CMS Manual System	Department of Health & Human Services (DHHS)
Pub. 100-14 Medicare End Stage Renal Disease Network Organizations	Centers for Medicare & Medicaid Services (CMS)
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I. SUMMARY OF CHANGES: We have revised the Table of Contents to and all sections of Chapter 4 – Information Management to incorporate the new ESRD information system called Consolidated Renal Operations in a Web-enabled Network (CROWN). We have added new hyperlinks, made revisions to some that changed, added new material on VISION data validating, revised three of the exhibits under a new section number and deleted the nine exhibits that were listed under the old section number.

NEW/REVISED MATERIAL - EFFECTIVE DATE: April 26, 2004
IMPLEMENTATION DATE: April 26, 2004

Disclaimer for manual changes only: The revision date and transmittal number apply to the red italicized material only. Any other material was previously published and remains unchanged. However, if this revision contains a table of contents, you will receive the new/revised information only, and not the entire table of contents.

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

R/N/D	CHAPTER/SECTION/SUBSECTION/TITLE
R	4/Table of Contents
R	4/10/ Background/Authority
R	4/20/Responsibilities
R	4/30/System Capacity
R	4/40/ Hardware/Software (HW/SW) Requirements
R	4/50/ CMS Computer Systems Access
R	4/60/Data Security
R	4/70/Confidentiality of Data
R	4/80/ Database Management
R	4/80/80.1/ Patient Database - Mandatory Data Element
R	4/80/80.2/ Patient Database Updates
R	4/80/80.3/ CMS-Directed Changes (Notifications) to the Network Patient Database
R	4/80/80.4/ Facility Database - Mandatory Data Elements
R	4/80/80.5/ Submission of Facility Database Elements
R	4/90/ ESRD Data and Reporting Requirements
R	4/100/ CMS ESRD Forms
R	4/100/100.1/ CMS ESRD Program Forms

R	4/100/100.2/ CMS ESRD Clinical Performance Measures (CPMs) Data Forms
D	4/100/100.3/ CMS ESRD Beneficiary Selection Form
R	4/110/ Collection, Completion, Validation, and Maintenance of the ESRD CMS Forms
R	4/110/110.1/ Processing Form CMS-2728-U3
R	4/110/110.2/ Processing Form CMS-2746 (ESRD Death Notification Form)
R	4/110/110.3/ Processing Form CMS-2744 (ESRD Facility Survey)
R	4/120/ Tracking System for ESRD Forms
R	4/130/ Compliance Rates for Submitting ESRD Forms
R	4/140/ CMS ESRD Forms Data Discrepancies and Data Corrections
R	4/150/ Renal Transplant Data
R	4/160/ Reporting on Continued Status of Medicare ESRD Beneficiaries
R	4/170/ Coordination of Additional Renal Related Information
N	4/180/ VISION Data Validation
D	4/180/Exhibit 4-1/ Engineering Review Board (ERB) Request Template (Hardware Information)
D	4/180/Exhibit 4-2/ Engineering Review Board (ERB) Request Template (Software Information)
D	4/180/Exhibit 4-3/ Application for Access to CMS Computer Systems
D	4/180/Exhibit 4-4/ Sample Notification of Data Element Changes Report
D	4/180/Exhibit 4-5/ Summary of Data Requirements
D	4/180/Exhibit 4-6/ Sample Edit Report
D	4/180/Exhibit 4-7/ Sample Medical Evidence Edit Report Cover Letter
D	4/180/Exhibit 4-8/ Letter to Center Requesting Overdue Follow-Up
D	4/180/Exhibit 4-9/ Sample Report of Medicare Beneficiaries Who Will End ESRD Status
N	4/190/ Exhibits
N	4/190/Exhibit 4-1/ Application for Access to CMS Computer Systems
N	4/190/Exhibit 4-2/ Summary of Data Requirements
N	4/190/Exhibit 4-3/ Letter to Center Requesting Overdue Follow-Up

III. ATTACHMENTS:

	Business Requirements
X	**Manual Instruction**
	Confidential Requirements
	One-Time Notification
	Recurring Update Notification

Medicare ESRD Network Organizations Manual

Chapter 4 - Information Management

Table of Contents

(Rev. 5, 03-12-04)

10 - Background/Authority

(Rev. 5, 03-12-04)

ENO 400

Data collected and maintained by End Stage Renal Disease (ESRD) Network Organizations and reports generated by the Networks are governed by §§1157, 1160 and 1881(c)(8) of the Social Security Act (the Act) as amended, and by regulations at 42 CFR 405.2112(j) and 42 CFR Part 480.

The Network is required to perform the data*/information* management and reporting activities listed in its Statement of Work using the Standard Information Management System (SIMS) developed to fulfill its data processing, information management, and reporting contractual requirements to CMS. The new system will be named the Renal Management Information System (REMIS). The Network will be required to use REMIS as directed by CMS.

The ESRD Networks and CMS are working together to build an integrated ESRD information system called Consolidated Renal Operations in a Web-enabled Network (CROWN). CROWN will facilitate the collection and maintenance of information about the Medicare ESRD program, its beneficiaries and the services provided to them. Maintenance of this information by CMS is mandated by legislation and regulation. (See Public Law 95-292, 42 CFR (Code of Federal Regulations], Part 480; and Public Law 92-603, Section 299I.)

We expect to modernize the collection and retrieval of ESRD data in a secure, Web-enabled environment. The new capabilities will allow dialysis facilities to enter information electronically and transmit it to the appropriate ESRD Network, and CMS also will be able to send feedback to the Networks and the facilities through the new environment.

20 - Responsibilities

(Rev. 5, 03-12-04)

ENO 405

The Network's responsibilities for data processing, information management, and reporting include the following:

- To *establish policies and procedures for maintaining CMS approved* computer hardware and software *and maintaining sufficient system capacity* to carry out its contractual responsibilities;

- To effectively manage the collection, validation, storage, and use of data, including data provided by CMS, for review, profiling, pattern analysis, and

sharing *appropriate data* with CMS and the State survey agency for use in their ESRD Medicare survey and certification activities;

- To ensure timely and accurate reporting by the facilities/providers;

- To maintain and ensure the integrity, accuracy, *and confidentiality* of ESRD patient and facility databases;

- To ensure the quality and accuracy of the *SIMS database* for inclusion in the ESRD Program Management and Medical Information System (PMMIS) and the United States Renal Data System (USRDS);

- To ensure current patient status is reported to CMS in a timely manner for appropriate enrollment and disenrollment into the Medicare program for ESRD benefits.

- *To train facilities in the proper procedures for completing and transmitting forms electronically including establishing facilities' access to Quality Net Exchange;*

- *To, at a minimum, on a quarterly basis, verify with dialysis facilities, patient event data maintained in SIMS; and*

- *To, at a minimum, on an annual basis, profile facilities based on glomerular filtration rates to ensure the appropriateness of renal replacement therapy. The results of this activity shall be reported in the Network's Annual Report and profile tables made available to CMS upon request.*

30 - System Capacity

(Rev. 5, 03-12-04)

ENO 410

The Network must maintain a system that provides the capacity to meet its contractual responsibilities for data collection, validation, entry, retrieval, profiling, analysis, reporting, and electronic data interchange. The system, at a minimum, shall utilize and consist of the following:

- *Vision software,* SIMS software, and *communication capability via Quality Net Exchange;*

- *Program documentation, for the entry and transmission of the CMS ESRD forms (described later in this section)*;

- CMS-approved software for the entry and transmission of the clinical performance measures (see Chapter 5 of this manual);

- *CMS approved hardware (HW) and software (SW) for transmitting and communicating with ESRD facilities and CMS Central and Regional Offices;*

> **NOTE:** *Networks shall not develop Network software products for facility use without approval from CMS.*

- CMS-*approved* statistical software for data analysis and profile analysis, including profiling patients and facilities by county, to facilitate disaster planning and other studies; and

- Provisions for disaster recovery *including regularly scheduled backup* of the databases and data system.

40 - Hardware/Software (HW/SW) Requirements

(Rev. 5, 03-12-04)

ENO 420

All HW/SW necessary for the ESRD Network Organizations, SIMS, VISION, and other supporting systems as determined by CMS, must be purchased through the Quality Improvement Organization (QIO) Standard Data Processing System (SDPS) Contractor, the Iowa Foundation for Medical Care, Inc. (IFMC). Requests for HW/SW are made by using the Remedy AR System software provided by CMS. See the CROWN website http://www.cms.hhs.gov/ESRD for a description of the SDPS Engineering Review Board (ERB) process. The Network maintains an accurate inventory of federally provided HW/SW as directed by CMS.

50 - CMS Computer Systems Access

(Rev. 5, 03-12-04)

ENO 425

After the award of the contract, if the Network requires access to CMS data systems, the Network must contact the CMS PO to obtain user identification (ID) and a password. If the individual assigned the user ID and password for the CMS data systems changes, *the Network must* submit the name of the replacement individual to the CMS PO using the form shown in Exhibit 4-1.

Each Network will be responsible for administering access to the Quality Net Exchange. It is recommended that the Networks' Data Managers be the main Qnet Exchange Administrators for the organization. Refer to CMS Web site for Qnet Exchange procedures: http://www.cms.hhs.gov/esrd/7.asp

60 - Data Security

(Rev. 5, 03-12-04)

ENO 430

*The Network must c*omply with the requirements found at 42 CFR 480.115; in OMB Circular A-130, "Management of Federal Information Resources;" CMS AIS Guide, "Systems Security Program Standards and Guidelines Handbook;" and the Privacy Act of 1974, 5 USC 552a. If the Network needs a copy of these documents, it must contact the PO.

In addition to the guidelines listed above, we recommend that Networks follow the security measures listed below:

- *Do not have modems (phone modems or cable modems) connected to any computer that is on the SDPS Network.*

- *In addition to electronic security, have precautions in place for physical security, including password-protected entry, and user logout when away from the desk or at the end of the day.*

- *Staff should guard their passwords like they would their social security numbers and other confidential information.*

- *Never put private information in Internet emails, regarding system or software passwords or information on how to gain access to the system.*

- *User IDs and passwords should be complex enough not to be easily figured out. For instance, do not use a visitor's User ID and [blank] for a password or a staff member's first name as an ID and his/her last name as a password.*

Networks' staff should not automatically forward their email to a non-SDPS account. It is fine to selectively forward emails after staff members have read them and made sure they contain no sensitive information, but not to automatically forward them. Networks should NEVER forward sensitive information outside of the SDPS system. ONLY SDPS accounts are within the protected environment. This means Networks, CMS and QIOs. Any data Networks send beyond this is at the Networks' own risk.

70 - Confidentiality of Data

(Rev. 5, 03-12-04)

ENO 435

All *patient specific* data provided to the Network by CMS and all reports containing confidential data prepared by the Network for CMS are considered confidential and may not be disclosed to other than the appropriate Network board(s), committee(s), and its administrative staff *as part of its contract work.*

As a result of §6219(b) of the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) (December 19, 1989), the confidentiality of data requirements found at 42 CFR 480 also apply to ESRD Networks. Section 1881(c) (8) specifies that the provisions of §§1157 and 1160 must apply with respect to Networks (including medical review

boards). Comply with all applicable CMS confidentiality and disclosure policies and regulations found at 42 CFR Part 480 Subpart B. (See Chapter 3 of this manual.)

80 - Database Management

(Rev. 5, 03-12-04)

ENO 440

*The Network must m*aintain patient and facility databases containing the *mandatory* data elements outlined in SIMS and perform various tasks related to these databases.

80.1 - Patient Database - *Mandatory* Data Elements

(Rev. 5, 03-12-04)

ENO 440.1

Networks maintain the mandatory data elements required by SIMS. The required data elements for ESRD patients and patient events can be found at www.simsproject.com/downloads_manualsinstructions.asp .

80.2 - Patient Database Updates

(Rev. 5, 03-12-04)

ENO 440.2

Networks continually update their SIMS local patient databases (or elements in their patient databases) on a regular basis to the SIMS Central Repository based on data received from the providers/facilities. Replication to the Central Repository shall be run nightly for all queued validated ready records based on a pre-determined schedule arranged through the SIMS contractor. The CMS will access the SIMS Central Repository on a regularly scheduled basis to obtain an update of the Networks' patient data for REMIS.

Networks are responsible for the validity and accuracy of the ESRD Patient database and for providing accurate data to CMS. Networks are required to run data clean up utilities supplied by the SIMS contractor on a regular basis or as directed by CMS.

The CMS may ask the Network to submit its patient database (some or all patients) to its designee for use in selecting patients for the annual Clinical Performance Measures (CPMs) data collection effort. The Network's patient database is due to CMS' designee within 30 calendar days of the request.

80.3 - CMS-Directed Changes *(Notifications)* to the Network Patient Database

(Rev. 5, 03-12-04)

ENO 440.3

The CMS may have additional or more current information on important patient data. The CMS will notify the Networks about important data element discrepancies in their patient database. The Networks review discrepancies and determine whether appropriate action is necessary. The Networks should update their database with accepted changes (e.g., beneficiary name, date of birth, Health Insurance Claim Number and Beneficiary Identification Code) contained in the PMMIS, and Provider Certification databases. The CMS will provide these changes to the Networks electronically through SIMS/REMIS. Advise CMS of any outstanding discrepancies related to these notifications.

80.4 - Facility Database - *Mandatory* Data Elements

(Rev. 5, 03-12-04)

ENO 440.4

Networks maintain the mandatory data elements listed in the SIMS Manual (which can be found at http://www.simsproject.com/downloads_manualsinstructions.asp*) for each facility in their network area that provides dialysis or transplant services. It is important to keep facility data current for the Dialysis Facility Compare Web site maintained by CMS. The facility data shall be updated on a daily basis but must be current no later than the 10th working day of the month.*

80.5 - Submission of Facility Database Elements

(Rev. 5, 03-12-04)

ENO 440.5

Networks update the SIMS Central Repository on a *nightly* basis, based upon data or information received from the facilities.

When requested by CMS, Networks verify data and upload all corrections to provider data for the National Listing of Medicare Providers Furnishing Kidney Dialysis and Transplant Services directly to the Central Repository in the SIMS system.

The CMS has the capacity to create data files and labels from the SIMS Central Repository *and* will create a monthly file for the "Dialysis Facility Compare" *Web site* (see http://www.medicare.gov/Dialysis/Home.asp).

Other organizations or individuals may ask the Network to generate and submit mailing labels of facility listings/rosters either electronically or by hardcopy. The Network may negotiate with them the time frame for completion.

When requested by CMS, *Networks* verify *and upload corrections to* provider data for the "National Listing of Medicare Providers" directly into SIMS. Corrections to provider data for this national listing must be uploaded to the Central Repository *within 30 days of the request*.

90 - ESRD Data and Reporting Requirements

(Rev. 5, 03-12-04)

ENO 445

Exhibit 4-2 provides a summary of the data and reporting requirements, and the Network's responsibilities for processing forms and maintaining the data.

100 - CMS ESRD Forms

(Rev. 5, 03-12-04)

ENO 450

Medicare-approved providers of renal services must complete various nonpayment forms that the Secretary of HHS determines are appropriate for collection of data deemed necessary for inclusion in the ESRD PMMIS Database.

100.1 - CMS ESRD Program Forms

(Rev. 5, 03-12-04)

ENO 450.1

These forms contain patient specific or aggregate information necessary for the operation of the national ESRD program. Each ESRD facility and provider in the network area will *transmit either electronically or by mail to* the *Networks the* following three CMS forms for use by the Networks, CMS, SSA, and the USRDS:

- Form CMS-2728-U3 - ESRD Medical Evidence Report, Medicare Entitlement, and/or Patient Registration (completed on each incident ESRD patient or each patient re-entering the Medicare program). *Dialysis and/or transplant facilities are required to submit the Medical Evidence Report to the Networks within 45 days from the date a patient is diagnosed with ESRD and either receives a transplant or starts a regular course of dialysis. This form is also required if a patient loses Medicare coverage and is re-applying for Medicare benefits.*

- Form CMS-2744 - ESRD Facility Survey (completed annually). *The survey period is January 1 through December 31. Every facility approved by Medicare to provide services to ESRD patients must furnish the information requested in the Survey; and*

- Form CMS-2746 - ESRD Death Notification or facility generated Death-Notification Form or VISION generated Death Notification Form. All facilities are to complete the Death Notification Form upon the death of an ESRD patient and submit it to the Networks within 30 days of the date of death.

100.2 - CMS ESRD Clinical Performance Measures (CPMs) Data Forms

(Rev. 5, 03-12-04)

ENO 450.2

These forms contain patient specific clinical information necessary to calculate the ESRD CPMs. These data are currently collected on a sample of dialysis patients annually on a voluntary basis. Refer to Chapter 5, §60 of this manual for additional information. Selected dialysis facilities in the network area will send the Network the following forms (as applicable) *and their facility computer generated equivalents* on their patients included in the CPM annual sample:

- Form CMS-820 - In-Center Hemodialysis (HD) Clinical Performance Measures Data Collection Form (completed annually on a sample of HD patients); *and*

- Form CMS-821 - Peritoneal Dialysis (PD) Clinical Performance Measures Data Collection Form (completed annually on a sample of PD patients).

110 - Collection, Completion, Validation, and Maintenance of the ESRD CMS Forms

(Rev. 5, 03-12-04)

ENO 455

The Network obtains completed CMS ESRD forms from each ESRD provider/facility and/or corporate owner in the network area either electronically or hardcopy. Until electronic reporting is mandatory from all dialysis facilities, electronic submission of data will be on a voluntary basis. The Network is responsible for marketing, instructing, and training the facilities and/or facility owner on the proper procedures for electronic submission. The Network is responsible for authorizing access to the Quality Net Exchange for the electronic transmission of ESRD Forms. The Network must also include all transmitted forms from the non-Medicare Veterans Health Administration (VHA) facilities, and voluntarily submitted forms from institutions such as prisons and nursing homes.

The Network ensures that all CMS ESRD forms listed in §100 are collected, completed, and validated according to the instructions in this section and the "ESRD Program

Instruction Manual for Renal Providers" (IMRP). *The Network* performs the following tasks in order to fulfill Network data responsibilities for the ESRD forms. *The Network:*

- Provides adequate supplies of the ESRD Death Notification (Form CMS-2746) to providers within the Network's geographical area (unless the Network's facilities/providers are using their own software to generate the Death Notification Form or electronic records).

- Ask providers to obtain supplies of the ESRD Medical Evidence Report, Medicare Entitlement, and/or Patient Registration (Form CMS-2728-U3) through the local SSA field offices.

NOTE: If the facility cannot obtain these forms in a timely manner through its local SSA field office, the Network provides an emergency supply. In addition, the Network may wish to provide start-up supplies to new facilities.

- Sends supplies of the blank Facility Survey (Form CMS-2744) to facilities/providers in the network area. Downloads and prints the form, which is in a PDF file format, from the Web site at http://www.cms.hhs.gov/esrd/2.asp. Facilities/providers can also be directed to the Web site. This form is completed once a year.

- Ensures that adequate written instructions for completing the forms, contained in the IMRP, and other information related to the forms are distributed to all providers as they are released from CMS.

- Distributes all CMS revisions to the IMRP to the facilities in its network area.

- Provides guidance, as needed, to the appropriate provider personnel about completion of the forms.

- *Provides instructions and training to the facilities and/or facility owners on the proper procedures for using VISION and Quality Net Exchange.*

- *Establishes a system for authorizing access to the Quality Net Exchange for the electronic transmission of ESRD forms.*

- Processes the forms received as instructed in §§110.1-110.3.

- *Monitors the accuracy and completeness of reports, and the validation of facility-level patient data. This activity is critical in assuring the integrity of the patient tracking system. Similarly, capturing data forms on all incident cases requires a mechanism for crosschecking so facilities can query and detect unreported forms. As VISION is implemented, the activities specified in §§110.1-110.3 will need to be retained in a format that is consistent with migration from hard copy to electronic reporting.*

110.1 - Processing Form CMS-2728-U3

(Rev. 5, 03-12-04)

ENO 455.1

Upon receipt *of hardcopy or electronic forms in the Network Office, the Network reviews the forms for completeness, and returns them for correction or completion to the provider/facility if necessary. Each form must provide the key data elements as established by CMS. Refer to the SIMS Web site for key data element listings located at:* www.simsproject.com/downloads_manualsinstructions.asp
Networks are to replicate validated forms to the Central Repository nightly. CMS will access the data from the Central Repository.

- If the patient has had a transplant, check the *REMIS* database to see if the Organ Procurement and Transplantation Network*/United Network for Organ Sharing* (OPTN*/UNOS*) has assigned a "dummy" number. This number will usually have "9FN" in the first 3 positions. If so, use this number *for the social security number in SIMS*.

- If a patient does not have a health insurance claim number, or a social security number, AND is not applying for Medicare benefits, and has not received a transplant, issue a "dummy" social security number using the following formula:

> Position 1 = X
> Positions 2-7 = Provider number of provider completing form
> Positions 8-9 = Sequential numbering

- Use of this "dummy" number should be a rare occurrence and only used, for example, in the case of foreign nationals or illegal aliens who generally do not have social security numbers.

Facilities must submit the Medical Evidence Report within 45 days after either a transplant or the start of a regular course of dialysis (whichever occurs first).

NOTE: The start of a regular course of dialysis is defined as the date of the first dialysis treatment after the physician has determined that the patient has ESRD and has written a prescription for a "regular course of dialysis," regardless of the dialysis setting and regardless of any acute treatments received prior to the implementation of the prescription.

If the data described *in the SIMS Web site* are not present, *the Network* returns the form to the provider, within one week of receipt, for completion of these data. Prior to returning the form, the Network may key and hold this form in SIMS until all mandatory data have been entered.

The Network enters the data from the form into SIMS *and replicates daily all the "queued validated ready" information from the CMS-2728 forms to the Central Repository.*

*The Network m*aintains a file of all CMS ESRD hard copy forms that are *entered at the Network.* The hard copy forms *are retained* for two years after the date of completion *and until electronic reporting through VISION is mandatory.* If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, *the Network* retains these forms for two years following the completion of that activity. *Following the retention period*, any forms that are patient-specific and are not maintained for the Network's use, or as documentation of actions specified above are shredded, incinerated, or otherwise completely destroyed, for patient privacy purposes.

110.2 - Processing Form CMS-2746 (ESRD Death Notification Form)

(Rev. 5, 03-12-04)

ENO 455.2

Upon receipt *of hardcopy or electronic forms in the Network Office, the Network reviews the forms for completeness, and returns them for correction or completion to the provider/facility if necessary. Each form must provide the key data elements as established by CMS. Refer to the SIMS Web site for key data element listings located at:* www.simsproject.com/downloads_manualsinstructions.asp

The Network returns to the *facility*/provider, within one week of receipt, forms that are missing information or that contain inaccurate data for the data items *described on the SIMS Web site*.

The Network enters the data from the form into SIMS *and replicates queued validated information on the CMS-2746 via SIMS to the Central Repository nightly.* After the data are *replicated* to *the Central Repository,* they will be added to the PMMIS after passing additional edits.

*The Network m*aintains a file of all CMS ESRD hard copy forms that are *entered at the Network.* The hard copy forms *are retained* for *at least* two years after the date of completion *and until electronic reporting through VISION is mandatory*. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, *the Network* retains these forms for two years following the completion of that activity. *Following the retention period*, any forms that are patient-specific and are not maintained for the Network's use, or as documentation of actions specified above are shredded, incinerated, or otherwise completely destroyed, for patient privacy purposes.

110.3 - Processing Form CMS-2744 (ESRD Facility Survey)

(Rev. 5, 03-12-04)

ENO 455.3

Form CMS-2744 is completed annually *by facilities/providers*. Upon receipt of these forms in the Network's office, the forms *are reviewed* for completeness. *Since* each form must have all the pertinent data elements completed, *the Network must* establish a mechanism to ensure that the number of forms *(CMS-2728 and CMS-2746)* submitted *by each facility/provider* to CMS match*es* the number of events reported *by that facility/provider* on Form CMS-2744.

EXAMPLE: If a *facility/*provider reports five deaths in a given year, the *facility/*provider should have submitted five Form CMS-2746s or facility/provider generated death notification forms for that year as described in the IMRP.

*The Network e*nter*s* the data from the forms into SIMS *and t*ransmit*s* the data directly to the *Central Repository using SIMS, by the 5th working day in April.*

*The Network t*ransmit*s* corrections to the survey data to CMS through SIMS by the third Friday of May of each year.

*The Network m*aintains a file of all CMS ESRD hard copy forms that are *entered at the Network.* The hard copy forms *are retained* for *at least* two years after the date of completion *and until electronic reporting through VISION is mandatory*. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, *the Network* retains these forms for two years following the completion of that activity.

120 - Tracking System for ESRD Forms

(Rev. 5, 03-12-04)

ENO 460

*The Network m*aintain*s*, through SIMS, a system to track receipt of the CMS ESRD forms from the facilities/providers to ensure that the forms are submitted timely and accurate*ly*. Instructions for determining timeliness and accuracy are contained in §130.

The Network ensure*s* that it act*s* upon any *data discrepancies or corrections* within two weeks of receipt. The Network track*s* all forms that it returns to *facilities/*providers for correction. (See §140 for instructions for resolving discrepant records.)

130 - *Compliance Rates for Submitting ESRD Forms*

(Rev. 5, 03-12-04)

ENO 465

Semi-annually, through SIMS, *the Network profiles the facilities/providers to determine their* compliance rates for submitting timely, complete, and accurate Medical Evidence (Form CMS-2728-U3) and Death Notification (Form CMS-2746) forms or facility and provider generated death notification reports. *The Network m*aintain*s* compliance rate information on-site and make*s* it available at CMS's request. The Network documents its attempts to contact *facilities/*providers to obtain missing forms and to correct discrepancies, and reports to the PO any problems encountered with individual *facility/*provider compliance regarding forms reporting that are not rectified at the Network level.

Acceptable rates for timeliness and completeness/accuracy for each form type are noted below. *The Network f*ollow*s* these instructions for notifying those facilities/providers with unacceptable semi-annual compliance rates and for providing each facility/provider with its annual compliance rates. The Network forwards a copy of the semi-annual and annual notifications to its PO.

A. Medical Evidence (Form CMS-2728-U3)

- Timeliness is defined as 45 days from the date the patient is determined to be end stage and has started regular chronic dialysis at that facility.

- Completeness and accuracy are defined as "all data fields *have passed all SIMS and REMIS edits.* "

B. Death Notification (Form CMS-2746) or Facility/Provider Generated Death Notification Forms

- Timeliness is defined as 30 days from the date of death.

- Completeness and accuracy are defined as "all data fields *have passed all SIMS and REMIS edits.* "

There are valid reasons why the Medical Evidence (Form CMS-2728) and Death Notification forms may not be submitted in a timely manner. For example, the Medicare ESRD-certified facility submitting Form CMS-2728 receives the patient 45 days after the patient first begins dialysis, or the patient dies outside of the facility's/provider's area and the facility/provider does not learn about the patient's death for more than 30 days after the patient died. Before a facility/provider is considered noncompliant with the timely submission of a form, *the Network should* determine why the form was late.

Timeliness is calculated by dividing the number of forms received late by the total number of forms received from the facility/provider for that month. The calculation only

includes those forms that are due for the first time. If the resulting ratio is not within the bounds described below, the facility/provider will be deemed noncompliant.

Completeness and accuracy are calculated by dividing the number of forms that are in error (*required* data elements are missing or are inaccurate) by the total number of forms received from the facility/provider for that month. Do not divide by the number of errors on the form. The ratio must be within the bounds described below.

On a semi-annual basis, *the Network* profile*s* each facility's/provider's compliance rates for timeliness, completeness, and accuracy for each form type. *The Network n*otif*ies* those facilities and providers that have a semi-annual average of greater than three forms (per-form-type) late and/or incomplete/inaccurate or a semi-annual average of greater than 20 percent of the forms (per-form-type) late and/or incomplete/inaccurate that they are at risk of being determined to be out of compliance.

On an annual basis, *the Network* evaluate*s* each facility's/provider's compliance rates for timeliness, completeness, and accuracy for each form type *and* notif*ies* each facility/provider of its annual compliance rates.

The annual compliance rate activity is performed during the first quarter of the calendar year for all forms submitted during the prior year for Medicare patients. Each facility and provider is required to maintain an annual average compliance rate of 90 percent for timeliness, completeness, and accuracy.

If a facility/provider does not maintain the required annual average compliance rate, *the Network should provide* assistance to the facility/*provider* to improve its performance. If the Network determines that the facility/*provider* is not making *a* reasonable attempt to improve its performance, *the Network should* prepare a sanction recommendation to the RO following the instructions in Chapter 7 of this Manual.

140 - CMS ESRD Forms *Data Discrepancies and* Data Corrections

(Rev. 5, 03-12-04)

ENO 470

When the Network makes changes to any of the SIMS patient data, it should replicate the information as soon as possible to the Central Repository. When the REMIS system reacts to the presence of modified data, the information will be automatically assumed into REMIS. Discrepancies in patient identification will appear as SIMS notifications from REMIS.

A. Notifications from REMIS to SIMS

The SIMS Notifications feature notifies users of differences in data between REMIS and SIMS. When the REMIS system senses a difference, it provides daily notification updates to a centralized staging table on the SIMS Central Repository.

Notifications are created when CMS patient data differ from the SIMS patient data. The Elements are:

- *SSN*

- *HIC*

- *SURNAME*

- *FIRSTNAME*

- *SEX*

- *DOB*

- *DOD*

- *Most recent TX (transplant) date*

- *Most recent TX fail date*

- *Most recent setting date*

The Network staff is expected to access these data through SIMS by selecting:

CROWN>CMS Data Updates – Four dropdown fields will be available (Record Type, Filter by Column, Value, and Action). The user will then select "Notifications" from the Record Type dropdown field. Using the Filter By Column and then filtering through by Value, Provider Number, Source, and Action fields, the user will be shown notifications that are in the Notification Table.

Networks are expected to search and view the data that have not been processed as well as items that have already been previously marked "under investigation" and update the status of each notification as it is reviewed.

- *Network users have the option of Accepting, Rejecting or marking any notification as "Under Investigation". New notifications will be available to Networks on a daily basis.*

  ACCEPT – This will update SIMS data with the CMS indicated changes.

  REJECT – This will not update SIMS data and will set the status of the notification to Reject.

  UNDER INVESTIGATION – This will not update SIMS data and will set the status of the notification to Under Investigation.

B. Processing Expectations:

Notifications should be processed within 60 days of receipt.
Notifications should not have an "under investigation" status for more than 60 days. Periodically, CMS will compare the number of records rejected and "under investigation" by each Network to the national average of all 18 Networks; CMS will also compare the amount of time records remain in the "unprocessed" and "under investigation" categories. Statistical outliers will be asked to explain the differences between their data and performance practice and those of the other Networks.

C. Determining the Correct Medicare HIC Number

If the patient is deceased and was an ESRD patient, the correct Medicare HIC number is still required. In cases where the patient died shortly after the onset of renal failure, it is possible that Medicare entitlement was never established. If this is the case, *the Network should* report the patient as "non-Medicare" on the appropriate *SIMS* screen *and assure that the related data is replicated to the Central Repository.* In some of these cases, the patient may have been previously enrolled in Medicare due to old age or disability. The CMS needs to know whether a person was actually an ESRD patient as opposed to an acute renal failure patient [i.e., a patient who was placed on dialysis but who was expected to recover function from his/her native kidney (not a transplanted kidney)]. If the person is definitely an ESRD patient, *the Network should* obtain a Medical Evidence Report, *enter it into SIMS, and assure that the related data is replicated to the Central Repository.*

One way of determining a correct name/number is to ask the facility/*provider* where the patient was, or is, being treated and to contact the billing office to obtain the correct Medicare HIC number, name, or information concerning the patient. The Network may also request a copy of the patient's Medicare card *from* the *facility/provider*. In the event that the patient is found to be non-Medicare, enter this fact on the appropriate *SIMS* screen.

D. Other Incorrect Data Elements

In addition to the Medicare HIC number, one of several other data elements could be incorrect. All of these data elements are used to match a master record:

- Beneficiary Identification Code (BIC), which is the letter at the end of the claim number;

- Spelling of the surname;

- Date of birth;

- Sex;

- First initial; *and*

- *SSN.*

If any of these elements are different from the ones the *facility/*provider reports, *the Network should* enter the correction *into SIMS and assure that the related data are replicated to the Central Repository.*

150 - Renal Transplant Data

(Rev. 5, 03-12-04)

ENO 475

The Organ Procurement and Transplantation Network*/United Network for Organ Sharing* (OPTN*/UNOS*) is responsible for collecting kidney transplant data. The OPTN*/UNOS makes* data *available* weekly *to CMS*. *The* data *includes* donor, renal *transplant* candidate, transplant recipient, and immunosuppression information. *When a transplant is reported to REMIS, REMIS will automatically generate a notification to SIMS, advising of the change in setting to "functioning transplant." When the Network analyst accepts the notification, the SIMS utility will automatically update the Network's SIMS database with the transplant data from REMIS.*

A. For Transplant Data

The Network may know about transplants that have not been reported to the OPTN*/UNOS*. *The Network should enter these data into SIMS, and replicate them to the Central Repository. The REMIS system will automatically react to the change in patient status. Networks are no longer required to manually enter this information directly into REMIS.*

B. For Transplant Follow-Up Data

The OPTN*/UNOS* will attempt to obtain the renal transplant follow-up data for six months after the due date of the registration and follow-up report.

- The OPTN*/UNOS* will *make available* a listing of those renal transplant recipient registration and renal recipient follow-up data it has been unsuccessful in obtaining.

- *The Network will* review the list of overdue renal transplant recipient registration and renal recipient follow-up *data* and contact the applicable transplant center, in

writing, and request that the center submit the missing data electronically to the OPTN/*UNOS*.

- *The Network should m*ake one attempt to request the missing renal transplant recipient registration and renal recipient follow-up *data* from the transplant center. If the second report of data submitted to the OPTN/*UNOS* does not list the required forms, *the Network will* notify the PO of the facility's/*provider's* noncompliance.

- Exhibit 4-3 contains suggested language for inclusion in the letter to the transplant center when requesting an overdue renal transplant candidate registration or renal recipient transplant follow-up form.

- Quarterly, the Network forwards to its PO a copy of the listing of overdue renal transplant recipient registration and renal recipient follow-up *data* it has *reviewed* from the OPTN/*UNOS*, annotated with the action(s) taken. For example, the Network indicates if a written request for the form was sent to the transplant center; if the transplant center submitted the delinquent form to the OPTN/*UNOS*; or, if after 90 days, it has been unsuccessful in obtaining the delinquent form. The quarterly annotated list may be submitted to the PO with the quarterly progress and status reports (quarterly reports are due in October, January, April, and July).

- *At the November 2001 meeting of the OPTN/UNOS Board of Directors, the Board approved new data submission standards as set forth in OPTN/UNOS Policy 7.8.1. The new standards became effective on July 1, 2002, and the standards state that:*

  Each OPO, Transplant Center and Histocompatibility Laboratory must meet the following standard for submission of data collected on all forms…to the UNOS Transplant Registries: 95% of expected forms complete within 3 months of the due date and 100% of expected forms complete within 6 months of the due date.

- *A transplant center becomes non-compliant with the data submission standards once the center has outstanding forms that are 6 or more months overdue from the expected due date.*

- *The UNOS Policy Compliance Department reviews transplant centers' form submission on a quarterly basis. If a transplant center fails to submit the required forms during the previous quarter and the forms are then 6 months past the expected due date, the center is referred to the Membership and Professional Standards Committee.*

- *If the Member fails to demonstrate full compliance with form submission policies after a letter of admonition is issued, the Policy Compliance Subcommittee could recommend an adverse action which could include recommending a probationary*

period to declaring a transplant center as a "member not in good standing" to termination of membership.

- If the Network finds serious errors or discrepancies in OPTN*/UNOS* data, it reports this to CMS for follow-up with the OPTN*UNOS*.

C. For Graft Failure Follow-up Data

The OPTN*/UNOS* provides the Network with a list of patients who have had a graft failure and for whom the OPTN*/UNOS* has been unable to obtain a follow-up form. (The OPTN*/UNOS* follows patients for 2 years after the graft fails.) The Network checks its database and notifies the OPTN*/UNOS* of the status of any patient(s) located as alive and back on dialysis, expired, or unknown to it.

160 - Reporting on Continued Status of Medicare ESRD Beneficiaries

(Rev. 5, 03-12-04)

ENO 480

It is the Network's responsibility to reflect current patient status within the SIMS Central Repository. A patient status is necessary to appropriately identify when Medicare benefits are to be terminated. Any changes to a patient status should be reflected in SIMS no later than *30* days after the change in patient status.

Each month, REMIS will generate a listing of patients whose ESRD coverage is being automatically extended based solely on the most recent SIMS event. This listing will only include those patients for whom there has been no new event since the last time the coverage was modified. Review this listing and enter an appropriate event into SIMS if the Network has any information that would contradict the extension of the coverage period.

170 - Coordination of Additional Renal Related Information

(Rev. 5, 03-12-04)

ENO 485

A. Veterans Health Administration (VHA)

*The Network p*rocess*es* CMS ESRD forms on VHA patients from all VHA facilities. The submission of data to the Network by VHA facilities on their ESRD patients is mandatory. The VHA released VHA Directive 2001-024 on April 23, 2001, to its dialysis and transplant units. This Directive provides instructions for participation in the United States Renal Data System through the completion of ESRD forms.

*The Network s*uppl*ies* the VHA units with the Medical Evidence Report and Death Notification forms. CMS ensures that the Network is supplied with adequate forms to meet the requests from VHA units. Each VHA facility must fill out the ESRD Facility Survey. Follow the instructions below when receiving data on VHA patients:

1. Completion of VHA Forms

Completion of CMS ESRD forms on VHA patients is mandatory on the part of the VHA. VHA facilities may but are not required to participate in Network activities (e.g., meetings, quality improvement projects, committee or Board members).

2. Submission of VHA Forms to CMS

The Network submits VHA patient data with the other CMS forms that are submitted on a monthly basis. If the forms do not pass the critical edits, the Network returns the unaccepted form(s) to the VHA facility, explains the problem, and requests the VHA unit to resubmit the form with the necessary corrections to it. The Network is not required to validate the information supplied by the VHA unit; however, the Network is required to track the VHA unit's compliance with forms submission, resubmission, completion, or accuracy.

VHA units must submit forms on VHA patients using their CMS provider number, which is an "F" number. VHA units should forward to the Network all copies of the ESRD forms that they complete (after they retain one copy for their files). The Network keeps one copy of each form for its files and destroys all other copies, to protect patient privacy.

If the VHA patient has a Medicare number with a BIC Number, the Network submits this information with the monthly CMS forms it is submitting.

The Network may share information with other Networks if it is discovered that VHA patients who received transplants in other network areas are now located in a new network area. Since information on VHA patients may not be otherwise available, information on the VHA transplant recipient may be the only source for the other Network.

B. Inquiries From Medicare+Choice (M+C) Organizations

The Network responds to permissible inquiries from its area M+C organizations regarding the ESRD status of Medicare beneficiaries who are members of the M+C organizations. Permissible inquiries are for those patients who have been on dialysis for at least 4 months and whose records are not retrievable through other CMS-provided electronic data sources. CMS provides the Network with a list of the M+C organizations in its network area. M+C organizations receive a *higher rate of* payment for Medicare enrollees with ESRD. It is important that M+C organizations are correctly paid for their members with ESRD.

NOTE: With the current demonstration project, M+C organizations have access to a CMS-supplied database that provides entitlement status. It is anticipated that this service will be extended to all M+C organizations, thereby replacing the labor-intensive case-by-case look-up and reporting by Networks.

1. Information to be Provided to M+C Organizations

*The Network p*rovide*s* the following types of information to M+C organizations upon written request:

- The patient's current dialysis/transplant functional status;

- The first date of dialysis or date of transplant; and

- The date Form CMS-2728 data was submitted to CMS.

The Network uses its local database or PMMIS database to provide the above information to the M+C organizations.

2. Information Not Required to be Provided to M+C Organizations

The Network is not required to answer any questions regarding the *date of death or the* status of a current or pending Medicare entitlement, application, or payment. The M+C organizations have been advised to refer entitlement and/or application questions to the SSA servicing office and to refer payment questions to the CMS RO*s*. In addition, the Network should not routinely provide M+C organizations with copies of Form CMS-2728. M+C organizations should obtain this information from the servicing dialysis facility.

If the Network suspects that either the M+C organization or its agents are abusing these privileges, report these matters along with any proof the Network may have to Janice Bailey, CMS, CBC, and DEPO, at E-mail address jbailey1@cms.hhs.gov *or Marla Kilbourne, CMS, CBC, and DEPO, at E-mail address* mkilbourne@cms.hhs.gov *.*

The Network reports to its PO in the Quarterly Progress and Status Report, the number of inquires received from M+C organizations during the quarter.

180 - VISION Data Validation

(Rev. 5, 03-12-04)

Annually, the Network validates 3 percent of patient and physician signatures on CMS-2728 forms received electronically through VISION and reports the results of this validation in its Network Annual Report.

190 - Exhibits

(Rev. 5, 03-12-04)

Exhibit 4-1 - Application for Access to CMS Computer Systems
Exhibit 4-2 - Summary of Data Requirements
Exhibit 4-3 - Letter to Center Requesting Overdue Follow-up

Exhibit 4-1 - Application for Access to CMS Computer Systems

(Rev. 5, 03-12-04)
Download a pdf document of this Exhibit at *www.cms.gov/mdcn/access.pdf* .

Exhibit 4-2 - Summary of Data Requirements

(Rev. 5, 03-12-04)

This exhibit provides a summary of a Network's responsibilities and the actions a Network must take to process forms and ensure the integrity of the data.

	DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
1.	Patient Database Update	SIMS	Schedule system updates for the date file is created. *Send to CMS designee within 30 days of CMS request.* (§80.2)	CMS *will access Central Repository and updated REMIS.* CMS *will* request patient database be sent to designee within 30 days.
2.	Monthly Change Notifications	CMS	Update Network database to reflect validated changes made by CMS. Advise CMS of any discrepancies. (§80.3)	Provides listings electronically and hardcopy.
3.	Mailing Labels	Facility/Provider provides data SIMS	*Maintain up-to-date facility/provider database.* (§80.5)	CMS to access SIMS *to create mailing* labels as necessary.
4.	Facility Roster	Facility/ Provider provides data SIMS	Schedule system updates for the date file is created. Submits data to other parties upon request. (§80.5)	CMS to access SIMS.

	DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
5.	Corrections to the Provider Listing	SIMS	*Maintain up-to-date facility/provider database. Upload CMS requested corrections to Central Repository within 30 days of request.* (§80.5)	CMS to access *Central Repository*. Notifies Network prior *to request for correction of provider data*. CMS corrects REMIS.
6.	Form CMS-2728 Medical *Evidence Report Form*	Facility/ Provider completes form	Checks form for completeness; enters into SIMS; *replicates* data *nightly* to *Central Repository*. Provides emergency and start up supply of forms to facility. (§110.1)	Performs edit checks; matches data against Master File.
7.	Form CMS-2746 Death Notification Form	Facility/ Provider completes form	Checks form for completeness; enters into SIMS; *replicates* data *nightly* to *Central Repository*. Provides supply of forms to facility. (§110.2)	Performs edit checks; matches data against Master File.
8.	Form CMS-2744 Facility Survey Form	Facility/ Provider completes survey form	Sends surveys to facilities; checks forms for completeness; enters into SIMS; *runs edit reports to check for serious errors and/or missing surveys. Replicates data from local Network server to SIMS Central Repository by 5th working day of April.* (§110.3)	*Runs edit reports for serious errors or missing records*. Notifies Networks of any discrepancies. *Runs survey tables and provide Networks with hardcopy reports.*
9.	Corrections to Form CMS 2744	Information from facility/provider	Makes corrections through SIMS. *Runs edit report; replicates data from local Network server to SIMS Central Repository by 3rd Friday in May.* (§110.3)	*Runs edit reports for serious errors or missing records*. Notifies Networks of any discrepancies. *Runs survey tables and provides Networks with*

	DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
				hardcopy reports.
10.	ESRD Form Compliance Rates	SIMS	Semi-annually, notifies facilities of unacceptable compliance rates; provides annual compliance rates to facilities; *provides assistance for improvement, or recommends sanction to RO* for non-compliant facilities. (§130)	Processes alternative sanction recommendations, as necessary.
11.	*REMIS Notifications*	Generated by CMS	Makes corrections and enters into *SIMS. Process within 60 days of receipt.* (§140)	Updates PMMIS.
12.	Renal Transplant Data	The Organ Procurement and Transplantation Network (OPTN)	Accesses REMIS *60 days after the end of quarter,* updates *SIMS database* as necessary on those transplant patients not in PMMIS; obtains follow-up data as requested by OPTN. (§150)	Updates PMMIS with OPTN transplant data *from Central Repository*; forwards quarterly reports to the OPTN; OPTN notifies Network of the follow-up data to be obtained.
13.	Reporting the Status of Medicare Beneficiaries	PMMIS	*Any changes to patient status updated in SIMS within 30 days of status change. Respond within 10 days of CMS request with resolution of status discrepancies.* (§160)	Accesses Central Repository *quarterly.*
14.	ESRD Forms on Veterans Affairs (VA) Patients	VA Facility completes forms.	Enters data into Network database; transmits data monthly to CMS data center. (§170)	Performs edit checks; matches data against Master File.
15.	Inquiries from M+C organizations	SIMS, REMIS	Provides ESRD functional status information to M+C organizations. (§170)	Not applicable.

	DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
16.	CPM Forms	Facility Completes *form*	Forwards *forms* to facility; enters data; submits to CMS *designee*.	Analyzes and publishes *results*.

Exhibit 4-3 - Letter to Center Requesting Overdue Follow-Up

(Rev. 5, 03-12-04)

Date

Transplant Center Name & Address

Dear Transplant *Facility/*Provider:

The Organ Procurement and Transplant Network*/United Network for Organ Sharing* (OPTN*/UNOS*) has informed the *ESRD* Network that the renal transplant recipient registration/renal transplant recipient follow-up form(s) for (patient's name) is overdue. Please submit the data within 30 days of the date of this letter. If you use Unet^{sm}, the electronic data submission tool, log onto www.unet.unos.org. If you submit paper forms, send to:

> OPTN Clinical Data Systems
> 720 Moorefield Park Drive, Suite 200
> Richmond, VA 23236

Under 42 CFR *Part 405*, Subpart U - Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services, *Section* 405.2133, you are required to furnish data and information to the Center*s* for Medicare & Medicaid Services (CMS) for the administration of the ESRD program. Under *Section* 405.2134, you are required to participate in Network activities. Failure to comply with these regulations by not submitting the applicable transplant follow-up form(s) to OPTN*/UNOS* can result in *our* recommend*ing* an alternative sanction to CMS.

If you have any questions, or wish to discuss these issues, please contact _____ at _____.

Sincerely,

Network Executive Director

Address