Medicare
End Stage Renal Disease Network Organizations Manual

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

Transmittal 13 **Date: AUGUST 22, 2001**

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NEW/REVISED MATERIAL--*EFFECTIVE DATE: October 8, 2001*

The title of Part 4 is changed from "Data and Reports" to "Information Management." Because we have revised this entire section since it was first published in May 1995, we have redlined the entire document. All 42 CFR 476 citations have been changed to reflect the recodified section to 42 CFR 480.

Section 400, Background/Authority, provides your statutory and regulatory authority for data collection.

Section 405, Responsibilities, lists your responsibilities for collecting, processing, and reporting data.

Section 410, System Capacity, describes the need for appropriate system capacity to fulfill your contract obligations.

Section 420, Hardware/Software (HW/SW) Requirements, requires you to purchase all your HW/SW through the Peer Review Organization Standard Data Processing System Contractor with the assistance of your project officer.

Section 425, CMS Computer Systems Access, advises you to contact your CMS project officer to obtain a user identification and password to access the CMS data system.

Section 430, Data Security, provides manual instructions for CMS data security guidelines.

Section 435, Confidentiality of Data, provides policies and regulations pertaining to the confidentiality and disclosure of information.

Section 440, Database Management, provides the requirements for data management including the minimum/critical data elements to be maintained in your database.

Section 440.1, Patient Database - Minimum/Critical Data Elements, describes the critical data elements that you must maintain in your patient database.

Section 440.2, Patient Database Updates, requires you to update your patient database on a regular basis to the Systems Information Management System (SIMS) central repository.

Section 440.3, CMS-Directed Changes to Your Patient Database, informs you that CMS will notify you of any changes to be made to important data elements in your patient database.

Section 440.4, Facility Database - Minimum Data Elements, lists the data elements that you must maintain in your facility database.

Section 440.5, Submission of Facility Database Elements, requires you to maintain a facility database containing the minimum data elements listed in §440.4.

Section 445, ESRD Data and Reporting Requirements, describes your data requirements and responsibilities.

Section 450, CMS ESRD Forms, lists CMS forms to be sent to you by each facility and provider in the network area.

Section 450.1, CMS ESRD Program Forms, lists the forms and time frames in which the forms are due to you and CMS.

Section 450.2, CMS ESRD Clinical Performance Measures (CPMs) Data Forms, lists the forms with patient-specific information needed to calculate the ESRD CPMs.

Section 450.3, CMS ESRD Beneficiary Selection Form, advises you that only Medicare patients dialyzing at home should complete this form.

Section 455, Collection, Completion, Validation, and Maintenance of the ESRD CMS Forms, requires you to ensure that all CMS forms listed in §450 are collected, completed, and validated as instructed in this section.

Section 455.1, Processing Form HCFA-2728-U3, describes the procedures to follow when processing Form HCFA-2728-U3 form.

Section 455.2, Processing Form HCFA-2746 (ESRD Death Notification Form), describes the procedures to follow when processing Form HCFA-2746 form.

Section 455.3, Processing Form HCFA-2744 (ESRD Facility Survey), describes the procedures to follow when processing Form HCFA-2744 form.

Section 460, Tracking System for ESRD Forms, requires you to maintain a tracking system for ESRD forms received from providers.

Section 465, ESRD Forms Submission Compliance Rates, requires you to track and profile facility and provider compliance rates for timeliness, completeness, and accuracy.

Section 470, CMS ESRD Forms Edit Reports and Data Corrections, requires you to research and resolve any identified data discrepancies.

Section 475, Renal Transplant Data, instructs you to update your database with the transplant data obtained from the Organ Procurement and Transplantation Network (OPTN) using the Renal Management Information System (REMIS).

Section 480, Reporting on Continued Status of Medicare ESRD Beneficiaries, requires you to investigate the treatment status of CMS-identified beneficiaries for whom no renal activity has been reported for a period of time.

Section 485, Coordination of Additional Renal Related Information, requires you to distribute the National Surveillance of Dialysis-Associated Disease form, process CMS ESRD forms from veterans' facilities, and respond to inquires from Medicare+Choice organizations.

Exhibit 4-1, Engineering Review Board (ERB) Request Template (Hardware Information), provides a template for requesting hardware from the ERB.

Exhibit 4-2, Engineering Review Board (ERB) Request Template (Software Information), provides a template for requesting software from the ERB.

Exhibit 4-3, Application for Access to CMS Computer Systems, provides a copy of the application form that you must complete to obtain an identification and password to enter the CMS computer systems.

Exhibit 4-4, Sample Notification of Data Element Changes Report, is an example of the patient database change notification that CMS sends to you.

Exhibit 4-5, Summary of Data Requirements, provides a summary table of your reporting requirements and responsibilities for processing forms and maintaining data integrity.

Exhibit 4-6, Sample Edit Report, is a sample of the edit report that CMS sends you when it finds discrepancies with your ESRD forms data.

Exhibit 4-7, Sample Medical Evidence Edit Report Cover Letter, is a sample of the form letter that CMS sends you along with the edit report listing the discrepancies found with your ESRD forms data.

Exhibit 4-8, Letter to Center Requesting Overdue Follow-Up, is a sample of the form letter that you use to advise the transplant center that the transplant patient follow-up data/forms to CMS and the Organ Procurement and Transplant Network are overdue.

Exhibit 4-9, Sample Report of Medicare Beneficiaries Who Will End ESRD Status, is an example of the request for a status report on specific ESRD beneficiaries for whom no renal activity had been reported to CMS for 8 months after dialysis was initiated or 32 months post-transplant.

PART 4

INFORMATION MANAGEMENT

PART 4

INFORMATION MANAGEMENT

Exhibits

400. BACKGROUND/AUTHORITY

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.

You are required to perform the data management and reporting activities listed in your Statement of Work using the Standard Information Management System (SIMS) developed to fulfill your data processing, information management, and reporting contractual requirements to CMS. CMS will be replacing the current Renal Beneficiary and Utilization System (REBUS), used to update the Program Management and Medical Information System (PMMIS) Database for the ESRD program. The new system will be named the Renal Management Information System (REMIS). You will be required to use REBUS/REMIS as directed by CMS.

405. RESPONSIBILITIES

Your responsibilities for data processing, information management, and reporting include the following:

- To have sufficient system capacity and the appropriate computer hardware and software to carry out your 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 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 and accuracy of ESRD patient and facility databases;
- To ensure the quality and accuracy of the data submitted to CMS for inclusion in the ESRD PMMIS and the United States Renal Data System (USRDS); and
- To ensure current patient status is reported to CMS timely for appropriate enrollment and disenrollment into the Medicare program for ESRD benefits.

410. SYSTEM CAPACITY

You must maintain a system that provides the capacity to meet your 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:

- SIMS software, and 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 Part 5 of this manual);
- Office automation software compatible with the CMS standard;
- Internet-capable electronic mail capability compatible with CMS, including the ability to send and receive attachments;
- Host on Demand 3270 Terminal Emulation Application via CMS Intranet;

- CMS-compatible web browser access for connection to REMIS;

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

- Provisions for disaster recovery of the databases and data system; and

- Sufficient hardware to run the above software applications.

420. HARDWARE/SOFTWARE (HW/SW) REQUIREMENTS

All HW/SW necessary for the ESRD Standard Information Management System (SIMS), as determined by CMS, must be purchased through the Peer Review Organization (PRO) Standard Data Processing System (SDPS) Contractor, the Iowa Foundation for Medical Care, Inc. (IFMC). In the event you require additional HW/SW, your request must be made and approved through the SDPS Engineering Review Board (ERB) process:

- Complete an ERB Request Template. (See Exhibit 4-1, Hardware Information, and Exhibit 4-2, Software Information, for the appropriate ERB Request Template.)

- Submit the completed template and documentation to the ERB (IFMC).

- The ERB will review the request and make its recommendation to the CMS Project Officer (PO).

- The CMS PO will assess the request. You will be notified of the decision through receipt of a copy of the ERB Request Template and, if approved, you will receive instructions for purchasing the requested HW/SW.

425. CMS COMPUTER SYSTEMS ACCESS

After the award of your contract, if you require access to CMS data systems, 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, submit the name of the replacement individual to the CMS PO using the form shown in Exhibit 4-3.

430. DATA SECURITY

Comply 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 you need a copy of these documents, contact your PO.

435. CONFIDENTIALITY OF DATA

All data provided to you by CMS and all reports containing confidential data prepared by you for CMS are considered confidential and may not be disclosed to other than the appropriate Network board(s), committee(s), and your administrative staff.

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,

including 42 CFR 480.101, 480.102(c), 480.103 - 480.109 480.115, 480.116, 480.120, 480.121, 480.130 - 480.134, 480.135 (a), (b) and (c), 480 137 - 480.143. (See Part 3 of this manual.)

440. DATABASE MANAGEMENT

Maintain patient and facility databases containing the minimum/critical data elements outlined in SIMS and perform various tasks related to these databases.

440.1 Patient Database - Minimum/Critical Data Elements.--Maintain the critical data elements required by SIMS.

A. General Information.--Provide the following information on all ESRD patients:

- Social security number;
- Health insurance claim number;
- Date of birth;
- Sex;
- Race;
- Ethnicity;
- First name;
- Last name;
- State or zipcode of residence;
- Patient employment status (from medical evidence form); and
- Medical coverage (from medical evidence form).

B. Event(s) Information.--An event is a major change in the patient's ESRD history such as modality shift; facility transfer; transplant, first, second; graft failure (failures), first, second; recovered function; discontinued dialysis; death; etc.

1. For All Events.--Provide the following information:

a. Type of event - use the following definitions to determine type of event:

- Dialysis after transplant - when a patient restarts dialysis therapy after a kidney transplant failure.
- Discontinue - when a patient discontinues ESRD therapy voluntarily or by physician’s recommendation.
- Loss to follow-up - report a patient's loss to follow-up if the facility is absolutely sure that no provider treats this patient. This event should be used sparingly.
- Modality shift - when a patient changes his/her modality of treatment (e.g., from in-center hemodialysis to home continuous ambulatory peritoneal dialysis (CAPD)).

- New ESRD patient - a patient who has been diagnosed with chronic renal disease and has never been on dialysis. A Form HCFA-2728 form is initiated for Medicare eligibility as well as registration in the ESRD program. This also includes a transplant patient who never dialyzed prior to transplantation.

- Recover function - when a patient regains renal function and is able to survive without ESRD therapy.

- Restart - patient who resumes dialysis after he/she discontinued dialysis and/or recovered kidney function.

- Transfer in - occurs when a patient, previously dialyzing as an outpatient in another approved renal facility, transfers to a new facility within or out of your network area. The transferring unit must provide a copy of the patient's Form HCFA-2728 form to the new facility.

- Transfer out - when a patient transfers from one outpatient chronic dialysis facility to another.

- Transfer out for transplant - when a dialysis patient leaves the dialysis unit for a kidney transplant at an approved renal transplant center.

- Transplant - when a patient receives a kidney transplant.

- Transplant failure - when the patient's transplanted kidney no longer functions and there is a need to resume dialysis on a regular basis.

b. Date of event; and

c. Provider at the time event occurred.

2. Patient Transfer Events.-- For transferred patients, provide the following information: (A patient must be receiving services in the network area for at least 6 months to be considered a transfer; otherwise, the patient is considered a transient.)

a. Date of most recent transfer into network area;

b. Date of most recent transfer out of network area; and

c. Previous State of residence (if known).

3. Historic Information.--If the patient began services in another Network, then transferred to your Network, obtain the information below from the prior servicing Network or from SIMS:

a. Date regular dialysis began;

b. Initial provider number (provider at time of onset, if known);

c. Primary cause of renal failure;

d. Initial patient residence zip code and State; and

e. Initial modality.

4. Death Information.--Provide the following:

a. Date of death;

b. Cause of death; and

c. Provider submitting death information.

C. Physician and Insurance Information.--Provide the following information:

1. Dialysis Physician's Universal Physicians Identification Number (UPIN).--Provide the most recent dialysis physician's UPIN (if known); and/or

2. Transplant Physician's UPIN.--Provide the most recent transplant physician's UPIN (if known).

440.2 Patient Database Updates.--Update your patient database (or elements in your patient database) on a regular basis to the SIMS central repository.

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

440.3 CMS-Directed Changes to Your Patient Database.--Monthly, if applicable, CMS will notify you to make changes to important data elements in your patient database. Update your database with validated changes (e.g., beneficiary name, date of birth, Health Insurance Claim Number and Beneficiary Identification Code) contained in the Social Security Master File, PMMIS, and Provider Certification databases. CMS will provide these changes to you either by hardcopy or electronically through REBUS/REMIS. Advise CMS, in writing, of any outstanding discrepancies related to these notifications. (See Exhibit 4-4 for a Sample Notification of Data Element Changes Report.)

440.4 Facility Database - Minimum Data Elements.--At least monthly, maintain and update in your facility database the following data elements for each facility in your network area that provides dialysis or transplant services:

- Provider number;
- Name, mailing and physical address, and phone number;
- County name where facility is physically located;
- Names of key staff (medical director, administrator, head nurse);
- Facility ownership type (profit, non-profit);
- Chain organization (Y/N);
- Chain/Corporate affiliation;
- Shifts starting at 5:00 PM or later (Y/N);
- Number of stations (as self reported by the facility); and

- Modalities offered (hemodialysis, peritoneal dialysis, and/or home training; as self-reported by the facility).

440.5 Submission of Facility Database Elements.--Through SIMS, maintain a facility database containing the minimum data elements listed in §440.4. Update the SIMS central repository on an ongoing basis, based upon data or information received from the facilities.

CMS has the capacity to create data files and labels from the SIMS central repository. Beginning February 2001, CMS will create a monthly file for the "Dialysis Facility Compare" website (www.medicare.gov/Dialysis/Home.asp).

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

By October 31 of each contract year, verify 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 by October 31 of each year.

445. ESRD DATA AND REPORTING REQUIREMENTS

Exhibit 4-5 provides a summary of the data and reporting requirements, and your responsibilities for processing forms and maintaining the data.

450. CMS ESRD FORMS

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. Other data collection forms may be submitted voluntarily, as indicated on the form.

450.1 CMS ESRD Program Forms.--These forms contain patient specific information necessary for the operation of the national ESRD program. Each ESRD facility and provider in the network area will send you the following three CMS forms for use by you, CMS, SSA, and the USRDS:

- Form HCFA-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);

- Form HCFA-2744 - ESRD Facility Survey (completed annually); and

- Form HCFA-2746 - ESRD Death Notification or facility generated Death-Notification Form (completed within 30 days after the death of the patient).

Dialysis and/or transplant facilities are required to submit the Medical Evidence Report (Form HCFA-2728-U3) to you 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.

The Death Notification (Form HCFA-2746) is due to you within 30 days of the date of death of the patient.

450.2 CMS ESRD Clinical Performance Measures (CPMs) Data Forms.--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 §525 of

this manual for additional information. Selected dialysis facilities in the network area will send you the following forms (as applicable) on their patients included in the CPM annual sample:

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

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

- Form HCFA-821-A - Dialysis Facility Clinical Performance Measures Data Collection Form.

450.3 CMS ESRD Beneficiary Selection Form.--The CMS ESRD Beneficiary Selection form is completed by the provider, signed by the patient, and sent directly to the fiscal intermediary.

- Form HCFA-382 - ESRD Beneficiary Selection (completed only by Medicare patients who are dialyzing at home).

455. COLLECTION, COMPLETION, VALIDATION, AND MAINTENANCE OF THE ESRD CMS FORMS

Ensure that all CMS ESRD forms listed in §450 are collected, completed, and validated according to the instructions in this section and the "ESRD Program Instruction Manual for Renal Providers" (IMRP). Perform the following tasks in order to fulfill your data responsibilities for the ESRD forms:

- Provide adequate supplies of the ESRD Death Notification (Form HCFA-2746) to providers within your geographical area (unless your 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 HCFA-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, provide an emergency supply. In addition, you may wish to provide start-up supplies to new facilities.

- Send supplies of the blank Facility Survey (Form HCFA-2744) to facilities/providers in your network area. Download and print the form, which is in a PDF file format, from the website at http://www.hcfa.gov/quality/5d.htm. Facilities/providers can also be directed to the website. This form is completed once a year.

- Ensure 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.

- Distribute all CMS revisions to the IMRP to the facilities in your network area.

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

- Process the forms received as instructed in §§455.1-455.3.

NOTE: It is anticipated that the Vital Information System to Improve Outcomes in Nephrology (VISION) project will be rolled out during this contract period, with national implementation during calendar year 2001. Until electronic reporting isrequired from all dialysis facilities for all patients, it will be on a voluntary basis. Your role in monitoring the accuracy and completeness of reports, and the validation of facility-level patient data are critical in assuring the integrity of the patient tracking system. Similarly, capturing data forms on all incident cases requires a mechanism for cross-checking so facilities can query and detect unreported forms. As VISION is implemented, the activities specified in §§455.1-455.3 will need to be retained in a format that is consistent with migration from hard copy to electronic reporting.

455.1 Processing Form HCFA-2728-U3.--Upon receipt of these forms in your office, review the forms for completeness. Each form must provide the following data elements, required by SIMS. Any item not listed in SIMS is not a critical data element. (Critical elements are subject to change.) The data elements are listed by field number and item name.

- The following field numbers with corresponding item names must be completed on all ESRD patients:

1. Patient's name (Last, First);
2. Health Insurance Claim (HIC) Number; and/or
3. Social Security Number (SSN).

- If the patient has had a transplant, check the PMMIS database to see if the Organ Procurement and Transplantation Network (OPTN) has assigned a "dummy" number. This number will usually have "9FN" in the first 3 positions. If so, use this number.

- 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" health insurance claim number and social security number using the following formula:

Position 1 = X
Positions 2-7 = Provider number of provider completing form
Positions 8-9 = Sequential numbering
Positions 10-11 (of HIC number) = ZZ

- 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.

4. Mailing address;
5. State and zipcode of residence;
6. Date of birth;
7. Sex;
8. Ethnicity;
9. Race; and
10. Medical coverage.
11. Is patient applying for ESRD Medicare coverage?
12. Primary cause of renal failure (ICD-9-CM code plus letter code from back of form);
13. Height, either in inches or centimeters;
14. Weight, either in pounds or kilograms; and
15. Patient employment status.
17. Was pre-dialysis/transplant EPO administered?
18e. Serum creatinine (mg/dl) and date of test; or
18f. Creatinine clearance (ml/min) and date of test.

- The following data elements must be provided if form was prepared in connection with the patient commencement of dialysis:

20. Medicare provider number and provider name;
21. Primary dialysis setting;
22. Primary type of dialysis;
23. Date regular dialysis began; and
24. Date patient started at current facility.

- The following data elements must be provided if form was prepared because the patient received a kidney transplant:

27. Date of transplant;
29. Medicare provider number; and
33. Current status of transplant.

- The following data elements must be provided if form was prepared because the patient is applying for waiver of qualifying period based on self-dialysis training provisions of the Social Security Act:

37. Medicare provider number of training facility;
38. Date training began;
39. Type of training;
40. Patient expected to complete (or has completed) training and will self-dialyze on a regular basis;
41. Date when patient completed, or is expected to complete, training; and
43. UPIN of physician personally familiar with patient's training.

- The following data elements must be provided if form was prepared because the patient is applying for early Medicare entitlement based on early transplant procedures:

30. Date patient admitted; and
32. Provider number.

- The following data elements must be provided for all forms:

46. UPIN of attending physician;
47. Attending physician's signature of attestation (stamp is not acceptable.); and
48. Date physician signed form.

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 critical data described above are not present, return the form to the provider, within 1 week of receipt, for completion of these data. Prior to returning the form, you may key and hold this form in SIMS until all mandatory data have been entered.

Enter the data from the form into SIMS. Subject each form to a clinical algorithm to determine if the patient meets the definition of ESRD.

After data entry of the form is complete, you will receive an edit exception report describing the status of this medical evidence form.

Maintain a file of all CMS ESRD hard copy forms that are processed. Retain the hard copy forms for two years after the date of completion. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, retained these forms for two years following the completion of that activity. After two years, shred, incinerate, or otherwise completely destroy, for patient privacy purposes, any forms that are patient-specific and are not maintained for your use, or as documentation of actions specified above.

455.2 Processing Form HCFA-2746 (ESRD Death Notification Form).--Upon receipt of these forms in your office, review the forms for completeness. Each form must have the following data elements completed. Any item not listed is not a critical data element.

- The following required data elements are listed by field number and item name:

  1. Patient's last and first name;
  2. Patient's HIC number;
  3. Patient's sex;
  4. Patient's State of residence;
  5. Patient's date of birth;
  6. Patient's date of death;
  8. Provider number; and
  11. Primary cause of death.

Return to the provider, within 1 week of receipt, forms that are missing information for the critical data items or that contain inaccurate data for the critical data items.

Enter the data from the form into SIMS. Transmit the data on an ongoing basis directly to the CMS Data Center (HDC) using SIMS. After the data are transmitted to CMS, they will be added to the PMMIS after passing additional edits.

Maintain a file of all CMS ESRD hard copy forms that are processed. Retain the hard copy forms for two years after the date of completion. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, retained these forms for two years following the completion of that activity. After two years, shred, incinerate, or otherwise completely destroy, for patient privacy purposes, any forms that are patient-specific and are not maintained for your use, or as documentation of actions specified above.

455.3 Processing Form HCFA-2744 (ESRD Facility Survey).--Form HCFA-2744 is completed annually. Upon receipt of these forms in your office, review the forms for completeness. Each form must have all the pertinent data elements completed. Establish a mechanism to ensure that the number of forms submitted to CMS match the number of events reported on Form HCFA-2744.

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

Enter the data from the forms into SIMS. Transmit the data directly to the HDC using SIMS. After the data are transmitted to CMS, they will be added to the PMMIS after passing additional edits.

Submit hard copies and electronic copies, as directed by CMS, of the completed forms to CMS by the 5th working day of April of each year.

Transmit corrections to the survey data to CMS through SIMS by the third Friday of May of each year.

Maintain a file of all CMS ESRD hard copy forms that are processed. Retain the hard copy forms for two years after the date of completion. If forms are necessary to document ongoing educational, quality assurance, or disciplinary actions beyond the retention period, such forms are to be retained for two years following the completion of that activity. After two years, shred, incinerate, or otherwise completely destroy, any forms that are not maintained for your use, or as documentation of actions specified above.

460. TRACKING SYSTEM FOR ESRD FORMS

Maintain, 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 all critical data fields, as listed in §455, are completed and are accurate. Instructions for determining timeliness and accuracy are contained in §465.

Develop a system to ensure that you act upon any forms edit reports within two weeks of receipt. The two-week period includes the date(s) you return the edit reports to CMS. Develop a system to track all forms that you return to providers for correction. (See §470 for instructions for resolving discrepant records.)

465. ESRD FORMS SUBMISSION COMPLIANCE RATES

Semi-annually, through SIMS, track and profile facility and provider compliance rates for submitting timely, complete, and accurate Medical Evidence (Form HCFA-2728-U3) and Death Notification (Form HCFA-2746) forms or facility and provider generated death notification reports. Maintain compliance rate information on-site and make it available at CMS's request. Document your attempts to contact providers to obtain missing forms and to correct discrepancies. Also, report to the PO any problems encountered with individual 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. Follow these instructions for notifying those facilities/providers with unacceptable semi-annual compliance rates and for providing each facility/provider with its annual compliance rates. Forward a copy of the semi-annual and annual notifications to your PO.

A. Medical Evidence (Form HCFA-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 critical data fields are complete and accurate to the extent possible using logic and Network data to determine accuracy."

B. Death Notification (Form HCFA-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 critical data fields are complete and accurate to the extent possible using logic and Network data to determine accuracy."

There are valid reasons why the Medical Evidence (Form HCFA-2728) and Death Notification forms may not be submitted in a timely manner. For example, the Medicare ESRD-certified facility submitting Form HCFA-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, 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 non-compliant.

Completeness and accuracy are calculated by dividing the number of forms which are in error (critical data elements are missing or are inaccurate; the critical data fields are found in §§455.1 and 455.2) 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, profile each facility's and provider's compliance rates for timeliness, completeness, and accuracy for each form type. Notify 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, evaluate each facility's and provider's compliance rates for timeliness, completeness, and accuracy for each form type. Notify 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 and/or provider does not maintain the required annual average compliance rate, provide assistance to the facility to improve its performance. If you determine that the facility is not making reasonable attempt to improve its performance, prepare a sanction recommendation to the RO following the instructions in Part 7 of this Manual.

470. CMS ESRD FORMS EDIT REPORTS AND DATA CORRECTIONS

After you transmit your monthly ESRD forms data to CMS, (see §450), CMS subjects the data to edit checks. CMS then generates an Edit Report describing any discrepancies found in the data. The Edit Report is sent monthly to you for research and resolution of any identified data discrepancies. Resolve the data discrepancies and enter the corrections in REBUS/REMIS within 60 calendar days of receipt of the Edit Report.

CMS may detect other discrepancies when data is merged into the PMMIS. In these cases, CMS will send you additional Edit Reports for processing. You are responsible for researching and resolving all errors noted in the edit report. Instructions for processing the Edit Reports and resolving the data discrepancies are noted later in this section. If time allows, correct minor errors labeled "warnings." (See Exhibit 4-6 for a sample edit report.)

A. Resolving Discrepant Records.--Using SIMS, transmit data from the ESRD CMS forms to the HDC on a regularly scheduled basis. When the data is received in the HDC, it is subjected to various edit checks. If the data from the form does not pass CMS's edit checks, CMS creates an edit report and sends you a form letter (see Exhibit 4-7) asking you to review, research, and resolve the discrepancies. All of the identifying characteristics on the incoming record must match those on the Medicare master record. Records that do not match are indicated as serious errors on the edit report, along with the statement, "Under investigation by CMS." If CMS's investigation fails to produce a matched record, the edit report will continue to show a serious error with the statement, "To be investigated by Network," until you provide the corrected information.

For example, if you determine that erroneous data was generated because a patient is non-Medicare, enter this information on the appropriate REBUS/REMIS screen, so that the investigation may be terminated.

B. Correcting the Data.--When resolving an error, make the changes directly in REBUS/REMIS, using the appropriate "Change Record" screens. Should the personal identifiers need to be modified the REBUS/REMIS "Refile" function should be used.

C. Error Messages.--If an error is labeled as a "warning," it is not necessary to correct it. However, if the correct information is available, report it. Serious errors that indicate the record did not match the Medicare master file, labeled, "To be investigated by Network," must always be investigated and resolved by transmitting the correct identifying information or determining whether the patient was a non-Medicare or non-ESRD Medicare patient.

D. 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, report the patient as "non-Medicare" on the appropriate REBUS/REMIS screen. In some of these cases, the patient may have been previously enrolled in Medicare due to old age or disability. CMS also 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, obtain a Medical Evidence Report and key it in on the next monthly REBUS/REMIS submission.

One way of determining a correct name/number is to ask the facility 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. You may also request the facility to send a copy of the patient's Medicare card to you. In the event that the patient is found to be non-Medicare, enter this fact on the appropriate REBUS/REMIS screen.

E. 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; and
- First initial.

If any of these elements are different from the ones the providers report, enter the correction directly into REBUS/REMIS by using the "refile" function.

475. RENAL TRANSPLANT DATA

The Organ Procurement and Transplantation Network (OPTN) is responsible for collecting kidney transplant data. The OPTN transmits data weekly, monthly, and quarterly. Weekly transmissions include data on the donor, renal candidate, transplant recipient, and immunosupression information. Monthly transmissions include data on the donor, renal candidate, transplant recipient, follow-up information, waitlist information, immunosuppresion and histocompatibility information, and deleted records. Quarterly transmissions include the type of data submitted monthly and any additional renal data. Access the transplant data from the OPTN through REBUS/REMIS. Instructions for using REBUS/REMIS are in the REBUS/REMIS Manual. Update your database with the transplant data obtained from the OPTN via REBUS/REMIS. Use this data to maintain status information on patients and in your quality assurance and improvement activities. Follow the instructions below for obtaining the renal transplant data from the OPTN.

Access the REBUS/REMIS system 60 days after the end of a quarter to obtain transplant data and transplant follow-up data to enter into and update your database.

A. For Transplant Data.--You may know about transplants that have not been reported to the OPTN. Using the REBUS/REMIS system, report to CMS those patients known to you, for whom the OPTN has not received transplant data. After receipt of unreported transplant information, wait a minimum of 60 calendar days from the end of the quarter in which the transplant event occurred before you enter the following basic patient information directly into REBUS/REMIS:

- Name;
- HIC (Medicare) Number;
- Date of transplant (obtained from the dialysis facility);
- Transplant provider number (obtained from the dialysis facility);
- Type of transplant (cadaver or living donor);
- If the patient is not on the CMS Master File, also enter the date of birth, sex, and State of residence. CMS reports these transplants to the OPTN for research and follow-up; and
- If, when accessing transplant data in PMMIS, you notice that a data element is incorrect which may prevent the record from matching the Master File, enter the correction(s) directly via REBUS/ REMIS if possible, using the "Refile" facility.

B. For Transplant Follow-up Data.--The OPTN will attempt to obtain the renal transplant follow-up data for 6 months after the due date of the registration and follow-up report.

- Quarterly, the OPTN will provide you with a listing of those renal transplant recipient registration and renal recipient follow-up data forms it has been unsuccessful in obtaining.
- Quarterly, review the list of overdue renal transplant recipient registration and renal recipient follow-up forms and contact the applicable transplant center, in writing, and request that the center submit the missing data electronically to the OPTN. The OPTN will provide a second report of data submitted between each quarterly report of overdue forms.

- Make one attempt to request the missing renal transplant recipient registration and renal recipient follow-up form from the transplant center. If the second report of data submitted to the OPTN does not list the required forms, notify the PO of the facility's noncompliance.

- Exhibit 4-8 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, forward to your PO a copy of the listing of overdue renal transplant recipient registration and renal recipient follow-up forms you have received from the OPTN, annotated with the action(s) you have taken. For example, indicate if a written request for the form was sent to the transplant center; if the transplant center submitted the delinquent form to the OPTN; or, if after 90 days, you have been unsuccessful in obtaining the delinquent form. The quarterly annotated list may be submitted to the PO with your quarterly progress and status reports (quarterly reports are due in October, January, April, and July).

- The OPTN can only offer corrective action(s) described in the OPTN Charter and Bylaws when they have been approved by the Secretary. For example, failure to submit data within time periods specified in the OPTN policies may result in the following:

  – A warning letter issued by the Membership and Professional Standards Committee (MPSC) or MPSC-Policy Compliance Subcommittee (PCSC), allowing a 60-day period to correct deficiencies and bring all data current. If the violation is not corrected within 75 days after the issuance of the warning letter:

  – Placing the Member on probation. If the violation involves a policy that is designated by the Secretary as covered in §1138 of the Act, and is not corrected within the Member's 30-day probationary period:

  – Requesting the Secretary to approve suspension of the Member's membership privileges for 60 days, and to suspend its ability to list patients on the waiting list and to receive organ offers for transplant related services. During this period, the Member's patients will be offered the opportunity to transfer to another Member's waiting list. If the Member fails to demonstrate full compliance by the end of the 60-day suspension period:

  – Recommending to the Secretary that the Member be expelled or that other action specifically identified in §121.10(c) of the OPTN Final Rule be taken.

- If you find serious errors or discrepancies in OPTN data, report this to CMS for follow-up with the OPTN.

C. For Graft Failure Follow-up Data.--The OPTN provides you with a list of patients who have had a graft failure and for whom the OPTN has been unable to obtain a follow-up form. (The OPTN follows patients for 2 years after the graft fails.) Check your database and notify the OPTN of the status of any patient(s) you locate as alive and back on dialysis, expired, or unknown to you.

480. REPORTING ON CONTINUED STATUS OF MEDICARE ESRD BENEFICIARIES

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 90 days after the change in patient status. CMS may pull census data from SIMS periodically during the year. This requires you keep your patient database up-to-date.

Each month, respond to either hard copy or electronically downloaded inquiries from CMS regarding the status of specific ESRD beneficiaries, which CMS has been unable to resolve by accessing the central repository in SIMS. Investigate the treatment status of the identified beneficiaries and respond to CMS within 45 days of receipt of the inquiries. The information to be entered includes the current setting and modality of beneficiaries for whom no renal activity has been reported (8 months after dialysis is initiated or 32 months post transplant). All corrections are to be entered into REBUS/REMIS (refer to the REBUS/REMIS Manual for complete instructions). (See Exhibit 4-9, Sample Report of Medicare Beneficiaries Who Will End ESRD Status.) If you have trouble entering these data via REBUS/REMIS, you may contact CMS for assistance.

485. COORDINATION OF ADDITIONAL RENAL RELATED INFORMATION

A. National Surveillance of Dialysis-Associated Disease Form.--Distribute the National Surveillance of Dialysis-Associated Disease Form to all ESRD facilities/providers annually. These survey forms are to be completed by the facility/provider on a voluntary basis and returned to you for submission to the Centers for Disease Control and Prevention by the fifth working day of April.

B. Veterans Health Administration (VHA).--Process 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.

Supply the VHA units with the Medical Evidence Report and Death Notification forms. CMS ensures that you are 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.--Submit VHA patient data with the other CMS forms that are submitted on a monthly basis. If the forms do not pass the critical edits, return the unaccepted form(s) to the VHA facility, explain the problem, and request the VHA unit to resubmit the form with the necessary corrections to you. You are not required to validate the information supplied by the VHA unit; however, you are 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 you all copies of the ESRD forms that they complete (after they retain one copy for their files). Keep one copy of each form for your files and destroy all other copies, to protect patient privacy.

If the VHA patient has a Medicare number with a BIC Number, submit this information with the monthly CMS forms you are submitting.

You 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, your information on the VHA transplant recipient may be the only source for the other Network.

C. Inquiries From Medicare+Choice (M+C) Organizations.--Respond to permissible inquiries from your 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 you with a list of the M+C organizations in your network area. M+C organizations receive a differential 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 an 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.--Provide 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 HCFA-2728 data were submitted to CMS.

Use your 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.--You are not required to answer any questions regarding 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 of Prepaid Health Care Operations and Oversight. In addition, you should not routinely provide M+C organizations with copies of Form HCFA-2728. M+C organizations should obtain this information from the servicing dialysis facility.

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

ENGINEERING REVIEW BOARD (ERB) REQUEST TEMPLATE (HARDWARE INFORMATION)

HARDWARE INFORMATION

Est. Total Price:

Description of hardware:

Justification for hardware: (Provide a narrative identifying reason for need.)

Narrative must address the following:

- Describe the current process. What are you currently doing that you want to change?
- Describe new process. How would acquiring hardware affect the process?

Manufacturer:

Model:

Number of units:

Number of users: (Identify the number of users, their associated responsibilities, and PRO program/contract where individual's time will be charged.)

Example:	Total 2 users	1 Statistician	analysis	CASPRO
		1 Director	admin	CASPRO

Frequency of use: (Provide the percentage of time the requested hardware will be utilized by the above referenced users.)

Example:	Position A Statistician	.25 CASPRO	.25 Pilot PRO (.50 PRO)
	Position B Director	.50 CASPRO	.25 PRO

Method of attachment (e.g., parallel port connection, SDPS LAN):

NOTE: This is the form to be used if:

1. **CMS/IFMC has instructed PROs to submit an ERB Request Form.**

***2. A PRO specific hardware (e.g., additional workstations, etc.) need has been identified. Submit ERB Request Template to SDPS Help Desk.**

***3. Hardware is needed for a "special studies"/project contract (i.e., CASPRO). When ERB Request Template is completed, submit to ERB via the SDPS Help Desk, PRO RO Project Officer, AND a copy to the SDPS Project Officer (with appropriate documentation).**

***Will need to attach the contract specialist's approval for hiring additional staff (when request is sent to SDPS Project Officer) as appropriate**.

(06/15/99)

(The next page is 4-37)

EXHIBIT 4-2

ENGINEERING REVIEW BOARD (ERB) REQUEST TEMPLATE (SOFTWARE INFORMATION)

SOFTWARE INFORMATION

Est. Total Price:

Description of software:

Manufacturer:

Name:

Version:

Purpose of software: (Provide a narrative, i.e., an enhancement, automating a manual process, replacing a current software, etc.) **Note: Will need to attach SofTrak metering report to verify need if software is currently a part of the SDPS configuration**.

Narrative must address the following:

- Describe the current process. What are you currently doing that you want to change?
- Describe new process. How would acquiring software affect the process?

Number of licenses:

License type (e.g., standalone, concurrent, site):

Will SofTrak be used to meter the licenses for this product?

Specific location(s) of where software is installed (hardware platform, directory, i.e., installation on a hard drive for specific workstation or installation on network):

NOTE: This is the form to be used if:

1. **CMS/IFMC has instructed PROs to submit an ERB Request Template.**

***2. A PRO specific software (e.g., additional software license, etc.) need has been identified.**

***3. Software is needed for a "special studies" contract (i.e., CASPRO). When ERB Request Template is completed, submit to ERB via the SDPS Help Desk, PRO RO Project Officer, AND a copy to the SDPS Project Officer (with appropriate documentation).**

***Will need to attach the contract specialist's approval for hiring additional staff (when request is sent to SDPS Project Officer) as appropriate.**

(06/15/99)

(The Next Page is 4-39)

APPLICATION FOR ACCESS TO CMS COMPUTER SYSTEMS

APPLICATION FOR ACCESS TO HCFA COMPUTER SYSTEMS

(Read and complete both sides of this form)

1. **Type of Request** ☐ NEW ☐ CHANGE ☐ RECERTIFY ☐ DELETE — Current UserID _____

2. **User Information**

☐ HCFA Employee ☐ Social Security Admin. ☐ FMC ☐ Contractor (non-Medicare) ☐ Fraud Investigation Database ☐ End-Stage Renal Disease Network ☐ Federal (other than HCFA) ☐ Mgd Care Org/Group Health Plan ☐ Railroad Retirement Board ☐ Medicare Contr/Intermediary/Carrier ☐ Peer Review Organization ☐ Researcher ☐ State Agency ☐ Vendor ☐ Other *(specify)*: _____

a. Last Name · First Name · MI	b. Email Address *(non-HCFA only)*	c. SSN *(see Privacy Act Advisory Statement on back)*
d. Mailing Address/Mail Stop	**e. HCFA Organization or Company Name**	**f. Contract Number(s) *(non-HCFA only)***
g. Daytime Telephone Number ( )	**h. Company Telephone Number** ( )	**i. Central Office Desk Location**

3. **Type of Access Required** (P= Production, D=Development, V=Validation, R=Remote/Dialup Access)

a. Application(s):	P	D	V	R
_____	( )	( )	( )	( )
_____	( )	( )	( )	( )
_____	( )	( )	( )	( )
_____	( )	( )	( )	( )
_____	( )	( )	( )	( )

b. Subsystems:	P	D	V	R
CICS	( )	( )	( )	( )
DB2	( )	( )	( )	( )
IDMS	( )	( )	( )	( )
M204	( )	( )	( )	( )
NDM	( )	( )	( )	( )
OMVS	( )	( )	( )	( )
TSO	( )	( )	( )	( )
WYLBUR	( )	( )	( )	( )
OTHER _____	( )	( )	( )	( )

c. **HCFA Desktop/LAN:**

	Email	No Email
Central Office	☐	☐
DC1	☐	☐
FMC	☐	☐
ATL1	☐	☐
BOS1	☐	☐
CHI1	☐	☐
DAL1	☐	☐
DEN1	☐	☐
KCM1	☐	☐
NYC1	☐	☐
PHI1	☐	☐
SEA1	☐	☐
SF01	☐	☐
Other _____	☐	☐

d. **Expected Frequency of Use:** *(non-HCFA only)*

☐ Daily ☐ Monthly ☐ Quarterly ☐ Annually

4. **Reason for Request**

FOR HCFA USE ONLY - DO NOT WRITE BELOW THIS LINE

5. **Authorization:** We acknowledge that our Organization is responsible for all resources to be used by the person identified above and that requested accesses are required to perform their duties. We understand that any change in employment status or access needs are to be reported immediately via submittal of this form.

Requesting HCFA Official	Approving HCFA Official *(non-HCFA only)*	HCFA RACF Group Administrator
Print Name	Print Name	Print Name
Signature / Date	Signature / Date	Signature / Date
Telephone Number / HCFA Userid	Title / Organization	Telephone Number
Contract Number / Contract Exp. Date or 'Not-to-Exceed' Date	Telephone Number / HCFA Userid	Desk Location / Organization or Region

(September 2000)

APPLICATION FOR ACCESS TO CMS COMPUTER SYSTEMS

PRIVACY ACT ADVISORY STATEMENT
Privacy Act of 1974, P. L. 93-579

The information on side 1 of this form is collected and maintained under the authority of Title 5 U.S. Code, Section 552a(e)(10). This information is used for assigning, controlling, tracking, and reporting authorized access to and use of HCFA's computerized information and resources. The Privacy Act prohibits disclosure of information from records protected by the statute, except in limited circumstances.

The information you furnish on this form will be maintained in the Individuals Authorized Access to the Health Care Financing Administration (HCFA) Data Center Systems of Records and may be disclosed as a routine use disclosure under the routine uses established for this system as published at 59 FED. REG. 41329 (08-11-94) and as HCFA may establish in the future by publication in the *Federal Register*.

Collection of the Social Security Number (SSN) is authorized by Executive Order 9397. Furnishing the information on this form, including your Social Security Number, is voluntary, but failure to do so may result in delaying the processing of this request.

SECURITY REQUIREMENTS FOR USERS OF HCFA'S COMPUTER SYSTEMS

HCFA uses computer systems that contain sensitive information to carry out its mission. Sensitive information is any information, which the loss, misuse, or unauthorized access to, or modification of could adversely affect the national interest, or the conduct of Federal programs, or the privacy to which individuals are entitled under the Privacy Act. To ensure the security and privacy of sensitive information in Federal computer systems, the Computer Security Act of 1987 requires agencies to identify sensitive computer systems, conduct computer security training, and develop computer security plans. HCFA maintains a system of records for use in assigning, controlling, tracking, and reporting authorized access to and use of HCFA's computerized information and resources. HCFA records all access to its computer systems and conducts routine reviews for unauthorized access to and/or illegal activity.

Anyone with access to HCFA Computer Systems containing sensitive information must abide by the following:

- Do not disclose or lend your IDENTIFICATION NUMBER AND/OR PASSWORD to someone else. They are for your use only and serve as your "electronic signature". This means that you may be held responsible for the consequences of unauthorized or illegal transactions.
- Do not browse or use HCFA data files for unauthorized or illegal purposes.
- Do not use HCFA data files for private gain or to misrepresent yourself or HCFA.
- Do not make any disclosure of HCFA data that is not specifically authorized.
- Do not duplicate HCFA data files, create subfiles of such records, remove or transmit data unless you have been specifically authorized to do so.
- Do not change, delete, or otherwise alter HCFA data files unless you have been specifically authorized to do so.
- Do not make copies of data files, with identifiable data, or data that would allow individual identities to be deduced unless you have been specifically authorized to do so.
- Do not intentionally cause corruption or disruption of HCFA data files.

A violation of these security requirements could result in termination of systems access privileges and/or disciplinary/adverse action up to and including removal from Federal Service, depending upon the seriousness of the offense. In addition, Federal, State, and/or local laws may provide criminal penalties for any person illegally accessing or using a Government-owned or operated computer system illegally.

If you become aware of any violation of these security requirements or suspect that your identification number or password may have been used by someone else, immediately report that information to your component's Information Systems Security Officer.

_____ _____

Signature of User **Date**

APPLICATION FOR ACCESS TO HCFA COMPUTER SYSTEMS

Instructions for Completing the Application for Access to HCFA Computer Systems

This form is to be completed and submitted whenever the following situations occur:
- A user **requires access** to a HCFA computer system to perform their job duties. (Submit NEW Request)
- A user **changes names**, has a **change in access needs**, **job duties**, or **moves to another component**. (Submit CHANGE Request)
- A user **retires, resigns**, is **removed from a contract with HCFA**, or for any reason **no longer requires access**. (Submit DELETE Request)
- A user receives notice that they must **recertify** their access needs. (Submit RECERTIFY Request)

Section 1: Type of Request COMPLETE FOR ALL REQUESTS. Check type of request and enter current HCFA UserID, if using one.

Section 2: User Information COMPLETE FOR NEW, CHANGE AND RECERTIFY REQUESTS. Check employee type, and complete blocks a. through i.

HCFA Employees – Blocks b., f. and h. may be left blank. If not stationed at HCFA Headquarters, provide a complete mailing address in block d. and leave block i. blank.

Non-HCFA Employees – Block i. may be left blank if not stationed at HCFA Headquarters. If unknown, contract number for block f. may be obtained from your Project Officer or your HCFA contact person.

Section 3: Type of Access Required COMPLETE FOR NEW, CHANGE AND RECERTIFY REQUESTS.

For NEW Requests – Check each type of access required. List the names of all applications you require access to (i.e., OSCAR, CROWD, CAFM, CLIA) in block a., Application(s). For each application, check the appropriate columns to indicate the environment(s) access is needed in, and if remote access is required. Use block b., Subsystems, to request access not specific to particular applications. If 'Other' is checked, be sure to specify here and in Section 4, Reason for Request. If access to a HCFA desktop or LAN is required, check for appropriate site in block c., HCFA Desktop/LAN. Non-HCFA employees should complete block d., Expected Frequency of Use.

For CHANGE Requests – If access needs have changed, enter an 'A' to add, or a 'D' to delete, for each type of access requiring a change. (Most changes in job duties or organizational placement require a change in access needs.) If 'Other' is checked, be sure to specify here and in Section 4, Reason for Request. For name changes only, leave this block blank and go to Section 4.

For RECERTIFY Requests – Check each type of access currently held and still required to perform your job duties. If additional accesses are required, note those types with an 'A'. (Those accesses currently held but not checked will be revoked.) If 'Other' is checked in block 3.b., Subsystems, or block 3.c., HCFA Desktop/LAN, be sure to specify here and in Section 4, Reason for Request.

Section 4: Reason for Request COMPLETE AS REQUIRED.

For NEW Requests *(non-HCFA only)* – Provide an explanation of what job duties require you to access a HCFA computer system. Include project accounting numbers, if applicable. If 'Other' has been checked in Section 3.b., Subsystems, or Section 3.c., HCFA Desktop/LAN, specify type here.

For CHANGE Requests – Note the nature of the action requiring a change. For name changes, include previous and new names. For organizational changes (reassignment, new position), include old and new organizational names. If 'Other' has been checked in Section 3.b., Subsystems, or Section 3.c., HCFA Desktop/LAN, specify here.

For DELETE Requests – Note the nature of the action requiring the removal of accesses.

For RECERTIFY Requests *(non-HCFA only)* – Provide an explanation of what job duties require you to access a HCFA computer system. Include project accounting numbers, if applicable. If 'Other' has been checked in Section 3.b., Subsystems, or Section 3.c., HCFA Desktop/LAN, specify here.

Read, sign and date the back of the form. Then obtain signatures for Section 5.

Section 5: Authorization COMPLETE FOR ALL REQUESTS.

HCFA Employees – **Requesting HCFA Official:** The immediate supervisor must sign and note the appropriate 'not-to-exceed' date (i.e., temporary employment), or 'N/A' if indefinite access is required. The **RACF Group Administrator** must also sign where noted. These responsibilities cannot be delegated.

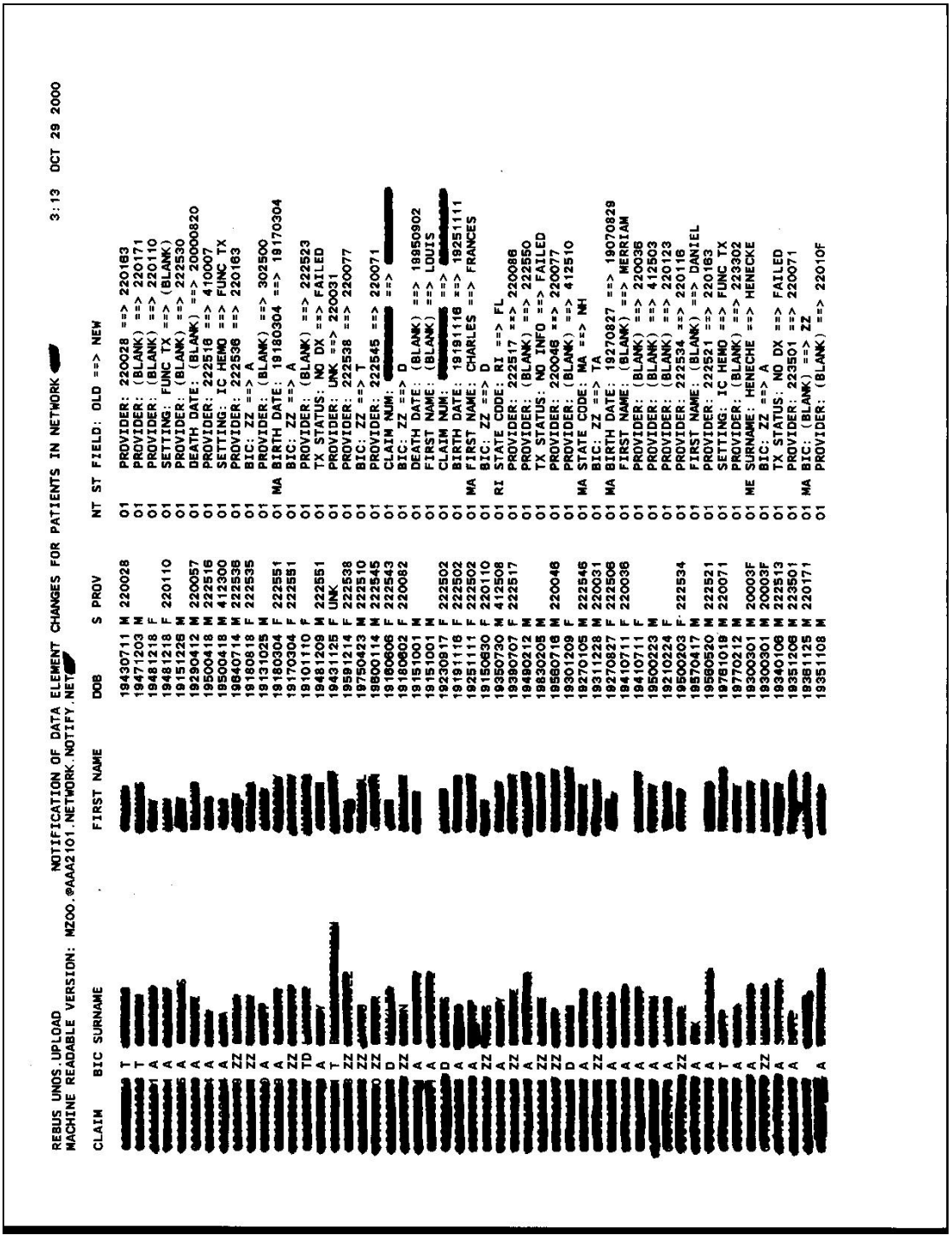
Non-HCFA Employees – **Requesting HCFA Official:** The Project Officer, if designated, must sign and complete the Requesting HCFA Official block. For Medicare Contractors/Intermediaries/Carriers, a Consortium Contractor Management Staff member must sign and complete the Requesting HCFA Official block. For others, the HCFA Liaison/Contact or ADP Coordinator must sign and complete the Requesting HCFA official block. (IT IS IMPORTANT THAT CONTRACT NUMBER AND EXPIRATION DATE ARE INCLUDED WHERE APPLICABLE. IF ACCESS IS REQUIRED FOR MULTIPLE CONTRACTS, THE NUMBER AND EXPIRATION DATE FOR THE CONTRACT WITH THE LONGEST PERIOD OF PERFORMANCE SHOULD BE USED. IF NO CONTRACTS APPLY, AN APPROPRIATE 'NOT-TO-EXCEED' DATE SHOULD BE NOTED, OR 'N/A' IF INDEFINITE ACCESS IS REQUIRED.) **Approving HCFA Official:** The immediate supervisor of the Requesting HCFA Official must sign and complete the Approving HCFA Official block. For Medicare Contractors/Intermediaries/Carriers, the Consortium Contractor Management Official must sign and complete the Approving HCFA Official block. The **RACF Group Administrator** must also sign where noted. These responsibilities cannot be delegated.

RACF Group Administrators – If applicable, note the preferred group for UserID assignment in Section 1.

(September 2000)

(The next page is 4-43)

SAMPLE NOTIFICATION OF DATA ELEMENT CHANGES REPORT



REBUS UNOS.UPLOAD NOTIFICATION OF DATA ELEMENT CHANGES FOR PATIENTS IN NETWORK 3:13 OCT 29 2000
MACHINE READABLE VERSION: N200.@AAA2101.NETWORK.NOTIFY.NET

CLAIM	BIC	SURNAME	FIRST NAME	DOB	S	PROV	NT	ST	FIELD: OLD ==> NEW
				19430711	M	220028	01		PROVIDER: 220028 ==> 220163
				19471203	M		01		PROVIDER: (BLANK) ==> 220171
				19481218	F		01		PROVIDER: (BLANK) ==> 220110
				19481218	F	220110	01		SETTING: FUNC TX ==> (BLANK)
				19151228	M		01		PROVIDER: (BLANK) ==> 222530
				19290412	M	220057	01		DEATH DATE: (BLANK) ==> 20000820
				19500418	M	222516	01		PROVIDER: 222516 ==> 410007
				19500418	M	412300	01		SETTING: IC HEMO ==> FUNC TX
				19840714	M	222538	01		PROVIDER: 222538 ==> 220163
				19180818	F	222535	01		BIC: ZZ ==> A
				19131025	M		01		PROVIDER: (BLANK) ==> 302500
				19180304	F	222551	01	MA	BIRTH DATE: 19180304 ==> 19170304
				19170304	F	222551	01		BIC: ZZ ==> A
				19101110	F		01		PROVIDER: (BLANK) ==> 222523
				19481209	M	222551	01		TX STATUS: NO DX ==> FAILED
				19431125	F	UNK	01		PROVIDER: UNK ==> 220031
				19591214	F	222538	01		PROVIDER: 222538 ==> 220077
				19750423	M	222510	01		BIC: ZZ ==> T
				19800114	M	222545	01		PROVIDER: 222545 ==> 220071
				19180606	F	222543	01		CLAIM NUM: [redacted] ==> [redacted]
				19180802	F	220082	01		BIC: ZZ ==> D
				19151001	M		01		DEATH DATE: (BLANK) ==> 19950902
				19151001	M		01		FIRST NAME: (BLANK) ==> LOUIS
				19230917	F	222502	01		CLAIM NUM: [redacted] ==> [redacted]
				19191116	F	222502	01	MA	BIRTH DATE: 19191116 ==> 19251111
				19251111	F	222502	01	MA	FIRST NAME: CHARLES ==> FRANCES
				19150830	F	220110	01		BIC: ZZ ==> D
				19350730	M	412508	01	RI	STATE CODE: RI ==> FL
				19390707	F	222517	01		PROVIDER: 222517 ==> 220086
				19490212	M		01		PROVIDER: (BLANK) ==> 222550
				19830205	M		01		TX STATUS: NO INFO ==> FAILED
				19580718	M	220046	01		PROVIDER: 220046 ==> 220077
				19301209	F		01		PROVIDER: (BLANK) ==> 412510
				19270105	M	222546	01	MA	STATE CODE: MA ==> NH
				19311228	M	220031	01		BIC: ZZ ==> TA
				19270827	F	222506	01	MA	BIRTH DATE: 19270827 ==> 19070829
				19410711	F	220036	01		FIRST NAME: (BLANK) ==> MERRIAM
				19410711	F		01		PROVIDER: (BLANK) ==> 220038
				19500223	M		01		PROVIDER: (BLANK) ==> 412503
				19210224	F		01		PROVIDER: (BLANK) ==> 220123
				19500203	F	222534	01		PROVIDER: 222534 ==> 220116
				19570417	M		01		FIRST NAME: (BLANK) ==> DANIEL
				19580520	M	222521	01		PROVIDER: 222521 ==> 220163
				19781019	M	220071	01		SETTING: IC HEMO ==> FUNC TX
				19770212	M		01		PROVIDER: (BLANK) ==> 223302
				19300301	M	20003F	01	ME	SURNAME: HENECHE ==> HENECKE
				19300301	M	20003F	01		BIC: ZZ ==> A
				19340106	M	222513	01		TX STATUS: NO DX ==> FAILED
				19351208	M	223501	01		PROVIDER: 223501 ==> 220071
				19381125	M	220171	01	MA	BIC: (BLANK) ==> ZZ
				19351108	M		01		PROVIDER: (BLANK) ==> 22010F

(The next page is 4-45)

EXHIBIT 4-5

SUMMARY OF DATA REQUIREMENTS

This exhibit provides a summary of your responsibilities and the actions you 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. (§ 440.2)	CMS may 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. (§ 440.3)	Provides listings electronically and hardcopy.
3. Mailing Labels	Facility/ Provider provides data SIMS	Schedule system updates for the date file is created. (§440.5)	CMS to access SIMS. Notifies Network 14 days prior. Uses 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. (§ 440.5)	CMS to access SIMS. Notifies Network 14 days prior. Distributes data upon request.
5. Corrections to the Provider Listing	SIMS	Schedule system updates for the date file is created. (§ 440.5)	CMS to access SIMS. Notifies Network 14 days prior. CMS corrects REBUS/REMIS.
6. Form HCFA-2728 Medical Evidence Form	Facility/ Provider completes form	Checks form for completeness; enters into SIMS; transmits data monthly to CMS data center. Provides emergency and start up supply of forms to facility. (§ 455.1)	Performs edit checks; matches data against Master File; generates edit reports.
7. Form HCFA-2746 Death Notification Form	Facility/ Provider completes form	Checks form for completeness; enters into SIMS; transmits data monthly to CMS data center. Provides supply of forms to facility. (§ 455.2)	Performs edit checks; matches data against Master File; generates edit reports.
8. Form HCFA-2744 Facility Survey Form	Facility/ Provider completes survey form	Sends surveys to facilities; checks forms for completeness; enters into SIMS; transmits data annually to CMS data center and submits hard copies of the forms to CMS. (§ 455.3)	Notifies Networks of any discrepancies.
9. Corrections to Form HCFA-2744	Information from facility/provider	Submits hardcopies of corrections to CMS. Makes corrections through SIMS. (§ 455.3)	Ensures corrections have been made after SIMS data is uploaded to PMMIS.

DATA TYPE	SOURCE	NETWORK RESPONSIBILITY	CMS ACTION
10. ESRD Form Compliance Rates	SIMS	Semi-annually, notifies facilities of unacceptable compliance rates; provides annual compliance rates to facilities; recommends alternative sanction for non-compliant facilities. (§ 465)	Processes alternative sanction recommendations, as necessary.
11. ESRD Forms Edit Reports	Generated by CMS	Makes corrections and enters into REBUS/REMIS. (§ 470)	Updates PMMIS.
12. Renal Transplant Data	The Organ Procurement and Transplantation Network (OPTN)	Accesses data quarterly through REBUS/REMIS; updates REBUS/REMIS as necessary on those transplant patients not in PMMIS; obtains follow-up data as requested by OPTN. (§ 475)	Updates PMMIS with OPTN transplant data; 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	Validates monthly the current setting of beneficiaries for which CMS is unable to resolve by accessing SIMS or for which no renal activity has been reported for 8 months after dialysis has been initiated and 32 months post transplant. Enter corrections via REBUS/REMIS. (§480)	Accesses SIMS for beneficiaries for which no renal activity has been reported (8 months after dialysis has been initiated or 32 months post transplant). Notifies Networks of beneficiaries not identified in SIMS central repository. Updates PMMIS and notifies SSA within 60 days.
14. National Surveillance of Dialysis-Associated Disease Form	Facility/ Provider completes form	Forwards completed forms to CDC. (§ 485)	Not applicable.
15. ESRD Forms on Veterans Affairs (VA) Patients	VA Facility completes forms voluntarily	Enters data into Network database; transmits data monthly to CMS data center. (§ 485)	Performs edit checks; matches data against Master File; generates edit reports for VA.
16. Inquiries from M+C organizations	SIMS, REMIS	Provides ESRD functional status information to M+C organizations (§485)	Not applicable.
17. CPM Forms	Facility Completes	Forwards to facility; enters data; submits to CMS	Analyzes and publishes.

EXHIBIT 4-6

SAMPLE EDIT REPORT

REBUS MEDICAL EVIDENCE EDIT REPORT

CLAIM	BIC	SURNAME	PHYS SIGN DATE	PROVIDER	NETWORK
XXX-68-5608-ZZ	XXXXNLEE, XXNCEPTION		05/26/1995	030010	15

---------- SERIOUS ERRORS: ---------
THIS DATA HAS NOT YET MATCHED MEDICARE MASTER FILE (NETWORK SHOULD INVESTIGATE)

-------- ALGORITHM RESULTS: ----------
PATIENT APPROVED
ESTIMATED CREATININE CLEARANCE VALUE IS LE 15.5 ML/MIN

CLAIM	BIC	SURNAME	PHYS SIGN DATE	PROVIDER	NETWORK
XXX-18-4046-D	XXXXLLI, XXRNADETTE		01/26/1996	052588	18

---------- SERIOUS ERRORS: ----------
DIALYSIS START: 01/22/1996 DATE MUST NOT BE AFTER PHYS SIGN DATE: ½/1996

THIS DATA HAS NOT YET MATCHED MEDICARE MASTER FILE (CMS WILL INVESTIGATE)

---------- ALGORITHM RESULTS: ----------
PATIENT APPROVED
SERUM CREATININE VALUE IS GE 8.0 MG/DL

---------- WARNINGS: ----------
TRANSPLANT DATE NOT YET REPORTED BY UNOS

(The next page is 4-49)

EXHIBIT 4-7

SAMPLE MEDICAL EVIDENCE EDIT REPORT COVER LETTER

Date

NOTE TO: End Stage Renal Disease (ESRD) Network executive Directors/Data Managers

Subject: Monthly Edit Report(s)

Enclosed, you will find the Medical evidence Edit Report for _____.

If you have any questions, please contact me at _____. Thank you for your cooperation.

Health Insurance Specialist
ISG/OCSQ

Enclosure

(The next page is 4-51)

EXHIBIT 4-8

LETTER TO CENTER REQUESTING OVERDUE FOLLOW-UP

Date

Transplant Center Name & Address

Dear Transplant Provider:

The Organ Procurement and Transplant Network (OPTN) has informed the 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, Subpart U – Conditions for Coverage of Suppliers of End Stage Renal Disease (ESRD) Services, §405.2133, you are required to furnish data and information to the Center for Medicare and Medicaid Services (CMS) (formerly the Health Care Financing Administration (HCFA) for the administration of the ESRD program. Under §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 can result in the recommendation of an alternative sanction to CMS.

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

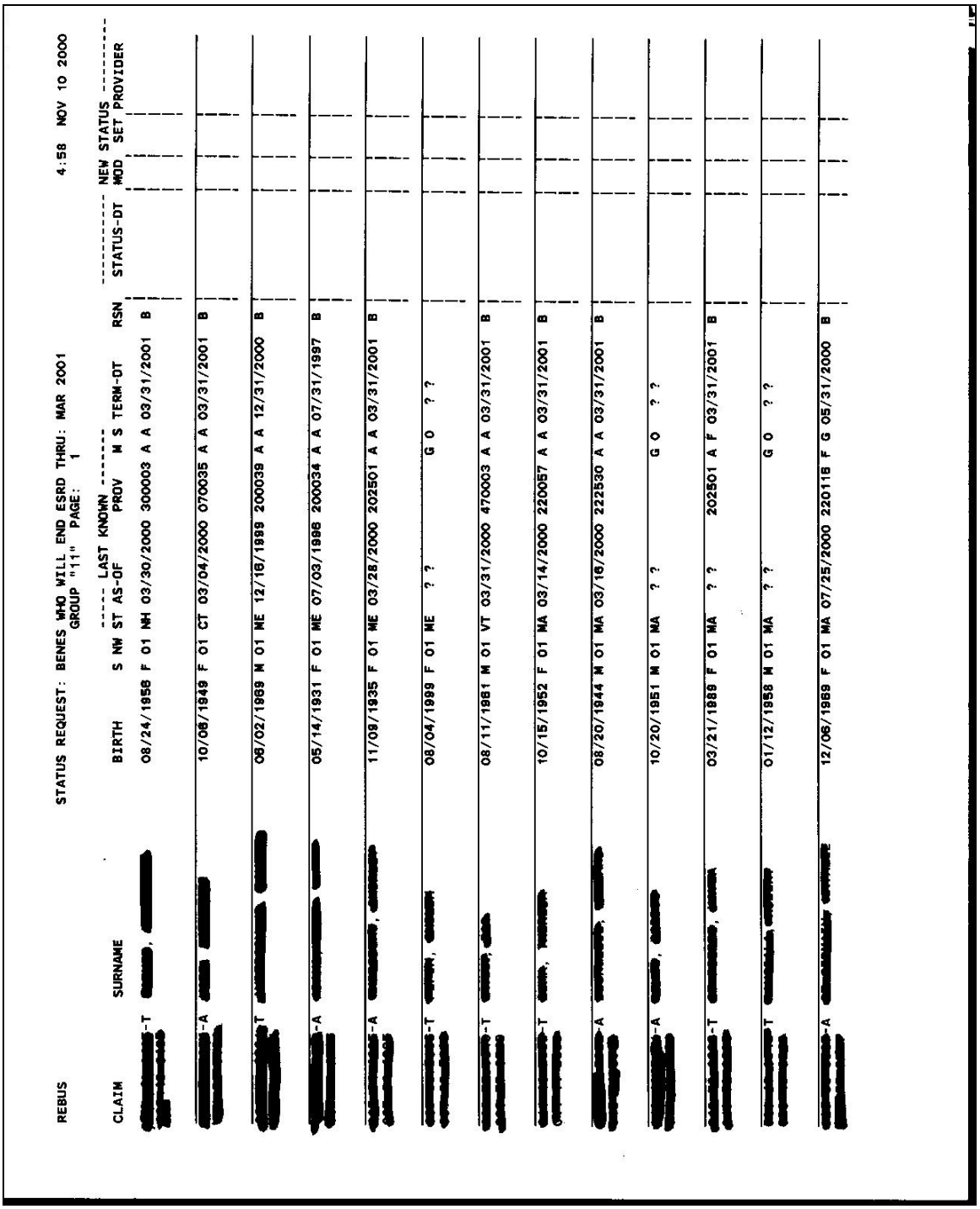
Sincerely,

Network Executive Director
Address

(The next page is 4-53)

EXHIBIT 4-9

SAMPLE REPORT OF MEDICARE BENEFICIARIES WHO WILL END ESRD STATUS



REBUS STATUS REQUEST: BENES WHO WILL END ESRD THRU: MAR 2001 4:58 NOV 10 2000
GROUP "11" PAGE: 1

CLAIM	SURNAME	BIRTH	S	NW	ST	LAST KNOWN AS-OF	PROV	M	S	TERM-DT	RSN	NEW STATUS STATUS-DT	MOD	SET	PROVIDER
-T		08/24/1958	F	01	NH	03/30/2000	300003	A	A	03/31/2001	B				
-A		10/08/1949	F	01	CT	03/04/2000	070035	A	A	03/31/2001	B				
T		08/02/1969	M	01	ME	12/16/1999	200039	A	A	12/31/2000	B				
-A		05/14/1931	F	01	ME	07/03/1998	200034	A	A	07/31/1997	B				
-A		11/08/1935	F	01	ME	03/28/2000	202501	A	A	03/31/2001	B				
-T		08/04/1999	F	01	ME	? ?		G	O	? ?					
-T		08/11/1961	M	01	VT	03/31/2000	470003	A	A	03/31/2001	B				
-T		10/15/1952	F	01	MA	03/14/2000	220057	A	A	03/31/2001	B				
-A		08/20/1944	M	01	MA	03/16/2000	222530	A	A	03/31/2001	B				
-A		10/20/1951	M	01	MA	? ?		G	O	? ?					
-T		03/21/1989	F	01	MA	? ?	202501	A	F	03/31/2001	B				
T		01/12/1958	M	01	MA	? ?		G	O	? ?					
-A		12/06/1989	F	01	MA	07/25/2000	220118	F	G	05/31/2000	B				