Chapter DHS 152

REIMBURSEMENT FOR TREATMENT OF CHRONIC RENAL DISEASE

DHS 152.01 Authority and purpose.
DHS 152.02 Definitions.
DHS 152.03 Eligibility and certification.
DHS 152.035 Events which affect eligibility.
DHS 152.04 Patient rights and responsibilities.
DHS 152.05 Certification of renal transplantation centers, dialysis centers and dialysis facilities.
DHS 152.06 Provider reimbursement.
DHS 152.065 Patient liability.
DHS 152.07 Standards for renal transplantation centers.
DHS 152.08 Standards for renal dialysis centers and facilities.
DHS 152.09 CRD program advisory committee.

Note: Chapter H 52 as it existed on June 30, 1988, was repealed and a new chapter HSS 152 was created effective July 1, 1988. Chapter HSS 152 as it existed on September 30, 1999, was renumbered to chapter HFS 152, Register, September, 1999, No. 525, eff. 10−1−99 and corrections made under s. 13.93 (2m) (b) 6. and 7., Stats., Register, September, 1999, No. 525. Chapter HFS 152 was renumbered chapter DHS 152 under s. 13.92 (4) (b) 1., Stats., and corrections made under s. 13.92 (4) (b) 7., Stats., Register January 2009 No. 637.

DHS 152.01 Authority and purpose. This chapter is promulgated under the authority of ss. 49.68 (2), 49.687 (1) and 227.11 (2) (a), Stats., to implement a treatment cost reimbursement program for residents of Wisconsin who have chronic renal disease.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88; am. Register, December, 1994, No. 468, eff. 1−1−95.

DHS 152.02 Definitions. In this chapter:

(1) "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.

(2) "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 but the ESRD unit retains responsibility for the services and for obtaining reimbursement.

(2m) "BadgerCare" means the medical assistance−related program established under s. 49.665, Stats., and chs. DHS 101 to 108.

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

(4) "CRD program advisory committee" means the committee appointed by the department under s. DHS 152.09.

(4m) "Current year" means the 12−month period beginning with the month of a patient's first application to the CRD program, or beginning with the month of a certified patient's subsequent annual recertification for the CRD program.

(5) "Department" means the department of health services.

(6) "Dialysis" means a process by which dissolved substances are removed from a patient's body by diffusion and osmosis from one fluid compartment to another across a semipermeable membrane.

(7) "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 a person who has a baccalaureate or advanced degree with major studies in food and nutrition or dietetics and at least 1 year of experience in clinical nutrition.

(8) "End−stage renal disease" or "ESRD" has the meaning prescribed for chronic renal disease or CRD in sub. (3).

(9) "ESRD unit" or "unit" means a free−standing or hospital−based renal dialysis facility, a renal dialysis center or a renal transplantation center.

(9m) "Family" means a patient and that patient's spouse, if any, and any other person who is claimed as a dependent of that patient or that patient's spouse or who claims that patient as a dependent under the U.S. internal revenue code for the purpose of filing a federal income tax return.

(9t) "Federal poverty guidelines" means the annually updated poverty income thresholds by family size published each year by the U.S. department of health and human services in the federal register.

Note: The federal poverty guidelines for 1999 were published in the *Federal Register,* March 18, 1999, 13428.

(9u) "Fiscal agent" means the organization under contract to the department to process claims and determine eligibility for services provided under the CRD program.

(10) "Free−standing renal dialysis facility" means a non−hospital unit which is approved by the department under this chapter to furnish chronic maintenance dialysis with or without self−care dialysis training.

(11) "Furnishes directly" means that the ESRD unit provides the service through its own staff and employees, or through individuals who are under personal contract to furnish services for the facility.

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

(13) "Hospital−based renal dialysis facility" means a hospital unit approved by the department to furnish one or more of the following dialysis services to ESRD patients:

(a) Outpatient dialysis;

(b) Inpatient dialysis;

(c) Home dialysis;

(d) Self−dialysis training.

(14) (a) "Income," for the period January 1, 1994 to June 30, 1994, has the meaning prescribed in s. 49.485 (1) (dm), 1991 Stats., except that a certified patient may for that period elect to use the definition under par. (b).

(b) "Income," beginning July 1, 1994, means a family's total earnings, including wages and salary and net income from self−employment, as well as unearned income including social security and supplemental security income, dividends and interest income, income from estates or trusts, net rental income, public assistance, pensions or annuities, unemployment compensation, maintenance or alimony, child support or family support, nontaxable deferred compensation, and nontaxable interest such as interest on federal, state or municipal bonds, but not capital gains income.

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

(15m) "Medical assistance" has the meaning specified in s. 49.43 (8), Stats.

(16) "Medicare" means the health insurance program operated by the U.S. department of health and human services under 42 USC 1395 to 1395zz and 42 CFR Pts. 405 to 421.

(17) "Nephrologist" means a physician licensed in Wisconsin or, if employed by an ESRD unit approved under this chapter in a border state, in that state, who is board−eligible or board−

certified by the American board of internal medicine, or by an equivalent certifying body as determined by the department on recommendation of the CRD program advisory committee, and who has a minimum of 12 months of fellowship training in nephrology or 2 years of experience in delivering care to ESRD patients. Pediatric training may be substituted for internal medicine board eligibility or board certification if the ESRD unit's services are associated with pediatric ESRD care.

(18) "Nurse" means a full−time supervisory nurse registered in Wisconsin or, if employed by an ESRD unit approved under this chapter in a border state, in that state, with at least 12 months of experience in clinical nursing and an additional 6 months of experience in nursing care of an outpatient dialysis or kidney transplantation patient, including training in and experience with the dialysis process, or 18 months of experience in nursing care of an outpatient dialysis or kidney transplantation patient, including training in and experience with the dialysis process. If the nurse is in charge of home dialysis or self−dialysis training, at least 3 months of the total required ESRD experience shall be in home dialysis or self−dialysis patient training.

(19) "Outpatient dialysis" means dialysis which is regularly furnished on an outpatient basis to an ESRD patient in a renal dialysis center, hospital−based renal dialysis facility or a free−standing renal dialysis facility.

(20) "Patient" means a person who has been diagnosed as having ESRD and who receives treatment for ESRD. "Patient" does not include a kidney donor.

(21) "Patient registry program" means a computerized list of all certified patients on dialysis which includes verification that each case has been reviewed by a transplant surgeon and that cases meeting criteria for a transplant are placed on the transplant list.

(22) "Provider" means a renal dialysis facility or center, a renal transplantation center, or another source of dialysis or transplantation services approved by the department.

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

(24) "Renal transplantation center" means a hospital unit approved by the department 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.

(25) "Resident" means any person who is living in Wisconsin with the intention of remaining permanently in the state. A person under the age of 18 is a resident if he or she is determined to be a resident in accordance with s. DWD 11.15.

Note: DWD 11.15 was repealed eff. 4−1−02.

(26) "Self−dialysis" means dialysis which is regularly furnished on an outpatient basis to an ESRD patient in a renal dialysis center, hospital−based renal dialysis facility or a free−standing renal dialysis facility, in which the ESRD patient is responsible for the dialysis treatment but is supervised by a dialysis nurse.

(26m) "SeniorCare" means the program of prescription drug assistance for eligible elderly persons under s. 49.688, Stats., and ch. DHS 109.

(27) "Social worker" means a person who provides counseling to an ESRD patient and his or her family, and has either completed a course of study with specialization in clinical practice at a graduate school of social work accredited by the council on social work education and holds a masters degree from that school, or has worked for at least 2 years as a social worker, 1 year of which was in a dialysis or transplantation setting, and receives consultation from a social worker who holds a masters degree from an accredited school of social work.

(28) "Transplant surgeon" means a physician licensed in Wisconsin or, if employed by an ESRD unit approved under this chapter in a border state, in that state, who is board−eligible or board−certified by the American board of surgery or by an equivalent certifying body as determined by the department on recommendation of the CRD program advisory committee, and who has a minimum of 12 months of training or experience in the performance of renal transplantation and the care of renal transplant patients in an accredited teaching institution.

(29) "Vascular surgeon" means a physician licensed in Wisconsin or, if employed by an ESRD unit approved under this chapter in a border state, in that state, who is board−eligible or board−certified by the American board of surgery or by an equivalent certifying body as determined by the department on recommendation of the CRD program advisory committee under s. DHS 152.09, and who has a minimum of 12 months of training or experience in the performance of vascular access procedures.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88; cr. (15m), Register, May, 1992, No. 437, eff. 6−1−92; emerg. cr. (9 g), am. (14), eff. 9−1−93; cr. (4m), (9m), (9t) and (9u), r. and recr. (14) and (25), Register, December, 1994, No. 468, eff. 1−1−95; CR 04−051: cr. (2m) and (26m) Register November 2004 No. 587, eff. 12−1−04; corrections in (2m), (5) and (26m) made under s. 13.92 (4) (b) 6. and 7., Stats., Register January 2009 No. 637.

DHS 152.03 Eligibility and certification. (1) CONDITIONS. To be eligible for the CRD program, a patient shall:

(a) Be a resident of Wisconsin;

(b) Be diagnosed as having ESRD;

(c) If eligible for medicare, register and pay the premium for coverage by medicare; and

(d) Provide to the department or its designated agent full, truthful and correct information necessary for the department to determine patient eligibility and liability, including information about any change in income of more than 10%. A patient shall be denied reimbursement if he or she refuses to provide information, withholds information or provides inaccurate information. The department may verify or audit a certified patient's total family income. The department may redetermine a certified patient's estimated total family income for the current year based on change in the family's financial circumstances.

(e) First apply for benefits under all other health care coverage programs for which the person may reasonably be eligible, including medicare, BadgerCare, medical assistance and SeniorCare.

(2) PATIENT CERTIFICATION. (a) 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.

(b) A statewide list of certified ESRD patients shall be maintained either by the department or by another agency upon arrangement with the department. This list shall 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.

(c) The department or its fiscal agent shall certify an eligible patient for reimbursement upon receipt from any dialysis unit approved under ss. DHS 152.05 and 152.08 or renal transplantation center approved under ss. DHS 152.05 and 152.07 of a satisfactorily completed application for certification submitted on behalf of the patient.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88; emerg. am. (1) (c), eff. 9−1−93; r. and recr. (1), am. (2) (c), Register, December, 1994, No. 468, eff. 1−1−95; CR 04−051: cr. (1) (e) Register November 2004 No. 587, eff. 12−1−04.

DHS 152.035 Events which affect eligibility. (1) Eligibility under the CRD program is terminated if any of the following events occur:

(a) The patient dies.

(b) The patient stops making medicare premium payments.

(c) The patient moves out of the state of Wisconsin.

(d) The patient no longer requires a regular course of chronic dialysis because the patient's kidneys resume function and the patient has not had a kidney transplant.

(2) An applicant who has died may be retroactively eligible for benefits only if the applicant had signed and completed an application prior to the date of the applicant's death.

History: CR 04−051: cr. Register November 2004 No. 587, eff. 12−1−04.

DHS 152.04 Patient rights and responsibilities. (1) A certified patient or, if the patient is a minor or has a guardian, the patient's parent or guardian shall inform the department within 30 days after there is any change in the patient's address, other sources of health care coverage, income of more than 10% or family size.

(2) (a) A patient applying for benefits or a certified patient may request an administrative hearing under subch. III of ch. 227, Stats., in the event that reimbursement is denied or certification is terminated.

(b) A request for a hearing shall be in writing and shall be filed with the department of administration's division of hearings and appeals within 45 days after the date of notice of denial of reimbursement or termination of certification. A request for a hearing is considered filed upon its receipt by the division of hearings and appeals.

Note: The mailing address of the Division of Hearings and Appeals is P.O. Box 7875, Madison, Wisconsin 53707.

(3) All information provided by a certified patient to the department or to a provider shall remain confidential and may not be used for any purpose other than to determine eligibility for benefits, patient liability and the types of medical services required for proper care. Statistical analyses of program data may not reveal patient identity.

(4) The department may not discriminate against or deny benefits to anyone on the basis of race, sex, age, national origin, marital status, creed, handicap, sexual orientation or ancestry.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88; am. (1), r. and recr. (2), Register, December, 1994, No. 468, eff. 1−1−95.

DHS 152.05 Certification of renal transplantation centers, dialysis centers and dialysis facilities. (1) CERTIFICATION. For purposes of reimbursement, all ESRD units in Wisconsin that are certified under medicare shall be considered certified by the department and shall comply with the requirements of this chapter.

(2) BORDER STATE ESRD UNITS. A border state ESRD unit that provides medical care services to Wisconsin residents shall be considered certified by the department as a provider if it is certified under medicare. These out−of−state ESRD units shall be subject to this chapter and the same contractual agreements as Wisconsin ESRD units.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88.

DHS 152.06 Provider reimbursement. (1) CLAIM FORMS. (a) A provider shall use claim forms furnished or prescribed by the department or its fiscal agent, except that a provider may submit claims by electronic media or electronic transmission if the provider or billing service is approved by the department for electronic claims submission.

(b) Claims shall be submitted in accordance with the claims submission requirements, claim form instruction and coding information provided by the department or its fiscal agent.

(c) Every claim submitted shall be signed by the provider or the provider's authorized representative, certifying to the truthfulness, accuracy and completeness of the claim.

(2) TIMELINESS. (a) A claim shall be submitted within 24 months after the date that dialysis or transplant services were provided, except that a claim may be submitted later if the department is notified within that 24 month period that the sole reason for late submission concerns another funding source and the claim is submitted within 180 days after obtaining a decision on reimbursement from the other funding source.

(b) A claim may not be submitted until after the patient has received the dialysis or transplant services.

(3) PAYMENT. (a) The department shall establish allowable charges for CRD services as a basis for reimbursing providers.

(b) Reimbursement may not be made for any portion of the cost of medical care which is payable under any other state or federal program, grant, contract or agreement.

(c) Before submitting a claim to the CRD program, a provider shall seek payment for services provided to a certified patient from medicare, medical assistance or another health care plan if the certified patient is eligible for services under medicare, medical assistance or the other health care plan.

(d) When benefits from medicare, medical assistance or another health care plan or other third party payer have been paid, in whole or in part to the provider, the amount of the payment from all other payers shall be indicated on or with the bill to the CRD program. The amount of the medicare, medical assistance, other health care plan or other third party payer reimbursement shall reduce the amount of the claim for CRD program payment.

(e) If a provider receives a payment under the program to which the provider is not entitled or in an amount greater than that to which the provider is entitled, the provider shall promptly return the amount of the erroneous or excess payment to the department.

(f) A provider may request a hearing to review a decision to deny payment or the level of payment. A request for a hearing shall be filed with the department's office of administrative hearings within 90 days after the date of the payment or decision to deny payment. A request for a hearing is considered filed upon its receipt by the office of administrative hearings. All appeals shall include written documentation and any information deemed necessary by the department. Hearings shall be conducted in accordance with subch. III of ch. 227, Stats.

Note: The mailing address of the Office of Administrative Hearings is P.O. Box 7875, Madison, Wisconsin 53707.

(g) A provider shall accept the amount paid under this section for the service as payment in full and may not bill the patient for any amount by which the charge for the service exceeds the amount paid for the service under this section.

(h) The department shall use common methods employed by managed care programs and the medical assistance program to contain costs, including prior authorization and other limitations regarding health care utilization and reimbursement.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88; cr. (8), r. and recr. Table, Register, May, 1992, No. 437, eff. 6−1−92; emerg. r. and recr. Table cr. (6) (d), eff. 9−1−93; r. and recr. Register, December, 1994, No. 468, eff. 1−1−95; CR 04−051: cr. (3) (g) and (h) Register November 2004 No. 587, eff. 12−1−04.

DHS 152.065 Patient liability. (1) CALCULATION. (a) A certified patient's liability to contribute toward the cost of treatment shall be calculated as follows:

1. If the patient's estimated total family income for the current year exceeds 300% of the federal poverty guidelines, the patient is liable to obligate or expend a portion of that income, as specified in sub. (2), to pay the medical expenses for treatment of kidney disease before the CRD program will provide assistance in paying for treatment;

2. The patient is liable for any deductible under sub. (3);

3. The patient is liable for a coinsurance amount based on the amount reimbursable by the CRD program and family size and income in accordance with sub. (4) and Table 152.065;

4. The sum of the patient's deductibles under sub. (3) and coinsurance obligation under sub. (4) in a year may not exceed the

applicable percentage of income limit in sub. (5) unless the annual deductibles under sub. (3) are greater; and

5. In addition, the patient is liable for a copayment amount under sub. (6) when the pharmacy bills the CRD program.

(b) If there are 2 or more certified patients in the same family, the family's liability shall be limited to the liability of one member of the family.

(2) INCOME DEDUCTIBLE. A certified patient whose estimated total family income in the current year is at or above 200% of the federal poverty guidelines shall obligate or expend the following percentage of that income to pay the cost of medical treatment for the chronic renal disease before the CRD program will provide assistance in paying for the cost of treatment:

(a) When total family income is from 200% to 250% of the federal poverty guidelines, 0.50% of that income.

(b) When total family income is more than 250% but not more than 275% of the federal poverty guidelines, 0.75% of that income.

(c) When total family income is more than 275% but not more than 300% of the federal poverty guidelines, 1.0% of that income.

(d) When total family income is more than 300% but not more than 325% of the federal poverty guidelines, 1.25% of that income.

(e) When total family income is more than 325% but not more than 350% of the federal poverty guidelines, 2.0% of that income.

(f) When total family income is more than 350% but not more than 375% of the federal poverty guidelines, 2.75% of that income.

(g) When total family income is more than 375% but not more than 400% of the federal poverty guidelines, 3.5% of that income.

(h) When total family income is more than 400% of the federal poverty guidelines, 4.5% of that income.

(3) MEDICARE–EQUIVALENT DEDUCTIBLES. (a) An amount equal to the medicare part A deductible, as defined under 42 USC 1395e and 42 CFR 409.82, shall be assessed all certified patients for the first inpatient hospital stay in a 12−month period.

(b) An amount equal to the medicare part B deductible, as defined under 42 USC 1395L (b), shall be assessed all certified patients for the first outpatient visit in a 12−month period.

(4) PATIENT COINSURANCE. (a) The coinsurance amount which a patient pays to the provider as part of the cost of treatment of the patient's chronic renal disease shall be based on the amount reimbursable by the program.

(b) A patient's coinsurance amount shall be determined at the time the patient is certified for coverage and redetermined annually thereafter.

(c) The amount of a patient's coinsurance shall be related to family size and income, rounded to the nearest whole dollar, and expressed as a percentage of the charges for treatment in accordance with the schedule in Table 152.065.

(5) LIMIT ON LIABILITY. (a) Each patient's liability in a year for medicare−equivalent deductibles under sub. (3) and coinsurance under sub. (4) may not exceed the following applicable percentage of the family's income, rounded to the nearest whole dollar, unless the annual deductibles under sub. (3) are greater:

1. For an income of up to $10,000, 3%;
2. For an income of $10,001, to $20,000, 4%;
3. For an income of $20,001 to $40,000, 5%;
4. For an income of $40,001 to $60,000, 6%;
5. For an income of $60,001 to $80,001, 7%;
6. For an income of $80,001 to $100,000, 9%; and
7. For an income of $100,001 and over, 10%.

(b) The limit on liability under par. (a) does not include the income deductible under sub. (2).

(6) PATIENT COPAYMENT. When a pharmacy directly bills the chronic renal disease program for a prescription received by an ESRD patient, the patient is responsible for a $7.50 copayment amount for each generic drug and a $15.00 copayment amount for each brand name drug.

(7) ESTATE RECOVERY. (a) An heir or beneficiary of the estate of a patient or a patient's surviving spouse may apply to the department for a waiver of an estate claim filed by the department pursuant to s. 49.682 or 49.849, Stats. The criteria for granting waivers in s. DHS 108.02 (12) (b) shall apply to applications under this subsection. All of the procedures and rights in s. DHS 108.02 (12) (b) to (e) shall apply to this subsection.

(b) For purposes of applying s. DHS 108.02 (12) (b) to (e) to this subsection the following definitions apply:

1. "Beneficiary" means any person nominated in a will to receive an interest in property other than in a fiduciary capacity;

2. "Decedent" means a deceased patient or the deceased surviving spouse of a patient who received benefits that are subject to recovery under s. 49.682 or 49.849, Stats.;

3. "Heir" means any person who is entitled under the statutes of intestate succession, ch. 852, Stats., to an interest in property of a decedent;

4. "Recipient" means a patient who received reimbursement under s. 49.48, Stats.; and

5. "Waiver applicant" means a beneficiary or heir of a decedent who requests the department to waive an estate claim filed by the department pursuant to s. 49.682 or 49.849, Stats.

(c) The department may make adjustments to and settle estate claims filed under s. 49.682 or 49.849, Stats., to obtain the fullest amount practicable.

Table 152.065
Patient Coinsurance Liability for the Direct Cost of Treatment

Annual Family Income	Percent of Charges for Which Patient is Liable, by Family Size									
	1	2	3	4	5	6	7	8	9	10+
$0−7,000	1%	0%	0%	0%	0%	0%	0%	0%	0%	0%
7,001−10,000	2	1	0	0	0	0	0	0	0	0
10,001−15,000	4	2	1	0	0	0	0	0	0	0
15,001−20,000	7	4	2	1	0	0	0	0	0	0
20,001−25,000	11	7	4	2	1	0	0	0	0	0
25,001−30,000	14	10	7	5	3	2	1	0	0	0
30,001−35,000	17	13	10	8	6	4	2	1	0	0
35,001−40,000	20	16	13	11	9	7	5	3	2	1
40,001−45,000	24	19	15	13	11	9	7	5	3	2
45,001−50,000	29	24	20	17	15	13	11	9	7	5
50,001−55,000	34	29	25	21	19	17	15	13	11	9
55,001−60,000	39	34	29	25	23	21	19	17	15	13
60,001−65,000	44	39	34	30	28	25	22	20	18	16
65,001−70,000	49	44	39	35	32	29	27	25	23	21
70,001−75,000	55	49	44	40	37	34	32	30	28	26
75,001−80,000	61	55	50	46	43	40	37	35	33	31
80,001−85,000	67	61	56	52	49	46	43	40	38	36
85,001−90,000	74	68	63	59	56	53	50	47	45	43
90,001−95,000	81	75	70	66	63	60	57	55	53	51
95,001−100,000	88	82	77	73	70	67	64	62	60	58
100,000+	97	91	86	82	79	76	73	71	69	67

Note: To illustrate how a patient's coinsurance liability is calculated, assume that the family has 2 members and an annual income of $38,000, and that a bill has been received for treatment in the amount of $600. The patient would be liable for 16% of that bill, or $96.

History: Cr. Register, December, 1994, No. 468, eff. 1−1−95; emerg. cr. (7), eff. 11−1−95; cr. (7), Register, April, 1996, No. 484, eff. 5−1−96; CR 02−070: am. (6) Register October 2002 No. 562, eff. 11−1−02; CR 04−051: am. (2) and (6), cr. (2) (f) to (h) Register November 2004 No. 587, eff. 12−1−04; corrections in (7) (a) and (b) (intro.) made under s. 13.92 (4) (b) 7., Stats., Register January 2009 No. 637; **corrections in (7) (a), (b) 2., 5., (c) made under s. 13.92 (4) (b) 7., Stats., Register December 2013 No. 696.**

DHS 152.07 Standards for renal transplantation centers. (1) GENERAL. To be reimbursed by the CRD program, renal transplantation centers shall comply with the standards in this section.

(2) STAFFING. A renal transplantation center shall have the following staff:

(a) A transplant surgeon;

(b) A nephrologist;

(c) Other physicians licensed in Wisconsin or, if employed by an ESRD unit approved under this chapter in a border state, in that state, 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;

(d) A nurse;

(e) A dietitian; and

(f) A social worker.

(3) SERVICES. The hospital housing the renal transplantation center shall:

(a) Be approved under ss. 50.32 to 50.39, Stats., and ch. DHS 124, meet all the requirements of 42 USC 1395x (e) and be a certified medicare provider;

(b) Be approved under 42 USC 1395rr (b);

(c) Have laboratory services approved for participation in medicare and under 42 CFR 493 (CLIA) 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 shall include:

1. Suitable maintenance of recipient sera and typing reagents;

2. Phenotyping for donors and recipients;

3. Updating and retyping for human lymphocyte antigens (HLA);

4. Screening of recipient sera for preformed antibodies with a suitable lymphocyte panel;

5. Testing the mixed lymphocyte cultures to determine cellularly defined antigens;

6. ABO blood grouping and typing;

7. Unusual pathogen culturing, fungal cultures, tissue cultures and tuberculosis cultures;

8. Immunofluorescence and electron microscopy;

9. Urine glucose, protein, and microscopy;

10. Complete blood count (CBC) and platelet count;

11. Blood gases and blood pH;

12. Serum calcium, potassium, phosphorous, and glucose;

13. Blood urea nitrogen (BUN), creatinine, serum glutamic−oxaloacetic transaminase (SGOT), serum glutamic−pyruvic transaminase (SGPT), lactic dehydrogenase (LDH) and prothrombin time; and

14. Spinal fluid and bone marrow exams;

(d) Have available other support services, including physical therapy, pharmacy, inhalation therapy, blood banking, dialysis, nerve conduction, cardiac catheterization, electroencephalography, diagnostic ultrasound, angiography and diagnostic radioisotopic scanning;

(e) Participate in a patient registry program; and

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

(4) PHYSICAL DESIGN. In regard to physical design, the renal transplantation center shall:

(a) Provide a minimum of 10 beds to accommodate patients before and after transplantation; and

(b) Have rooms on the unit designed to provide isolation or segregation from patients with an infection or a communicable disease.

(5) EQUIPMENT AND SUPPLIES. In regard to equipment and supplies, the renal transplantation center shall have:

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

(b) Emergency resuscitation equipment available on the premises.

(6) POLICIES AND PROCEDURES. In regard to policies and procedures, the renal transplantation center shall have:

(a) Unit policies and procedures which shall be in writing and updated at least annually. These policies and procedures shall relate to the operation of the unit and shall include infection control and emergency evacuation policies and procedures; and

(b) Patient care policies and procedures which shall be in writing and updated at least annually. These policies and procedures shall include the development of an individualized care plan for every patient, a list of patient rights and responsibilities and a grievance mechanism which is made available to all patients.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88; am. (3) (c) 13., Register, December, 1994, No. 468, eff. 1−1−95; correction in (3) (a) made under s. 13.92 (4) (b) 7., Stats., Register January 2009 No. 637.

DHS 152.08 Standards for renal dialysis centers and facilities. (1) GENERAL. To be reimbursed by the CRD program, renal dialysis centers and free−standing and hospital−based renal dialysis facilities shall comply with the standards in this section.

(2) STAFFING. A renal dialysis center shall have the following staff and a hospital−based renal dialysis facility or a free−standing renal dialysis facility shall make available the following staff directly, under arrangement or under agreement:

(a) A nephrologist;

(b) A vascular surgeon;

(c) Other physicians licensed in Wisconsin or, if employed by an ESRD unit approved under this chapter in a border state, in that state, with experience in the following specialties: cardiology, endocrinology, hematology, neurology, psychiatry, urology, orthopedics, pathology, pediatrics if children are under care, and radiology;

(d) A nurse;

(e) A dietitian; and

(f) A social worker.

(3) SERVICES. A renal dialysis center or facility shall:

(a) Be approved under 42 USC 1395rr (b);

(b) Comply with all local ordinances, state rules and federal regulations relating to ambulatory medical care facilities, including but not limited to those for building, zoning, fire and safety, health and civil rights;

(c) Provide self−care dialysis training and kidney transplantation to all suitable patients either directly or under arrangement or agreement;

(d) Have laboratory services approved for participation in medicare and under 42 CFR 493 (CLIA) and available on a 24−hour emergency basis for dialysis−related tests. Laboratory services shall include:

1. Urine glucose and microscopy;

2. Complete blood count (CBC) and platelet count;

3. Prothrombin time;

4. ABO blood grouping, Rh typing and cross−matching;

5. Serum glucose, calcium, potassium, phosphorous and magnesium;

6. Blood urea nitrogen (BUN), creatinine, uric acid, serum glutamic−oxaloacetic transaminase (SGOT), lactic dehydrogenase (LDH) and alkaline phosphatase;

7. Blood pH and gases;

8. Pathogen cultures;

9. Tissue typing and spinal fluid analysis; and

10. Serum hepatitis screening;

(e) Maintain clinical records for each patient in accordance with professional principles; and

(f) Have available other support services, including physical therapy, pharmacy, inhalation therapy, blood banking, medical records and nuclear medicine.

(4) PHYSICAL DESIGN. In regard to physical design, a renal dialysis center or facility shall:

(a) Provide 80 square feet per patient bed to permit movement of emergency equipment;

(b) Have separate clean and sterile work areas to separate contaminated and soiled materials from the patient care area;

(c) Provide space for instrument maintenance and storage;

(d) Have adequate space for refrigerated and non−refrigerated storage, with separate facilities for food storage;

(e) Provide electrical connections at each dialysis station in accordance with federal and state electrical safety regulations;

(f) Have unit plumbing, including check cut−off valves and back−flow preventors, which assumes adequate incoming water pressure to conform to equipment requirements and to prevent back−flow from waste lines. Treated water shall be delivered through pipes of inert materials containing no copper;

(g) Provide appropriate means for disposal of solid waste, preferably by incineration;

(h) Provide a convenient toilet room with a toilet and wash basin for patient use only;

(i) Have a janitor's closet within or adjacent to the unit; and

(j) Provide space for linen storage.

(5) EQUIPMENT AND SUPPLIES. In regard to equipment and supplies, a renal dialysis center or facility shall:

(a) Have equipment available to sterilize items that require sterilization;

(b) Provide equipment in accordance with federal and state safety specifications and appropriately clean the equipment following each dialysis procedure;

(c) Provide treatment of water used for the dialysate to remove fluorides and prevent health hazards due to mineral content;

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

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

(6) POLICIES AND PROCEDURES. In regard to policies and procedures, a renal dialysis center or facility shall have:

(a) Unit policies and procedures, in writing and updated at least annually. These policies and procedures shall relate to the operation of the unit and shall include infection control and emergency evacuation policies and procedures;

(b) Patient care policies and procedures, in writing and updated at least annually. These policies and procedures shall include the development of individualized long and short term patient care plans for every patient and a list of patient rights and responsibilities, including a grievance mechanism, which is made available to all patients; and

(c) Home dialysis and self−dialysis policies and procedures, in writing. The home or self−dialysis training unit shall develop additional policies and procedures, updated at least annually, to govern home dialysis and self−dialysis training and home analysis and self−dialysis activities. These policies and procedures shall include appropriate evaluation and surveillance of home dialysis and self−dialysis patients and equipment.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88; am. (3) (d) 6., Register, December, 1994, No. 468, eff. 1−1−95.

DHS 152.09 CRD program advisory committee. **(1)** A CRD program advisory committee shall be established by the department and shall be given staff support by the department. The committee shall consist of 12 Wisconsin citizens, as follows:

(a) Four physicians, 2 of whom are nephrologists and the other 2 transplant surgeons;

(b) One dietician involved in ESRD patient care;

(c) Two nurses involved in ESRD patient care;

(d) One social worker involved in ESRD patient care; and

(e) Four public members.

(2) Appointments to the committee shall be made by the department 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 committee shall elect its own chairperson.

(3) The committee shall meet at the discretion of the chairperson, on petition of any 5 members or by the request of the department.

(4) The committee shall advise the department about defining, clarifying or otherwise modifying policies and operational procedures to implement s. 49.48, Stats.

(5) The department may establish technical advisory subcommittees from the committee membership to advise staff of the department on changes and progress in technology and science requiring changes in rules or procedures for the administration of the program.

History: Cr. Register, June, 1988, No. 390, eff. 7−1−88.