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Chapter HSS 152

REIMBURSEMENT FOR TREATMENT OF CHRONIC RENAL DISEASE

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Note: Chapter H 52 as it existed on June 30, 1988, was repealed and a new Chapter HSS 152 was created effective July 1, 1988.

HSS 152.01 Authority and purpose. This chapter is promulgated under the authority of ss. 49.48 (2) and 140.05 (3), 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.

HSS 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.

(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. HSS 152.09.

(5) "Department" means the department of health and social 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.

(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 employes, 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) "Income" has the meaning prescribed in s. 71.09 (7) (a) 6, Stats.

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

(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.

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(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 individual who is living in Wisconsin for purposes of employment or with the intention of remaining permanently or for an indefinite period in Wisconsin. An individual under age 18 is a resident if he or she is determined to be a resident in accordance with s. HSS 201.15. An individual who at or after age 18 becomes incapable of indicating intent to maintain Wisconsin residence indefinitely is a resident only if Wisconsin is the state in which the individual most recently established residence before becoming incapable of indicating intent. In this subsection, "incapable of indicating intent" has the meaning prescribed in s. HSS 103.03 (3) (a) 1.

(26) "Self-dialysis" means dialysis which is regularly furnished on an outpatient basis to an ESRD patient in a renal dialysis center, hospitalbased 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.

(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.

(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 Register, October, 1991, No. 430 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. HSS 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.

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HSS 152.03 Patient eligibility and certification. (1) PATIENT ELIGIBIL-ITY. (a) To be eligible for the CRD program, a patient shall be a permanent resident of Wisconsin and be diagnosed as having ESRD. If the patient is eligible for medicare, the patient shall register and pay the premium for coverage by medicare as a condition for becoming eligible for this program.

(b) Patients are responsible for providing to the department or its designated agent full, truthful and correct information necessary to determine eligibility and liability. A patient shall be denied reimbursement if he or she refuses to provide information, withholds information or provides inaccurate information.

(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 shall certify an eligible patient for reimbursement upon receipt of a satisfactorily completed application for certification.

Note: To obtain an application form for the CRD program, write Bureau of Community Health and Prevention, P.O. Box 309, Madison WI 53701.

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

HSS 152.04 Patient rights and responsibilities. (1) A certified patient shall inform the department within 30 days of any change in address, other sources of coverage, income or family size.

(2) A certified patient has the right to an administrative hearing under subch. III of ch. 227, Stats., in the event benefits are terminated or payment for medical services is denied.

Note: The request for a hearing should be addressed to the Department's Office of Administrative Hearings, 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.

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HSS 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.

HSS 152.06 Provider reimbursement. (1) PROCEDURES. The department shall use procedures established for the medical assistance program under ch. HSS 106 to reimburse providers for the cost of ESRD services.

(2) CLAIM FORMS. (a) Providers shall use claim forms specified by the department.

(b) Providers shall make all reasonable attempts to ensure that the information contained on the claim forms is complete and accurate. Where applicable, codes specified by the department shall be used in preparing the claim forms.

(c) Every claim submitted shall be signed by the provider or the provider's authorized representative.

(3) TIMELINESS. (a) A claim shall be submitted within 24 months after the date that dialysis or transplantation services were provided.

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

(c) If a third party source of insurance or payment is identified, the provider shall, before submitting a claim to the department, seek to obtain from that third party payment for the medical care. If the third party denies coverage, the provider may then submit a claim, with a copy of the denial, for the unpaid amount for services directly resulting from ESRD.

(4) PAYMENT. (a) The department shall establish allowable charges for ESRD 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) Providers shall identify third party resources legally liable for paying in whole or in part the cost of ESRD services provided to the patient.

(d) The department shall pay only the portion of the allowable cost of covered medical care directly resulting from chronic renal disease after all health insurance and other payments have been received and the patient's liability has been ascertained. These payments may not be used for purposes of gaining medical assistance eligibility under ch. HSS 103.

(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) The provider may appeal the level of payment or a decision to deny payment. That appeal shall be submitted to the department's office of administrative hearings within 6 months after the event. 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 Department's Office of Administrative Hearings is P.O. Box 7875, Madison, Wisconsin 53707.

(5) PATIENT DEDUCTIBLE. (a) An amount equal to the medicare part A deductible, as defined under 42 USC 1895e 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.

(6) PATIENT COINSURANCE. (a) The coinsurance amount which a patient pays as part of the cost of treating 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 annually thereafter, and shall be redetermined upon the patient's notification to the department of a change in family size or income.

(c) The amount of a patient's coinsurance shall be related to family size and income and expressed as a percentage of the charges for treatment in accordance with the schedule in Table 152.06.

(7) PATIENT LIABILITY. Each patient's total liability in a calendar year shall consist of the sum of the applicable deductibles and the amount of coinsurance but may not exceed the following applicable percentage of the family's income unless the annual deductible under sub. (5) is greater:

1. For an income 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%; Register, October, 1991, No. 430

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- 4. For an income of \$40,001 to \$60,000, 6%;
- 5, For an income of \$60,001 to \$80,000, 7%;
- 6. For an income of \$80,001 to \$100,000, 9%; and
- 7. For an income of \$100,001 and over, 10%.

Table 152.06

PATIENT LIABILITY FOR THE COST OF TREATMENT

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18 22	15 19	13 17	11 15	9 13	7 11	5 9	3 7	1 2 5 9
<u>30</u> 34	27 30	<u>25</u> 28	23 26	21 24	19 22	17 20	15 18	13 16
44 49	40 45	38 43	36 41	84 39	82 37	30 35	28 33	21 26 31
62 69	57 64	$\frac{55}{62}$	53 60	51 68	49 56	47 54	45 52	36 48 50 57
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Note: To illustrate how a patient's liability is calculated, assume that the family has 4 members and an annual income of \$40,000, and that a bill has been received for treatment rendered in the amount of \$600. The patient would be liable for 11% of that bill, or \$66.

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

HSS 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;

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(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. HSS 124, meet all the requirements of 42 USC 1395x (e) and be a certified medicare provider;

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

(c) Have laboratory services approved for participation in medicare and under ch. HSS 165 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-oxalorcetic transaminase (SGOT), serum glutamic-pyruvic transminase (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.

HSS 152.08 Standards for renal dialysis centers and facilities. (1) GEN-ERAL. 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;

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(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 ch. HSS 165 and available on a 24-hour emergency basis for dialysis-related tests. Laboratory services shall include:

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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 glutamicoxaloagetic 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;

 (\mathbf{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.

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(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.

HSS 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

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(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.