Medicare
End Stage Renal Disease Network Organizations Manual

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

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NEW/REVISED MATERIAL--*EFFECTIVE DATE: October 25, 2002*

All references to the Health Care Financing Administration (HCFA) have been changed to its new designation, the Centers for Medicare & Medicaid Services (CMS).

Sections 745 through 780, the ESRD Grievance sections of Part 7, have been revised and renumbered as §§750 - 795.

Section 700, Authority, references to the Health Care Financing Administration (HCFA) have been changed to its new designation, the Centers for Medicare & Medicaid Services (CMS).

Section 705, Network's Role Prior to Initiating Sanction Recommendation, changes a regulatory citation from 42 CFR 476.137 to 42 CFR 480.137.

Section 720, Project Officer (PO) Role in Sanction Procedures, Health Care Financing Administration (HCFA) have been changed to its new designation, the Centers for Medicare & Medicaid Services (CMS).

Section 735, Duration and Removal of Alternative Sanction, Health Care Financing Administration (HCFA) have been changed to its new designation, the Centers for Medicare & Medicaid Services (CMS).

Section 750, Definitions for the ESRD Complaint and Grievance Process, contains definitions you are to use in reference to the grievance and complaint process.

Section 755, ESRD Complaints and Grievances, states the statutory authority for you to investigate, make determinations, and resolve grievances.

Section 760, Role of Network in Handling a Complaint/Grievance, describes the various roles you might assume in resolving a grievance.

Section 765, ESRD Complaint and Grievance Process, describes the sequence of activities when handling a complaint.

Section 765.1, Facility Awareness of the Complaint/Grievance Process, describes the requirement to educate complainant about the grievance process.

Section 765.2, Use of Facility Complaint/Grievance Process, describes the use of required facility grievance protocols.

Section 765.3, Determination of Your Involvement, describes when you should become involved in resolving grievances.

Section 765.4, Receiving a Complaint/Grievance, describes the types and sources of grievances received.

Section 765.5, Request of Grievance in Writing, describes the request for a grievance to be submitted in writing.

Section 765.6, Referring Complaints and Grievances, describes how, when, and to whom complaints and grievances should be referred.

Section 765.7, Written Acknowledgment of Grievances, describes the requirement for a written acknowledgment of a grievance.

Section 765.8, Investigation of Complaints and Grievances, describes the procedure for investigating a complaint or a grievance.

Section 765.9, Life-Threatening Situations, describes your response to life-threatening situations.

Section 765.10, Challenging Patient Situations, describes your response to challenging patient situations.

Section 765.11, Advocating for Patient Rights, describes how you should advocate for patient rights with the understanding that the patient is responsible for his/her behavior.

Section 765.12, Addressing a Complaint or Grievance, describes your procedures for addressing a complaint or grievance.

Section 765.13, Follow-up of a Grievance, requires you to follow-up with the complainant after resolving a complaint.

Section 765.14, Conclusion of a Grievance Investigation, describes the procedure for concluding an investigation.

Section 770, Report and Letter to the Grievant, describes the required contents of your report.

Section 775, Potential Outcomes of Complaint/Grievance Process, describes several possible outcomes for the resolution of beneficiary grievances.

Section 780, Improvement Plans (IPs), describes the method designed to correct a problem or pattern of questionable care you have identified.

Section 780.1, Content of IPs, describes what the facility must provide in its IP.

Section 780.2, Time Periods for Review and Acceptance/Rejection of IPs, describes the parameters for acceptance/rejection of IPs.

Section 780.3, IP Tracking System, requires you to track all IPs in the Standard Information Management System (SIMS).

Section 780.4, Conclusion of IP, describes the procedure to follow at the conclusion of the approved time period for completion of the IP.

Section 780.5, Non-Compliance With IP, describes the procedure to follow if the facility has not complied with the IP.

Section 785, Confidentiality and Disclosure of Information, describes confidentiality requirements.

Section 785.1, Identity of Complainant/Grievant, describes the requirement to obtain permission before releasing a complainant's identity.

Section 785.2, Identity of Practitioner, describes the requirement to obtain permission before releasing a practitioner's identity.

Section 785.3, Identity of Facility, permits you to release identity of facilities involved in grievances with substantiated care issues.

Section 790, Personal Representative, describes the delegation of a patient representative.

Section 795, Conflict of Interest, describes potential conflicts of interest.

Exhibit 7-1, ESRD Network Complaint Process, is a new flow chart outlining the complaint process.

Exhibit 7-2, ESRD Grievance Process, is a new flow chart outlining the grievance process.

Exhibit 7-3, ESRD Inquiry Process, is a new flow chart outlining the inquiry process.

Exhibit 7-4, Time Table for Complaints and Grievances, provides a summary timetable for your complaint and grievance process.

Exhibit 7-5, Model Response Letter of Acknowledgement of a Written Complaint/Grievance, is a model of a letter you may use to respond to a complaint/grievance.

Exhibit 7-6, Consent to Disclose Identity – Model Form, provides a model of a letter to request the complainant's consent to be identified.

Exhibit 7-7, Designation of a Representative – Model Form, is a form you may provide an inquirer to have the beneficiary designate him or her as a representative.

Exhibit 7-8, Final Response to Grievant – Model Letter, is an example of a final response letter to the complainant of the result of your grievance investigation.

PART 7

SANCTIONS AND ESRD GRIEVANCES

Sanctions

ESRD Grievances

PART 7

SANCTIONS AND ESRD GRIEVANCES

Exhibits

Section

Sanctions

700. AUTHORITY

If a facility or provider fails the requirement in §1881(c)(3) of the Act to cooperate in achieving the goals and plans of the Network of ESRD facilities to which it belongs, and that failure does not jeopardize patient health and safety, the Centers for Medicare and Medicaid Services (CMS)-formerly known as the Health Care Financing Administration- regional office (RO), the Secretary's designee, may impose sanctions as an alternative to terminating coverage of ESRD services furnished by that supplier. (See 42 CFR 405.2181.)

705. NETWORK'S ROLE PRIOR TO INITIATING SANCTION RECOMMENDATION

The Network must have a plan for monitoring facilities'/providers' compliance with Network goals. Your plan for monitoring facility's/provider's compliance with Network goals must be distributed to CMS and to all facilities/providers in the network area. You must use your monitoring plan to identify facilities/providers that consistently fail to cooperate with Network plans and goals or to follow the recommendation of the Medical Review Board (MRB).

If you identify a facility that is not cooperating with you in meeting your goals and objectives and are considering recommending a sanction to the RO serving the involved facility, discuss the situation with your project officer (PO). Consult your PO or Survey and Certification Branch for guidance if you are uncertain whether you have enough documentation to proceed with the sanction recommendation. If after 3 months, you have exhausted all reasonable efforts to gain facility compliance, and have documented that the facility has failed to cooperate with Network goals and objectives, you may recommend to the RO the imposition of an alternative sanction. (See 42 CFR 405.2181.) Alternative sanction recommendations must be facility focused, not physician focused. However, physicians who fail to comply with the Network performance goals to such a degree that they are considered to be failing to meet their obligation to provide quality care must be referred to the Quality Improvement Organization (QIO) or the Office of the Inspector General and/or the Board of Examiners for Physicians. Before you submit an alternative sanction recommendation to your PO, document the details of the situation and that the facility is still not in compliance with Network goals and plans, including the following deficiencies:

- Consistently fails to cooperate with and meet performance expectations in regards to Network plans or goals as specified in your contract with CMS;
- Consistently fails to follow recommendations of the MRB;
- Fails to permit the Network MRB, without just cause, to conduct an on-site review; or
- Fails to submit data as required so that you can prepare your Network Annual Report.

All fraud and abuse cases should be referred to Federal or State fraud and abuse enforcement agencies responsible for the investigation or identification of fraud or abuse in the Medicare or Medicaid programs. (See 42 CFR 480.137.)

710. WRITTEN DOCUMENTATION REQUIREMENTS FOR SANCTION RECOMMENDATION

To support your recommendation that an ESRD facility should be recommended for an alternative sanction, provide the RO with the following written documentation which can be in the form of written correspondence between the facility and you, written notes, and/or contact reports documenting telephone conversations:

- Documentation that the facility was notified in writing of your goals and objectives;
- Documentation of the goal, objective, or plan that the facility has failed to meet;
- Actions you took to inform the facility that it was not complying with your goals, objectives, or plans;
- Documentation that the facility was given an opportunity to make corrections;
- Follow-up actions you took to resolve the problem (e.g., documentation of phone calls to the facility asking for specific information) which demonstrate your attempts to work with the facility to resolve the problem; and
- Documentation of the facility's failure to submit an action plan, or the submission of an unacceptable action plan, if applicable.

If the facility's failure to meet the Network's goals, plans, etc., causes you to fail to meet your statutory contractual obligations, you must take action. Use your professional judgment in deciding when you have provided enough assistance to the facility. A maximum time of 3 months is allowed for the facility to meet the Network's goals, plans, etc.

715. FORWARDING SANCTION RECOMMENDATION TO APPROPRIATE REGIONAL OFFICE (RO)

Alert your RO Project Officer (PO) of your intent to recommend a sanction after you have fully documented, in writing, the facility's failure to comply with your goals and objectives. Submit two copies of your documentation and a cover letter addressed to the appropriate Associate Regional Administrator (ARA) through your RO PO and include:

- The name, address, and Medicare provider number of the facility;
- The Network goal or objective with which the facility failed to comply;
- A brief summary of the basis for the sanction recommendation;
- An outline of what documentation and action the facility must submit and follow in order to remove the sanction;
- The individual in the Network whom the RO can contact for further information and assistance; and
- The name and phone number of your PO.

Organize the information in notebook form with a chronological summary and a table of contents.

NOTE: Appropriate RO is defined as the RO that services the State where the facility is located.

720. PROJECT OFFICER'S (PO) ROLE IN SANCTION PROCEDURES

The RO PO forwards the sanction recommendation for processing to the ARA of the RO that services the State where the facility is located. The PO will also alert CMS CO of a potential sanction action against an ESRD facility.

725. RO ROLE IN SANCTION PROCEDURES

The RO (Survey and Certification Branch) has the responsibility for implementation of an alternative sanction recommendation. When an alternative sanction recommendation is received, the RO will:

- Review the sanction recommendation for completeness, and determine if there is sufficient information to process the sanction recommendation and the type of sanction to impose;

- Notify the RO Survey and Certification Branch and the State survey agency of the potential sanction action to determine if there has been any State action past or pending;

- Select the mechanism that provides the most effective means to encourage the facility to come into compliance with the requirement; and

- Review the sanction recommendation and make the final determination whether or not to sanction a facility.

If additional information and/or assistance is needed to process the case, the RO will contact you.

730. RO ROLE IN NOTICE AND APPEAL RIGHTS

The RO Survey and Certification Branch notifies the facility of the alternative sanction and its effective date. The effective date of the sanction is at least 30 days after the date of the notice.

When the RO proposes to apply an alternative sanction, the facility is given written notice of the proposed sanction and 15 days in which to request a hearing. Unless the facility requests a hearing within 15 days, the RO notifies the Network and the public about the reasons for the sanction and when it will take effect. If the facility requests a hearing, the RO will provide an informal hearing by an official who was not involved in making the sanction decision. During the informal hearing, the facility:

- May be represented by counsel;

- Has access to the information on which the allegation was based; and

- May present oral or written evidence and documentation to refute the finding of failure to participate in Network activities and pursue Network goals.

If the written decision, based on the informal hearing, supports application of the alternative sanction, the RO, at least 30 days before the effective date of the sanction, will provide the facility with a second written notice that specifies the effective date of and the reasons for the sanction. The RO will notify the Network and the public of the sanction.

735. DURATION AND REMOVAL OF ALTERNATIVE SANCTION

An alternative sanction remains in effect until the facility is in substantial compliance with the requirements to participate in your Network's activities and pursue your Network's goals, or the facility is terminated from the Medicare program by the CMS RO for lack of compliance. The RO will remove the alternative sanction when the facility demonstrates and documents that the reason for the sanction is eliminated. The RO may ask for your assistance in verifying the facility's compliance with the requirements.

When a sanction is based on failure to participate in Network activities (see 42 CFR 405.2134) and pursue Network goals, the sanction action can be removed when CMS finds that the supplier of ESRD services is making a reasonable effort to comply with the statutory requirement.

740. QUALITY OF CARE REFERRALS

If at any time while conducting your contract activities, you identify situations or collect information which indicates that a physician may be failing to meet his/her obligation to provide quality care, refer the issue to the appropriate QIO for peer review or Office of Inspector General and the Board of Examiners for Physicians for follow-up. Concurrently, advise your PO of the situation and your actions.

750. DEFINITIONS FOR THE ESRD COMPLAINT AND GRIEVANCE PROCESS

Closed – A complaint or grievance has been handled to the extent available to Network resources. (See §775 A.).

Complaint – A written, verbal, or electronic request for assistance initiated by or on behalf of an ESRD patient(s) regarding concern(s) about ESRD issues including but not limited to care, treatment, or providers.

Complainant – An individual who expresses a concern by filing a complaint.

Grievance – A request for a formal investigation of a complaint, or a serious complaint involving a facility, physician, or other provider.

Grievant – An individual who expresses a concern through a formal process by filing a grievance.

Inquiry – A written, verbal, or electronic request from individuals or facilities for information, referral, or educational materials that usually does not require problem resolution.

Medicare Beneficiary – An individual who, due to age, disability, or end stage renal disease, is entitled to receive benefits under Medicare.

Personal Representative – An individual designated to represent another individual for a designated reason and a specific length of time. (See §790)

Referred – The complainant or grievant has been directed to the agency or individual that can most appropriately respond to the complaint or grievance. Or the complainant/grievant has been given the appropriate contact information for the best agency or individual to assist him/her with the concern and will make the contact himself/herself. (See §765.6 and §775.C)

Reopened – A previously closed complaint or grievance that has reoccurred. (See §775D.)

Resolved – The complaint or grievance has been explained, corrected, or settled by the Network so that the complainant is in agreement with the determination or outcome. (See §775B.)

755. ESRD COMPLAINT AND GRIEVANCES

Section 1881(c)(2)(D) of the Act and CMS regulations at 42 CFR §405.2112 (g) require you to implement procedures for evaluating and resolving patient grievances. In addition, the Omnibus Budget Reconciliation Act amended the Act in 1989 to provide ESRD Network Organizations with confidentiality in the medical review process (see §1160 of the Act) and a limitation on your liability. (See §1157 of the Act.)

It is your responsibility to assure that an impartial review of grievances occurs without conflict of interest. (See §795.)

760. ROLE OF THE NETWORK IN HANDLING A COMPLAINT/GRIEVANCE

Your role in resolving a complaint, grievance, or inquiry will vary, depending upon the situation. The following are examples of different roles that you may assume:

A. Expert Investigator.--When the quality of care provided to a patient(s) is an issue, the investigation's focus is the individual complaint and any overall patterns of care within the facility related to the complaint. For example, if a patient complains about the procedures used to initiate dialysis, investigate the complaint by reviewing the techniques used by the facility to initiate dialysis on potentially affected patients.

B. Facilitator.--When communication between the patient and the facility is problematic, your role may be to facilitate communication and the resolution of differences.

C. Advocate.--You should advocate for individual patient rights and/or the rights of all patients at a facility, depending on the situation presented. There may be situations when you must act for the greater good, such as with threatening or violent patients.

D. Referral Agent.--Issues not specifically ESRD Network issues, such as staff safety, compliance with the Conditions for Coverage (CfC), and fraud, are handled by either SAs or other local, State, or Federal agencies. Each Network must maintain a list of appropriate local, State, and Federal resources to use as referrals for beneficiaries and/or complainants in need of assistance.

E. Coordinator.--Where potentially serious quality of care concerns and/or Conditions for Coverage (CfC) issues are involved, alert the appropriate Regional Office (RO) and your Regional Office Project Officer (RO PO) immediately and coordinate your investigation with the SA in order to avoid duplication of effort and conflicting outcomes.

F. Educator.--When patients, families or facility staff request or require information/education about ESRD, treatment of ESRD, or appropriateness of care, you may act as an educator providing the requested information or a referral to an appropriate resource.

765. ESRD COMPLAINT AND GRIEVANCE PROCESS

You are responsible for implementing a procedure for receiving, evaluating, and resolving complaints/grievances by determining the appropriate action(s) needed to assist the complainant and to resolve the concern. (Refer to §750.) Document all complaints and grievances in SIMS. It is expected that most complaints will be resolved quickly and will not become a formal grievance.

You may, in resolving a complaint involving patient care, gather information on the telephone, by letter/email or by conducting on-site reviews or performing other investigative activities concerning care provided by a facility or a provider as appropriate (as determined by the MRB and 42 CFR 405.2112). In making a determination, you should utilize recognized standards of care to assure proper treatment for ESRD patients.

If there is resolution of the complaint through your intervention as an advocate, facilitator, or educator, the informal complaint process may be used and the formal grievance process is not required. However, if you are requested by the beneficiary to conduct a formal review and evaluation, or if a formal process is the best way to address a complaint, the formal grievance process should be initiated. (See Exhibit 7-1, ESRD Network Complaint Process and Exhibit 7-2, ESRD Grievance Process).

765.1 Facility Awareness of the Complaint/Grievance Process.--Provide all new ESRD patients in your jurisdiction with information about patient's rights and how to file a complaint or grievance with you and with the State survey agency. Provide your toll-free number. In addition, assure that each facility is aware of its responsibility to inform its patients of the facility's grievance procedure (in accordance with 42 CFR §405.2138(e)).

765.2 Use of Facility Complaint/Grievance Process.--All ESRD patients should be informed about the facility complaint/grievance process and encouraged to use it before requesting your assistance. However, there may be instances when the patient does not wish to approach the facility staff or provider and requests your assistance. It is not mandatory that patients utilize the facility grievance process before contacting you.

For example, a patient may be concerned about the attitudes of the staff at the facility, but is afraid to approach the facility staff for fear of retribution. In this instance, you may investigate and try to resolve the problem, or refer it to an appropriate agency (see §765.3). If you refer the complaint to the SA, your activities should be coordinated with the SA and the RO to avoid duplication of effort and ensure the best outcome for the patient.

You are responsible for acting on all complaints or grievances directed to you. You are not expected to monitor web sites for quality of care issues.

765.3 Determination of Your Involvement.--You have the authority under §1881 (c)(2)(D) of the Act to act on all complaints/grievances regarding a Medicare certified facility or made by a Medicare beneficiary alleging a facility's failure to provide care and services to which beneficiaries are entitled. All complaints alleging a situation that you believe could affect the health or safety of beneficiaries should be acted on immediately by the Network and may be referred to the SA or other appropriate authority. You may have a confidential conversation with the SA or other appropriate authority in order to determine whether the case should be referred.

It is important for you to determine if the complaint/grievance is an issue appropriately handled by the Network or if it should be referred. Make a preliminary determination when the complaint is first received. Then make a final determination after you have gathered information about the complaint/grievance. You may refer a complaint or grievance at any time during the complaint/grievance process.

765.4 Receiving a Complaint/Grievance.--You may receive a written or verbal inquiry, complaint, or grievance from an ESRD patient, a personal representative (see §790), a family member, a friend, a facility employee, a physician, a federal or State agency, a patient advocate, or a concerned individual. In addition, other sources, such as the media, may make you aware of quality of ESRD care issues that should prompt an investigation. You may be requested to investigate certain cases by your RO PO. You may also receive referrals of complaints affecting or by ESRD patients from Quality Improvement Organization(s) (QIOs), SAs, other ESRD Networks, the Medicare 1-800 Hotline, and Medicare intermediaries. You are not expected to monitor web sites for quality of care issues.

You should receive all complaints and grievances directed at you. Complaints or grievances may be made anonymously. A complainant's or grievant's identity must remain confidential unless specific permission is given by the complainant or grievant to use or release his/her name. Always ask the complainant/grievant if his/her name can be revealed before you begin your investigation. Always document the complainant's position on maintaining confidentiality and when possible obtain a written authorization. Do not wait for written authorization before beginning your investigation.

When written or verbal complaints/grievances are received, they should be documented by entering them into SIMS. You should keep supporting documents and related correspondence in a confidential file. There may be occasions when a complaint/grievance recurs and a closed case needs to be reopened because of a further need for review, investigation, and/or action. When you reopen a case count it as a new case, but link it to the previous case so that you can watch for patterns. If a case is linked to another case or there are multiple complainants/grievants, document the linkage in the SIMS Contact section until SIMS is able to automatically link related cases.

When a complainant/grievant contacts you with a problem there are 3 options for handling any given situation:

1. An informal complaint process, which allows you to communicate with the facility/practitioner by phone, letter, fax, email, or in person. This process does not require a formal written report to the complainant. The Network will work with the involved parties to shepherd a workable solution.

2. A formal grievance process, which is usually a longer process involving a CMS-specified investigation process, a grievance determination, due process for the involved parties and a final written report.

3. A referral to an appropriate agency or entity is done when you believe that the issue falls under that agency's or entity's authority and would be more appropriately handled by that agency or entity.

You can recommend one of the above options to the complainant, but you must present all options. Use the complaint handling option the complainant prefers. A grievance automatically initiates the formal process. Regardless of whether a formal or informal process is used initially, the process used may be changed later.

Within 5 days of receipt, acknowledge all written complaints either in writing or by phone. If you write a letter to a complainant state the complaint, explain the options for handling the situation, and provide a Network contact person and your 1-800 phone number. All grievances should be acknowledged in writing within 5 working days of receipt. (See Exhibit 7-4, Model Response Letter of Acknowledgement for a Written Complaint/Grievance.)

In responding to a grievance or written complaint, explain in writing the disclosure provisions that will govern your final grievance response, and advise that the final response will include as much information as you are permitted to disclose under those provisions.

- Advise that in a grievance/complaint you will not reveal the grievant's/ complainant's identity during your investigation/review process without his/her consent. However, explain that because of the small patient population in dialysis facilities, identification of the complainant or grievant by the provider/involved practitioner may occur even when confidentiality is maintained;

- Advise anonymous complainants/grievants that their complaint/grievance will be investigated but you will be unable to report back to them without their name and address. Explain that because of the small patient population in dialysis facilities, the provider/involved practitioner may be able to identify them, even when anonymity is maintained;

- Advise that the complainant or grievant needs to inform you, either by telephone or in writing, of his/her decision regarding the use of his/her name in the investigation/resolution process. (See Exhibit 7-4, Model Response Letter of Acknowledgement for a Written Complaint/Grievance, and Exhibit 7-5, Consent to Disclose Identity – Model Form);

- Advise the grievant, but not the complainant, that once your review is completed, you are required to advise the provider/involved practitioner of your determination and solicit comments prior to the release of your response to the grievant. Thirty days are allowed for the submission of comments;

- Advise the complainant/grievant that information that explicitly or implicitly identifies the practitioner is confidential and cannot be disclosed without the practitioner's consent (see 42 CFR 480.133(a)(2)(B)(iii) and §785); and that none of the confidential information in the grievance response letter may be used in litigation. (See 42 CFR 480.107); and

Assure the complainant/grievant that regardless of whether his/her name remains confidential, you will investigate the complaint/grievance and you will act on your findings. If the case is

investigated as anonymous complaint, you will be unable to provide him/her with a final report without their name and address.

765.5 Request of Grievance in Writing.--Whenever possible, a grievance received via telephone or in person should be confirmed by the grievant in writing; however, a written confirmation is not required.

Once a grievance is received/initiated, start your investigation of the grievance immediately. For a potential life-threatening situation refer the complaint to the SA and immediately notify your RO PO and the RO responsible for the State in which the dialysis facility is located. (See §765.9)

765.6 Referring Complaints and Grievances.--You are responsible for reviewing the issue(s) raised by a complaint or grievance and determining the action required. If you are uncertain about how to handle a complaint or grievance consult your RO PO to determine if the complaint or grievance would more appropriately be handled by another agency, organization, or licensing board. If the complaint/grievance is not a Network issue, advise the complainant/grievant and either provide the referral information to the complainant/grievant or make the referral to:

A. Carrier, Fiscal Intermediary (FI) and RO Medicare Coordinator.--If the grievance concerns a payment or denial of services, refer the complainant to the appropriate carrier or intermediary or to the RO representative who works with carriers or intermediaries.

B. State Survey Agency (SA).--Life threatening situations should be referred immediately to the SA. (See §765.9.) Other situations involving CfC may also be referred. (See §765.3.) The SA has the authority and the responsibility to act on complaints within the scope of the CfC. You may provide quality improvement (QI) assistance to the facility even if you have referred the complaint to the SA. You may also provide QI assistance, if the facility requests assistance as a result of an SA investigation.

C. Quality Improvement Organization (QIO).--Refer complaints or grievances involving hospital inpatient stays, nursing homes, home health agencies, and ambulatory surgical centers to the QIO for peer review in the State where the hospital or service provider is located whether or not the complaint/grievance is specifically related to ESRD treatment or services. The complaint or grievance may involve care or services for comorbid conditions. EXAMPLE: An ESRD patient complains that he failed to receive diabetic foot care while in the hospital. The lack of care resulted in a gangrenous heel ulcer and his foot being amputated. You should refer this complaint to the QIO responsible for the area where the physician and hospital is located. EXAMPLE: A dialysis facility staff person complains that several ESRD patients with pneumonia had been discharged prematurely from a particular hospital and have had to be readmitted within a few days of discharge due to serious complications. The complaint should be referred for review to the QIO responsible for the state in which the hospital is located.

D. CMS Regional Office.--Refer complaints/grievances that are potential or alleged fraud or abuse cases to the CMS RO. Refer to the CMS Web site for the most recent Associate Regional Administrator (ARA) list. EXAMPLE: A Medicare ESRD patient alleges that a provider is submitting charges to Medicare for treatments and services that were not rendered. You should refer this complaint to the CMS RO.

E. State Licensing Boards.--Refer complaints/grievances about a physician or other provider services furnished in private offices, clinics or other ambulatory settings to the appropriate QIO for review, investigation and a determination as to whether the complaint/grievance should be referred to an accreditation, licensing, or certification agency. EXAMPLE: A relative of an ESRD patient complained that her father's doctor failed to treat his decubitus ulcer, which became infected and resulted in a fatal septicemia. Since the alleged lack of care resulted in the death of the

complainant's father, you should refer the case to the QIO for peer review and discuss the case with the RO PO to determine whether or not the case should also be referred to the State Physicians' Licensing Board.

F. Managed Care Organization (MCO).--If the patient is a known managed care patient, refer complaints/grievances about services furnished contractually for the MCO to the MCO's department for patient complaints. If the complaint is about the MCO itself refer the complaint to the CMS RO repsonsible for the state in which the MCO is located. EXAMPLE: A patient complained that their MCO is preventing them from receiving a transplant by requiring them to use an out-of-state transplant center when a local Medicare certified center is available. The patient should be referred to the CMS RO.

765.7 Written Acknowledgement of Grievances.--When a formal grievance is received, written acknowledgement should be provided to the grievant within 5 business days. The letter of acknowledgement must:

- State the grievance;
- Advise that you will look into the issues raised by the grievant;
- Explain the disclosure provisions that will govern your final response. (See §765.5.)
- Explain the review process and provide approximate time frames. Explain that you will notify the grievant of any delays;
- Advise that additional information/documentation can be submitted at any time;
- Advise the grievant if the grievance is more appropriately handled by another agency. If the grievance is referred, provide a contact person and the name, address, and phone number of the agency receiving the referral; and
- Provide your name, address, and toll-free telephone number and a contact person who the grievant should contact to provide additional information about his/her grievance or to check on the progress of your investigation.

765.8 Investigation of Complaints and Grievances.--The focus of an investigation is to gather information objectively in order to determine the validity of the allegation stated in the grievance or complaint. Start your investigation by obtaining as much information as is available and/or necessary in order to fully understand the issue(s). Information may be gathered from the complainant/grievant, and/or facility by phone, letter, fax, e-mail, in person, or on-site visit. During the investigation of a complaint/grievance the Network staff and/or the MRB may interview the complainant/grievant, patients, facility staff and may review medical records or other records to make determinations about the quality of care provided. If in gathering information about the complaint or grievance, you observe a situation, which you believe poses a substantial risk to the public health, not related to the complaint/grievance, advise the facility that they should report the problem to the SA or that you will report it for them.

765.9 Life-Threatening Situations.--If the complaint or grievance appears to present an immediate and serious threat to patient health and safety, forward it immediately (within 24 hours of receipt or determination) to the appropriate SA and RO Associate Regional Administrator (ARA) or ARA designee, which services the state/SA where the facility is located. Keep your RO PO informed. Although initial contact with the appropriate RO may be via telephone, immediately follow the call with a written confirmation of the situation either by e-mail or FAX. If the RO requests your assistance, make yourself available to consult and/or begin your investigation immediately. If your RO asks you to investigate the complaint/grievance, report your findings to the RO as soon as possible.

765.10 Challenging Patient Situations.--If a complaint or grievance involves discharge of a disruptive, abusive, or violent patient, investigate the situation by obtaining information from all involved parties. In all cases the safety of all patients and/or staff should be the primary concern during the resolution process. Try to determine what the facility and the patient have done to resolve the problem. Upon admission, the facility should advise the patient of the facility rules and discharge policy and should, when possible, make an effort to work with the patient toward a successful outcome. You may facilitate communication between the patient/complainant and the facility staff, but you should not provide services that are the responsibility of the facility and the facility social worker (i.e., finding placement in another facility). If on investigation, you believe the facility or its policy(ies) and procedure(s) may be in violation of the CfC, you should refer the situation. Before you refer the case, you should advise the facility of the problem and provide the facility with an opportunity to self-report or have you refer the situation to the SA. (See 42 CFR §405.2138.)

765.11 Advocating for Patient Rights.--You should advocate for patient rights with the understanding that the patient is responsible for his/her behavior. Patient rights are found at 42 CFR §405.2138. If attempts to resolve the complaint/problem(s) fail and the facility wants to discharge the patient, you may request that the facility provide advance discharge notice preferably 30 days before discharge. The facility should also be notified that they are required to assist with alternate placement. Whenever possible the patient's nephrologist should be involved in the discharge and transfer planning. If the patient requests, you should provide the patient with a list of facilities. If a patient has been discharged from a unit and the unit was unable to place the patient in another outpatient dialysis facility and the patient is no longer being followed by a dialysis facility social worker, you may assist the patient if requested by the patient. It is not the responsibility of the Network to place patients in dialysis facilities. You should evaluate your involvement on a case-by-case basis with consultation from your RO PO and the SA as appropriate.

765.12 Addressing a Complaint or Grievance.--Address complaints and grievances as described in §760. Assist in the resolution of the complaint or grievance by acting in the appropriate capacity between the complainant/grievant and the facility, physician, provider, or supplier. Advise the facility and practitioner that you will be responding to the grievant or complainant. When appropriate, a complaint or grievance may be resolved by requiring the facility to develop and implement an improvement plan (IP). You should monitor the progress the facility makes to correct or improve the problem. A complaint/grievance may be closed on the completion of the improvement plan. If on completion of the improvement plan, the facility has failed to adequately address/correct the identified problem, you can ask that a revised improvement plan be carried out or after you have notified the facility you may refer the complaint/grievance to the SA or other appropriate agency.

765.13 Follow-Up of a Grievance.--After addressing a grievance, you may want to follow-up with the grievant if you have concerns about the correction or recurrence of the problem. In following up on a grievance try to determine if the outcome of the grievance process met the needs of the grievant/patient. Grievant satisfaction is desired not required.

765.14 Conclusion of a Grievance Investigation.--As required at 1154 (a)(19) of the Act advise the facility, physician and/or involved practitioner of your findings and recommendations. At least 30 days prior to reporting your final determination to the grievant provide the involved physician and/or practitioner with an opportunity to submit additional information or comments relating to the initial grievance determination. Comments may be made in writing before a final Network determination is made and the letter to the grievant is written. (See 42 CFR 480.105.)

- Afford the involved practitioner 15 calendar days (within the 30 day time period prior to sending the response letter to the grievant) to respond. Advise the physician and the facility that you will be sending a final report to the grievant. Advise the physician that his/her response, if there is one, must be received prior to the release of the report to the grievant if it is to be included in the response letter.

- Send a letter containing a grievance report (see §770) to all of the involved parties, the grievant/patient representative, provider and facility. Protect the confidentiality of the grievant and the practitioner, unless the grievant and/or the practitioner have agreed to the release of his/her name. (See §785.) The Network should conclude a formal grievance within 90 calendar days of receipt of the grievance. In those instances where more than 90 days are required for the determination to be made and the grievance process to be completed, notify all parties including the RO PO, of the reason for the delay and the anticipated date for the conclusion of the activity.

- In concluding a grievance investigation, advise the grievant to contact the Network if the problem is not resolved or if it occurs again. If the problem is a recurring one at the involved facility, the Network should follow-up by checking with the grievant and/or the facility to make sure the problem was actually resolved and remained resolved.

770. REPORT AND LETTER TO THE GRIEVANT

Your report to the grievant should be contained in a summary letter that includes the following:

- A brief description of the grievance and the investigation;

- The extent to which the problem described in the grievance was verified; and

- If the situation resulted in Network recommendations to the facility; and/or

- If the situation has been or is being corrected by the facility; and whether the facility in implementing an Improvement Plan (IP) will be monitored to assure correction/improvement is being made. (See Exhibit 7-7, Final Response to Grievant Model Letter.)

If you have facilitated a resolution of the grievance, you should list the agreed upon actions and remedies (facility, provider and grievant/patient responsibilities) as well as information on how to contact you and a person at the facility that will be in charge of implementing the facility's actions.

Your report to the grievant should be of a general nature and should not detail all the specifics of the investigation. Do not identify the practitioner without the consent of the practitioner(s) at issue. (See 42 CFR 480.133 (a). Do not use the name of another patient without his/her permission. In the grievance report, a Network may disclose facility-specific information concerning the grievance. (See §785 below and 42 CFR 480.133.)

If your MRB is involved in the grievance process, the deliberations of the MRB are considered predecisionary and confidential and are not to be released.

In addition, the letter should include a detailed explanation of other options and contacts for those options, such as referral to the SA or RO, which the grievant may pursue if he/she is not satisfied with the Network grievance process including the outcome. (See Exhibit 7-7, Final Response to the Grievant Model Letter.)

775. POTENTIAL OUTCOMES OF COMPLAINT/GRIEVANCE PROCESS

There are several possible outcomes for beneficiary complaints and grievances.

A. Complaint/Grievance Is Closed.--A case is closed and your complaint/grievance activities may be suspended when the complaint or grievance has been referred, investigated, or acted on by another agency or when no further action can be taken or required of the Network. The following situations are examples of when it is unnecessary for you to continue your investigation or to make a determination:

- Complainant died and the complaint became moot because it only pertained to that person and the complaint was not related to the death, e.g., the complainant wanted to dialyze on a different shift; or

- The provider is no longer in business, and the Network is unable to pursue an investigation.

In both of these situations, you should keep your RO PO informed about of the situation.

The complainant/grievant may be dissatisfied with the results of the investigation because the Network is:

- Unable to confirm the alleged problem; or

- Unable to modify facility activity to the extent that the complainant/grievant desires. (In some instances, although a Network has identified a situation that is problematic for the complainant, there may be no regulatory requirement that the provider change their policies, procedures or behaviors in the problematic area.)

EXAMPLE: The facility's hours of operation did not allow the beneficiary to schedule dialysis at a convenient time for his/her job. Although it is preferred that facilities accommodate their patients' work schedules, there is no requirement in the CfC. If the facility cannot adjust the patient's treatment times and if the patient requests the Network's assistance, the Network should assist the patient in identifying alternative options, such as a nearby facility with extended treatment hours.

B. Complaint/Grievance Is Resolved.--The complaint/grievance is considered to be resolved when 1.) the complaint/grievance has been explained, corrected or settled by you so that the complainant/grievant is in agreement with the determination and/or the outcome, or 2.) the involved parties comply with the desired outcome.

Examples of when a complainant/grievant may be in agreement with the outcome are:

- Your assistance with communications between the complainant/grievant and the facility staff results in a satisfactory outcome for the complainant/grievant;

- Investigation determines that it is appropriate for the facility to implement changes and an acceptable improvement plan is developed, carried out, and results in satisfactory facility changes; or

- An explanation/educational effort resolves the complainant's/grievant's concern.

C. Complaint/Grievance Is Referred.--A complaint or grievance may be referred when a complainant makes a request for referral or when you and your RO PO determine that the concern/grievance falls under the authority or jurisdiction of another entity or agency, or if the complainant/grievant is dissatisfied with the Network determination. A complaint or grievance can be referred so that it may be assessed by another appropriate entity. (See §765.6.)

D. Complaint/Grievance Is Reopened.--A complaint or grievance is reopened when a complaint or grievance, that had previously been resolved, becomes an issue for the complainant/grievant again. The case is opened as a new case but is linked to the original case so that you can have the benefit of the original case work and determine if a pattern exits. You should document the linkage as a narrative in the SIMS - Background section. (See §765.4.)

780. IMPROVEMENT PLANS (IPs)

You should request an IP if you have determined that a single problem or a pattern of substandard care exists which has, or may have, an impact on the health or well-being on one or more Medicare beneficiaries. The intervention designed should correct the problem(s) identified. The facility or provider develops the intervention and you approve it. However, if requested, you should assist the facility in the development of the intervention. When you require an IP be developed, inform your RO PO and enter the IP and related activities into SIMS. Facility IPs may be shared with the RO and SA on request.

780.1 Content of IPs.--A facility must submit its IP in writing or electronically. The IP should:

- Identify and confirm an opportunity for improvement;
- Develop and describe implementation of an intervention activity to correct the problem;
- Describe the staff and material resources that will be dedicated to the intervention;
- Provide an expeditious timetable including all interim steps and a final completion date; and
- Propose a methodology, which will allow you to periodically monitor the intervention activities and outcomes to ensure that the problem has been corrected and that it does not recur.

780.2 Time Periods for Review and Acceptance/Rejection of IPs.--The facility has 15 calendar days to submit an IP after it is requested and you have up to 30 days to accept or reject the IP. An IP must be finalized and implemented within 60 calendar days of notification (within 15 days of Network approval of the IP). If possible the IP should be completed within 1-3 months.

780.3 IP Tracking System.--You should develop an internal tracking system to ensure adherence to the IP scope and time line until the capability is in SIMS. You should also contact the facility at least once a month to offer assistance and support.

780.4 Conclusion of IP.--At the conclusion of the approved time period (usually 1-3 months) for completion of the IP, determine whether the facility has complied with the plan and if the problem has been adequately addressed. The determination may be made by either onsite inspection or off-site review of material provided by the facility or by a conference call with the involved parties, or any combination of the above.

780.5 Non-Compliance With IP.--If you determine that the facility has not complied with the IP, after timely Network internal reviews, a decision will be made by the Network as to whether to amend the existing IP, recommend a sanction to the RO, and/or refer the situation to the SA. The Network should notify its PO of the facility's non-compliance and the action that will be taken.

785. CONFIDENTIALITY AND DISCLOSURE OF INFORMATION

A patient's/complainant's/grievant's identity is confidential information and may not be revealed unless the patient/complainant/grievant or personal representative (see Exhibit 7-5, Consent to Disclose Identity – Model Form) has specifically authorized release of his/her name. You are subject to §1160 of the Act and 42 CFR Part 480 and should comply with these disclosure requirements. 42 CFR Part 480 permits disclosure of the patient's identity to the SA on request of the SA.

Maintain all complaint investigation/resolution correspondence and documentation (not captured in SIMS) in a confidential file in a locked cabinet. On request, provide the RO PO with the complaint/grievance file and SIMS documentation for on-site review. The RO PO will advise the ARA or the ARA designee at the appropriate RO about the grievance when the situation requires ARA involvement.

785.1 Identity of Complainant/Grievant.--Ask the complainant/grievant if they may be identified during the investigation and resolution process. Verbal consent for the release of the complainant's/grievant's identity should be obtained during the first contact. Be sure to document the complainant's/grievant's consent or non-consent. You are not required to wait for written authorization before taking action.

Consult with the complainant/grievant throughout the complaint/grievance process. If you are unable to pursue resolution of the complaint/grievance without releasing the complainant's/grievant's identity, advise the complainant/grievant immediately. The complainant/grievant may reconsider and authorize the release of his/her name. If the patient still does not wish you to release/use his/her name you may act on the complaint or refer the complaint as an anonymous complaint. If the complaint/grievance has become irresolvable due to confidentiality issues advise the complainant/grievant in writing that the process cannot be continued, and outline other available alternatives (referral to the SA if the complaint is a CfC issue). A potentially irresolvable complaint/grievance can occur when a patient's refusal to authorize release of his/her name prevents the facility from focusing its corrective action. Occasionally, however, the problem may be resolved without the release of his/her name, if by having raised the concern, the facility becomes sensitive to the issue and makes an effort to improve or correct the situation generally. (See Exhibit 7-5, Consent to Disclose Identity – Model Form.)

785.2 Identity of Practitioner.--The identity of a practitioner should not be used in the grievance report letter without the consent of the practitioner at issue. (See 42 CFR 480.133 (a)(2)(iii).)

785.3 Identity of Facility.--The identification of a facility and disclosure of facility information, may occur upon request to Federal and State enforcement agencies, licensing and certification bodies, State and local public health officials. (See 42 CFR 480.135 through 480.138 for disclosure provisions). In addition, it is acceptable to release aggregate statistics about the number and types of complaints/grievances as long as individual patients/complainants/ grievants cannot be identified implicitly or explicitly.

790. PERSONAL REPRESENTATIVE

A personal representative is an individual designated by a court of competent jurisdiction or by the beneficiary, as evidenced by a document signed by such beneficiary, to act on their behalf. An individual/patient/beneficiary may designate whomever he/she chooses as his/her personal representative. An individual may designate a representative by executing a Power of Attorney, a Durable Power of Attorney, or a signed and dated proxy statement. The patient representative may act for the person they represent in any capacity that the person authorizes (e.g., financial actions,

health care decisions, or advocacy that may be limited to a single transaction or an ongoing responsibility). The court may appoint a Guardian of the Person or a Representative Payee if the individual is deemed incompetent. The appointment may be for a single action/transaction or it may last for the life of the individual. The names of the involved parties, the duration of the appointment and the extent of the power should be stated in the court document. Whenever a third party acts as a representative of an adult patient in the filing of a complaint/grievance, you should have a copy of the document appointing them as representative before releasing any confidential information or the results of Network activities. (See Exhibit 7-6, Designation of a Representative – Model Form.)

A third party can, however, file a complaint or grievance on behalf of a patient without being a lawfully appointed personal representative. Even though a third party may file a complaint, they would not be authorized to receive a report of findings that contained any confidential information (information that would implicitly or explicitly identify a patient or a practitioner) unless they obtained legal appointment or personal designation in writing by the patient and provided you with a copy of the document.

795. CONFLICT OF INTEREST

Ensure that a conflict of interest or potential conflict of interest does not exist among members of a complaint/grievance committee, a MRB committee, or a BOD handling a grievance. Any individual, who has direct involvement with the complainant/grievant or the provider under investigation, whether it is a financial, professional or personal relationship, should be excluded from participation in the investigation and resolution of the complaint/grievance. (See §1881 (c) of the Act.)

Exhibit 7-1

ESRD Network Complaint Process

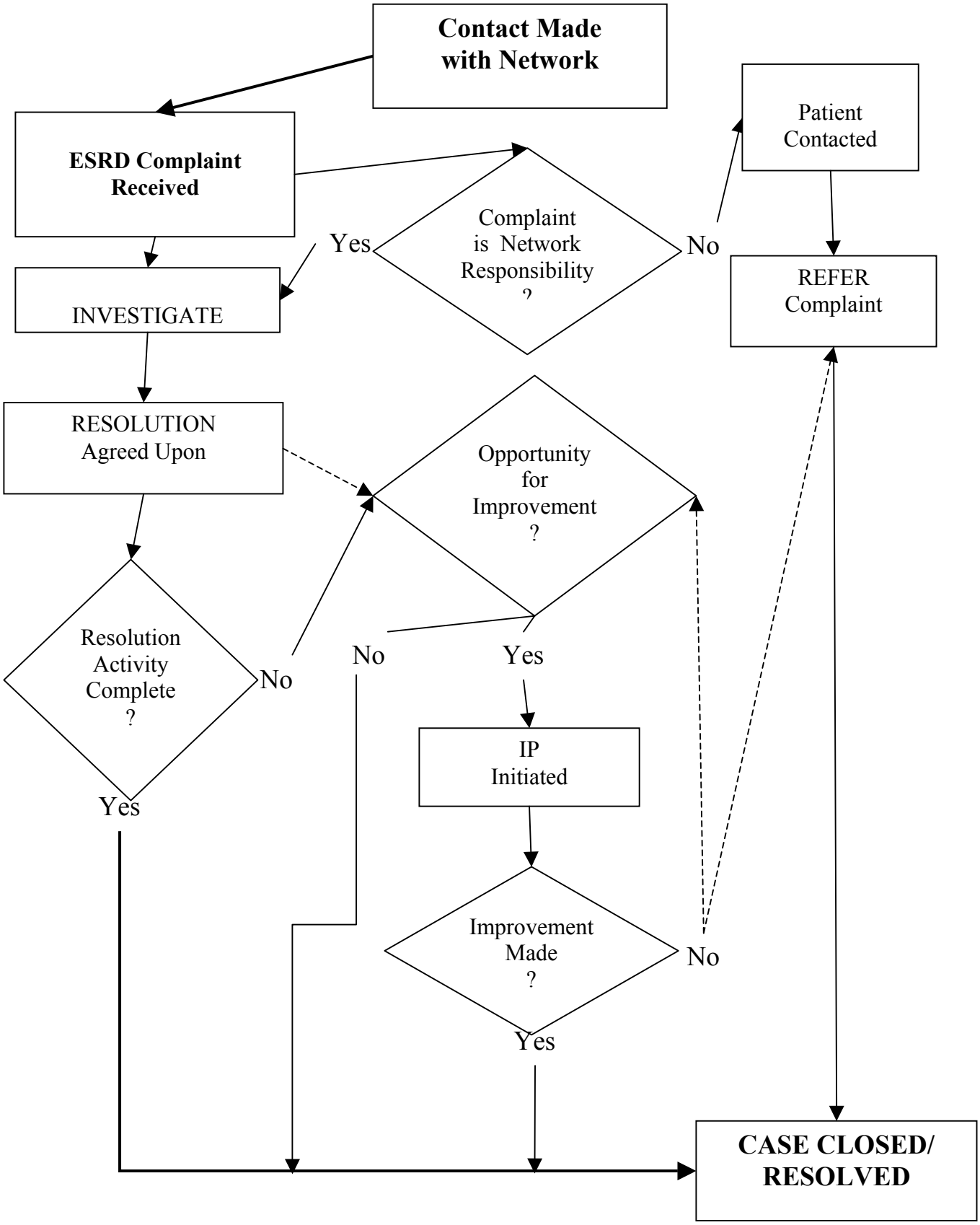

Exhibit 7-2

ESRD Grievance Process

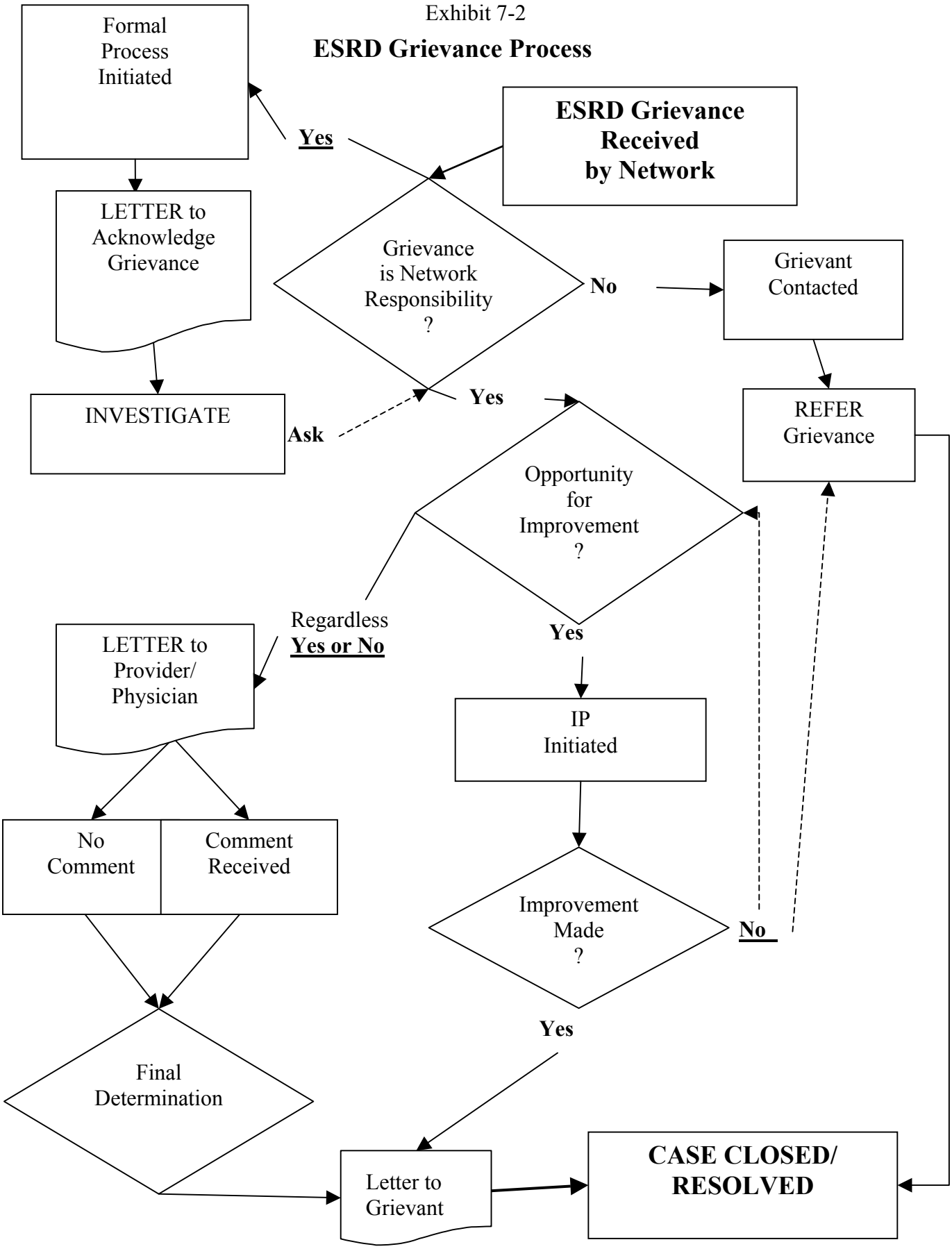

Exhibit 7-3

ESRD Inquiry Process

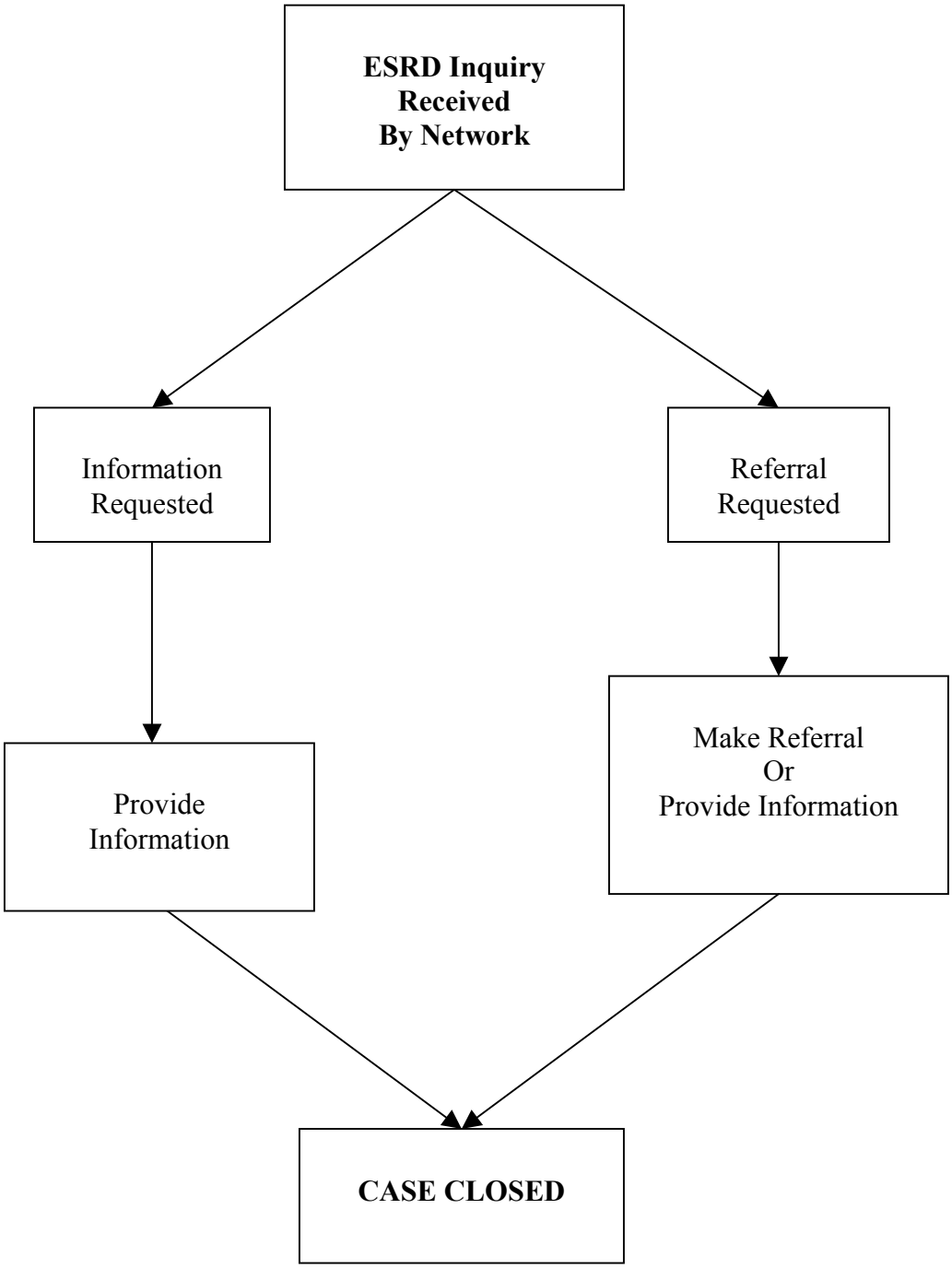

Exhibit 7-4

Time Table for Complaints and Grievances

Contact Type	Acknowledge Complaint	Investigation, Review, and Make Initial Determination	Notice of Disclosure to Provider & Request for Provider Comment	Final Report/ Letter	Total Days
Complaint (verbal)	Acknowledge Complaint & describe complaint/grievance process during first contact	Gather information & try to resolve the complaint as quickly as possible	Letter **not** required.	Follow-up by phone or letter as appropriate	Usually 1 – 90 days plus follow-up as necessary
Complaint (written)	Letter of acknowledgement Sent within 5 business days from receipt of complaint letter.	Gather information &try to resolve the complaint as quickly as possible	Letter **not** required.	Follow-up by phone or letter as appropriate	Usually 1 – 90 days plus follow-up as needed.
Complaint that becomes a grievance	Letter of acknowledgement sent within 5 business days from the time a complaint becomes a grievance	Up to 50 calendar days for intake and resolution	30 days (includes response time from the provider)	5 days after 30 day response time – letter sent to grievant	Up to 90 days plus follow-up as needed
Grievance	Letter of acknowledgement sent within 5 business days from receipt of grievance	Up to 50 calendar days for intake and resolution	30 days (includes response time from the provider)	5 days after 30 day response time – letter sent to grievant	Up to 90 days plus follow-up as needed
Life Threatening Situation	Forward to SA within 24 hours of receipt or determination and notify complainant/ grievant	If unsure of complaint validity gather information and make referral if appropriate	N/A	N/A	24 Hours
	Plan Submission	**Network Approval**	**Plan Implementation**	**IP Completed & Evaluated**	**Follow-up**
Improvement Plan	15 Calendar days from determination of need	Up to 30 Calendar days	Within 15 calendar days of approval	Usually 30 calendar days after initiation	1-3 months As appropriate

All complaints should be handled as quickly as possible. Whenever possible the time frame should be shortened, with the exception of the time allowed for the notice of determination to the provider. Do not shorten the time allowed for the provider/facility response, unless a response is received prior to the end of the 30 day period and no follow-up is needed.

Exhibit 7-5

Model Response Letter of Acknowledgement of a Written Complaint/Grievance

(Your Letterhead)

(Date)
(Name of Complainant/Grievant)
(Address)
(City, State, and Zip Code)

Dear (Name of Complainant/Grievant):

We have received your complaint/grievance of (date) concerning (restate the complaint/grievance). We will begin our investigation. However, we need to know whether we have your permission to use your name while investigating and trying to resolve your complaint. We have enclosed a consent form. Please complete all sections indicated on the form and return it to us using the enclosed addressed envelope. You may also call us with the requested information. The Network phone number is (Network phone number). Please contact us as soon as possible either by phone or in writing. If you choose to complete the sections indicated on the form, be sure to sign and date the form before returning it to us.

The (Network Name) is the End Stage Renal Disease Network Organization authorized by the Medicare Program to receive, investigate, and when possible resolve complaints made by or on behalf of Medicare beneficiaries in the State(s) of (name state(s)). The Network responsibilities include collecting the available information to determine the nature and extent of a problem and/or whether the services you received met medically acceptable standards. When quality of care concerns are identified, we either request the facility to carry out a corrective action plan or we ask the State Survey Agency to look into your problem and take appropriate action.

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

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

Sincerely,

Exhibit 7-6

Consent to Disclose Identity – Model Form

(To Be Used If Verbal Authorization Has Not Been Given)

CONSENT TO DISCLOSE YOUR IDENTITY

(Name of Requesting Network) will not reveal your name to the facility, doctor or provider involved in your (complaint or grievance as appropriate) without your consent. Your (complaint or grievance) will be handled as an anonymous (complaint or grievance) if we cannot use your name. An anonymous (complaint or grievance) is more difficult to investigate, and may prevent your concerns from being fully addressed. The choice is, however, yours.

It is important for you to know that it is unlawful for a facility or its staff to retaliate against a patient or complainant for filing a complaint or grievance. If at any time you should feel that you are being discriminated against, please contact us (your Network name) or your State survey agency immediately.

Insert wording below if this form is being sent to a grievant:

When our inquiry is complete, before we send you our final response explaining our findings; we are required by law to:

1. Send a copy of those findings to the involved facility, doctor and/or provider for their review and comment; and
2. Obtain permission from the doctor to use his/her name in the letter that we write to you.

To avoid having your identity revealed, you can choose to receive a general response from us stating that we have completed our review. This general response would not discuss the outcomes of the review, but would serve to protect your identity.

---------- Cut on this line ----------

Please use a check mark below to indicate either YES or NO:

- ❑ YES, my identity may be revealed during the investigation of my grievance. (If this consent form is in response to a grievance add: Please send me a grievance report letter).
- ❑ NO, I do NOT want my identity revealed during the investigation of my (complaint or grievance). (If this consent form is in response to a grievance add: Please, send me a general notice.)

(Signature) (Date)

(Print Your Name) (Date)

Exhibit 7-7

Designation of a Representative – Model Form

(The Network may use this form to inform an inquirer that the beneficiary may designate him or her as a representative. (See §790))

If you are acting as a personal representative of a living beneficiary who has filed a complaint or grievance with (name of the ESRD Network) (known as the Network). The Network must receive written authorization from the beneficiary designating you as his/her personal representative or you may provide a copy of a court order designating you as Guardian. You may send the Network a copy of the document appointing you the beneficiary\'s representative or the completed form below with the beneficiary designating you as his/her representative.

I,_____ designate _____
(Beneficiary's Name – Print) (Personal Representative's Name – Print)

who is my _____, to represent me in the matter
(State Relationship to Beneficiary)

stated below. I understand that once I designate a personal representative they will communicate with the Network and will act on my behalf in regard to the complaint/ grievance that I have made concerning:

_____
(State the complaint/grievance)

_____

_____

_____

_____

_____

_____

I understand that if I file a complaint and use the informal process, the Network will communicate with my personal representative. If I file a grievance, the outcome letter written in response to my grievance will be sent to my representative. It will be the responsibility of my representative to share the outcome letter with me.

_____
(Beneficiary's Signature) (Date)

_____
(Witness' Name) (Date)

Exhibit 7-8

Final Response to Grievant – Model Letter

YOUR LETTERHEAD

Date of Final Report:

Name of Beneficiary (or Personal Representative):

Address:

City, State, and Zip Code:

Dear (Name of Beneficiary or Personal Representative):

The (Network Name) is the End Stage Renal Disease (ESRD) Network Organization authorized by the Medicare Program to receive and to the extent possible, resolve grievances lodged by or on behalf of Medicare ESRD patients in the State of _____. We look into complaints and grievances about the quality of dialysis and transplant services and care provided to Medicare patients or in Medicare certified facilities. Our responsibilities include discussing the grievance with the involved party(ies), reviewing dialysis facility records, as necessary, and making a determination as to whether the grievance was or was not confirmed and the appropriate action to be taken. Where quality of care concerns are identified, we provide education and feed back to practitioners and physicians, and may require a quality improvement plan to be developed and carried out by the facility. In addition, we may refer the grievance to the State Survey Agency for follow-up.

Based on your grievance received on (date), the Network has investigated your grievance regarding the (care/services) (you or the name of the beneficiary as appropriate) received on (date) at (name of the dialysis facility). You were concerned about (Restate the grievance. Include issues raised by the grievant.).

Insert A or B below:

A. Involved Practitioner/Physician Does Not Consent to Disclosure to the Inquirer, include the following:

We have carefully examined your concern(s) and conducted a thorough review of the relevant records and information pertaining to the grievance (you or the name of the beneficiary as appropriate) raised. Federal regulations prohibit us from releasing information about our review without the consent of the involved physician. Because your physician/practitioner did not give (his or her) consent, we are unable to release specific information about the results of our review. This does not necessarily mean that we found a problem with the services (you or the name of the beneficiary) received. However, if warranted by our review, we will take further action to address our findings.

B. Involved Practitioner/Physician Consents to Disclosure to the Inquirer, include the following:

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

B.1. If the Network finds the grievance was unsubstantiated, insert the following:

After a thorough review of (your or name of the beneficiary) information and the information that we gathered regarding the grievance, we have determined that the grievance you made was not substantiated. Specifically: (Give a summary of the grievance findings

keeping in mind that you can not implicitly or explicitly identify the MRB reviewer(s), another practitioner, or another patient without their consent.).

B.2. If the Network found the grievance to be substantiated, insert the following:

We were able to confirm your grievance about (the quality of services or situation) (you or the name of the beneficiary) (received or experienced) and will initiate the following action: (Summarize the Network action in handling the grievance and the resulting responsibilities of the involved parties. Keep in mind that you can not implicitly or explicitly identify the MRB reviewer(s), another practitioner, or another patient without their consent)

C. If the physician's/practitioner's name is used Close with:

Please note that this letter and the information concerning (name of the practitioner/physician) contained in this letter is confidential and cannot be given to anyone else, unless the practitioner/physician gives (his or her) consent to the disclosure.

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

Name of the Network Complaint Contact Person
Name of the Network
Network Address (include zip code)
Telephone Number (include toll-free number, if different)

If you have been dissatisfied with the grievance process or the outcome of the process you may contact the State Agency, which is responsible for making sure that the care provided at your facility is safe and in compliance with Medicare requirements.

Name of a Complaint Contact Person
Name of the appropriate State Survey Agency
Address (include zip code)
Telephone number (including toll-free number, if possible)

You may also contact the Assistant Regional Administrator (ARA) at the Regional Office of the Center for Medicare & Medicaid Services. The address is:

Name of you ARA
Centers for Medicare & Medicaid Services Region (Region Number)_
Address (including zip code)
Telephone Number (toll free- if possible)

Sincerely yours,

Executive Director
(Name of Network)

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