# **CMS Manual System** Pub. 100-14 Medicare End Stage Renal Disease Network Organizations

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

**Transmittal 4** 

Date: DECEMBER 24, 2003

#### I. SUMMARY OF CHANGES:

We have revised Chapter 3 – Confidentiality and Disclosure and its Table of Contents to add a new subsection and clarify several sections on disclosing and redisclosing confidential information. We have added the new process the Network must follow when a law enforcement agency contacts the Network for consultation about a data request under the new subsection 60.5.1. We have also placed the new and revised hyperlinks in the following sections/subsections:

Subsection 10.1, Extension of Confidentiality Provisions - revised to correct a statutory citation for a hyperlink in <u>\$1160</u> of the Act to correctly direct the reader to Title XI of the Act.

Section 20, General Requirements - revised to correct a regulatory citation for a hyperlink in 42 CFR 480.130 - 143 to 42 CFR 480.130 - 480.142.

Subsection 40.1, Definition of Confidential Information - revised to correct the regulatory citation for the hyperlink in  $\underline{42 \text{ CFR } 480.101}$  to  $\underline{42 \text{ CFR } 480.101(b)}$ .

Subsection 40.6, Disclosure and Redisclosure of Patient-Specific Information by SA - establishes a new hyperlink to Title XI of the Act and  $\frac{\$1160(b)(1)(C)}{\$1160(b)(1)(C)}$ .

Subsection 60.5.1, Updated Process for Law Enforcement Agency Requests to Obtain CMS/Medicare Data - establishes a new hyperlink to Title XI of the Act and  $\frac{1160(b)(1)(A)}{2}$ .

Subsection 60.8, Disclosures to Quality Improvement Organizations (QIOs) - establishes a new hyperlink to <u>42 CFR 476.71</u>.

#### NEW/REVISED MATERIAL - EFFECTIVE DATE: February 10, 2004 IMPLEMENTATION DATE: February 10, 2004

Disclaimer: The revision date and transmittal number apply only to red italicized material. Any other material was previously published and remains unchanged.

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	3/Table of Contents
R	3/10/10.1/ Extension of Confidentiality Provisions
R	3/20/ General Requirements
R	3/20/20.2/ Responsibility to Protect Information
R	3/20/20.3/ Network's Notification Requirement
R	3/20/20.4/ Verification and Amendment of ESRD Information
R	3/20/20.5/ Individual's Access to Information About Himself or Herself
R	3/20/20.5/20.5.1/ Disclosure to Beneficiary
R	3/20/20.5/20.5.2/ Disclosure to Beneficiary's Representative
R	3/20/20.6/20.6.1/ Practitioners and Reviewers
R	3/20/20.6/20.6.2/ Health Care Facilities
R	3/30/30.2/ Disclosure of Nonconfidential Information
R	3/40/40.1/ Definition of Confidential Information
R	3/40/40.3/ Disclosure and Redisclosure of ESRD Facility Information Among
	ESRD Networks, State Survey Agencies (SA), and Department of Health and
	Human Services (DHHS) Regional Offices
R	3/40/40.4/ Disclosure of Confidential Information to Elected Officials
R	3/40/40.5/ Disclosure of Information - Contract Deliverables
R	3/40/40.6/ Disclosure and Redisclosure of Patient-Specific and Practitioner-
	Specific Information by SA
R	3/60/60.1/ Disclosure to DHHS
R	3/60/60.2/ Disclosure for Purposes of Monitoring and Evaluation
R	3/60/60.4/ Disclosure to Intermediaries and Carriers
R	3/60/60.5/ Disclosures to Federal and State Enforcement Agencies
Ν	3/60/60.5/60.5.1/ Updated Process for Law Enforcement Agency Requests to
	Obtain CMS/Medicare Data
R	3/60/60.6/ Disclosure to State and Local Public Health Officials
R	3/60/60.7/ Disclosure for Purposes of Conducting Review
R	3/60/60.8/ Disclosures to Quality Improvement Organizations (QIOs)
R	3/70/ Disclosure of Network Information Involving Beneficiary Complaints
R	3/80/80.1/ Independent Research Activities
R	3/80/80.2/ Department Research Activities
R	3/90/ Disclosure of Network Sanction Information
R	3/100/100.3/ Notifying Recipients About Redisclosing Confidential
	Information

# II. SCHEDULE OF CHANGES (R = REVISED, N = NEW, D = DELETED)

# Medicare ESRD Network Organizations Manual

# **Chapter 3 - Confidentiality and Disclosure**

Table of Contents

#### (Rev. 4, 12-24-03)

- 10 Statutory and Regulatory Requirements
  - 10.1 Extension of Confidentiality Provisions
  - 10.2 Regulations in 42 CFR Part 480
- 20 General Requirements
  - 20.1 Network Access to Information
  - 20.2 Responsibility to Protect Information
  - 20.3 Network's Notification Requirement
  - 20.4 Verification and Amendment of ESRD Information
  - 20.5 Beneficiary's Access to Information About Himself or Herself
    - 20.5.1 Disclosure to Beneficiary
    - 20.5.2 Disclosure to Beneficiary's Representative
  - 20.6 Disclosure of Information About Practitioners, Reviewers, and Facilities
    - 20.6.1 Practitioners and Reviewers
    - 20.6.2 Health Care Facilities
- 30 Nonconfidential Information
  - 30.1 Types of Nonconfidential Information
  - 30.2 Disclosure of Nonconfidential Information
- 40 Confidential Information
  - 40.1 Definition of Confidential Information
  - 40.2 Disclosure of Confidential Information
  - 40.3 Disclosure and Redisclosure of ESRD Facility Information Among ESRD Networks, State Survey Agencies (SA), and Department of Health and Human Services (DHHS) Regional Offices
  - 40.4 Disclosure of Confidential Information to Elected Officials
  - 40.5 Disclosure of Information Contract Deliverables
  - 40.6 Disclosure and Redisclosure of Patient-Specific and *Practitioner*-Specific Information by SA
- 50 Disclosure of Network Deliberations
- 60 Disclosure of Confidential Network Information to Officials and Agencies 60.1 - Disclosure to DHHS

- 60.2 Disclosure for Purposes of Monitoring and Evaluation
- 60.3 Disclosure to Consultants and Subcontractors
- 60.4 Disclosure to Intermediaries and Carriers
- 60.5 Disclosures to Federal and State Enforcement Agencies 60.5.1 – Updated Process for Law Enforcement Agency Requests to Obtain CMS/Medicare Data
- 60.6 Disclosure to State and Local Public Health Officials
- 60.7 Disclosure for Purposes of Conducting Review
- 60.8 Disclosures to Quality Improvement Organizations (QIOs)
- 60.9 Disclosures to Medical Review Boards
- 70 Disclosure of Network Information Involving Beneficiary Complaints
- 80 Disclosure of Network Information for Research Purposes
  - 80.1 Independent Research Activities
  - 80.2 Department Research Activities
- 90 Disclosure of Network Sanction Information
- 100 Redisclosure of Network Information
  - 100.1 Redisclosure of Nonconfidential Information
  - 100.2 Redisclosure of Confidential Information
  - 100.3 Notifying Recipients About Redisclosing Confidential Information

#### 10 - Statutory and Regulatory Requirements

(Rev. 1, 07-11-03)

#### ENO 300

#### **10.1 - Extension of Confidentiality Provisions**

(Rev. 4, 12-24-03)

#### ENO 300.A

Section 6219 of the Omnibus Budget Reconciliation Act of 1989 (PL 101-239) amended <u>§1881(c)(8)</u> of the Social Security Act (the Act) to extend the confidentiality provision of <u>§1160</u> of the Act to ESRD Network Organizations (including medical review boards [MRBs]). Section 1160 of the Act provides the statutory basis for the disclosure of information. It also:

• Establishes the scope of the Network's authority to disclose information for program purposes, including any required disclosures;

- Addresses the Network's responsibility to protect information and/or data collected from unauthorized disclosure and provides penalties for unauthorized disclosure; and
- Exempts the Network from the disclosure provisions contained in the Freedom of Information Act.

# 10.2 - Regulations in 42 CFR Part 480

#### (Rev. 1, 07-11-03)

#### ENO 300.B

These regulations, which apply for the most part to ESRD Networks as well as to QIOs, contain rules concerning the Network's authority to disclose information and the Network's responsibility to protect information from unauthorized disclosure. The statute and regulations apply only to information that the Network generates and acquires as a result of its Medicare review and required CMS data collection activities.

# 20 - General Requirements

#### (Rev. 4, 12-24-03)

### ENO 305

All *identifiable* data provided to the Network by CMS and all materials prepared *by the Network* for CMS are considered confidential and cannot be disclosed to anyone other than the Network staff except as provided by <u>42 CFR 480.130 – 480.142</u>. *Confidential information is defined as any information that explicitly or implicitly identifies an individual patient, practitioner, or reviewer; sanction reports and recommendations; quality review studies which identify patients, practitioners, or institutions (defined at 42 CFR 480.101(b))*. The Network must comply with all applicable rules CMS establishes relating to confidentiality and disclosure.

# **20.1 - Network Access to Information**

#### (Rev. 1, 07-11-03)

#### ENO 305A

As specified in <u>42 CFR 405.2139(b)</u>, the ESRD facility must make medical records available for the Network's inspection as required to carry out its statutory responsibilities.

# **20.2 - Responsibility to Protect Information**

#### (Rev. 4, 12-24-03)

#### ENO 305.B

As specified in <u>42 CFR 480.115</u>, the Network must implement reasonable security measures to ensure the integrity of its information and to prevent unauthorized access. Instruct officers, employees, and *all* committee members of their responsibility to maintain the confidentiality of information. Network information means any data or information collected, acquired, or generated by a Network in the exercise of its duties and functions under title XVIII of the Act.

# 20.3 - Network's Notification Requirement

#### (Rev. 4, 12-24-03)

#### ENO 305.C

Prior to disclosing Network information, *the Network must* comply with any applicable notification requirements in <u>42 CFR 480.104(a)</u> and <u>480.105</u>, *as well as* with the general notice requirements specified in <u>42 CFR 480.116</u>. Exceptions to the notice requirements are found in <u>42 CFR 480.106</u>.

# 20.4 - Verification and Amendment of ESRD Information

#### (Rev. 4, 12-24-03)

#### ENO 305.D

If for any reason the facility, *practitioner* or physician has concerns about Network information pertaining to the patient, practitioner, and/or facility and requests an amendment of pertinent information in the Network's possession, <u>42 CFR 480.134</u> requires the Network to:

- Verify the accuracy of any information the Network has submitted concerning patients, practitioners, reviewers, and facilities;
- Make any necessary corrections if the individual or facility requests an amendment of pertinent information that is in its possession;
- Forward the amended information to the requestor if the information being amended has already been disclosed, and when the amended information may affect decisions about a particular facility, practitioner, or case under review; and
- Annotate the request, if the Network disagrees with the request for amendment, with the reasons for the request and the reasons for refusal, and include or attach annotations to any disclosure of the information.

# 20.5 - Beneficiary's Access to Information About Himself or Herself

#### (Rev. 4, 12-24-03)

#### ENO 305.E

As specified in <u>42 CFR 480.132(a)(2)</u>, *the Network must* disclose information about *a beneficiary* to himself/herself within 30 calendar days of receipt of the request.

#### 20.5.1 - Disclosure to Beneficiary

#### (Rev. 4, 12-24-03)

#### ENO 305.E.1

*The Network must d*isclose information to the beneficiary or his/her representative as specified in 42 CFR 480.132. A beneficiary is entitled to have access to information pertaining to him or her, including psychiatric records and records concerning alcohol/drug abuse. However, if knowledge of the information would be harmful to the beneficiary, *the Network must* disclose the information to his/her representative rather than to the beneficiary. *The Network d*etermines whether direct disclosure could harm the beneficiary in accordance with 42 CFR 480.132(a)(2).

When a beneficiary's request for his/her medical record is not related to an appeal of *a* denial determination, as specified in  $\underline{42 \text{ CFR } 478.24(a)}$ , the Network provides him/her with any applicable records in its possession, as required by 42 CFR 480.132(a). Before disclosing information under this authority, *the Network* removes any material that explicitly or implicitly identifies practitioners, other patients, or Network reviewers, if no consent is given for disclosure. *It d*iscloses the Network deliberations and quality review study information only as specified in  $\underline{42 \text{ CFR } 480.139(a)}$  and  $\underline{480.140}$ .

**NOTE:** The Network may encourage the beneficiary to seek the medical record from the appropriate health care facility *(the facility possessing the original medical record)* directly. If the beneficiary declines this advice, the Network is still bound to provide the records as specified above.

# 20.5.2 - Disclosure to Beneficiary's Representative

#### (Rev. 4, 12-24-03)

#### ENO 305.E.2

*The Network d*iscloses information to the beneficiary's representative instead of directly to the beneficiary when required by 42 CFR 480.132, or when the beneficiary designates a representative. If the beneficiary chooses to designate a representative or a beneficiary's

condition necessitates the designation of a representative, a properly designated beneficiary representative may exercise the same rights and privileges as the beneficiary in seeking beneficiary information. If the beneficiary is deceased, *the Network must* disclose the information to the first appropriate individual according to the following order:

- To the executor of the estate or personal representative, as established by law or the deceased's will;
- To the administrator of the estate; or
- To an individual verified in writing to be the beneficiary's designated representative.

# **20.6 - Disclosure of Information About Practitioners, Reviewers, and Facilities**

(Rev. 1, 07-11-03)

ENO 305.F

# 20.6.1 - Practitioners and Reviewers

(Rev. 4, 12-24-03)

#### ENO 305.F.1

*The Network must d* is close information to practitioners and the Network reviewers as specified in 42 CFR 480.133(a)(1). The Network may also disclose information on a particular practitioner or reviewer to a third party if the individual identified in the information consents to the disclosure. The disclosed information, however, cannot identify other individuals without their consent.

A practitioner may designate another party (e.g., corporate owner) as his/her agent for the receipt of specific data from a Network/QIO. The Network may upon the written request of a practitioner transmit specified data to the agent either in lieu of or in addition to transmitting it to the practitioner. The Network must receive from the practitioner a designation of the agent and request to send specific data to the agent.

These items may be contained in the same written instrument. In addition, when the requested data is sent to the agent, the agent must be advised that:

"There are specific limitations on redisclosing any data received from an ESRD Network under §1160 of the Act and in 42 CFR 480.107 and 42 CFR 480.140. Any person who discloses information not authorized under these provisions will, if convicted, be subject to a fine of up to \$1000.00, or be imprisoned for no more than six months, or both, and will pay the cost of prosecution."

The Network should inform its CMS Project Officer of such arrangements and maintain adequate documentation of the arrangement. The Network may charge the reasonable costs of the disclosure in accordance with the provisions of 42 CFR 480.104(c).

#### 20.6.2 - Health Care Facilities

(Rev. 4, 12-24-03)

#### ENO 305.F.2

*The Network must d*isclose information to health care facilities as specified in 42 CFR 480.133(a)(1). Facility-specific information is nonconfidential unless the material is part of the Network's deliberations or contains confidential information (such as quality review studies which identify patients, practitioners, or facilities), as defined in 42 CFR 480.101(b). *The Network must d*isclose quality review study information only as specified in 42 CFR 480.140.

A provider may designate another party (e.g., corporate owner) as his/her agent for the receipt of specific data from a Network/QIO. The Network may upon the written request of a provider transmit specified data to the agent either in lieu of or in addition to transmitting it to the provider. The Network must receive from the provider a designation of the agent and request to send specific data to the agent. These items may be contained in the same written instrument. In addition, when the requested data is sent to the agent, the agent must be advised that:

"There are specific limitations on redisclosing any data received from an ESRD Network under §1160 of the Act and in 42 CFR 480.107 and 42 CFR 480.140. Any person who discloses information not authorized under these provisions will, if convicted, be subject to a fine of up to \$1000.00, or be imprisoned for no more than six months, or both, and will pay the cost of prosecution."

The Network should inform its CMS Project Officer of such arrangements and maintain adequate documentation of the arrangement. The Network may charge the reasonable costs of the disclosure in accordance with the provisions of 42 CFR 480.104(c).

# **30 - Nonconfidential Information**

(Rev. 1, 07-11-03)

ENO 310

# **30.1 - Types of Nonconfidential Information**

(Rev. 1, 07-11-03)

#### ENO 310.A

Nonconfidential information generally includes any information that does not meet the definition of confidential information found in 42 CFR 480.101(b). It includes, but is not limited to, those items specified in 42 CFR 480.120(a).

Facility-specific information that does not contain the Network's deliberations or confidential information (as defined by 42 CFR 480.101(b)) is nonconfidential.

# **30.2 - Disclosure of Nonconfidential Information**

#### (Rev. 4, 12-24-03)

#### ENO 310.B

*The Network must d*isclose nonconfidential information, upon request, as specified in 42 CFR 480.120. As provided by <u>42 CFR 480.121</u>, the Network may also disclose nonconfidential information on its own initiative.

Upon request, the Network may disclose material such as lists of its meetings and dates of their occurrence, as long as there is no confidential information included in the material. *It may d*isclose summaries of proceedings of meetings, if the material contains no confidential information. The Network may release any of the ESRD Network-approved *Network Annual Report*, which do not explicitly or implicitly identify a patient, practitioner, or *physician* without prior approval.

The Network may release utilization data (e.g., treatment information not specifically related to quality of care) without prior approval when the cell size is 11 or greater if:

- The utilization data are single dimension counts (i.e., referring to one characteristic such as transplants, peritoneal patients) by:
  - 1. State;
  - 2. Facility; or

- 3. Zip code.
- The utilization data are two dimension counts by geographic area and:
  - 1. Age interval;
  - 2. Modality; or
  - 3. Sex.
- The utilization data are multi-dimensional counts by any characteristics that do not include geographic data lower than State level.

# 40 - Confidential Information

(Rev. 1, 07-11-03)

ENO 315

# 40.1 - Definition of Confidential Information

#### (Rev. 4, 12-24-03)

#### ENO 315.A

Confidential information, as defined in <u>42 CFR 480.101(b)</u>, is information that explicitly or implicitly identifies an individual patient, practitioner, or reviewer, sanction reports and recommendations, quality review studies that identify patients, practitioners, or facilities, and Network deliberations. Information that implicitly identifies individuals is information so unique *or number so small* that identification of an individual patient, practitioner, or reviewer *would be obvious*.

# 40.2 - Disclosure of Confidential Information

(Rev. 1, 07-11-03)

ENO 315.B

Disclose confidential information only as authorized under <u>42 CFR 480.130 through 480.143</u>.

# 40.3 - Disclosure and Redisclosure of ESRD Facility Information Among ESRD Networks, State Survey Agencies (SA), and Department of Health and Human Services (DHHS) Regional Offices

(Rev. 4, 12-24-03)

#### ENO 315.C

A Network must disclose confidential facility-specific and patient-specific information (data and observation), upon request, to a SA, and/or a CMS RO that is responsible for the Medicare certification of that institution. (See <u>42 CFR 480.130</u> and <u>480.138(a)(1)</u>.) *Disclosure of quality review study information is limited to substantial risks to public health and the enforcement of fraud and abuse as defined at 42 CFR 480.140(a). The Network must disclose all information requested by the Department in the manner and form required except as limited by 42 CFR 480.139 (a) and 42 CFR 480.140. The Network should disclose Network information that displays patterns of care to the extent that it is required by a licensure, accreditation, or certification agency to carry out a function of that agency. (See 42 CFR 480.138(a)(1) and <u>480.140(a)(1)</u>.) One such function could be to focus survey resources on specific facilities or specific areas within a facility.* 

**NOTE:** Upon request, SAs must disclose facility-specific information (data and observations) to the public, including the ESRD Networks. (See <u>42 CFR 431.115</u>.) SAs may use data received from a Network to direct the survey of a provider's performance, but must have its own documentation to support deficiencies cited.

As specified in <u>42 CFR 480.135(a)</u>, the Network *must disclose or arrange for disclosure of information to individuals and facilities within the Network review system* as necessary to fulfill its duties and functions under title XVIII of the Act. As specified in 42 CFR 480.135(c), a *Network must* disclose confidential information *about patients or practitioners who are subject to review by the other Network. This includes sanction information, as well as the usual quality review information.* 

*Per 42 CFR 480.133(a), the Network must d*isclose practitioner-specific information about potential and confirmed quality problems to the involved practitioner and to the facility where the services were furnished. *It must s*end all notices regarding quality

problems to both the practitioner and facility. An institution should designate specific officials to receive Network notices and other confidential disclosures.

# 40.4 - Disclosure of Confidential Information to Elected Officials

#### (Rev. 4, 12-24-03)

#### ENO 315.D

If a beneficiary or practitioner writes to an elected official requesting assistance, *the beneficiary or practitioner must consent to having the elected official receive* information about his/her situation. Accordingly, when an elected official *is designated by the beneficiary or practitioner as his/her representative, the elected official may receive* information from the Network on behalf of a beneficiary or practitioner. *The* Network *should disclose* the same information *to the elected official* that it would disclose to the beneficiary or practitioner. *(See 42 CFR 480.132.) Another option is to advise the beneficiary or practitioner to request the information in writing. When the beneficiary/practitioner receives his or her information from the Network then the beneficiary/practitioner can provide the information to the elected official provided the information includes no other confidential information related to other individuals or entities.* 

# 40.5 - Disclosure of Information - Contract Deliverables

#### (Rev. 4, 12-24-03)

#### ENO 315.E

Deliverables prepared under a Network contract (e.g., Annual Report, Quarterly Progress, and Status Reports) may be released to the public after approval by the Network's PO. *The Network should forward all requests for disclosure of material, other than aggregate data, to the PO who will make a disposition of the request in accordance with applicable CMS policies and Government requirements.* 

# 40.6 - Disclosure and Redisclosure of Patient-Specific and *Practitioner*-Specific Information by SA

#### (Rev. 4, 12-24-03)

#### ENO 315.F

Patient-specific and practitioner-specific information are not releasable by the SA to the public. (See <u>42 CFR 431.115(h)(3)</u>.) <u>Section 1160(b)(1)(C)</u> of the Act requires a Network to disclose provider-specific and practitioner-specific (but not patient-specific) information to assist appropriate State agencies recognized by the Secretary as responsible for licensing and certification of providers or practitioners at the request of

the agency relating to a specific case or a possible pattern of substandard care. This information must be disclosed only to the extent it is required by the agency in carrying out its respective functions within the jurisdiction of the agency under State law. 42 CFR 480.107 addresses redisclosure that apply to a person or organization that has obtained Network information and the exceptions under which redisclosure is permissible. 42 CFR 480.107(i) allows the State licensing or certification agencies recognized by CMS to disclose information as necessary in a judicial, administrative or other formal legal proceeding resulting from an investigation conducted by the agency.

# 50 - Disclosure of Network Deliberations

(Rev. 1, 07-11-03)

#### ENO 320

Regardless of any other provision, the Network discloses its deliberations only as specified in 42 CFR 480.139(a).

# 60 - Disclosure of Confidential Network Information to Officials and Agencies

(Rev. 1, 07-11-03)

ENO 325

# 60.1 - Disclosure to DHHS

#### (Rev. 4, 12-24-03)

#### ENO 325.A

Upon request, *the Network must* disclose confidential information to the Department in the manner and form required as specified in 42 CFR 480.130.

# 60.2 - Disclosure for Purposes of Monitoring and Evaluation

#### (Rev. 4, 12-24-03)

#### ENO 325.B

Upon request, the Network discloses confidential information to CMS or any person, organization, or agency authorized by the Department or Federal statute to monitor its performance, as specified in <u>42 CFR 480.131</u>. The information *that the Network is* required to *disclose may include* copies of medical records of Medicare beneficiaries that are maintained by health care facilities or health care practitioners.

# 60.3 - Disclosure to Consultants and Subcontractors

(Rev. 1, 07-11-03)

ENO 325.C

As specified in <u>42 CFR 480.135(b)</u>, the Network discloses information to consultants and subcontractors when the individual/organization needs the information to provide the Network with specified services.

# 60.4 - Disclosure to Intermediaries and Carriers

(Rev. 4, 12-24-03)

#### ENO 325.D

*The Network must d*isclose confidential information to intermediaries and carriers as specified in 42 CFR 480.136, which authorizes disclosure of information relevant to the intermediary's or carrier's responsibility for making proper payment determinations. This includes disclosures needed to coordinate medical review activities between the Network and the intermediary or carrier.

# 60.5 - Disclosures to Federal and State Enforcement Agencies

(Rev. 4, 12-24-03)

#### ENO 325.E

*The Network must* disclose confidential information relevant to an investigation of fraud or abuse of the Medicare or Medicaid programs to Federal and State enforcement agencies under the terms stated in the regulation. (See 42 CFR <u>480.106(b)</u>, <u>480.130</u>, <u>480.137</u>, <u>480.138(b)</u>, <u>480.139(a)</u>, and <u>480.140(a)(1)</u>, (b), and (e).)

**NOTE:** The facility and/or practitioner is not to be notified of any information released to Federal and/or State enforcement agencies in potential fraud or abuse cases.

# 60.5.1 Updated Process for Law Enforcement Agency Requests to Obtain CMS/Medicare Data

(Rev. 4, 12-24-03)

Sections <u>1160(b)(1)(A)</u> of the Act and 42 CFR 480.137 of the regulation require that a Network disclose confidential information relevant to an investigation of fraud or abuse of the Medicare or Medicaid programs, when a written request is received from a State or Federal law enforcement agency responsible for the investigation or identification of fraud or abuse.

1. When a law enforcement agency contacts an ESRD Network for consultation about a data request, the initial discussion should include the purpose and goal of the data request and whether the Network has the requested data or if another entity is a more appropriate source of the needed data. Upon receiving a data request from a law enforcement agency, the Network will notify its project officer and examine its sources of data for the most recent 36-month period for the substantive matter(s) in question or the specific period requested by the law enforcement agency. In consultation with the Network, the law enforcement agency should also make known the following:

- Type of data and the fields of information needed
- Name and or other identifying information for practitioner(s), provider(s) or facility(ies) (e.g., Unique Physician Identification Number, etc.)
- *Time period necessary for the inquiry (approximate beginning and ending dates unless the concern is ongoing)*
- Format or medium for data to be provided (e.g., tape, CD-ROM, paper, etc.).

(See 42 CFR 480.133, 480.137, 480.139, and 480.142.)

2. After consulting with the appropriate Network, determining the availability of the desired data, and following the "US Department of Justice - Updated Process, Model Letters and Forms to Request Protected Health Information pursuant to the Privacy Act and HIPPA Privacy Rule", the law enforcement agency should send a signed letter of request to the Network, identifying the appropriate authority under which the information is being sought and specifying the details of the request. Upon receipt of the letter, the Network will provide the relevant data, reports and findings to the requesting agency in the format(s) requested within 30 days when data for the most recent 36-month period is being sought directly from the Network. If it is necessary for the Network to seek and acquire other data from CMS or another affiliated Medicare contractor, the time period required to acquire the data for the requesting agency will be extended beyond 30 days.

3. When appropriate, the Network will use analytic tools or make a referral to the appropriate QIO or other appropriate entity, which will use analytic tools to look for possible indicators of fraud in addition to the specific alleged conduct that was the cause of the law enforcement agency's data request. When a Network makes a referral to a QIO or other entity for data analysis in response to a law enforcement agency data request, the agency or entity receiving the referral will then deal directly with the law enforcement agency in responding to the agency's data request. The Network can only make such referrals in those situations in which there is a legal basis under §1160 of the Act or 42 CFR 480 for disclosing data to the QIO or other entity.

# 60.6 - Disclosure to State and Local Public Health Officials

#### (Rev. 4, 12-24-03)

#### ENO 325.F

The Network discloses information to State and local public health officials whenever it determines that the disclosure of the information is necessary to protect against a substantial risk to the public health. If the requested information is necessary to protect against an imminent danger to individuals or the public health, the Network *must* release facility and patient-specific data to State and local authorities that need the information to respond to the situation. (See <u>42 CFR 480.106(a)</u> and <u>480.138(a)(2)</u>.) The Network notifies CMS when it makes such a disclosure, and it sends a notice simultaneously to the facility that must still be given the opportunity to comment on the information about itself.

# 60.7 - Disclosure for Purposes of Conducting Review

#### (Rev. 4, 12-24-03)

#### ENO 325.G

The Network discloses or arranges for disclosure of information to individuals *and institutions* within its Network review *jurisdiction* as necessary to fulfill *their* particular duties and functions under the statute. (See <u>42 CFR 480.135(a)</u>.)

# 60.8 - Disclosures to Quality Improvement Organizations (QIOs)

#### (Rev. 4, 12-24-03)

#### ENO 325.H

Disclose to QIOs information, *needed by the QIO* to fulfill their particular duties and functions under Title XI, Part B, *of the Act and 42 CFR 480.135 carrying out quality of care review in hospitals, Home Health Associations, out patient surgery clinics, etc. as described in* <u>42 CFR 476.71</u> on patients and practitioners who are subject to review by the QIO.

# 60.9 - Disclosures to Medical Review Boards

(Rev. 1, 07-11-03)

#### ENO 325.I

Disclose to MRBs established under <u>§1881</u> of the Act information on patients, practitioners, and institutions receiving or furnishing ESRD services who are subject to review by the ESRD Network Organizations.

# 70 - Disclosure of Network Information Involving Beneficiary Complaints

#### (Rev. 4, 12-24-03)

#### ENO 330

The Network is required to conduct an appropriate review of all written complaints from Medicare beneficiaries (or their designated representatives) about the quality of Medicare services. (See \$1881(c)(2)(D) of the Act.) Ensure that any disclosure of information is consistent with applicable provisions of 42 CFR Part 480. (See Chapter 7, \$\$100 of this manual *on the grievance process*.)

# 80 - Disclosure of Network Information for Research Purposes

(Rev. 1, 07-11-03)

ENO 335

# 80.1 - Independent Research Activities

#### (Rev. 4, 12-24-03)

#### ENO 335.A

The Network does not disclose information that *implicitly or* explicitly identifies patients, practitioners, or reviewers without their consent. Upon approval from CMS, the Network may disclose information after deleting all confidential identifiers and any other information from which identification of the individual can be deduced. The Network may replace the confidential identifiers with numerical or alphabetical codes that researchers can use to track specific patients or practitioners without knowing the actual identifies of the individuals. After the Network deletes all identifying information, the remaining material is nonconfidential and may be disclosed upon approval. *At least 30 days prior to the disclosure of non-confidential information, the Network must notify an identified institution of its intent to disclose information about the institution (other than reports routinely submitted to CMS, or Medicare intermediaries, or to or from Network* 

subcontractors, or to or from the institution) and provide the institution with a copy of the information. (See 42 CFR 480.105(a).)

# **80.2 - Department Research Activities**

#### (Rev. 4, 12-24-03)

#### ENO 335.B

Research entities that conduct research activities for CMS as contractors or subcontractors of the Department, and who are bound by a CMS confidentiality agreement, have access to the Network's confidential information when it is needed to accomplish the Department's objectives. *The Network provides* this information in the manner and form required to the Department component to whom the request *for data* was issued in accordance with <u>42 CFR 480.130</u>. The Department component will then rerelease this information to the requestor under <u>480.107(b)</u> *if the release is designed to carry out specific responsibilities of the Secretary*.

#### 90 - Disclosure of Network Sanction Information

#### (Rev. 4, 12-24-03)

#### ENO 340

*The Network* discloses sanction recommendation reports and relevant sanction information to the Office of the Inspector General (OIG), CMS, and agencies that investigate and prosecute fraud and abuse *a*s specified in <u>42 CFR 480.142</u>.

Concurrent with the Network's final notice, the Network provides the affected practitioner or other person with a copy of the complete sanction report and recommendations that it is submitting to OIG.

#### 100 - Redisclosure of Network Information

(Rev. 1, 07-11-03)

ENO 345

#### **100.1 - Redisclosure of Nonconfidential Information**

(Rev. 1, 07-11-03)

#### ENO 345.A

There are no statutory or regulatory restrictions that limit a recipient's redisclosure of nonconfidential information.

# 100.2 - Redisclosure of Confidential Information

(Rev. 1, 07-11-03)

#### ENO 345.B

All recipients of confidential information, including SAs, cannot redisclose the information except under the limited circumstances authorized by <u>42 CFR 480.107</u>.

For example, recipients of the Network's confidential information (beneficiaries and practitioners) may redisclose information about themselves provided the redisclosure does not explicitly or implicitly identify another individual.

# 100.3 - Notifying Recipients About Redisclosing Confidential Information

#### (Rev. 4, 12-24-03)

#### ENO 345.C

According to <u>42 CFR 480.104(a)(2)</u>, the Network is required to inform recipients, in writing, that they cannot redisclose confidential information previously disclosed to them, except as permitted under <u>42 CFR 480.107</u>. *This warning must accompany the confidential information from the Network, furthermore* the Network's written notice should also advise the recipient of the penalties for unauthorized disclosures *as stated in 42 CFR 480.108*.

The Network explains in its notice to the recipient that, except as authorized in 42 CFR 480.107, confidential information cannot be redisclosed unless the individuals who would be identified consent to the redisclosure, or all confidential personal identifiers are removed. The notice can be a separate attachment to the information provided, or can be included within the *information*.

As part of the Network's responsibility to educate individuals and facilities about its review process, the Network conducts activities that inform individuals and facilities in its area of the rules and restrictions applicable to confidential information. (See <u>42 CFR 480.116</u>.) Improper redisclosures of confidential information are generally inadvertent rather than intentional. Accordingly, the Network provides educational programs to avoid problems.