by the provider(s) and/or practitioner(s), identify goals of the change, and describe the evaluation methodology.

**NOTE:** QIOs may include additional information if necessary to demonstrate the success of the QII.

A Quality Innovation Network-QIO should work with its COR to determine the best method for ensuring continuous progress related to successful completion of system-wide changes, including determining when the System-wide Change Report must be uploaded into the CMS-designated case review system. A QII is deemed “completed” once the pertinent period of data collection has been fulfilled, and the QIO is able to demonstrate that the goals of the system-wide change

have been attained.

Pursuant to its contract, a Quality Innovation Network-QIO shall submit a report, in accordance with agreed-upon timeframes with the COR, that describes progress on the initiation, development, implementation, and conclusion for each QII. The report shall identify successful interventions (e.g., tools and resources) used in each QII. In addition, the report shall include the details of any unsuccessful QIIs based on the unwillingness of practitioner(s) and/or provider(s) to participate or instances when the QIO decided not to initiate a QII. A representative from the QIO shall be prepared to discuss the progress of their QII efforts with the COR on an as-needed basis.

## Appendix

### Appendix 5-1.1 – Medicare Quality of Care Complaint Form

*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

#### Medicare QUALITY OF CARE COMPLAINT FORM

##### Information to Help You Fill Out the “Quality of Care Complaint” Form

The Medicare Program works to ensure that beneficiaries get the best care possible. We take your concern(s) seriously, and we would like to get more information to help us review your request. Use of this form will ensure that we process your concerns in an efficient manner. Quality Improvement Organizations (QIOs), are under contract with Medicare and are required to conduct reviews of all written complaints from beneficiaries about the quality of services not meeting professionally recognized standards of health care. You may contact the QIO for assistance in completing this form or for general assistance regarding your complaint.

Please use this step-by-step instruction sheet when completing your “Quality of Care Complaint” Form. Be sure to complete all sections of the form. In addition, if your personal information has been included in the form based on contact you have had with the QIO for your State, please review the information to confirm its accuracy.

1. Print the name of the Medicare beneficiary who has a complaint about the quality of health care he/she received.
2. Include the *beneficiary's* Medicare *beneficiary identifier* if known.
3. Check the appropriate box designating the sex of the individual listed in number 1. In addition, please indicate the age of the beneficiary in the blank space provided, if known.
4. Check the appropriate box or boxes indicating the race/ethnicity of the individual listed in number 1. Please note that this information is strictly voluntary and has no impact on the processing of the complaint.
5. Print the name of the beneficiary's authorized representative if someone other than the beneficiary will be the contact for the processing of the complaint.
6. Print the contact information for the beneficiary or for the beneficiary's authorized representative who is authorized to be the contact for the processing of the complaint.
7. Provide a brief description of the incident or concern. The description should include any information you believe is relevant to the review of your complaint, including:



- Dates and times,
- Identification of physicians and provider staff involved,
- Information from witnesses if available, and
- A description of what happened; and
- If you require more space to describe your complaint, you may attach additional sheets of paper and you may provide any documents you believe support your complaint.

**PLEASE NOTE:** If you raise concerns that are not quality of care concerns within the scope of the QIO’s authority, your complaint will be referred to the appropriate entity.

1. By signing the form, you are authorizing the QIO to review your complaint and render a formal determination. The processing of your complaint may require requesting and reviewing of pertinent medical records.
2. PLEASE keep this page for your information. Only mail the second page (Medicare Quality of Care Complaint Form) to the QIO. The phone number of your QIO is \_\_\_\_\_. A decision on your complaint will be made within \_\_\_ days of receiving the signed complaint form.

Form CMS-10287 (Revised 07/14)

<b>MEDICARE QUALITY OF CARE COMPLAINT FORM</b>		
<b>1. Beneficiary Name:</b>		
<b>2. Medicare <i>beneficiary identifier</i>:</b>		
<b>3. Sex:</b> Male__ Female__ <b>Age:</b> _____ <b>Date of Birth:</b> _____		
<b>4. Race/Ethnicity</b> (Completion of this section is <u>voluntary</u> ): How would you describe your race? Please mark one or more boxes. American Indian or Alaska Native__ Native Hawaiian or Other Pacific Islander __ White__ Asian __ Black or African American__ Hispanic or Latino__		
<b>5. Beneficiary’s Authorized Representative’s Name (If applicable):</b>		
<b>6. Contact Information:</b>		
Street/Apt.		
City:	State:	Zip:
Phone:	Alternate Phone:	
<b>7. Briefly Describe the incident or your concerns:</b> Include dates and times, persons involved, and description of what happened. Include attachments, if appropriate.		

**8.** May we reveal your identity during the review of your complaint? Yes\_\_ No \_\_  
If you check “no” we cannot review your complaint as a written beneficiary complaint. However, based on the circumstances of your complaint, we may choose to review your complaint as a general quality of care review. You will not receive any information or notice about a general quality of care review if the QIO chooses to perform one.

**9.** Check “yes” here if you authorize the QIO to forward your address or other contact information to the entity that conducts beneficiary satisfaction surveys. If you check “yes”, you will be contacted by telephone or postal mail to conduct a brief survey about your satisfaction with the service you received from the QIO. **If you leave this question blank, a surveyor will contact you about your satisfaction.**  
Yes\_\_ No\_\_

**For your information:** If you have any questions about your complaint, please call \_\_\_\_\_. You will be contacted within \_\_\_\_ days upon the QIO’s receipt of the signed complaint form. The QIO will use a physician who practices in the same or similar clinical area as the physician who provided your care in completing its review. You may provide any information you believe is relevant to your complaint, including copies of documentation, names of witnesses, etc. A decision will be made on your complaint within \_\_\_\_ days of receiving the signed complaint form. If your complaint includes concerns not within the scope of the QIO’s authority, the concerns will be referred to the appropriate entity.

**10. By signing this form, I am requesting that the QIO review my complaint.**

Signature of Beneficiary/Representative:

Date:

According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-1102. The time required to prepare and distribute this collection is 10 minutes per notice, including the time to select the preprinted form, complete it and deliver it to the beneficiary. If you have comments concerning the accuracy of the time estimates or suggestions for improving this form, please write to CMS, PRA Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850

## Appendix 5-1.2 – Appointment of Representative Form (Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

Form Approved OMB No.0938-0950

Name of Party	Medicare Number (beneficiary as party) or National Provider Identifier Number (provider as party)
<b>APPOINTMENT OF REPRESENTATIVE</b>	

### Section 1: Appointment of Representative

**To be completed by the party seeking representation (i.e., the Medicare beneficiary, the provider or the supplier):**

I appoint this individual, \_\_\_\_\_ to act as my representative in connection with my claim or asserted right under Title XVIII of the Social Security Act (the “Act”) and related provisions of Title XI of the Act. I authorize this individual to make any request; to present or to elicit evidence; to obtain appeals information; and to receive any notice in connection with my appeal, wholly in my stead. I understand that personal medical information related to my appeal may be disclosed to the representative indicated below.

Signature of Party Seeking Representation		Date
Street Address		Phone Number (with Area Code)
City	State	Zip Code

### Section 2: Acceptance of Appointment

**To be completed by the representative:**

I, \_\_\_\_\_, hereby accept the above appointment. I certify that I have not been disqualified, suspended, or prohibited from practice before the Department of Health and Human Services (DHHS); that I am not, as a current or former employee of the United States, disqualified from acting as the party’s representative; and that I recognize that any fee may be subject to review and approval by the Secretary.

I am a / an \_\_\_\_\_

(Professional status or relationship to the party, e.g. attorney, relative, etc.)

Signature of Representative		Date
Street Address		Phone Number (with Area Code)
City	State	Zip Code

### Section 3: Waiver of Fee for Representation

**Instructions: This section must be completed if the representative is required to, or chooses to waive their fee for representation.** (Note that providers or suppliers that are representing a beneficiary and furnished the items or services may not charge a fee for representation and **must** complete this section.)

I waive my right to charge and collect a fee for representing \_\_\_\_\_ before the Secretary of DHHS.

Signature

Date

### Section 4: Waiver of Payment for Items or Services at Issue

**Instructions: Providers or suppliers serving as a representative for a beneficiary to whom they provided items or services must complete this section if the appeal involves a question of liability under section 1879(a)(2) of the Act.** (Section 1879(a)(2) generally addresses whether a provider/supplier or beneficiary did not know, or could not reasonably be expected to know, that the items or services at issue would not be covered by Medicare.)

I waive my right to collect payment from the beneficiary for the items or services at issue in this appeal if a determination of liability under §1879(a)(2) of the Act is at issue.

Signature

Date

### Charging of Fees for Representing Beneficiaries before the Secretary of DHHS

An attorney, or other representative for a beneficiary, who wishes to charge a fee for services rendered in connection with an appeal before the Secretary of DHHS (i.e., an Administrative Law Judge (ALJ) hearing, Medicare Appeals Council review, or a proceeding before an ALJ or the Medicare Appeals Council as a result of a remand from federal district court) is required to obtain approval of the fee in accordance with 42 CFR 405.910(f).

The form, "Petition to Obtain Representative Fee" elicits the information required for a fee petition. It should be completed by the representative and filed with the request for ALJ hearing or request for Medicare Appeals Council review. Approval of a representative's fee is not required if: (1) the appellant being represented is a provider or supplier; (2) the fee is for services rendered in an official capacity such as that of legal guardian, committee, or similar court appointed representative and the court has approved the fee in question; (3) the fee is for representation of a beneficiary in a proceeding in federal district court; or (4) the fee is for representation of a beneficiary in a redetermination or reconsideration. If the representative wishes to waive a fee, he or she may do so. Section III on the front of this form can be used for that purpose. In some instances, as indicated on the form, the fee must be waived for representation.

### Approval of Fee

The requirement for the approval of fees ensures that a representative will receive fair value for the services performed before DHHS on behalf of a beneficiary, and provides the beneficiary with a measure of security that the fees are determined to be reasonable. In approving a requested fee, the ALJ or Medicare Appeals Council will consider the nature and type of services rendered, the complexity of the case, the level of skill and competence required in rendition of the services, the amount of time spent on the case, the results achieved, the level of administrative review to which the representative carried the appeal and the amount of the fee requested by the representative.

### Conflict of Interest

Sections 203, 205 and 207 of Title XVIII of the United States Code make it a criminal offense for certain officers, employees and former officers and employees of the United States to render certain services in matters affecting the Government or to aid or assist in the prosecution of claims against the United States. Individuals with a conflict of interest are excluded from being representatives of beneficiaries before DHHS.

### Where to Send This Form

Send this form to the same location where you are sending (or have already sent) your: appeal if you are filing an appeal, grievance if you are filing a grievance, initial determination or decision if you are requesting an initial determination or decision. If additional help is needed, contact your Medicare

plan or 1-800-MEDICARE (1-800-633-4227). TTY users please call 1-877-486-2048.

CMS does not discriminate in its programs and activities. To request this publication in an alternative format, please call: 1-800-MEDICARE or email: **[AltFormatRequest@cms.hhs.gov](mailto:AltFormatRequest@cms.hhs.gov)**.

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According to the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number. The valid OMB control number for this information collection is 0938-0950. The time required to prepare and distribute this collection is 15 minutes per notice, including the time to select the preprinted form, complete it and deliver it to the beneficiary. If you have comments concerning the accuracy of the time estimates or suggestions for improving this form, please write to CMS, PRA Clearance Officer, 7500 Security Boulevard, Baltimore, Maryland 21244-1850.

**Appendix 5-1.3 – Quality Review Decision (QRD) Form**  
*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary’s Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**Quality Review Decision (QRD) Form**  
**Case Summary**

Case ID#:  State: Choose a State

**Patient Details**

Patient Name:   
*Medicare beneficiary identifier:*

Date of Birth: Click here to enter a Date of Birth. Date QRD Created: Enter QRD Created date.  
Date of Death: Click here to enter a Date of Death.

Beneficiary Point of View:

**Health Service Encounter**

Provider/Practitioner Name:   
Provider CCN:  Service Start Date: Click here to enter Service Start Date  
Provider/Practitioner NPI:  Service End Date: Click here to enter Service End Date.  
Reason for Health Service Encounter/Admitting Diagnosis:

Case Summary Notes:

**Review Details**

Review Analyst:

Review Due Date:

**Review Analyst Assessment**

Please note that the information below must be prepared for each  
Quality of Care (QoC) Concern identified in the complaint

Case ID#:

QoC Concern #:

**Concern Summary**

Concern Category: \_\_\_\_\_

Improvement may be needed in: \_\_\_\_\_

**Quality of Care Concern**

**Identified by:**

**Source:**

Practitioners involved:

Name:            NPI:

**Relevant Standard of Care:**

Standard of Care Category:

Standard of Care Source:

Standard of Care Publication Date:

**Additional Information:**



## **Initial Determination Peer Review**

Case ID#:

QoC Concern #:

### **Conclusion:**

- Standard of Care Met
- Standard of Care Not Met
  - Grossly and flagrantly violated the obligation in §1156(a)(2) of the Act, in one or more instances, to provide care that is of a quality that meets professionally recognized standards (Sanction Activity Required)
  - Failed in a substantial number of cases (more than three) to substantially comply with the obligation in §1156(a)(2) of the Act, to provide care that is of a quality that meets professionally recognized standards (Sanction Activity Required)
  - Substantial failure to comply with the obligation in §1156(a)(2) of the Act to provide care that is of a quality that meets professionally recognized standards (Quality Improvement Initiative recommended; consider referral for technical assistance with QII)
  - Significant concern (Quality Improvement Initiative recommended; consider referral for technical assistance with QII)
  - Non-significant concern (Quality Improvement Initiative recommended; QIO to consider offering advice or an alternative approach or education)

### **Agree with QIO Identified Standard of Care:**

- Agree
- Do Not Agree
- Concern Identified by IDPR

**Reason for Disagreement: Relevant Standard of Care:**

Standard of Care Category:

Standard of Care Source:

Standard of Care Date:

**Rationale/Justification:**

**Conflict of Interest Statement:**

I do not have a material, professional, familial, or financial conflict of interest regarding any parties associated with this case including any referring entity, any health benefits plan, the patient or his/her family, the care providers, the facility, or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended (prescribed) or provided; nor have I accepted compensation for my independent review activities that is dependent in any way on the specific outcome of the case or had involvement with the case prior to its referral to independent review.

**Initial Determination Peer Reviewer Name (print):**

\_\_\_\_\_  
**Initial Determination Peer Reviewer Signature:**

\_\_\_\_\_  
**Date: Minutes Spent on Case:**

**Final Initial Determination Peer Review**

Case ID#:

QoC Concern #:

**Written Response Received from practitioner and/or provider:**

**Relationship of Information to Standard of Care:**

**Conclusion:**

Standard of Care Met

Standard of Care Not Met

Grossly and flagrantly violated the obligation in §1156(a)(2) of the Act, in one or more instances, to provide care that is of a quality that meets professionally recognized standards (Sanction Activity Required)

Failed in a substantial number of cases (more than three) to substantially comply with the obligation in §1156(a)(2) of the Act, to provide care that is of a quality that meets professionally recognized standards (Sanction Activity Required)

- Substantial failure to comply with the obligation in §1156(a)(2) of the Act to provide care that is of a quality that meets professionally recognized standards (Quality Improvement Initiative recommended; consider referral for technical assistance with QII)
- Significant concern (Quality Improvement Initiative recommended; consider referral for technical assistance with QII)
- Non-significant concern (Quality Improvement Initiative recommended; QIO to consider offering advice or an alternative approach or education)

**Rationale/Justification:**

**Conflict of Interest Statement:**

I do not have a material, professional, familial, or financial conflict of interest regarding any parties associated with this case including any referring entity, any health benefits plan, the patient or his/her family, the care providers, the facility, or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended (prescribed) or provided; nor have I accepted compensation for my independent review activities that is dependent in any way on the specific outcome of the case or had involvement with the case prior to its referral to independent review.

**Initial Determination Peer Reviewer Name:**

\_\_\_\_\_

**Initial Determination Peer Reviewer Signature:**

**Date:**

**Minutes Spent on Case:**

**Reconsideration Peer Review**

Case ID#:

QoC Concern #:

**Written Reconsideration Request Received from practitioner and/or provider:** Click here to enter received date.

**Conclusion:**

- Standard of Care Met
- Standard of Care Not Met
  - Grossly and flagrantly violated the obligation in §1156(a)(2) of the Act, in one or more instances, to provide care that is of a quality that meets professionally recognized standards (Sanction Activity Required)
  - Failed in a substantial number of cases (more than three) to substantially comply with the obligation in §1156(a)(2) of the Act, to provide care that is of a quality that meets professionally recognized standards (Sanction Activity Required)

- Substantial failure to comply with the obligation in §1156(a)(2) of the Act to provide care that is of a quality that meets professionally recognized standards (Quality Improvement Initiative recommended; consider referral for technical assistance with QII)
- Significant concern (Quality Improvement Initiative recommended; consider referral for technical assistance with QII)
- Non-significant concern (Quality Improvement Initiative recommended; QIO to consider offering advice or an alternative approach or education)

**Rationale/Justification:**

**Agree with QIO Identified Standard of Care:**

- Agree
- Do Not Agree
- Concern Identified by RPR

**Reason for Disagreement: Relevant Standard of Care:**

Standard of Care Category:

Standard of Care Source:

Standard of Care Date:

**Conflict of Interest Statement:**

I do not have a material, professional, familial, or financial conflict of interest regarding any parties associated with this case including any referring entity, any health benefits plan, the patient or his/her family, the care providers, the facility, or the developer or manufacturer of the principal drug, device, procedure, or other therapy being recommended (prescribed) or provided; nor have I accepted compensation for my independent review activities that is dependent in any way on the specific outcome of the case or had involvement with the case prior to its referral to independent review.

**Reconsideration Peer Reviewer Name:**

---

**Reconsideration Peer Reviewer Signature:**

---

**Date:** \_                      **Minutes Spent on Case:**

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**Appendix 5-2 – Beneficiary Quality of Care Complaint: Initial Acknowledgement Letter to Beneficiary/Beneficiary Representative**  
*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**QIO LETTERHEAD**

**INITIAL NOTIFICATION**

Date of Notice  
Name of Addressee  
Address  
City, State, and Zip Code

Beneficiary Name  
Medicare *beneficiary identifier*  
Practitioner/Provider Name  
Practitioner/Provider Number (CCN/NPI/UPN)  
Date(s) of Service

Dear [insert name of Beneficiary/ or Representative here]:

We have received your written quality of care complaint(s). Thank you for taking the time to bring your health care concern(s) to our attention.

[Insert QIO name here] is the Beneficiary and Family Centered Care Quality Improvement Organization (QIO) authorized by the Centers for Medicare & Medicaid Services (CMS) to review medical services provided to people with Medicare in [Insert QIO area/region here]. As part of our mission, we review all written complaints about the health care that was provided by a physician and/or facility to people with Medicare. The goal of our review is to determine if that care was appropriate and followed acceptable medical standards. Our review is based on what is written in the medical record but is not limited to your specific complaints. During the review, we may find other concerns about the care you received. You will get our result(s) in writing when the review is completed.

These are examples of the types of factors we can review in a medical record:

- Was your medical condition diagnosed correctly?
- Did you get the right medication for your medical problem?
- Did the doctor perform the right surgery?

- Was the care given to you by the staff done correctly?

Our review process does not address issues such as billing, customer service, communication, legal, or any other issues that are not noted in the medical record. We understand that these issues are important, but our quality of care review is limited to the medical care reflected in the entries in the medical record.

If a quality of care concern is identified, we offer education and feedback to providers to improve the quality of care for people with Medicare. The following is a summary of the concerns identified in your written complaint.

### **Summary of Concern(s)**

What the Medicare Complaint Process CAN Address

This first section of the summary letter contains the parts of your complaint(s) that can be addressed by a review of the medical record.

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER.**

#### PREPARATION NOTE FOR THE QIO

The summary must include the specific concerns identified by the beneficiary and any concerns identified by the QIO based on the initial intake analysis. (See § 5110.1)

This information should be consistent with the information contained in the QRD Form. (See §5230.2)]

What the Medicare Complaint Process CANNOT Address

This second section of the summary letter contains any part of your complaint(s) that may be related to customer service, billing, legal, or other issues that cannot be addressed by a review of the medical record.

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER.**

#### PREPARATION NOTE FOR THE QIO

The summary must include the specific concerns identified by the beneficiary and any concerns identified by the QIO based on the initial intake analysis. (See §5110.1)

This information should be consistent with the information contained in the QRD Form. (See §5230.2)]

We want to make sure that we clearly understand your quality of care concerns. **Please feel free to contact us with any questions or comments you may have.**

[Insert QIO Name]  
[Insert QIO Contact Person]  
[Insert QIO Address]  
[Insert QIO Contact Number]  
[Insert QIO Fax Number]

It is important to let you know that the actual time needed to complete our review will depend on the time needed to obtain the necessary medical records and responses from the practitioner(s)/provider(s) involved. If there are any delays in the process, we will contact you.

Once again, thank you for bringing your concerns to our attention.

Sincerely,

Medical Director (or designated physician)  
[Insert title here]

## **Appendix 5-3 – Beneficiary Quality of Care Complaint: Interim Determination Letter for Practitioners and Providers**

***(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)***

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**NOTE: This letter is optional since the Interim Determination can be given to Providers/Practitioners via phone and/or in writing. (See §5055.1)**

### **QIO LETTERHEAD**

Date of Notice

QIO Liaison for Provider or Practitioner's Name

Name of Addressee

Address

City, State, and Zip Code

Beneficiary Name

Medicare *beneficiary identifier*

Practitioner/Provider Name

Practitioner/Provider Number (CCN/NPI/UPN)

Date(s) of Service

Dear: [insert name of Practitioner or Provider here]

The [Insert QIO name here] is the Quality Improvement Organization (QIO) authorized by the Centers for Medicare & Medicaid Services (CMS) to review medical services provided to Medicare beneficiaries in [Insert QIO area/region here]. One of the functions we perform is the review of health care provided to Medicare beneficiaries to determine if the care provided was consistent with professionally recognized standards of health care, normally referred to as a Quality of Care Review. QIOs conduct these reviews to investigate complaints initiated by beneficiaries or the patients' representatives about the health care they received. In addition, Quality of Care Reviews may be performed as a result of other tasks that CMS assigns to the QIO.

### **Opportunity for Discussion**

As part of the review process, we are required to give you an opportunity to discuss our initial findings before we make our final decision. Your response can be written or oral and must be received within 7 calendar days from the receipt of this letter in order for us



to consider information you provide in our Final Determination. Please be advised that this is not an opportunity for you to submit additional medical information. If additional medical information is submitted, we will not consider it in rendering the Final Determination. However, we welcome any policies, guidelines, rationale, and/or evidence-based information you would like us to consider in the review.

### **Summary of Findings**

A QIO Peer Reviewer has reviewed the care provided to [Insert name of beneficiary who has consented here] by [name of practitioner] or at [name of provider]. Based on an evaluation of the information received, the following is the summary of our review.

#### **Confirmed and/or identified concern(s):**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN LETTER**

#### **PREPARATION NOTE FOR QIO**

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- The standard of care associated with each concern,
- A statement of the analysis and findings for each concern, and
- A statement to the practitioner informing him/her that their consent is not required for the QIO to disclose specific findings about the review to the beneficiary.

This information should be consistent with the information contained in the QRD Form (See §5230.2)].

#### **Please direct your response to:**

[Insert QIO Name]  
[Insert QIO Contact Person]  
[Insert QIO Address]  
[Insert QIO Contact Number]  
[Insert QIO Fax Number]

If you have any questions about this letter or would like to make arrangements to discuss this case, contact the person listed above.

If the concerns involve both a physician/practitioner and a provider, the physician/practitioner and the representative for the provider may respond separately to the opportunity for discussion. However, we strongly encourage coordination of the responses.

If we do not receive your response within 7 calendar days from the receipt of this letter, the Initial Determination will become our Final Determination, and we will send you a letter noting this change. The information in this letter is confidential, and you may disclose it only in accordance with Federal regulations found in 42 CFR Part 480.

If you have any questions about this letter, please contact the above-named person within the time frame described above.

Sincerely,

Medical Director (or designated physician)  
[Insert title here]

## **Appendix 5-4 – Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (For Beneficiary Complaints)**

*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

### **QIO LETTERHEAD**

Date of Notice  
Name of Addressee  
Address  
City, State, and Zip Code

Patient Name (when the patient has consented to disclosure)

*Medicare beneficiary identifier*

Practitioner/Provider Name (If this applies)  
Practitioner/Provider Number (If this applies)  
Date of Admission/Service  
Medical Record Number (if known)

Dear:

Previously, you were afforded the opportunity to discuss our review of care you provided in our letter (dated \_\_\_\_). This letter constitutes our Final Initial Determination based on a careful review of the information provided by the beneficiary in filing the complaint, information contained in the medical information, as well as any information provided during the opportunity for discussion.

### **Summary of Findings**

The results of our review are as follows:

#### **PREPARATION NOTE FOR QIO**

The summary must include:

- the specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- the standard of care associated with each concern, and
- a statement of the analysis and findings regarding each concern, including specific information detailing the evaluation of information obtained as a result of the opportunity for discussion and any differences and/or changes between the Interim and Final Initial Determinations.

The information should be consistent with the information contained in the Quality Review Decision (QRD) Form.

Consent to Release Findings to the Beneficiary

We will inform beneficiaries about whether the care they were provided did or did not meet professionally recognized standards of care. In order for us to release to the beneficiary more specific facts about the actions of particular practitioners involved in the care of the beneficiary, and how their actions did or did not meet the standard of care, we must obtain consent from those practitioner(s) The findings we propose releasing to the beneficiary are attached to (or included in) this letter. If you are a practitioner, please review the language and indicate consent to our disclosing the information to the beneficiary within thirty calendar days from the date of this letter. Please note that we will treat your failure to indicate your consent as your declining to consent and the beneficiary will not be informed of these specific findings. In order to facilitate release of these specific findings to the beneficiary, please contact the QIO representative named below to discuss the attached findings:

Name of QIO Contact Person

Address

Telephone Number

**PREPARATION NOTE FOR QIO:**

- If the notice is addressed to the provider and/or physician practice or some other practitioner, insert the name of the practitioner(s) also notified and include the statement:
  - The following practitioner, [insert name(s)] also has been notified of our Final Initial Determination and contacted to obtain his/her consent to disclose the specific findings to the beneficiary.
- If the notice is addressed to a practitioner, insert the name of the provider if applicable. Do not specify other physicians or practitioners you may be notifying.
- If the notice is addressed to the provider and will also be sent to a physician practice or some other practitioner, insert into the provider's notice the name(s) of the practitioner(s) also notified and include the statement:
  - The following practitioner(s), [insert name(s)] also has been notified of our Final Initial Determination and contacted to obtain his/her consent to disclose the specific findings to the beneficiary.
- If the notice is addressed to a practitioner or physician practice, insert the name of the provider if applicable. Do not specify other physicians or practitioners you may be notifying.

Right to Request a Re-Review

**PREPARATION NOTE FOR QIO**

The QIO must select the appropriate paragraph depending on whether a **Retrospective** or **Concurrent** Review is being conducted (Do NOT include "For

Retrospective Review” or “For Concurrent Review” heading in the actual letter). In addition, the references to the other practitioners receiving the letter should not be included if addressed to a practitioner.

**For Retrospective Review**

We are also notifying (name (See NOTES above)) of our Final Initial Determination. If you or (name (See NOTES above)) disagree with this Final Initial Determination, either party may request a Re-Review. To request a Re-Review, you must submit your request in writing within 15 calendar days from the date of this letter. Your request for a Re-Review may include additional information and/or documentation, including medical information you believe supports your request for a Re-Review.

**For Concurrent Review**

We are also notifying (name (See NOTES above)) of our Final Initial Determination. If you or (name (See NOTES above)) disagree with this Final Initial Determination, you must submit your request in writing within 5 calendar days from the date of this letter. Your request for a Re-Review may include additional information and/or documentation, including medical information you believe supports your request for a Re-Review.

Your request for a Re-Review may be submitted via mail or facsimile to the following address:

QIO Name  
Address  
Facsimile Number

Please be advised that if a Re-Review is requested, you [practitioner] will again be provided the opportunity to consent to our disclosing information to the beneficiary after the Re-Review determination.

The information in this notice is confidential and may be re-disclosed only in accordance with federal regulations found in 42 CFR Part 480.

Sincerely,

Medical Director (or designated physician)  
(Include title)

## **Appendix 5-4.1 – Beneficiary Quality of Care Complaint: Final Determination Letter to Practitioners and Providers**

*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

### **QIO LETTERHEAD**

Date of Notice  
QIO Liaison for Provider or Practitioner's Name  
Name of Addressee  
Address  
City, State, and Zip Code

Beneficiary Name  
Medicare *beneficiary identifier*  
Practitioner/Provider Name  
Practitioner/Provider Number (CCN/NPI/UPN)  
Date(s) of Service

Dear [insert name of Practitioner or Provider here]:

In our Initial Determination Letter, dated [insert date here], you were given the opportunity to discuss our review of the care you provided. This letter constitutes our Final Determination based on a review of the complaint, the medical information, and any correspondence provided during the opportunity for discussion.

### **Summary of Review**

A QIO Peer Reviewer has reviewed the care provided to [Insert name of beneficiary relevant to the complaint] by [name of practitioner] or at [name of provider]. Based on an evaluation of the information received, the following is the summary of our review.

**Confirmed and/or identified concern(s) [should be the same as in the Interim Determination Letter]**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER**

### **PREPARATION NOTE FOR THE QIO**

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- The standard of care associated with each concern,
- A statement of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information and, if held, information obtained as a result of the opportunity for discussion with the involved practitioner or provider, and
- For each concern, there should be a statement about whether or not the care provided was consistent with standards of health care.

This information should be consistent with the information contained in the QRD Form (See §5230.2)]

If [Insert QIO name here] identifies quality of care concerns that represent a significant departure from the expected standard of health care and/or identifies patterns of care that may have significance beyond a single episode, a determination may be made that further intervention activities are required. If this occurs, you will be notified in writing and given the opportunity to discuss the concern(s) with [Insert QIO name here].

**Non-confirmed concern(s):**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER.**

**PREPARATION NOTE FOR QIO**

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the initial intake (See §5110.1).
- The standard of care associated with each concern and a statement of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information and, if held, information obtained as a result of the opportunity for discussion with the involved practitioner or provider.

This information should be consistent with the information contained in the QRD Form (See §5230.2)]

This information will be entered into [the CMS database]. On an ongoing basis, we analyze patterns of care involving quality concerns that may have significance beyond a single episode. The QIO provides this information to CMS as requested.

Please be advised that the Medicare Beneficiary has the right to request Reconsideration. If a request is received, this determination may or may not change as a result of the QIO reviewing this case again during the Reconsideration process. In the event that the Reconsideration does result in a change in the Final Determination, you will be notified in writing.]

**Right to Request Reconsideration**

If you disagree with this Final Determination, you may also request Reconsideration by submitting your request within 3 calendar days from the receipt of this letter. Your request for Reconsideration may include additional information and/or documentation, including

Your request for Reconsideration can be either written or oral using the contact information below:

[Insert QIO Name]  
[Insert QIO Contact Person]  
[Insert QIO Address]  
[Insert QIO Contact Number]  
[Insert QIO Fax Number]

Please be advised that if Reconsideration is requested, this determination may or may not change as a result of the QIO reviewing this case again during the Reconsideration process. In the event that the Reconsideration does result in a change in the Final Determination, you will be notified in writing.

The information in this notice is confidential and may be disclosed only in accordance with Federal regulations found in 42 CFR Part 480.

Sincerely,

Medical Director (or designated physician)

[Insert title here]



**Appendix 5-4.2 – Beneficiary Quality of Care Complaint: Final Determination Letter to Beneficiary/ Beneficiary Representative**  
*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**QIO LETTERHEAD**

Date of Notice  
Name of Addressee  
Address  
City, State, and Zip Code

Beneficiary Name  
Medicare *beneficiary identifier*  
Practitioner/Provider Name  
Practitioner/Provider Number (CCN/NPI/UPN)  
Date(s) of Service

Dear [insert name of Beneficiary or Representative]

Thank you for your patience while we completed a full and comprehensive review of the quality of care concerns you raised [(If available, include copy of the quality of care concern form signed by the complainant)]. Our Final Determination is based on a physician's careful review of:

- Information you provided in filing the complaint
- Medical information
- Any information provided during the practitioner/provider's opportunity for discussion.

**Summary of Review**

The following is the summary of our review.

**Confirmed and/or identified concern(s):**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER.**

## PREPARATION NOTE FOR THE QIO

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the initial review (See §5110.1),
- The standard of care associated with each concern, and
- A summary of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information and, if held, information obtained as a result of the opportunity for discussion with the involved practitioner or provider.

The information should be consistent with the information contained in the QRD Form (See §5230.2)]

### **Non-confirmed concern(s):**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN LETTER**

## PREPARATION NOTE FOR THE QIO

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- The standard of care associated with each concern, and
- A summary of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information, and including any information obtained as a result of the opportunity for discussion with the involved practitioner or provider.

The information should be consistent with the information contained in the QRD Form (See §5230.2].

### **Your Right to Request a Reconsideration**

If you disagree with this determination, you may request Reconsideration by submitting your request within three (3) calendar days from the receipt of this letter. You may provide additional information and/or documentation, including medical information that will help with your request.

Your request for Reconsideration can be either written or oral using the contact information below:

[Insert QIO Name]  
[Insert QIO Contact Person]  
[Insert QIO Address]  
[Insert QIO Contact Number]  
[Insert QIO Fax Number]

**NOTE:** The determination in this letter may or may not change as a result of us reviewing this case again during the Reconsideration process. If it does, you will be notified in writing.

The information in this notice is confidential and may be disclosed only in accordance with Federal regulations found in 42 CFR Part 480.

Sincerely,

Medical Director (or designated physician)  
[Insert title here]

## **Appendix 5-5 – Re-Review Determination Letter to Providers/Practitioners with Request to Disclose (For Beneficiary Complaints)**

*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

### **QIO LETTERHEAD**

Date of Notice  
Name of Addressee  
Address  
City, State, and Zip Code

Patient Name (when the patient has consented to disclosure)

*Medicare beneficiary identifier*

Practitioner/Provider Name (if this applies)  
Practitioner/Provider Number (if this applies)  
Date of Admission/Service  
Medical Record Number (if known)

Dear:

Previously, you received our Final Initial Determination letter, dated \_\_\_\_\_, about care you provided [to the beneficiary listed above. (Only include where the beneficiary has consented to the disclosure of his or her name.)] We received your request for a Re-Review, and have completed the Re-review. This letter conveys the final results of our Re-Review and constitutes our FINAL decision on this matter. The Re-review was completed by a Peer Reviewer who was not involved in the original Determination.

### **Summary of Re-Review Findings**

Based on a thorough review of all information, the Re-Review Peer Reviewer has determined

#### **PREPARATION NOTE FOR QIO**

The summary must include:

- the specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- the standard of care associated with each concern, and
- a statement of the analysis and findings regarding each concern, including the analysis of any additional information submitted as part of the Re-

Review request and/or changes between the Initial Determination and Re-Review.

This information should be consistent with the information contained in the Quality Review Decision (QRD) Form.

Consent to Release Findings to the Beneficiary

We will inform beneficiaries about whether the care they were provided did or did not meet professionally recognized standards of care. In order for us to release more specific findings to the beneficiary, we must obtain consent from practitioner(s) involved in the care of the patient. The findings we propose releasing to the beneficiary are attached to (or included in) this letter. If you are a practitioner, please review the language and indicate consent to our disclosing the information within thirty calendar days from the date of this letter. Please note that we will treat your failure to indicate your consent as your declining to consent, and the beneficiary will not be informed of these specific findings. In order to facilitate release of these specific findings to the beneficiary, please contact the QIO representative named below to discuss the attached findings:

Name of QIO Contact Person

Address

Telephone Number

**PREPARATION NOTE FOR QIO:**

- If the notice is addressed to the provider or practitioner group, insert the name of the practitioner(s) also notified and the following language.
- The following practitioner, [insert name(s)] also has been notified of our Re-Review decision and contacted to obtain his/her consent to disclose the specific findings to the beneficiary.
- If the notice is addressed to the practitioner, insert the name of the provider if applicable. Do not specify other practitioners you may be notifying.
- If the notice is addressed to the provider and will also be sent to a physician practice or some other practitioner, insert into the provider's notice the name(s) of the practitioner(s) also notified and include the statement:
  - The following practitioner(s), [insert name(s)] also has been notified of our Final Initial Determination and contacted to obtain his/her consent to disclose the specific findings to the beneficiary.
- If the notice is addressed to a practitioner or physician practice, insert the name of the provider if applicable. Do not specify other physicians or practitioners you may be notifying.

Again, this constitutes the QIO's FINAL decision on this matter, and no further appeal rights are available. The information in this notice is confidential and may be re-disclosed only in accordance with Federal regulations found in 42 CFR Part 480.

Sincerely,

Medical Director (or designated physician)  
(Include title)

**Appendix 5-5.1 – Beneficiary Quality of Care Complaint:  
Reconsideration Determination Letter to Practitioners and Providers  
(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)**

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**QIO LETTERHEAD**

**FINAL NOTIFICATION**

Date of Notice  
QIO Liaison for Provider's or Practitioner's Name  
Name of Addressee  
Address  
City, State, and Zip Code

Beneficiary Name  
Medicare *beneficiary identifier*  
Practitioner/Provider Name  
Practitioner/Provider Number (CCN/NPI/UPN)  
Date(s) of Service

**[NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER.**

- If the notice is addressed to the provider or practitioner group, insert the name of the practitioner(s) also notified.
- If the notice is addressed to the practitioner, insert the name of the provider if applicable. Do not specify other practitioners you may be notifying.
- If the notice is addressed to the provider and will also be sent to a physician practice or some other practitioner, insert into the provider's notice the name(s) of the practitioner(s) also notified.
- If the notice is addressed to a practitioner or physician practice, insert the name of the provider if applicable. Do not specify other physicians or practitioners you may be notifying.]

Dear [Insert name of Practitioner or Provider here]:

You previously received our letter, dated [insert date here], about care you provided to [insert beneficiary name here]. We received your request for Reconsideration and have completed the Peer Review. Following CMS policy, a Peer Reviewer who was not involved in the prior determination of the initial review completed the Reconsideration review. This letter conveys the results of your Reconsideration review and constitutes our final decision on this matter.

### **Summary of Reconsideration Review**

Based on a review of the information received, the following is the summary of our Reconsideration review.

**Confirmed and/or identified concern(s) [should be the same as Final Determination letter]:**

**[NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER.**

#### **PREPARATION NOTE FOR THE QIO**

The summary of confirmed concerns must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- The standard of care associated with each concern, and
- A summary of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information and, if held, information obtained as a result of the opportunity for discussion with the involved practitioner or provider.

The information should be consistent with the information contained in the QRD Form (See §5230.2).

**Non-confirmed concern(s): NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN LETTER**

#### **PREPARATION NOTE FOR THE QIO**

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- The standard of care associated with each concern, and



- A summary of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information and, if held, information obtained as a result of the opportunity for discussion with the involved practitioner or provider.

The information should be consistent with the information contained in the QRD Form (See §5230.2)]

This information will be entered into [the CMS database]. On an ongoing basis, we analyze patterns of care involving quality concerns that may have significance beyond a single episode. The QIO provides this information to CMS upon request.

Again, this constitutes the QIO's final decision on this matter, and no further appeal rights are available. The beneficiary or patient representative will be notified of the results of the QIO Quality of Care Review. The information in this notice is confidential and may be disclosed only in accordance with Federal regulations found in 42 CFR Part 480.

Sincerely,

Medical Director (or designated physician)  
[Insert title here]

**Appendix 5-5.2 – Beneficiary Quality of Care Complaint:  
Reconsideration Determination Letter to Beneficiary/Beneficiary  
Representative**

*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**NOTE: This letter template applies to beneficiary complaints received after July 31, 2014.**

QIO LETTERHEAD

Date of Notice  
Name of Addressee  
Address  
City, State, and Zip Code

Beneficiary Name  
Medicare *beneficiary identifier*  
Practitioner/Provider Name  
Practitioner/Provider Number (CCN/NPI/UPN)  
Date(s) of Service

Dear [insert name of Beneficiary or Representative here]

We received your request for a different reviewer to look at your quality of care concerns under the Reconsideration process. The Reconsideration review findings are below, and this is our final determination about the quality of the medical care you received.

**Summary of Review**

The following is the summary of our Reconsideration Peer Review.

**Confirmed and/or identified concern(s) [should be the same as Final Determination letter]:**

**[NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER.**

PREPARATION NOTE FOR THE QIO

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- The standard of care associated with each concern, and
- A summary of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information and, if held, information obtained as a result of the opportunity for discussion with the involved practitioner or provider.

The information should be consistent with the information contained in the QRD Form (See §5230.2)]

**Non-confirmed concerns:**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN LETTER**

PREPARATION NOTE FOR THE QIO

The summary must include:

- The specific concerns identified by the beneficiary and any concerns identified by the QIO based on the Scope of Review (See §5110.1),
- The standard of care associated with each concern, and
- A summary of the analysis and facts the QIO determines are pertinent to its findings, including references to medical information and, if held, information obtained as a result of the opportunity for discussion with the involved practitioner or provider.

The information should be consistent with the information contained in the QRD Form (See §5230.2)]

This information will be entered into [the Centers for Medicare & Medicaid Services (CMS) database]. On an ongoing basis, we review quality of care services and concerns that may identify patterns of care that may have significance beyond a single episode. The QIO provides this information to CMS as requested to improve the overall quality of care for all Medicare beneficiaries.

Again, this is the final decision on this matter, and no further appeal rights are available. In addition, the information in this notice is confidential and may be disclosed only in accordance with Federal regulations found in 42 CFR Part 480.

Thank you for sharing your concerns with us. If you have any questions, please do not hesitate to contact us:

[Insert QIO Name]

[Insert QIO Contact Person]

[Insert QIO Address]

[Insert QIO Contact Number]

[Insert QIO Fax Number]

Sincerely,

Medical Director (or designated physician)

[Insert title here]

## **Appendix 5-6 – General Quality of Care Reviews - Initial Determination Letter with Right to Request Reconsideration to Practitioners and Providers**

*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

### **QIO LETTERHEAD**

### **INITIAL NOTIFICATION**

Date of Notice

QIO Liaison for Provider or Practitioner's Name

Name of Addressee

Address

City, State, and Zip Code

Beneficiary Name

Medicare *beneficiary identifier*

Practitioner/Provider Name

Practitioner/Provider Number (CCN/NPI/UPN)

Date(s) of Service

Dear [Insert name of Practitioner or Provider here]:

You are receiving this notification because [Insert QIO name here] identified a potential quality of care concern about care you provided to [Insert beneficiary name here].

[Insert QIO name here] is the Quality Improvement Organization (QIO) authorized by the Centers for Medicare & Medicaid Services (CMS) to review Medicare cases in [Insert QIO area/region here] to determine if the health care services provided to Medicare beneficiaries meet professionally recognized standards of care, are medically necessary, and are delivered in the most appropriate setting. Our primary purpose is to identify areas where health care services can be improved and provide feedback to facilities and practitioners. This Peer Review is intended to be a collegial interaction with the goal of improving patient care.

We have completed our review of the episode of care referenced above. A [Insert QIO name here] Peer Reviewer has carefully reviewed the medical information.

### **Summary of Review**

Based on a review of the information received, the following is the summary of our review.

**Confirmed and/or identified concern(s):**

**[NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER**

**PREPARATION NOTE FOR THE QIO:**

The review findings must include:

- A statement for each quality of care concern that care did or did not meet the standard(s) of care,
- The standard(s) identified by the QIO for each quality of care concerns, and
- A specific statement conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard.

**Non-confirmed concern(s):**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN LETTER**

**PREPARATION NOTE FOR QIO:**

The review findings must include:

- A statement for each of the quality of care concerns that care did or did not meet the standard(s) of care,
- The standard(s) identified by the QIO for each quality of care concerns, and
- A statement for each quality of care concern that care did or did not meet the standard(s) of care.

If you disagree with this quality of care concern(s) determination, you may request Reconsideration. Your request should include the reason for your dissatisfaction with our determination and any additional information you may wish to submit. Your request for Reconsideration can be written or oral and must be submitted within three (3) calendar days from receipt of this letter using the following contact information:

[Insert QIO Name]  
[Insert QIO Contact Person]  
[Insert QIO Address]  
[Insert QIO Contact Number]  
[Insert QIO Fax Number]

**NOTE:** If a request for Reconsideration is not submitted within the appropriate timeframe, this notification will be considered our Final Determination.

This information will be entered into [the Centers for Medicare & Medicaid Services (CMS) database]. On an ongoing basis, we analyze patterns of care involving quality concerns that may have significance beyond a single episode. The QIO provides this information to CMS as requested to improve the overall quality of care for all Medicare beneficiaries.

The information in this notice is confidential and may be disclosed only in accordance with Federal regulations found in 42 CFR Part 480. Thank you for your participation in the improvement of the Medicare program.

Sincerely,

Medical Director (or designated physician)  
[Insert title here]

**Appendix 5-7 – General Quality of Care Reviews: Final  
Reconsideration Determination Letter to Practitioners and Providers  
(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)**

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

**NOTE: Use this letter template if a request for reconsideration is submitted within the appropriate timeframe.**

QIO LETTERHEAD

**FINAL NOTIFICATION**

Date of Notice

QIO Liaison for Provider or Practitioner's Name

Name of Addressee

Address

City, State, and Zip Code

Beneficiary Name

Medicare *beneficiary identifier*

Practitioner/Provider Name

Practitioner/Provider Number (CCN/NPI/UPN)

Date(s) of Service

Dear [insert name of Practitioner or Provider here]:

You previously received our Initial Determination letter, dated [Insert date here], about the care you provided to [Insert beneficiary name here]. We received your request for Reconsideration, and have completed the Reconsideration Peer Review. A [Insert QIO name here] Peer Reviewer has carefully reviewed the medical information, and any additional information that was provided. This Peer Reviewer was not the same Peer Reviewer who initially reviewed this matter. This letter conveys the results of your Reconsideration and constitutes our final decision on this matter.

**Summary of Review**

Based on a review of the information received, the following is the summary of our review.

**Confirmed and/or identified concern(s):**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN THE LETTER**



**PREPARATION NOTE FOR THE QIO:**

The review findings must include:

- A statement for each quality of care concern that care did or did not meet the standard(s) of care,
- The standard(s) identified by the QIO for each quality of care concern, and
- A specific summary conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard.

**Non-confirmed concern(s):**

**NOTE: The following is for instructional purposes ONLY. DO NOT INCLUDE IN LETTER**

**PREPARATION NOTE FOR QIO:**

The review findings must include:

- A statement for each quality of care concern that care did or did not meet the standard(s) of care,
- The standard(s) identified by the QIO for each quality of care concern, and
- A specific summary conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard.]

This information will be entered into [the Centers for Medicare & Medicaid Services (CMS) database]. On an ongoing basis, we analyze patterns of care involving quality concerns that may have significance beyond a single episode. The QIO provides this information to CMS as requested.

The information in this notice is confidential and may be disclosed only in accordance with Federal regulations found in 42 CFR Part 480. Thank you for your participation in the improvement of the Medicare program.

Sincerely,

Medical Director (or designated physician)  
[Insert title here]

**Appendix 5-8 – REQUEST FOR QIO REVIEW FORM**  
*(Rev. 32, Issued: 04-12-19, Effective: 05-13-19, Implementation: 05-13-19)*

*The term Medicare beneficiary identifier (Mbi) is a general term describing a beneficiary's Medicare identification number. For purposes of this manual, Medicare beneficiary identifier references both the Health Insurance Claim Number (HICN) and the Medicare Beneficiary Identifier (MBI) during the new Medicare card transition period and after for certain business areas that will continue to use the HICN as part of their processes.*

TO: QIO Name  
Address  
City, State, Zip

**I. Requesting Agency/Organization and Contact Person**

Agency/Organization: \_\_\_\_\_ Phone #: \_\_\_\_\_  
Contact Person: \_\_\_\_\_ Email: \_\_\_\_\_

**II. Patient Information**

Patient Name: \_\_\_\_\_ *Medicare beneficiary identifier:* \_\_\_\_\_  
\_\_\_\_\_  
Date of Birth: \_\_\_\_\_ Sex: Male \_\_\_\_\_ Female \_\_\_\_\_  
Facility Name: \_\_\_\_\_  
Provider Name: \_\_\_\_\_ Provider Phone #: \_\_\_\_\_  
Admit Date: \_\_\_\_\_ Discharge Date: \_\_\_\_\_

**III. Referral**

Type of Referral (check one): Quality of Care: \_\_\_\_\_ Other: \_\_\_\_\_

Reason for Review Request or Quality of Care Concern Identified (be specific): (Quality of Care e.g., over-prescribing drugs or prescribing the wrong drug, failing to diagnose a medical problem that is found later, misreading x-rays to identify a medical problem, failing to get back to a patient with medical results in a timely manner, failing to provide appropriate care after a surgical procedure)  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Reviewer's Signature Date

Do you need an update on case upon completion of QIO's review? (Check one):

Yes \_\_\_\_\_ No \_\_\_\_\_

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**THIS SECTION FOR QIO USE ONLY**

Was a review conducted? Yes \_\_\_\_\_ No \_\_\_\_\_

Review Results: \_\_\_\_\_

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Additional Information: \_\_\_\_\_

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**Appendix 5-9 – Best Practices**

**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

**Beneficiary Complaint Review**

<b>Review Type</b>	<b>Timing</b>	<b>Reference</b>
<b>Intake Stage</b>		
QIO during initial intake of information from the beneficiary will accept the complaint when received in writing	The date of service on which the care that gave rise to the complaint occurred is less than three (3) years from the date of the phone call to the QIO. If service was more than 3 years before the date of the call or complaint to the QIO, the QIO cannot review the matter under 42 CFR 476.120(a).	5045.2
QIO intakes initial information from the beneficiary	One (1) business day of initial contact	5030.2
QIO responds to messages received after hours	Next business day	5030.2
QIO mails Complaint form	One (1) business day of Intake	5040
Failure to return form, QIO contacts beneficiary	Fifteen (15) calendar days from mailing	5040.2
Failure to return form, the QIO has insufficient information to proceed with a review and closes complaint. Review processed as Quality of Care Review if serious or urgent concern present.	Thirty-one (31) calendar days from mailing	5040.2
QIO uploads form into CMS-designated case review system for Review Analyst review	One (1) business day of receipt	5040.3
Review Analyst contacts beneficiary, orally acknowledges receipt of complaint	One (1) business day of receipt	5040.3
<b>Immediate Advocacy</b>		

<b>Review Type</b>	<b>Timing</b>	<b>Reference</b>
Look back period for Immediate Advocacy	Six (6) months from the date of service which care occurred involving the complaint	5035.2
Time frame for QIO to make a final decision for an Immediate Advocacy	Eight (8) hours to two (2) days is average, but no more than ten calendar days from the time the Immediate Advocacy began	5035.4
Review Analyst updates CMS-designated system about result of Immediate Advocacy	One (1) business day after Immediate Advocacy is completed	5035.5
<b>Requesting Medical Information</b>		
Medical information requested	One (1) business day from receipt of written complaint	5045.2
Due date of all medical information	Fourteen (14) calendar days from date of request or sooner if complaint involves a gross and flagrant of substantial quality of care issue.	5045.2
Medical information not received by deadline calendar day 14 <b>or earlier if</b> concern was potentially gross and flagrant or a substantial quality of care issue and QIO determines that circumstances warrant earlier receipt of information.	Contact the COR immediately who contacts provider by the next business day	5045.2
Medical information not received by calendar day 30	Contact COR and notify the Beneficiary on the next business day	5045.3
Medical information received	Immediately date-stamp and upload into CMS-designated case review system within one business day	5045.4
Information missing/illegible in medical information	Contact provider/practitioner and provide five (5) calendar days to submit corrections	5045.4
<b>Quality of Care Review Stage</b>		

<b>Review Type</b>	<b>Timing</b>	<b>Reference</b>
Review Analyst completes Quality Review Decision (QRD) Form and forwards package to Initial Determination Peer Reviewer(s) (IDPR)	Within a reasonable amount of time to ensure the ten calendar day timeframe is met	5050.2
IDPR completes review and returns package to Review Analyst and reviews IDPR decision	Within the 10 calendar day timeframe from receipt of the medical record	5050.2
<b>Opportunity for Discussion Stage</b>		
Review Analyst offers opportunity for discussion	One (1) business day after reviewing the IDPR determination	5055.1
Response to opportunity for discussion	Seven (7) calendar days from initial offer	5055.1
Extension of response time for opportunity for discussion	Additional seven (7) calendar days in rare circumstances	5055.1
Review Analyst forwards to IDPR information received during opportunity for discussion	One (1) business day from receipt of oral/written response	5055.4
IDPR considers information received and makes Final Determination	Three (3) business days	5055.4
No response to offer of opportunity for discussion	Seven (7) calendar days, then Interim Initial Determination becomes Final Determination	5055.6
Review Analyst forwards Final Initial Determination Letter	Three (3) business days of receipt of all of the QRD Form or one business day of expiration of opportunity for discussion if no response received	5055.6
Practitioner/provider requests a Reconsideration	Three (3) calendar days from receipt of the Final Determination Letter	5060
IDPR destroys copies of all materials	Thirty (30) calendar days	5055.8
<b>Beneficiary Complaint Reconsideration Procedure</b>		

<b>Review Type</b>	<b>Timing</b>	<b>Reference</b>
Beneficiary must inform QIO of his/her request for a Reconsideration in writing or by phone	No later than three (3) calendar days following the initial notification of the QIO's determination	5060
Review Analyst forwards Beneficiary Complaint folder to Reconsideration Peer Reviewer	Within one (1) business day of receipt of request	5060
RPR completes the Reconsideration review, returns folder, and the beneficiary and provider are notified of the decision.	Within five (5) calendar days after receiving any medical or other records needed for reconsideration	5060.1
Review Analyst mails Final Decision to beneficiary	Within five (5) calendar days of request or if later within 5 calendar days of receipt of medical information	5060.4

**Appendix 5-10 – General Quality of Care - Best Practices**  
**(Rev. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)**

**General Quality of Care Review**

<b>Review Type</b>	<b>Timing</b>	<b>Reference</b>
<b>Intake Stage</b>		
QIO intake person forwards folder to Review Analyst	One (1) business day of receipt of referral/identification of concern	5110
<b>Requesting Medical Information</b>		
Medical information requested	One (1) business day from receipt/identification of concern	5110.2
Due date of medical information	Fourteen (14) calendar days from date of request or sooner if complaint involves a gross and flagrant of substantial quality of care issue.	5110.2
Medical information not received by deadline calendar day 14 <b>or earlier if</b> concern was potentially gross and flagrant or a substantial quality of care issue and QIO determines that circumstances warrant earlier production of medical records)	Contact COR immediately	5110.2
Medical information not received by the next business day following deadline	COR calls practitioner/provider the next business day	5110.2
Medical information not received from provider, then initiate claim denial	15 calendar days from date of request or sooner if complaint involves a gross and flagrant of substantial quality of care issue.	5110.2
QIO receives medical information	Immediately date-stamp and upload into CMS-designated case review system within one business day	5110.4
Information missing/illegible in medical information	QIO contacts provider/practitioner and provides five (5) calendar days to submit corrections	5110.4
<b>Quality of Care Review Stage</b>		



<b>Review Type</b>	<b>Timing</b>	<b>Reference</b>
Review Analyst completes QRD Form and forwards package to Initial Determination Peer Reviewer (IDPR)	Within a reasonable amount of time to ensure the 10-calendar-day time frame is met	5115.1
IDPR completes review, returns package to the Review Analyst, and notifies practitioner/provider of Initial Determination Decision	Ten (10) calendar days from receipt of package, including all medical information	5115.2
IDPR destroys copies of all materials	Thirty (30) calendar days after Final Initial Determination	5115.5
<b>Reconsideration Stage</b>		
Practitioner/provider must file a written or oral request for a Reconsideration	Three (3) calendar days following the receipt of the QIO Initial Determination	5115.5
Review Analyst forwards Beneficiary Complaint folder to the Reconsideration Peer Reviewer	Within one (1) business day of receipt of request	5115.5
Review Analyst prepares and mails Final Decision Letter	Within five (5) calendar days after receipt of request for a reconsideration, or 5 calendar days after receiving all medical information	5120.1

## Transmittals Issued for this Chapter

<b>Rev #</b>	<b>Issue Date</b>	<b>Subject</b>	<b>Impl Date</b>	<b>CR#</b>
<u>R32QI</u>	04/11/2019	Update to Publication (Pub.) 100-10 to Provide Language-Only Changes for the New Medicare Card Project	05/13/2019	11206
<u>R28QIO</u>	10/21/2016	QIO Manual Chapter 5 – “Quality of Care Review	10/21/2016	N/A
<u>R17QIO</u>	04/06/2012	QIO Manual Chapter 5 – “Quality of Care Review	05/07/2012	N/A
<u>R09QIO</u>	08/29/2003	Change in Terminology to CMS and QIO	N/A	N/A

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