Medicare ESRD Network Organizations

Chapter 10 – Sanctions and Referrals

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(Rev. 9, 04-18-08)

10 - Background/Authority

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

Section §1881(c)(2)(G) of the Social Security Act (the Act) provides that a Network shall identify facilities and providers that are not cooperating toward meeting the Network goals and assist such facilities/providers in developing appropriate plans for correction. Networks are to report facilities that continue to be non-compliant and those that are not providing appropriate medical care to the Secretary via CMS.

Section §1881(c)(3) provides that based upon information/data provided by the Network on a facility/provider's consistent failure to cooperate with the Network plans or goals or to follow the recommendations of the Network Medical Review Board (MRB), the Secretary may terminate or withhold certification until a determination is made and validated that the provider/facility is making reasonable and appropriate efforts to cooperate with the Network. Based upon a facility/provider's failure to cooperate, the Network can recommend sanction by providing supporting information/data to the Secretary's designee, the CMS Regional Office (RO), utilizing the processes outlined in this chapter.

Code of Federal Regulations (CFR) 42 CFR 405.2134 stipulates as a condition for coverage under Subpart U that a facility/provider must participate in Network activities and pursue Network goals. 42 CFR 405.2081 provides clarifications on the basis for sanction/alternative sanction, while 42 CFR 405.2182 and 2184 provide information on appeal rights for termination of coverage due to sanction/alternative sanction.

Section 1157(a) of the Act states that anyone who provides the ESRD Network with information regarding the sanction will not be held liable as long as:

- *The information is relevant to the performance of the Medicare contract; and*
- *The person providing the information believes the information is true and has no reason to believe that the information was false.*

Section 1157 (b) of the Act provides liability protection to any employee or any person providing professional services to an ESRD Network during the performance of their duties, functions, or activities.

If the RO decides to impose a sanction, the public must be informed of the sanction in accordance with 42 CFR § 405.2182 along with the provider, which must also be informed of its right to appeal the sanction (42 CFR § 405.2184).

20 - Responsibility

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

The Network's responsibilities for sanction recommendations and referrals include the following:

- *Recommend sanction to CMS for facilities/providers that consistently fail to comply with Network goals and/or are not providing appropriate medical care;*

- *Provide documentation throughout the process to support the recommendation and associated investigation;*

- *Track and trend dialysis facility data to monitor facility non-compliance and return to compliance;*

- *Refer to the QIO or the state/jurisdiction Inspector General's office any information collected while conducting contract activities that indicates that a physician may be failing to meet his/her obligation to provide quality care or is involved in Medicare fraud.*

30 - Requirements for Participation in Network Activities

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

The Network must establish a policy and procedure to ensure that facilities are recommended to CMS for sanction when indicated by the failure to provide data, participate in Network activities, or pursue Network goals.

42 CFR, Subpart U, §405.2100-405.2184, describes the Conditions for Coverage for suppliers of end stage renal disease services, and the Medicare State Operations Manual, Pub. 100-07, provides guidance for ensuring compliance by certified facilities/providers with these Conditions. At a minimum, facilities/providers are expected to provide data to the Network to assist CMS in maintaining accurate and complete data on ESRD patients, participate in Network activities, and pursue Network goals.

The Network must have a plan for monitoring facilities'/providers' compliance with participation in Network activities and working toward Network goals. The plan for monitoring facility/provider compliance with Network goals must be provided to CMS and distributed to all facilities/providers in the Network's area. The Network must use its monitoring plan to identify facilities/providers that consistently fail to cooperate with Network plans and goals or to follow the recommendations of the Medical Review Board (MRB). The Network must notify facilities/providers of the potential for a sanction recommendation based upon the failure to pursue Network goals.

If the Network identifies a facility/provider that is not cooperating in meeting the Network's goals and or is not providing appropriate medical care, the Network recommends to CMS the imposition of a sanction for that provider/facility. The Network should consult its Project Officer (PO) for guidance if it is uncertain whether there is enough evidence to recommend sanction. As a general rule, if the Network has worked with the facility for at least three months, has exhausted all reasonable efforts to gain facility compliance, and has documented that the facility has failed to cooperate, the Network may recommend to the RO the imposition of a sanction. (See 42 CFR 405.2180 and 2181). Before the Network submits a sanction recommendation to the PO, the Network must document the details of

the situation, including actions taken by the Network and the response (or lack of response) by the facility and that the facility has been and continues to be out of compliance with Network goals and plans. The recommendation could be based on the facility:

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

Sanction recommendations must be facility-focused, not physician-focused. 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 care of an acceptable level of quality must be referred to the QIO or Inspector General's office in the appropriate state/jurisdiction for investigation and possible action.

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 Program (see 42 CFR 480.137).

40 - Network Documentation Requirements for Sanction Recommendations

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

To support its recommendation for a sanction of an ESRD facility/provider, the Network must provide the RO with the following:

- *Evidence that the facility was notified in writing of the Network's goals and objectives;*
- *Description and details of the goal(s), objective(s) that the facility has failed to meet;*
- *Actions the Network has taken to inform the facility that it was not complying with Network goals, objectives, or plans (see Exhibit 10-1 for a sample letter);*
- *Evidence to demonstrate that the facility was given an opportunity to make corrections;*
- *Description of follow-up actions taken to resolve the problem (e.g., documentation of phone calls or site visits to the facility asking for specific information) that demonstrate the Network's attempts to work with the facility*

to resolve the problem; and

- *Documentation of the facility's failure to submit an action plan, submission of an unacceptable action plan, or failure to carry out an approved action plan.*

Documentation to support the Network's recommendation for a sanction can be in the form of copies of written correspondence between the facility and the Network, written notes, and/or dated contact reports of telephone conversations.

If the facility consistently fails to meet the Network's goals, plans, and/or objectives, the Network must take action. The Network must use its professional judgment in deciding when it has provided enough assistance to the facility. It is not acceptable to allow facility non-compliance to continue for a protracted time period (e.g., more than six months); continued non-compliance should be discussed with the PO to avoid unreasonable delay in addressing these issues.

50 - Network Recommendation for Sanctions

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

The Network shall alert its PO of its intent to recommend a sanction after the Network has provided full documentation to the facility, in writing, of the facility's failure to comply with Network goals and objectives (see Exhibit 10-2). The Network shall submit two copies of its documentation and a cover letter to the Associate Regional Administrator (ARA) for the RO that oversees the Medicare services of the state/jurisdiction where the facility is located (see Exhibit 10-3). The Network must organize the information in notebook form with a chronological summary and a table of contents. The notebook shall contain all of the following information:

- *The name, address, and Medicare provider number of the involved facility;*
- *The Network goal(s) or objective(s) with which the facility has failed to comply;*
- *A brief summary of the basis for the sanction recommendation;*
- *Compilation of the evidence outlined in Section 40 above;*
- *An outline of what action(s) the facility must take and documentation that must be submitted 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 the Network's PO.*

60 - Project Officer (PO) Role in Sanction Procedures

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

The PO will forward the sanction recommendation for processing to the ARA in the RO that oversees the Medicare services of the state/jurisdiction where the facility is located. The PO will also alert CMS Central Office (CO) of a potential sanction action against an ESRD facility.

The PO will also serve as a conduit between the RO Survey and Certification staff and the Network. The PO will provide guidance to the Network throughout the sanction process and provide final outcome information to CO after the case is settled.

70 - Regional Office (RO) Role in Sanction Procedures

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

The Survey and Certification Branch in the RO has the responsibility for implementation of a sanction or an alternative sanction based upon the evidence received from the Network.

When a sanction recommendation is received, the Survey and Certification Branch will:

- *Review the sanction recommendation for completeness and determine if there is sufficient information to process the sanction recommendation;*
- *Determine the type of sanction to impose (sanction vs. alternative sanction);*
- *Notify the State Survey Agency of the potential sanction action to determine if there have been any relevant State Survey findings or actions, past or pending; and determine whether a state or federal survey should be conducted, based on the sanction recommendation;*
- *Select the mechanism that provides the most effective means to encourage the facility to come into compliance with the requirement; and*
- *Make the final determination whether to sanction a facility.*

The sanction the RO imposes is at its discretion; however, the RO should select the mechanism that provides the most effective means to encourage the facility to come into compliance with the requirement. The Network may be asked to assist the RO in determining which sanction to impose; i.e., sanction vs. alternative sanction

Alternative sanction: If an ESRD facility fails to participate in the activities and pursue the goals of the ESRD Network in its geographic area (see 42 CFR 405.2134), but the failure does not jeopardize patient health and safety or justify termination; the RO may choose to impose an alternative sanction. An alternative sanction could include any or all of the following:

- *Denial of payment for services furnished to patients first accepted for care after the effective date of sanction, as specified in the sanction notice;*

- *Reduction of payments by 20 percent for all ESRD services furnished by the supplier for each 30-day period after the effective date of sanction; and*

- *Withholding of all payments, without interest, for all ESRD services furnished by the supplier to Medicare beneficiaries after the effective date of the sanction.*

The RO will notify the facility of the sanction imposed, the facility's appeal rights, and the procedure for removal of the sanction. The effective date of the sanction must be at least 30 days after the date of the notice. At the same time, the RO will notify the fiscal intermediary, the PO, and the Network of the specific sanction and its effective date.

80 - RO Role in Notice and Appeal Rights

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

When the RO proposes to apply an alternative sanction, the facility will be given written notice of the proposed sanction and 15 days in which to request a hearing. If a facility does not request a hearing, the RO will notify 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;*
- *Will have 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/or pursue Network goals.*

If the written decision of the hearing official supports application of the alternative sanction, the RO will provide the facility and the public at least 30 days' notice before the effective date of the sanction. The notice will specify the effective date and the reasons for the sanction. The RO will also provide a copy of this notice to the Network and its PO.

90 - Duration and Removal of Alternative Sanctions

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

An alternative sanction will remain in effect until the facility is in substantial compliance with the requirement to participate in the Network's activities and pursue the Network's goals, or the facility is terminated from the Medicare Program for lack of compliance. The RO Survey and Certification Branch will remove the sanction when the facility/provider demonstrates and documents that the reason for the sanction is eliminated.

Each sanction notice must explain what is required for correction of the particular problem(s). Once the facility informs the RO of its corrective actions, the RO will verify compliance with the requirements and inform the fiscal intermediary, the PO, the applicable Network, and CMS CO that the sanction is to be removed. Prior to removing

the sanction, the RO may ask the Network for its assistance in verifying the facility's compliance with the requirements.

The evidence or proof of compliance required to remove the sanction will depend upon the reasons for applying the sanction. For example, if a facility is sanctioned for failing to submit data forms, the RO removes the sanction when the facility submits the delinquent forms. A site visit to verify compliance is not necessary in this instance; however, the Network would likely be asked to validate the facility's compliance with forms submission. Alternatively, if the RO sanctions a facility for failure to comply with established criteria and standards relating to quality and appropriateness of care, then a site visit to verify successful implementation of a plan of correction might be necessary to determine when the sanction should be lifted.

100 - Resources

(Rev. 9; Issued: 04-18-08; Effective Date: 04-01-08; Implementation Date: 05-19-08)

The following resources can be used to clarify the sanction process and the roles of all parties involved, as outlined above:

1. *Section §1881(c)(2)(G) of the Act*
2. *Section §1881(c)(3) of the Act*
3. *42 CFR, Subpart U, §405.2100-2184*
4. *Medicare State Operations Manual, Publication 100-07, Internet-Only Manuals.*

Exhibit 10-1
Sample Non-Compliance Letter to Facility

[ESRD Network letterhead]

[Date of correspondence]

[Name and address of dialysis facility/unit]

Dear [Dr. / Mr. / Ms.] [Name of facility Administrator]:

The purpose of this notice is to inform you that the Medical Review Board for [name of ESRD Network], the ESRD quality improvement organization for the [state/Commonwealth/etc.] of [name of state/jurisdiction], has reviewed the performance of [name of dialysis facility/unit] and found the facility deficient in [area of deficiency, e.g., meeting or working toward Network goals].

As a requirement of your Medicare certification, your facility must comply with the Conditions for Coverage as stated in Section 1881(c) of the Social Security Act and 42 CFR Sub Part U §405.2134 "Participation in network activities." The Network activities reflect the national ESRD Program goals that are established by the Centers for Medicare & Medicaid Services (CMS) as a part of the ESRD Network contract. The Network distributes the Network's goals annually to all dialysis facilities in the Network region and posts them on the Network website ([Network web address]) for ongoing reference.

[Facility/unit name] has failed to meet the following:
[List of expectations that are not being met].

Consequently, you are expected to provide the Network with a Quality Improvement Plan (QIP) to address how you intend to correct these deficient practices, a timeline for implementation, and the method you will use to determine the effectiveness of your efforts. Please submit your QIP by [date] for approval by the Network. The results of your QIP should be reported to the Network no later than [date]. If you have any questions, need assistance with developing the QIP, or need to request a change in dates, please contact the Network at [Network phone number] and ask for [name of the appropriate staff member] by [date].

Thank you for your prompt attention to this matter. We look forward to hearing from you by [date]. Failure to promptly and completely respond to this notification letter can potentially lead to a recommendation to CMS for sanction against your provider status.

Sincerely,
[Signature]

[Name]
Executive Director
[Name of ESRD Network]

Exhibit 10-2
Sample Sanction Recommendation Letter to Facility

[ESRD Network letterhead]

[Date of correspondence]

[Name and address of dialysis facility/unit]

Dear [Dr. / Mr. / Ms.] [Name of facility Administrator]:

The purpose of this notice is to inform you that the Medical Review Board for [name of the ESRD Network], the ESRD quality improvement organization for the [state/Commonwealth/etc.] of [name of state/jurisdiction], has reviewed the performance of [name of the dialysis facility/unit] and found the facility deficient in [area of deficiency, e.g., meeting or working toward the Network goals] as required in the Medicare Conditions for Coverage and described to you in our correspondence dated [date of Exhibit 10-1]

Consequently, the members of the Medical Review Board have [unanimously (if applicable)] determined that [facility/unit name] is out of compliance with Section 1881(c) of the Social Security Act and 42 CFR Sub Part U §405.2134 "Participation in network activities" and are recommending that the Centers for Medicare & Medicaid Services (CMS) impose a sanction on [facility name].

Specifically, [facility/unit name] failed to: [description of failure, e.g., the facility failed to submit a Quality Improvement Plan (QIP), the facility failed to submit an acceptable QIP, or the facility was unwilling or unable to work toward Network goals].

On request, [name and title of Network contact person] is available to discuss the reasons for this recommendation and subsequent action. [She/He] can be reached at [Network phone number].

Sincerely,

[Signature]

[Name]
Executive Director
[Name of ESRD Network]

Exhibit 10-3
Sample Letter to CMS Requesting Sanction Action

[ESRD Network letterhead]

[Date of correspondence]

[Name and address of the ARA in the Regional Office that has jurisdiction over the problematic facility]

Through: [Name of Network's Project Officer]

Dear [ARA name]:

Recommendation:
After [time period] of working with [name of facility], it has become apparent to the [Executive Board/Board of Directors] and Medical Review Board (MRB) of the [name of ESRD Network] that [facility name] is out of compliance with the statutory requirements, as follows: [list of ways in which the facility has failed to meet statutory obligations, e.g.,

- *Consistent failure to cooperate with Network plans or goals as specified in the Network contract;*
- *Consistent failure to follow the recommendations of the MRB, which have been approved by CMS;*
- *Failure, without just cause, to permit an on-site review by the Network MRB; or*
- *Failure to submit data as required.]*

[Network name]'s [Executive Board/Board of Directors] and MRB, after reviewing and giving due consideration to the performance of [facility name] and the outcomes of actions taken to correct performance deficiencies, recommend that a sanction be imposed upon [facility name].

[Network name] has been monitoring [facility name] since [date] because [facility name] [short summary of problems and actions taken, to include:

- *Supporting information for recommendation;*
- *Clinical Performance Measures outcome data that were deficient;*
- *Other causes for concern, e.g., high mortality ratio, high number of complaints; and*
- *Actions, including facility Quality Improvement Plan (QIP) activities that were monitored and assessed to determine non-compliance.]*

The deficient practices identified above, which may contribute to poor patient outcomes, represent the failure of [facility name] to [description of the overarching problem, e.g., follow the MRB's recommendations to implement a QIP].

[Network name] understands that only CMS has the authority to impose and remove sanctions, and that the responsibility for the appeals process lies with CMS. [Network name] is willing and available to serve in an advisory capacity as CMS makes its decisions regarding [facility name]. [Network name] is available to discuss the findings described in the enclosed summary report and to provide additional information, if necessary.

[Network name]'s contact person is [Executive Director or designee].

Thank you for your consideration of this recommendation.

Sincerely,

[Signature]

[Name of Executive Director]
On behalf of [Executive Board/Board of Directors] and Medical Review Board, [name of ESRD Network]

cc: [CMS Central Officer ESRD Program Manager]
[Centers for Medicaid and State Operations contact person]

Enclosures:
Facility characteristics [Name, certification number, certification date , address, phone, FAX, affiliation, back-up hospital, services provided, number of stations, number of shifts, days of operation, patient census, availability of other facilities in the immediate geographic area, and names of the Chief Executive Officer, Medical Director, Administrator, Nurse Manager, and Social Worker]

History of Network efforts to work with [facility name] [Summary of efforts made and facility response]

Supporting evidence for this recommendation [Details of chart reviews, site visits, facility patient outcomes, facility Quality Improvement Plans and results, etc.]

Transmittals Issued for this Chapter

Rev #	Issue Date	Subject	Impl Date	CR#
R09ESRD	04/18/2008	ESRD Network Organizations: Sanctions and Referrals	05/19/2008	5967