# Chapter H 52

# KIDNEY TRANSPLANT AND DIALYSIS

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**H 52.01 Introduction.** (1) POLICY. Section 49.48, Wis. Stats., aid for treatment of kidney disease published June 28, 1974, establishes as policy that all permanent residents of Wisconsin are protected from the destructive costs of chronic kidney disease. The state shall pay the residual reasonable cost of medical treatment for permanent residents of the state who suffer from chronic renal disease and have been certified in the disease treatment phase of the program in approved facilities after payment from other sources such as Medicare and/or private insurance coverage has been utilized.

(2) CHRONIC RENAL DISEASE NETWORK. Public Law 92–603, Section 299I, Social Security Amendments of 1972, provides that the Medicare program will have the responsibility for financing care for persons with a particular diagnosis—end stage renal disease—(if eligible for benefits and after qualifying for entitlement) and for reimbursement of most of the costs of the 2 particular modalities of therapy, namely dialysis and renal transplantation. The final policies of April, 1974, from the department of health, education, and welfare relating to this law call for the development of a network approach to end stage renal disease care (chronic renal disease). The concept here described calls for the recognition and establishment of a connected network of facilities based on coordinated patient referral and medical care which reflect regional planning and effective and efficient utilization of resources and manpower. The law requires certification or approval of facilities, and the establishment of such devices as local medical review boards (LMRB) and for professional consultation within the network to promote and ensure the high quality care of patients. The description of resources in the rules and regulations therefore describes a series of facilities through which patients flow for certification and care including renal transplantation centers, comprehensive dialysis centers, hospital based satellite dialysis centers, free-standing dialysis facilities, and home dialysis services.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.

**H 52.02 Definitions.** (1) CHRONIC RENAL DISEASE (CRD). The guidelines text under Section 299I of Public Law 92–603 defines chronic renal disease as ". . . that stage of renal impairment which cannot be favorably influenced by conservative management alone, and requires dialysis and/or kidney transplantation to maintain life or health."

(2) DIALYSIS. Dialysis means a process by which waste products are removed from the body by diffusion from one fluid compartment to another across a semipermeable membrane. There are 2 types of dialysis in common clinical usage: Hemodialysis—where blood is passed through an artificial kidney machine and the waste products diffuse across a man-made membrane into a bath solution known as dialysate after which the cleansed blood is returned to the patient's body; and, peritoneal dialysis—where the waste products pass from the patient's body, through the peritoneal membrane into the peritoneal (abdominal) cavity where the bath solution (dialysate) is introduced and removed periodically. While there are processes, such as hemoperfusion and diafiltration, which may become a substitute for, or replace, dialysis in the future, their limited usage in this country today does not merit their separate definition or consideration in these rules.

(3) MAXIMUM CARE CHRONIC DIALYSIS. Maximum care chronic dialysis means regular dialysis treatments which are given to the unstable CRD patient with medical complications, in order to sustain life and ameliorate uremia. Currently, such treatments are usually given 2 or more times a week.

(4) BACK-UP DIALYSIS. Back-up dialysis means dialysis given to a patient under special circumstances, in a situation other than the patient's usual dialysis environment. Examples are dialysis of a home dialysis patient in a limited care unit when his own equipment fails, inpatient dialysis when patient illness requires more comprehensive care on an inpatient basis, and pre- and post-operative dialysis provided to transplant patients, particularly when the newly grafted organ is unable to assume its full function immediately.

(5) ACUTE DIALYSIS. Acute dialysis means dialysis given to patients on an intensive care, inpatient basis. Acute dialysis may be given to patients with CRD during periods of acute illness (acute, back-up dialysis); it may be given to patients without CRD who require dialysis for certain conditions, such as, acute renal failure and certain drug ingestions.

(6) SELF-DIALYSIS. Self-dialysis means regular maintenance dialysis performed by a trained patient at home or within an outpatient facility. In home dialysis, the patient performs dialysis at home with the assistance of a trained partner. In "self-care" dialysis in an outpatient facility, the patient performs dialysis in a facility removed from the home with the assistance of a trained partner or a health professional. In both, professional supervision and performance of the dialysis are limited.

(7) LIMITED CARE DIALYSIS. Limited care dialysis means regular uncomplicated maintenance dialysis on an outpatient basis in a facility which is part of a comprehensive dialysis center or in a satellite dialysis facility, whether hospital based or free standing. The actual dialysis procedure is carried out by or under supervision of health professionals.

(8) SELF-DIALYSIS TRAINING. Self-dialysis training means the education or training of a patient and family member or helper to enable the patient to perform self-dialysis.

(9) SELF-DIALYSIS TRAINING PROGRAM. Self-dialysis training program means a program which educates and trains a patient and/or helper to perform self-dialysis at home or in a facility. Such a program includes an assessment of the patient's home and family conditions to determine if the environment is suitable.

(10) ORGAN PROCUREMENT. Organ procurement means the identification of a prospective donor and the surgical removal of a donor kidney.

(11) ORGAN PRESERVATION. Organ preservation means the maintenance of a kidney after it has been removed from the donor and until it has been transplanted into a recipient.

(12) TISSUE TYPING AND IMMUNOLOGIC TESTING. Tissue typing and immunologic testing means laboratory procedures used to determine the degree of compatibility between a donor organ and a potential recipient of a kidney transplant. They include procedures such as:
(a) Identification of tissue "types"
(b) Performance of a cross match for cytotoxic antibodies, and
(c) Related specialized tests of immunologic reactions.

(13) LIVING RELATED DONOR TRANSPLANTATION. Living related donor transplantation means a transplant where the organ is donated and removed from a living, blood relative of the patient and transplanted into the patient.

(14) CADAVERIC DONOR TRANSPLANTATION. Cadaveric donor transplantation means transplantation where the donated organ is taken from an individual who has been pronounced dead according to currently accepted medical criteria.

(15) CADAVERIC ORGAN PROCUREMENT, TRANSPORTATION, AND STORAGE. Cadaveric organ procurement, transportation, and storage means the organ is removed, transported, and stored by methods of an approved facility, from a donor, who has been pronounced dead according to current medical criteria.

(16) VASCULAR ACCESS MECHANISM OR DEVICE. Vascular access mechanism or device means a surgically prepared connection between an artery and a vein with or without use of a mechanical device.

(17) PERITONEAL ACCESS DEVICE. Peritoneal access device means a device inserted into the peritoneal cavity to provide peritoneal dialysis.

(18) "DIRECTLY PROVIDES" OR "PROVIDES DIRECTLY." "Directly provides" or "provides directly" means that the hospital (or facility) provides the service through its own staff and employes, or through individuals who are under contract with the facility to provide such services.

(19) "UNDER ARRANGEMENT." "Under arrangement" means that the hospital (or facility) arranged for another facility to provide the services but assumes responsibility for such services and bills for the services.

(20) "BY AN AGREEMENT" OR "HAS AN AGREEMENT." "By an agreement" or "has an agreement" means that the hospital (or facility) has an agreement whereby another facility undertakes to provide

services to patients who become the patients of the other facility (for these services provided), and the other facility bills for their services furnished.

(21) "PROVIDES ON THE PREMISES." "Provides on the premises" means that the hospital provides the services on its own premises or on premises that are contiguous with or immediately in proximity to its own.

(22) HOME DIALYSIS SUPPORT SERVICES. Home dialysis support services means the services of professional care, consultation, provision of supplies, back-up, and equipment repair required by home dialysis patients.

(23) TRANSPLANT RECIPIENT REGISTRY. Transplant recipient registry means a prospective listing of patients, including certain medical and demographic data on those patients who are awaiting a renal transplant.

(24) COMPREHENSIVE DIALYSIS CENTER. Comprehensive dialysis center means a hospital based center which is staffed and equipped to provide evaluation, treatment and followup of CRD patients and maintains or provides by agreement, training facilities for self-care and home dialysis.

(25) HOSPITAL BASED SATELLITE DIALYSIS FACILITY. Hospital based satellite dialysis facility means a facility that has as its primary mission the provision of maintenance dialysis services to CRD patients living in their medical service area. It will have a clearly defined affiliation agreement with one or more comprehensive dialysis centers.

(26) FREE-STANDING SATELLITE DIALYSIS FACILITY. Free-standing satellite dialysis facility means a facility that has as its primary mission the provision of limited care and self-care dialysis in a non-hospital based unit for CRD patients in their medical service area and will operate in the context of an affiliation agreement with one or more comprehensive dialysis centers.

(27) HOME DIALYSIS. Home dialysis means self-dialysis conducted in the patient's home with equipment and supplies provided and installed under the supervision of a comprehensive dialysis center.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.

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**H 52.03 Patient acceptance and certification.** (1) PATIENT ELIGIBILITY. Patients eligible for this program shall be those permanent residents of the state who have been diagnosed to have chronic renal disease as defined under "Section 299I of Public Law 92–603." That section defines chronic renal disease as ". . . that stage of renal impairment which cannot be favorably influenced by conservative management alone, and requires dialysis and/or kidney transplantation to maintain life or health." It is the intent of this legislation (section 49.48, Wis. Stats.) to provide protection from the destructive costs of kidney disease treatment to all permanent residents of this state who have chronic renal disease requiring dialysis and/or kidney transplantation, including those who may not be entitled to benefits under Medicare (Section 299I of Public Law 92–603).

(2) CERTIFICATION OF ELIGIBILITY. Eligibility for coverage of dialysis shall be certified by the department upon the recommendation by a nephrologist. Eligibility for coverage of renal transplantation shall be certified by the department upon notification of acceptance by a transplant surgeon in an approved transplant center. Recertification for eligibility for both programs shall be required at least annually.

(3) THERAPEUTIC APPROACHES. Suitable therapeutic approaches will be offered the patient by his primary physician and the program of treatment will be planned according to patient desires as is medically feasible. The options include:

(a) A conservative regime permitting delay of or better preparation for subsequent therapy.

(b) Dialysis and living related donor transplantation.

(c) Dialysis and subsequent cadaveric transplantation.

(d) Dialysis only.

(e) No treatment (that is, none of the above).

(4) PATIENT REGISTRY FOR CHRONIC RENAL DISEASE. (a) A statewide list of certified CRD patients shall be maintained by the department, that is, either by departmental personnel or by another agency on arrangement with the department. This list will include names of all certified dialysis and transplant patients in the state.

(b) A statewide registry shall be maintained either by departmental personnel or by another agency on arrangement with the department and the information shall be provided by the dialysis centers and transplant centers in conformity with ultimate federal guidelines for CRD patient registries and any additional information deemed necessary and appropriate by the department. Such information will include identification of patients and responsible physicians and dialysis centers, acceptance into transplant programs, tissue typing, and other information usually appearing in such registries. Such information will be submitted for home dialysis patients by the chronic renal disease patient care center supervising their home dialysis program.

(5) PATIENT FOLLOWUP. A primary physician shall be identified for each patient accepted and certified in the program and responsible for patient followup within the CRD network.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.

**H 52.04 Kidney transplant centers.** (1) STAFFING. The following staffing is essential for a transplant center: (a) *Medical.* 1. Nephrologist. Physician licensed in Wisconsin, certified by the American Board of Internal Medicine, or an equivalent certifying body as determined by the department on recommendation of the state advisory review committee, with a minimum of one year fellowship training in nephrology or 2 years' experience delivering care to CRD patients in an institution approved as a teaching center by the appropriate board. Pediatric training may be substituted for internal medicine if transplantation is associated with a pediatric center and patient load.

2. Transplant surgeon. Physician licensed in Wisconsin, certified by the American Board of Surgery, or an equivalent certifying body as determined by the department on recommendation of the state advisory review committee, with a minimum of one year's training

in renal transplantation in an accredited teaching institution or 2 years' experience performing renal transplants.

3. Urologist. When the transplant surgeon is not a urologist, a urologist certified by the American Board of Urology, or an equivalent certifying body as determined by the department on recommendation of the state advisory review committee, should be available for consultation and participation as a member of the transplant team.

4. Immunologist. The transplant team should have access to consultation from a physician licensed in Wisconsin with experience and training in immunology.

5. Anesthesiologist. A physician, licensed in Wisconsin, certified by the American Board of Anesthesiology, or an equivalent certifying body as determined by the department on recommendation of the state advisory review committee, to provide service during and following the surgical procedure.

6. Other medical personnel. The medical staff available within the transplant center must include physicians licensed in Wisconsin and board certified, or with approved training in the following specialties: cardiology, endocrinology, hematology, neurology, infectious disease, orthopedics, pathology, psychiatry, nuclear medicine, and radiology.

(b) *Allied and paramedical personnel.* 1. Nurse. At least one full-time supervisory nurse, registered in Wisconsin, with additional specialized training and/or experience as follows: a minimum of 6 months' training in a teaching institution providing care to transpant patients or a minimum of 2 years of experience in caring for dialysis and transplant patients, and also meets Section 405.1024 of Health Insurance Regulations.

2. Dietician. A dietician meeting American Dietetics Association standards for qualification to provide diet management and counseling for CRD patient needs.

3. Social worker. A social worker, certified by the Academy of Certified Social Workers, to provide social service and counseling needs of CRD patients and their families.

4. Pharmacist. A pharmacist, registered in Wisconsin, with experience in the selection, procurement and dispensing of pharmaceutical products essential to the management of CRD patients.

5. Technician. Specially trained and experienced technicians, certified or registered where applicable, in the fields of surgical assistance, inhalation therapy, medical technology, blood bank procedures, and dialysis.

(2) FACILITIES/SERVICES. (a) The facility (hospital) housing the kidney transplant center shall meet the following basic requirements:

1. Is a facility approved under the Hospital Regulations and Approval Act, Wis. Stats. 140.23 to 140.29, and which meets all the requirements of Section 1861 (e) of the Social Security Act, and has entered into an agreement to participate in the Medicare program.

2. Can be reasonably expected to perform a minimum of 25 kidney transplants per year.

3. Has a successfully operating dialysis program which meets the requirements and standards of section 49.48 of Chapter 308, Wisconsin Laws of 1973.

4. Has a review committee composed of one or more of each of the following: nephrologist, nurse (as defined above), social worker (as defined above), and other appropriate personnel as indicated

below who will monitor and review the care of patients receiving services under the program. The committee when acting on prospective transplant patients, shall also include one or more transplant surgeons. Psychiatric consultation as well as other subspecialty consultation will be obtained as appropriate.

5. Has CRD patient care policies which govern transplant procedures, nursing care, medical and other services and which are developed by professional staff including the advice of a nephrologist surgeon, registered nurse, dialysis technician, social worker, psychiatrist, and administrator.

(b) The facility shall include the following essential elements:

1. A transplant service that provides a minimum of 10 beds to accommodate pre- and post-transplantation patients.

2. Service rooms located and designed to provide isolation and/or segregation from patients with infectious and/or communicable disease.

3. Operating rooms designed and equipped according to current standards plus provision of readily available perfusion equipment and space for its storage and use.

4. Donor kidney preservation equipment in an approved facility, so that the donor kidney shall be preserved by currently accepted medical methods as recommended by the state advisory review committee on CRD.

5. Laboratory services 24 hours per day including but not limited to: CBC, platelet count, ABO blood cross matching, blood gases, blood ph, serum calcium, serum potassium, BUN, creatinine, serum glucose, prothrombin time, spinal fluid exam, urine sediment, urine glucose, and other procedures as recommended by the state CRD review committee.

6. Immunofluorescence and electron microscopy.

7. Unusual pathogen culturing, fungal cultures, tissue cultures, and TB cultures.

8. Tissue typing.

9. Serum hepatitis control program.

10. Outpatient services for the evaluation, care, and followup of transplant and CRD patients.

11. Cadaveric kidney preservation.

(3) STANDARDS FOR CADAVERIC ORGAN ACQUISITION. (a) *Purpose.* To enhance the likelihood of success of cadaveric kidney transplantation and reduce wastage of procured cadaveric organs.

(b) *Standards.* The transplant centers in the state will adopt a set of standards for cadaveric donor selection, cadaveric kidney preservation, and criteria for transplantability, and will work out appropriate arrangements with cooperating hospitals in the state and their medical-surgical staff to implement the cadaveric organ acquisition program.

(c) *Reimbursement.* The formula for reimbursement will be consistent with those available under Medicare with the intent of providing coverage for these services to those state patients not entitled to Medicare benefits as defined by the Social Security Amendments and Medicare regulations, despite presence of end stage renal disease requiring dialysis and renal transplantation.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.

**H 52.05 Comprehensive and satellite dialysis centers and home dialysis services.** (1) COMPREHENSIVE DIALYSIS CENTERS. (a) *Staffing.* The comprehensive dialysis center for chronic (CRD) patients and backup services to intermediate and/or satellite dialysis centers shall have the following personnel:

1. Medical. a. A physician licensed in Wisconsin, certified by the American Board of Internal Medicine, or an equivalent certifying body as determined by the department on recommendation of the state advisory review committee, and having a minimum of one year of formal training in a teaching institution in CRD patient care or a minimum of 2 years' experience delivering CRD care.

b. The surgeon performing the vascular access procedures (cannula/shunt fistula placement and revisions) is certified by any appropriate American Surgical Specialty Board, or an equivalent certifying body as determined by the department on recommendation of the state advisory review committee, and has either a minimum of one year's formal training at a teaching institution in vascular surgery, or 2 years' experience performing vascular access procedures.

c. Other medical specialties. The facility is capable of providing its CRD patients timely specialty evaluation and consultation in cardiology, endocrinology, hematology, neurology, psychiatry, urology, orthopedics, pathology, pediatrics (if children are under care).

2. Nursing. There is at least one nurse, registered in Wisconsin responsible for CRD care on a full-time basis with a minimum of either: 6 months' additional training in a teaching institution providing dialysis and CRD patient care or 2 years' experience caring for CRD and dialysis patients, and also meets Section 405.1024 (c) of the Health Insurance Regulations.

3. Dietetic. A qualified dietician who meets the American Dietetics Association standards for qualification and provides diet management and counseling for CRD patient needs.

4. Social work. The facility provides a social worker, eligible for certification by the Academy of Certified Social Workers for the social service and counseling needs of CRD patients and their families.

5. Dialysis technical support. There shall be sufficient personnel trained in dialysis techniques available for the proper performance of dialysis and preparation and maintenance of dialyzing equipment and supplies.

6. CRD patient care review committee. There shall be a review committee composed of one or more of each of the following: nephrologist, nurse (as defined above), social worker (as defined above), and when appropriate, dialysis technician, who shall monitor and review the care of patients receiving services under the program. Psychiatric and other consultation should be called upon as appropriate.

7. CRD patient care policy. The center will develop a statement of policies, procedures, and safeguards governing the dialysis activities which will be reviewed and updated at least annually by a CRD patient review committee.

(b) *Facilities/services.* 1. The facility housing the dialysis center shall be approved by the department and meet all the requirements of Section 1861 (e) of the Social Security Act and have entered into an agreement to participate in the Medicare program.

2. The comprehensive dialysis center shall have a minimum of 4 dialysis stations and provide an average of at least 20 dialysis treatments per week, or such minimum numbers as may be required by federal regulations.

3. Physical design. a. There shall be grade level or ramp access to the structure and in multi-story structures, ready access to elevators large enough for bed or litter.

b. Patient bed areas for the administration of maximum care chronic or acute dialysis shall have adequate space for emergency equipment at bedside and shall be a minimum of 80 square feet per bed for new construction.

c. Privacy for patients shall be provided.

d. Space for linen storage shall be provided.

e. A janitor's closet shall be provided within or adjacent to the unit.

f. Space for adequate refrigerated and nonrefrigerated storage shall be provided. These shall be separate from facilities for food storage.

g. Work areas shall be designed and maintained to separate clean and/or sterile from contaminated or soiled materials.

h. A toilet room with water closet and lavatory shall be convenient for patient use only.

i. Space shall be provided for instrument maintenance and storage of equipment and for disassembling, preparation, and testing of dialyzers.

j. Electrical connections shall be provided at each station in accordance with electrical safety regulations of the federal Medicare program or any regulations of Wisconsin which may supersede them.

k. Sterilization equipment shall be available to process items requiring sterilization.

l. Water used for the dialysate shall be checked for quality and mineral content, including fluorides, and maintained at acceptable standards compatible with the safety and health of patients. The facility shall abide by the recommendations of the technical advisory committee relative to the prevention of health hazards due to minerals.

m. Plumbing for the unit shall be designed to assure adequate incoming water pressure to conform to equipment requirements and prevent back flow from waste lines. Necessary check and cut off valves shall be provided. Tested or treated water shall be delivered through pipes of inert material containing no copper.

n. Appropriate means shall be arranged for disposal of solid waste (preferably incineration).

o. All equipment shall be appropriately cleaned following each dialysis.

4. Equipment and supplies. a. Dialysis equipment. Equipment used may vary according to professional practice, patient needs, or current state of technology. All equipment used shall be approved for general specifications as to safety by the department through its technical advisory subcommittee.

b. Dialysate delivery system. Dialysate may be delivered by central delivery or individual units. It may be prepared by batch method or continuously by proportioning pumps. In either case, the quality and

consistency of the dialysate shall be monitored to ensure patient safety.

c. Ancillary equipment. The following equipment shall also be available for acute care either in the unit or readily available to it, such as, cannulation trays, chronic infusion pumps, intubation trays, and emergency resuscitation equipment.

5. Minimal service needs. a. Inpatient acute and maximum care chronic dialysis facilities to support the CRD patient needs.

b. Inhalation therapy.

c. Emergency (24 hours per day) laboratory services of C.B.C., platelet count, ABO blood cross matching, blood gases, blood ph, serum calcium and potassium, BUN, serum glucose, prothrombin time, spinal fluid exam, urine sediment and urine glucose and other laboratory services as specified by the state advisory review committee.

d. Limited care dialysis in an outpatient facility for patients who cannot perform self-dialysis, either as a part of the center program or by arrangement with another approved center.

e. Serum hepatitis control program.

f. The hospital provides either directly or under arrangement with another facility, angiography, nuclear medicine, immunofluorescence and electron microscopy and resources for unusual pathogen cultures.

g. Outpatient services for the evaluation, care and followup of CRD patients, including cannula and fistula care.

h. The hospital provides either directly or indirectly by an agreement with another facility for self-dialysis training programs and home dialysis support services. This includes procedures for the evaluation of home conditions for home dialysis, or if unsuitable, for self-dialysis or limited care dialysis in an outpatient facility.

i. The hospital provides by an agreement with a facility already certified to provide the service under Medicare: evaluation of its patients for transplantation and prospective patient registration for transplantation.

(2) HOSPITAL BASED SATELLITE DIALYSIS FACILITIES AND FREE-STANDING SATELLITE DIALYSIS FACILITIES. (a) These 2 types of dialysis facilities as approved by the department, meet and comply with all local, state, and federal regulations relating to ambulatory medical care facilities including but not limited to: building, zoning, fire, safety, health, civil rights.

(b) Professional staff of the facility (physicians, nurses, etc.) are currently licensed or registered in accordance with state regulations.

(c) The facility maintains records of all licenses, registrations, and certification documents for all staff.

(d) The facility has an effective governing body which designates an administrator to administer the program and policies and who has appropriate graduate education in a health related field.

(e) Administrative arrangements and affiliation agreements. 1. These facilities will have an affiliation agreement with one or more comprehensive dialysis centers to accomplish the following objectives:

a. Initial evaluation and long-term medical management planning for all new CRD patients who are candidates for dialysis and/or renal transplantation. This will include consideration of training for

self-dialysis and living related donor or cadaveric donor renal transplantation.

b. Periodic reevaluation of current patient status and management plan.

c. Referral arrangements with a comprehensive dialysis center for consultation and management of problems or complications which require capabilities not available in these facilities. Such services would include: vascular access, diet counseling, psychiatric and social services, and other consultative services in any of the recognized subspecialty fields of medicine or surgery.

2. The facility agrees that no charge will be made for a covered dialysis service that is in excess of the charge determined to be reasonable for that facility by the department.

3. The facility agrees to bill the department and not the patient for amounts reimbursable under the program.

4. The facility has a minimum of 2 maintenance dialysis stations and provides an average of at least 10 dialysis treatments per week, or such minimum numbers as may be required by federal regulations.

5. The facilities will provide directly or through affiliation agreement with a comprehensive dialysis center, self-care dialysis training for all patients found suitable for this modality of treatment.

(f) CRD patient care policies. Patient care policies are to be developed by a CRD patient care review committee of the facility. These policies are to be in written form and govern the total medical care, hemodialysis, and other services. They should be reviewed at least annually.

(g) Medical services. If there is a closed staff in the facility, dialysis is carried out under the direction of the medical director or his designate. If an open staff is maintained, dialysis will be under the supervision of the attending physician. 1. Referral of CRD patients. All patients coming under treatment in these facilities will be on referral from a nephrologist.

2. Selection of patients. All patients will have to satisfy the criteria for eligibility as previously defined.

(h) Medical director. There shall be a medical director of the facility who is a physician licensed in the state of Wisconsin, certified or is eligible for certification by the American Board of Internal Medicine or an equivalent certifying body as determined by the department on recommendation of the state advisory review committee, with at least one year of training in a comprehensive dialysis center and/or two years' experience in the care of CRD patients; or such training and experience as may be required by federal regulations. The director shall be available for service to the dialysis center and its patients as necessary.

(i) Nursing service. Nursing care shall be provided under the direct on-site supervision of a full-time nurse, registered in Wisconsin, designated as the nurse in charge. She shall have had 6 months of additional training in an approved comprehensive dialysis center or a minimum of 2 years' experience in dialysis and CRD patient care, or such training and experience as may be required by federal regulations.

(j) Dialysis technical support. There shall be sufficient personnel trained in dialysis techniques available for the proper performance of

dialysis and preparation and maintenance of dialyzing equipment and supplies.

(k) Pharmaceutical services. The free-standing and the hospital based satellite dialysis facilities shall have available pharmaceutical services which are under the supervision of a qualified pharmacist registered in the state of Wisconsin and in accordance with federal, state, and local laws.

(l) CRD patient care evaluation and utilization review. The medical staff and administrator shall be responsible for ongoing review of patient care to ensure highest possible standards. They shall form a patient care review or utilization review committee which will cooperate with the local appropriate professional standards review organization.

(m) Dietary services. If food is furnished to patients, the service shall be supervised by a qualified dietician and include dietary control and standards. If no food is to be furnished, this is to be specified in the patient care standards.

(n) Clinical records. A clinical record shall be maintained for each patient admitted in accordance with professional principles.

(o) Laboratory services. Laboratory services shall only be provided on written order of a physician including routine hemodialysis related tests such as hemoglobin, BUN, and hematocrit determinations. Laboratory services may be provided by purchase or agreement with sources outside the facility which are approved by the department. Laboratories providing services shall participate in the department laboratory evaluation program.

(p) Dialysis equipment and facilities. Dialysis equipment and related facilities shall conform to the standards for hospital based dialysis centers as stated in Wisconsin CRD program and Medicare regulations.

(3) HOME DIALYSIS, SELF-CARE AT HOME. Home self-dialysis has many psychological and energy saving advantages for CRD patients. (a) Patient selection for home dialysis. Home dialysis training and implementation shall be instituted by the attending physician in accordance with patient review and selection procedures established by a comprehensive dialysis center when such a plan seems feasible and acceptable to the patient and the person or persons who will be assisting him in his home.

(b) Home care training. The patient and his home care assistant shall be given instruction in a dialysis center which has simulated a home dialysis environment with the equipment and supplies which will be used in the home. The medical, nursing, dietary, and social work and dialysis technicians' staffs shall work with the patient and his assistant in preparing for this change.

(c) Safety standards. Adequate safeguards shall be taken to ensure patient safety in the actual installation and development of the home dialysis site.

(d) Medical supervision. Medical and nursing staffs of the center shall arrange appropriate visits to the home dialysis site to evaluate the quality and consistency of the care being given and for purposes of medical evaluation and followup.

(e) Monitoring. Staff of the department shall monitor the com-

pliance of the home dialysis self-care as to expected standards and quality.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.

**H 52.06 Provisional certification of facilities.** Upon submission of an acceptable plan of correction of deficiencies, any CRD facility in operation on June 29, 1974, and approved for Medicare reimbursement, may be granted provisional certification by the department on advice of the state advisory review committee, until January 1, 1977.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.

**H 52.07 Cost reimbursement procedures.** (1) PROCEDURES. The department shall use procedures for purchase of medical care which have been established for other government supported programs such as Medicare, Medicaid, and vocational rehabilitation.

(2) THIRD PARTY PAYMENTS. The facility shall assist the department by processing and collection of third party payments.

(3) COORDINATION OF BILLINGS. The business office and insurance office personnel in cooperation with the social services personnel of the dialysis and transplant facilities will assist in coordinating all billings related to the cost of dialysis, transplant, or other related procedures which are not covered by subsection (2) above.

(4) COMPLETION OF FORMS. The facility will complete forms used by the department to discharge their fiscal responsibility described in section 49.48 (3) (a), (b), (c), and (d), Wis. Stats.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.

**H 52.08 Advisory committees.** (1) STATE ADVISORY REVIEW COMMITTEE ON CRD PROGRAM. (a) An advisory committee on the CRD program shall be established by the department, consisting of 14 Wisconsin citizens representing the following professional and lay groups:

3 physicians—including at least 2 nephrologists
2 renal transplant surgeons
1 hospital administrator from a hospital that operates a comprehensive dialysis center
1 nurse involved in CRD patient care
1 social worker involved in CRD patient care
1 psychiatrist, clinical psychologist, or rehabilitation counsellor
5 lay persons representing the consumer-patient group, with at least one on home dialysis

Appointments will be for 3 year staggered terms, with replacement of members from the same category to complete unexpired terms of members unable to complete their terms. The group will elect its own chairman.

(b) The advisory review committee will meet semi-annually or more often as required on discretion of the chairman or on petition of any 5 members of the committee.

(c) The advisory review committee (ARC) shall function as an advisory committee to the department for the purpose of clarifying and defining and from time to time modifying policies and operational procedures, in order to carry out the legislative intent of the chronic renal disease program, section 49.48, Wis. Stats. The appropriate

areas of concern of the ARC will include but not be restricted to the following:

1. Criteria and procedures, initial and continuing, for entitlement of patients to benefits.

2. Certification of dialysis and transplant centers and facilities for purposes of reimbursement under the program.

3. Reimbursement policies and procedures.

4. Registry system of patients in all the dialysis and transplant health care programs in the state, including specific data requirements, methodology of updating, distribution of information, safeguards of privileged information.

5. Ensuring that this program is in general agreement with Medicare policies and regulations, yet provides the supplement benefits provided for in the state of Wisconsin legislation and operates in a fashion that does not impose an unnecessary duplication of procedural requirements which would impair the efficient operation of the program.

(d) Technical advisory subcommittees. The department may establish technical advisory subcommittees whose function will be to advise the staff of the department on changes and progress in technology and science requiring changes in rules, regulations or procedures in the administration of the program.

(e) Fiscal advisory subcommittee. The department may establish a fiscal advisory subcommittee to advise the staff of the department on implementation of H 52.07 (1) "Cost reimbursement procedures," such as the definition of "reasonable cost," "expenses," the "difference in cost" mentioned in the statutes, the limitation of the excess of the charges above Medicare and/or Medicaid payments and provide recommendations for other fiscal problems.

(2) STATE PROFESSIONAL COORDINATING COMMITTEE. Ad hoc committees of professionals representing the transplant centers and comprehensive dialysis centers and services may be established to advise and assist in the coordination of efforts, establishment of professional standards for operation and the articulation of procedures affecting patient flow between centers and between dialysis and transplant procedures.

**History:** Cr. Register, January, 1975, No. 229, eff. 2–1–75.