CMS Manual System

Pub. 100-10 Medicare Quality Improvement Organizations

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

Transmittal 17 **Date: April 6 2012**

SUBJECT: QIO Manual Chapter 5 – "Quality of Care Review"

I. SUMMARY OF CHANGES: Chapter 5 has undergone necessary and extensive changes. These changes are intended to provide a more organized and logical flow of the content, standardization of QIO processes and clear step-by-step instructions. In addition, the revised manual chapter includes content that is not part of the current chapter. This chapter provides up-to-date information and will be of great value to all stakeholders.

NEW/REVISED MATERIAL - EFFECTIVE DATE*: May 7, 2012
IMPLEMENTATION DATE: May 7, 2012

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

II. CHANGES IN MANUAL INSTRUCTIONS: (*N/A if manual not updated.*)
(R = REVISED, N = NEW, D = DELETED) – (*Only One Per Row.*)

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	5/5000/Introduction to Quality of Care Reviews
D	5/5005/Scope of Review
R	5/5010/Organization of Chapter
D	5/5015/Referrals
R	5/5020/Authority for Conducting Quality of Care Reviews
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III. FUNDING: No additional funding will be provided by CMS; contractor activities are to be carried out within their operating budgets.

IV. ATTACHMENTS:

	Business Requirements
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	Confidential Requirements
	One-Time Notification
	One-Time Notification -Confidential
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***Unless otherwise specified, the effective date is the date of service.**

Quality Improvement Organization Manual
Chapter 5 - Quality of Care Review

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(Rev. 17, Issued: -04-06-12)

5000 – *Introduction to Quality of Care Reviews*

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

This chapter provides instructions for Quality Improvement Organizations (QIOs) to follow in conducting Quality of Care Reviews and in assisting providers and practitioners in improving the quality of health care through Quality Improvement Initiatives. Quality health care is 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 within the range of care they fall. 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 manual instructions related to that review activity, e.g., chapter 4 for medical necessity reviews, chapter 7 for an expedited appeal review, chapter 9 for sanction activities.

5010 – *Organization of Chapter*

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

QIOs conduct two types of Quality of Care Reviews, Quality of Care Reviews initiated because a beneficiary has complained (referred to as Beneficiary Complaint Reviews) and Quality of Care 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 Reviews).

The two sources of a Beneficiary Complaint Review are:

1. *A written complaint filed by a beneficiary, or*
2. *An oral complaint by a beneficiary where 1) the beneficiary agrees to participate in Expedited Resolution or 2) where a "serious or urgent" concern(s) has been raised.*

There are three sources for General Quality of Care Reviews:

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, e.g., medical necessity reviews, expedited discharge appeals, Emergency Medical Treatment and Labor Act (EMTALA) reviews.*
2. *Referrals: A Quality of Care Review conducted in response to referrals from other entities, e.g., Medicare Administrative Contractors, state-based organizations, the Office of the Inspector General, the Office for Civil Rights, including anonymous referrals.*
3. *Tracking and Trending: A Quality of Care review conducted as a result of tracking and trending of data.*

The chapter is organized based on the two types of Quality of Care Reviews, with Beneficiary Complaint Reviews addressed first (See §5100), followed by General Quality of Care Reviews (See §5500). For each type of review, the instructions address the processing of the review as a Retrospective Review and then as a Concurrent Review. For Retrospective Beneficiary Complaint Reviews, (See §5200). For Concurrent Beneficiary Complaint Reviews, (See §5300). For Retrospective General Quality of Care Reviews, (See §5540), and for Concurrent General Quality of Care Reviews, (See §5600).

In addition, the process steps for each type of review have been separated into four stages to facilitate identification of roles and steps associated with various aspects of the process. The four stages are as follows:

Stage 1: Intake Stage

Stage 2: Quality of Care Review Stage

Stage 3: Opportunity for Discussion Stage

Stage 4: Re-Review Stage

***NOTE:** §1154(a)(14) of the Social Security Act 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 §5120) during the Intake Stage if a written complaint has not yet been received. The manual instructions also address a QIO's ability to offer a Post-Peer Review alternative dispute resolution process, called Direct Advocacy (See §5400), for those complaints submitted in writing that Peer Reviewers determine contain no significant quality of care concerns.*

5020 – *Authority for Conducting Quality of Care Reviews*

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

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 reviews 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 are involved with reviewing the quality of services, under paragraph (a)(1)(B), and that a reasonable allocation of such activities is made 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.
42 FCR 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 sanctions.

5030 – *Definitions Related to Quality of Care Reviews*

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

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.*

Appointed Representative: *An individual appointed by a beneficiary to represent the beneficiary in the Beneficiary Complaint Review process.*

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.*

Beneficiary Representative: *An individual identified as an authorized or appointed representative of a beneficiary.*

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

Concurrent Review: *A Quality of Care Review (i.e., a Beneficiary Complaint Review or a General Quality of Care Review) while the beneficiary remains in the provider setting or conducted at the same time the care is being provided to the beneficiary.*

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 (Chapter 9).*

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

Gross and Flagrant Violation: *A violation of an obligation has occurred in one or more instances which presents an imminent danger to the health, safety, or well-being of a beneficiary or unnecessarily places the beneficiary in high-risk situations: The obligation is to provide health care economically and only when, and to the extent, medically necessary; to provide care of a quality that meets professionally recognized standards of health care; and to provide care that is supported by evidence of medical necessity and quality. See §1156 (a) of the Act, 42 CFR Part 1004 and Chapter 9.*

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), Definitions.*

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

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: *The care under question has been demonstrated in more than three instances.*

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

Physician: *A doctor of medicine ,osteopathy, dentistry, optometry, podiatry or another individual, who is authorized under State or Federal law to practice medicine and surgery, or osteopathy, dentistry, optometry, or podiatry. This includes medical officers in American Samoa, the Northern Mariana Islands and the Trust Territory of the Pacific Islands. See §1154(c)..*

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 Re-Review Peer Reviewer must meet the requirements of this definition. See §1154(c) of the Act and 42 CFR §476.98(a)(1) and (b), "Utilization and Quality Control Review—Reviewer Qualifications and Participation." In addition, a peer reviewer of services furnished or proposed to be furnished by a physician must be reviewed by another physician with the same credentials and with active staff privileges in one or more hospitals in the QIO's area. In cases in which there is no peer match available, the QIO can use another physician reviewer without the same expertise. (See §476.98(a)(2.).)*

Practitioner: *An individual credentialed within a recognized health care discipline and involved in providing the services of that discipline to patients. See 42 CFR §§476.1 and 480.101(b). For purposes of individuals who have provided services, the term includes physicians, unless otherwise stated in this Chapter.*

Quality (Health) 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 (Health) Care Concern*: A concern that care provided did not meet a professionally recognized standard of health care.*

Quality of (Health) Care Review: *A review conducted by a QIO to determine whether the quality of services provided to beneficiaries was consistent with professionally recognized standards of health care. A Quality of Care Review can either be a Beneficiary Complaint Review or a General Quality of Care Review.*

Quality Improvement Initiative: *Any formal activity plan designed to assist the provider/practitioner in identifying the root cause of a concern(s), developing a framework in which the concern(s) is addressed and improving a process or system.*

Re-Review Peer Reviewer: *A Peer Reviewer who conducts the re-review segment of a Quality of Care Review.*

Retrospective Review: *A Quality of Care Review (i.e., a Beneficiary Complaint Review or a General Quality of Care Review) conducted after the beneficiary has been discharged from the provider setting or after services are provided to a beneficiary.*

Serious or Urgent (quality of care) Concern: *A concern that any beneficiary has been exposed to serious harm as a result of the quality of care provided or that any beneficiary may potentially be exposed to imminent future harm as a result of the quality of care provided.*

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

Substantial Violation: *A violation of an obligation has occurred in a single occurrence of care provided that if it occurred more than twice would require the QIO to initiate sanction activities pursuant to Chapter 9. The obligation involves providing health care only when it is economical and medically necessary, of a quality that meets professionally recognized standards of health care, and supported by evidence of medical necessity and quality. See §1156 (a) of the Act and 42 CFR Part 1004*

Substantial Violation in a Substantial (3 or more) Number of Cases: *A pattern of providing care that would require the QIO to initiate sanction activities pursuant to Chapter 9. It involves care that violates the obligation to provide health care only when it is economical and medically necessary, of a quality that meets professionally recognized standards of health care, and supported by evidence of medical necessity and quality. See §1156 (a) of the Act and 42 CFR Part 1004*

5100 – Beneficiary Complaint (Oral or Written) Review

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

These instructions address the processing requirements QIOs must follow in completing both Retrospective and Concurrent Beneficiary Complaint Reviews. ***NOTE:*** *While the processing requirements for Retrospective and Concurrent Reviews are similar, certain time frames associated with the Concurrent Review Process are significantly shorter. The instructions begin by addressing the initial intake of information from a beneficiary by the Intake Specialist, which is the same for both Retrospective and Concurrent Reviews. (See §§5110 – 5110.4.) The initial intake of information includes the QIO's determination regarding 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 Retrospective or Concurrent Beneficiary Complaint Review. The instructions will then detail the processing instructions for those complaints for which Immediate Advocacy has been offered. (See §§5120-5120.5.) The chapter will then address the processing instructions for Retrospective Beneficiary Complaint Reviews (See §§5200 – 5250.4) and Concurrent Beneficiary Complaint Reviews (See §§5300 – 5350.4). For information on the applicable time frames, see Appendices 5-9, Retrospective Beneficiary Complaint Review Time Frames and 5-10, Concurrent Beneficiary Complaint Review Time Frames.*

5100.1 – Eligibility for Beneficiary Complaint Review

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

For a complaint to be eligible for a Beneficiary Complaint Review the complaint must meet the following requirements:

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),*
3. *Express concern about the quality of care received.*

Please see §5210.2 (Retrospective Beneficiary Complaint Reviews) and §5310.2 (Concurrent Beneficiary Complaint Reviews) for oral complaints that contain one or more "Serious or Urgent" concerns.

5110 – Beneficiary Complaint Intake Stage

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

QIOs may become aware of a potential beneficiary complaint through a phone call or correspondence, including the receipt of a complaint by regular mail, e-mail, or facsimile. The Medicare Quality of Care Complaint Form, CMS-10287 (Complaint Form) has been developed for beneficiaries to use in submitting a complaint (See Appendix 5-1). See §§5210-5210.3 and §§5310-5310.3 of this chapter for information regarding the use of the Complaint Form.

It is anticipated that, in most instances, a beneficiary's initial contact with a QIO regarding a potential complaint will be made by telephone. 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 they are calling with regard to a complaint about the quality of care they have received, the beneficiary will be transferred to the appropriate stated-based QIO. It is expected that QIOs will immediately enter any information received into the CMS-designated case review system (See §5110.4) so that it is readily accessible to pertinent staff. The Intake Specialist is responsible for ensuring that enough information is obtained from the beneficiary during calls to complete the review.

5110.1 – Scope of Complaint

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

In obtaining information from the beneficiary regarding 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 articulate that the practitioner and/or provider did not "meet professionally recognized standards of care."

The QIO is to avoid narrowly focusing the scope of a review based on a beneficiary's statements regarding why care was problematic since most beneficiaries are not health care practitioners or providers and therefore, do not have sufficient knowledge and/or experience to render such judgments about care received. In addition, as the expert in conducting Quality of Care Reviews, the QIO should not focus solely on a beneficiary's assumptions and/or conclusions about the care received since these assumptions and/or conclusions may be misleading or not relate to the actual problem encountered by a beneficiary. For instance, a beneficiary's statement regarding 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. Below are

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

- *Example 1: A beneficiary's husband contacts the QIO and complains about the care his wife received while in the hospital. In discussing his concerns, the husband specifically mentions the length of time he and his wife waited in the Emergency Room prior to her being admitted and also mentions that he believes she received the incorrect medication during her 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 wife. The QIO's review must include ALL care provided to the wife by the hospital from the wife's arrival in the Emergency Room through the conclusion of the wife's hospital stay. The QIO must convey information regarding any Quality of Care Concern for which care did not meet professionally recognized standards of care related to the wife's hospital stay as well as the QIO's conclusions regarding the specific items mentioned by the husband (Emergency Room wait and medication error) even if the standard of care was met for these. See §5250.3 (Retrospective Review) and §5350.3 (Concurrent Review) for detailed instructions regarding the preparation of the Letter to Beneficiary-QIO's Final Decision.*

- *Example 2: A beneficiary contacts the QIO to complain that he requested - but never received - medication during a six-hour stay in a hospital and that he 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 Psych-hospital and should not have been allowed to leave. In this scenario, the scope of the QIO's review is not limited to the beneficiary's failure to receive the medication he requested. The QIO's review must include ALL care provided to him by the Psych-hospital, including the Psych-hospital's failure to properly "lock-down" the facility, which resulted in the beneficiary being able to leave. The QIO must convey information regarding 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 regarding the specific items mentioned by the beneficiary (failure to receive requested medication and the length of his wait time).*

- *Example 3: A beneficiary representative called to complain that his uncle, an elderly beneficiary, had told him that he had been given the wrong antibiotic medication 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 over-dose 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 regarding any Quality of Care Concern for which care did not meet professionally recognized standards of care (i.e., the over-dose of the anti-seizure medication) as well as the QIO's conclusions regarding the specific item mentioned by the beneficiary representative (wrong antibiotic medication) even where the QIO's review demonstrates that the standard of care was met with regard to the antibiotic medication.*

See §5250.3 (Retrospective Review) and §5350.3 (Concurrent Review) for detailed instructions regarding the preparation of the Final Decision to Beneficiary Letter.

5110.2 – Initial Information Collection

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

Upon receipt of a call from a beneficiary or in reviewing a complaint received via correspondence, the staff member, hereinafter referred to as the "Intake Specialist", must collect and record basic information regarding the potential complaint in the CMS-designated case review system within one (1) business day of the initial contact. In addition, the Intake Specialist must make a determination regarding whether the complaint is eligible for Immediate Advocacy or if a Peer Review is required within this same time frame.

Messages received after normal business hours must be responded to the next business day. The list below is information determined necessary for processing a beneficiary complaint. As such, the Intake Specialist should attempt to collect the following information during the initial phone call with the beneficiary. Much of the information may already be accessible using the CMS-designated case review system. If specific information is not readily available, the Intake Specialist must ensure appropriate follow up is made to obtain the information from the beneficiary.

The Intake Specialist should obtain or note the following information:

1. *The beneficiary's name, age, date of birth, sex, HIC number, and race/ethnicity (if willing to provide).*
2. *The beneficiary's phone number, address and e-mail address.*
3. *The name of the caller if other than the beneficiary, i.e., the beneficiary representative, including the beneficiary representative's phone number, address and e-mail address.*
4. *The date and time the complaint is received.*
5. *General information regarding the health care issue(s) surrounding the complaint. The focus of the information collected must be on the general circumstances relating 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 complaints. QIOs are cautioned to avoid narrowly focusing the scope of a review based on the beneficiary's statements regarding why care was problematic since most beneficiaries are not health care practitioners or providers and therefore, do not have sufficient knowledge and/or experience to render such judgments about care received. See §5110.1, "Scope of Complaint" for additional instructions regarding the nature of the complaint. The Intake Specialist should be able to identify the following from the information provided:*
    a. *The state in which the complaint originates (The QIO for the state in which the care was received has authority to conduct the review.).*
    b. *The name of the practitioner(s) or provider(s) who is/are the subject of the complaint.*
    c. *The setting in which the complaint originates, e.g., during a physician's office visit, during a hospital admission, skilled nursing facility stay, or other.*
    d. *Whether the beneficiary:*
        i. *Has been discharged from the facility or is no longer receiving services, or*
        ii. *Is still in the facility or is still receiving the services in question*

NOTE: *For instances where the beneficiary is "still in the facility," or is "still receiving services in question," the QIO must process the complaint as a Concurrent Beneficiary Complaint Review. See §5300, Concurrent Beneficiary Complaint Review. However, the QIO should identify the approximate date(s) on which the problematic care was received in comparison to the date of the actual call to the QIO.*

e. *Whether the beneficiary intends to file a written complaint.*

f. *Information regarding the overall severity of the Quality of Care Concerns involved in the complaint in order to make a determination as to whether Immediate Advocacy could be offered or any concern could be deemed "gross and flagrant," "substantial," or "serious or urgent." If any of the concerns raised by the beneficiary could be designated "gross and flagrant," "substantial," or "serious or urgent" the complaint is not eligible for Immediate Advocacy. See §5120 for information and process requirements regarding Immediate Advocacy. The Intake Specialist may consult with a Review Analyst as needed in making such determinations.* ***NOTE:*** *Once a written complaint is received, Immediate Advocacy may not be offered.*

6. *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), but is the responsibility of another CMS component or contractor, such as a fiscal intermediary, carrier or Medicare Administrative Contractor (MAC), the caller must be provided with sufficient information to contact the appropriate entity or the Intake Specialist may offer to refer the matter to the other entity after obtaining the beneficiary's oral agreement to do so (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 has responsibility, e.g. an expedited discharge appeal, the Intake Specialist must follow the procedures in place for those issues.*

7. *In situations where the beneficiary states that he/she may harm themselves or others or where the beneficiary indicates other patients may be at risk of potential harm, the Intake Specialist must immediately contact the Review Analyst to discuss the circumstances.*

8. *Any additional information that may be helpful in processing the complaint, e.g., notes related to the conversation, any discussions with internal staff about the complaint.*

9. *Request permission to disclose to the provider/practitioner the beneficiary's name and the reason for any medical information being requested. The Intake Specialist must explain that even if the beneficiary chooses to not disclose his/her name as part of the complaint process, the QIO will need to request his or her medical information to review the complaint. Because of the need to request medical information, the QIO cannot guarantee anonymity. The provider, and in particular the practitioner, may be presumed to know that the medical information is being requested because of a complaint even if the QIO does not disclose the reason for the medical information request.*

5110.3 – Initial Offer of Review

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

After collecting the above information from the beneficiary, the Intake Specialist must:

1. *Briefly review the information collected, including the concern(s) raised by the beneficiary and ask the beneficiary if s/he has any additional information to provide.*

2. *Make a determination regarding whether Immediate Advocacy could be used to resolve the complaint (See §5120) or if the complaint should be reviewed in accordance with the Peer Review process (See §5200 for Retrospective Reviews and §5300 for Concurrent Reviews). In making this determination, the Intake Specialist must consider the information collected (See §5110.2) from the beneficiary, including the Scope of the Complaint. See §5110.1.*
3. *If the complaint is deemed eligible for Immediate Advocacy, the Intake Specialist must discuss the availability of Immediate Advocacy with the beneficiary and then ask the beneficiary whether s/he has any questions regarding Immediate Advocacy in general. The Intake Specialist must also provide information regarding the Beneficiary Satisfaction Survey and ask the beneficiary if s/he would like to participate in the Survey.*
4. *If the complaint is deemed ineligible for Immediate Advocacy, the Intake Specialist must explain the Peer Review process and ask the beneficiary whether s/he has any questions regarding the process in general. The Intake Specialist must also provide information regarding the Beneficiary Satisfaction Survey and ask the beneficiary if s/he would like to participate in the Survey.*
5. *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 complainant that a Review Analyst will be calling the beneficiary within one (1) business day of receipt of the signed Complaint form.*

5110.4 – Use of CMS-Designated Case Review System

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

QIOs are required to use the CMS-designated case review system to record all data/information collected regarding a complaint. This includes any information provided by the beneficiary during the initial intake of the complaint, including a thorough description of the complaint, any notes from the Intake Specialist or other individuals involved in processing the complaint, including the names of staff inputting information in the CMS-designated case review system. This is designed to facilitate the resolution of any questions that may arise regarding a specific complaint and ensures that all pertinent information regarding a complaint is uniformly recorded and centrally located in the CMS-designated case review system.

5120 – Immediate Advocacy

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

Based on the nature of the concern(s) raised by the beneficiary during the Intake Stage, the Intake Specialist may recommend the use of Immediate Advocacy. Immediate Advocacy is an informal process used by the QIO to quickly resolve an oral complaint. In this process, the QIO makes immediate/direct contact with a provider and/or practitioner for the beneficiary. The Intake Specialist must summarize what Immediate Advocacy entails for the beneficiary and obtain the beneficiary's oral consent to participate in Immediate Advocacy before proceeding. A beneficiary may discontinue Immediate Advocacy at any time. See §5120.5 for additional information regarding discontinuation of Immediate Advocacy. The use of Immediate Advocacy is not appropriate for situations where the beneficiary does not want his/her identity disclosed to the provider and/or practitioner.

5120.1 – Objectives of Immediate Advocacy

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

The objectives of Immediate Advocacy are:

- *Provide flexibility in resolving complaints in situations when the traditional Peer Review process is not in and of itself going to reach complete resolution (e.g., 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.*

5120.2 – Eligibility for Immediate Advocacy

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

Prior to obtaining a written beneficiary complaint, the QIO may offer Immediate Advocacy to the beneficiary in situations when:

1. *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 regarding resources and/or services covered by Medicare, such as a wheel chair that was not delivered; or a beneficiary concerned about the quality of communication with their practitioner and/or provider), or*
2. *The beneficiary complains about a matter that, while related to the clinical quality of health care received by the beneficiary, 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 where the beneficiary has multiple concerns and the Intake Specialist determines that at least one of the concerns is "gross and flagrant," "substantial", or "serious or urgent."*

Below are examples of complaints that 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 s/he received a different colored pill than expected and would like the QIO to call the facility to find out what drug was given.*

5120.3 – Practitioner/Provider Consent to Participate in Immediate Advocacy

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

Immediately upon obtaining the beneficiary's oral consent to participate in Immediate Advocacy, the practitioner/provider must be contacted to obtain oral consent to participate in Immediate

Advocacy. The practitioner/provider must be informed about the receipt of a complaint and the beneficiary's desire to pursue resolution of the complaint through Immediate Advocacy. The QIO must 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. Upon obtaining the practitioner/ provider's oral consent to participate in Immediate Advocacy, the QIO should follow the Immediate Advocacy procedures in §5120.4 in order 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 §5200, Retrospective Beneficiary Complaint Review or §5300, Concurrent Beneficiary Complaint Review.

5120.4 – Immediate Advocacy Procedures

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

Once oral consent has been obtained for all parties, the QIO may either use conference call/three-way call or make a call on behalf of the beneficiary in order to obtain resolution of the beneficiary's oral complaint. The focus should be on providing a quick and amicable resolution of these complaints within a short time frame, usually within eight (8) hours but no more than 2 business days. A Peer Review is not to be performed in light of the types of issues to be addressed using Immediate Advocacy. In addition, the provider/practitioner must not be asked to submit medical information.

In some circumstances, the provider/practitioner may be unavailable for a period of time after the beneficiary consents to the use of Immediate Advocacy. In these situations, the QIO must contact the beneficiary to explain the circumstances and discuss all available options. In no instance should the use of Immediate Advocacy extend beyond 10 days from the initial contact with the practitioner/provider.

After Immediate Advocacy has been carried out, the QIO must update the CMS-designated case review system 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, there may be certain instances where the beneficiary remains dissatisfied after its completion. 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 §5800.

5120.5 – Discontinuation of Immediate Advocacy

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

If, at any point, a beneficiary expresses his/her desire to stop pursuing a complaint through the Immediate Advocacy process, the QIO must inform the beneficiary of his/her right to file a written complaint in accordance with §5200, Retrospective Beneficiary Complaint Review or §5300, Concurrent Beneficiary Complaint Review.

If, at any point, the QIO becomes aware of additional information that would render the complaint ineligible for Immediate Advocacy, the QIO must immediately stop Immediate Advocacy proceedings and advise all parties that Immediate Advocacy will be discontinued. The QIO may recommend to the beneficiary that s/he submit a written complaint. For complaints

submitted in writing, the QIO must follow the instructions set forth in §5200, Retrospective Beneficiary Complaint Review or §5300, Concurrent Beneficiary Complaint Review. The QIO may follow the requirements detailed in §5210.2 (Retrospective Beneficiary Complaint Review) or §5310.2 (Concurrent Beneficiary Complaint Review) for "serious or urgent" quality of care issues or otherwise act accordingly in light of the information presented.

A beneficiary may choose to file his/her complaint in writing at any time, which will render the complaint ineligible for Immediate Advocacy.

5200 – Retrospective Beneficiary Complaint Review

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

The following instructions detail the steps the QIO must adhere to in completing the Intake Stage where the QIO has determined:

- *the beneficiary has already been discharged from the provider setting and/or services are no longer being provided (Retrospective Review), and*
- *Immediate Advocacy could be used but the beneficiary expresses an intent to file a written complaint, OR*
- *Immediate Advocacy is not appropriate and the beneficiary expresses an intent to file a written complaint, OR*
- *Immediate Advocacy is not appropriate, a written complaint is not submitted but the QIO determines that the complaint involv*es a "serious or urgent" concern. When a QIO *regards a concern as serious or urgent, the QIO is authorized under §1154(a)(1) of the Act to perform a quality of care review of the services related to that concern.*

5210 - Retrospective Beneficiary Complaint: Preparation and Forwarding of Complaint Form

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

After ending the intake call described in §5100, the Intake Specialist must immediately input basic information obtained during the phone call into the Complaint Form, except in situations where the beneficiary has requested that the form be e-mailed.

Prohibition on Emailing Pre-filled Forms to Beneficiaries: *The QIO may not pre-fill any information on the Complaint Form where the beneficiary requests delivery of the form through e-mail.*

The Complaint Form must be pre-filled prior to sending the form via facsimile or mail. The QIO may also direct the beneficiary to the QIO's website or CMS' forms Web page to obtain a copy of the form. The Intake Specialist must pre-fill the following sections of the form prior to mailing or faxing it to the beneficiary:

- *The beneficiary's name,*
- *The beneficiary's Medicare # (HICN),*
- *The beneficiary's sex and age (if known),*
- *The beneficiary's race/ethnicity (if the respondent is willing to voluntarily provide it),*
- *The name of the beneficiary's authorized representative (if someone other than the beneficiary will be the contact),*

- *The pertinent contact information, including street address and phone numbers for either the beneficiary or representative, and*
- *A brief description of the complaint following the requirements of §5110.1.*

The Intake Specialist must mail, fax or email the form to the beneficiary within one (1) business day of the information being collected. ***NOTE:*** *Where the beneficiary requests the form to be sent via email, the QIO must not pre-fill the form.*

Prohibition Against Forwarding Additional Information: *The QIO must not forward any additional information to the beneficiary at this time. The QIO may only mail, fax or e-mail the Complaint Form and the Appointment of Representative Form, if applicable (see the discussion of this Appointment Form in the note below). The QIOs are prohibited from using any independently developed complaint forms. QIOs may only use the official Complaint Form (CMS 10287).*

For a copy of the Complaint Form, see Appendix 5-1, "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 http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf .

NOTE: *For situations when a Beneficiary Representative contacts the QIO to file a complaint on behalf of a beneficiary, the QIO must question the beneficiary representative regarding his/her status as a "representative" of the beneficiary. A Beneficiary Representative may be appropriate in situations where a beneficiary has chosen his or her own representative or in cases in which the QIO determines that a beneficiary is mentally, physically or legally unable to participate effectively in the complaint process as well as being unable to designate his or her own representative. The QIO must disclose the information to a person whom the beneficiary has identified as his/her representative or the QIO determines is responsible for the beneficiary.*

In identifying a responsible person, the QIO must first attempt to identify a representative in the medical record. The QIO should consider any relevant information it finds in the record, but should be certain to consider other reliable information to find the most appropriate representative. In making this determination, the QIO also should consider any State law requirements that exist regarding the designation of representatives. Moreover, the QIO must advise the beneficiary representative that any evidence of the person's status as the authorized representative, e.g., a written request from the beneficiary, a court decree, should be provided to the QIO when the written complaint is submitted. 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 http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf .

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 returning the completed forms by e-mail to the QIO's e-mail address, the beneficiary must be advised that while returning the completed form by e-mail 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. E-mailed forms or facsimiles are deemed "written" for purposes of §5210.3.

5210.1 – Retrospective Beneficiary Complaint: Follow-up Regarding Return of Signed Complaint Form

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

If the signed Complaint Form is not received within 14 calendar days of the date of the mailing, faxing or e-mailing of the form, the Intake Specialist must follow up with the beneficiary. The Intake Specialist shall determine if the beneficiary still intends on filing a written complaint. The Intake Specialist must do this no later than calendar day 15 (or the next business day) after the date of the forwarding of the Complaint Form. Upon contact, if the beneficiary continues to indicate a desire to file a written complaint, the Intake Specialist must work with the beneficiary to determine any additional steps necessary to ensure return of a signed Complaint Form, including forwarding of another Complaint Form. If the beneficiary no longer intends to file a written complaint, or after additional follow up, the beneficiary still does not submit the signed Complaint Form by calendar day 30, the Intake Specialist must contact the beneficiary on calendar day 31 (or the next business day) and advise the beneficiary that the case will be closed (See §5210.2), but that the beneficiary may submit the signed Complaint Form at any time.

5210.2 – Retrospective Beneficiary Complaint: Complaints Not Submitted in Writing (i.e. Oral Complaints)

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

In those instances where a beneficiary contacts the QIO regarding a complaint, but does not submit a signed Complaint Form by calendar day 31—or advises the QIO during the initial discussion that s/he will not submit a written complaint—the QIO must close the case in the CMS-designated case review system. The pertinent QIO must conduct a Quality of Care Review in accordance with §1154(a)(1)(B) and the procedures in §5230, "Retrospective Beneficiary Complaint: Quality of Care Review Stage," if the following apply:

1. *The QIO collects sufficient information to complete a Quality of Care Review, and*
2. *The concern(s) identified by the beneficiary in an oral complaint is considered serious or urgent.*

A serious or urgent quality of care concern(s) is a concern(s) that any beneficiary has been exposed to serious harm as a result of the quality of care provided or that any beneficiary may potentially be exposed to imminent future harm as a result of the quality of care provided. Should the QIO determine that the matter involves a serious or urgent concern and the QIO has sufficient information to complete its Review, the QIO may immediately request the medical information and begin the review.

***NOTE:** Since oral complaints are not processed as written beneficiary complaints, the beneficiary shall not receive the results of the review. As such, the disclosure process detailed in §5240.6, "Retrospective Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/Providers with Request to Disclose," §5250.2, "Retrospective Beneficiary Complaint: Preparation of Re-Review Disclosure Package," and 5250.3, "Retrospective Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary," are not applicable.*

5210.3 – Retrospective Beneficiary Complaint: Receipt of a Signed Beneficiary Complaint

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

Upon receipt of the signed Complaint Form, the Intake Specialist must date stamp the form and scan it into the CMS-designated case review system, along with the original envelope, facsimile or email so that it can be available for the pertinent QIO Review Analyst (RA) within one (1) business day. The original envelope, facsimile, or email from the beneficiary indicating the post-mark/date received must be kept with the original signed Complaint Form and placed in the Beneficiary Complaint Folder. Emailed forms or facsimiles are deemed "written."

5220 – Retrospective Beneficiary Complaint: Preparation of Beneficiary Complaint Folder

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

The Intake Specialist will be responsible for preparing the official Beneficiary Complaint Folder for maintenance at the QIO. A duplicate copy of the folder may be required for use by an off-site Peer Reviewer. See §5220.4 for more detailed information regarding the content and organization of the folder.

5220.1 – Retrospective Beneficiary Complaint: Forwarding of Complaint to Review Analyst

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

Upon receipt of the Beneficiary Complaint through the CMS-designated case review system, the RA must review the Complaint Form and information in the CMS-designated case review system to ensure that he or she understands the specific concern(s) involved. This shall include those instances when multiple concerns have been raised, whether the concerns relate to a single complaint or multiple complaints. The RA must then contact the beneficiary to orally acknowledge receipt of the complaint within one (1) business day of receipt of the complaint through the CMS-designated case review system.

During the discussion with the beneficiary, the RA must obtain additional information (if necessary), and describe the complaint process to the beneficiary in more detail. The RA shall describe his or her role, the Initial Determination Peer Reviewer's (IDPR's) role, the Peer Review process in general, and the anticipated time frames related to the resolution of the review.

If the RA is unable to reach the beneficiary by phone, the RA must follow-up/call-back the beneficiary. The RA shall initiate the review immediately, even in those instances when the beneficiary cannot be immediately contacted, unless information necessary for completing the review is still needed. Follow-up/call-back to obtain this additional information shall be completed no later than five (5) business days from the date of the initial call attempt. If the RA is unable to reach the beneficiary by phone, the RA shall contact the beneficiary by letter advising the beneficiary that a review cannot be conducted until the necessary information is received.

5220.2 – Retrospective Beneficiary Complaint: Requesting Medical Information
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

The Intake Specialist must request medical information as soon as the written complaint (See §5210.3) is received with sufficient information to identify the pertinent practitioner and/or provider, i.e., no later than one (1) business day after receipt of the complaint (See Step 1 below). However, in situations when the beneficiary has raised a serious or urgent complaint as discussed in §5210.2, "Retrospective Beneficiary Complaint: Complaints Not Submitted in Writing (i.e., Oral Complaints)," the Intake Specialist need not wait for receipt of the written complaint before requesting medical information and beginning the review. For serious or urgent complaints, the Intake Specialist shall request medical information as soon as sufficient information has been obtained to identify the pertinent practitioners and providers. See 42 CFR §476.78(b)(2), "Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations —Responsibilities of Health Care Facilities," and §480.111(a), "QIO Access to Records and Information of Institutions and Practitioners" regarding a QIO's right to request medical information.

Providers are obligated to forward all required information within 30 calendar days of the request or within 21 calendar days where a potential "serious reportable event" has been identified or where the QIO determines that other circumstances exist which warrant earlier receipt of the medical information. See 42 CFR §476.78(b)(2). Practitioners should be informed that they are expected to provide information within the same timeframes. For purposes of conducting Beneficiary Complaint reviews, providers will be given 21 days for any instance where the QIO determines that a "Gross and Flagrant," "substantial," or "Serious or Urgent" concern may be present. Practitioners should likewise meet this timeframe for these kinds of concerns. A Medicare Advantage Plan is responsible for submitting medical information, except when it has specifically delegated this responsibility to the provider. Should an MA Plan fail to submit medical information as requested within the prescribed 21 or 30 day time frame, the matter must be referred to the pertinent CMS Regional Office Project Officer (Project Officer). If the responsibility for submitting medical information has been delegated to the MA provider, the Project Officer should collaborate with the Division of Medicaid and State Operations regarding any options that may be pursued in light of the provider's Medicare Provider Agreement.

In situations in which a provider fails to submit medical information within the required timeframe, the provider may be subject to a denial of payment under 42 CFR 476.90. In some situations where either a practitioner or provider fails to submit medical information within the required twenty-one (21) or thirty (30) calendar day time frame, the QIO should advise the practitioner or provider that, based on §1156(a)(3), sanctions may be initiated because of the failure to support the provision of items or services with evidence of the medical necessity for and quality of the items or services.

***NOTE:** Upon receipt of the medical information at any step, follow the instructions as outlined in §5220.4, "Retrospective Beneficiary Complaint: Review and Preparation of Medical Information."*

QIOs must complete the following steps in requesting medical information:

***Step 1:** Request the medical information within one (1) business day of receiving the written complaint. The Intake Specialist may contact the practitioner and/or provider by phone and follow up with a facsimile or mailed letter. The letter must clearly indicate the specific date on*

which the medical information was first requested since this date will be used to determine when, for a provider, a denial of the claim shall be issued. See §5220.3 for information regarding a claim denial. ***NOTE:*** *The date of the letter may be used if it corresponds to the date of the first request. The Intake Specialist must advise a practitioner and/or provider that, in order to expedite the QIO's review and ensure that the QIO receives all necessary information in a timely manner, the QIO expects the provider or practitioner to submit the requested information within ten (10) calendar days from the date on which the medical information was first requested.*

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

Step 2: *The QIO should follow up as necessary to ensure adherence to the ten (10) calendar day requested submission deadline. Before making contact, the QIO should review the CMS-designated case review system to confirm that the medical information has not been received. If the medical information is not received by calendar day fifteen (15) from the date of the original request, then on the next business day immediately following calendar day fifteen (15), the QIO must contact senior leadership for the provider, e.g., the Chief Financial Officer, and advise of the potential claims denial(s) associated with the failure to submit the medical information by calendar day twenty-one (21) or calendar day thirty (30). See 42 CFR §476.78(b)(2). This step is meant to furnish a provider with adequate notice to correct any problems associated with submitting medical information, and to help the provider avoid potential penalties or claims denials. Practitioner s should be reminded that, under §1156(a)(3), items or services provided by or ordered by practitioners must be supported by evidence of medical necessity and quality, in such form and fashion and at such time as may reasonably be required by a QIO in the exercise of its duties and responsibilities. For uniformity, QIOs are expected to establish "form and fashion and reasonable time" components that align with those for providers. The QIO should point out that any unreasonable delay in providing medical information could lead to sanctions under §1156(b).*

Step 3: *If the medical information is not received from a provider or practitioner by calendar day twenty-one (21) or calendar day thirty (30), the QIO must immediately contact their Project Officer and provide sufficient information so that the Project Officer is prepared to contact the provider or practitioner. The QIO must follow up with the Project Officer to advise her or him if/when the medical information is received.*

Step 4: *Upon receiving a call from the QIO regarding a provider's or a practitioner's failure to provide medical information, the Project Officer shall call the Medical Records Department, the QIO liaison, or senior leadership and convey the responsibilities associated with the request for the medical information the next business day after calendar day twenty-one (21) or thirty (30). The Project Officer should assess the willingness to comply with the request for medical information and explain the potential repercussions of failure to provide the medical information, including issuance of a denial of the claim, notification of the Division of Medicaid and State Operations, potential for the QIO to conduct additional reviews, etc. — the Project Officer shall advise the contact that if the medical information is not received within the next calendar day, a claim denial shall be carried out for any claim associated with the care described in the complaint.*

Step 5: *If the medical information is not received from a provider by calendar day twenty-three (23) or calendar day thirty-two (32), proceed in accordance with §5220.3, "Retrospective Beneficiary Complaint: Issuing a Claim Denial."* ***NOTE:*** *In instances when the QIO completes a claim denial in accordance with §5220.3, the provider is still required to comply with its*

responsibility to forward the medical information to the QIO for the QIO to complete the Quality of Care Review. For providers and practitioners, a Project Officer may recommend additional action depending on the particular facts of the situation, e.g., recommending that the QIO conduct additional Quality of Care Reviews on other patients for whom similar claims have been submitted for payment by the practitioner or provider.

In instances where the requested medical information is not received within forty (40) calendar days, the beneficiary must be advised in writing:

- *The QIO is unable to complete the review as a result of the practitioner's and/or provider's failure to submit the medical information.*
- *FOR COMPLAINTS RELATED TO PROVIDERS ONLY: CMS has initiated action to deny Medicare payment to the provider for the services surrounding the care referenced in the beneficiary's Complaint.*
- *Based on §1156(a)(3), sanctions may be initiated against a provider or practitioner for failing to support the items or services they have provided with evidence of the quality of the items or services.*
- *Should the medical information be received within the next 30 days, the beneficiary will be contacted and advised that the review will be completed.*

5220.3 – Retrospective Beneficiary Complaint: Issuing a Claim Denial

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

A QIO is authorized to deny a provider's claim in situations where the QIO has requested information from a provider and despite sufficient notice and a reasonable amount of time to respond, the provider fails to forward the requested information. See 42 CFR §476.90(b). In processing the denial of the claim, the QIO should coordinate with the pertinent Project Officer. If the requested medical information is submitted before the denial of the claim is finalized, the QIO must stop the denial and complete the review. If the medical information is received after the denial of the claim has been finalized, payment must be re-instituted. The QIO should complete the review. The Project Officer should be consulted regarding any additional action the QIO should take, e.g., completion of additional Quality of Care Reviews for the same provider.

5220.4 – Retrospective Beneficiary Complaint: Review and Preparation of Medical Information

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

Upon receipt of the medical information, the Intake Specialist must immediately date-stamp the information to indicate the date received, unless the information is received electronically and scan the information, including the original envelope, into the CMS-designated case review system within one (1) business day. The Intake Specialist must keep the original envelope with the medical information. The Intake Specialist ensures all information in the medical information is complete, appropriately organized, and legible. If the medical information is incomplete or illegible (poor copy), the Intake Specialist contacts the practitioner and/or provider by phone and allows an additional five (5) calendar days for submission of the documentation necessary to complete the medical information. QIOs must follow the procedures

for issuing claims denials in §5220.3 when complete medical information is not received in accordance with either the twenty-one (21) or thirty (30) calendar day time frame. See Appendix 5-9, "Retrospective Beneficiary Complaint Review Time Frames."

The Intake Specialist shall organize the medical information in accordance with the following tabs. The contents of each tab shall be placed in chronological order:

TAB 1: Emergency Room Record/Admission Record

TAB 2: History and Physical

TAB 3: Consultations

TAB 4: Practitioner Orders

TAB 5: Practitioner Progress Notes

TAB 6: Nursing Notes.

TAB 7: Ancillary, e.g., Labs, X-rays, Medication Administration Record, Treatment Administration Record, etc

TAB 8: Miscellaneous

TAB 9: Discharge Summary

***NOTE:** QIOs are authorized to upload medical information received directly into the CMS-designated case review system, and the QIO must also upload the information into the CMS-designated case review system within one (1) business day.*

If the Intake Specialist, RA, or physician reviewer(s) determine that handwritten information in the medical information cannot be deciphered, the QIO may contact the facility and request a typed/transcribed portion of the problem sections of the medical information. The QIO must make every effort to limit the amount of typed/transcribed information requested. Failure to comply with a request for typed/transcribed information shall be treated as a failure to provide the medical information if the missing information precludes the completion of the review. QIOs must follow the procedures in §5220.3 for processing a denial of the claim when applicable.

5230 – Retrospective Beneficiary Complaint: Quality of Care Review Stage

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

The Review Analyst (RA) initiates the Retrospective Quality of Care Review stage for Beneficiary Complaint Reviews by conducting a preliminary review of the written complaint and each of the Quality of Care Concerns. For those instances when the beneficiary raises multiple concerns that are potentially unrelated, the RA shall make a determination regarding whether the QIO shall process the concerns as a single complaint with multiple concerns, or as multiple complaints. In making this determination, the RA must consider the following:

Total number of concerns,

Relationship or inter-relatedness between the concerns,

Time frames associated with the concerns,

Impact of different practitioner and/or provider involvement in each of the concerns,

Health care issues related to each of the concerns,

Beneficiary's own statements regarding the relationship between the concerns, and

Other factors deemed relevant as identified by the RA.

The importance of a particular criterion may be different for different complaints, and the QIO must consider the totality of the circumstances. The RA should consult with the Intake Specialist or Medical Director in making the determination to separate complaints that have been uploaded into CMS-designated case review system as a single complaint. If a decision is made to process concerns as separate complaints, the RA must communicate the rationale for the decision to the beneficiary and detail the rationale in the CMS-designated case review system.

5230.1 – Retrospective Beneficiary Complaint: New Concerns Raised by the Beneficiary

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

As a result of the QIO's broad focus regarding the scope of the complaint, the QIO should rarely become aware of new Quality of Care Concerns after the complaint has entered the Quality of Care Stage. See Scope of Complaint, §5110.1. New issues/concerns may be added to the original complaint if the Interim Initial Determination step has not been completed. In the rare event that a new issue/concern(s) is raised by the beneficiary following the completion of the Interim Initial Determination (See §5230.3), the new issue/concern will be processed as a separate/new complaint.

5230.2 – Retrospective Beneficiary Complaint: Preparation of Quality Review Decision (QRD) Form

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

Once a determination has been made regarding the number of complaints and the specific Quality of Care Concern(s) to be addressed during the Retrospective review, a Quality Review Decision Form must be prepared for each complaint. See Appendix 5-2, "Quality Review Decision (QRD) Form." This standardized form replaces the Physician Reviewer Assessment Format previously followed by all QIOs. The new QRD Form has been created to better account for the multiple individuals who are involved in the review of a beneficiary complaint and to ensure information related to every beneficiary complaint—and in particular every quality of care concern—is maintained in an organized, detailed, and consistent fashion throughout the review process. The RA must complete the following steps:

Using the CMS-designated case review system, the RA must prepare a QRD Form that sets out each individual concern and forward the package to the IDPR within three (3) business days of receipt of the medical information. This includes separately completing the following steps for each concern:

a. *Evaluate the beneficiary complaint and each Quality of Care Concern in accordance with §5110.1, Scope of Complaint.*
b. *Evaluate the quality of care with regard to the admission diagnosis and treatment plan established for the beneficiary, if applicable.*
c. *Evaluate the quality of care for any blatant issues, including potential Never Events that should be identified.*
d. *Research evidence-based practices related to each Quality of Care Concern(s), while considering the definition of Quality Care including reference to relevant norms and criteria. If no quality of care standard(s) exists, then the Review Analyst must identify norms, best practices and established guidelines and then recommend a potential quality*

of care standard(s). In completing this step, the RA must thoroughly research all available information, including the following:

- *Nurse Screening Criteria (InterQual, Milliman, etc.), and*
- *Generally available resources, including information available via Internet searches.*

A Review Analyst Assessment section must be completed for each Quality of Care Concern in the complaint and/or identified by the RA.

e. *Evaluate additional information pertinent to the case, but unrelated to the standard(s) of care. This may include:*

- *CMS-available information, which may include Web-based resources, e.g., Nursing Home and Hospital Compare;*
- *State-based resources, which may include Web-based literature/information, as well as, practitioner-specific information related to license revocations and referrals to the state medical conduct organizations.*

f. *Research all available data (minimum of three (3) years) to determine whether the QIO has received similar complaints on the same practitioner and/or provider and/or if other potential concerns related to the same practitioner and/or provider are identifiable.*

g. *Prepare the package for forwarding to the Initial Determination Peer Reviewer (IDPR).*

5230.3 – Retrospective Beneficiary Complaint: Receipt and Review by the Initial Determination Peer Reviewer (IDPR)

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

The RA mails the package to the IDPR within three (3) business days of the receipt of the Medical Information and the IDPR then initiates his/her review. The IDPR must review the Quality of Care Concern(s) identified by the beneficiary and any additional concern(s) identified by the RA. For individual concerns, the IDPR evaluates the standard(s) identified by the RA on the QRD Form and checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care as delineated by the RA. If the IDPR identifies quality of care concerns that were not raised by the beneficiary or identified by the RA, the IDPR must indicate this and identify pertinent research detailing the standard of care he/she used to evaluate the concern.

If the IDPR determines that the standard(s) identified by the RA for a specific concern(s) is incorrect or not thorough, the IDPR identifies the correct standard(s) and provides an explanation regarding the change. For those instances when the IDPR determines that the standard(s) is incorrect, the IDPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care in the QRD Form.

The IDPR then applies the standard(s) of care to the specific facts of the case and the Quality of Care Concern(s) at issue. The IDPR evaluates the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The IDPR must evaluate whether the quality of care standard for each of the identified concerns is met based on the facts of the case and directly link his/her decisions to elements contained in the evidence-based standard(s). The IDPR also assesses the responsibility of the individual identified by the beneficiary—if the individual identified is different from the individual who is responsible for the standard(s) not being met.

In addition, the IDPR considers any historical data pertinent to the concern(s) as provided by the RA, and highlights specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met. The IDPR should also include any other information the IDPR deems relevant to his/her Interim Initial Determination. If the IDPR concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the IDPR must thoroughly explain these justifications.

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

- *The care grossly and flagrantly, in one or more instances, violated the provider's/practitioner obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed to substantially comply with the obligation (less than three cases) to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act); or*
- *The care did not meet the standard of care, but was less than a substantial violation of the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care, i.e., it was either significant or non-significant.*

The IDPR must complete his/her review of the package, adhere strictly to the format in the QRD Form and return the package to the Review Analyst within seven (7) calendar days of receipt of the package. The IDPR signs and dates the QRD Form and indicates the amount of time spent reviewing the complaint. Except in circumstances when the IDPR conducts the review on the QIO premises, the IDPR may maintain a signed copy of his or her completed QRD Form and additional notes. These are maintained to facilitate any additional review necessary based on the receipt of additional information during the Opportunity for Discussion Stage.

5230.4 – Retrospective Beneficiary Complaint: Return and Review of Interim Initial Determination

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

Immediately upon receipt of the Beneficiary Complaint folder from the IDPR, the Review Analyst must ensure all necessary information has been returned and the QRD Form has been signed. The RA has two (2) business days to review the package to ensure the IDPR rendered a decision on all quality of care concerns, the content adheres to the correct format, and the rationale for conclusions is clear.

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

If the IDPR determined that the standard(s) of care was met for all concerns, the RA should follow the procedures detailed in §5240.6, "Retrospective Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/Providers with Request to Disclose."

If the IDPR determined that the standard(s) of care was not met for any one or more of the concerns, and the concerns are not sanctionable, the RA should follow the procedures detailed in §5240, "Retrospective Beneficiary Complaint: Opportunity for Discussion Stage."

5240 – Retrospective Beneficiary Complaint: Opportunity for Discussion Stage

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

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

5240.1 – Retrospective Beneficiary Complaint: Notification of Opportunity for Discussion

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

After reviewing the Interim Initial Determination package from the IDPR, and if the RA determines that the IDPR has identified a concern(s) for which the standard(s) of care was not met, the practitioner and/or provider must be offered the opportunity to discuss the concern(s). The RA must make the offer within two (2) business days of the receipt of the package from the IDPR.

In offering the opportunity, the QIO shall make every effort to discuss the IDPR's Interim Initial Determination as expeditiously as possible. The time frame for obtaining a response from the provider and/or practitioner shall not extend beyond 15 calendar days from the date the offer was originally made, except in rare circumstances, e.g., the practitioner is unavailable (out of the country) for the entire 15 day period. In these rare circumstances, a practitioner may be provided an additional seven (7) calendar days to respond to the offer.

The QIO shall initiate contact with the practitioner and/or provider. Initial contact may be by phone; however, the QIO should document the date on which the offer was first made to the practitioner and/or provider, and this may include sending to the practitioner and/or provider a facsimile or letter detailing the specific concern(s) at issue. A QIO must allow for a practitioner to use a representative to respond to the Opportunity for Discussion. See Appendix 5-3, "Interim Initial Determination Letter for Practitioners or Providers."

5240.2 – Retrospective Beneficiary Complaint: Oral or Written Response to Opportunity for Discussion

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

A practitioner and/or provider must be afforded the opportunity to orally and/or in writing convey his/her disagreement with the conclusions rendered by the IDPR in the Interim Initial Determination. The offer of the Opportunity for Discussion can be made by the RA, the IDPR or the Medical Director, depending on the QIO's established practice within the state. However, the RA must participate in discussions between the IDPR and the practitioner and/or provider. For complex cases, it is recommended that the Medical Director participate.

NOTE: *For instances when the practitioner and/or provider responds to the Opportunity for Discussion by agreeing with the concern(s) identified, the agreement should then be documented and the QIO should follow the requirements in §5240.5, "Retrospective Beneficiary Complaint: No Response to Opportunity for Discussion."*

Oral responses: *The RA must prepare a summary of any oral response submitted. During the oral discussion, the practitioner and/or provider shall be advised of the need to focus on the specific element(s) of the standard(s) of care which is being disputed in the IDPR's Interim Initial Determination.*

Written responses: *The practitioner and/or provider shall be advised of the need to focus on the IDPR's conclusions related to specific elements of the standard(s) of care. Written statements submitted for the Opportunity for Discussion must be sent to the RA.*

5240.3 – Retrospective Beneficiary Complaint: Prohibition on Submission of New/Additional Medical Information

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

The submission of new and/or additional medical information is prohibited in response to the offer of the Opportunity for Discussion. In instances when the practitioner and/or provider requests to submit new and/or additional medical information, the QIO must advise the practitioner and/or provider of his/her right to request a Re-Review and that any new and/or additional medical information can be considered during the Re-Review process.

5240.4 – Retrospective Beneficiary Complaint: Review of Information Submitted during Opportunity for Discussion Stage

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

The RA reviews his or her summary of any oral response submitted by the practitioner or practitioner representative, and/or provider, or the written Opportunity for Discussion response, in light of the quality of care concern(s) raised during the IDPR review. For both oral and written responses, the RA must make every effort to highlight/summarize specific facts provided by the practitioner and/or provider during the discussion in relationship to particular elements of the standard(s) of care that could alter the IDPR's Interim decision. (As noted in §5240.3, facts provided during the discussion stage cannot include new medical information.) The RA must also detail any information/rationale provided by the practitioner and/or provider that appears to be unrelated to the standard(s) of care.

The RA shall forward the information, along with specific issues identified in the response, to the IDPR for consideration within one (1) business day of completing an oral discussion and/or receiving the written response.

Upon receipt of additional information during the Opportunity for Discussion, the IDPR must make his/her Final Initial Determination no later than three (3) business days from his or her receipt of the additional information. The QIO must ensure that the same Peer Reviewer renders both the Interim and Final Initial Determinations, unless rare circumstances exist, e.g., the Interim IDPR is unavailable as a result of serious illness.

In most instances, the RA will not be required to mail the IDPR the entire Beneficiary Complaint Folder. The IDPR must use the copy of the QRD Form from the Interim Initial Determination in evaluating the information the practitioner and/or provider supplied to the RA during the Opportunity for Discussion. Additional materials will not be mailed for situations where the practitioner and/or provider conveyed information orally directly to the IDPR. The RA and the IDPR will coordinate to ensure all pertinent information is considered in the Final Initial Determination. After making the Final Initial Determination, the IDPR re-signs the QRD Form and mails it back to the RA. The signed form may also be faxed to expedite review.

5240.5 – Retrospective Beneficiary Complaint: No Response to Opportunity for Discussion

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

If no response is received to the offer of the Opportunity for Discussion within 15 calendar days, the Interim Initial Determination becomes the Final Initial Determination. The IDPR need not sign the QRD Form again to denote this result; however, the RA will note on the QRD Form that no response was received.

5240.6 – Retrospective Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/Providers with Request to Disclose

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

Upon receipt of the QRD Form, the RA prepares the Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4) conveying the decision to the practitioner and/or provider, advising the practitioner and/or provider of the right to request a Re-Review within fifteen (15) calendar days if the standard(s) of care was not met for any concern, and requesting the practitioner's consent to disclose the specific findings to the beneficiary within thirty (30) calendar days.

***NOTE:** For provider-related issues, consent to disclose is generally not required. Provider-specific information is non-confidential, except as specified in 42 CFR 480.101(b) (definition of confidential information), and is generally disclosable as long as it does not explicitly or implicitly identify a beneficiary or explicitly or implicitly identify a practitioner or QIO reviewer who has not consented to disclosure. See CMS Publication 100-10, Quality Improvement Organization Manual, Chapter 10 for additional information.*

The RA must forward to the provider or practitioner at issue the Final Initial Determination Letter to Providers/Practitioners within three (3) business days of receiving the QRD Form detailing the Final Initial Determination from the IDPR, or, when no response to the Opportunity for Discussion period is received, within one (1) business day following the end of this period.

In addition, the RA must include the language that the QIO proposes to convey to the beneficiary in the "Letter to the Beneficiary-QIO's Final Decision" Appendix 5-6. See §5250.3, "Retrospective Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary."

If the practitioner requests a Re-Review, consent to disclose the information is not needed at this time, and the letter must advise the practitioner that if he or she requests a Re-Review, the practitioner's consent will again be requested after the Re-Review determination is made.

If the practitioner and/or provider do not request a Re-Review within fifteen (15) calendar days, then the practitioner and/or provider may not be granted a Re-Review, absent extraordinary circumstances.

5240.7 – Retrospective Beneficiary Complaint: Failure to Respond to the Final Initial Determination and Right to Re-Review

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

For instances in which a provider fails to respond to the Re-Review offer in the Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4) within the fifteen (15) calendar day period, the QIO will prepare and send the "Letter to the Beneficiary-QIO's Final Decision," Appendix 5-6, no later than one (1) business day after the 15 days have expired. For instances when a practitioner fails to request a Re-Review offer within the fifteen (15) calendar day period in response to the Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4), the QIO must wait for the practitioner's response to the QIO's request to disclose, up until the end of the thirty (30) calendar day period, to determine what information the QIO can disclose to the beneficiary. When the practitioner responds or the 30 days expires, the QIO shall prepare and send the "Letter to the Beneficiary-QIO's Final Decision," Appendix 5-6, no later than one (1) business day after the receipt of the practitioner's consent/non-consent or the expiration of the thirty (30) day period. A practitioner's failure to respond to the "Final Initial Determination Letter to Practitioners/Providers with Request to Disclose" shall be treated as a denial for disclosure purposes, and the letter to the beneficiary shall not include specific practitioner-related information. The QIO shall follow the procedures in §5250.3, "Retrospective Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary," for preparing the letter (Appendix 5-6). The QIO shall follow the procedures in §5250.4, "Retrospective Beneficiary Complaint: Procedures for Closing a Complaint Review" for closing the case in the CMS-designated case review system. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5240.8 – Retrospective Beneficiary Complaint: Responsibility to Protect Information and Destruction of Materials

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

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

No later than thirty (30) calendar days after the IDPR renders his/her final decision, the IDPR must destroy all copies of materials in his/her possession associated with the review in compliance with QIO security procedures. The original documentation will be maintained by the QIO at its facility.

5250 – Retrospective Beneficiary Complaint: Re-Review Stage

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

The practitioner and/or provider may request a Re-Review within fifteen (15) calendar days of receipt of the Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4). Additional evidence may also be submitted as part of the Re-Review

process. Upon receipt of a Re-Review request, the Review Analyst must forward the Beneficiary Complaint folder with the following items to the Re-Review Peer Reviewer (RRPR):

- *QRD Form*
- *Medical information*
- *Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4). See §5250.3 "Retrospective Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary," for letter content.*
- *Interim Initial Determination Letter*
- *Information received related to the offer of the Opportunity for Discussion Stage*
- *Any new evidence submitted in requesting the Re-Review*

The package with the above information must be forwarded to the RRPR within one (1) business day of the receipt of the request for a Re-Review. See §5250.1, "Retrospective Beneficiary Complaint: Re-Review Peer Reviewer."

5250.1 – Retrospective Beneficiary Complaint: Re-Review Peer Reviewer

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

The RRPR must be different than the Peer Reviewer who conducted the Interim and Final Initial Determinations. In making his/her determination, the RRPR shall review all information forwarded by the Review Analyst. The RRPR shall use the QRD Form in rendering his/her determination(s).

The RRPR receives the mailed package from the Review Analyst and initiates the Re-Review.

***NOTE:** The RRPR will not receive beneficiary complaints when the IDPR has identified a concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standards of health care as required by §1156(a) of the Act. These concerns will result in the initiation of sanction proceedings in accordance with Chapter 9.*

The RRPR must review each Quality of Care Concern identified in the complaint and any additional concerns identified by the RA or the IDPR during the review of the medical information, and complete the QRD form for each concern.

- *The RRPR evaluates the standard(s) identified by the RA and the IDPR for each Quality of Care Concern on the QRD Form.*
- *The RRPR checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care for each Quality of Care Concern as delineated by the RA and IDPR.*
- *If the RRPR determines that the standard(s) identified by the RA and/or IDPR for a specific concern(s) is incorrect or not thorough, the RRPR must identify the correct standard(s) and provide an explanation regarding the change.*
- *For those instances when the RRPR determines that the standard(s) is incorrect, the RRPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care and consult with the Medical Director to obtain*

the Medical Director's concurrence on the standard to be used in evaluating the concern(s).

***NOTE:** The RA shall be included in this consultation.*

Completion of the Analysis/Justification: Upon determining the standard(s) of care to be used, the RRPR then applies the standard(s) of care to the specific facts of the case and the quality of care concern(s) at issue. The RRPR evaluates the information contained in the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The RRPR must directly link his/her decisions to elements contained in the evidence-based standard(s) when deciding whether quality of care for each of the identified concerns is met based on the facts of the case. The RRPR must also assess the responsibility of the individual identified by the beneficiary if that individual is different from the individual who is responsible for the standard(s) not being met.

In addition, the RRPR must consider any historical data pertinent to the concern(s) as provided by the RA, highlight specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met, and include any other information the RRPR deems relevant to his or her Re-Review Determination. If the RRPR, in his/her determination, concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the RRPR must thoroughly explain these justifications in completing the Analysis/Justification section of the QRD Form.

The RRPR must complete a separate analysis for each quality concern. Upon completion of the Analysis/Justification section, the RRPR must check off the appropriate box indicating his/her decision that the standard(s) of care was met or not met. If the RRPR determines that the standard(s) of care was not met, the RRPR must also check off the appropriate box indicating whether:

- *The care grossly and flagrantly, in one or more instances, violated the provider's/practitioner's obligation to provide care that is of a quality that meets professionally recognized standards of health care (See §1156(a) of the Act);*
- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standards of health care in §1156(a);*
- *The care failed to substantially comply with the obligation (less than three cases) to provide care that is of a quality that meets professionally recognized standards of health care in §1156(a) (less than three cases); or*
- *The care did not meet the standard of care but was less than a substantial violation of the obligation to provide care that is of a quality that meets professionally recognized standards of health care, i.e., it was either significant or non-significant.*

The RRPR must complete his/her review of the package, adhere strictly to the requirements of the QRD Form and return the package to the Review Analyst within seven (7) calendar days. The RRPR must sign and date the QRD Form and indicate the amount of time spent reviewing the concern(s).

***NOTE:** If the RRPR has identified a concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standards of health care as*

required by §1156(a) of the Act, then the RA must initiate sanction proceedings in accordance with Chapter 9.

5250.2 – Retrospective Beneficiary Complaint: Preparation of Re-Review Disclosure Package

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

The Review Analyst receives the package from the RRPR and examines it to ensure all necessary information is returned. The RA identifies the Re-Review Decision on the QRD Form and prepares the "Re-Review Disclosure Package" which includes the Re-Review Determination Letter to Providers/Practitioners with Request to Disclose (See Appendix 5-5) and the language to be conveyed to the beneficiary in the Final Decision Letter (Appendix 5-6). The RA may utilize the language used previously, unless substantial changes have been made. The QIO may explore changes to the disclosure letter to facilitate the practitioner's agreement to release more detailed information to the beneficiary. Consent is not needed to disclose specific findings related to a provider. However, a QIO has the discretion to offer a provider a comment period, as described below. The RA forwards the package to the practitioner and/or provider (if the QIO has offered the comment period) within one (1) business day of its receipt from the RRPR.

The practitioner has thirty (30) calendar days to respond to the disclosure request in the Re-Review Determination Letter to Providers/Practitioners with Request to Disclose (Appendix 5-5). The failure to respond shall be treated as a denial for disclosure purposes.

The QIO is generally not required to obtain provider consent to disclose provider-related issues. Provider-specific information is non-confidential, except as specified in 42 CFR §480.101(b) (definition of confidential information), and may generally be disclosed as long as it does not explicitly or implicitly identify a beneficiary or identify a practitioner or QIO reviewer who has not consented to disclosure. See Chapter 10 of the QIO Manual. The QIO may afford a provider the opportunity to comment on the language to be conveyed to the beneficiary in the letter (Letter to the Beneficiary-QIO's Final Decision (Appendix 5-6)). Provider comments must be received within fourteen (14) calendar days.

5250.3 – Retrospective Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary

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

For all complaints involving either providers or practitioners, the letter to the beneficiary (Appendix 5-6) shall include:

1. *A statement for each of the quality of care concerns that care did or did not meet the standard of care,*
2. *Inclusion of the standard identified by the QIO for each of the quality of care concerns,*
3. *A statement that this constitutes the QIO's final decision on the complaint and that no further rights are available.*

In all situations involving a provider or in those situations in which a practitioner has consented to disclosure of more details about a case, the letter should also include a specific statement conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard,

NOTE: Specific facts that will disclose the identity of a particular practitioner should not be disclosed in situations in which a practitioner has not consented to disclosure of those particular facts.

The pertinent practitioner and/or provider must receive a copy of the Letter to Beneficiary – QIO's Final Decision.

NOTE
For cases involving practitioners, the RA shall prepare and mail the QIO's Final Decision (Letter to the Beneficiary-QIO's Final Decision (Appendix 5-6)) within three (3) business days of receipt of consent/non-consent for disclosure or no later than one (1) business day after the 30 day consent period ends.

For cases involving providers, the RA shall prepare and mail the letter (Letter to the Beneficiary-QIO's Final Decision (Appendix 5-6)) within three (3) business days of the receipt of the package from the RRPR or within one (1) business day of the expiration of the fourteen (14) calendar day provider-comment period (if offered).

***NOTE:** This section is only to be completed for written complaints; for oral complaints, please see §5210.2, "Retrospective Beneficiary Complaint: Complaints Not Submitted in Writing (i.e., Oral Complaints)."*

5250.4 – Retrospective Beneficiary Complaint: Procedures for Closing a Complaint Review

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

The RA must denote in the CMS-designated case review system that the beneficiary complaint is completed and is closed, except in those situations where the RA determines that Direct Advocacy, a post-peer review alternative dispute resolution process, should be made available to the beneficiary. See §5400. The RA must place all final documents in the Beneficiary Complaint Folder for maintenance and filing. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5300 – Concurrent Beneficiary Complaint Review

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

The following instructions detail the steps a QIO must adhere to in completing the Intake Stage where the QIO has determined:

- *the beneficiary has not yet been discharged from the provider setting and/or services are still being provided (Concurrent Review), and*
- *Immediate Advocacy could be used but the beneficiary expresses an intent to file a written complaint, OR*
- *Immediate Advocacy is not appropriate and the beneficiary expresses an intent to file a written complaint, OR*
- *Immediate Advocacy is not appropriate, a written complaint is not submitted but the QIO determines that the complaint involves a "serious or urgent" concern.*

5310 – Concurrent Beneficiary Complaint: Preparation and Forwarding of Standard Complaint Form

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

After ending the intake call described in §5110, the Intake Specialist must immediately input basic information obtained during the phone call into the Complaint Form, except in situations where the beneficiary has requested that the form be e-mailed.

Prohibition on Emailing Pre-filled Forms to Beneficiaries: *The QIO may not pre-fill any information on the Complaint Form where the beneficiary requests delivery of the form through e-mail.*

The Complaint Form must be pre-filled prior to sending the form via facsimile or mail. The QIO may also direct the beneficiary to the QIO's website or CMS' forms Web page to obtain a copy of the form. The Intake Specialist must pre-fill the following sections of the form prior to mailing or faxing it to the beneficiary:

- *The beneficiary's name,*
- *The beneficiary's Medicare # (HICN),*
- *The beneficiary's sex and age (if known),*
- *The beneficiary's race/ethnicity (if the respondent is willing to voluntarily provide it),*
- *The name of the beneficiary's authorized representative (if someone other than the beneficiary will be the contact),*
- *The pertinent contact information, including street address and phone numbers for either the beneficiary or representative, and*
- *A brief description of the complaint following the requirements of §5110.1.*

The Intake Specialist must mail, fax or email the form to the beneficiary within one (1) business day of the initial contact. The QIO should develop an internal process to ensure concurrent complaints are received in writing on a fast track basis (e. g., by fax). ***NOTE:*** *Where the beneficiary requests the form to be sent via email, the QIO must not pre-fill the form.*

Prohibition Against Forwarding Additional Information: *The QIO must not forward any additional information to the beneficiary at this time. The QIO may only mail, fax or e-mail the Complaint Form and the Appointment of Representative form, if applicable (see the discussion of this Appointment Form in the note below). The QIOs are prohibited from using any independently developed complaint forms. QIOs may only use the official Complaint Form (CMS 10287).*

For a copy of the Complaint Form, see Appendix 5-1, "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 http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf .

NOTE: *For situations when a Beneficiary Representative contacts the QIO to file a complaint on behalf of a beneficiary, the QIO must question the beneficiary representative regarding his/her status as a "representative" of the beneficiary. A Beneficiary Representative may be*

appropriate in situations where the beneficiary has chosen his or her own representative or in cases in which the QIO determines that a beneficiary is mentally, physically or legally unable to participate effectively in the complaint process as well as being unable to designate his or her own representative. The QIO must disclose the information to a person whom the beneficiary has identified as his/her representative or the QIO determines is responsible for the beneficiary.

In identifying a responsible person, the QIO must first attempt to identify a representative in the medical record. The QIO should consider any relevant information it finds in the record, but should be certain to consider other reliable information to find the most appropriate representative. In making this determination, the QIO also should consider any State law requirements that exist regarding the designation of representatives. Moreover, the QIO must advise the beneficiary representative that any evidence of the person's status as the authorized representative, e.g., a written request from the beneficiary, a court decree, should be provided to the QIO when the written complaint is submitted. 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 http://www.cms.hhs.gov/cmsforms/downloads/cms1696.pdf .

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 returning the completed forms by e-mail to the QIO's e-mail address, the beneficiary must be advised that while returning the completed form by e-mail 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. E-mailed forms or facsimiles are deemed "written" for purposes of §5310.3.

5310.1 – Concurrent Beneficiary Complaint: Follow-up Regarding Return of Signed Complaint Form

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

For Concurrent Beneficiary Complaint Reviews, the QIO should attempt to have the beneficiary return the signed complaint form by facsimile in order to expedite the receipt. If the signed Complaint Form is not received within 14 calendar days of the date of the mailing, faxing or e-mailing of the form, the Intake Specialist must follow up with the beneficiary. The Intake Specialist shall determine if the beneficiary still intends on filing a written complaint. The Intake Specialist must do this no later than calendar day 15 (or the next business day) after the original date of the forwarding of the Complaint Form. Upon contact, if the beneficiary continues to indicate a desire to file a written complaint, the Intake Specialist must work with the beneficiary to determine any additional steps necessary to ensure return of a signed Complaint Form, including forwarding of another complaint form. If the beneficiary no longer intends to file a written complaint, or after additional follow up, the beneficiary still does not submit the signed Complaint Form by calendar day 30, the Intake Specialist must contact the beneficiary and advise the beneficiary that the case will be closed (See §5310.2), but that the beneficiary may submit the signed Complaint Form at any time.

5310.2 – Concurrent Beneficiary Complaint: Complaints Not Submitted in Writing (i.e., Oral Complaints)

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

In those instances where a beneficiary contacts the QIO regarding a complaint, but does not submit a signed Complaint Form by calendar day 31—or advises the QIO during the initial discussion that s/he will not submit a written complaint—the QIO must close the case in the CMS-designated case review system. The pertinent QIO must conduct a Quality of Care Review in accordance with §1154(a)(1)(B) and the procedures in §5330, "Concurrent Beneficiary Complaint: Quality of Care Review Stage," if the following apply:

1. *The QIO collects sufficient information to complete a Quality of Care Review, and*
2. *The concern(s) identified by the beneficiary in an oral complaint is considered serious or urgent.*

A serious or urgent quality of care concern(s) is a concern(s) that any beneficiary has been exposed to serious harm as a result of the quality of care provided or that any beneficiary may potentially be exposed to imminent future harm as a result of the quality of care provided. Should the QIO determine that the matter involves a serious or urgent concern and the QIO has sufficient information to complete its review, the QIO may immediately request the medical information and begin the review.

***NOTE:** Since oral complaints are not processed as written beneficiary complaints, the beneficiary shall not receive the results of the review; as such the disclosure process detailed in §5340.6, "Concurrent Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/Providers with Request to Disclose," §5350.2, "Concurrent Beneficiary Complaint: Preparation of Re-Review Disclosure Package," and §5350.3, "Concurrent Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary" are not applicable.*

5310.3 – Concurrent Beneficiary Complaint: Receipt of a Signed Beneficiary Complaint

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

Upon receipt of the signed Complaint Form, the Intake Specialist must date stamp the form and upload it into the CMS-designated case review system, along with the original envelope, facsimile or email so that it can be available for the pertinent QIO Review Analyst (RA) within one (1) business day. The original envelope, facsimile, or email from the beneficiary indicating the post-mark/date received must be kept with the original signed Complaint Form and placed in the Beneficiary Complaint Folder. See §5320, "Concurrent Beneficiary Complaint: Preparation of Beneficiary Complaint Folder," for specific requirements.

5320 – Concurrent Beneficiary Complaint: Preparation of Beneficiary Complaint Folder

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

The Intake Specialist will be responsible for preparing the official Beneficiary Complaint Folder for maintenance at the QIO. Should the RA determine that a copy of the Beneficiary Complaint Folder is required, e.g., for use by an off-site Peer Reviewer, a duplicate copy of the folder may

be prepared. See §5320.4, for more detailed information regarding the content and organization of the folder.

5320.1 – Concurrent Beneficiary Complaint: Forwarding of Complaint to Review Analyst

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

Upon receipt of the Beneficiary Complaint through the CMS-designated case review system, the RA must review the Complaint Form and information in the CMS-designated case review system to ensure that he or she understands the specific concern(s) involved. This shall include those instances when multiple concerns have been raised, whether the concerns relate to a single complaint or multiple complaints. The RA must then contact the beneficiary to orally acknowledge receipt of the complaint within one (1) business day of receipt of the signed complaint form.

During the discussion with the beneficiary, the RA must obtain additional information (if necessary), and describe the complaint process to the beneficiary in more detail. The RA shall describe his or her role, the Initial Determination Peer Reviewer's (IDPR's) role, the Peer Review process in general, and the anticipated time frames related to the resolution of the review.

If the RA is unable to reach the beneficiary by phone, the RA must follow-up/call-back the beneficiary. The RA shall initiate the review immediately, even in those instances when the beneficiary cannot be immediately contacted, unless information necessary for completing the review is still needed. Follow-up/call-back to obtain this additional information shall be completed by close of business on the date of the initial call attempt. If additional follow up attempts are necessary, the RA must continue to initiate contact; however if the RA is unable to reach the beneficiary within three (3) calendar days, the RA shall contact the beneficiary by letter and advise the beneficiary that the review cannot be conducted until the necessary information is received.

5320.2 – Concurrent Beneficiary Complaint: Requesting Medical Information

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

The Intake Specialist must request the medical information as soon as the written complaint (See §5310.3) is received with sufficient information to identify the pertinent practitioner and/or provider, i.e., no later than one (1) business day after receipt of the written complaint. However, in situations when the beneficiary has raised a serious or urgent complaint as discussed in §5310.2, "Concurrent Beneficiary Complaint: Complaints Not Submitted in Writing (i.e. Oral Complaints)," the Intake Specialist need not wait for receipt of the written complaint before requesting the medical information and beginning the review. For serious or urgent complaints, the Intake Specialist shall request the medical information as soon as sufficient information has been obtained to identify the pertinent practitioners and providers. See 42 CFR 476.78(b)(2), "Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations —Responsibilities of Health Care Facilities," and §480.111(a), "QIO Access to Records and Information of Institutions and Practitioners" regarding a QIO's right to request medical information. QIOs must complete the following steps in requesting medical information.
***NOTE:** Upon receipt of the medical information at any step, follow the instructions as outlined in §5320.4, "Concurrent Beneficiary Complaint: Review and Preparation of Medical Information."*

The Intake Specialist must request the medical information within one (1) business day of receipt of the written complaint. The Intake Specialist may contact the practitioner and/or provider by phone and follow up with a facsimile. The correspondence must clearly indicate the specific date on which the medical information was first requested since this date will be used to determine when, for a provider, a denial of the claim could be issued and the date the medical information is due to the Intake Specialist. ***NOTE:*** *The date of the letter may be used if it corresponds to the date of the first request. The Intake Specialist must advise a practitioner and/or provider that, in order to expedite the QIO's review and ensure that the QIO receives all necessary information in a timely manner, the QIO expects the provider or practitioner to submit the requested information by close of business the next business day, i.e., one (1) business day after receipt of the request.*

The Intake Specialist should normally contact the Medical Records Department and/or the QIO liaison. QIOs may contact either/both the Medical Records Department or the QIO liaison based on procedures they have established with a provider or practitioner.

In situations where a practitioner or provider fails to submit medical information within the required twenty-one (21) or thirty (30) calendar day time frame, the QIO should advise the practitioner or provider that, based on §1156(a)(3), sanctions may be initiated because of the failure to support the provision of items or services with evidence of the quality of the items or services.

In instances where the requested medical information is not received within forty (40) calendar days, the beneficiary must be advised in writing:

- *The QIO is unable to complete the review as a result of the practitioner's and/or provider's failure to submit the medical information.*
- ***FOR COMPLAINTS RELATED TO PROVIDERS ONLY:*** *CMS has initiated action to deny Medicare payment to the provider for the services surrounding the care referenced in the beneficiary's Complaint.*
- *Based on §1156(a)(3), sanctions may be initiated against a provider or practitioner for failing to support the items or services they provided with evidence of the quality of the items or services.*
- *Should the medical information be received within the next 30 days, the beneficiary will be contacted and advised that the review will be completed.*

5320.3 – Concurrent Beneficiary Complaint: Issuing a Claim Denial

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

A QIO is authorized to deny a provider's claim in situations where the QIO has requested information from the provider and despite sufficient notice and a reasonable amount of time to respond, the provider fails to forward the requested information. See 42 CFR §476.90(b).
In processing the denial of the claim, the QIO should coordinate with the pertinent Project Officer. If the requested medical information is submitted before the denial of the claim is finalized, the QIO must stop the denial and complete the review. If the medical information is received after the denial of the claim has been finalized, payment must be re-instituted. The QIO should complete the review. The Project Officer should be consulted regarding any additional action the QIO should take, e.g., completion of additional Quality of Care Reviews for the same provider.

5320.4 – Concurrent Beneficiary Complaint: Review and Preparation of Medical Information

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

Upon receipt of the medical information, the Intake Specialist must immediately date-stamp the information to indicate the date received, unless the information is received electronically and scan the information, including the original envelope, into the CMS-designated case review system within one (1) business day. The Intake Specialist must keep the original envelope with the medical information. The Intake Specialist ensures all information in the medical information is complete, appropriately organized, and legible. If the medical information is incomplete or illegible (poor copy), the Intake Specialist contacts the practitioner and/or provider by phone and requests the documentation necessary to complete the medical information be forwarded via fax within one (1) calendar day. QIOs must follow the procedures for issuing a denial of a claim in §5320.3 when the complete medical information is not received in accordance with either the twenty-one (21) or thirty (30) calendar day time frame. See Appendix 5-10 for additional information regarding time frames.

The Intake Specialist shall organize the information in the medical information in accordance with the following tabs. The contents of each tab shall be placed in chronological order:

TAB 1: Emergency Room Record/Admission Record

TAB 2: History and Physical

TAB 3: Consultations

TAB 4: Practitioner Orders

TAB 5: Practitioner Progress Notes

TAB 6: Nursing Notes

TAB 7: Ancillary, e.g., Labs, X-rays, Medication Administration Record, Treatment Administration Record, etc.

TAB 8: Miscellaneous

TAB 9: Discharge Summary

***NOTE:** QIOs are authorized to upload medical information received directly into the CMS-designated case review system, and the QIO must also upload the information into the CMS-designated case review system within one (1) business day.*

If the Intake Specialist, RA, or physician reviewer(s) determine that handwritten information in the medical information cannot be deciphered, the QIO may contact the facility and request a typed/transcribed portion of the problem sections of the medical information. The QIO must make every effort to limit the amount of typed/transcribed information requested. Failure to comply with a request for typed/transcribed information shall be treated as a failure to provide the medical information if the missing information precludes the completion of the review. QIOs must follow the procedures in §5320.3 for processing a denial of the claim when applicable.

5330 – Concurrent Beneficiary Complaint: Quality of Care Review Stage

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

The Review Analyst (RA) initiates the Quality of Care Review stage by conducting a preliminary review of the beneficiary's written complaint and each of the Quality of Care Concerns. For

those instances when the beneficiary raises multiple concerns that are potentially unrelated, the RA shall make a determination regarding whether the QIO shall process the concerns as a single complaint with multiple concerns, or as multiple complaints. In making this determination, the RA must consider the following:

- *Total number of concerns*
- *Relationship or inter-relatedness between the concerns*
- *Time frames associated with the concerns*
- *Impact of different practitioner and/or provider involvement in each of the concerns*
- *Health care issues related to each of the concerns*
- *Beneficiary's own statements regarding the relationship between the concerns*
- *Other factors deemed relevant as identified by the RA*

The importance of a particular criterion may be different for different complaints and the QIO must consider the totality of the circumstances. The RA should consult with the Intake Specialist or Medical Director in making the determination to separate complaints that have been uploaded into the CMS-designated case review system as a single complaint. If a decision is made to process concerns as separate complaints, the RA must communicate the rationale for the decision to the beneficiary and detail the rationale in the CMS-designated case review system.

5330.1 – Concurrent Beneficiary Complaint: New Concerns Raised by the Beneficiary

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

As a result of the QIO's broad focus regarding the scope of the complaint, the QIO should rarely become aware of new quality of care issues after the complaint has entered the Quality of Care Stage. See Scope of Complaint, §5110.1. New issues/concerns may be added to the original complaint if the Interim Initial Determination step has not been completed. In the rare event that a new issue/concern(s) is raised by the beneficiary following the completion of the Interim Initial Determination, the new issue/concern will be processed as a separate/new complaint.

5330.2 – Concurrent Beneficiary Complaint: Preparation of Quality Review Decision (QRD) Form

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

Once a determination has been made regarding the number of complaints and the specific Quality of Care Concern(s) to be addressed, the RA must prepare a Quality Review Decision Form for each complaint. See Appendix 5-2 "Quality Review Decision (QRD) Form." This standardized form replaces the Physician Reviewer Assessment Format previously followed by all QIOs. The new QRD Form has been created to better account for the multiple individuals who are involved in the review of a beneficiary complaint and to ensure information related to every beneficiary complaint—and in particular every Quality of Care Concern—is maintained in an organized, detailed, and consistent fashion throughout the review process. The RA must include the following information in the QRD Form.

Using the CMS-designated case review system, the RA must prepare a QRD Form that sets out each individual concern and forward the package to the IDPR immediately upon receipt of the

medical information, but no later than in one (1) business day. This includes separately completing the following steps for each concern:

a. *Evaluate the beneficiary complaint and each quality of care concern in accordance with §5110.1, "Scope of Complaint,"*

b. *Evaluate the quality of care with regard to the admission diagnosis and treatment plan established for the beneficiary, if applicable.*

c. *Evaluate the quality of care for any blatant issues, including potential Never Events that should be identified.*

d. *Research evidence-based practices related to each quality of care concern(s), while considering the definition of Quality Care, including reference to relevant norms and criteria. If no quality of care standard(s) exists, then the RA must identify norms, best practices and established guidelines and then recommend a potential quality of care standard(s). In completing this step, the RA must thoroughly research all available information, including the following:*

   - *Nurse Screening Criteria (InterQual, Milliman, etc.), and*
   - *Generally available resources, including information available via Internet searches.*

   A Review Analyst Assessment section must be completed for each Quality of Care Concern in the complaint and/or identified by the RA.

e. *Evaluate additional information pertinent to the case, but unrelated to the standard(s) of care. This may include:*

   - *CMS-available information, which may include Web-based resources, e.g., Nursing Home and Hospital Compare;*
   - *State-based resources, which may include Web-based literature/information, as well as, physician-specific information related to license revocations and referrals to the state medical conduct organizations.*

f. *Research all available data (minimum of three (3) years) to determine whether the QIO has received similar complaints on the same practitioner and/or provider and/or if other potential concerns related to the same practitioner and/or provider are identifiable.*

g. *Prepare the package for forwarding to the Initial Determination Peer Reviewer (IDPR)*

5330.3 – Concurrent Beneficiary Complaint: Receipt and Review by the Initial Determination Peer Reviewer (IDPR)

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

The RA mails the package to the IDPR within one (1) business day and the IDPR then initiates his/her review. The IDPR must review the Quality of Care Concern(s) identified by the beneficiary and any additional concern(s) identified by the RA. For individual concerns, the IDPR evaluates the standard(s) identified by the RA on the QRD Form and checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care as delineated by the RA. If the IDPR identifies Quality of Care Concerns that were not raised by the beneficiary or identified by the RA, the IDPR must ensure the concern is identified in the QRD Form and identify pertinent research detailing the standard of care used to evaluate the concern.

If the IDPR determines that the standard(s) identified by the RA for a specific concern(s) is incorrect or not thorough, the IDPR identifies the correct standard(s) and provides an explanation regarding the change. For those instances when the IDPR determines that the standard(s) is incorrect, the IDPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care on the QRD Form.

The IDPR then applies the standard(s) of care to the specific facts of the case and the Quality of Care Concern(s) at issue. The IDPR evaluates the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The IDPR must evaluate whether the quality of care standard for each of the identified concerns is met based on the facts of the case and directly link his/her decisions to elements contained in the evidence-based standard(s). The IDPR also assesses the responsibility of the individual identified by the beneficiary—if the individual identified is different from the individual who is responsible for the standard(s) not being met.

In addition, the IDPR considers any historical data pertinent to the concern(s) as provided by the RA, and highlights specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met. The IDPR should also include any other information the IDPR deems relevant to his/her Interim Initial Determination. If the IDPR concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the IDPR must thoroughly explain these justifications.

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

- *The care grossly and flagrantly, in one or more instances, violated the provider's/practitioner's obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed (less than three cases) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act); or*
- *The care did not meet the standard of care, but was less than a substantial violation of the obligation to provide care that is of a quality that meets professionally recognized standards of health care, i.e., it was either significant or non-significant .*

The IDPR must complete his/her review of the package, adhere strictly to the format in the QRD Form and return the package to the RA within one (1) business day. The IDPR signs and dates the QRD Form and indicates the amount of time spent reviewing the complaint. Except in circumstances when the IDPR conducts the review on the QIO premises, the IDPR may maintain a signed copy of his or her completed QRD Form and additional notes. These are maintained to facilitate any additional review necessary based on the receipt of additional information during the Opportunity for Discussion Stage.

5330.4 – Concurrent Beneficiary Complaint: Return and Review of Interim Initial Determination

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

Immediately upon receipt of the Beneficiary Complaint folder from the IDPR, the RA must ensure all necessary information has been returned and the QRD Form has been signed. The RA has one (1) business days to review the package to ensure the IDPR rendered a decision on all quality of care concerns, the content adheres to the correct format, and the rationale for conclusions is clear.

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

If the IDPR determined that the standard(s) of care was met for all concerns, the RA should follow the procedures detailed in §5340.6, "Concurrent Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/Providers with Request to Disclose."

If the IDPR determined that the standard(s) of care was not met for any one or more of the concerns, and the concerns are not sanctionable, the RA should follow the procedures detailed in §5340, "Concurrent Beneficiary Complaint: Opportunity for Discussion Stage."

5340 – Concurrent Beneficiary Complaint: Opportunity for Discussion Stage

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

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

5340.1 – Concurrent Beneficiary Complaint: Notification of Opportunity for Discussion

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

Because this is a concurrent review, the QIO shall make every effort to complete the Opportunity for Discussion as expeditiously as possible. If the IDPR determines that a concern(s) has been identified for which the standard of care was not met, the IDPR must immediately contact the RA. Once the RA has been notified, the QIO can immediately contact the practitioner and/or provider to discuss the concern even if the IDPR has not finalized his/her entire review. The IDPR must provide as much detail as possible to facilitate the expediting of the Opportunity for Discussion. The IDPR must complete his or her review within one (1) business day after receipt of the medical information.

The QIO shall initiate contact with the practitioner and/or provider by phone. However, the QIO should document the date on which the offer was first made to the practitioner and/or provider, and may include sending to the practitioner and/or provider a facsimile or letter detailing the specific concern(s) at issue. A QIO must allow a practitioner to use a representative to respond to the Opportunity for Discussion. Because this is a Concurrent

Beneficiary Complaint Review, a provider and/or practitioner must respond to the offer to discuss within one (1) business day. Additional days may not be provided under any circumstances.

5340.2 – Concurrent Beneficiary Complaint: Oral or Written Response to Opportunity for Discussion

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

A practitioner and/or provider must be afforded the opportunity to orally and/or in writing convey his/her disagreement with the conclusions rendered by the IDPR in the Interim Initial Determination. The offer of the Opportunity for Discussion can be made by the RA, the IDPR or the Medical Director, depending on the QIO's established practice within the state. However, the RA must participate in discussions between the IDPR and the practitioner and/or provider. For complex cases, it is recommended that the Medical Director participate.

***NOTE:** For instances when the practitioner and/or provider responds to the Opportunity for Discussion by agreeing with the concern(s) identified, the agreement should then be documented and the QIO should follow the requirements in §5340.5, "Concurrent Beneficiary Complaint: No Response to Opportunity for Discussion."*

***Oral responses:** The RA must prepare a summary of any oral response submitted. During the oral discussion, the practitioner and/or provider shall be advised of the need to focus on the specific element(s) of the standard(s) of care which is being disputed in the IDPR's Interim Initial Determination.*

***Written responses:** The practitioner and/or provider shall be advised of the need to focus on the IDPR's conclusions related to specific elements of the standard(s) of care. Written statements submitted for the Opportunity for Discussion must be sent to the RA.*

5340.3 – Concurrent Beneficiary Complaint: Prohibition on Submission of New/Additional Medical Information

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

The submission of new and/or additional medical information is prohibited in response to the offer of the Opportunity for Discussion. In instances when the practitioner and/or provider requests to submit new and/or additional medical information, the QIO must advise the practitioner and/or provider of his/her right to request a Re-Review and that any new and/or additional medical information can be considered during the Re-Review process.

5340.4 – Concurrent Beneficiary Complaint: Review of Information Submitted During Opportunity for Discussion Stage

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

The RA reviews his or her summary of any oral response submitted by the practitioner or practitioner's representative, and/or provider, or the written Opportunity for Discussion response, in light of the quality of care concern(s) raised during the IDPR review. For both oral and written responses, the RA must make every effort to highlight/summarize specific facts provided by the practitioner and/or provider during the discussion in relationship to particular elements of the standard(s) of care that could alter the IDPR's conclusion. (As noted in §5340.3, facts provided during the discussion stage cannot include new medical information.) The RA

must also detail information provided by the practitioner and/or provider that appears to be unrelated to the standard(s) of care.

The RA shall immediately forward the information, along with the specific issues identified in the response, to the IDPR. Upon receipt of this additional information during the Opportunity for Discussion, the IDPR must make his/her Final Initial Determination no later than one (1) business day of receipt of the additional information. The QIO must ensure that the same Peer Reviewer renders both the Interim and Final Initial Determinations, unless rare circumstances exist, e.g., the Interim IDPR is unavailable as a result of serious illness.

In most instances, the RA will not be required to send the IDPR the entire Beneficiary Complaint Folder as a result of the initiation of the Opportunity for Discussion. The IDPR must use the copy of the QRD Form from the Interim Initial Determination in evaluating the additional information provided, along with the additional information supplied by the RA from the practitioner and/or provider. Additional materials will not be mailed for situations where the practitioner and/or provider conveyed information orally directly to the IDPR. The RA and the IDPR will coordinate to ensure all pertinent information is considered in the Final Initial Determination. After making the Final Initial Determination, the IDPR re-signs the QRD Form and faxes it back to the RA.

5340.5 – Concurrent Beneficiary Complaint: No Response to Opportunity for Discussion

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

If no response is received to the offer of the Opportunity for Discussion, the Interim Initial Determination becomes the Final Initial Determination. The IDPR need not sign the QRD Form again to denote this result; however, the RA will note on the QRD Form that no response was received.

5340.6 – Concurrent Beneficiary Complaint: Preparation of Final Initial Determination Letter to Practitioners/ Providers with Request to Disclose

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

Upon receipt of the QRD Form, the RA prepares the "Final Initial Determination Letter for Practitioners/Providers with Request to Disclose" (Appendix 5-4) conveying the decision to the practitioner and/or provider and that the practitioner must indicate whether s/he agrees to disclose the specific findings to the beneficiary.

NOTE: *For provider-related issues, consent to disclose is generally not required. Provider-specific information is non-confidential, except as specified in 42 CFR 480.101(b) (definition of confidential information), and is generally disclosable as long as it does not explicitly or implicitly identify a beneficiary or explicitly or implicitly identify a practitioner or QIO reviewer who has not consented to disclosure. See CMS Publication 100-10, Quality Improvement Organization Manual, Chapter 10 for additional information.*

The RA must forward to the provider or practitioner at issue the Final Initial Determination Letter to Providers/Practitioners conveying the decision to the practitioner and/or provider within one (1) business day after receipt of the faxed QRD Form detailing the Final Initial Determination from the IDPR, or, when there is no response to the Opportunity for Discussion, within one (1) business day of the expiration of the Opportunity for Discussion period.

The letter will also convey to the practitioner and/or provider that they have five (5) calendar days to request a Re-Review if the standard(s) of care was not met for any concern(s). The letter will also convey that the practitioner has 30 calendar days to respond to the request for consent to release the specific findings. In addition, the letter must advise the practitioner and/or provider that if he or she requests a Re-Review, the practitioner's consent will be requested after the Re-Review determination is made.

The RA must include the language that the QIO proposes to convey to the Beneficiary. See §5350.3, "Concurrent Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary."

If the practitioner requests a Re-Review, consent to disclose the information is not needed at this time. In addition, if the practitioner and/or provider do not request a Re-Review within five (5) calendar days, then the practitioner and/or provider may not be granted a request for a Re-Review, absent extraordinary circumstances.

5340.7 – Concurrent Beneficiary Complaint: Failure to Respond to the Final Initial Determination and Right to Re-Review

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

For instances in which a provider fails to respond to the Re-Review offer in the Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4) within the five (5) calendar day period, the QIO will prepare and send the "Letter to the Beneficiary-QIO's Final Decision," Appendix 5-6, no later than one (1) business day after the 5 days have expired. For instances when a practitioner fails to respond to request a Re-Review offer within the five (5) calendar day period in response to the Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4), the QIO must wait for the practitioner's response to the QIO's request to disclose, up until the end of the thirty (30) calendar day period, to determine what information the QIO can disclose to the beneficiary. When the practitioner responds or the 30 days expires, QIO shall prepare and send the "Letter to the Beneficiary-QIO's Final Decision," Appendix 5-6, no later than one (1) business day after the receipt of the practitioner's consent/non-consent or the expiration of the thirty (30) day period. A practitioner's failure to respond to the request to disclose details to the Beneficiary shall be treated as a denial for disclosure purposes, and the letter to the Beneficiary conveying the QIO's Final Decision shall not include specific practitioner-related information. The QIO shall follow the procedures in §5350.3, "Concurrent Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary," for preparing the Final Decision Letter. (See Appendix 5-6). The QIO shall follow the procedures in §5350.4, "Concurrent Beneficiary Complaint: Procedures for Closing a Beneficiary Complaint Review" for closing the case in the CMS-designated case review system. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5340.8 – Concurrent Beneficiary Complaint: Responsibility to Protect Information and Destruction of Materials

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

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

No later than thirty (30) calendar days after the Final Initial Determination by the IDPR, the IDPR must destroy all copies of materials in his/her possession associated with the review in compliance with QIO security procedures. The original will be maintained by the QIO at its facility.

5350 – Concurrent Beneficiary Complaint: Re-Review Stage

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

The practitioner and/or provider may request a Re-Review within five (5) calendar days of receipt of the "Final Initial Determination Letter to Practitioners/Providers with Request to Disclose (Appendix 5-4). Upon receipt of a Re-Review request, the Review Analyst must forward the Beneficiary Complaint Folder with the following items to the Re-Review Peer Reviewer (RRPR):

- *QRD Form,*
- *Medical information,*
- *Final Decision Letter. See §5350.3, "Concurrent Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary," for letter content,*
- *Interim Initial Determination Letter,*
- *Information received related to the offer of the Opportunity for Discussion Stage, and*
- *Any new evidence submitted in requesting the Re-Review.*

The Beneficiary Complaint Folder with the above information must be forwarded to the RRPR within one (1) business day of the receipt of the request for a Re-Review. See §5350.1, "Concurrent Beneficiary Complaint: Re-Review Peer Reviewer."

5350.1 – Concurrent Beneficiary Complaint: Re-Review Peer Reviewer

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

The RRPR must be different than the Peer Reviewer who conducted the Interim and Final Initial Determinations. In making his/her determination, the RRPR shall review all information forwarded by the Review Analyst. The RRPR shall use the QRD Form in rendering his/her determination(s).

The RRPR receives the package from the Review Analyst and initiates the Re-Review.

***NOTE:** The RRPR will not receive beneficiary complaints when the IDPR has identified a concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standards of health care as required by §1156(a) of the Act. These concerns will result in the initiation of sanction proceedings in accordance with Chapter 9.*

The RRPR must review each quality of care concern identified in the complaint and any additional concerns identified by the RA or the IDPR during the review of the medical information, and complete the QRD form for each concern.

- *The RRPR evaluates the standard(s) identified by the RA and the IDPR on the QRD Form;*

- *The RRPR checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care as delineated by the RA and IDPR;*
- *If the RRPR determines that the standard(s) identified by the RA and/or IDPR for a specific concern(s) is incorrect or not thorough, the RRPR must identify the correct standard(s) and provide an explanation regarding the change;*
- *For those instances when the RRPR determines that the standard(s) is incorrect, the RRPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care and consult with the Medical Director to obtain the Medical Director's concurrence on the standard to be used in evaluating the concern(s).*

***NOTE:** The RA shall be included in this consultation*

Completion of the Analysis/Justification: Upon determining the standard(s) of care to be used, the RRPR then applies the standard(s) of care to the specific facts of the case and the quality of care concern(s) at issue. The RRPR evaluates the information contained in the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The RRPR must directly link his/her decisions to elements contained in the evidence-based standard(s) when deciding whether quality of care standard(s) for each of the identified concerns is met based on the facts of the case. The RRPR must also assess the responsibility of the individual identified by the beneficiary if that individual is different from the individual who is responsible for the standard(s) not being met.

In addition, the RRPR must consider any historical data pertinent to the concern(s) as provided by the RA, highlight specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met, and include any other information the RRPR deems relevant to his or her Re-Review Determination. If the RRPR, in his/her determination, concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the RRPR must thoroughly explain these justifications in completing the Analysis/Justification section of the QRD Form.

The RRPR must complete a separate analysis for each concern. Upon completion of the Analysis/Justification portion of the QRD Form, the RRPR must check off the appropriate box indicating his/her decision that the standard(s) of care was met or not met. If the RRPR determines that the standard(s) of care was not met, the RRPR must also check off the appropriate box indicating whether:

- *The care grossly and flagrantly, in one or more instances, violated the provider's/practitioner's obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156 of the Act);*
- *The care failed to substantially comply with the obligation (less than three cases) to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act); or*
- *The care did not meet the standard of care but was less than a substantial violation of the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care, i.e., it was either significant or non-significant.*

The RRPR must complete his/her review of the package, adhere strictly to the requirements in the QRD Form and return the package to the Review Analyst within one (1) calendar day. The RRPR must sign and date the QRD Form and indicate the amount of time spent reviewing the concern(s).

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

5350.2 – Concurrent Beneficiary Complaint: Preparation of Re-Review Disclosure Package

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

The Review Analyst receives the package from the RRPR and examines it to ensure all necessary information is returned. The RA notes the Re-Review Decision on the QRD Form and prepares the "Re-Review Disclosure Package" which includes the Re-Review Determination Letter to Providers/Practitioners with Request to Disclose (Appendix 5-5) and the language to be conveyed to the beneficiary in the Final Decision letter (Appendix 5-6). The RA may utilize the language used previously, unless substantial changes have been made. The QIOs may explore changes to the disclosure letter to facilitate the practitioner's agreement to release more detailed information. The RA forwards the Package to the practitioner and/or provider within one (1) business day of the RA's receipt of the Package from the RRPR.

The practitioner has thirty (30) calendar days from the date of the letter to respond to the disclosure request in the Re-Review Determination Letter to Providers/Practitioners with Request to Disclose (Appendix 5-5). The failure to respond shall be treated as a denial for disclosure purposes.

The QIO is not required to obtain provider consent to disclose provider-related issues. Provider-specific information is non-confidential, except as specified in 42 CFR §480.101(b) (definition of confidential information), and may be disclosed as long as it does not explicitly or implicitly identify a beneficiary or identify a practitioner or QIO reviewer who has not consented to disclosure. See Chapter 10 of the QIO Manual for additional information. The QIO may afford a provider the opportunity to comment on the language to be conveyed to the beneficiary in the Final Decision letter (Appendix 5-6). Provider comments must be received within five (5) calendar days.

5350.3 – Concurrent Beneficiary Complaint: QIO's Final Decision, Preparing and Mailing Letter to Beneficiary

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

For all complaints involving either providers or practitioners, the "Letter to the Beneficiary-QIO's Final Decision" (Appendix 5-6) shall include:

1. *A statement for each of the quality of care concerns that care did or did not meet the standard of care,*
2. *Inclusion of the standard identified by the QIO for each of the quality of care concerns,*

3. *A statement that this constitutes the QIO's final decision on the complaint and that no further appeal rights are available.*

In all situations involving a provider or in those situations in which a practitioner has consented to disclosure of more details about a case, the letter should also include a specific statement conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard,

NOTE: Specific facts that will disclose the identity of a particular practitioner should not be disclosed in situations in which a practitioner has not consented to disclosure of those particular facts.

The pertinent practitioner and/or provider must receive a copy of the Letter to Beneficiary – QIO's Final Decision.

***NOTE:** For cases involving practitioners, the RA shall prepare and mail the Letter to the Beneficiary-QIO's Final Decision (Appendix 5-6) within three (3) business days of receipt of the consent/non-consent for disclosure or no later than one (1) business day after the 30 day period to obtain consent ends.*

For cases involving providers, the RA shall prepare and mail the Final Decision Letter (Appendix 5-6) within three (3) business days of the receipt of the package from the RRPR or within one (1) business day of the expiration of the fourteen (14) calendar day provider-comment period (if offered).

***NOTE:** This section is only to be completed for written complaints; for oral complaints, please see §5310.2, "Concurrent Beneficiary Complaint: Complaints Not Submitted in Writing, (i.e., Oral Complaints)."*

5350.4 – Concurrent Beneficiary Complaint: Procedures for Closing a Beneficiary Complaint Review

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

The RA must denote in the CMS-designated case review system that the Beneficiary Complaint is completed and is closed, except in those situations where the RA determines that Direct Advocacy, a post-peer review alternative dispute resolution process should be made available to the beneficiary. See §5400. The RA must place all final documents in the Beneficiary Complaint Folder for maintenance and filing. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5400 – Direct Advocacy

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

In situations where a complaint has been processed through the Beneficiary Complaint Review process (Retrospective or Concurrent) and no significant quality of care concern has been found, the QIO may offer an additional opportunity for the beneficiary and provider or practitioner to resolve their dispute through Direct Advocacy, which is an alternative dispute resolution process used after the peer review process has been completed,

Direct Advocacy is an informal process used by a QIO to resolve a continuing concern of the beneficiary after the QIO has completed the formal Peer Review process. It entails the QIO directly contacting the practitioner and/or provider to discuss the beneficiary's continuing

concerns. The QIO must summarize what Direct Advocacy entails for the beneficiary and obtain the beneficiary's oral consent to participate in Direct Advocacy before proceeding. A beneficiary may discontinue Direct Advocacy at any time during the process. See §5400.5 for additional information regarding discontinuation of Direct Advocacy. The use of Direct Advocacy is not appropriate for situations where the beneficiary does not want his/her identity disclosed to the provider and/or practitioner.

Prior to offering the use of Direct Advocacy, the QIO may consider other factors impacting the successful use of Direct Advocacy, including, but not limited to:

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

Direct advocacy must not be used where Immediate Advocacy was attempted, but the beneficiary ultimately filed a written complaint.

5400.1 – Objectives of Direct Advocacy

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

The objectives of Direct Advocacy are:

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

5400.2 – Eligibility for Direct Advocacy

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

A QIO may offer Direct Advocacy to a beneficiary in situations when:

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

Below are examples of complaints that are appropriate for Direct 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 s/he received a different colored pill than expected and would like the QIO to call the facility to find out what drug was given.*

5400.3 – Practitioner/Provider Consent to Participate in Direct Advocacy

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

Immediately upon obtaining the beneficiary's oral consent to participate in Direct Advocacy (DA), the practitioner/provider must be contacted to obtain oral consent to participate in DA. The QIO must ensure the practitioner/provider has received notice of the resolution of the original complaint and the beneficiary's desire to continue pursuing resolution of the complaint through DA. The QIO must convey sufficient information regarding the nature of the complaint to enable the practitioner/provider to make an informed decision about agreeing to participate in DA. Upon obtaining the practitioner/ provider's oral consent to participate in DA, the QIO should follow the DA procedures in §5400.4 in order to resolve the concerns.

If the practitioner/ provider opts not to participate in the DA process, the QIO must immediately contact the beneficiary and inform him/her of the practitioner's/provider's decision not to participate. The QIO must inform the beneficiary that the QIO's review of the matter has ended.

5400.4 – Direct Advocacy Procedures

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

Once oral consent has been obtained for all parties, the QIO may either use a conference call/three-way call or make a call on behalf of the beneficiary in order to obtain resolution of the beneficiary's concerns. The focus should be on providing a quick and amicable resolution of the concerns within a short time frame, usually within eight (8) hours but no more than 2 business days.

In some circumstances, the provider/practitioner may be unavailable for a period of time after the beneficiary consents to the use of Direct Advocacy. In these situations, the QIO must contact the beneficiary to explain the circumstances. In no instance should the use of DA extend beyond 10 days from the beneficiary's consent to use DA.

After DA has been carried out, the QIO must update the CMS-designated case review system to reflect resolution of the complaint through the use of DA and close the case accordingly.

5400.5 – Discontinuation of Direct Advocacy

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

If, at any point, a beneficiary expresses his/her desire to stop pursuing his/her concerns through the DA process, the QIO must inform the beneficiary that the QIO's role in the review of his/her

complaint has ended and that the case will be closed. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5500 – General Quality of Care Reviews

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

The following sections will provide instructions for Quality Improvement Organizations to follow in reviewing quality of care concerns received and/or identified from the three (3) sources other than from Beneficiary Complaints. These sources are collectively referred to as General Quality of Care Reviews and include:

1. *Concerns Identified During Other Review Activities: Quality of Care reviews conducted when a potential quality of care concern(s) is identified during the course of any other review activity, e.g., medical necessity reviews, expedited discharge appeals, Emergency Medical Treatment and Labor Act (EMTALA) reviews. See §5510, "Concerns Identified During Other Review Activities."*
2. *Referrals: Quality of care reviews conducted in response to referrals from other entities, e.g. contractors, state-based organizations, the Office of the Inspector General, the Office for Civil Rights, including anonymous referrals. See §5520, "Referrals."*
3. *Tracking and Trending: Quality of Care reviews conducted as a result of tracking and trending of data. See §5530, "Tracking and Trending of Data."*

The processing instructions are identical for all three sources. The instructions will first address the Retrospective General Quality of Care Reviews, i.e., the beneficiary is no longer in the provider setting or is no longer receiving care (See §§5540-5580.4), and then the instructions will address how to process Concurrent General Quality of Care Reviews, i.e., the beneficiary remains in the provider setting and/or care is still being provided (See §§5600-5640.4). As with Beneficiary Complaint Reviews, the instructions for both the Retrospective and Concurrent processes have been separated into four stages to facilitate identification of roles and steps associated with various aspects of the process.

The four stages are as follows:

Stage 1: Intake Stage

Stage 2: Quality of Care Review Stage

Stage 3: Opportunity for Discussion Stage

Stage 4: Re-Review Stage

5510 – Concerns Identified During Other Review Activities

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

During the course of conducting any other review, e.g., appeal review, medical necessity review, Higher Weighted DRG review, EMTALA review, QIOs may identify potential Quality of Care Concerns. When a potential Quality of Care Concern is identified, the QIO must conduct a Retrospective General Quality of Care Review (See §§5540-5580.4) or a Concurrent General Quality of Care Review (See §§5600-5640.4) as applicable.

5520 – Referrals
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

Medicare Administrative Contractors (MACs), Fiscal Intermediaries (FIs), carriers, Medicare Health Plans, State Medicaid survey and certification agencies (SSA), other CMS contractors, as well as CMS staff may refer cases involving potential Quality of Care Concerns to QIOs. The QIOs must conduct General Quality of Care Reviews on all referrals when sufficient information is conveyed to complete the review. When a potential quality of care concern is referred, the QIO must conduct a Retrospective General Quality of Care Review (See §§5540-5580.4) or a Concurrent General Quality of Care Review (See §§5600-5640.4) as applicable.

If the individual making the complaint is identifiable as a beneficiary or beneficiary representative, and the QIO is able to initiate direct contact with the beneficiary or beneficiary representative, the QIO shall process the case in accordance with the Beneficiary Complaint Review procedures. See §5200 for Retrospective Beneficiary Complaint Reviews or §5300 for Concurrent Beneficiary Complaint Review procedures.

5520.1 – Referrals from Other Federal Government Organizations
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

All referrals of potential Quality of Care Concerns from Federal government organizations outside of the Centers for Medicare & Medicaid Services, e.g., the Office of the Inspector General, the Department of Justice (DOJ) or the Office for Civil Rights, must be approved by the Central Office (CO) Beneficiary Protection Program leads. Upon receipt, the QIO must submit a written request to the Program leads through the appropriate CMS Regional Office Project Officer. Upon identification of potential Quality of Care Concerns, the QIO must follow the process requirements set forth in §5500, "General Quality of Care Reviews." When a potential Quality of Care Concern is referred, the QIO must conduct a Retrospective General Quality of Care Review (See §§5540-5580.4) or a Concurrent General Quality of Care Review (See §§5600-5640.4) as applicable.

5520.2 – Overlap of Review Authority
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

QIOs may receive referrals of potential Quality of Care Concern(s) from other organizations or entities when the referring organization or entity identifies what may be a quality concern during the course of conducting a mandatory review based on its jurisdictional requirements. QIOs must work with these organizations to ensure any necessary coordination. The QIO is responsible for ensuring that organizations, including contractors, have clearly-defined direction regarding the types of cases that warrant referral to the QIO. When a potential Quality of Care Concern is referred, the QIO must conduct a Retrospective General Quality of Care Review (See §§5540-5580.4) or a Concurrent General Quality of Care Review (See §§5600-5640.4) as applicable.

5530 – Tracking and Trending of Data
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

Quality Improvement Organizations must conduct analyses of data from all review types to identify potential Quality of Care Concerns. Analysis may be conducted within or across provider-settings. In addition, QIOs must make every attempt to identify Quality of Care

Concerns related to health disparities issues, including racial, ethnic or socio-economic indicators. When a potential Quality of Care Concern is identified, the QIO must conduct a Retrospective General Quality of Care Review (See §§5540-5580.4) or a Concurrent General Quality of Care Review (See §§5600-5640.4) as applicable.

5540 – Retrospective General Quality of Care Review

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

The following instructions detail the steps the QIO must adhere to in reviewing quality of care concerns received and/or identified from sources other than Beneficiary Complaints (Concerns Identified During Other Review Activities, Referrals, and Tracking and Trending) and the beneficiary is no longer receiving care, i.e., a Retrospective Review.

5550 – Retrospective General Quality Review: Preparation of General Quality of Care Review Folder

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

The QIO's Intake Specialist will be responsible for preparing the General Quality of Care Review folder. Should a copy of the folder be needed, e.g., for use by an off-site Peer Reviewer, a duplicate copy of the folder may be prepared. The folder will be forwarded to the Review Analyst (RA) within one (1) business day of receipt of a referral or the identification of a potential Quality of Care Concern as a result of tracking and/or trending of data.

For instances where a Quality of Care Concern is identified during the course of other review activities, the Intake Specialist will prepare/organize any information necessary to enable the Quality of Care Review to be completed in addition to the original review activity. For example, in completing an expedited discharge appeal review, the Peer Reviewer identifies a Quality of Care Concern. The QIO should establish procedures to enable the same Peer Reviewer who identified the Quality of Care Concern to complete the Quality of Care Review.

5550.1 – Retrospective General Quality Review: Review of Folder by Review Analyst

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

Upon receipt of the General Quality of Care Review Folder from the Intake Specialist, the RA must review the information in the folder as well as the information in the CMS-designated case review system to ensure that he or she understands the specific concern(s) involved.

5550.2 – Retrospective General Quality Review: Requesting Medical Information

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

The following steps may not apply for those instances where the QIO already possesses medical information as a result of another review activity being conducted. As such, the instructions are written as related to requests for medical information in response to General Quality of Care Reviews conducted as a result of referrals and/or tracking and trending of data.

***NOTE:** Upon receipt of the medical information at any step, follow the instructions as outlined in §5550.4, "Retrospective General Quality Review: Review and Preparation of Medical Information." See 42 CFR §476.78(b)(2), "Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations —Responsibilities of Health Care Facilities," and*

§480.111(a), "QIO Access to Records and Information of Institutions and Practitioners" regarding a QIO's right to request medical information.

Providers are obligated to forward all required information within 30 calendar days of the request or within 21 days where a potential "serious reportable event" has been identified or where the QIO determines that other circumstances exist which warrant earlier receipt of the medical information. See 42 CFR §476.78(b)(2). Practitioners should be informed that they are expected to provide information within the same timeframes. For purposes of conducting General Quality of Care Reviews, providers will be given 21 days for any Quality of Care Review as a result of a referral from another organization or entity or for any instance where the QIO determines that a "Gross and Flagrant," "substantial," or "Serious or Urgent" concern may be present. Practitioners should be informed that they are expected to meet the same deadlines, since the 21 and 30 calendar days can be interpreted as "reasonable requirements" for a QIO to conduct its review under section 1156(a)(3). Medicare Advantage Plans are responsible for submitting medical information absent a specific delegation to the provider. Should an MA Plan fail to submit medical information as requested within the prescribed 21 or 30 day time frame, the matter must also be referred to the pertinent CMS Regional Office Project Officer (Project Officer). When a provider has been specifically delegated the responsibility to submit medical information, the Project Officer will collaborate with the Division of Medicaid and State Operations regarding any options that may be pursued in light of the provider's Medicare Provider Agreement.

In situations where a provider fails to submit medical information within the required timeframe, the provider may be subject to a denial of payment under 42 CFR 476.90. In some situations where either a practitioner or provider fails to submit medical information within the required twenty-one (21) or thirty (30) calendar day time frame, the QIO should advise the practitioner or provider that, based on §1156(a)(3), sanctions may be initiated because of the failure to support the provision of items or services with evidence of the medical necessity for and quality of the items or services.

***NOTE:** Upon receipt of the medical information at any step, follow the instructions as outlined in §5550.4, "Retrospective General Quality Review: Review and Preparation of Medical Information."*

QIOs must complete the following steps in requesting medical information:

***Step 1:** Request the medical information within one (1) business day after receipt of the referral or the identification of a potential quality of care concern as a result of tracking and/or trending of data. The Intake Specialist may contact the practitioner and/or provider by phone and follow up with a facsimile or mailed letter. The letter must clearly indicate the specific date on which the medical information was first requested, since this date will be used to determine when, for a provider, a denial of the claim shall be issued. See §5550.3 for information regarding a claim denial. **NOTE:** The date of the letter may be used if it corresponds to the date of the first request. The Intake Specialist must advise a practitioner and/or provider that, in order to expedite the QIO's review and ensure that the QIO receives all necessary information in a timely manner, the QIO expects the provider or practitioner to submit the requested medical information within ten (10) calendar days from the date on which the medical information was first requested.*

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

Step 2: *The QIO should follow up as necessary to ensure adherence to the calendar day ten (10) submission deadline. If the medical information is not received by calendar day fifteen (15) from the date of the original request, then on the next business day immediately following calendar day fifteen (15), the Intake Specialist must contact senior leadership for a provider, e.g., the Chief Financial Officer, and advise of the potential claims denial(s) associated with the failure to submit the medical information by calendar day twenty-one (21) or calendar day thirty (30). See 42 CFR 476.78(b)(2). This step is meant to furnish a provider with adequate notice to correct any problems associated with submitting medical information, and to help the provider avoid potential penalties or claims denials. Practitioner s should be reminded that, under §1156(a)(3), items or services provided by or ordered by practitioners must be supported by evidence of medical necessity and quality, in such form and fashion and at such time as may reasonably be required by a QIO in the exercise of its duties and responsibilities. For uniformity, QIOs are expected to establish "form and fashion and reasonable time" components that align with those for providers. The QIO should point out that any unreasonable delay in providing medical information could lead to sanctions under §1156(b).*

Step 3: *If the medical information is not received from a provider by calendar day twenty-one (21) or (30) thirty, the QIO must immediately contact their Project Officer on the next business day and provide sufficient information so that the Project Officer is prepared to contact the provider. The QIO must follow up with the project Officer to advise her or him if/when the medical information is received.*

Step 4: *Upon receiving a call from the QIO regarding a provider's failure to submit medical information, the Project Officer shall call the Medical Records Department, the QIO liaison, or senior leadership and convey the responsibilities associated with the request for the medical information. The Project Officer should assess the willingness to comply with the request for medical information and explain the potential repercussions of failure to provide the medical information, including issuance of a denial of the claim, notification of the Division of Medicaid and State Operations, potential for the QIO to conduct additional reviews, etc. The Project Officer shall advise the contact that if the medical information is not received by the next calendar day, a claim denial shall be carried out for any claim associated with the Quality of Care being reviewed.*

Step 5: *If the medical information is not received from a provider by calendar day twenty-three (23) or calendar day thirty-two (32), the QIO must proceed in accordance with §5550.3, "Retrospective General Quality Review: Issuing a Claim Denial."* ***NOTE:*** *In instances when the QIO completes a claim denial, the provider is still required to comply with its responsibility to forward the medical information to the QIO for the QIO to complete the review. For providers and practitioners, a Project Officer may recommend additional action depending on the particular facts of the situation, e.g., recommending that the QIO conduct additional Quality of Care Reviews on other patients for whom similar claims have been submitted for payment by the practitioner or provider.*

5550.3 – Retrospective General Quality Review: Issuing a Claim Denial

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

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

In processing the denial of the claim, the QIO should coordinate with the pertinent Project Officer. If the requested medical information is submitted before the denial of the claim is finalized, the QIO must stop the denial and complete the review. If the medical information is received after the denial of the claim has been finalized, payment must be re-instituted. The QIO should complete the review. The Project Officer should be consulted regarding any additional action the QIO should take, e.g., completion of additional Quality of Care Reviews for the same provider.

5550.4 – Retrospective General Quality Review: Review and Preparation of Medical Information

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

Upon receipt of the medical information, the Intake Specialist must immediately date-stamp the information to indicate the date received, unless the information is received electronically, and scan the information, including the original envelope, into the CMS-designated case review system within one (1) business day. The Intake Specialist must keep the original envelope with the medical information. The Intake Specialist ensures all information in the medical information is complete, appropriately organized, and legible. If the medical information is incomplete or illegible (poor copy), the Intake Specialist contacts the practitioner and/or provider by phone and allows an additional five (5) calendar days for submission of the documentation necessary to complete the medical information. QIOs must follow the procedures for issuing a claim denial in §5550.3 when complete medical information is not received in accordance with either the twenty-one (21) or thirty (30) calendar day time frame. See Appendix 5-11, "General Quality of Care Retrospective Review Time Frames."

The Intake Specialist shall organize the information in the medical information in accordance with the following tabs. The contents of each tab shall be placed in chronological order:

- *TAB 1: Emergency Room Record/Admission Record*
- *TAB 2: History and Physical*
- *TAB 3: Consultations*
- *TAB 4: Practitioner Orders*
- *TAB 5: Practitioner Progress Notes*
- *TAB 6: Nursing Notes*
- *TAB 7: Ancillary, e.g., Labs, X-rays, Medication Administration Record, Treatment Administration Record, etc.*
- *TAB 8: Miscellaneous*
- *TAB 9: Discharge Summary*

***NOTE:** QIOs are authorized to upload medical information received directly into the CMS-designated case review system, and the QIO must also upload the information into the CMS-designated case review system within one (1) business day.*

If the Intake Specialist, RA, or peer reviewer determines that handwritten information in the medical information cannot be deciphered, the QIO may contact the facility and request a typed/transcribed portion of the problem sections of the medical information. The QIO must make every effort to limit the amount of typed/transcribed information requested. Failure to comply with a request for typed/transcribed information shall be treated as a failure to provide

the medical information if the missing information precludes the completion of the review. The IDPR may be consulted prior to making the determination to pursue a denial of the claim. QIOs must follow the procedures in §5550.3 for processing these denials.

5560 – Retrospective General Quality Review: Quality of Care Review Stage

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

In addition to referrals for Quality of Care Reviews and Quality of Care Reviews as a result of tracking and trending of data, the RA may also identify potential Quality of Care Reviews during the course of the QIO's work responsibilities related to other review activities. In these situations, the RA initiates the Quality of Care Review stage by conducting a preliminary review of each quality of care concern(s) identified.

5560.1 – Retrospective General Quality Review: Preparation of Quality Review Decision (QRD) Form

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

Once a determination has been made regarding the specific concern(s) to be addressed, the RA must prepare a Quality Review Decision (QRD) Form containing all potential concerns that have been identified. See Appendix 5-2, "Quality Review Decision (QRD) Form." This standardized form replaces the Physician Reviewer Assessment Format previously followed by all QIOs. The new QRD Form has been created to better account for the multiple individuals who are involved in a Quality of Care review and to ensure information related to every Quality of Care Concern is maintained in an organized, detailed, and consistent fashion throughout the review process.

Using the CMS-designated case review system, the RA must prepare a QRD Form that sets out each individual concern and forward the package to the IDPR within three (3) business days of receipt of the medical information. In completing the QRD Form, the RA must do each of the following:

a. *Evaluate each Quality of Care Concern.*
b. *Evaluate the quality of care with regard to the admission diagnosis and treatment plan established for the beneficiary, if applicable.*
c. *Research evidence-based practices related to each Quality of Care Concern(s), while considering the definition of Quality Care, including reference to relevant norms and criteria. If no quality of care standard(s) exists, then the RA must identify norms, best practices and established guidelines and then recommend a potential quality of care standard(s). In completing this step, the RA must thoroughly research all available information, including the following:*
    - *Nurse Screening Criteria (InterQual, Milliman, etc.), and*
    - *Generally available resources, including information available via Internet searches. A Review Analyst Assessment section must be completed for each Quality of Care Concern.*
d. *Evaluate additional information pertinent to the case, but unrelated to the standard(s) of care. This may include:*
    - *CMS-available information, which may include Web-based resources, e.g., Nursing Home and Hospital Compare; and*

- *State-based resources, which may include Web-based literature and information as well as practitioner-specific information related to license revocations and referrals to the state medical conduct organizations.*

e. *Research all available data (minimum of three (3) years) to determine whether similar complaints have been received on the same practitioner and/or provider and/or if other potential concerns related to the same practitioner and/or provider are identifiable.*

f. *Prepare the package for forwarding to the Initial Determination Peer Reviewer (IDPR).*

5560.2 – Retrospective General Quality Review: Receipt and Review by the Initial Determination Peer Reviewer (IDPR)

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

The IDPR will initiate a review of each Quality of Care Concern(s) upon receipt of the package from the RA. The IDPR evaluates the standard(s) identified by the RA for each concern on the QRD Form and checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care as delineated by the RA. If the IDPR identifies new Quality of Care Concerns, the IDPR must identify the concern, as well as the specific standard(s) of care for each concern, and include pertinent research supporting the standard of care s/he used to evaluate each concern.

If the IDPR determines that the standard(s) identified by the RA for a specific concern(s) is incorrect or not thorough, the IDPR identifies the correct standard(s) and provides an explanation regarding the change. For those instances when the IDPR determines that the standard(s) is incorrect, the IDPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care.

The IDPR then applies the standard(s) of care to the specific facts of the case and the Quality of Care Concern(s) at issue. The IDPR evaluates the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The IDPR must evaluate whether the quality of care standard for each of the identified concerns is met based on the facts of the case and directly link his/her decisions to elements contained in the evidence-based standard(s). The IDPR also assesses the individual responsibility for the standard(s) not being met.

In addition, the IDPR considers any historical data pertinent to the concern(s) as provided by the RA, and highlights specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met. The IDPR should also include any other information the IDPR deems relevant to his/her Interim Initial Determination. If the IDPR concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the IDPR must thoroughly explain these justifications.

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

- *The care grossly and flagrantly, in one or more instances, violated the provider's practitioner's obligation to provide care that is of a quality that meets professionally recognized standards of health care (See §1156(a) of the Act);*

- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed to substantially comply with the obligation (less than three cases) to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act); or*
- *The care did not meet the standard of care, but was less than a substantial violation of the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care, i.e., it was either significant or non-significant.*

The IDPR must complete his/her review of the package, adhere strictly to the format in the QRD Form and return the package to the Review Analyst within seven (7) calendar days of the receipt of the package. The IDPR signs and dates the QRD Form and indicates the amount of time spent reviewing the package. Except in circumstances when the IDPR conducts the review on the QIO premises, the IDPR may maintain a signed copy of his/her completed QRD Form and additional notes. These are maintained to facilitate any additional review necessary based on the receipt of additional information during the Opportunity for Discussion Stage.

5560.3 – Retrospective General Quality Review: Return of Interim Initial Determination

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

Immediately upon receipt of the General Quality of Care Review folder from the IDPR, the Review Analyst must ensure all necessary information has been returned and the QRD Form has been signed. The Review Analyst has two (2) business days to review the package to ensure the IDPR rendered a decision on all quality of care concerns, the content adheres to the correct format, and the rationale for conclusions is clear.

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

If the IDPR determined that the standard of care was met for all concerns, the RA should follow the procedures detailed in §5570.6, "Retrospective General Quality Review: Preparation of Final Determination Letter."

If the IDPR determined that the standard of care was not met for any one or more of the concerns, and the concerns are not sanctionable, the RA should follow the procedures detailed in §5570, "Retrospective General Quality Review: Opportunity for Discussion Stage."

5570 – Retrospective General Quality Review: Opportunity for Discussion Stage

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

Before the QIO concludes that the quality of services does not meet professionally recognized standards of health care, the QIO must provide the provider and/or practitioner with reasonable notice and opportunity for discussion of the concerns found.

5570.1 – Retrospective General Quality Review: Notification of Opportunity for Discussion

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

After reviewing the Interim Initial Determination package from the IDPR, if the RA determines that the IDPR has identified a concern(s) for which the standard(s) of care was not met, the practitioner and/or provider must be offered the opportunity to discuss the concern(s). The RA must make the offer within two (2) business days of the receipt of the package from the IDPR.

In offering the opportunity, the QIO shall make every effort to discuss the IDPR's Interim Initial Determination as expeditiously as possible. The time frame for obtaining a response shall not extend beyond 15 calendar days from the date the offer was originally made, except in rare circumstances, e.g., the practitioner is unavailable (out of the country) for the entire 15 day period. In these rare circumstances, a practitioner may be provided an additional seven (7) calendar days to respond to the IDPR's offer to discuss.

The QIO shall initiate contact with the practitioner and/or provider. Initial contact may be by phone; however, the QIO should document the date on which the offer was first made to the practitioner and/or provider, and this may include sending to the practitioner and/or provider a facsimile or letter detailing the specific concern(s) at issue. A QIO must allow for a practitioner to use a representative to respond to the Opportunity for Discussion. See Appendix 5-3, "Interim Initial Determination Letter for Practitioners/Providers."

5570.2 – Retrospective General Quality Review: Submission of Oral or Written Response to Opportunity for Discussion

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

A practitioner and/or provider must be afforded the opportunity to orally and/or in writing convey his/her disagreement with the conclusions rendered by the IDPR in the Interim Initial Determination. The offer of the Opportunity for Discussion can be made by the RA, the IDPR or the Medical Director, depending on the QIO's established practice within the state. However, the RA must participate in discussions between the IDPR and the practitioner and/or provider. For complex cases, it is recommended that the Medical Director participate.

***NOTE:** For instances when the practitioner and/or provider responds to the Opportunity for Discussion by agreeing with the concern(s) identified, the agreement should then be documented and the QIO should follow the requirements in §5570.5, "Retrospective General Quality Review: No Response Received to Opportunity for Discussion."*

***Oral responses:** The RA must prepare a summary of any oral response submitted. During the oral discussion, the practitioner and/or provider shall be advised of the need to focus on the specific element(s) of the standard(s) of care which is being disputed in the IDPR's Interim Initial Determination.*

***Written responses:** The practitioner and/or provider shall be advised of the need to focus on the IDPR's conclusions related to specific elements of the standard(s) of care. Written statements submitted for the Opportunity for Discussion must be sent to the RA.*

5570.3 – Retrospective General Quality Review: Prohibition on Submission of New/Additional Medical Information

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

The submission of new and/or additional medical information is prohibited during the Opportunity for Discussion. In instances when the practitioner and/or provider requests to submit new and/or additional medical information, the QIO must advise the practitioner and/or provider of his/her right to request a Re-Review and that any new and/or additional medical information can be considered during the Re-Review process.

5570.4 – Retrospective General Quality Review: Review of Information Submitted during Opportunity for Discussion Stage

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

The RA reviews his or her summary of any oral response submitted by the practitioner or practitioner representative, and/or provider, or the written Opportunity for Discussion response. This information is reviewed in light of the quality of care concern(s) raised during the IDPR review. For both oral and written responses, the RA must make every effort to highlight/summarize specific facts provided by the practitioner and/or provider during the discussion in relationship to particular elements of the standard(s) of care that could alter the IDPR's conclusion. (As noted in §5240.4, facts provided during the discussion stage cannot include new medical information.) The RA must also detail information provided by the practitioner and/or provider that appears to be unrelated to the standard(s) of care.

The RA shall forward the information, along with specific issues identified in the response, to the IDPR for consideration within one (1) business day of the completion of the RA's oral discussion and/or the receipt of the written response.

Upon receipt of additional information during the Opportunity for Discussion, the IDPR must make his/her FINAL Initial Determination no later than three (3) business days from his/her receipt of the additional information. The QIO must ensure that the same Peer Reviewer renders both the Interim and Final Initial Determinations, unless rare circumstances exist, e.g., the Interim IDPR is unavailable as a result of serious illness.

In most instances, the RA will not be required to mail the IDPR the entire General Quality of Care Review folder. The IDPR must use the copy of the QRD Form from the Interim Initial Determination in evaluating the information the practitioner and/or provider supplied to the RA during the Opportunity for Discussion. Additional materials will not be mailed for situations where the practitioner and/or provider conveyed information orally directly to the IDPR. The RA and the IDPR will coordinate to ensure all pertinent information is considered in the Final Initial Determination. After making the Final Initial Determination, the IDPR re-signs the QRD Form and mails it back to the RA. The signed form may also be faxed to expedite review.

5570.5 – Retrospective General Quality Review: No Response Received to Opportunity for Discussion

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

If no response is received to the offer of the Opportunity for Discussion within 15 calendar days, the Interim Initial Determination becomes the Final Initial Determination. The IDPR need not

sign the QRD Form again to denote this result; however, the RA will note on the QRD Form that no response was received.

5570.6 – Retrospective General Quality Review: Preparation of Final Determination Letter

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

Upon receipt of the QRD Form, the RA prepares the "Final Determination Letter (General Quality of Care Reviews)," Appendix 5-7, conveying the decision to the practitioner and/or provider. The letter must be forwarded within three (3) business days of the receipt of the QRD Form detailing the Final Initial Determination from the IDPR, or, when no response is received to the Opportunity for Discussion, within one (1) business day of the expiration of the opportunity period.

The letter must advise the practitioner and/or provider of his/her right to request a Re-Review if the standard(s) of care was not met for any concern(s). The letter will convey to the practitioner and/or provider that s/he has 15 calendar days to request a Re-Review if the standard(s) of care was not met for any concern(s) and that this will be the last communication regarding the QIO's decision if no request for a Re-Review is received. See §5570.7, "Retrospective General Quality Review: Failure to Respond to the Final Initial Determination and Right to Re-Review," for information related to a practitioner and/or provider failure to respond to the Re-Review request.

If the practitioner and/or provider does not request a Re-Review within 15 calendar days, then the practitioner and/or provider may not be granted a request for a Re-Review, absent extraordinary circumstances. See §5570.7.

5570.7 – Retrospective General Quality Review: Failure to Respond to the Final Initial Determination and Right to Re-Review

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

For instances when the practitioner and/or provider fails to request a Re-Review within 15 calendar days, the QIO is not required to forward another letter to the practitioner detailing that no additional review will be conducted. The QIO shall follow the procedures in §5580.4, "Retrospective General Quality Review: Procedures for Closing Review," for closing the case in the CMS-designated case review system. In situations where no Re-Review Request is received, the Final Initial Determination represents the QIOs Final Decision, and no further appeal rights exist. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5570.8 – Retrospective General Quality Review: Responsibility to Protect Information and Destruction of Materials

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

As specified at 42 CFR §480.115, the QIO has a responsibility to protect information and must implement reasonable security measures to ensure the integrity of information and prevent unauthorized access. See Chapter 10 of the QIO Manual.

No later than thirty (30) calendar days after the Final Initial Determination by the IDPR, the IDPR must destroy all copies of materials in his/her possession associated with the review in

compliance with QIO security procedures. The original will be maintained by the QIO at its facility.

5580 – Retrospective General Quality Review: Re-Review Stage
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

The practitioner and/or provider may request a Re-Review within 15 calendar days of receipt of the Final Determination Letter (General Quality of Care Reviews), Appendix 5-7. Additional evidence may also be submitted as part of the Re-Review process. Upon receipt of a Re-Review request, the Review Analyst must forward the General Quality of Care Review folder with the following items to the RRPR:

- *QRD Form,*
- *Medical information,*
- *Final Determination Letter conveying the decision to the practitioner and/or provider,*
- *Interim Initial Determination Letter,*
- *Information received related to the offer of the Opportunity for Discussion Stage, and*
- *Any new evidence submitted in requesting the Re-Review.*

The folder with the above information must be forwarded to the RRPR within one (1) business day of the receipt of the request for a Re-Review. See §5580.1, "Retrospective General Quality Review: Re-Review Peer Reviewer."

5580.1 – Retrospective General Quality Review: Re-Review Peer Reviewer
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

The RRPR must be different than the Peer Reviewer who conducted the Interim and Final Initial Determinations. In making his/her determination, the RRPR shall review all information forwarded by the Review Analyst. The RRPR shall use the QRD Form in rendering his/her determination(s) on each Quality of Care Concern.

The RRPR receives the mailed package from the Review Analyst and initiates the Re-Review.

***NOTE:** The RRPR will not receive General Quality of Care Reviews when the IDPR has identified a concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act). These concerns will initiate sanction proceedings in accordance with Chapter 9.*

The RRPR must review each potential quality of care concern identified by the RA and/or the IDPR. For each:

- *The RRPR evaluates the standard(s) identified by the RA and the IDPR on the QRD Form*
- *The RRPR checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care as delineated by the RA and IDPR*
- *If the RRPR determines that the standard(s) identified by the RA and/or IDPR for a specific concern(s) is incorrect or not thorough, the RRPR must identify the correct standard(s) and provide an explanation regarding the change*

- *For those instances when the RRPR determines that the standard(s) is incorrect, the RRPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care and consult with the Medical Director to obtain the Medical Director's concurrence on the standard to be used in evaluating the concern(s).*

***NOTE:** The RA shall be included in this consultation.*

In the rare instance when an RRPR identifies a new concern(s), the RRPR must contact the RA and refer the newly identified concern to the RA to initiate processing at the Quality of Care Review Stage. The RRPR must not evaluate the concern since the matter will be eligible for review by an IDPR.

Completion of the Analysis/Justification: Upon determining the standard(s) of care to be used, the RRPR then applies the standard(s) of care to the specific facts of the case and the quality of care concern(s) at issue. The RRPR evaluates the information contained in the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The RRPR must directly link his/her decisions to elements contained in the evidence-based standard(s) when deciding whether quality of care for each of the identified concerns is met based on the facts of the case. The IDPR also assesses the individual responsibility for the standard(s) not being met.

In addition, the RRPR must consider any historical data pertinent to the concern(s) as provided by the RA, highlight specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met, and include any other information the RRPR deems relevant to his/her Re-Review Determination. If the RRPR, in his/her determination, concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the RRPR must thoroughly explain these justifications in completing the Analysis/Justification section of the QRD Form.

The RRPR must complete a separate analysis for each quality concern. Upon completion of the Analysis/Justification section, the RRPR must check off the appropriate box indicating his/her decision that the standard(s) of care was met or not met. If the RRPR determines that the standard(s) of care was not met, the RRPR must also check off the appropriate box indicating whether:

- *The care grossly and flagrantly, in one or more instances, violated the provider's/practitioner's obligation to provide care that is of a quality that meets professionally recognized standards of health care (See §1156(a) of the Act);*
- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed to substantially comply with the obligation (less than three cases) to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act), or*
- *The care did not meet the standard of care but was less than a substantial violation of the obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care, i.e., it was either significant or non-significant.*

The RRPR must complete his/her review of the package, adhere strictly to the format in the QRD Form, sign and date the Form and indicate the amount of time spent completing the review. The RRPR must return the package to the Review Analyst within seven (7) calendar days.

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

5580.2 – Retrospective General Quality Review: Preparation of Re-Review Package

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

The Review Analyst (RA) receives the package from the RRPR and examines it to ensure all necessary information is returned. The RA identifies the Re-Review decision on the QRD Form and prepares the "Re-Review Determination Letter (General Quality of Care Review)." See §5580.3 and Appendix 5-8, "Re-Review Determination Letter (General Quality of Care Review)." The RA may use the language in the "Final Determination Letter (General Quality of Care Review)" unless substantial changes have been made. The RA mails the Re-Review Determination Letter to the practitioner and/or provider within one (1) business day of receiving the Re-review package from the RRPR.

5580.3 – Retrospective General Quality Review: Preparation and Mailing of Final Re-Review Determination Letter

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

In preparing the Re-Review Determination letter (Appendix 5-8), the RA must ensure the letter includes the following:

1. *A statement for each of the quality of care concerns that care did or did not meet the standard(s) of care,*
2. *Inclusion of the standard(s) identified by the QIO for each of the quality of care concerns,*
3. *A specific statement conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard, and*
4. *A statement that this constitutes the QIO's final decision on the complaint and that no further appeal rights are available.*

5580.4 – Retrospective General Quality Review: Procedures for Closing Review

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

The RA must denote in the CMS-designated case review system that the General Quality of Care Review is being closed by following all applicable requirements. The RA must place all final documents in the General Quality of Care Folder for maintenance and filing. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5600 – Concurrent General Quality of Care Review

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

The following instructions detail the steps QIOs must adhere to in reviewing quality of care concerns received and/or identified from sources other than Beneficiary Complaints (Concerns Identified During Other Review Activities, Referrals, and Tracking and Trending) and the beneficiary remains in the provider setting and/or care is still being provided, i.e., a Concurrent Review.

5610 – Concurrent General Quality Review: Preparation of General Quality of Care Review Folder

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

The Intake Specialist will be responsible for preparing the General Quality of Care Review folder for maintenance at the QIO. Should the RA determine that a hard copy of the folder is required, e.g., for use by an off-site Peer Reviewer, a duplicate of the folder may be prepared. The folder will be prepared and forwarded to the Review Analyst (RA) within one (1) business day of receipt of a referral or the identification of a potential Quality of Care Concern as a result of tracking and/or trending of data.

For instances where a Quality of Care Concern is identified during the course of other review activities, the Intake Specialist will prepare/organize any information necessary to enable the Quality of Care Review to be completed in addition to the original review activity. For example, in completing an expedited discharge appeal review, the Peer Reviewer identifies a Quality of Care Concern. The QIO should establish procedures to enable the same Peer Reviewer who identified the Quality of Care Concern to complete the Quality of Care Review.

5610.1 – Concurrent General Quality Review: Review of Folder by Review Analyst

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

Upon receipt of the General Quality of Care Review folder from the Intake Specialist, the RA must review the information in the folder as well as the information in the CMS-designated case review system to ensure that he or she understands the specific concern(s) involved.

5610.2 – Concurrent General Quality Review: Requesting Medical Information

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

The following steps may not apply for those instances where the QIO already possesses a copy of the medical information as a result of another review activity being conducted. As such, the instructions are written as related to requests for medical information in response to Concurrent General Quality of Care Reviews conducted as a result of referrals and/or tracking and trending of data. ***NOTE:*** *Upon receipt of the medical information at any step, follow the instructions as outlined in §5610.4, "Concurrent General Quality Review: Review and Preparation of Medical Information." See 42 CFR 476.78(b)(2), "Review Responsibilities of Utilization and Quality Control Quality Improvement Organizations —Responsibilities of Health Care Facilities," and §480.111(a), "QIO Access to Records and Information of Institutions and Practitioners" regarding a QIO's right to request medical information.*

The Intake Specialist must request the medical information within one (1) business day of the identification of a Quality of Care concern. The Intake Specialist may contact the practitioner and/or provider by phone and follow up with a facsimile. The correspondence must clearly indicate the specific date on which the medical information was first requested since this date

will be used to determine when, for a provider, a denial of the claim could be issued, and the date the medical information is due to the QIO. ***NOTE:*** *The date of the letter may be used if it corresponds to the date of the first request. The Intake Specialist must advise a practitioner and/or provider that, in order to expedite the QIO's review and ensure that the QIO receives all necessary information in a timely manner, the QIO expects the provider or practitioner to submit the requested medical information by close of business the next business day, i.e., one (1) business day after receipt of the request.*

The QIO should normally contact the Medical Records Department and/or the QIO liaison. QIOs may contact either/both the Medical Records Department or the QIO liaison based on procedures they have established with that provider or practitioner.

In situations where a practitioner or provider fails to submit medical information within the required twenty-one (21) or thirty (30) calendar day time frame, the QIO should advise the practitioner or provider that based on §1156(a)(3), sanctions may be initiated because of the failure to support the provision of items or services with evidence of the quality of the items or services.

5610.3 – Concurrent General Quality Review: Issuing a Claim Denial

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

A QIO is authorized to deny a provider's claim in situations where the QIO has requested information from the provider and despite sufficient notice and a reasonable amount of time to respond, the provider fails to forward the requested information. See 42 CFR §476.90(b). In processing the denial of the claim, the QIO should coordinate with the pertinent Project Officer. If the requested medical information is submitted before the denial of the claim is finalized, the QIO must stop the denial and complete the review. If the medical information is received after the denial of the claim has been finalized, payment must be re-instituted. The QIO should complete the review. The Project Officer should be consulted regarding any additional action the QIO should take, e.g., completion of additional Quality of Care Reviews for the same provider.

5610.4 – Concurrent General Quality Review: Review and Preparation of Medical Information

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

Upon receipt of the medical information, the Intake Specialist must immediately date-stamp the information to indicate the date received, unless the information is received electronically and scan the information, including the original envelope, into the CMS-designated case review system within one (1) business day. The Intake Specialist must keep the original envelope with the medical information. The Intake Specialist ensures all information in the medical information is complete, appropriately organized, and legible. If the medical information is incomplete or illegible (poor copy), the Intake Specialist contacts the practitioner and/or provider by phone and requests that the documentation necessary to complete the medical information be sent via fax but no later than the next calendar day. QIOs must follow the procedures for issuing a claim denial in §5610.3 when complete medical information is not received in accordance with either the twenty-one (21) or thirty (30) calendar day time frame. See Appendix 5-12 for additional information regarding time frames.

The Intake Specialist shall organize the information in the medical information in accordance with the following tabs. The contents of each tab shall be placed in chronological order:

TAB 1: Emergency Room Record/Admission Record

TAB 2: History and Physical

TAB 3: Consultations

TAB 4: Practitioner Orders

TAB 5: Practitioner Progress Notes

TAB 6: Nursing Notes

TAB 7: Ancillary, e.g., Labs, X-rays, Medication Administration Record, Treatment Administration Record, etc.

TAB 8: Miscellaneous

TAB 9: Discharge Summary

***NOTE:** QIOs are authorized to upload medical information received directly into the CMS-designated case review system, and the QIO must also upload the information into the CMS-designated case review system within one (1) business day.*

Upon receipt of complete and legible medical information, the Intake Specialist must upload the information into the CMS-designated case review system immediately, but no later than one (1) business day after receipt. If the Intake Specialist, RA, or physician reviewer(s) determines that handwritten information in the medical information cannot be deciphered, the QIO may contact the facility and request a typed/transcribed portion of the problem sections of the medical information. The QIO must make every effort to limit the amount of typed/transcribed information requested. Failure to comply with a QIO request for typed/transcribed information shall be treated as a failure to provide the medical information if the missing information precludes the completion of the review. The IDPR may be consulted prior to making the determination to pursue a denial of the claim. QIOs must follow the procedures in §5610.3 for issuing a denial of a claim.

5620 – Concurrent General Quality Review: Quality of Care Review Stage

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

In addition to referrals for Quality of Care Reviews and Quality of Care Reviews as a result of tracking and trending of data, the RA may also identify potential Quality of Care Reviews during the course of his or her work responsibilities related to other review activities. In these situations, the RA initiates the Quality of Care Review stage by conducting a preliminary review of each Quality of Care Concern(s) identified.

5620.1 – Concurrent General Quality Review: Preparation of Quality Review Decision (QRD) Form

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

Once a determination has been made regarding the specific concern(s) to be addressed, the RA must prepare a Quality Review Decision (QRD) Form. See Appendix 5-2, "Quality Review Decision (QRD) Form." This standardized form replaces the Peer Reviewer Assessment Format previously followed by all QIOs. The new standardized form has been created to better account for the multiple individuals who are involved in a Quality of Care review and to ensure

information related to every Quality of Care Concern is maintained in an organized, detailed, and consistent fashion throughout the review process.

Using the CMS-designated case review system, the RA must prepare a QRD Form that sets out each individual concern and forward the package to the IDPR immediately upon receipt of the medical information, but no later than in one (1) business day. This includes separately completing the following steps for each concern:

a. *Evaluate each quality of care concern,*

b. *Evaluate the quality of care with regard to the admission diagnosis and treatment plan established for the beneficiary, if applicable,*

c. *Research evidence-based practices related to each Quality of Care Concern(s), while considering the definition of Quality Care, including reference to relevant norms and criteria. If no quality of care standard(s) exists, then the RA must identify norms, best practices and established guidelines and then recommend a potential quality of care standard(s). In completing this step, the RA must thoroughly research all available information, including the following:*

   - *Nurse Screening Criteria (InterQual, Milliman, etc.)*
   - *Generally available resources, including information available via Internet searches*

d. *Evaluate additional information pertinent to the case, but unrelated to the standard(s) of care. This may include:*

   - *CMS-available information, which may include Web-based resources, e.g., Nursing Home and Hospital Compare; and*
   - *State-based resources, which may include Web-based literature and information, as well as, practitioner-specific information related to license revocations and referrals to the state medical conduct organizations.*

   A Review Analyst Assessment section must be completed for each Quality of Care Concern in the complaint and/or identified by the RA.

e. *Research all available data (minimum of three (3) years) to determine whether similar complaints have been received on the same practitioner and/or provider and/or if other potential concerns related to the same practitioner and/or provider are identifiable.*

f. *Prepare the package for forwarding to the Initial Determination Peer Reviewer (IDPR).*

5620.2 – Concurrent General Quality Review: Receipt and Review by the Initial Determination Peer Reviewer (IDPR)

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

The Review Analyst mails the package immediately to the IDPR and the IDPR then initiates his/her review. The IDPR must review the Quality of Care Concern(s) identified by the RA. For each individual concern, the IDPR evaluates the standard(s) identified by the RA on the QRD Form and checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care as delineated by the RA. If the IDPR identifies new Quality of Care Concerns, the IDPR must identify the concerns on the QRD Form as well as the specific standard of care for each concern, and include pertinent research supporting the standard of care s/he used to evaluate each concern.

If the IDPR determines that the standard(s) identified by the RA for a specific concern(s) is incorrect or not thorough, the IDPR identifies the correct standard(s) and provides an explanation regarding the change. For those instances when the IDPR determines that the standard(s) is incorrect, the IDPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care.

The IDPR then applies the standard(s) of care to the specific facts of the case and the quality of care concern(s) at issue. The IDPR evaluates the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The IDPR must evaluate whether the quality of care standard for each of the identified concerns is met based on the facts of the case and directly link his/her decisions to elements contained in the evidence-based standard(s). The IDPR also assesses the individual responsibility for the standard(s) not being met.

In addition, the IDPR considers any historical data pertinent to the concern(s) as provided by the RA, and highlights specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met. The IDPR should also include any other information the IDPR deems relevant to his/her Interim Initial Determination. If the IDPR concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the IDPR must thoroughly explain these justifications.

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

- *The care grossly and flagrantly, in one or more instances, violated the provider's/practitioner's obligation to provide care that is of a quality that meets the professionally recognized standards of health care (See §1156(a) of the Act);*
- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed to substantially comply with the obligation (less than three cases) to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act); or*
- *The care did not meet the standard of care, but was less than a substantial violation of the obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care, i.e., it was either significant or non-significant.*

The IDPR must complete his/her review of the package, adhere strictly to the format in the QRD Form, sign and date the Form and indicate the amount of time spent completing the review. The IDPR must return the package to the Review Analyst within one (1) business day. Except in circumstances when the IDPR conducts the review on the QIO premises, the IDPR may maintain a signed copy of his or her completed QRD Form and additional notes. These are maintained to facilitate any additional review necessary based on the receipt of additional information during the Opportunity for Discussion Stage.

5620.3 – Concurrent General Quality Review: Return and Review of Interim Initial Determination

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

The RA has one (1) business day to review the package to ensure all necessary information has been returned, the IDPR rendered a decision on all quality of care concerns, the content adheres to the correct format, and the rationale for conclusions is clear.

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

If the IDPR determined that the standard of care was met for all concerns, the RA should follow the procedures detailed in §5630.6, "Concurrent General Quality Review: Preparation of Final Determination Letter."

If the IDPR determined that the standard of care was not met for any one or more of the concerns, and the concerns are not sanctionable, the RA should follow the procedures detailed in §5630, "Concurrent General Quality Review: Opportunity for Discussion Stage."

5630 – Concurrent General Quality Review: Opportunity for Discussion Stage

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

Before the QIO concludes that the quality of services does not meet professionally recognized standards of health care, the QIO must provide the provider and/or practitioner with reasonable notice and opportunity for discussion of the concerns found.

5630.1 – Concurrent General Quality Review: Notification of Opportunity for Discussion

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

Because this is a concurrent review, the QIO shall make every effort to complete the Opportunity for Discussion as expeditiously as possible. If the IDPR determines that a concern(s) has been identified for which the standard of care was not met, the IDPR must immediately contact the RA. Once the RA has been notified, the QIO can immediately contact the practitioner and/or provider to discuss the concern, even if the IDPR has not finalized his/her entire review. The IDPR must provide as much detail as possible to facilitate the expediting of the Opportunity for Discussion. The IDPR must complete his/her review within one (1) business day after receipt of the package from the RA.

The QIO shall initiate contact with the practitioner and/or provider by phone. However, the QIO should make a reasonable effort to document the date on which the offer was first made to the practitioner and/or provider, including sending to the practitioner and/or provider a facsimile or letter detailing the specific concern(s) at issue. A QIO must allow for a practitioner to use a representative to respond to the Opportunity for Discussion. Because this is a Concurrent General Quality of Care Review, a provider and/or practitioner must respond to the offer to discuss within one (1) business day, and additional days may not be provided under any circumstances.

5630.2 – Concurrent General Quality Review: Submission of Oral or Written Response to Opportunity for Discussion

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

A practitioner and/or provider must be afforded the opportunity to orally and/or in writing convey his/her disagreement with the conclusions rendered by the IDPR in the Interim Initial Determination. The offer of the Opportunity for Discussion can be made by the RA, the IDPR or the Medical Director, depending on the QIO's established practice within the state. However, the RA must participate in discussions between the IDPR and the practitioner and/or provider. For complex cases, it is recommended that the Medical Director participate.

NOTE: *For instances when the practitioner and/or provider responds to the Opportunity for Discussion by agreeing with the concern(s) identified, the agreement should then be documented and the QIO should follow the requirements in §5630.5, "Concurrent General Quality Review: No Response Received to Opportunity for Discussion."*

Oral responses: *The RA must prepare a summary of any oral response submitted. During the oral discussion, the practitioner and/or provider shall be advised of the need to focus on the specific element(s) of the standard(s) of care which is being disputed in the IDPR's Interim Initial Determination.*

Written responses: *The practitioner and/or provider shall be advised of the need to focus on the IDPR's conclusions related to specific elements of the standard(s) of care. Written statements submitted for the Opportunity for Discussion must be sent to the RA.*

5630.3 – Concurrent General Quality Review: Prohibition on Submission of New/Additional Medical Information

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

The submission of new and/or additional medical information is prohibited during the Opportunity for Discussion. In instances when the practitioner and/or provider asks to submit new and/or additional medical information, the QIO must advise the practitioner and/or provider of his/her right to request a Re-Review and that any new and/or additional medical information can be considered during the Re-Review process.

5630.4 – Concurrent General Quality Review: Review of Information Submitted during Opportunity for Discussion Stage

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

The RA reviews his or her summary of any oral response submitted by the practitioner or practitioner's representative, and/or provider, or the written Opportunity for Discussion response, in light of the quality of care concern(s) raised during the IDPR review. For both oral and written responses, the RA must make every effort to highlight/summarize specific facts provided by the practitioner and/or provider during the discussion in relationship to particular elements of the standard(s) of care that could alter the IDPR's conclusion. The RA must also detail information provided by the practitioner and/or provider that appears to be unrelated to the standard(s) of care.

The RA shall immediately forward the information, along with the specific issues identified in the response, to the IDPR. Upon receipt of additional information during the Opportunity for Discussion, the IDPR must make his/her Final Initial Determination no later than one (1) business day from his or her receipt of the additional information. The QIO must ensure that the same Peer Reviewer renders both the Interim and Final Initial Determinations, unless rare circumstances exist, e.g., the Interim IDPR is unavailable as a result of serious illness.

In most instances, the RA will not be required to send the IDPR the entire General Quality of Care Review folder. The IDPR must use the copy of the QRD Form from the Interim Initial Determination in evaluating the additional information provided, along with the additional information supplied by the RA from the practitioner and/or provider. Additional materials will not be mailed for situations where the practitioner and/or provider conveyed information orally directly to the IDPR. The RA and the IDPR will ensure all pertinent information is considered in the Final Initial Determination. After making the Final Initial Determination, the IDPR re-signs the QRD Form and faxes it back to the RA.

5630.5 – Concurrent General Quality Review: No Response Received to Opportunity for Discussion

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

If no response is received to the offer of the Opportunity for Discussion, the Interim Initial Determination becomes the Final Initial Determination. The IDPR need not sign the QRD Form again to denote this result; however, the RA will note on the QRD Form that no response was received.

5630.6 – Concurrent General Quality Review: Preparation of Final Determination Letter

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

Upon receipt of the QRD Form, the RA prepares the "Final Determination Letter (General Quality of Care Reviews)," Appendix 5-7, conveying the decision to the practitioner and/or provider.

The Final Determination Letter conveying the decision to the practitioner and/or provider must be sent within one (1) business day after receipt of the package from the IDPR. The letter will also convey to the practitioner and/or provider that they have 5 calendar days to request a Re-Review if the standard(s) of care was not met for any concern(s). See §5630.7, "Concurrent General Quality Review: Failure to Respond to the Final Initial Determination and Right to Re-Review," for information related to a practitioner's and/or provider's failure to request a Re-Review.

5630.7 – Concurrent General Quality Review: Failure to Respond to the Final Initial Determination and Right to Re-Review

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

If the practitioner and/or provider do not request a Re-Review within 5 calendar days, then the practitioner and/or provider may not be granted a request for a Re-Review, absent extraordinary circumstances. The QIO shall follow the procedures in §5640.4, "Concurrent General Quality Review: Procedures for Closing a General Quality of Care Review," for closing the case in the

CMS-designated case review system. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5630.8 – Concurrent General Quality Review: Destruction of Materials Associated With the Review

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

As specified at 42 CFR §480.115, the QIO has a responsibility to protect information and must implement reasonable security measures to ensure the integrity of information and prevent unauthorized access. See Chapter 10 of the QIO Manual.

No later than thirty (30) calendar days after the Final Initial Determination by the IDPR, the IDPR must destroy all copies of materials in his/her possession associated with the review in compliance with QIO security procedures. The original will be maintained by the QIO at its facility.

5640 – Concurrent General Quality Review: Re-Review Stage

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

The practitioner and/or provider may request a Re-Review within five (5) calendar days of receipt of the Final Determination Letter (General Quality of Care Reviews), Appendix 5-7. Upon receipt of a Re-Review request, the Review Analyst must forward the General Quality of Care Review folder with the following items to the RRPR:

- *QRD Form,*
- *Medical information,*
- *Final Initial Determination Letter conveying the decision to the practitioner and/or provider,*
- *Interim Initial Determination Letter,*
- *Information received related to the offer of the Opportunity for Discussion Stage, and*
- *Any new evidence submitted in requesting the Re-Review.*

The folder with the above information must be forwarded to the RRPR within one (1) business day of the receipt of the request for a Re-Review. See §5640.1, "Concurrent General Quality Review: Re-Review Peer Reviewer."

5640.1 – Concurrent General Quality Review: Re-Review Peer Reviewer

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

The RRPR must be different than the physician reviewer who conducted the Interim and Final Initial Determinations. In making his/her determination, the RRPR shall review all information forwarded by the Intake Specialist. The RRPR shall use the QRD Form in rendering his/her determination(s).

The RRPR receives the package from the Intake Specialist and initiates the Re-Review.

***NOTE:** The RRPR will not receive General Quality of Care Reviews when the IDPR has identified a concern(s) as either gross or flagrant, or the care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a*

quality that meets professionally recognized standards of care as required by §1156(a) of the Act. These concerns will result in the initiation of sanction proceedings in accordance with Chapter 9.

The RRPR must review each identified quality of care concern and complete the QRD form for each concern:

- *The RRPR evaluates the standard(s) identified by the RA and the IDPR on the QRD Form;*
- *The RRPR checks off the appropriate box indicating whether s/he concurs or does not concur with the standard(s) of care as delineated by the RA and IDPR;*
- *If the RRPR determines that the standard(s) identified by the RA and/or IDPR for a specific concern(s) is incorrect or not thorough, the RRPR must identify the correct standard(s) and provide an explanation regarding the change; and*
- *For those instances when the RRPR determines that the standard(s) is incorrect, the RRPR must include references to relevant literature/research supporting his/her decision on the appropriate standard(s) of care and consult with the Medical Director to obtain the Medical Director's concurrence on the standard to be used in evaluating the concern(s).*

***NOTE:** The RA shall be included in this consultation.*

Completion of the Analysis/Justification: Upon determining the standard(s) of care to be used, the RRPR then applies the standard(s) of care to the specific facts of the case and the quality of care concern(s) at issue. The RRPR evaluates the information contained in the medical information based on the standard(s) as identified, including each evidenced-based element of the standard(s) of care. The RRPR must directly link his/her decisions to elements contained in the evidence-based standard(s) when deciding whether quality of care for each of the identified concerns is met based on the facts of the case. The RRPR must also assess the responsibility of the individual identified by the beneficiary if that individual is different from the individual who is responsible for the standard(s) not being met.

In addition, the RRPR must consider any historical data pertinent to the concern(s) as provided by the RA, highlight specific evidence from the review of the medical information demonstrating that specific elements within the standard(s) of care are met or not met, and include any other information the RRPR deems relevant to his or her Re-Review Determination. If the RRPR, in his/her determination, concludes that there are extenuating circumstances to take into consideration, e.g., emergent circumstances or exceptional complexity, the RRPR must thoroughly explain these justifications in completing the Analysis/Justification section of the QRD Form.

The RRPR must complete a separate analysis for each concern. Upon completion of the Analysis/Justification portion of the QRD Form, the RRPR must check off the appropriate box indicating his/her decision that the standard(s) of care was met or not met. If the RRPR determines that the standard(s) of care was not met, the RRPR must also check off the appropriate box indicating whether:

- *The care grossly and flagrantly, in one or more instances, violated the provider's/practitioner's obligation to provide care that is of a quality that meets professionally recognized standard(s) of health care (See §1156(a) of the Act);*

- *The care failed in a substantial number of cases (three or more) to substantially comply with the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act);*
- *The care failed to substantially comply with the obligation (less than three cases) to provide care that is of a quality that meets the professionally recognized standard(s) of health care (See §1156(a) of the Act); or*
- *The care did not meet the standard of care but was less than a substantial violation of the obligation to provide care that is of a quality that meets the professionally recognized standard(s) of health care, i.e., it was either significant or non-significant.*

The RRPR must complete his/her review of the package, adhere strictly to the requirements in the QRD Form and return the package to the Review Analyst within one (1) calendar day. The RRPR must sign and date the QRD Form and indicate the amount of time spent reviewing the concern(s).

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

5640.2 – Concurrent General Quality Review: Preparation of Re-Review Package

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

The Review Analyst receives the package from the RRPR and examines it to ensure all necessary information is returned. The RA notes the Re-Review decision on the QRD Form and then prepares the "Re-Review Determination Letter (General Quality of Care Reviews)," in accordance with §5640.3. The RA may utilize the language used previously in the Final Determination Letter unless substantial changes have been made. The RA forwards the letter to the practitioner and/or provider within one (1) business day of receiving the Re-review package from the RRPR.

5640.3 – Concurrent General Quality Review: Preparation and Mailing of Final Re-Review Determination Letter to the Practitioner or Provider

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

In preparing the "Re-Review Determination Letter (General Quality of Care Reviews)" (Appendix 5-8), the RA must ensure the letter includes the following:

1. *A statement for each of the quality of care concerns that care did or did not meet the standard(s) of care,*
2. *Inclusion of the standard(s) identified by the QIO for each of the quality of care concerns,*
3. *A specific statement conveying facts describing how the practitioner and/or provider did or did not meet specific criteria within the standard, and*
4. *A statement that this constitutes the QIO's final decision on the complaint and that no further appeal rights are available.*

The RA shall prepare and mail the Final Re-Review Determination Letter to the practitioner and/or provider within one (1) business day of receipt of the RRPR's Re-Review decision.

5640.4 – Concurrent General Quality Review: Procedures for Closing a General Quality of Care Review

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

The RA must denote in the CMS-designated case review system that the General Quality of Care Review is being closed by following all applicable requirements. The RA must place all final documents in the proper folder for maintenance and filing. The QIO may pursue Quality Improvement Initiatives in accordance with §5800 if deemed appropriate.

5800 – Quality Improvement Initiatives

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

A Quality Improvement Initiative (QII) is any formal plan designed to assist a provider/practitioner in identifying the root cause of a concern(s), develop a framework in which to address the concern(s) and improve a process or system. A QII may consist of system-wide and/or non-system-wide changes and may be based on a single, confirmed concern or multiple confirmed concerns. QIIs must be initiated for all confirmed concerns except the following:

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

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

QIOs must consider all aspects of the case they are reviewing when evaluating methods to improve care, and shall employ data analysis techniques to identify potential opportunities for improvement. In addition, QIOs should consider the impact of changes within, as well as across, settings. For example, if a physician provides care in more than one setting (e.g., an inpatient acute care setting and a skilled nursing facility), the QIO should use information available from all settings to determine improvements in one or all of the settings. QIOs may work with one, several, or all providers concerned to improve the level of the physician's performance; however, QIOs may not share information among providers without the specific consent of the physician and/or providers.

5810 – Unwillingness to Cooperate

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

In some instances, the practitioner(s) and/or provider(s) may clearly express intent not to cooperate with the QIO regarding Quality Improvement Initiatives. In these situations, the QIO must advise the practitioner(s) and/or provider(s) that the matter may be referred to CMS' Regional Office (or to a state survey agency through the Regional Office). In addition, the QIO

may refer the matter to other CMS contractors, e.g., Medicare Administrative Contractors, with appropriate review authority over the practitioner's and/or provider's activities or to the State Board of Licensing. The practitioner and/or provider(s) may also be subject to additional reviews focusing on identified areas of concern in appropriate situations.

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

5820 – Development of a Quality Improvement Initiative
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

The QIO is to work with the practitioner(s) and/or provider(s) to develop a QII, which consists of a Root Cause Analysis of the concern(s) and an Intervention and Improvement Plan (IIP). QIOs must ensure that all QIIs are cost-effective. The results of QIIs should be reproducible without necessitating exorbitant time and/or monetary expenditures. The QIO shall assist the practitioner(s) and/or provider(s) in leveraging all opportunities for improvement. In addition, the QIO should work with both the administrative and the medical staffs (e.g., a hospital quality assurance committee) when providing information and developing, implementing, and monitoring QIIs.

5830 – Time Frames for Development of a Quality Improvement Initiative
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

The initial planning of a QII must be finalized within 30 calendar days of the confirmation of a concern(s). The implementation of a QII may be delayed an additional 30 calendar days after the IIP is completed to obtain sufficient baseline data from which improvements can be measured. Periodic reviews should be conducted during the implementation of interventions to gauge whether potential improvements are being realized.

5840 – Quality Improvement Initiative Not Needed
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

QIOs have the authority to pursue QIIs in all situations where Quality of Care Concerns are confirmed but a Corrective Action Plan (covered under Chapter 9) is not appropriate. However, there are situations where a QII may not be appropriate. For example:

- *A case is referred to a federal or state enforcement agency responsible for the investigation or identification of fraud or abuse of the Medicare program,*
- *The practitioner(s) and/or provider(s) provides evidence that the concern(s) is a single, isolated instance and does not effectively allow for improvement,*
- *The underlying problem has already been identified and action taken to correct it (e.g., a Medicare coder who has been making numerous errors has been retrained and is now performing well),*
- *The concern(s) will be resolved by a QII that has already been initiated,*
- *The source of the concern is a physician and the physician has retired, expired or moved his/her practice out of the state. **NOTE:** When a practitioner has moved his/her practice out of the state, the QIO must forward any pertinent information to the QIO in the new state of practice. The appropriate Project Officer must be provided with pertinent information related to the forwarding of concerns between QIOs.*

5850 – Quality Improvement Initiative Root Cause Analysis
(Rev. 17, Issued: -04-06-12, Effective: 05-07-12 Implementation: 05-07-12)

When a concern is confirmed, consult with the practitioner(s) and/or provider(s) to determine the root cause. This includes requesting that the practitioner(s) and/or provider(s) afford the QIO the opportunity to review any root cause analysis independently completed.

The QIO must clearly identify the following:

- *The specific Quality of Care Concern(s) at issue,*
- *The type of facility or practitioner specialty involved,*
- *How the concern(s) has impacted the patient or patient care in general,*
- *The impact of the concern(s) on the practitioner's or the provider's operations,*
- *If there were any injuries or harm resulting from the concern,*
- *The prevalence of the concern,*
- *If the concern was linked to CMS-identified or other nationally-identified health care initiatives,*
- *Any health disparities issues associated with the concern(s),*
- *If the QIO has any data or information evidencing other instances of the same concern(s) within the same or a different provider setting(s) and with the same or a different practitioner(s),*
- *If the practitioner(s) and/or provider(s) is willing to cooperate in the Quality Improvement Initiative, (**NOTE:** the failure to cooperate is not justification for initiation of sanction proceedings), and*
- *Current baseline data relevant to the concern(s).*

In establishing the baseline, the QIO must employ evidence-based techniques to obtain a clear snapshot of the current environment. In determining the baseline, the QIO must request data from the practitioner and/or provider that demonstrates other occurrences of the same or related concerns (or opportunities for the same and/or similar occurrences), including a time frame during which the other instances occurred. Data prior to and after the time period during which the actual concern arose should be considered. In most instances, QIOs should not request data for periods more than three years prior to the time period during which the actual concern arose.

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

The QIO must also consider any relevant information related to best practices developed or identified by the QIO or other QIOs.

5860 – "Stand-Alone" or Isolated Concerns

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

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

5870 – Intervention and Improvement Plan

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

Once the Root Cause Analysis has been completed, the QIO must develop the Intervention and Improvement Plan (IIP) in consultation with the practitioner(s) and/or provider(s). The QIO must identify the intended outcome(s) of intervention(s) and whether the identified outcome(s) is mutually established with the practitioner(s) and/or provider(s). The IIP must list the specific action(s) the practitioner(s) and/or provider(s) will take to correct the underlying cause of the concern(s) and identify a time frame for initiating and completing the IIP. During the implementation period, the IIP must ensure periodic review of the specific intervention(s) against baseline data so that improvements can be monitored and any appropriate adjustments to the initiative considered.

5880 – Monitoring Quality Improvement Initiatives

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

At any point during the time period that interventions are being implemented, if the QIO, practitioner(s) and/or provider(s) determine that improvement is not being attained, the parties should meet as soon as possible to discuss possible reasons for the failure to achieve improvements and explore alternatives that may achieve the desired improvements. The parties should share data and mutually agree to the modifications to the Intervention and Improvement Plan, using the format of the original plan as detailed in §5870, "Intervention and Improvement Plan."

5890 – Reporting Results of System-Wide Change Quality Improvement Initiatives

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

QIOs must report Quality Improvement Initiative (QII) System-Wide Changes to CMS. Attribution of the improvements to the specific interventions identified by the QIO and/or in consultation with the practitioner and/or provider is an integral part of the System-Wide Change QIIs. Documented improvement is required and is defined as any amount of quantitative improvement in a process or outcome related to the Quality of Care Concern that is attributable to the QIO's activity. In reporting the System-Wide Change, QIOs must document the problem, define interventions as implemented by the provider(s) and/or practitioner(s), identify goals of the change, and detail the evaluation methodology.

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

The QIO should work with its Project Officer to determine the best method for ensuring continuous progress related to successful completion of System-Wide Changes, including determining when the System-Wide Change Report must be uploaded into the CMS-designated case review system. A QII is deemed "completed" once the pertinent period of data collection has been fulfilled, and the QIO is able to demonstrate that the goals of the System-Wide Change have been attained. In addition, QIOs should be prepared to discuss the progress of their efforts with the Project Officer on an as-needed basis.

INSTRUCTIONS FOR THE MEDICARE QUALITY OF CARE COMPLAINT FORM

Medicare contracts with Quality Improvement Organizations (QIOs) to review complaints from people with Medicare about the quality of health care services. Follow the instructions below to describe your complaint.

If you need help with this form or if you need help with your complaint call your QIO. Their phone number is _____. If your complaint isn't about the quality of care you got, the QIO will refer your complaint to the right organization.

Follow the directions below and complete each line of the form. If your personal information is already included on the form, please make sure it's correct.

Line 1: *Print the name of the person with Medicare who got the services related to the complaint.*

Line 2: *Include this person's Medicare (HICN) number, if known.*

Line 3: *Check the box next to this person's sex. Write this person's age in the blank space.*

Line 4: *Check the box or boxes that show this person's race or ethnicity. Please note that this information is* ***strictly voluntary*** *and* ***won't*** *impact your complaint.*

Line 5: *If the person with Medicare* ***won't*** *be the primary contact during the complaint process, print the name of the person's authorized representative.*

Line 6: *Print the contact information for the person who will be the primary contact during the complaint process—either the person with Medicare or the authorized representative.*

Line 7: *Check the box indicating whether you would like the doctor or provider who was involved in your complaint to know your name. If you check "No," the QIO* ***won't*** *reveal your name.*

Line 8: *Describe what happened. Include any information you believe would help the reviewer, including dates and times; names and addresses of doctors, staff and providers; information from witnesses, if available. If you need more space, you can attach additional sheets of paper. You can also include any documents you believe support your complaint.*

Line 9: *By signing the form, you are authorizing the QIO to review your complaint and give you a formal decision. The QIO may need to request your medical records related to the complaint.*

Once you've finished the form, do the following:

- *Keep these instructions (page 1) for your information.*
- *Make a copy of the form (page 2). Keep a copy for yourself and mail a copy to the QIO.*

The QIO will send you a decision on your complaint within _____ days of getting the signed complaint form.

MEDICARE QUALITY OF CARE COMPLAINT FORM

1. NAME

2. MEDICARE NUMBER (HICN)

3. SEX	DATE OF BIRTH
☐ Male ☐ Female	

4. RACE/ETHNICITY *(This section is voluntary):*

A. Are you Hispanic or Latino? ☐ Yes ☐ No

B. How would you describe your race? Please mark one or more boxes.

☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander

☐ White ☐ Asian

☐ Black or African American

5. AUTHORIZED REPRESENTATIVE'S NAME *(if primary contact for the complaint)*

6. CONTACT INFORMATION FOR PRIMARY CONTACT:

STREET/APT.

CITY	STATE	ZIP

PHONE	ALTERNATE PHONE

7. During the review of your complaint, do you want the doctor or provider staff involved in the complaint to know your name?

☐ Yes ☐ No

8. Briefly describe the incident or your concerns: Include names, addresses, dates, and times involved. You can attach additional sheets of paper or other documents.

9. BY SIGNING THIS FORM, I AM REQUESTING THAT THE QIO REVIEW MY COMPLAINT.

SIGNATURE OF BENEFICIARY OR REPRESENTATIVE	DATE

Appendix 5-2 – Quality Review Decision (QRD) Form

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

Quality Review Decision (QRD) Form

Case Summary

Case ID: ***State:***

Patient Details

Patient Name:
HIC #: ***Primary Language:***
Date of Birth: ***Age:***
Date of Death, if applicable: ***Gender:***
City:

Street Address:
State: ***Zip Code:***

Beneficiary Point of View

Health Care Events on Case

Place of Service Name:
Place of Service CCN:
Place of Service NPI:
Service Start Date: ***Service End Date:***

Practitioners Involved:
NPI: ***Name:***

Reason For Health Care Encounter:

Notes:

Acute Diagnosis:
Diagnosis Code: ***Diagnosis Date:***

Diagnosis Code Description:

Review Details

Review ID: ***Review Start Date:***
Review Type: ***Review Due Date:***
Review Analyst:

Concern Summary

Incident Start Date: ***Incident End Date:***

Keyword:
Category:

Concern Description:

Concern Notes:

RA Assessment

Review Analyst:
Provider/Practitioner Failure:
Explanation:
Submitted Date:
RA Disposition:

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

Review Analyst Assessment

Quality of Care Concern *1 of X:* ***:*** *[To be summarized by Review Analyst]*

Identified by:

❑ *Beneficiary* (**Note:** *QIOs may only conduct Quality of Care Reviews for non-written concerns raised by beneficiaries if the concern is considered "serious or urgent." For additional instructions, see Chapter 5 of the QIO manual.)*

❑ *Review Analyst*

❑ *Initial Determination Peer Reviewer*

Relevant Standard of Care:

In this section, the Review Analyst will include:

- *The standard of care identified, and if no clear standard of care exists, a recommended standard of care*
- *References to where the standard of care was found, e.g., literature, web-sites,*
- *Currency of standard of care*
- *Whether standard of care was in place at the time the concern arose (e.g., standard established in 2009 will not be pertinent to concern that arose in 1994)*
- *Who is responsible for the standard of care*

Additional Information: *In this section, the Review Analyst must provide information regarding:*

- *Any historical data pertaining to the same physician, practitioner or provider both related and unrelated to the identified concern (minimum three year "look back")*
- *Any other information the Review Analyst deems pertinent*

Interim Initial Determination Peer Review

***Quality of Care Concern** 1 of X:*

Concurrence with Identified Standard of Care:
❑ *Concur* ❑ *Do Not Concur* ❑ *Not Applicable (Concern Identified by IDPR)*

***Relevant Standard of Care:** For those instances where the IDPR identifies a concern, the IDPR must identify the standard of care to be used. For those instances where the Review Analyst identified a standard of care but the IDPR does not concur with the standard, the IDPR must specify what aspects of the standard are inaccurate. The IDPR must include references to relevant literature/research supporting his/her disagreement with the standard of care identified by the RA.*

***Analysis/Justification:** The IDPR must apply the standard of care to the specific facts of the case and this quality of care concern. The IDPR must identify the specific individual(s) the IDPR deems responsible for the standard of care not being met. The IDPR must also assess the responsibility of the individual identified by the beneficiary if different from the individual responsible for the standard not being met. Consider any historical data pertinent to the concern, and highlight specific evidence from the review of the medical information demonstrating that specific criteria within the standard of care are or are not met, and any other information the IDPR deems relevant to his/her Interim Initial Determination.*

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 (three or more) 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 (less than three cases) 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 Required)*
- ❑ *Significant concern (Quality Improvement Initiative Required)*
- ❑ *Non-significant concern (Quality Improvement Initiative Required)*

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 Signature**: _____ **Date:** _____*
***Minutes Spent on Case:** _____*

Final Initial Determination Peer Review

***Quality of Care Concern** 1 of X: Note: If IDPR identifies a new quality of care concern, the IDPR must identify the relevant standard of care prior to beginning his/her review.*

***Written Response Received from practitioner and/or provider:** ❑ Yes ❑ No*

If no written response received, the RA must summarize any information otherwise provided by practitioner and/or provider.

***Relationship of Information to Standard of Care:** [The IDPR must identify how the information provided relates to the standard of care. If the information is related to factors outside the standard of care, the IDPR must indicate this.]*

***Analysis/Justification:** The IDPR must apply the standard of care to the specific facts of the case and this quality of care concern. The IDPR must consider any historical data pertinent to the concern, and highlight specific evidence from the review of the medical information demonstrating that specific criteria within the standard of care are or are not met, and any other information the IDPR deems relevant to his/her FINAL Initial Determination.*

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 services that are of a quality that meets professionally recognized standards. (Sanction Activity Required)*
- ❑ *Failed in a substantial number of cases (three or more) to substantially comply with the obligation in §1156(a)(2) of the Act (Sanction Activity Required)*
- ❑ *Substantial failure (less than three cases) to comply with the obligation in §1156(a)(2) of the Act (Quality Improvement Initiative Required)*
- ❑ *Significant concern (Quality Improvement Initiative Required)*
- ❑ *Non-significant concern (Quality Improvement Initiative Required)*

***Initial Determination Peer Reviewer Signature**: _____ **Date:** _____*
***Minutes Spent on Case:** _____*

Re-Review Peer Review

***Quality of Care Concern** 1 of X:*

Concurrence with Identified Standard of Care:
❑ *Concur* ❑ *Do Not Concur* ❑ *Not Applicable (Concern Identified by RRPR)*

***Relevant Standard of Care:** For those instances where the RRPR identifies a concern, the RRPR must identify the standard of care to be used. For those instances where the Review Analyst and/or IDPR identified a standard of care but the RRPR does not concur with the standard, the RRPR must specify what aspects of the standard are inaccurate. The RRPR must include*

references to relevant literature/research supporting his/her disagreement with the standard of care identified by the RA and/or IDPR.

Analysis/Justification: *The RRPR must apply the standard of care to the specific facts of the case and this quality of care concern. The RRPR must consider any historical data pertinent to the concern, and highlight specific evidence from the review of the medical information demonstrating that specific criteria within the standard of care are or are not met, and any other information the RRPR deems relevant to his/her Re-Review Determination.*

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 (Sanction Activity Required)*
- ❑ *Failed in a substantial number of cases (three or more) to substantially comply with the obligation in §1156(a)(2) of the Act (Sanction Activity Required)*
- ❑ *Substantial failure (less than three cases) to comply with the obligation in §1156(a)(2) of the Act (Quality Improvement Initiative)*
- ❑ *Significant concern (Quality Improvement Initiative)*
- ❑ *Non-significant concern (Quality Improvement Initiative)*

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 the referring entity, the 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; 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.

***Re-Review Peer Reviewer Signature**: _____ **Date:** _____*
***Minutes Spent on Case:** _____*

Appendix 5-3 – Interim Initial Determination Letter for Practitioners and Providers

(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 (for beneficiary complaints, identify only if the beneficiary has consented)
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:

The (QIO name) is the Quality Improvement Organization (QIO) authorized by the Medicare program to review medical services provided to Medicare patients in the State of _____. One of the functions we perform is the review of health care provided to Medicare beneficiaries to determine if the care met professionally recognized standards of care, normally referred to as a Quality of Care Review. These reviews are conducted as a result of complaints filed by beneficiaries or because of other work we perform.

> ***PREPARATION NOTE FOR QIO***
> *Use the preceding paragraph with the following sentence included where the review was conducted as a result of a beneficiary complaint and the beneficiary has agreed to his/her name being used:*
> - *This review is the result of a complaint being filed by a Medicare beneficiary, [Beneficiary's name].*

<u>Summary of Findings</u>
A QIO Peer Reviewer has reviewed the care provided to (name of patient who has consented) at (name of provider or practitioner) for (specify the procedure, treatment, condition, and/or services).
Based on a review of the information contained in the medical information, the Peer Reviewer has identified the following concern(s) regarding the care provided:

> ***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.*

This information should be consistent with the information contained in the Quality Review Decision (QRD) Form.

Opportunity for Discussion

As part of our review process, we are required to afford you an opportunity to discuss our initial findings, referred to as the Interim Initial Determination, before we render our final decision, referred to as the Final Initial Determination. Your response can be in writing or orally by telephone, and we must receive your response within __ (The QIO must indicate pertinent time frame depending on whether it is a Retrospective or Concurrent review) calendar days from the date of this letter in order for us to consider information provided by you in our Final Initial Determination. Please be advised that this is not an opportunity for you to submit additional medical information. If additional medical information is submitted, we will not consider it in rendering the Final Initial Determination.

Direct your response to:

Name of QIO Contact Person
Address
Telephone Number

If you have any questions concerning this letter or would like to make arrangements to discuss this case with a QIO Peer Reviewer, you must contact the above-named person within the timeframe included above. This will give us time to consider any information you provide before we must issue our Final Initial Determination.

We are also notifying (name (See PREPARATION NOTE below)) of our concerns and offering an opportunity to discuss the concerns we have raised. If the concerns involve both a physician/practitioner and a provider, the physician/practitioner and the representative for the provider may respond separately to the opportunity for discussion. However, we strongly encourage coordination of the responses.

PREPARATION NOTE FOR QIO:

- *If the notice is addressed to the provider or physician practice, insert the name of any practitioner(s) also notified.*
  - *The following practitioner, [insert name(s)] has been contacted to obtain his/her consent to disclose to the beneficiary specific facts about the actions of that particular practitioner(s) when providing care 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 we do not receive your response within __ calendar days from the date of this letter, the Interim Initial Determination will become Final, and we will send you a Final Initial Determination Letter with this information. The information in this letter is confidential, and you may re-disclose it only in accordance with Federal regulations found in 42 CFR Part 480.

Sincerely,

Medical Director (or designated physician)
Include Title

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 care of the beneficiary, and how their actions did or did not meet the standard of care, we must obtain consent from those practitioner(s) The findings we propose releasing to the beneficiary are attached to (or included in) this letter. If you are a practitioner, please review the language and indicate consent to our disclosing the information to the beneficiary within thirty calendar days from the date of this letter. Please note that we will treat your failure to indicate your consent as your

declining to consent and the beneficiary will not be informed of these specific findings. In order to facilitate release of these specific findings to the beneficiary, please contact the QIO representative named below to discuss the attached findings:

Name of QIO Contact Person
Address
Telephone Number

PREPARATION NOTE FOR QIO:

- *If the notice is addressed to the provider and/or physician practice or some other practitioner, insert the name of the practitioner(s) also notified and include the statement:*
  - *The following practitioner, [insert name(s)] also has been notified of our Final Initial Determination and contacted to obtain his/her consent to disclose the specific findings to the beneficiary.*
- *If the notice is addressed to a practitioner, insert the name of the provider if applicable. Do not specify other physicians or practitioners you may be notifying.*
- *If the notice is addressed to the provider and will also be sent to a physician practice or some other practitioner, insert into the provider's notice the name(s) of the practitioner(s) also notified and include the statement:*
  - *The following practitioner(s), [insert name(s)] also has been notified of our Final Initial Determination and contacted to obtain his/her consent to disclose the specific findings to the beneficiary.*
- *If the notice is addressed to a practitioner or physician practice, insert the name of the provider if applicable. Do not specify other physicians or practitioners you may be notifying.*

Right to Request a Re-Review

PREPARATION NOTE FOR QIO

The QIO must select the appropriate paragraph depending on whether a ***Retrospective*** *or* ***Concurrent*** *Review is being conducted (Do NOT include "For Retrospective Review" or "For Concurrent Review" heading in the actual letter). In addition, the references to the other practitioners receiving the letter should not be included if addressed to a practitioner.*

For Retrospective Review

We are also notifying (name (See NOTES above)) of our Final Initial Determination. If you or (name (See NOTES above)) disagree with this Final Initial Determination, either party may request a Re-Review. To request a Re-Review, you must submit your request in writing within 15 calendar days from the date of this letter. Your request for a Re-Review may include additional information and/or documentation, including medical information you believe supports your request for a Re-Review.

For Concurrent Review

We are also notifying (name (See NOTES above)) of our Final Initial Determination. If you or (name (See NOTES above)) disagree with this Final Initial Determination, you must submit your request in writing within 5 calendar days from the date of this letter. Your request for a Re-Review may include additional information and/or documentation, including medical information you believe supports your request for a Re-Review.

Your request for a Re-Review may be submitted via mail or facsimile to the following address:

QIO Name
Address
Facsimile Number

Please be advised that if a Re-Review is requested, you [practitioner] will again be provided the opportunity to consent to our disclosing information to the beneficiary after the Re-Review determination.

The information in this notice is confidential and may be re-disclosed only in accordance with federal regulations found in 42 CFR Part 480.

Sincerely,

Medical Director (or designated physician)
(Include title)

Appendix 5-5 – 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 5-6 – Letter to the Beneficiary-QIO's Final Decision

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

QIO LETTERHEAD

Date of Notice
Name of Beneficiary (or Representative)
Address
City, State, and Zip Code

Patient Name
Health Insurance Claim (HIC) Number
Practitioner/Provider Name (practitioner name only with consent)
Practitioner/Provider Number (practitioner number only with consent)
Date of Admission/Service
Medical Record Number (if known)

Dear (Name of Beneficiary or Representative):

This letter contains the final results of our review of the complaint you filed on _____. As a result of our review, we determined that [some or all of]the care you received [did/did not] meet professionally recognized standards of care.

In completing our review, we considered the information contained in your original complaint, as well as information contained in your medical information and provided by your [practitioner/provider].

Summary of Findings

PREPARATION NOTE FOR QIO

The summary of findings to the beneficiary 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),*
- *Information regarding the standard of care associated with each concern,*
- *For each concern, a statement indicating whether the care involved did or did not meet professionally recognized standards of care. For concerns that are confirmed, provide information regarding the specific aspect(s) of the standard that were not met,*
- *In cases involving a practitioner, if consent has been obtained from the practitioner to disclose additional, more detailed findings, the detailed findings as agreed to by the practitioner,*
- *If consent has not been obtained from the practitioner to disclose more detailed findings, the following statement must be included:*
    - *Please be advised that before we can release more specific findings to you, we must obtain the consent of the practitioner as required by Federal regulation. In this situation, the practitioner did not consent to the release of more specific findings to you, and as a result, we are prohibited from providing them to you.*

The QIO must address all information (standard of care, met/not met, detailed findings) for each concern before proceeding to address subsequent concerns. The information

should be consistent with the information contained in the Quality Review Decision (QRD) Form.

PREPARATION NOTE FOR QIO
The QIO must include the following statement for those situations where a concern(s) is confirmed:

Based on the confirmed concern(s), we have initiated a quality improvement initiative with the practitioner and/or provider to ensure that the concern is resolved for future patients.

If you have questions and/or concerns regarding this matter, please contact:

Beneficiary Complaint Contact Person
Name of QIO
Address (including zip code)
Telephone Number (include toll-free number, if different)

Sincerely yours,

Designated Physician
(Include title)

Appendix 5-7 – Final Determination Letter (General Quality of Care Reviews)

(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
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 Involved Parties:

(QIO name) is the Quality Improvement Organization (QIO) authorized by the Medicare program to review Medicare cases in (State) to determine if the health care services provided to Medicare beneficiaries meet professionally recognized standards of care, are medically necessary and 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 (QIO name) Peer Reviewer has carefully reviewed the medical information, and any additional information that was provided.

Our Peer Reviewer determined that a quality concern(s) does/does not exist. The review findings are attached to (included in) this letter.

QIO PREPARATION NOTE:

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,*
- *Inclusion of the standard(s) identified by the QIO for each of the 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.*

This information will be entered into (QIO name) database. If (QIO name) 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 additional interventions are required. If this occurs, you will be notified in writing and given the opportunity to discuss the concern(s) with (QIO name).

If you disagree with our quality of care concern(s) determination, you may request a re-review. To request a re-review, you must submit your request in writing within [Insert the pertinent language depending on whether the review is retrospective or concurrent:

For Retrospective reviews:
15 calendar days from the date of this notice.
For Concurrent reviews:
5 calendar days from the date of this notice.]

Your written request should include the reason for your dissatisfaction with our determination and any additional information you might wish to submit. Send your written request to:

QIO Name
Address
Phone Number

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 5-8 – Re-Review Determination Letter to the Provider or Practitioner (General Quality of Care Reviews)

(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
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 Involved Parties:

(QIO name) is the Quality Improvement Organization (QIO) authorized by the Medicare program to review Medicare cases in (State) to determine if the health care services provided to Medicare beneficiaries meet professionally recognized standards of care, are medically necessary and 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.

A Peer Reviewer, not involved in the initial review, has completed the Re-Review. The Peer Reviewer determined that a quality concern(s) does/does not exist. The review findings are attached to (included in) this letter.

QIO PREPARATION NOTE:
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,*
- *Inclusion of the standard(s) identified by the QIO for each of the 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.*

This information will be entered into our database. If (QIO name) 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 additional interventions are required. If this occurs, you will be notified in writing and given the opportunity to discuss the concern(s) with (QIO name).

This Re-Review decision is FINAL and there are no further appeal rights. 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 5-9 – Retrospective Beneficiary Complaint Review Time Frames

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

Retrospective Beneficiary Complaint Review		
Review Type	**Timing**	**Reference**
INTAKE STAGE		
Intake Specialist (IS) Initial Intake of Information from beneficiary	One business day of initial contact	5110.2
IS responds to messages received after-hours	Next business day	5110.2
IS mails Complaint form	One business day of Intake	5210
Failure to return form, IS contacts beneficiary	Fifteen calendar days from mailing	5210.1
Failure to return form, IS closes complaint. Review processed as Quality of Care Review if "Serious or Urgent" concern present.	Thirty-one calendar days from mailing	5210.2
IS Uploads Form into CMS-designated case review system for RA review	One business day of receipt	5210.3
RA contacts beneficiary - orally acknowledges receipt of complaint	One business day of receipt	5220.1
RA follows up w/bene on Incomplete information rec'd	Five business days	5220.1
Requesting Medical Information		
Medical Information requested	One business day from receipt of written complaint	5220.2
Due Date of Medical Information	Ten calendar days from date of request	5220.2
Medical Information Not Received by calendar day fifteen	Follow up next business day	5220.2
Medical Information Not Received by calendar day twenty-one or thirty	Contact PO immediately	5220.2
Medical Information Not Received by calendar day twenty-one or thirty	PO calls practitioner/provider the next business day	5220.2
Medical Information Not Received, then initiate Claim Denial for providers	Calendar day twenty-three or Thirty-two	5220.2/5220.3
Medical Information Not Received by calendar day forty	Written notice sent to beneficiary	5220.2
Medical Information Received	Immediately date stamp and upload into CMS-designated case review	5220.4

	system within 1 business day	
Information missing/illegible in Medical Information	*Five calendar days to submit corrections*	*5220.4*
QUALITY OF CARE REVIEW STAGE		
RA Completes QRD Form and forwards package to IDPR	*Within three business days of receipt of Medical Information*	*5230.2/5230.3*
IDPR Completes Review and returns package to RA	*Seven calendar days from receipt of package*	*5230.3*
RA reviews IDPR decision	*Two business days from receipt*	*5230.4*
OPPORTUNITY FOR DISCUSSION STAGE		
RA offers opportunity for discussion	*Two business days from receipt of package from IDPR*	*5240.1*
Response to Opportunity for Discussion	*Fifteen calendar days from initial offer*	*5240.1*
Extension of response time for opportunity for discussion	*Additional seven calendar days in rare circumstances*	*5240.1*
RA forwards to IDPR information received during opportunity for discussion	*One business day from receipt of oral/written response*	*5240.4*
IDPR considers information received and makes Final determination	*Three business days*	*5240.4*
No response to offer of opportunity for discussion	*Fifteen calendar days then Interim Initial Determination becomes Final*	*5240.5*
RA forwards Final Initial Determination Letter and Request to Disclose	*Three business days of receipt of the QRD Form or one business day of expiration of Opportunity for Discussion if no response received*	*5240.6*
Practitioner consent to release specific findings due	*Thirty calendar days*	*5240.6*
Practitioner/Provider Request for a Re-Review	*Fifteen calendar days*	*5240.6/5250*
Preparation of final letter to beneficiary for failure to respond to the consent request	*For practitioners: One business day from receipt of consent OR one business day after thirty day period. For providers: One business day after 15 calendar days*	*5240.7*
Destruction of COPIES by IDPR	*Thirty calendar days*	*5240.8*
RE-REVIEW STAGE		
RA forwards Beneficiary Complaint Folder to RRPR	*Within one business day of receipt of request*	*5250*
RRPR Completes Re-Review and returns Folder	*Within seven calendar days*	*5250.1*
RA mails Re-Review Disclosure package	*One business day*	*5250.2*
Practitioner consent to release of findings due	*Thirty calendar days*	*5250.2*
If offered by QIO, provider	*Fourteen calendar days*	*5250.2*

comments on Re-Review Final Decision due		
RA Mails Final Decision to Beneficiary	*For practitioners: Within three business days of practitioner's consent/non-consent or no later than one business day after thirty day consent period ends. For providers: Within three business days of receipt of package from RRPR or one day from the expiration of fourteen calendar day comment period, if offered.*	*5250.3*

Appendix 5-10 – Concurrent Beneficiary Complaint Review Time Frames

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

Concurrent Beneficiary Complaint Review		
Review Type	***Timing***	***Reference***
INTAKE STAGE		
Intake Specialist (IS) Initial Intake of Information from beneficiary	*One business day of initial contact*	*5110.2*
IS responds to messages received after-hours	*Next business day*	*5110.2*
IS mails complaint form	*One business day of Intake*	*5310*
Failure to return form, IS contacts beneficiary	*Fifteen calendar days from mailing*	*5310.1*
Failure to return form, then IS closes complaint. Review processed as Quality of Care Review if "Serious or Urgent" concern present.	*Thirty-one calendar days from mailing.*	*5310.2*
IS Uploads Form into CMS-designated case review system for RA Review	*One business day of receipt*	*5310.3*
RA contacts beneficiary - orally acknowledges receipt of complaint	*One business day of receipt*	*5320.1*
RA follows up w/bene on Incomplete information rec'd	*Three business days*	*5320.1*
Requesting Medical Information		
Medical information requested	*One business day from receipt of written complaint*	*5320.2*
Due Date of medical information	*Next business day*	*5320.2*
Medical Information Not Received by calendar day forty	*Sent letter to beneficiary*	*5320.2*
Medical Information Received	*Immediately date stamp and upload into CMS-designated case review system within 1 business day*	*5320.4*
Information missing/illegible in Medical Information	*Next calendar day*	*5320.4*
QUALITY OF CARE REVIEW STAGE		
RA completes QRD form and forwards package to IDPR	*Immediately upon receipt of the medical information but no later than one business day.*	*5330.2/5330.3*
IDPR completes review and returns package to RA	*One business day*	*5330.3/5340.1*
RA reviews IDPR decision	*One business day from receipt*	*5330.4*
OPPORTUNITY FOR DISCUSSION STAGE		
RA offers Opportunity for	*One business day from receipt*	*5340.1*

Discussion		
Response time for Opportunity for Discussion	*One business day*	*5340.1*
RA forwards to IDPR information received during opportunity for discussion	*Immediately*	*5340.4*
IDPR considers information received	*No later than one business day of the receipt of the information*	*5340.4*
No response to opportunity for discussion	*Interim becomes the Final*	*5340.5*
RA forwards Final Initial Determination Letter and Request to Disclose	*Within one business day of the receipt of the updated QRD or expiration of the Opportunity for Discussion period*	*5340.6*
Practitioner consent to release specific findings due	*Thirty calendar days*	*5340.6*
Practitioner/Provider Request for a Re-Review	*Five calendar days*	*5340.6/5350*
RA sends Final Decision Letter	*For practitioners: One business day from receipt of consent OR one business day after thirty day period. For providers: One business day after 5 calendar days.*	*5340.7*
IDPR Destroys COPIES of all materials	*Thirty calendar days after Final Initial Determination*	*5340.8*
RE-REVIEW STAGE		
RA forwards Beneficiary Complaint Folder to RRPR	*One business day after receipt of request*	*5350*
RRPR completes Re-Review and returns folder to RA	*One calendar day*	*5350.1*
RA mails Re-Review Disclosure package	*One business day*	*5350.2*
Practitioner consent to release of findings	*Thirty calendar days*	*5350.2*
If offered by QIO, provider comments on Re-Review Final Decision due	*Five calendar days*	*5350.2*
RA Mails Final Decision to Beneficiary	*For practitioners: Within three business days of practitioner's consent/non-consent or no later than one business day after thirty day consent period ends. For providers: Within three business days of receipt of package from RRPR or one day from the expiration of fourteen calendar day comment period, if offered.*	*5350.3*

Appendix 5-11 – Retrospective General Quality of Care Review Time Frames

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

Retrospective General Quality of Care Review		
Review Type	**Timing**	**Reference**
INTAKE STAGE		
Intake S (IS) forwards folder to RA	One business day of receipt of referral/identification of concern	5550
Requesting Medical Information		
Medical information requested	One business day from receipt/identification of concern	5550.2
Due Date of medical information	Ten calendar days from date of request	5550.2
Medical information not received by calendar day fifteen	Follow up next business day	5550.2
Medical information Not Received by calendar day twenty-one or thirty	Contact PO immediately	5550.2
Medical Information Not Received by calendar day twenty-one or thirty	PO calls practitioner/provider the next business day	5550.2
Medical information Not Received from provider, then initiate Claim Denial	Calendar day twenty-three or thirty-two	5550.2
IS receives medical information	Immediately date stamp and upload into CMS-designated case review system within 1 business day	5550.4
Information missing/illegible in Medical information	Five calendar days to submit corrections	5550.4
QUALITY OF CARE REVIEW STAGE		
RA completes QRD Form and forwards package to IDPR	Within three business days from receipt of package from IDPR	5560.1
IDPR's completes review and returns package to RA	Seven calendar days from receipt of package	5560.2
RA reviews IDPR decision	Two business days from receipt	5560.3
OPPORTUNITY FOR DISCUSSION STAGE		
RA offers opportunity for discussion	Two business days from receipt of package from IDPR	5570.1
Response time for opportunity for discussion	Fifteen calendar days from initial offer	5570.1
Extension of response time for opportunity for discussion	Additional seven calendar days in rare circumstances	5570.1
RA forwards to IDPR information received during opportunity for discussion	One business day from receipt of oral/written response	5570.4
IDPR considers information received and makes Final	Three business days	5570.4

determination		
No response to offer of opportunity for discussion	*Fifteen calendar days, then Interim Initial Determination becomes Final*	*5570.5*
RA sends Final Determination Letter to provider/practitioner	*Three business days of receipt of the QRD Form or one business day of expiration of Opportunity for Discussion if no response received*	*5570.6*
Request for a Re-Review	*Fifteen calendar days*	*5570.6/5580*
Destruction of COPIES by IDPR	*Thirty calendar days after Final Initial Determination*	*5570.8*
RE-REVIEW STAGE		
RA forwards Beneficiary Complaint Folder to RRPR	*Within one business day of receipt of request*	*5580*
RRPR Completes Re-Review and returns Folder to IS. IS forwards to RA	*Within seven calendar days*	*5580.1*
RA prepares and mails Re-Review Determination Letter	*One business days*	*5580.2*

Appendix 5-12 – Concurrent General Quality of Care Review Time Frames

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

Concurrent General Quality of Care Review		
Review Type	**Timing**	**Reference**
INTAKE STAGE		
Intake Specialist (IS) forwards folder to RA	One Business day of receipt of referral or identification of concern	5610
Requesting Medical Information		
Medical information requested	One business day from receipt/identification of concern	5610.2
Due date of medical information	Next business day	5610.2
IS receives medical information	Immediately date stamp and upload into CMS-designated case review system within 1 business day	5610.4
Information missing/illegible in Medical information	Five calendar days to submit corrections	5610.4
QUALITY OF CARE REVIEW STAGE		
RA completes QRD Form, forwards package to IDPR	One business day of receipt of medical information	5620.1
IDPR completes review and returns to RA	One business day from receipt	5620.2
RA reviews folder	One business day	5620.3
OPPORTUNITY FOR DISCUSSION STAGE		
RA offers Opportunity for Discussion	One business day from receipt of package from IDPR	5630.1
Response time for Opportunity for Discussion	One business day from date of offer	5630.1
RA forwards to IDPR information received during Opportunity for Discussion	Immediately	5630.4
IDPR considers information received	One business day	5630.4
No response to Opportunity for Discussion	Interim Initial Determination becomes Final	5630.5
RA sends Final Initial Determination Letter	One business day of receipt of the QRD Form/package from IDPR or one business day after expiration of the Opportunity for Discussion if no response received	5630.6
Request for a Re-Review	Five calendar days	5630.7/5640
IDPR destroys COPIES of all materials	Thirty calendar days	5630.8
RE-REVIEW STAGE		
RA forwards folder to RRPR	One business day after receipt of request	5640
RRPR completes Re-Review	One calendar day	5640.1

and returns Folder to RA		
RA prepares and mails Re-Review Determination Letter	*One business day*	*5640.2*