

Chapter H 52

CHRONIC RENAL DISEASE PROGRAM

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Note: Chapter H 52 as it existed on November 30, 1979 was repealed and a new chapter H 52 was created effective December 1, 1979.

H 52.01 Introduction. (1) **POLICY.** Section 49.48, 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 specifically relating to kidney disease 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, private insurance and other governmental coverage has been utilized.

(2) **REFERRAL SYSTEM.** 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 rules and regulations of June 3, 1976, from the department of health, education and welfare relating to this law call for coordinated patient referral and medical care which reflect planning and effective and efficient utilization of resources and manpower. The law requires certification or approval of facilities and for professional consultation 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 renal patients flow for care including renal transplantation centers, renal dialysis centers, and renal dialysis facilities which furnish renal transplantation, outpatient dialysis, inpatient dialysis, and home dialysis training services.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.

H 52.02 Definitions. (1) "Chronic renal disease (CRD) or end stage renal disease (ESRD)" means that stage of renal impairment which is virtually irreversible and requires a regular course of dialysis or kidney transplantation to maintain life.

(2) "Dialysis" means a process by which dissolved substances are removed from a patient's body by diffusion from one fluid compartment to another across a semipermeable membrane. The 2 types of dialysis which are currently in common clinical practice are: hemodialysis—where blood is passed through an artificial kidney 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, and 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 for chronic dialysis in this state at this time does not merit separate definition or consideration in these rules.

(3) "Outpatient dialysis" means dialysis which is regularly furnished on an outpatient basis to an ESRD patient (at any level of patient involvement) in a renal dialysis center, hospital-based renal dialysis facility, or a free-standing renal dialysis facility.

(4) "In-patient dialysis" means dialysis which, because of medical necessity, is furnished to an ESRD patient on a temporary in-patient basis in a hospital.

(5) "Back-up dialysis" means dialysis given to a patient under special circumstances, in a situation other than the patient's usual dialysis environment.

Note: Examples are: dialysis of a home dialysis patient in a dialysis unit when equipment fails, in-patient dialysis when patient illness requires more comprehensive care on an in-patient basis, and post-operative dialysis provided to transplant patients—particularly when the newly grafted organ is unable to assume its full function immediately.

(6) "Home dialysis" means dialysis performed by a trained ESRD patient or helper, or both at home.

(7) "Home or self dialysis training program" means a program which formally trains an ESRD patient or helper, or both, to perform dialysis at home or in an approved unit.

(8) "Home dialysis support services" means the services of assessment and surveillance of the patient's home and family conditions to include: a suitable environment, professional care and consultation, record-keeping, installation and maintenance of equipment, periodic testing of water and electrical systems, annual review sessions, back-up dialysis, and the provision of supplies on an ongoing basis.

(9) "Outpatient dialysis station" means a designated area with the plumbing, electrical system, dialysis machine, bed or lounge chair, and other equipment needed to perform a dialysis procedure on an ESRD patient.

(10) "Organ procurement" means the process of acquiring donor kidneys.

(11) "Organ procurement agency" means an organization which performs or coordinates the performance of harvesting, preserving, and transporting donated kidneys along with maintaining a system to locate prospective recipients of these kidneys.

(12) "Histocompatibility testing" means laboratory procedures used to determine the degree of compatibility between a donor organ and a potential recipient of a kidney transplant.

(13) "Living related donor transplant" means a transplant in which the organ is donated and removed from a living blood relative of the patient and transplanted into the patient.

(14) "Cadaveric donor transplant" means a transplant in which the donated organ is removed from an individual who has been pronounced dead according to currently accepted medical criteria and transplanted into a patient.

(15) "Transplant recipient registry" means a prospective list of patients, including certain medical and demographic data on those patients awaiting a renal transplant.

(16) "Furnishes directly" means the ESRD unit provides the service through its own staff and employes, or through individuals who are under direct contract to furnish services personally for the facility (i.e., not through "agreements" or "arrangements").

(17) "Furnishes on premises" means the ESRD unit furnishes services on its main premises; or on its other premises that are contiguous with or in immediate proximity to the main premises and under the direction of the same professional staff and governing body as the main premises.

(18) "Arrangement" means a written document executed between an ESRD unit and another unit, in which the other unit agrees to furnish specified services to patients. The ESRD unit retains responsibility for the services and for obtaining reimbursement.

(19) "Agreement" means a written document executed between an ESRD unit and another unit in which the other unit agrees to assume responsibility for furnishing specified services to patients and for obtaining reimbursement for those services.

(20) "Renal dialysis center" means a hospital unit which is approved to furnish the full spectrum of diagnostic, therapeutic (including inpatient dialysis furnished directly or under arrangement), and rehabilitative services (except renal transplantation) required for the care of ESRD patients.

(21) "Hospital-based renal dialysis facility" means a hospital unit which is approved to furnish one or more of the following dialysis services to ESRD patients: outpatient dialysis, inpatient dialysis, home or self dialysis training.

(22) "Free-standing renal dialysis facility" means a non-hospital unit which is approved to furnish outpatient dialysis and home or self dialysis training.

(23) "Renal transplantation center" means a hospital unit which is approved to furnish transplantation and other medical and surgical specialty services required for the care of ESRD transplant patients, including inpatient dialysis furnished directly or under arrangement or agreement.

(24) "Transplant surgeon" means a physician licensed in Wisconsin who is board eligible or board 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 12 months training or experience in the performance of renal transplantation and the care of renal transplant patients in an accredited teaching institution.

(25) "Nephrologist" means a physician licensed in Wisconsin, who is board eligible or board 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 12 months of fellowship training in nephrology or 2 years experience delivering care to ESRD patients. Pediatric training may be substituted for internal medicine if services are associated with pediatric ESRD care.

(26) "Vascular surgeon" means a physician, licensed in Wisconsin, who is board eligible or board 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 12 months training or experience in performance of vascular access procedures.

(27) "Nurse" means at least one full-time supervisory registered nurse, licensed in Wisconsin, with at least 12 months of experience in clinical nursing, and an additional 6 months of experience in nursing care of the outpatient dialysis or kidney transplantation patient, including training in and experience with the dialysis process, or 18 months of experience in nursing care of the outpatient dialysis or kidney transplantation patient, including training in and experience with the dialysis process. If the nurse is in charge of home or self dialysis training, at least 3 months of the total required ESRD experience shall be in home or self dialysis patient training.

(28) "Dietitian" means a person who is eligible for registration by the American dietetic association and has at least 1 year of experience in clinical nutrition; or has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics, and has at least 1 year of experience in clinical nutrition.

(29) "Social worker" means a person to provide counselling to ESRD patients and their families who is licensed in the state, if applicable, and has completed a course of study with specialization in clinical practice at, and holds a masters degree from, a graduate school of social work accredited by the council on social work education; or has served for at least 2 years as a social worker, 1 year of which was in a dialysis or transplantation setting and has established a consultative relationship with a social worker who holds a master degree from an accredited school of social work.

(30) "Department" means the Wisconsin department of health and social services.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.

H 52.03 Patient eligibility, certification, therapeutic approaches, and referral. (1) **PATIENT ELIGIBILITY.** Patients eligible for this program shall be those permanent residents of the state who have been diagnosed to have end stage renal disease. End stage renal disease if defined as, "That stage of renal impairment which is virtually irreversible, and requires a regular course of dialysis or kidney transplantation to maintain life." It is the intent of this legislation (s. 49.48, Stats.) to provide protection from the destructive costs of kidney disease treatment to all permanent residents of this state who have end stage renal disease requiring dialysis or kidney transplantation, including those

who may not be entitled to benefits under Medicare (section 299I of Public Law 92-603).

(2) **PATIENT CERTIFICATION.** Certification for coverage of dialysis shall be determined by the department upon the recommendation of a nephrologist from an approved dialysis unit. Certification for coverage of renal transplantation shall be determined by the department upon the recommendation of a transplant surgeon from an approved renal transplantation center. A statewide list of certified ESRD patients shall be maintained either by the department or by another agency on arrangement with the department. This list will include names of all certified outpatient dialysis and kidney transplant patients in the state. Additional information deemed necessary and appropriate by the department shall be provided by the dialysis and transplant centers to determine eligibility and facilitate reimbursement.

(3) **THERAPEUTIC APPROACHES.** A qualified primary physician, who is responsible for the patient's follow-up, shall be identified for each patient accepted and certified in the program. Suitable therapeutic approaches will be offered to 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: outpatient dialysis (including self dialysis), home dialysis, or transplantation.

(4) **REFERRAL.** All patients must be referred to other medical personnel by a nephrologist or transplant surgeon.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.

H 52.04 Renal transplantation centers. (1) **STAFFING.** The following staff shall be furnished directly by a renal transplantation center:

(a) *Medical.*

1. Transplant Surgeon.

2. Nephrologist.

3. Other medical personnel. The medical staff available must include physicians licensed in Wisconsin with experience in the following specialties: cardiology, endocrinology, hematology, neurology, infectious disease, orthopedics, pathology, psychiatry, nuclear medicine, radiology, urology, immunology, anesthesiology, gastroenterology, vascular surgery, pediatrics (if pediatric patients are under care), neurosurgery, and cardiovascular surgery.

(b) *Allied personnel.*

1. Nurse.

2. Dietitian.

3. Social worker.

(2) **SERVICES.** The hospital housing the renal transplantation center shall meet the following basic requirements:

(a) Is approved under the Hospital Regulations and Approval Act, s. 50.32 to 50.39, Stats., which meet all the requirements of Section 1861 (e) of the Social Security Act, and is a certified Medicare Provider.

(b) Is approved under Section 299I of the Social Security Amendment of 1972 (P.L. 92-603).

(c) Has Medicare and state approved laboratory services available for cross-matching of recipient serum and donor lymphocytes for preformed antibodies by an acceptable technique on a 24-hour emergency basis. Other available laboratory services include: suitable maintenance of recipient sera and typing reagents; phenotyping for donors and recipients; updating and retyping for HL-A and better defined antigens as indicated; screening of recipient sera for preformed antibodies with a suitable lymphocyte panel; testing the mixed lymphocyte cultures to determine cellularly defined antigens; ABO blood grouping and Rh typing; unusual pathogen culturing, fungal cultures, tissue cultures, and TB cultures; immunofluorescence and electron microscopy; urine glucose, protein, and microscopy; CBC and platelet count; blood gases and blood pH; serum calcium, potassium, phosphorous, and glucose; BUN, creatinine, SGOT, LDH, and prothombin time; spinal fluid and bone marrow exam.

(d) Other support services available must include: physical therapy, pharmacy, inhalation therapy, blood banking, dialysis, nerve conduction, cardiac catheterization, electroencephalography, diagnostic ultrasound, angiography, and diagnostic radioisotopic scanning.

(e) Participates in a patient registry program.

(f) Provides outpatient services for the evaluation, care, and follow-up of renal transplantation patients.

(3) **PHYSICAL DESIGN.** The renal transplantation center shall meet the following basic requirements:

(a) Provides a minimum of 10 beds to accomodate pre—and post—transplantation patients.

(b) Has rooms on the unit designed to provide isolation or segregation from patients with infections or communicable diseases.

(4) **EQUIPMENT AND SUPPLIES.** The renal transplantation center shall meet the following basic requirements:

(a) Has donor kidney preservation equipment on the premises or available under arrangement or agreement, and the donor kidneys are preserved by currently acceptable medical methods.

(b) Has emergency resuscitation equipment available.

(5) **POLICIES AND PROCEDURES.** The renal transplantation center shall provide the following written policies and procedures:

(a) Unit policies and procedures. The renal transplantation center shall develop written policies and procedures, updated at least annually.

(b) Patient care policies and procedures. The renal transplantation center shall develop written policies and procedures, updated at least annually. These policies and procedures shall include a patient's bill of rights and responsibilities (including a grievance mechanism) which is made available to all patients.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.

H 52.05 Renal dialysis centers and facilities. (1) **STAFFING.** The following staff shall be furnished directly by a renal dialysis center or furnished directly, under arrangement or under agreement by a hospital-based renal dialysis facility or free-standing renal dialysis facility:

(a) *Medical.*

1. Nephrologist.
2. Vascular Surgeon.

3. Other medical personnel. The medical staff available must include physicians licensed in Wisconsin with experience in the following specialties: cardiology, endocrinology, hematology, neurology, psychiatry, urology, orthopedics, pathology, pediatrics (if children are under care), and radiology.

(b) *Allied personnel.*

1. Nurse.
2. Dietitian.
3. Social Worker.

(2) **SERVICES.** Renal dialysis centers and facilities shall meet the following requirements:

(a) Is approved under Section 299I of the Social Security Amendment of 1972 (P.L. 92-603).

(b) Complies with all local, state, and federal regulations relating to ambulatory medical care facilities, including but not limited to: building, zoning, fire, safety, health, and civil rights. Shall provide self-care dialysis training and kidney transplantation to all suitable patients either directly or under arrangement or under agreement.

(c) Has Medicare and state approved laboratory services available, on a 24-hour emergency basis, for dialysis related tests including but not limited to: urine glucose, and microscopy; CBC and platelet count; prothrombin time; ABO blood grouping, Rh typing and cross-matching; serum glucose, calcium, potassium, phosphorus, and magnesium; BUN, creatinine, uric acid, SGOT, LDH, and alkaline phosphatase; blood pH and gases; pathogen cultures; tissue typing, spinal fluid analysis; and serum hepatitis screening.

(d) Maintains clinical records for each patient in accordance with professional principles.

(e) Has other support services including: physical therapy, pharmacy, inhalation therapy, blood banking, medical records, and nuclear medicine.

(3) **PHYSICAL DESIGN.** Renal dialysis centers and facilities shall meet the following requirements:

(a) Provides 80 square feet per patient bed area for adequate emergency equipment space.

(b) Has separate clean and sterile work areas to separate contaminated and soiled materials.

- (c) Provides space for instrument maintenance and storage.
- (d) Has adequate space for refrigerated and non-refrigerated storage with separate facilities for food storage.
- (e) Provides electrical connections at each station in accordance with federal and state electrical safety regulations.
- (f) Has unit plumbing (including check, cut-off valves, and back flow preventors) which assumes adequate incoming water pressure to conform to equipment requirements and prevent back flow from waste lines. Treated water shall be delivered through pipes of inert materials containing no copper.
- (g) Provides appropriate means for disposal of solid waste (preferably incineration).
- (h) Provides a convenient toilet room with water closet and lavatory for patient use only.
- (i) Has a janitors closet within or adjacent to the unit.
- (j) Provides space for linen storage.

(4) EQUIPMENT AND SUPPLIES. Renal dialysis centers and facilities shall meet the following requirements:

- (a) Has sterilization equipment available to process items requiring sterilization.
- (b) Provides equipment in accordance with federal and state safety specifications which is appropriately cleaned following each dialysis procedure.
- (c) Provides treatment of the water used for the dialysate which removes fluorides, and abides by the recommendations of the advisory review committee regarding the prevention of health hazards due to mineral content.

(d) Provides safeguards to ensure patient safety in the installation and maintenance of home dialysis equipment.

(e) Has cannulation trays, infusion pumps, intubation trays, and emergency resuscitation equipment available.

(5) POLICIES AND PROCEDURES. Renal dialysis centers and facilities shall provide the following written policies and procedures:

(a) *Unit policies and procedures.* The unit shall develop written policies and procedures, updated at least annually, including infection control and emergency evacuation policies and procedures.

(b) *Patient care policies and procedures.* The unit shall develop written policies and procedures, updated at least annually. These policies and procedures shall include the development of an individualized long and short term patient care plan for every patient and a patient's bill of rights and responsibilities (including a grievance mechanism) which is made available to all patients.

(c) *Home or self dialysis policies and procedures.* The home or self dialysis training unit shall develop additional policies and procedures, updated at least annually, governing home or self dialysis training and

home or self dialysis activities. These policies and procedures shall include appropriate evaluation and surveillance of the home or self dialysis patient and equipment.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.

H 52.06 Certification of ESRD units. Certification of dialysis and transplant centers and facilities for purposes of reimbursement under the program may be granted by the department based upon ESRD certification under the Medicare program, adherence to chapter H 52 or an acceptable plan of correction of deficiencies, and the advice of the state CRD program advisory review committee. Recertification shall be required annually.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.

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 ESRD units shall assist the department by processing and collecting third party payments. The ESRD provider shall bill the department and not the patient for amounts reimbursable under the CRD program.

(3) **COMPLETION OF FORMS.** The ESRD provider shall complete forms used by the department to discharge their fiscal responsibility described in s. 49.48 (3) (a), (b), (c), and (d), Stats.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.

H 52.08 State CRD program advisory review committee (ARC).

(1) A CRD program advisory committee shall be established and maintained by the department, consisting of 14 Wisconsin citizens representing the following professional and lay groups:

- (a) 3 physicians—including at least 2 nephrologists.
- (b) 2 renal transplant surgeons.
- (c) 1 hospital administrator from a hospital that operates a dialysis center.
- (d) 1 nurse involved in ESRD patient care.
- (e) 1 social worker involved in ESRD patient care.
- (f) 1 psychiatrist, clinical psychologist, or rehabilitation counselor.
- (g) 5 lay persons representing the consumer-patient group.

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.

(2) The ARC will meet as required on discretion of the chairman or on petition of any 5 members of the committee.

(3) The 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 CRD Program, s. 49.48, Stats. The appropriate areas of concern of the ARC will include but not be restricted to the following:

- (a) Entitlement of patients to benefits.
 - (b) Certification of dialysis and transplant centers and facilities for purposes of reimbursement under the program.
 - (c) Reimbursement policies and procedures.
 - (d) Certification of patients for reimbursement.
 - (e) Provision of supplemental benefits to ESRD patients which are in general agreement with Medicare policies and regulations.
- (4) 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.
- (5) 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.

History: Cr. Register, November, 1979, No. 287, eff. 12-1-79.