Medicare
Peer Review Organization Manual

Department of Health and Human Services (DHHS)
HEALTH CARE FINANCING ADMINISTRATION (HCFA)

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HEADER SECTION NUMBERS	PAGES TO INSERT	PAGES TO DELETE
Table of Contents - Part 5	5-1 - 5-1 (1 p.)	5-1 - 5-1 (1 p.)
5020 - 5050	5-11 - 5-21 (11 pp.)	5-11 - 5-20 (10 pp.)
Exhibit 5-16 (Cont.) - Exhibit 5-19	5-73 - 5-80 (8 pp.)	5-73 - 5-80 (9 pp.)

NEW/REVISED MATERIAL--*EFFECTIVE DATE: JANUARY 22, 2001*

Section 5020, Review Process, is revised to specify that the Peer Review Organization (PRO) will advise the beneficiary that the final response to the complaint will include as much information as permitted under the disclosure provisions. This section also clarifies that any information which explicitly or implicitly identifies the practitioner, is confidential and cannot be disclosed without the practitioner's consent.

Section 5025, Notice of Disclosure, is revised to specify that the PRO should release review findings about an involved provider even when an involved practitioner does not consent to disclosure of information about himself or herself. The involved practitioner is only permitted to consent to or prohibit the disclosure of information that explicitly or implicitly identifies that practitioner. This section also clarifies that 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, patient, or PRO reviewer who has not consented to disclosure.

Section 5030, Final Response To Complainants, is revised to clarify that if a complaint involves a practitioner and a provider, the PRO should disclose review findings about the provider, as long as the findings to be disclosed do not explicitly or implicitly identify a practitioner, PRO reviewer, or patient who has not consented to disclosure. The involved practitioner is only permitted to consent to or prohibit the disclosure of information which explicitly or implicitly identifies that practitioner. If the PRO is unable to disclose information about a practitioner, the PRO ensures that necessary action will be taken, and in particular, it will describe any quality improvement effort initiated with the provider that is relevant to the issues of the complaint.

Section 5035, Disclosure of Quality Review Information To Complainants, is revised to clarify that if the practitioner's consent is not secured, the PRO should still disclose review findings about a provider, as long as the findings to be disclosed do not explicitly or implicitly identify a practitioner, PRO reviewer, or patient who has not consented to disclosure. Only information that explicitly or implicitly identifies the practitioner may not be disclosed without the practitioner's consent. The note in §C has been deleted.

Exhibit 5-16, Request for Information Model Form, is revised to state that practitioner consent must be obtained in order to release information that explicitly or implicitly identifies him/her. In addition, the exhibit explains that even if the beneficiary consents to disclose his or her identity, the physician may choose not to give his or her consent to release information that explicitly or implicitly identifies him/her. The PRO will then send a response to the beneficiary that includes as much information responsive to the beneficiary's complaint as permitted under the disclsoure provisions.

Exhibit 5-17, Final Response to Inquirer Model Notice (Concern Involved Practitioner*), is revised to add an asterisk to the title to call the PROs attention to the instructions written at the bottom of Exhibit 17. The PRO is directed to follow the guidelines in section 5035E and prepare one response using appropriate language from both Exhibits 5-17 and 5-18 for a complaint that involves a provider and one or more practitioners. Exhibit 5-17 is also revised to delete the "select" option under existing paragraph A, and to specify that the PRO is required to provide a period of review and comment to the involved practitioner and secure the involved practitioner's consent to disclosure of information about himself/herself. The title of paragraph B is revised as follows: Beneficiary (or representative) Consents to Disclosure of Beneficiary's Identity but Involved Practitioner Does Not Consent to Disclosure to the Inquirer. Finally, a new paragraph C is being added for situations where the beneficiary or his or her representative consents to disclosure of the beneficiary's identify and the involved practitioner consents to disclosure of information identifying him or her.

Exhibit 5-18, Final Response to Inquirer Model Notice (Concern Involved Provider (Facility)*), is revised to add an asterisk to the title to call the PROs' attention to the instructions written at the bottom of Exhibit 18. The PRO is directed to follow the guidelines in §5035E and prepare one response using appropriate language from both Exhibits 5-17 and 5-18 for a complaint that involves a provider and one or more practitioners. A note was added to explain that provider-specific information, including review findings, 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, PRO reviewer or another patient who has not consented to disclosure.

PART 5

BENEFICIARY COMPLAINT REVIEW

Exhibits

o Noncoverage 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);

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

o Physical plant issues to the Office of Survey and Certification in the HCFA RO, Office of Civil Rights, or the Center for Health Plans and Providers; and

o Non-immediate review request of M+C issued notices of noncoverage to the appropriate M+C organization.

NOTE: Contact your RO 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

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 time frames 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 time frames 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 time frames 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.

1. 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. Recontact 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).

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

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

o Reiterate the nature of the complaint;

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

o 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; and

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

o 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; and;

- 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.

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

o 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);

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

o Provide the name, address, and telephone number of the PRO 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+C organization as specified in your MOA.

C. Receive Medical Records.--When conducting retrospective review, allow providers and M+C organizations 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+C organization 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+C organizations that ensures timely receipt of records (e.g., on-site 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 time frames, issue a technical denial and refer the problem to your RO 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+C organizations fail to submit medical records/requested documentation within the prescribed time frame, refer the problem to your RO 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 time frame) 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

Prior to releasing your final response to the complainant, afford the provider/involved practitioner notice of disclosure. (See §5020.F for disclosure time frames.) 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, PRO reviewer, or patient who has not consented to disclosure);
- 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 Part 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 480.101(b) (definition of confidential information), and disclosable as long as it does not explicitly or implicitly identify a practitioner, PRO 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.

1. 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.

o 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; and

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

o Provide the mailing address that comments should be submitted to and the name and telephone number of the PRO 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

o 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.)

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

o 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);

o Provide the name, address, and telephone number of the PRO 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

o 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:

1. 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:

o 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); and

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

o 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; and

- 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;

o Provide the mailing address comments should be submitted to, the title and telephone number of the PRO 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

o 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.)

2. 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 subsection A.2. 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

After you have afforded the provider/involved practitioner notice of disclosure, release your final written response to the complainant. (See §5020 subsection G for final response time frames.) Responses must be understandable and written in "plain English." Follow the confidentiality/disclosure requirements in §5035 and Part 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:

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

o Your letterhead;

o Date of notice;

o Name and address of complainant; and

o Case identifying information (health insurance claim number; provider name and number; when applicable, date of admission/service; and medical record number).

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

o A personalized salutation line (e.g., "Dear Mr. Smith" instead of "Dear

Beneficiary" or "Dear Representative");

- o A brief explanation of your duties and functions under the Act;
- o A brief summary of the background of the case including, for example, the date of admission/services and name of facility;
- o A restatement of the specifics of the complaint. Include all issues raised by the complainant; and
- o The title, address, and telephone number of a PRO 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.

3. Signature.--Include the signature of the PRO 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.)

- o Advise the complainant of the provider's and involved physician's opportunity for discussion, when applicable;
- o Advise the complainant whether the care received meets recognized standards of quality and give a complete fact-specific summary of your review findings;
- o Detail the action you are initiating or will initiate if you confirm a quality concern. Provide specifics, when appropriate;
- o 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
- o 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 subsection A, include these elements in the notices to complainants:

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

o 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 PRO reviewer, or a patient who has not consented to disclosure;

o 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

o 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:

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

o 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

Disclosure of PRO 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 Part 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, PRO 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 PRO 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:

o To date, HCFA policy has generally been that the only time a PRO 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.

o 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 subsection 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, PRO 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

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, SAs, HCFA ROs, 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 RO 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

Participate in the overall beneficiary complaint network with other entities such as intermediaries, carriers, SAs, 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 PRO-related complaints to you, and obtain similar information for referring complaints to them.

5050. DATA ANALYSIS AND REPORTING REQUIREMENTS

Enter your complaint review findings from the PRAF (see §5020 subsection D) into your data base 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 Data Base 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.

VI. CONSENT TO DISCLOSE YOUR IDENTITY

(The PRO 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 check mark 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.

Exhibit 5-16 (Cont.)

Request for Information Model Form

VII. DESIGNATION OF A REPRESENTATIVE

(The PRO may use this paragraph to inform an inquirer that the beneficiary must designate him (or her) as the representative.) (See §5010.B.1.)

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, _____ designate _____
(Beneficiary's Name--Print) (Representative's Name--Print)

who is my_____, to represent me in this matter. I understand that once I
(State Relationship)

designate a representative, all following correspondence will be sent to my representative.

_____ _____
(Beneficiary's Signature) (Date)

VIII. LEGAL AUTHORIZATION

(The PRO 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 PRO 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.

o _____ Executor of estate.

o _____ Administrator of estate (no executor).

o _____ Surviving spouse (no will probated).

o _____ Next-of-kin (specify relationship).

o Other (specify):

X. SIGNATURE

Please sign and date this form below:

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

_____ _____
(Your signature) (Date)

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

YOUR LETTERHEAD

Date of Notice:

Name of Beneficiary (or Representative):

Address:

City, State, and Zip Code:

(PRO will show HIC #, Provider Name, Provider Number, Date of Admission/Service, and Medical Record Number to the letter.)

Dear (Name of Beneficiary or Representative):

The (PRO name) is the Peer Review Organization (PRO) 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 PRO 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 through 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:

Exhibit 5-17 (Cont.)

Final Response to Inquirer Model Notice
(Concern Involved Practitioner*)

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, PRO 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 PRO 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 PROs' action in handling the concern but ensure that you do not disclose information that explicitly or implicitly identifies a practitioner, PRO 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 PRO
Address (including zip code)
Telephone Number (include toll-free number, if different)

Exhibit 5-17 (Cont.)

Final Response to Inquirer Model Notice
(Concern Involved Practitioner*)

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 section 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)*)

YOUR LETTERHEAD

Date of Notice:

Name of Beneficiary (or Representative):

Address:

City, State, and Zip Code:

(PRO will show HIC #, 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 (PRO name) is the Peer Review Organization (PRO) 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, PROs 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 (you or name of beneficiary) initial written concern, our PRO 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, PRO reviewer, or patient who has not consented to disclosure).

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

(If the PRO 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 PROs' actions in handling the complaint but ensure that you do not disclose information that explicitly or implicitly identifies a practitioner, a PRO 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 PRO
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 section 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
(FFS and Managed Care)

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 time frame will increase accordingly