

Medicare ESRD Network Organizations Manual

Chapter 3 - Confidentiality and Disclosure

Table of Contents

10 - Statutory and Regulatory Requirements.....	2
10.1 - Extension of Confidentiality Provisions.....	2
10.2 - Regulations in 42 CFR Part 480.....	3
20 - General Requirements	3
20.1 - Network Access to Information.....	3
20.2 - Responsibility to Protect Information.....	3
20.3 - Network's Notification Requirement.....	4
20.4 - Verification and Amendment of ESRD Information.....	4
20.5 - Individual's Access to Information About Himself or Herself.....	5
20.5.1 - Disclosure to Beneficiary	5
20.5.2 - Disclosure to Beneficiary's Representative	5
20.6 - Disclosure of Information About Practitioners, Reviewers, and Facilities ..	6
20.6.1 - Practitioners and Reviewers	6
20.6.2 - Health Care Facilities	6
30 - Nonconfidential Information	7
30.1 - Types of Nonconfidential Information.....	7
30.2 - Disclosure of Nonconfidential Information.....	7
40 - Confidential Information	8
40.1 - Definition of Confidential Information	8
40.2 - Disclosure of Confidential Information.....	9
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	9
40.4 - Disclosure of Confidential Information to Elected Officials.....	10
40.5 - Disclosure of Information - Contract Deliverables	10
40.6 - Disclosure and Redisclosure of Patient-Specific and Facility-Specific Information by SA	10
50 - Disclosure of Network Deliberations	11
60 - Disclosure of Confidential Network Information to Officials and Agencies.....	11
60.1 - Disclosure to DHHS	11
60.2 - Disclosure for Purposes of Monitoring and Evaluation	11

60.3 - Disclosure to Consultants and Subcontractors	11
60.4 - Disclosure to Intermediaries and Carriers	12
60.5 - Disclosures to Federal and State Enforcement Agencies	12
60.6 - Disclosure to State and Local Public Health Officials	12
60.7 - Disclosure for Purposes of Conducting Review.....	13
60.8 - Disclosures to Quality Improvement Organizations (QIOs)	13
60.9 - Disclosures to Medical Review Boards.....	13
70 - Disclosure of Network Information Involving Beneficiary Complaints	13
80 - Disclosure of Network Information for Research Purposes.....	14
80.1 - Independent Research Activities	14
80.2 - Department Research Activities	14
90 - Disclosure of Network Sanction Information.....	14
100 - Redislosure of Network Information	15
100.1 - Redislosure of Nonconfidential Information	15
100.2 - Redislosure of Confidential Information	15
100.3 - Notifying Recipients About Redisclosing Confidential Information	15

10 - Statutory and Regulatory Requirements

(Rev. 1, 07-11-03)

ENO 300

10.1 - Extension of Confidentiality Provisions

(Rev. 1, 07-11-03)

ENO 300.A

Section 6219 of the Omnibus Budget Reconciliation Act of 1989 (PL 101-239) amended [§1881\(c\)\(8\)](#) of the Social Security Act (the Act) to extend the confidentiality provision of §1160 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. 1, 07-11-03)

ENO 305

All data provided to the Network by CMS and all materials prepared for CMS are considered confidential and cannot be disclosed to anyone other than the Network staff except as provided by [42 CFR 480.130 - 143](#). 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 [42 CFR 405.2139\(b\)](#), 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. 1, 07-11-03)

ENO 305.B

As specified in [42 CFR 480.115](#), the Network must implement reasonable security measures to ensure the integrity of its information and to prevent unauthorized access. Instruct officers, employees, and 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. 1, 07-11-03)

ENO 305.C

Prior to disclosing Network information, comply with any applicable notification requirements in [42 CFR 480.104\(a\)](#) and [480.105](#). Also, comply with the general notice requirements specified in [42 CFR 480.116](#). Exceptions to the notice requirements are found in [42 CFR 480.106](#).

20.4 - Verification and Amendment of ESRD Information

(Rev. 1, 07-11-03)

ENO 305.D

If for any reason the facility 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, [42 CFR 480.134](#) 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 - Individual's Access to Information About Himself or Herself

(Rev. 1, 07-11-03)

ENO 305.E

As specified in [42 CFR 480.132\(a\)\(2\)](#), disclose information about an individual to himself/herself within 30 calendar days of receipt of the request.

20.5.1 - Disclosure to Beneficiary

(Rev. 1, 07-11-03)

ENO 305.E.1

Disclose 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, disclose the information to his/her representative rather than to the beneficiary. Determine 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 the Network's denial determination, as specified in [42 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, remove any material that explicitly or implicitly identifies practitioners, other patients, or Network reviewers, if no consent is given for disclosure. Disclose the Network deliberations and quality review study information only as specified in [42 CFR 480.139\(a\)](#) and [480.140](#).

NOTE: The Network may encourage the beneficiary to seek the medical record from the appropriate health care facility 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. 1, 07-11-03)

ENO 305.E.2

Disclose 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, 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.
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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. 1, 07-11-03)

ENO 305.F.1

Disclose 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.

20.6.2 - Health Care Facilities

(Rev. 1, 07-11-03)

ENO 305.F.2

Disclose 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\(b\)](#). Disclose quality review study information only as specified in [42 CFR 480.140](#).

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. 1, 07-11-03)

ENO 310.B

Disclose nonconfidential information, upon request, as specified in 42 CFR 480.120. As provided by [42 CFR 480.121](#), 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. Disclose summaries of proceedings of meetings, if the material contains no confidential information. The Network may release any of the ESRD Network-approved deliverable, which do not explicitly or implicitly identify a patient, practitioner, or reviewer (e.g., the approved Network Annual Report), 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. 1, 07-11-03)

ENO 315.A

Confidential information, as defined in [42 CFR 480.101](#), is information that explicitly or implicitly identifies an individual patient, practitioner, or reviewer, sanction reports and recommendations, quality review studies which identify patients, practitioners, or facilities, and Network deliberations. Information that implicitly identifies individuals is information so unique that identification of an individual patient, practitioner, or reviewer may be deduced from an examination of the information.

40.2 - Disclosure of Confidential Information

(Rev. 1, 07-11-03)

ENO 315.B

Disclose confidential information only as authorized under [42 CFR 480.130 through 480.143](#).

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. 1, 07-11-03)

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 [42 CFR 480.130](#) and [480.138\(a\)\(1\)](#).) The Secretary has the legislative authority to request and receive whatever information is required to make certification determinations for Medicare providers and suppliers. (See [42 CFR 480.107\(b\)](#).) Disclose the 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 [480.140\(a\)\(1\)](#).) 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 [42 CFR 431.115](#).) Facility-specific information that is released by the Network to the SA is releasable to the public by the SA in whole or in part if it is used as the basis for citing deficiencies, whether or not the deficiencies result in an enforcement action. 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 [42 CFR 480.135\(a\)](#), the Network discloses confidential information as necessary to fulfill its duties and functions under title XVIII of the Act. This includes any disclosures needed to properly complete an appeal. As specified in 42 CFR 480.135(c), disclose confidential information to another Network when the material is related to practitioners who are subject to review by the other Network. This includes sanction information, as well as the usual quality review information.

Disclose practitioner-specific information about potential and confirmed quality problems to the involved practitioner and to the facility where the services were furnished. Send 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. 1, 07-11-03)

ENO 315.D

If a beneficiary or practitioner writes to an elected official requesting assistance, the elected official has the implied consent of the individual to receive Network information about his/her situation. Accordingly, when an elected official requests information from the Network on behalf of a beneficiary or practitioner, the Network discloses the same information that it would disclose to the beneficiary/practitioner if he/she had made the request directly.

40.5 - Disclosure of Information - Contract Deliverables

(Rev. 1, 07-11-03)

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. 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 Facility-Specific Information by SA

(Rev. 1, 07-11-03)

ENO 315.F

Patient-specific and practitioner-specific information are not releasable by the SA to the public. (See [42 CFR 431.115\(h\)\(3\)](#).) Confidential information released by the Network to the SA is not subject to subpoena or discovery in a civil action, including an administrative, judicial, or arbitration proceeding, and is not releasable to the public by the SA. Therefore, a SA may not use the Network's data and/or information as the basis for citing a deficiency and must keep information received from the Network separate from the routine survey records. Both the Network and the SAs must be very clear about the exact uses that data will be put to in the certification process because of issues regarding the confidentiality and releasability of data.

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. 1, 07-11-03)

ENO 325.A

Upon request, 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. 1, 07-11-03)

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 [42 CFR 480.131](#). The information required to be disclosed includes 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 [42 CFR 480.135\(b\)](#), 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. 1, 07-11-03)

ENO 325.D

Disclose 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. 1, 07-11-03)

ENO 325.E

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 [480.106\(b\)](#), [480.130](#), [480.137](#), [480.138\(b\)](#), [480.139\(a\)](#), and [480.140\(a\)\(1\), \(b\), 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.

60.6 - Disclosure to State and Local Public Health Officials

(Rev. 1, 07-11-03)

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 may release facility and patient-specific data to State and local authorities that need the information to respond to the situation. (See [42 CFR 480.106\(a\)](#) and [480.138\(a\)\(2\)](#).) 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. 1, 07-11-03)

ENO 325.G

The Network discloses or arranges for disclosure of information to individuals within its Network reviews area as necessary to fulfill its particular duties and functions under the statute. (See [42 CFR 480.135\(a\)](#).)

60.8 - Disclosures to Quality Improvement Organizations (QIOs)

(Rev. 1, 07-11-03)

ENO 325.H

Disclose to QIOs information, as necessary to fulfill their particular duties and functions under Title XI, Part B, 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 [§1881](#) 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. 1, 07-11-03)

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.)

80 - Disclosure of Network Information for Research Purposes

(Rev. 1, 07-11-03)

ENO 335

80.1 - Independent Research Activities

(Rev. 1, 07-11-03)

ENO 335.A

The Network does not disclose information that 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 identities of the individuals. After the Network deletes all identifying information, the remaining material is nonconfidential and may be disclosed upon approval.

80.2 - Department Research Activities

(Rev. 1, 07-11-03)

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. Provide this information in the manner and form required to the Department component to whom the request was issued in accordance with [42 CFR 480.130](#). The Department component will then re-release this information to the requestor under [480.107\(b\)](#).

90 - Disclosure of Network Sanction Information

(Rev. 1, 07-11-03)

ENO 340

As specified in [42 CFR 480.142](#), disclose sanction recommendation reports to the Office of the Inspector General (OIG), CMS, and agencies that investigate and prosecute fraud and abuse. Disclose relevant sanction information.

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 [42 CFR 480.107](#).

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. 1, 07-11-03)

ENO 345.C

According to [42 CFR 480.104\(a\)\(2\)](#), the Network is required to inform recipients, in writing, that they cannot redisclose confidential information previously disclosed to them, except as permitted under [42 CFR 480.107](#). The Network's written notice should also advise the recipient of the penalties for unauthorized disclosures.

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 notice to the recipient.

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 [42 CFR 480.116](#).) Improper redisclosures of confidential information are generally inadvertent rather than intentional. Accordingly, the Network provides educational programs to avoid problems.