Quality Improvement Organization Manual

Chapter 5 - Quality of Care Review

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(Rev. 28, 10-21-16)

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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 *C*hapter 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. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

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 Compliant 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 # (HICN);*
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)

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**.

Appendix 5-1.3 – Quality Review Decision (QRD) Form

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

Quality Review Decision (QRD) Form

Case Summary

Case ID#: *State: Choose a State*

Patient Details

Patient Name: *HIC#:*

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:

_____

Appendix 5-2 – *Beneficiary Quality of Care Complaint: Initial Acknowledgement Letter to Beneficiary/Beneficiary Representative*

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

QIO LETTERHEAD

INITIAL NOTIFICATION

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

Beneficiary Name
Medicare # (HICN)
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 5-4 – Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (For Beneficiary Complaints)

(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

QIO LETTERHEAD

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

Patient Name (when the patient has consented to disclosure)
Health Insurance Claim (HIC) Number
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

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

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 # (HICN)
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. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

QIO LETTERHEAD

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

Beneficiary Name
Medicare # (HICN)
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. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

QIO LETTERHEAD

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

Patient Name (when the patient has consented to disclosure)
Health Insurance Claim (HIC) Number
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. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

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 # (HICN)
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. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

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 # (HICN)
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. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

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 # (HICN)
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. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

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 # (HICN)
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. 28, Issued: 10-21-16, Effective: 10-21-16, Implementation: 10-21-16)

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: _____ HIC #: _____

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 _____

THIS SECTION FOR QIO USE ONLY

Was a review conducted? Yes_____ No_____

Review Results: _____

Additional Information: _____

Appendix 5-9 – *Best Practices*

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

Beneficiary Complaint Review

Review Type	*Timing*	*Reference*
	Intake Stage	
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*
	Immediate Advocacy	

Review Type	*Timing*	*Reference*
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*
Requesting Medical Information		
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 ***or earlier if*** *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*
Quality of Care Review Stage		

Review Type	Timing	Reference
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*
Opportunity for Discussion Stage		
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*
Beneficiary Complaint Reconsideration Procedure		

Review Type	*Timing*	*Reference*
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

Review Type	*Timing*	*Reference*
	Intake Stage	
QIO intake person forwards folder to Review Analyst	*One (1) business day of receipt of referral/identification of concern*	*5110*
	Requesting Medical Information	
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 ***or earlier if*** *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*
	Quality of Care Review Stage	

Review Type	*Timing*	*Reference*
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*
Reconsideration Stage		
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

Rev #	Issue Date	Subject	Impl Date	CR#
R28QIO	10/21/2016	QIO Manual Chapter 5 – "Quality of Care Review	10/21/2016	N/A
R17QIO	04/06/2012	QIO Manual Chapter 5 – "Quality of Care Review	05/07/2012	N/A
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