Supporting Statement
for the Conditions for Coverage for
End Stage Renal Disease (ESRD) Facilities
and Supporting Regulations Contained in
42 CFR 405.2100-.2171
CMS-R-52

A. Background

The Centers for Medicare and Medicaid (CMS) is requesting a reapproval of 0938-0386, CMS-R-52, to remain in compliance with the Paperwork Reduction Act (PRA). CMS published a Notice of Proposed Rulemaking (CMS-3818-P) on February 5, 2005. The public comment period ended on May 5, 2005. CMS-3818-P proposed a complete overhaul of the existing Medicare ESRD conditions for coverage at 42 CFR §405, Subpart U. Currently, CMS is in the process of reviewing voluminous public comments on CMS-3818-P and must publish a final rule by February 5, 2008, as required by the Medicare Modernization Act. This is an update of the PRA under the existing rules. The agency will update the PRA pursuant to publication of a final rule.

End-stage renal disease (ESRD) is a kidney impairment that is irreversible and permanent and requires a regular course of dialysis or kidney transplantation to maintain life. Dialysis is the process of removing dissolved substances from the patient's body to maintain the chemical balance of the blood when the kidneys have failed.

Section 299I of the Social Security Amendments of 1972 (P.L. 92-603) originally extended Medicare coverage to insured individuals, their spouses, and their dependent children with ESRD who require dialysis or transplantation. Subsequently, the ESRD Amendments of 1978 (Pub. L. 95-292) amended title XVIII of the Social Security Act (the Act) by adding section 1881. Section 1881(b)(1) of the Act authorizes the Secretary to prescribe health and safety requirements (known as conditions for coverage) that a facility providing dialysis and transplantation services to ESRD patients must meet to qualify for Medicare reimbursement. Final regulations were published June 3, 1976. Subsequent to the publication of the final regulations, the ESRD Amendments of 1978 were enacted to amend title XVIII of the Act to include section 1881(c). This section establishes ESRD network areas and Network organizations to assure the effective and efficient administration of ESRD program benefits. The requirements from section 1881(b) and (c) are implemented in regulations at 42 CFR part 405, subpart U, Conditions for Coverage for ESRD facilities.

On April 7, 1986, the Consolidated Omnibus Budget Reconciliation Act of 1975 (COBRA) (P.L. 99-272) was enacted which requires the Secretary to maintain renal disease Network organizations as authorized under section 1881(c) of the Act, and not merge the Network organizations into other organizations or entities. On April 15, 1986, we published a notice of proposed rulemaking to implement section 9214 of P.L. 99-272. A final rule (HSQ-115) was published August 26, 1986. This rule revised the requirements in regulations pertaining to the ESRD networks and organizations and establishes new, more efficient Network organizations.

Revisions resulting from two additional rules: HSQ-137--ESRD: Responsibilities of Network Organizations, published January 21, 1988; and BERC-434--Medicare Program: Standards for the Reuse of Hemodialyzer Filters and Other Dialysis Supplies, published October 2, 1987, are also included. Currently, these requirements are approved under OMB control number 0938-0386. The requirements for which we are seeking approval are listed below:

Section 405.2112: ESRD Network Organizations

CMS will designate an administrative governing body (network organization) for each network. The functions of a network organization include but are not limited to the following:

(f) On or before July 1 of each year , submitting to CMS an annual report that contains the following information:

(1) A statement of the network goals.

(2) The comparative performance of facilities regarding the placement of patients in appropriate settings for--

(i) Self-care;
(ii) Transplants; and
(iii) Vocational rehabilitation programs

(3) Identification of those facilities that consistently fail to cooperate with the goals specified under paragraph (f)(1) of this section or to follow the recommendations of the medical review board.

(4) Identification of facilities and providers that are not providing appropriate medical care; and

(5) Recommendations with respect to the need for additional or alternative services in the network including self-dialysis training, transplantation and organ procurement.

(j) Collecting, validating, and analyzing such data as necessary to prepare the reports required under paragraph (f) of this section and the Secretary's report to Congress on the ESRD program and to assure the maintenance of the registry established under section 1881(c)(7) of the Act.

Section 405.2123: Reporting of Utilization Rates for Classification

Each hospital furnishing renal transplantation services must submit an annual report to CMS on its utilization rates. The report must include both the number of transplants performed during the most recent year of operation and the number performed during each of the preceding two calendar years.

Section 405.2136: Governing Body and Management

The ESRD facility is under the control of an identifiable governing body, or designated person(s) so functioning, with full legal authority and responsibility for the governance and operation of the facility. The governing body adopts and enforces rules and regulations relative to its own governance and to the health care and safety of patients, to the protection of the patients' personal and property rights, and to the general operation of the facility. The governing body receives and acts upon recommendations from the network organization. The governing body appoints a chief executive officer who is responsible for the overall management of the facility.

(**a) Standard: Disclosure of Ownership**

The ESRD facility supplies full and complete information to the State survey agency (Section 405.1902(a)) as to the identity of:

(1) Each person who has any direct or indirect ownership interest of 10 percent or more in the facility, or who is the owner (in whole or in part) of any mortgage, deed, or trust, note, or other obligation secured (in whole or in part) by the facility or any property or assets or the facility;

(2) each officer and director of the corporation, if the facility is organized as a corporation; and

(3) each partner, if the facility is organized as a partnership; and promptly reports to the State survey agency any changes which would affect the current accuracy of the information so required to be supplied.

(b) Standard: Operational Objectives

The operational objectives of the ESRD facility, including the services that it provides, are established by the governing body and delineated in writing. The governing body adopts effective administrative rules and regulations that are designed to safeguard the health and safety of patients and to govern the general operations of the facility, in accordance with legal requirements. Such rules and regulations are in writing and dated. The governing body ensures that they are operational, and that they are reviewed at least annually and revised as necessary. If the ESRD facility is engaged in the practice of hemodialyzer reuse, the governing body ensures that there are written policies and procedures with respect

to reuse, to assure that recommended standards and conditions are being followed, and requires that the patient be informed of the policies and procedures.

(1) The objectives of the facility are formulated in writing and clearly stated in documents appropriate for distribution to patients, facility personnel, and the public.

(2) A description of the services provided by the facility, together with a categorical listing of the types of diagnostic and therapeutic procedures that may be performed, is readily available upon request to all concerned.

(4) The operational objectives and administrative rules and regulations of the facility are reviewed at least annually and revised as necessary by the administrative staff, medical director, and other appropriate personnel of the facility, and are adopted when approved by the governing body.

(c) Standard: Chief Executive Officer

The governing body appoints a qualified chief executive officer who, as the ESRD facility's administrator: Is responsible for the overall management of the facility; enforces the rules and regulations relative to the level of health care and safety of patients, and to the protection of their personal and property rights; and plans, organizes, and directs those responsibilities delegated to him by the governing body. Through meetings and periodic reports, the chief executive officer maintains on-going liaison among the governing body, medical and nursing personnel, and other professional and supervisory staff of the facility, and acts upon recommendations made by the medical staff and the governing body. In the absence of the chief executive officer, a qualified person is authorized in writing to act on the officer's behalf.

(1) The governing body delineates in writing the responsibilities of the chief executive officer, and ensures that he/she is sufficiently free from other duties to provide effective direction and management of the operations and fiscal affairs of the facility.

(3) The responsibilities of the chief executive officer include but are not limited to:

(i) Implementing the policies of the facility and coordinating the provision of services, in accordance with delegation by the governing body.

(ii) Organizing and coordinating the administrative functions of the facility, redelegating duties as authorized and establishing formal means of accountability for those involved in patient care.

(iii) Authorizing expenditures in accordance with established policies and procedures.

(iv) Familiarizing the staff with the facility's policies, rules, and regulations, and with applicable Federal, State, and local laws and regulations.

(v) Maintaining and submitting such records and reports, including a chronological record of services provided to patients, as may be required by the facility's internal committees and governing body, or as required by the Secretary.

(vi) Participating in the development, negotiation, and implementation of agreements or contracts into which the facility may enter, subject to approval by the governing body of such agreements or contacts.

(vii) Participating in the development of the organizational plan and ensuring the development and implementation of an accounting and reporting system, including annual development of a detailed budgetary program, maintenance of fiscal records, and quarterly submission to the governing body of reports of expenses and revenues generated through the facility's operation.

(viii) Ensuring that the facility employs the number of qualified personnel needed; that all employees have appropriate orientation to the facility and their work responsibilities upon employment; and that they have an opportunity for continuing education and related development activities.

(d) Standard: Personnel Policies and Procedures

The governing body, through the chief executive officer of the ESRD facility, is responsible for maintaining and implementing written personnel policies and procedures that support sound patient care and promote good personnel practices. These policies and procedures ensure that:

(1) All members of the facility's staff are qualified to perform the duties and responsibilities assigned to them and meet such Federal, State, and local professional requirements as may apply.

(2) A safe and sanitary environment for patients and personnel exists, and reports of incidents and accidents to patients and personnel are reviewed to identify health and safety hazards. Health supervision of personnel is

provided, and they are referred for periodic health examinations and treatments as necessary or as required by Federal, State, and local laws. Procedures are established for routine testing to ensure detection of hepatitis and other infectious diseases.

(4) Complete personnel records are maintained on all personnel. These include health status reports, resumes of training and experience, and current job descriptions that reflect the employees' responsibilities and work assignments.

(5) Personnel policies are written and made available to all personnel in the facility. The policies provide for an effective mechanism to handle personnel grievances.

(6) All personnel of the facility participate in educational programs on a regular basis. These programs cover initial orientation, and continuing in-service training, including procedures for infection control. Records are maintained showing the content of training sessions and the attendance at such sessions.

(e) Standard: Use of Outside Resources

If the ESRD facility makes arrangements for the provision of a specific service as authorized in this subpart, the responsibilities, functions, objectives, and the terms of each arrangement, including financial provisions and charges, are delineated in a document signed by an authorized representative of the facility and the person or agency providing the service. The chief executive officer when utilizing outside resources, as a consultant, assures that he is apprised of recommendations, plans for implementation, and continuing assessment through dated, signed reports, which are retained by the chief executive officer for follow-up action and evaluation of performance.

(f) Standard: Patient Care Policies

The ESRD facility has written policies, approved by the governing body, concerning the provision of dialysis and other ESRD services to patients. The governing body reviews implementation of policies periodically to ensure that the intent of the policies is carried out. These policies are developed by the physician responsible for supervising and directing the provision of ESRD services, or the facility's organized medical staff (if there is one) for review of such policies from time to time, but at least annually, by a group of professional personnel associated with the facility, including, but not limited to, one or more physicians and one or more registered nurses experienced in rendering ESRD care.

(1) The patient care policies cover the following:

(i) Scope of services provided by the facility (either directly or under arrangement);

(ii) Admission and discharge policies (in relation to both in-facility care and home care);

(iii) Medical supervision and physician services;

(iv) Patient long-term programs, patient care plans and methods of implementation;

(v) Care of patients in medical and other emergencies;

(vi) Pharmaceutical services;

(vii) Medical records (including those maintained in the ESRD facility and in the patients' homes to ensure continuity of care);

(viii) Administrative records;

(ix) Use and maintenance of the physical plant and equipment;

(x) Consultant qualifications, functions, and responsibilities; and

(xi) The provision of home dialysis support services, if offered.

(g) Standard: Medical Supervision and Emergency Coverage

The governing body of the ESRD dialysis and/or transplant facility ensures that the health care of every patient is under the continuing supervision of a physician and that a physician is available in emergency situations.

(2) The governing body ensures that there is always available medical care for emergencies, 24 hours a day, 7 days a week. There is posted at the nursing/monitoring station a roster with the names of the physicians to be called, when they are available for emergencies, and how they can be reached.

(h) Standard: Medical Staff

The governing body of the ESRD facility designates a qualified physician as director of ESRD services; the appointment is made upon the recommendation of the facility's organized medical staff, if there is one. The governing body establishes written policies regarding the development, negotiation, consummation, evaluation, and termination of appointments to the medical staff.

Section 405.2137: Patient long-term program and patient care plan

Each facility maintains for each patient a written long-term program and a written patient care plan to ensure that each patient receives the appropriate modality of care and the appropriate care within the modality. The patient, or where appropriate, parent or legal guardian is involved with the health team in the planning of care. A copy of the current program and plan accompany the patient on inter-facility transfer.

(a) Standard: Patient Long-term Program

There is a written long-term program representing the selection of a suitable treatment modality (i.e., dialysis or transplantation) and dialysis setting (e.g., home or self-care) for each patient.

(2) The program is formally reviewed and revised in writing as necessary by a team which includes but is not limited to the physician director of the dialysis facility or center where the patient is presently being treated, in addition to the other personnel listed in paragraph (a)(1) of this section at least every 12 months or more often as indicated by the patient's response to treatment (see Sec. 405.2161(b)(1) and Sec. 405.2170(a)).

(4) A copy of the patient's long-term program accompanies the patient on inter-facility transfer or is sent within one working day.

(b) Standard: Patient Care Plan

There is a written patient care plan for each patient of an ESRD facility (including home dialysis patients under the supervision of the ESRD facility; see section 405.2163(e)), based upon the nature of the patient’s illness, the treatment prescribed, and an assessment of the patient’s needs.

(1) The patient care plan is personalized for the individual, reflects the psychological, social, and functional needs of the patient, and indicates the ESRD and other care required as well as the individualized modifications in approach necessary to achieve the long-term and short-term goals.

(4) The care plan for patients whose medical condition has not become stabilized is reviewed at least monthly by the professional patient care team described in paragraph (b)(2) of this section. For patients whose condition has become stabilized, the care plan is reviewed every six months. The care plan is revised as necessary to ensure that it provides for the patients' ongoing needs.

Sec. 405.2138 Condition: Patients' rights and responsibilities

The governing body of the ESRD facility adopts written policies regarding the rights and responsibilities of patients and, through the chief executive officer, is responsible for development of, and adherence to, procedures implementing such policies. These policies and procedures are made available to patients and any guardians, next of kin, sponsoring agency(ies), representative payees (selected pursuant to section 205(j) of the Social Security Act and Subpart Q of 20 CFR, Part 404), and to the public. The staff of the facility is trained and involved in the execution of such policies and procedures. The patients' rights policies and procedures ensure at least the following:

(a) Standard: Informed Patients. All patients in the facility:

(1) Are fully informed of these rights and responsibilities, and of all rules and regulations governing patient conduct and responsibilities;

(2) Are fully informed of services available in the facility and of related charges including any charges for services not covered under title XVIII of the Social Security Act;

(3) Are fully informed by a physician of their medical condition unless medically contraindicated (as documented in their medical records).

(4) Are fully informed regarding the facility's reuse of dialysis supplies, including hemodialyzers. If printed materials such as brochures are utilized to describe a facility and its services, they must contain a statement with respect to reuse; and

(5) Are fully informed regarding their suitability for transplantation and home dialysis.

(b) Standard: Participation in Planning. All patients treated in the facility:

(1) Are afforded the opportunity to participate in the planning of their medical treatment and to refuse to participate in experimental research;

(2) Are transferred or discharged only for medical reasons or for the patient's welfare or that of other patients, or for nonpayment of fees (except as prohibited by title XVIII of the Social Security Act), and are given advance notice to ensure orderly transfer or discharge.

(c) Standard: respect and dignity

All patients are treated with consideration, respect, and full recognition of their individuality and personal needs, including the need for privacy in treatment. Provision is made for translators where a significant number of patients exhibit language barriers.

(d) Standard: confidentiality

All patients are ensured confidential treatment of their personal and medical records, and may approve or refuse release of such records to any individual outside the facility, except in case of their transfer to another health care institution or as required by Federal, State, or local law and the Secretary for proper administration of the program.

(e) Standard: grievance mechanism

All patients are encouraged and assisted to understand and exercise their rights. Grievances and recommended changes in policies and services may be addressed to facility staff, administration, the network organization, and agencies or regulatory bodies with jurisdiction over the facility, through any representative of the patient's choice, without restraint or interference, and without fear of discrimination or reprisal.

Section 405.2139 Condition: Medical records

The ESRD facility maintains complete medical records on all patients (including self-dialysis patients within the self-dialysis unit and home dialysis patients whose care is under the supervision of the facility) in accordance with accepted professional standards and practices. A member of the facility's staff is designated to serve as supervisor of medical records services, and ensures that all records are properly documented, completed, and preserved. The medical records are completely and accurately documented, readily available, and systematically organized to facilitate the compilation and retrieval of information.

(a) Standard: Medical Record

Each patient's medical record contains sufficient information to clearly identify the patient, to justify the diagnosis and treatment, and to document the results accurately. All medical records contain the following general categories of information: Documented evidence of assessment of the needs of the patient, whether the patient is treated with a reprocessed hemodialyzer, of establishment of an appropriate plan of treatment, and of the care and services provided (sec 405.2137(a) and (b)); evidence that the patient was informed of the results of the assessment described in 405.2138(a)(5); identification and social data; signed consent forms referral information with authentication of diagnosis; medical and nursing history of patient; report(s) of physician examination(s); diagnostic and therapeutic orders; observations, and progress notes; reports of treatments and clinical findings; reports of laboratory and other diagnostic tests and procedures; and discharge summary including final diagnosis and prognosis.

(b) Standard: Protection of Medical Record Information

The ESRD facility safeguards medical record information against loss, destruction, or unauthorized use. The ESRD facility has written policies and procedures which govern the use and release of information contained in medical records. Written consent of the patient, or of an authorized person acting in

behalf of the patient is required for release of information not provided by law. Medical records are made available under stipulation of confidentiality for inspection by authorized agents of the Secretary, as required for administration of the ESRD program under Medicare.

(d) Standard: Completion of Medical Records and Centralization of Clinical Information

Current medical records and those of discharged patients are completed promptly. All clinical information pertaining to a patient is centralized in the patient's medical record. Provision is made for collecting and including in the medical record medical information generated by self-dialysis patients. Entries concerning the daily dialysis process may either be completed by staff or trained self-dialysis patients, trained home dialysis patients or trained assistants and countersigned by staff.

(e) Standard: Retention and Preservation of Records

Medical records are retained for a period of time not less than that determined by the State statute governing records retention or statute of limitations; or in the absence of a State statute, five years from the date of discharge; or, in the case of a minor, three years after the patient becomes of age under State law, whichever is longest.

Section 405.2140 Condition: Physical Environment

The physical environment in which ESRD services are furnished affords a functional, sanitary, safe, and comfortable setting for patients, staff, and the public.

(b) Standard: Favorable environment for patients

The facility is maintained and equipped to provide a functional, sanitary, and comfortable environment with an adequate amount of well-lighted space for the service provided.

(1) There are written policies and procedures in effect for preventing and controlling hepatitis and other infections. These policies include, but are not limited to, appropriate procedures for surveillance and reporting of infections, housekeeping, handling and disposal of waste and contaminants, and sterilization and disinfection, including the sterilization and maintenance of equipment. Where dialysis supplies are reused, there are written policies and procedures covering the rinsing, cleansing, disinfection, preparation and storage of reused items which conform to requirements for reuse in 405.2150.

(c) Standard: Contamination Prevention

The facility employs appropriate techniques to prevent cross-contamination between the unit and adjacent hospital or public areas including, but not limited to, food service areas, laundry, disposal of solid waste and blood-contaminated

equipment, and disposal of contaminants into sewage systems. Waste storage and disposal are carried out in accordance with applicable local laws and accepted public health procedures. The written patient care policies (see Sec. 405.2136(f)(1)) specify the functions that are carried out by facility personnel and by self-dialysis patients with respect to contamination prevention. Where dialysis supplies are reused, records are maintained that can be used to determine whether established procedures covering the rinsing, cleansing, disinfection, preparation and storage of reused items, conform to requirements for reuse in section 405.2150.

(d) Standard: Emergency Preparedness

Written policies and procedures specifically define the handling of emergencies which may threaten the health and safety of patients. Such emergencies would exist during a fire or natural disaster or during functional failures in equipment. Specific emergency preparedness procedures exist for different kinds of emergencies. These are reviewed and tested at least annually and revised as necessary by, or under the direction of, the chief executive officer. All personnel are knowledgeable and trained in their respective roles in emergency situations.

(1) There is an established written plan for dealing with fire and other emergencies which, when necessary, is developed in cooperation with fire and other expert personnel.

Section 405.2171 Condition: Minimal service requirements for renal transplant center

Kidney transplantation is furnished directly by a hospital which is participating as a provider of services in the Medicare program and is approved by the Secretary as a Renal Transplantation Center. The Renal Transplantation Center is under the overall direction of a hospital administrator and medical staff; if operated by an organizational subsidiary, it is under the direction of an administrator and medical staff member (or committee) who are directly responsible to the hospital administrator and medical staff, respectively. Patients are accepted for transplantation only on the order of a physician, and their care continues under the supervision of a physician.

(e) Standard: Organ Procurement

If a renal transplantation center utilizes the services of an organ procurement agency to obtain donor organs, it has a written arrangement covering these services. The renal transplantation center agrees to notify the Secretary in writing within 30 days of termination of such arrangements.

B. Justification

1. Need and Legal Basis

The information collection requirements described herein are part of the Medicare and Medicaid Conditions for Coverage for Suppliers of ESRD Services. The requirements fall into two categories: record keeping requirements and reporting requirements. With regard to the record keeping requirements, CMS uses these conditions for coverage to certify health care facilities that want to participate in the Medicare or Medicaid programs. These record keeping requirements are no different than other conditions for coverage in that they reflect comparable standards developed by industry organizations such as the Renal Physicians Association, American Society of Transplant Surgeons, and the National Association of Patients on Hemodialysis and Transplantation.

For the reporting requirements, the information is needed to assess and ensure proper distribution and effective utilization of ESRD treatment resources while maintaining or improving quality of care. All of the reports specified above are geared toward ensuring that facilities and networks achieve and maintain utilization rates which reflect cost-effective service provision. It is CMS's responsibility to closely monitor ESRD service utilization to prevent over-expansion of facilities and resultant underutilization. Collection of this information is authorized by Section 1881 of the Act and required by 42 CFR 405.2100 through 405.2171. Several of these sections have been revised as reflected in HSQ-137 published January, 1988 and BERC-434 published October, 1987, as well as all other sections containing information collection requirements.

2. Information User

The general record keeping requirements prescribed in this regulation are used by dialysis facilities. CMS and the health care industry believe that the availability to the facility of the type of records and general content of records are routine and consistent with health care facility standards.

The reporting associated with this regulation is used in reports to Congress, by CMS, and the facilities. The reporting requirements are to assist in improving quality of care as well as to provide the most economic services available. The reports that are submitted are used by CMS to analyze for budgetary issues which enables CMS to maximize utilization rates and also make sure all services are available throughout the ESRD program. The reports are used by the facilities as self-assessment tools to measure their performance and available services to those facilities throughout the networks. The Secretary is required by the Act to submit to Congress each year a report on the ESRD program. The Congress uses this report as a basis to make legislative changes.

3. Improved Information Technology

This regulation does not prescribe how the facility should prepare or maintain these reports and records. Facilities are free to take advantage of any technological advances which they find appropriate for their needs.

4. Duplication of Similar Information

These are unique requirements which are specified in a way so as not to duplicate existing facility practice. If a facility already maintains these general records, regardless of format, they are in compliance with this requirement. In addition, the general nature of these requirements makes variations in the substance and format of these records from one facility to another acceptable.

5. Small Businesses

These requirements do affect small businesses. However, the general nature of the requirements allows the flexibility for facilities to meet the requirement in a way consistent with their existing operations.

6. Less Frequent Collection

The reporting associated with this regulation is statutorily mandated and must be collected annually. The reports must be submitted because ESRD facilities have timeframes they must meet in order to qualify for reimbursement for the next calendar year. The Secretary establishes the rates for reimbursement based on the most recent information available. CMS does not prescribe the manner, timing, or frequency of the records or information required to be available.

7. Special Circumstances

There are no special circumstances for collecting information.

8. Federal Register Notice/Outside Consultations

The 60-day Federal Register notice published on April 7, 2006.

9. Payments/Gifts to Respondents

There were no payments/gifts to respondents.

10. Confidentiality

CMS does not pledge confidentiality.

11. Sensitive Questions

There are no sensitive questions.

12. Burden Estimates

Networks

Number of Networks	18
Average Network Budget	$1,045,362
33% Budgetary projection for data information collection and reporting requirements (33% = $344,969)	
Total Network Cost	$6,209,442

The $6,209,442 figure is derived by multiplying the total number of Networks (18) times the average Network cost for data and information collection and reporting requirements (18 x $344,969 = $6,209,442). Annual review and updating of Network plans is included in the above estimate.

Facility

There is no additional record keeping or cost to the facility. Normal industry practice material is embodied in the medical records and billing procedures.

Total hours for these particular requirements is 160,702 hours. The computation for these hours is as follows:

The burden for this request is based on 4,757 existing facilities with an average increase of 153 new facilities each year. Burden is also computed using the current number of ESRD networks (18).

405.2112 Designation of ESRD networks

(f) 1-5 On or before July 1 of each year submit to CMS an annual report.

Initial Development Time (IDT)

The obtaining information and coordination necessary for compliance with this requirement necessitates collection of facility data and establishment of a report format. We estimate this would take approximately 4.5 hours.

Initial Development	4.5 hours	
times networks	x 18	
Total burden	hours	81

(j) No burden. Burden is included under standard (f) of this section.

405.2123: Reporting of utilization rates for initial classification

Each hospital furnishing transplantation services will report the number of transplants performed during the most recent year of operation and the number performed during each of the preceding two calendar years.

IDT- We estimate data extraction and reporting should take about four (4) hours per facility.

Review and Rewrite Annually (R&RA)

R&RA- The updating of data and report format will probably still take about three (3) hours

Initial development	4 hours
times new facilities	x153
Subtotal burden	612 hours

R&RA		3 hours
times all facilities	x4,757	
Subtotal burden	14,271 hours	
Total burden	14,883 hours	

(The products included in the Network Annual Reports are resultant deliverables of the Network data collection/validation and profiling activities supplemented by special and routine quality assurance and assessment requirements.)

405.2136 Governing Body and Management

(a) 1-3 Facility will supply full and complete information to the State survey agency regarding each person with any direct or indirect ownership interest of 10 percent and more plus officers and directors of any corporation or partnership.

IDT- Initial development of ownership of facility requirement can be quite involved because of the complexity of many corporate structures and parent organizations. An estimate of 16 hours is considered reasonable.

R&RA- Once ownership is established, minor changes should not require more than four (4) hours.

Initial Development	16 hours
times new facilities	x153
Subtotal burden	2,448 hours

R&RA		2 hours
times all facilities	x 4,757	
Subtotal burden		9,514 hours

Total Burden 11,962 hours

405.2136 Governing Body and Management

(b) Operational and facility objectives and services provided are delineated in writing by the governing body which ensures that they are operational and reviewed and revised as necessary, at least annually.

IDT- Establishing facility objectives and ensuring that they are operationally effective we estimate would take about 12 hours.

R&RA- Any revisionary action should not significantly modify the established objectives and should not exceed 3.5 hours.

Initial development	12 hours	
times new facilities	x 153	
Subtotal burden	1,836 hours	

R&RA		3.5 hours
	times all facilities	x 4,757
Subtotal burden	16,649 hours	
Total burden	18,485 hours	

405.2136 Governing Body and Management

(b)(1) Objectives are clearly stated in writing appropriate for distribution to patients, facility personnel and the public. Due to the technical nature of the material, we estimate completion would take about four (4) hours.

IDT- This material would take about four (4) hours to prepare.

R&RA- Specific modification or updating to include or eliminate service(s) or approved procedure(s) should take approximately 2.5 hours.

Initial Development	4 hours	
times new facilities	x 153	
Subtotal burden	612 hours	

R&RA		2.5 hours
times all facilities	x 4,757	
Subtotal burden	11,892 hours	
Total burden	12,504 hours	

405.2136 Governing Body and Management

(b)(2) Description of services provided and a categorical listing of types of diagnostic and therapeutic procedures that may be performed is readily available.

IDT- This material would take about four (4) hours to prepare.

R&RA- Specific modification or updating to include or eliminate service(s) or approved procedure(s) should take approximately 2.5 hours.

Initial development	4 hours
times new facilities	x 153
Subtotal burden	612 hours

R&RA	2.5 hours
times all facilities	x 4,757
Subtotal burden	11,892 hours
Total burden	12,504 hours

405.2136 Governing Body and Management

(b)(4) Operational objectives and administrative rules and regulations are reviewed at least annually and revised as necessary.

R&RA- Revisions are seldom of a major nature and should not exceed 2.5 hours.

R&RA	2.5 hours
times all facilities	x 4,757
Total burden	11,892 hours

405.2136 Governing Body and Management

(c)(3)(iv) Maintains and submits such records and reports, including a chronological record of services provided to patients, as may be required by internal committees, the governing body, the Medical Review Board or the Secretary.

IDT- Maintenance of reports and records would take an initial effort of about four (4) hours.

R&RA- This is an ongoing function and would require essentially the same amount of time for completion - four (4) hours.

Initial development	4 hours

times new facilities	x 153
Subtotal burden	612 hours

R&RA	4 hours
times all facilities	x 4,757
Subtotal burden	19,028 hours
Total burden	19,640 hours

405.2136 Governing Body and Management

(d) 1-6 Maintains and implements written personnel policies and procedures that support good personnel practices and sound patient care.

IDT- Personnel policies and procedures reflective of sound patient care should take an initial effort of about four (4) hours.

R&RA- Revisionary changes should not exceed one (1) hour.

Initial development	4 hours
times new facilities	x 153
Subtotal burden	612 hours

R&RA	1 hour
times all facilities	x 4,757
Subtotal burden	4,757
Total burden	5,369 hours

405.2136 Governing Body and Management

(e) Use of outside resources. The responsibilities, functions, objectives and terms of each arrangement including financial provisions and changes are in writing and signed by both parties. Signed reports are obtained on follow-up action and performance evaluations.

IDT- Entering into an arrangement that includes the responsibilities, functions and financial provisions is a significant undertaking and would take at least 12 hours.

R&RA- Revisionary action to established arrangements should normally not exceed three (3) hours.

Initial development	12 hours
times new facilities	x 153
Subtotal burden	1,836 hours

R&RA		3 hours
times all facilities	x 4,757	
Subtotal burden	14,271 hours	
Total burden	16,107 hours	

405.2136 Governing Body and Management

(f) The facility has written patient care policies concerning the provision of dialysis and other ESRD services. They are reviewed at least annually and changed as necessary. The governing body makes reviews periodically to ensure the intent of the policies is carried out. These revisionary changes and reviews are commonly accepted as good medical practice. This requirement does not impose any additional burden since it would be performed in the absence of this Federal regulation. Therefore, the burden associated with this requirement is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

405.2136 Governing Body and Management

(g) Medical supervision and emergency coverage

Assurance of posting at the nursing/monitoring station of names of physicians and where they may be located at all times.

IDT- Medical supervision and emergency coverage is mainly a matter of coordination, adjustment, and flexibility. Initial development would probably take approximately five (5) hours.

R&RA Minor changes in established posting would probably not exceed one (1) hour.

Initial development	5 hours	
times new facilities	x 153	
Subtotal burden	765 hours	
R&RA		1 hour
times all facilities	x 4,757	
Subtotal burden	4,757 hours	
Total burden	5,522 hours	

405.2136 Governing Body and Management

(h) Medical Staff. Written policies are established for the establishment and termination of appointments to the medical staff.

IDT- Initial development of medical staff policies and procedures would require approximately seven (7) hours.

R&RA Once established, modification or revision to the Medical staff policies should normally not exceed two (2) hours.

Initial development	7 hours	
times new facilities	x 153	
Subtotal burden	1,071 hours	
R&RA		2 hours
times all facilities	x 4,757	
Subtotal burden	9,514 hours	
Total burden	10,585 hours	

405.2137 Patient long-term program and patient care plan

Patient long term programs and patient care plans are considered standard industry practice. This requirement does not impose any additional burden since it would be performed in the absence of this Federal regulation. Therefore, the burden associated with this requirement is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

405.2138 Patient rights and responsibilities

Written policies relating to the rights and responsibilities of patients and facilities are made available to patients' guardians, next of kin, sponsoring agencies, representative payers and the public.

IDT- Initial development is complicated in this area by the increased mobility of the dialysis patient and the unusual nature of the treatment itself. About five (5) hours would be required to meet this requirement.

R&RA- Once established, modification or changes in patient rights and responsibilities would normally be minimal and should require no more than 1.5 hours.

Initial development	5 hours	
times new facilities	x 153	
Subtotal burden	765 hours	
R&RA		1.5 hours
times all facilities	x 4,757	
Subtotal burden	7,135 hours	
Total burden	7,900 hours	

405.2139 Medical Records

Maintaining complete medical records is Standard Industry Practice. This requirement does not impose any additional burden since it would be performed in the absence of this Federal regulation. Therefore, the burden associated with this requirement is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

405.2140 Physical Environment

ESRD services are furnished in sanitary and safe physical environments. This is Standard Industry Practice. This requirement does not impose any additional burden since it would be performed in the absence of this Federal regulation. Therefore, the burden associated with this requirement is exempt from the PRA in accordance with 5 CFR 1320.3(b)(2).

405.2140 Physical Environment

(d) Written policies and procedures specifically define the handling of emergencies which may threaten the health and safety of patients.

IDT- We anticipate such policies should take 4.5 hours to develop initially.

R&RA- Any revisionary action should be minor in nature and could be accomplished within an hour.

Initial development	4.5 hours	
times new facilities	x 153	
Subtotal burden	688 hours	
R&RA		1 hour
times all facilities	x 4,757	
Subtotal burden	4,757 hours	
Total burden	5,445 hours	

405.2171 Minimal Service Requirements for Renal Transplant Center

(e) Organ Procurement. A renal transplantation center utilizing the

service
s
of an organ procurement agency to obtain donor organs must have a written arrangement covering these services.

IDT- The written arrangement has to be very specific because of the unusual nature of this operation, both functional and financial. It requires considerable cooperation between the Organ Procurement Agency and the transplant facility and should take approximately 4.5 hours to develop.

R&RA- Once established, a change in the agreement would take about 1.5 hours.

Initial development	4.5 hours	
times new facilities	x 153	
Subtotal burden	688 hours	
R&RA		1.5 hours
times all facilities	x 4,757	
Subtotal burden	7,135 hours	
Total burden	7,823 hours	

The grand total is 160,702 hours. However, the burden is calculated to be 160,710 burden hours. The ICRAS system rounds the numbers which accounts for the disparity between 160,702 and 160,710.

13. Capital Costs (Maintenance of Capital Costs)

There are no capital costs associated with this regulation.

14. Cost to Federal Government

There is no significant additional survey cost since collection and reporting requirement compliance is generally accomplished by record review rather than extensive onsite survey activity.

15. Burden Changes

The number of ESRD facilities as of 2003 was approximately 4,297. In the first quarter of 2006 there are approximately 4,797 facilities. The burden for this request is based on 4,757 existing facilities due to an average increase of approximately 153 new facilities each year for the past three years. The burden has also been computed using the current number of ESRD networks which has remained at 18. Therefore, there has been an increase in burden due to the number of respondents. This is an adjustment.

16. Publication and Tabulation Dates

There are no publication or tabulation dates.

17. Expiration Date

CMS would like to display the expiration date.

18. Certification Statement

There are no exceptions.

C. Collections of Information Employing Statistical Methods

This section does not apply. No statistical methods were employed.