CMS Manual System

Pub. 100-10 Medicare Quality Improvement Organizations

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

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CHAPTERS	REVISED SECTIONS	NEW SECTIONS	DELETED SECTIONS
5		Table of Contents	
5		5000 - 5050	
5 - Exhibit		Exhibits 5-15 - 5-20	

NEW/REVISED MATERIAL - EFFECTIVE DATE: August 29, 2003

Throughout Chapter 5, all references to Health Care Financing Administration (HCFA) are changed to Centers for Medicare & Medicaid Services (CMS), and all references to Peer Review Organization (PRO) are changed to Quality Improvement Organization (QIO).

Workload and Costs: These instructions do not represent an increase in workloads or costs.

NOTE: Normally red, italic font identifies new material. However, because this release is a new manual, normal text font is used for the initial release.

Quality Improvement Organization Manual

Chapter 5 - Quality of Care Review

TABLE OF CONTENTS (Rev. 9, 08-29-03)

5000 – Authority

(Rev. 9, 08-29-03)

Section 1154(a)(14) of the Social Security Act (the Act) requires you to review all written complaints received from Medicare beneficiaries or their designated representatives alleging that the quality of services (for which payment may otherwise be made under Medicare) does not meet professionally recognized standards of health care. Section 1154(a)(1)(B) of the Act requires you to conduct Fee-For-Service (FFS) quality review for the purpose of determining whether the quality of services meets professionally recognized standards of health care. Section 1154(a)(4)(B) of the Act requires you to conduct Medicare + Choice (M+C) quality review for the purpose of determining whether the quality of services meets professionally recognized standards of health care,

including whether appropriate health care services have not been provided or have been provided in inappropriate settings, and whether enrollees have adequate access to health care services. Section 1154(a)(14) of the Act also requires you to inform beneficiaries or their designated representatives of the final disposition of the complaint.

Section 1160 of the Act provides that all information gathered by you is to be kept confidential, except when release of information is expressly permitted by regulation. 42 CFR 480.32 addresses disclosure of information about patients, and 42 CFR 480.133 addresses disclosure of information about practitioners, reviewers, and institutions.

5005 - Scope of Review

(Rev. 9, 08-29-03)

Review all complaints that fall within your review jurisdiction and where the medical record is available, regardless of when the services were furnished. This includes services furnished prior to the effective date of your contract with the Centers for Medicare & Medicaid Services (CMS) (see 42 CFR 476.70). When complaints meet the statutory requirements specified in §1154(a)(14) of the Act, follow the review process detailed in §5020. When complaints do not meet these statutory requirements, follow the instructions provided in §5010. When complaints do not fall within your review jurisdiction, refer them to the appropriate entity as specified in §5015.B.

Review complaints involving FFS and services provided or arranged by a Medicare contracting Medicare + Choice Organization (M+CO) for which Medicare payment may otherwise be made when all of the following conditions are met.

A. Type of Services -- The services must be covered by Medicare regardless of whether they were covered for this particular beneficiary or whether Medicare payment was made (see 42 CFR 424.5(a)(1)). For example, review the Medicare covered services provided in a Medicare-certified Skilled Nursing Facility or Skilled Nursing Facility distinct part of a hospital, even if the beneficiary's Skilled Nursing Facility days may have been exhausted at the time. Consult the intermediary when you have questions about whether the services are covered by Medicare.

B. Source of Services -- The services must have been furnished by a health care practitioner, or an institutional or non-institutional provider of health care, including M+COs, who, at the time services were furnished, were qualified to have payment made to them (see 42 CFR 424.5(a)(2)). Sources of services include:

- Ambulatory Surgical Centers (ASCs);
- Comprehensive Outpatient Rehabilitation Facilities (CORFs);
- Emergency Rooms (ERs);

- Home Health Agencies (HHAs);
- Hospices;
- Hospital Outpatients Areas (HOPAs);
- Inpatient Hospitals/Units;
- Outpatient physical therapy and speech/language pathology services;
- Critical Access Hospitals (CAHs);
- Skilled Nursing Facilities (SNFs);
- SNF swing-beds within inpatient hospitals/CAHs;
- Specialty hospitals (e.g., psychiatric and rehabilitation);
- Physicians' offices; and
- Community Mental Health Facilities (CMHFs).

42 CFR 480.111 authorizes you to have access to and obtain medical records which are pertinent to health care services furnished to Medicare beneficiaries, and are held by any institution or practitioner in the QIO area. Review complaints involving end-stage renal disease (ESRD) services that relate to general and patient, SNF, HHA, ER, ASC, or HOPA services. Refer complaints relating to ESRD dialysis facility services or conditions to the appropriate ESRD Network organization.

NOTE: Maintain written agreements with hospitals, SNFs, HHAs, and CAHs as required by §§1866(a)(1)(F)(i) and (ii) of the Act (see Chapter 3 of the QIO Manual). As needed, you may develop written agreements with other types of providers (e.g., hospices, CORFS).

C. Recipient of Services -- The services must have been furnished while the individual was eligible to have payment made for him or her (i.e., was a Medicare beneficiary) (see 42 CFR 424.5(a)(3)). When it is not apparent that the complaint concerns a Medicare beneficiary, check the Beneficiary Eligibility Status Tapes (BEST) through the Regional Office, the Social Security Office, or the intermediary/carrier to determine Medicare status.

5010 - Complaints That Do Not Meet Statutory Requirements

(Rev. 9, 08-29-03)

As specified in §1154(a)(14) of the Act, you must conduct an appropriate review of all written complaints about the quality of services covered by Medicare which do not meet professionally recognized standards of health care if the complaint is filed with the QIO by an individual entitled to Medicare benefits for such services or by a person acting on the individual's behalf. When complaints meet these statutory requirements, follow the review process detailed in §5020. When complaints do not meet these statutory requirements, follow the review process detailed below.

NOTE: The review process detailed in this section does not apply to immediate review of notices of non-coverage (see Chapter 7 of the QIO Manual).

A. Processing Complaints Not Submitted in Writing -- When a complaint is not submitted in writing, process the complaint as follows:

- Complaints Received by Telephone or in Person -- When a complaint is received by telephone or in person, advise that the complaint must be submitted in writing. Explain that at some point (depending upon the setting in which the services were provided), you will request the beneficiary's consent to disclose his or her name to the provider/practitioner (see §5035 Subsection D). Offer assistance, when needed, in preparing the written complaint (e.g., take the information over the telephone on a summary of concern form (Exhibit 5-16), and mail the form along with a cover letter (Exhibit 5-15) and self-addressed stamped envelope to the complainant for verification and signature). Inform beneficiaries that they may designate a representative to prepare the written complaint and advise them that if they do, all subsequent correspondence will be directed to that representative (see §5010.B.1). Develop an internal plan that ensures complaints are received in writing on a fast-track basis (e.g., fax, Federal Express) when the beneficiary is still in the facility.

- Anonymous and Oral Complaints -- You are required to review any anonymous or oral complaints you believe are serious or urgent in nature and take corrective action when review findings warrant. Follow the instructions/timeframes specified in §5020 when requesting/receiving medical records, completing reviews, and providing re-reviews, as applicable (Do not acknowledge receipt of complaint). Do not send the complainant a final response since the complaint was not submitted in writing (see 42 CFR 480.132(a)(1)(i)). Do not furnish a notice of disclosure to the provider/involved practitioner since there will be no external disclosure (i.e., no final response to the complainant). If the complaint is later submitted in writing by the beneficiary or representative, furnish a notice of disclosure to the provider/involved practitioner prior to sending a final response to the complainant.

B. Processing Complaints That Are Not Submitted by Beneficiary or Require Designation of Representative -- When a complaint requires designation of a representative or is submitted by someone other than the beneficiary or representative, process the complaint as follows:

- Designation of a Representative -- A beneficiary may designate whomever he/she chooses as a representative. The designation must be submitted in writing by the beneficiary (see 42 CFR 480.132(a)(1)(ii) and Exhibit 5-16, Part B). When a complaint is submitted by someone other than the beneficiary on behalf of the beneficiary (including an advocate such as an area agency on aging, ombudsman, or congressperson), advise that he/she must be designated by the beneficiary. Develop an internal plan that ensures designation of a representative is completed on a fast-track basis (e.g., fax, Federal Express) when the beneficiary is still in the facility.

    - When the involved practitioner consents to disclosure, and the attending physician informs you that direct disclosure of your review findings would be harmful to the beneficiary, contact the beneficiary's representative (see 42 CFR 480.132(c)(2) and §5035.C). You are expected to be sensitive when contacting the beneficiary (if the beneficiary is mentally, physically, or legally unable to designate a representative, determine the representative in accordance with 42 CFR 480.132(c)(3)). When preparing your final response, explain why the response is being released to a representative rather than the beneficiary.

    - Once a representative has been designated, direct all subsequent correspondence to that representative. In those cases where the beneficiary designates a representative, send a follow-up written notice to the beneficiary to confirm the designation and to advise that all future correspondence will be sent to the representative. Do not send any further correspondence to the beneficiary. If the beneficiary is deceased, direct correspondence as specified in §10010.F. If the beneficiary should die after a representative is designated, direct correspondence to the representative previously designated by the beneficiary.

- Complaints From Other Sources -- You are required to review written complaints received from sources other than the beneficiary or representative (e.g., practitioners), and take corrective action when review findings warrant. Follow the instructions/timeframes specified in §5020 when acknowledging receipt of complaints, requesting/receiving medical records, completing reviews, and providing re-review, as applicable (tailor your acknowledgment accordingly. Include a statement advising that a thorough review will be made, but due to confidentiality requirements, you are unable to provide a final report of your review findings). Do not send the complainant a final response since the complaint was not submitted by the beneficiary or representative (see 42 CFR 480.132(a)(i)). Do not furnish a notice of disclosure to the provider/involved practitioner since there will be no external disclosure (i.e., no final response to the complainant).

C. Processing Complaints That Do Not Involve Quality Issues -- When a complaint involves a FFS utilization issue rather than a quality issue, process the complaint as follows:

- FFS Utilization Complaints -- You are required to conduct utilization review (i.e., for medical necessity/appropriateness of setting), as mandated under §§1154(a)(1)(A) and (C) of the Act when complaints involve FFS utilization issues. As with quality complaints, FFS utilization complaints must be submitted in writing by the beneficiary or representative (follow instructions in §§5010.A and B when complaints do not meet these requirements). When a complaint involves both quality and FFS utilization issues, process each issue separately. For quality issues, follow the review process outlined in §5020. For FFS utilization issue(s), follow the review process outlined below.

    - Acknowledge Receipt of Complaint -- Follow the acknowledgment requirements specified in §5020.A (when a complaint involves both quality and FFS utilization issues, one acknowledgment can be used. In these cases, tailor your notice to include the quality elements specified in §5020.A.2). Include the following information in your acknowledgment:

        - Provide a brief statement concerning your duties and functions under the Act and your case review process;

        - Reiterate the nature of the complaint;

        - State that you will conduct a complete review of the medical records and thoroughly examine all the issues raised by the complainant;

        - Explain that your review process is lengthy. Be as clear as possible in your explanation. Provide the approximate timeframe a final response can be expected. State that you will notify the complainant if you experience any delays with your review;

        - Advise that additional information/documentation can be submitted at any time; and

        - Provide the name, address, and telephone number of the QIO person the complainant should contact to provide additional information about his/her complaint or to check the progress of your review. Also, include a toll-free number if the contact number is not toll-free, or advise that you will accept collect calls if you do not have a toll-free number.

    - Request/Receive Medical Records -- Follow instructions in §§5020.B and C when requesting and receiving medical records.

- Complete Review -- Conduct utilization reviews as directed in Chapter 4, complete the Physician Reviewer Assessment Format (PRAF) when the case is referred for physician review (see §§4300-4325), and deny payment/send initial denial notices, when appropriate (see §§7100-7115). (Adhere to the confidentiality requirements specified in Chapter 10 of the QIO Manual when disclosing utilization review findings.) When conducting the review, keep in mind that over/underutilization of services may also represent a quality concern (e.g., when a procedure is found to be medically unnecessary). See §4400ff. for settings subject to utilization review.

- Conduct Reconsideration -- Conduct reconsiderations, when requested, as specified in §§7400-7440.

5015 – Referrals

(Rev. 9, 08-29-03)

A. Processing Complaints Referred From Other Entities -- Review beneficiary complaints referred from the Regional Office or other entities, such as State Agencies (SAs), carriers, intermediaries, or M+COs that meet the scope of your review (see §5005).

The SA is not required to refer all complaints to you that involve quality issues. In some States, it is the law that the SA reviews all complaints it receives. To assist you and the SA in understanding your areas of responsibility, develop a written plan with the SA that explains the types of complaints each will be responsible for reviewing, and the exchange of information involving deficiencies in survey and certification requirements or confirmed quality concerns. Involve your Regional Office Project Officer when you and the SA cannot agree on what types of issues each should review or when there are multiple issues that require Project Officer coordination/assistance. You need not submit your plan to CMS for approval. However, you must provide it to CMS upon request.

NOTE: SA means the State health agency or other appropriate State or local agency used by CMS to perform survey/certification and review functions for Medicare. You may receive complaint referrals from the SA through the Regional Office's Survey and Certification Operations Branch or directly from the SA.

B. Referring Complaints to Other Entities -- Screen each complaint to determine if it contains non-QIO issues requiring referral to another entity (e.g., M+COs). Keep in mind that the disposition of a complaint may change based upon review of the Medical record (i.e., you may determine during the course of review that there are non-QIO issues requiring referral). (Always obtain the complainant's consent prior to referral.) When a complaint involves both QIO and non-QIO issues, process your portion of the complaint as specified in §5030, and process the non-QIO issues as follows:

- Requesting Consent -- If consent/non-consent has not been received earlier in the review process, request the complainant's consent within 5 calendar days of receipt of the complaint or discovery during course of review (within 1 full working day when the beneficiary is still in the facility). You can request and receive consent either in writing or by telephone, whichever method is more expedient. When the telephone is used, document the file with a report of contact or similar method of documentation. When the complaint involves QIO and non-QIO issues, you can use your acknowledgment notices to request consent (see §5020.A).

    - Actively pursue obtaining the complainant's response (i.e., exhaust all avenues of communication). If after aggressive pursuit, you are unable to obtain a response, assume the complainant does not wish to consent to referral and advise him/her accordingly by certified mail (instances of non-response should be rare).

    - Include the following elements in your request:

        - Briefly explain your duties and functions under the Act;

        - Reiterate the nature of the complaint;

        - Explain that the complaint is not under your review jurisdiction and that you would recommend referring it to the entity responsible for review;

        - Ask that the complainant advise you (either by telephone or in writing) whether or not you can refer the complaint;

        - Provide the name, address, and telephone number (along with a contact person, if known) of the entity you will refer the complaint to if the complainant consents;

        - Advise that the responsible entity will respond directly to the complainant if you subsequently refer the complaint; and

        - Provide the name, address, and telephone number of the responsible QIO person the complainant can contact for any questions. Also, include a toll-free number if the contact number is not toll-free, or advise that you will accept collect calls if you do not have a toll-free number.

- Referring Complaint -- Refer the complaint, along with any pertinent information that may be helpful, within 5 calendar days of receipt of consent from complainant or discovery of referral issues if consent was previously received

(within 1 full working day when the beneficiary is still in the facility). Notify the complainant in writing when you refer the complaint (include elements listed in §5015.B, with modification). When consent was received by telephone, send your notification by certified mail.

- Maintain a list of other organizations that review beneficiary complaints. The list should include organizations such as the Joint Commission for the Accreditation of Health Care Organizations (JCAHO), State licensing/certification boards, insurance commission licensing boards, SAs, consumer protection division of the Attorney General's Office, offices of consumer affairs, State long-term care and other ombudsman programs, advocacy groups, Department of Health, and area and a clear explanation of the type of assistance each organization provides. QIOs are expected to use this list to identify the appropriate referral organization(s) for each situation.

- Examples of appropriate referrals include:

    - Advanced directive issues to your Regional Office Project Officer;

    - Anti-dumping issues to your Regional Office Project Officer (see §9130);

    - Billing issues to the appropriate intermediary;

    - ESRD dialysis facility services/conditions issues to the appropriate ESRD Network organization (see §5005.C);

    - Fraud and abuse issues to the appropriate Federal or State fraud and abuse enforcement agency (physicians), or appropriate intermediary (providers) (see §9200);

    - Non-coverage issues (i.e., services or items excluded from Medicare coverage such as cosmetic surgery, dental care, routine foot care, routine physical checkups, hearing aids, eyeglasses) to the appropriate intermediary, carrier, managed care plan, or insurance counseling program (see §4125 for coverage review);

    - Non-licensed personnel (e.g., housekeeping, admissions staff) issues to the appropriate state agency;

    - Physical plant issues to the Office of Survey and Certification in the CMS Regional Office, Office of Civil Rights, or the Center for Health Plans and Providers; and

- Non-immediate review request of M+C issued notices of non-coverage to the appropriate M+CO.

NOTE: Contact your Regional Office Beneficiaries Services Branch when you cannot determine the appropriate intermediary or carrier (agency) for referral, or if an intermediary or carrier incorrectly refers complaints involving billing issues to you.

5020 - Review Process

(Rev. 9, 08-29-03)

As specified in §1154(a)(14) of the Act, you must conduct an appropriate review of all written complaints about the quality of services. Beneficiary complaints must be submitted in writing, by the beneficiary or designated representative, and involve the quality of Medicare services received. When complaints meet these statutory requirements, follow the review process detailed in this section. When complaints do not meet these statutory requirements, follow the instructions contained in §5010.

The timeframes for processing beneficiary complaints depend on whether the beneficiary is still in the facility/receiving services (concurrent review) or has been discharged from the facility/is no longer receiving services (retrospective review). The timeframes for concurrent review are compressed to enable you to intervene quickly to take corrective action when a quality concern is confirmed. Whether review is concurrent or retrospective, timing of review begins when a complaint is received in writing from the beneficiary or representative, and you have adequate information to initiate the review (e.g., Health Insurance Claim number). The timeframes are the same for FFS and M+C reviews. See Exhibits 5-19 and 5-20 for retrospective and concurrent review timetables.

A. Acknowledge Receipt of Complaint -- When conducting a retrospective review, acknowledge complaint within 5 calendar days of receipt. For concurrent review, acknowledge complaint within one full working day of receipt.

- Acknowledgment Requirements -- Your initial acknowledgment can be oral. When this method of acknowledgment is used, document the file with a report of contact or similar method of documentation. Always follow-up in writing. Use this opportunity to personalize your written communication with the complainant. You may use a standardized format including use of stock language, when appropriate. When a standardized format is used, your acknowledgment must be tailored to address the particular circumstances of each complaint. Do not use form letters where you simply insert case identifying information. Re-contact the complainant whenever you experience any delays with your review and provide the reason for the delay (e.g., medical records/requested documentation are not provided timely).

- Acknowledgment Elements -- Include the following elements in your acknowledgment:

- Briefly explain your duties and functions under the Act and your beneficiary complaint review process;

- Reiterate the nature of the complaint;

- Advise that you will conduct a complete review of the medical records and thoroughly examine all the issues raised by the complainant;

- Explain the disclosure provisions (discussed in detail in §5035) that govern your final response, and advise that the final response to the complaint will include as much information responsive to the complaint as you are permitted to disclose under those provisions;

- Advise that information that explicitly or implicitly identifies the practitioner is confidential and cannot be disclosed without that practitioner's consent;

- Assure that regardless of how much information you will be able to disclose, you will take necessary action, when appropriate;

- Explain the potential for disclosing the complainant's identity to the provider/involved practitioner (see §5035.D);

- Advise that you will not reveal the complainant's identity during your review process. Once your review is completed, you are required to give the provider/involved practitioner a copy of your final response and solicit comments prior to its release to the complainant;

- Advise that the complainant's identity can be kept confidential only if he/she decides to receive a general final response from you;

- Advise that should the complainant decide to consent to disclose his or her identity, there is the further possibility that the involved practitioner may not permit disclosure of information that explicitly or implicitly identifies that practitioner, and in that case, you will send a response that includes as much information responsive to the complaint as may otherwise be provided;

- Advise that the complainant needs to inform you, either by telephone or in writing, of his/her decision (you are expected to actively pursue obtaining the complainant’s response as detailed in §5035.D);

NOTE: If you have already obtained the complainant’s response, tailor this element accordingly.

- Explain that your review process is lengthy. Be as clear as possible in your explanation. Provide the approximate timeframe a final response can be expected. Advise that you will notify the complainant if you experience any delays with your review;

- Provide the name, address, and telephone number of any other entity that can also review the complaint (see §5015 regarding maintaining a list of referral organizations);

- Advise that additional information/documentation can be submitted at any time; and

- Provide the name, address, and telephone number of the QIO hotline person the complainant should contact to provide additional information about his/her complaint or to check on the progress of your review. Also, include a toll-free number if the contact number is not toll-free, or advise that you will accept collect calls if you do not have a toll-free number.

NOTE: You may wish to use this opportunity to include information of a general nature on beneficiary outreach/marketing/communications activities or disease prevention/health promotion topics and attach related material (e.g., schedule of meetings with beneficiary groups, brochures, pamphlets, fact sheets, newsletters). Use your judgment when determining if this type of information is appropriate to include in your acknowledgment notice.

B. Request Medical Records -- When conducting retrospective review for FFS patients, request medical records from providers within 5 calendar days of receipt of the beneficiary complaint. For concurrent review, request medical records within one full working day of receipt of the beneficiary complaint. For M+C patients, request medical records through the M+CO as specified in your Memorandum of Agreement (MOA).

C. Receive Medical Records -- When conducting retrospective review, allow providers and M+COs 30 calendar days from the date of your request to photocopy and send medical records to you. When documentation is incomplete or illegible, allow an additional 15 calendar days from the date of your request for submission of the requested documentation (see §4135).

When conducting concurrent review, the provider or M+CO must submit the medical records by close of business of the next working day after receipt of your request. Develop a plan with providers and M+COs that ensures timely receipt of records (e.g., onsite review, express mail).

When an inpatient hospital (including a swing-bed provider) or Ambulatory Surgery Center fails to submit the medical records or requested documentation for a FFS patient within the prescribed timeframes, issue a technical denial and refer the problem to your

Regional Office Project Officer (see §7101.B). If the medical records/requested documentation is subsequently submitted, reopen the case and complete your review.

When other providers (including physician offices) or M+COs fail to submit medical records/requested documentation within the prescribed timeframe, refer the problem to your Regional Office Project Officer. In cases involving a FFS patient, the Project Officer will collaborate with the Division of Medicaid and State Operations to threaten revocation of the provider's Provider Agreement for failure to comply with the terms of the agreement, or if the case involves a physician's office, the Project Officer will contact the physician directly to determine why the medical record/requested documentation was not forwarded to you. In cases involving M+C beneficiaries, the Project Officer will consult with the Center for Health Plans and Providers regarding regulatory or contractual actions that may be taken.

D. Complete Quality Review -- Complete quality review (see §4105), including completion of PRAF, when applicable (see §§4300-4325). When conducting a quality review, bear in mind that:

- FFS quality review involves determining whether the quality of services meet professionally recognized standards of health care as addressed under §1154(a)(1)(B) of the Act; and

- M+C quality review involves determining whether the quality of services meet professionally recognized standards of health care, including whether appropriate health care services were not provided or were provided in inappropriate settings, and whether enrollees had adequate access to health care services as addressed under §1154(a)(4)(B) of the Act.

When you do not identify any potential quality concerns during retrospective review, complete your review and send written determination notices to the provider/involved practitioner within 15 calendar days after receipt of the medical records. When the beneficiary is still in the facility, complete your review and send written determination notices to the provider/involved practitioner within one full working day after receipt of the medical records. Include notice of disclosure in your determination notices as specified in §5020.F.

When you identify a potential quality concern during retrospective review, send a potential quality concern notice to the provider/involved practitioner within 15 calendar days after receipt of the medical records (see §7230). Afford the provider/involved practitioner 20 calendar days from the date of your notice to discuss the potential concern (see §4515). Complete your review and send written determination notices to the provider/involved practitioner within 15 calendar days of the expiration of the opportunity for the discussion period. When you identify a potential quality concern during concurrent review, solicit the views of the provider/involved practitioner prior to completing your review. Make every attempt to contact the provider/involved practitioner before you make a determination. Complete your review and send written

determination notices to the provider/involved practitioner within one full working day after receipt of the medical records. When you do not confirm a quality concern, include notice of disclosure in your determination notice as specified in §5020.F. When you confirm a quality concern, afford re-review in your confirmed quality concern notice as specified in §5020.E.

E. Afford Re-review -- When you confirm a quality concern, afford the provider/involved practitioner 30 calendar days from the date of your confirmed quality concern notice to request a re-review of your determination (see §7310). During this time, give the provider/involved practitioner the opportunity to present additional documentary materials (e.g., new evidence) for consideration.

When a re-review is requested, complete your re-review and send written re-review determination notices to the provider/involved practitioner within 15 calendar days from the date of the re-review request. Include notice of disclosure in your re-review determination notices. If a re-review is not requested, send notice of disclosure to the provider/involved practitioner upon expiration of the opportunity for the re-review period.

F. Afford Notice of Disclosure -- Afford the provider/involved practitioner 30 calendar days from the date you give notice of disclosure to respond. If the involved practitioner is not the attending physician, afford the attending physician 15 calendar days (within the 30 day notice of disclosure timeframe) to respond. See §5025 for notice of disclosure requirements.

G. Respond to Complainant -- Provide a final response to the complainant within five calendar days of the expiration of the notice of disclosure period. See §5030 for final response requirements.

5025 - Notice of Disclosure

(Rev. 9, 08-29-03)

Prior to releasing your final response to the complainant, afford the provider/involved practitioner notice of disclosure (see §5020.F. for disclosure timeframes). As specified in 42 CFR 480.105, provide notice of disclosure to allow the:

- Provider/involved practitioner to comment on your final response to the complainant;

- Involved practitioner to consent to or prohibit the disclosure of information that explicitly or implicitly identifies that practitioner (however, the involved practitioner is only permitted to consent to or prohibit the disclosure of information that explicitly or implicitly identifies that practitioner. If applicable, you should still release review findings about an involved provider, as long as the

findings to be disclosed do not explicitly or implicitly identify a practitioner, QIO reviewer, or patient who has not consented to disclosure); and

- Attending physician to render an opinion regarding the appropriateness of direct disclosure to the beneficiary (i.e., whether releasing your review findings directly to the beneficiary would be harmful).

Adhere to the disclosure requirements specified in §5035 and Chapter 10 when providing notice of disclosure.

NOTE: If the involved practitioner is not the "attending physician," do not secure the involved practitioner opinion with regard to the appropriateness of direct disclosure to the beneficiary.

A. Complaints Involving Providers -- Provider-specific information is non-confidential, except as specified in 42 CFR 480.101(b) (definition of confidential information), and disclosable as long as it does not explicitly or implicitly identify a practitioner, QIO reviewer, or a patient who has not consented to disclosure. Include the following elements in the written determination notice you send to the provider when review is completed and no quality concern is found or after re-review is afforded when a quality concern is confirmed.

- Notice to Provider -- Include the following elements in the written determination notice you send to the provider when review is completed and no quality concern is found, or after re-review is afforded when a quality concern is confirmed.

    - Ask for any comments on your final response to the complainant (see §5035.A);

    - Advise that comments must be submitted in writing within 30 calendar days from the date of your notice;

    - Advise that comments submitted to you will be attached to your final response to the complainant;

    - Provide the mailing address that comments should be submitted to and the name and telephone number of the QIO person the provider can contact with any questions. Also, include a toll-free number if the contact number is not toll-free, or advise that you will accept collect calls if you do not have a toll-free number; and

    - Send a copy of your final response as it would be sent to the complainant (do not send a copy of the actual letter addressed to the complainant).

- Notice to Attending Physician -- Also send a separate written notice to the attending physician and include the following elements:

- Ask for the attending physician's opinion regarding the appropriateness of direct disclosure of your review findings to the beneficiary. Advise that he/she needs to inform you either by telephone or in writing (see §5035.C);

- Provide the name, address, and telephone number of the QIO person the attending physician should contact to render an opinion. Also, include a toll-free number if the contact number is not toll-free, or advise that you will accept collect calls if you do not have a toll-free number; and

- Attach a copy of your final response, as it would be sent to the complainant.

B. Complaints Involving Practitioners -- When complaints involve practitioners, provide written notice of disclosure as follows:

- Notice to Involved Practitioner -- Include the following elements in the written determination notice you send to the involved practitioner when review is completed and no quality concern is found, or after re-review is afforded when a quality concern is confirmed:

    - Ask for consent to disclose to the complainant any information that explicitly or implicitly identifies the involved practitioner (see §5035.B);

    - If the involved practitioner is the attending physician, advise that he/she also needs to render an opinion regarding the appropriateness of direct disclosure of your review findings to the beneficiary (see §5035.C);

    - Advise that a response can be in writing or by telephone;

    - Ask for any comments to your final response to the complainant (see §5035.B);

    - Advise that comments must be submitted in writing within 30 calendar days from the date of your notice;

    - Advise that if he/she consents to the disclosure of information that explicitly or implicitly identifies him/her any comments submitted to you will be attached to your final response to the complainant;

    - Provide the mailing address comments should be submitted to, the title and telephone number of the QIO person to contact should the involved practitioner wish to respond by telephone regarding consent to disclosure, and the appropriateness of direct disclosure to the beneficiary. Also,

include a toll-free number if the contact number is not toll-free, or advise that you will accept collect calls if you do not have a toll-free number; and

- Attach a copy of your final response, as it would be sent to the complainant (do not send the actual copy of the letter addressed to the beneficiary).

- Notice to Attending Physician -- If the attending physician is not the involved practitioner, send a separate written notice to the attending physician and include the elements specified in §5025.A. However, do not include any information that explicitly or implicitly identifies the involved practitioner. Instead, only identify the beneficiary and the particular episode of care. In addition, do not attach a copy of your final response to the complainant.

5030 - Final Response to Complainants

(Rev. 9, 08-29-03)

After you have afforded the provider/involved practitioner notice of disclosure, release your final written response to the complainant (see §5020.G. for final response timeframes). Responses must be understandable and written in "plain English." Follow the confidentiality/disclosure requirements in §5035 and Chapter 10 when responding to complainants.

Final response model notices are provided in Exhibits 5-17 and 5-18. You are not required to use these model notices. However, if you do not, you must ensure the following elements are addressed.

A. Basic Elements for All Notices -- Include these elements in all notices to complainants:

- Heading -- Include the following information in the heading of the notice:

  - Your letterhead;

  - Date of notice;

  - Name and address of complainant; and

  - Case identifying information (Health Insurance Claim number; provider name and number; when applicable, date of admission/service; and medical record number).

- Body -- Include the following information in the body of the notice:

- A personalized salutation line (e.g., "Dear Mr. Smith" instead of "Dear Beneficiary" or "Dear Representative");

- A brief explanation of your duties and functions under the Act;

- A brief summary of the background of the case including, for example, the date of admission/services and name of facility;

- A restatement of the specifics of the complaint. Include all issues raised by the complainant; and

- The title, address, and telephone number of a QIO contact person. Also, include a toll-free number if the contact number is not toll-free, or advise that you will accept collect calls if you do not have a toll-free number.

➢ Signature -- Include the signature of the QIO physician assigned this authority. Include his/her title.

NOTE: You may wish to use this opportunity to include information of a general nature on your beneficiary outreach/marketing/communications activities or disease prevention/health promotion topics and attach related material (e.g., schedule of meetings with beneficiary groups, brochures, pamphlets, fact sheets, newsletters). Use your judgment when determining if this type of information is appropriate to include in your final response.

B. Elements for Provider-related Complaints or When Involved Practitioner Consents to Disclosure -- In addition to the elements specified in §5030.A, include these elements in the notices to complainants:

NOTE: In cases where the attending physician renders the opinion that direct disclosure could harm the beneficiary, explain why the response is being released to a representative rather than the beneficiary (see §5035.C).

➢ Advise the complainant of the provider's and involved physician's opportunity for discussion, when applicable;

➢ Advise the complainant whether the care received meets recognized standards of quality and give a complete fact-specific summary of your review findings;

➢ Detail the action you are initiating or will initiate if you confirm a quality concern. Provide specifics, when appropriate;

➢ Advise that information that explicitly or implicitly identifies a practitioner is confidential and cannot be further disclosed (do not include notices involving provider concerns); and

- Attach any comments received from the provider or involved practitioner pertaining to your final response to the complainant.

C. Elements When Involved Practitioner Does Not Consent to Disclosure -- In addition to the elements specified in §5030.A., include these elements in the notices to complainants:

- Assure that you conducted a complete review of the medical records and thoroughly examined all issues raised by the complainant;

- Explain that you are unable to provide any information that explicitly or implicitly identifies the involved practitioner because applicable regulations prohibit the release of such information without the involved practitioner's consent;

- However, if the concern also involves a provider, you should disclose review findings about the provider, as long as the findings to be disclosed do not explicitly or implicitly identify a practitioner, a QIO reviewer, or a patient who has not consented to disclosure;

- Explain that your inability to disclose information that explicitly or implicitly identifies the involved practitioner does not mean that you found any problem with the care furnished; and

- Assure that even though you are unable to disclose information that explicitly or implicitly identifies the involved practitioner, you are taking necessary action if your review warrants it. In particular, describe any quality improvement efforts you have initiated with the provider that are relevant to the issues raised in the complaint.

D. Elements When Complainant Does Not Consent to His or Her Identity Disclosure -- In addition to the elements specified in §5030.A., include these elements in the notices to complainants:

- Assure that you conducted a complete review of the medical records and thoroughly examined all issues raised by the complainant;

- Explain that you are unable to provide any information about your review findings because applicable laws and regulations prohibit the disclosure of the complainant's identity without his or her consent. Once your review is completed, you are required to give the provider/involved practitioner a copy of your final response and solicit comments prior to its release to the complainant. This required disclosure to the provider/involved practitioner for comment could result in disclosure of the complainant's identity. Because the complainant has withheld consent to disclosure of his or her identity, you cannot make the disclosure to the provider/practitioner.

- Explain that your inability to disclose your review findings does not mean that you found any problem with the care furnished, and

- Assure that even though you are unable to disclose your review findings, you are taking necessary action if your review warrants it.

5035 - Disclosure of Quality Review Information to Complainants

(Rev. 9, 08-29-03)

Disclosure of QIO quality review information is governed by Federal confidentiality regulations at 42 CFR Part 480. Apply these disclosure requirements regardless of whether a quality concern was confirmed (follow procedures contained in Chapter 10 for disclosing quality of care information to providers and practitioners).

A. Disclosing Provider Information to Complainant -- Provider-specific information is non-confidential, except as specified in 42 CFR 480.101(b) (definition of confidential information), and disclosable as long as it does not explicitly or implicitly identify a practitioner, QIO reviewer, or patient who has not consented to disclosure. Therefore, inform the complainant of your provider-specific review findings and, when applicable, what corrective action was/will be taken.

Regardless of whether a quality concern is confirmed, concurrent with the 30-day notice of disclosure period, afford the provider an opportunity to comment on your final response to the complainant prior to its release (see §5025.A). Attach any comments received from the provider (pertaining to your final response) to your final response to the complainant, or forward comments separately when received after the notice of disclosure period (see 42 CFR 480.105(a)).

B. Disclosing Practitioner Information to Complainant -- Information that explicitly or implicitly identifies a practitioner is confidential and may not be disclosed without the practitioner's consent. Therefore, concurrent with the 30-day notice of disclosure period, specifically request that the involved practitioner consent to or prohibit the disclosure of any information that explicitly or implicitly identifies him/her (see 42 CFR 480.133(a)(2)(iii)). Also, afford the involved practitioner an opportunity to comment on your final response to the complainant prior to its release (see §5025.B.1).

If the involved practitioner consents to disclosure, inform the complainant of your review findings and, when applicable, what corrective action was/will be taken. Attach any comments received from the involved practitioner (pertaining to your final response) to your final response to the complainant, or forward comments separately when received after the notice of disclosure period (see 42 CFR 480.105(b)). In accordance with 42 CFR 480.104(a)(2), advise the complainant that information concerning a practitioner is confidential and cannot be further disclosed (see §5030.B).

If the involved practitioner does not consent to disclosure, do not disclose any information that explicitly or implicitly identifies the involved practitioner. However, you should still disclose review findings about the provider, as long as the findings to be disclosed do not explicitly or implicitly identify a practitioner, a QIO reviewer, or a patient who has not consented to disclosure. Do not attach any comments received from the involved practitioner to your final response to the complainant (see §5030.C).

You are expected to actively pursue obtaining a response (i.e., exhaust all avenues of communication). Consider contacting the party around day 20 to verify that your notification was received and continue with friendly reminders after that. If after active pursuit you are still unable to obtain a response by day 35, assume non-consent to disclosure and inform the involved practitioner accordingly by certified mail (Instances of non-response should be rare). When the response is by telephone, send a written confirmation by certified mail.

C. Disclosing Patient-specific Information to the Complainant -- The following discussion does not apply if the complainant is a beneficiary representative. When the complainant is the beneficiary himself or herself, follow these instructions. Your final response to a complaint may include patient-specific information that could be harmful if released to the beneficiary. Therefore, concurrent with the 30-day notice of disclosure period, seek the involved practitioner/attending physician's opinion regarding the appropriateness of direct disclosure of your review findings to the beneficiary (see §5025 and 42 CFR 480.132(a)(2)). Do not seek the involved practitioner's/attending physician's opinion when a representative has been designated since your final response will not be released to the beneficiary.

For all complaints, seek the attending physician's opinion. If the attending physician renders an opinion that direct disclosure could be harmful to the beneficiary, develop a plan for designation of a representative as specified in §5010.B.1 (see 42 CFR 480.132(c)).

You are expected to actively pursue obtaining a response (i.e., exhaust all avenues of communication). Consider contacting the party around day 20 to verify that your notification was received and continue with friendly reminders after that. If after active pursuit, you are still unable to obtain a response by day 35, assume direct disclosure will not harm the beneficiary and inform the involved practitioner/attending physician accordingly by certified mail (instances of non-response should be rare). When the response is by telephone, send a written confirmation by certified mail.

D. Disclosing Complainant Information to Provider/Involved Practitioner -- Information related to a beneficiary complaint is confidential and may not be disclosed to the provider/involved practitioner except to the extent necessary to comply with review requirements. For example, do not release the complaint or disclose specific details of the complaint. Secondly, do not reveal the reason for your review (i.e., beneficiary complaint) when requesting medical records or providing an opportunity to discuss a potential quality concern.

However, there are two ways in which the reason for the review, and the identity of the complainant would be revealed to the provider/involved practitioner:

- To date, CMS policy has generally been that the only time a QIO should request the record for services performed in a physician's office is for the purpose of responding to a beneficiary complaint. For this reason, requesting a record from a physician's office is tantamount to notifying a physician that the person whose record you request has filed a written complaint about the physician. You should therefore notify the complainant at the outset that, in order to investigate the complaint, you must have his/her consent to divulge his/her name to the physician and explain that the reason the record is requested will be evident to the physician.

- With any complaint, regardless of setting, in the process of providing notice of disclosure, you will unavoidably disclose the complainant's identity when you give the provider/involved practitioner a copy of your final response and solicit comments prior to its release to the complainant. The complainant's identity can be kept confidential only if he/she relinquishes the right to a detailed final response from you, thereby, eliminating the need for notice of disclosure.

    - Therefore, when acknowledging receipt of the complaint, specifically request that the complainant consent to or prohibit the disclosure of his/her identity (see §5020.A.2). If the complainant consents to disclosure, afford the provider/involved practitioner notice of disclosure and send a detailed final response to the complainant (unless the involved practitioner does not consent to disclosure of information about himself or herself). If the complainant does not consent to disclosure, do not afford the provider/involved practitioner notice of disclosure, and send a general final response to the complainant (see §5030.D). You are expected to actively pursue obtaining a response (i.e., exhaust all avenues of communication). Consider contacting the complainant around day 20 to verify that your notification was received and continue with friendly reminders after that. If after active pursuit you are still unable to obtain a response, assume the complainant does not want his/her identity disclosed (i.e., relinquishes the right to a detailed final response from you), and advise him/her accordingly by certified mail (instances of non-response should be rare). When the response is by telephone, send a written confirmation by certified mail.

E. Disclosing Multiple Provider/Practitioner Information to Complainant -- When the complaint involves care provided by more than one provider, more than one practitioner, or both a provider and practitioner, inform the complainant of your review findings for each, but do not provide any information that explicitly or implicitly identifies a practitioner, QIO reviewer, or a patient who has not consented to disclosure of such information. For example, if a complaint concerns care received during an admission and

involves both provider and practitioner care, advise the complainant concerning the care provided by each. In this example, if a practitioner does not consent to disclose information that explicitly or implicitly identifies him/her, then the final response should include relevant review findings (that do not explicitly or implicitly identify that practitioner) about the care furnished by the provider. Follow the disclosure provisions for provider and practitioner information, respectively set forth in §§5025, 5030, and 5035.

5040 - Corrective Actions

(Rev. 9, 08-29-03)

You may engage in a variety of activities, including the development of corrective action plans, to improve care rendered by providers/involved practitioners when quality concerns are identified. When affording opportunity for discussion, encourage dynamic dialogue by having a telephone line available during normal working hours, and advising providers/involved practitioners of the number. Use your confirmed quality concern and re-review notices as an educational tool by clearly outlining your review findings/concerns and the preferred course of action. You may consider coordinating efforts with other entities such as intermediaries, carriers, State Agencies, CMS Regional Offices, Office of the Inspector General (OIG), or State licensing/certification boards to effectuate corrective action (in these instances, follow the disclosure guidelines specified in §10050). You may also consider initiating improvement projects, when appropriate/feasible.

If the beneficiary is still in the facility, intervene immediately to take corrective action. If you identify a potentially dangerous or life threatening situation, contact your Regional Office Project Officer immediately by telephone. The Project Officer, with input from you, will determine the appropriate course of action.

NOTE: When you identify failure by a practitioner in a substantial number of cases to comply with his/her obligations and/or a gross and flagrant violation as specified in §1156(b) of the Act and 42 CFR 1004.1(b), initiate sanction procedures as specified in §9020.

5045 - Coordination With Other Entities

(Rev. 9, 08-29-03)

Participate in the overall beneficiary complaint network with other entities such as intermediaries, carriers, State Agencies, State licensing/certification boards, insurance commission licensing boards, the JCAHO, ombudsman groups, and consumer advocacy groups. Advise these groups of your role and responsibility in investigating beneficiary complaints, and solicit information regarding their role and responsibility. Provide them

with information on how and where to send QIO-related complaints to you, and obtain similar information for referring complaints to them.

5050 - Data Analysis and Reporting Requirements

(Rev. 9, 08-29-03)

Enter your complaint review findings from the PRAF (see §5020.D) into your database for pattern analysis. On an ongoing basis, analyze your data for potential improvement projects.

Enter all beneficiary complaint data into the Standard Data Processing System (SDPS) as specified in your contract, the SDPS Database Administrator Guide, or other administrative directives. To ensure the integrity of your data, review data should only be reported under beneficiary complaints when it meets the requirements specified in §5010. All other complaint review data should be reported under case review.

Exhibit 5-15 - Request for Information Model Cover Letter

(Rev. 9, 08-29-03)

YOUR LETTERHEAD

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

Dear (Name of Inquirer):

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 _____. You may already know, we review written complaints about the quality of Medicare services received by Medicare patients. Our responsibilities include a review of medical records to determine whether services meet medically acceptable standards of services, are medically necessary, and are delivered in the most appropriate setting. Where quality concerns are identified, we provide education and feedback to practitioners/attending physicians and other medical personnel to improve the quality of services received.

Select A or B below:

A. When written inquiry is received, use:

We have received your written inquiry of (date) concerning (restate the specifics of the complaint). Before we can review your concerns, we need you to provide additional written information.

B. When telephone inquiry is received, use:

We have received your telephone inquiry of (date) concerning (restate the specifics of the complaint). Before we can review your concerns, we need you to send us your written inquiry clearly stating your concerns. We also need you to provide additional information.

Please complete the enclosed form and place it in the stamped addressed envelope we have provided. Complete all sections indicated on the form, including your signature and the date it was signed. Return that enclosed form to us as soon as possible.

If you have any questions or would like assistance in filling out the enclosed form, please contact us at:

QIO Contact Person
QIO Name
QIO Address
QIO Telephone Number
(Include toll-free number, if different)

Sincerely yours,

Enclosure (see Exhibit 5-16)

Exhibit 5-16 - Request for Information Model Form

(Rev. 9, 08-29-03)

To Conduct Our Review We Need Additional Information:

I. Identifying Information

(The QIO supplies this information.)

Please read this information carefully and make any necessary corrections.

Name of Inquirer:
Street:
City, State, and Zip Code:
Phone Number:

Date of Contact:
Name of Beneficiary:
Beneficiary's Medicare HIC Number:
Provider/Facility Name:
Dates of Service:

II. Information Needed

(The QIO may insert the appropriate paragraph(s) based on the information needed. Use typeface no smaller than 12 point.)

III. Summary of Concerns

(The QIO may use this paragraph to follow-up in writing when you have received an inquiry by telephone.) (See §5010.A.)

Your concern(s) must be sent to us in writing. To help you, we have summarized the information you gave us over the telephone. Please review our summary and make any changes you believe are necessary. You may add additional information to our summary.

IV. Request for Additional Information

(The QIO may use this lead sentence to begin your paragraph requesting specific additional information.)

In order to begin our review, we also need additional information from you. Please provide the following:

V. Consent to Refer Your Concern(s)

(The QIO may use this paragraph to request the inquirer's consent prior to referring the concern(s) to another entity for review.) (See §5020.B.)

After we begin our review of your concern(s), we may encounter issues we are unable to address. If so, we may refer your concern(s) to the appropriate agency to address those issues (for example, the Medicare contractor that pays claims). We will not refer your inquiry without your permission; therefore, please check one of the choices below.

YES _____, if necessary, you may refer my inquiry.
NO _____, you may not refer my inquiry.

VI. Consent to Disclose Your Identity

(The QIO may use these paragraphs to request consent to disclose the inquirer’s identity.) (See §5050.D.)

A. Review: Without your consent, we will not reveal your name to the practitioner(s) (or provider(s)) involved in your concern(s) during our review. Also, we will not disclose that the medical records are being reviewed.

However, when our review is completed, but before we can send you our final response detailing our review findings, we are required by law to:

1. Send a copy of the proposed disclosure to the involved practitioner and/or provider for review and comment; and

2. Obtain the involved practitioner's consent to release information that explicitly or implicitly identifies him/her.

This required action would of necessity reveal your identity.

B. Release of Findings: To avoid having your identity revealed, you can choose to receive only a general response from us stating that we have completed our review.

Even if you consent to disclose your identity and request a final response that discusses the detailed outcome of our review, the practitioner may choose not to give consent to release information that explicitly or implicitly identifies him/her. In this case, you would receive a response that includes as much information responsive to your complaint as may otherwise be provided.

Please use a checkmark below to indicate **YES** or **NO**:

YES _____, send a detailed final response to me. I understand that my identity may be revealed and that any involved doctor(s) may still not consent to disclose information that identifies him/her. If this happens, I understand that I will receive a response that includes as much information responsive to my complaint as may otherwise be provided.

NO, _____, send only a general response to me. I do not want my identity revealed.

VII. Designation of a Representative

(The QIO may use this paragraph to inform an inquirer that the beneficiary must designate him/her as the representative.) (See §5010.B.)

If you are acting on behalf of the beneficiary, that person must designate you as representative before we can review your concern(s) on their behalf. To designate you as their representative, the beneficiary (Beneficiary's Name) must complete the following:

I (Beneficiary's Name -- Print) designate (Representative's Name -- Print) who is my (State Relationship), to represent me in this matter. I understand that once I designate a representative, all following correspondence will be sent to my representative.

(Beneficiary's Signature) (Date)

VIII. Legal Authorization

(The QIO may use this paragraph to request a copy of the document(s).)

We must have documentation that you are legally authorized to act on behalf of (Beneficiary's Name). Please provide a copy of the document granting you this authority (e.g., general or durable power of attorney).

IX. Relationship to Beneficiary

(The QIO may use these data to establish the inquirer's relationship when the beneficiary is deceased.) (See §10010.F.)

We need to know your relationship to (Deceased Name). Please check the appropriate box below.

- Executor of estate
- Administrator of estate (no executor)
- Surviving spouse (no will probated)
- Next-of-kin (specify relationship)
- Other (specify)

X. Signature

Please sign and date this form below.

I, (Print Name), affirm that this information is accurate.

(Your Signature) (Date)

Exhibit 5-17 - Final Response to Inquirer Model Notice (Concern Involved Practitioner*)

(Rev. 9, 08-29-03)

YOUR LETTERHEAD

Date of Notice
Name of Beneficiary (or Representative)
Address

City, State, and Zip Code

(QIO will show Health Insurance Claim Number, Provider Name, Provider Number, Date of Admission/Service, and Medical Record Number to the letter.)

Dear (Name of Beneficiary or Representative):

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 _____. We review written complaints about the quality of Medicare services received by Medicare patients. Our responsibilities include a review of medical records to determine whether services meet medically acceptable standards of services, are medically necessary, and are delivered in the most appropriate setting. Where quality concerns are identified, we provide education and feedback to practitioners/attending physicians and other medical personnel to improve the quality of services received.

Based on your initial written concern(s) received on (date), our QIO physicians reviewed the medical records regarding the services (you or name of beneficiary) received on (date) (at name of facility or by name of facility). You were concerned about (restate the specifics of the complaint. Include all issues raised by the complainant).

Insert A, B, or C below:

A. Beneficiary (or representative) Does Not Consent to Disclosure of Beneficiary's Identity: When the beneficiary (or representative) does not consent to disclosure, include the following:

We have carefully examined your concern(s) and conducted a thorough review of the medical records pertaining to the services that (you or name of beneficiary) received. Federal regulations require us to provide a period of review and comment to the involved practitioner and to secure the involved practitioner's consent to disclose information to you that identifies him/her. Since you have informed us that you do not want your identity (or the beneficiary's identity) disclosed, we are providing you with a general response stating that we have completed our review. This does not necessarily mean that we found a problem with the services (you or name of beneficiary) received. However, we will take appropriate action if warranted by our review findings.

B. Beneficiary (or representative) Consents to Disclosure of Beneficiary's Identity But Involved Practitioner Does Not Consent to Disclosure to the Inquirer: When the involved practitioner does not consent to disclosure of information that explicitly or implicitly identifies him/her, include the following:

We have carefully examined your concern(s) and conducted a thorough review of the medical records pertaining to the services that (you or name of beneficiary) received. Federal regulations prohibit us from releasing information that identifies the involved practitioner without his or her consent. Because the involved practitioner did not give

(his or her) consent, we are unable to release information that would explicitly or implicitly identify him/her. This does not necessarily mean that we found a problem with the services (you or name of beneficiary) received. However, we will take appropriate action if warranted by our review findings.

(**NOTE:** In those cases where the attending physician renders an opinion that direct disclosure could harm the beneficiary, explain why the response is being released to a representative rather than the beneficiary.)

C. Beneficiary (or representative) Consents to Disclosure of Beneficiary's Identity and Involved Practitioner Consents to Disclosure to the Inquirer: When the involved practitioner consents to disclosure of information that identifies him/her, include the following:

Before reaching our decision, we gave (name of involved practitioner/attending physician) an opportunity to review our response concerning the services (you or name the beneficiary) received. (If appropriate, include: "Attached is a copy of (his or her) comments.")

After a thorough review of (your or name of beneficiary) medical record and any additional information provided by (name of involved practitioner/attending physician), we have determined that the services (you or name of beneficiary) received ("did not meet professionally recognized standards of quality" or "did meet professionally recognized standards of quality"). Specifically: (Give a complete fact-specific summary of your review findings, keeping in mind that you cannot disclose information that explicitly or implicitly identifies a practitioner, QIO reviewer, or patient who has not consented to disclosure).

Please note that the information concerning (name of practitioner/attending physician) contained in this letter is confidential and cannot be given out to anyone else, unless that practitioner's identity is not disclosed or (he/she) has given consent.

(**NOTE:** In those cases where the attending physician renders an opinion that direct disclosure could harm the beneficiary, explain why the response is being released to a representative rather than the beneficiary.)

After selecting A, B, or C, above, continue with the following:

(If the QIO confirmed a quality concern, insert the following: We share your concern about the quality of services (you or name of beneficiary) received and will initiate the following action: (Summarize the QIO's action in handling the concern, but ensure that you do not disclose information that explicitly or implicitly identifies a practitioner, QIO reviewer, or patient who has not consented to disclosure)).

If (you or name of beneficiary) have/has other 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)

Enclosures: (Include involved practitioner(s)/attending physician(s) and/or provider(s) comments, and informational material, when applicable and appropriate.)

*For a complaint that involves a provider and one or more practitioners, follow the guidelines in §5035.E. and prepare one response using appropriate language from both Exhibits 5-17 and 5-18.

Exhibit 5-18 - Final Response to Inquirer Model Notice (Concern Involved Provider (Facility)*)

(Rev. 9, 08-29-03)

YOUR LETTERHEAD

Date of Notice
Name of Beneficiary (or Representative)
Address
City, State, and Zip Code

(QIO will show Health Insurance Claim Number, Provider Name, Provider Number, Date of Admission/Service, and Medical Record Number at the end of the letter.)

Dear (Name of Beneficiary or Representative):

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 _____. We review medical records to determine if the services meet medically acceptable standards of services, are medically necessary, and are delivered in the most appropriate setting. We also review written inquiries about the quality of Medicare services received by Medicare patients. Where quality concerns are identified, QIOs are to provide education and feedback to providers and their medical staffs to improve the quality of services received in those facilities.

In response to (your or name of beneficiary) initial written concern, our QIO physicians have reviewed the medical records concerning the services (you or name of beneficiary) received on (date) (at name of facility or by name of facility). (You were or name of representative was) concerned about (restate the specifics of the complaint. Include all issues raised by the inquirer).

As required by Federal regulations, prior to reaching our decision we gave (name of facility) an opportunity to discuss the services (you or name of beneficiary) received. (If appropriate, include: "Attached is a copy of their comments.")

After a thorough review of your medical records and any additional information provided by the facility, we determined that the services (you or name of beneficiary) received ("did not meet professionally recognized standards of quality" or "did meet professionally recognized standards of quality"). Specifically: (Give a complete fact-specific summary of your review findings).

(**NOTE:** Provider-specific information is non-confidential, except as specified in 42 CFR 480.101(b) (definition of confidential information), and disclosable as long as it does not explicitly or implicitly identify a practitioner, QIO reviewer, or patient who has not consented to disclosure).

(If the QIO confirmed a quality concern, insert the following: We share (your or name of beneficiary) concern about the quality of services (you or name of beneficiary) received and will initiate the following action: (Summarize the QIO's actions in handling the complaint, but ensure that you do not disclose information that explicitly or implicitly identifies a practitioner, a QIO reviewer, or a patient who has not consented to disclosure)).

If (you or name of beneficiary) have/has other concerns regarding this matter, please contact us:

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)

Enclosures: (Provider comments, when applicable; and, informational material, when appropriate.)

*For a complaint that involves a provider and one or more practitioners, follow the guidelines in §5035.E. and prepare one response using appropriate language from both Exhibits 5-17 and 5-18.

Exhibit 5-19 - Beneficiary Complaint Timetable for Retrospective Review (Fee-For-Service and Managed Care)

(Rev. 9, 08-29-03)

CALENDAR DAYS TO COMPLETE

REVIEW SCENARIOS	Acknowledge Complaint/ Request Medical Records	Receive Medical Records *	Complete Review	Provide Opportunity for Discussion	Complete Review	Provide Opportunity for Re-Review	Complete Re-Review	Provide Notice of Disclosure	Respond to Complaint	Total Days
No Quality Concern Found	5	30	15	NA	NA	NA	NA	30	5	85
Quality Concern Resolved	5	30	15	20	15	NA	NA	30	5	120
Quality Concern Confirmed, Re-Review Not Requested	5	30	15	20	15	30	NA	30	5	150
Quality Concern Confirmed, Re-Review Requested	5	30	15	20	15	30	15	30	5	165

*If documentation is incomplete or illegible, allow an additional 15 days for submission of requested information. Total timeframe will increase accordingly.

Exhibit 5-20 - Beneficiary Complaint Timetable for Concurrent Review (Fee-For-Service and Managed Care)

(Rev. 9, 08-29-03)

CALENDAR DAYS TO COMPLETE

REVIEW SCENARIOS	Acknowledge Complaint/ Request Medical Records	Receive Medical Records *	Complete Review	Provide Opportunity for Re-Review	Complete Re-Review	Provide Notice of Disclosure	Respond to Complaint	Total Days
No Quality Concern Found	1	1	1	NA	NA	30	5	38
Quality Concern Confirmed, Re-Review Not Requested	1	1	1**	30	NA	30	5	68
Quality Concern Confirmed, Re-Review Requested	1	1	1**	30	15	30	5	83

*Represents full working days.
**Includes opportunity for discussion.