

Intermountain End-Stage Renal Disease Network, Inc.

(ESRD Network Organization #15, referred to in this document as "the Network")

Protocol for Evaluation of Patient Complaints and Grievances

AUTHORITY

Section 9335 (f)(5) of Public Law 99-509, the Omnibus Budget Reconciliation Act of 1986, requires that each End-Stage Renal Disease Network Organization implement a procedure for evaluating and resolving patient grievances. The Intermountain End-Stage Renal Disease Network, Inc. (Network #15) patient grievance protocol has been developed to incorporate the Centers for Medicare and Medicaid Services (CMS) Part 7, Sanctions and ESRD Grievances, in the "ESRD Network Organization Manual." This protocol applies only to matters of concern or grievances relating to patients and their care.

In addition, Section 405.2138 of the ESRD Final Regulations published in the June 3, 1997 Federal Register states that "All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal."

The reader of this document is requested to refer to the CMS Part 7, Sanctions and Grievances in the "ESRD Network Organizations Manual" for further detail and examples and must refer to such portion of the manual if the answer to any question is not readily apparent from a reading of this Protocol. The numbers appearing in parentheses throughout this document refer to specific sections of the above-referenced manual.

DEFINITIONS OF INQUIRY, COMPLAINT AND GRIEVANCE

Complaints and grievances are those issues involving ESRD patients brought to the Network's attention by a patient or a patient's representative, a family member, friend, facility employee, physician, a federal or state survey agency (SSA), patient advocate, concerned individual, and through the media, QIOs, other ESRD Networks, the Medicare 1-800 Hotline, and Medicare Intermediaries (765.4). The nature of the issues upon which the Network can act are covered in the federal ESRD regulations and deal with certain federal standards for or assurances to patients (e.g., quality of care, confidentiality, respect and dignity, patient information, participating in planning).

A complaint does not involve the application of formal CMS-specified protocol procedures in its processing; typically, a complaint can be resolved by Network personnel fostering patient-facility dialogue, as well as Network communication with the patient and facility, or Network referral to another resource (765.4). Inquiries may also be taken care of through the provision of educational materials or through a clarification of information. However, an unresolved complaint may become a formal patient grievance.

As specified by CMS, the Network will use the following definitions:

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

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.

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

GRIEVANCES THAT WILL BE EVALUATED BY THE NETWORK

Complaints and Grievances that will be evaluated and processed by the Network include:

1. Medicare beneficiary complaints originating in a Medicare-certified ESRD dialysis facility or transplantation center (**765.3**). (Complaints originating from those other than living Medicare-eligible beneficiaries or their designated patient representatives will be examined to determine whether quality of care issues are raised. CMS guidance on the applicability of these grievance procedures will be sought.)
2. Grievance referrals specifically related to ESRD services from Quality Improvement Organizations (QIO), State Survey Agencies (SSA), or other sources (**765.4**).

GRIEVANCES THAT WILL NOT BE PROCESSED BY THE NETWORK

The Network may not investigate grievances in non-Medicare certified units or involving non-Medicare eligible beneficiaries unless it is believed that the issue will have an adverse impact upon Medicare patients (**765.3**). ESRD grievances in non-ESRD related settings will be referred to the appropriate health care organization. For example: grievances involving correctional institutions are referred to the Department of Corrections.

The Network may 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 (**765.6**). The complaint or grievance may involve care or services for co-morbid conditions.

If the complaint involves a reimbursement or insurance issue, or denial of services the complainant will be referred to the appropriate carrier, intermediary, or CMS Regional Office (**765.6**).

If the complaint involves survey and certification issues, the complainant may be referred to the State Survey Agency (SSA). However, the Network may provide Quality Improvement (QI) assistance to the facility even if the complaint is referred to the SSA (**765.6**).

If the complaint involves potential or alleged fraud or abuse, the complainant will be referred to the Federal or State Fraud Abuse enforcement agencies (765.6). The Network Board of Directors and the Medical Review Board (MRB) Grievance Subcommittee should consult with legal counsel and CMS prior to investigating a grievance for which legal action is pending or anticipated.

If a formal grievance is referred to another authority, reasons for referral will be described in a letter to the complainant, along with information as to whom to contact (765.7).

EMERGENCY OR LIFE THREATENING SITUATIONS

Written or telephone grievances involving immediate life-threatening issues will be reported by telephone or fax to the CMS Associate Regional Administrator, Division of Quality Improvement and State Agency immediately (within 24 hours) and will be followed by written confirmation (email or fax). At the Regional Office's (RO) request, the Network will commence investigation immediately or offer consultative services. The patient will be informed of the ROs involvement. Every effort will be made to complete the investigation as soon as possible (765.9).

PATIENT COMPLAINTS OR GRIEVANCES THAT ARE NOT LIFE THREATENING

Any patient, family member, or other person who reports a complaint to the Network by telephone or letter thereby accesses the Network's complaint and grievance procedures (765.4). If it appears that the caller's complaint can be satisfied with an intervention such as a referral, a transfer, provision of information, or the contacting of facility personnel, Network staff will attempt to facilitate a resolution. If the complaint would be better handled as a formal grievance, a grievance packet will be mailed to the complainant (765). A patient may designate whomever s/he chooses as a representative (this information must be provided on the grievance form). A grievance received by telephone is to be confirmed by the complainant in writing before an investigation is commenced, unless the complainant cannot or does not wish to do so or the complaint involves a potential for a threat to lives (765.5).

COMPLAINTS MORE APPROPRIATELY HANDLED AT THE UNIT LEVEL

If the Network believes a complaint would be more appropriately handled at the facility level that recommendation may be made to the patient. If the patient refuses this suggestion, the Network will investigate the complaint (765.2).

DETERMINATION OF NETWORK RESPONSIBILITY

Complaints and grievances will be directed to the Director of Patient Services. Network staff will determine whether the complaint is appropriate for Network consideration or should be referred (765.6). If there is a question as to whether or where a complaint should be referred, direction will be sought from the Network R.O. Project Officer (ROPO). The MRB Chairperson or Network President may be consulted when making this determination. Within five working days of receiving a grievance, the Network will respond to the grievant in writing acknowledging receipt of the grievance (765.4).

NETWORK ROLE IN PROCESSING GRIEVANCES

The Network's role in investigating grievances will vary according to the issue involved and alternatives for resolution. In most instances it is expected that the Network will serve as a referral agent, a coordinator, a facilitator, an educator, and or as an advocate for patient rights (760). The Network is also authorized to act as an expert investigator, to gather information from the complainant/grievant and/or facility by phone, letter, fax, email, or to make on-site reviews and to interview other staff and patients (765.8).

NOTIFICATION OF FACILITY MEDICAL DIRECTOR AND ADMINISTRATOR

Within 15 days of the receipt of a grievance, the facility Medical Director and Administrator will be notified that a grievance has been filed and may be asked to submit requested information. If the Medical Director and/or Administrator's response suggests a resolution or willingness to work with the patient toward a resolution, the Network will assume a facilitative role.

GRIEVANCE RESOLUTION PERSONNEL

Any or all of the following may assist in the grievance resolution process: the Grievance Subcommittee, Medical Review Board members, Board of Directors members and specific Network staff, namely the Director of Patient Services, Executive Director, and/or Director of Quality Improvement.

ADMINISTRATIVE REVIEW

Complaints and Inquiries:

In most situations the review will be handled by the Network staff (including the Director of Patient Services, Director of Quality Improvement, and /or Executive Director.) If necessary, the concern/inquiry may be referred to an MRB Subcommittee.

Formal Grievance:

In some situations, the review may be handled by the Network staff (including the Director of Patient Services, Quality Improvement Director, and/or Executive Director.) If necessary, the grievance may be referred to an MRB Subcommittee.

APPOINTMENT OF MRB GRIEVANCE SUBCOMMITTEE

In situations involving clinical or medical matters, it may be appropriate to appoint a Subcommittee of and from the MRB to review the issues raised in a grievance and to make a determination. Care will be taken to appoint MRB member(s) with experience relevant to the grievance and strict conflict of interest procedures will be observed. Any individual who has a financial, professional or personal involvement with the beneficiary or the provider, or who resides in or practices in the same state, is excluded from participation on the MRB Subcommittee (795). The Grievance Subcommittee will always have at least a chairperson plus two other members.

MRB REVIEW PROCESS

MRB Subcommittee members will be mailed a copy of the grievance, staff findings, relevant documentation, and the facility's comments. The Subcommittee may be asked to respond with written comments, to deliberate by conference call, or to meet in person (765.8). The Subcommittee will make a determination as to the merit of the grievance, and will suggest any

changes that may be recommended to the facility. The MRB Subcommittee may also recommend an on-site review or request additional information prior to making a determination. This may include interviews with patients, providers, or facility staff as appropriate.

TIME ALLOCATED FOR INVESTIGATION

The Network will conclude its investigation within 90 calendar days of the receipt of the grievance. In those instances where more than 90 days are required, all parties, including the CMS Project Officer, will be notified in writing of the reason for the delay and the date anticipated for conclusion of the activity (765.14). If potential life-threatening issues are involved, a grievance (whether in written or verbal form) must be forwarded within 24 hours of receipt to the appropriate SSA and RO Associate Regional Administrator (ARA) and the investigation must be concluded as soon as possible (765.9).

DRAFT REPORT

A draft report of the finding will be submitted to the facility Medical Director and Administrator, who will have 30 calendar days from the date of receipt to submit comments (765.14).

FINAL REPORTS

The full final report will be sent to the Medical Director and Administrator, with the confidentiality of the complainant protected, unless the complainant has agreed in writing to release his/her name (765.14). All documentation can be viewed onsite by the ROPO when requested (785).

A general report will also be made to the complainant (770). This report will inform the complainant that a thorough investigation of the grievance has been conducted and will stipulate the extent to which the problem described in the grievance was verified as a result of the investigation. In addition, the report will indicate whether the grievance has been resolved or whether the facility is implementing an Improvement Plan (IP).

The report to the complainant should be of a general nature and should not detail the specifics of the investigation. The Network may disclose facility-specific information but may not disclose practitioner specific-information without written consent. If the Network MRB is involved in the grievance process, the deliberations of the MRB are confidential and are not to be released. In addition, a detailed explanation of other options, such as referral to the SSA or RO will be included, which the complainant may pursue if he/she is not satisfied with the investigation.

IMPLEMENTATION OF AN IMPROVEMENT PLAN

In those instances in which the MRB Grievance Subcommittee determines that there are opportunities to improve care within the facility, an Improvement Plan (IP) may be implemented (780). The IP will be developed by the facility in conjunction with the Network, subject to the approval of the MRB Grievance Subcommittee. The IP will include the following (780.1):

1. Confirmation and identification of the existence of the problems and opportunities for improvement;
2. A description of all steps to be taken to correct the problems;
3. A description of staff and material resources that will be directed to the effort;
4. An expeditious timetable including all interim steps and a final completion date; and,

A methodology that allows periodic Network monitoring of the IP to ensure that the problem is corrected efficiently and that it does not recur.

ACCEPTANCE AND MONITORING OF IMPROVEMENT PLAN

The facility has 15 calendar days to submit the IP and the Network has 30 calendar days to accept or reject the plan (780.2). IP's must be finalized and implemented within 60 calendar days after the date the Network requested the IP. If possible the IP should be completed within 1-3 months.

The Network will maintain a tracking system showing the status of all IPs, which will be reported to CMS in the quarterly progress report (780.3). The Network will contact the facility at least once a month to offer assistance and support (780.4). At the end of the time allowed for implementation of the plan, the Network will determine whether the facility has complied with the plan and if the plan has been adequately addressed (780.5). If the goals of the IP have not been met, the Network may amend the IP, implement focused review, or recommend a sanction. A decision to recommend a sanction must be made by the Medical Review Board with concurrence from the Network Board of Directors. The Network should notify its PO of the facility's non-compliance and the action that will be taken.

CONFIDENTIALITY

Complainant/Grievant Confidentiality

The complainant/grievant identity will be confidential and will be released only with specific authorization (785.1). If it appears that proceeding with fact-finding or other steps in the grievance resolution process may compromise confidentiality, the process will be suspended and the complainant/grievant notified in writing of the Network's concern. At that point the complainant/grievant will be given any possible alternatives to the Network grievance process (785.1). The process of resolution will be resumed only with the complainant/grievant's written permission and acknowledgment of the potential risk to confidentiality.

Facility Confidentiality

The identity of facilities that have been involved in a patient grievance is releasable (785.3). Aggregate statistics about the number and types of grievances are releasable, as long as patient confidentiality is maintained. (Per CMS national protocol for resolution of ESRD Medicare patient grievances. Attachment J, Section IX B, CMS Contract 500-91-ED33).

This protocol has been updated to reflect CMS Organization Manual, Part 7, Sanctions and ESRD Grievances (dated March 12, 2004).