Chapter HSS 153

HEMOPHILIA HOME CARE

HSS 153.01 Definitions. (1) "Department" means the department of health and social services.

(2) "Approved source" means a provider who has a written agreement with a comprehensive hemophilia treatment center for the distribution of blood products and infusion supplies to certified hemophilia patients in compliance with the hemophilia home care program.

(3) "Agreement" means a written understanding between 2 or more parties with respect to the effect upon specific subsequent rights and duties.

(4) "Comprehensive hemophilia treatment center" means a center and its satellite facilities, approved by the department, which provides services, including development of the maintenance program, to persons with hemophilia and related inherited plasma factor defects.

(5) "Hemophilia and related inherited plasma factor defects" means any genetically transmitted bleeding disorder resulting from a deficiency of functional clotting factor which has been confirmed by laboratory tests and is treatable by administration of plasma or plasma derivatives.

(6) "Home care" means the self-infusion of plasma clotting factor on an outpatient basis by the patient or by a person trained in such procedures.

(7) "Income" means income as defined in s. 71.09 (7) (a) 1, Stats.

(8) "Maintenance program" means the individual's therapeutic and treatment regimen, including medical, dental, social and vocational rehabilitation and home health care.

(9) "Net worth" means the sum of the value of assets minus liabilities. Liquid assets include such items as personal property, consisting of cash, savings accounts, securities and similar items, and the cash surrender value of life insurance on the life of the patient, spouse, parent and other persons responsible for the patient's support. Real property includes the house and lot, after excluding the first $10,000 of the full value of the home as determined by the assessment ratio of the taxation district.

(10) "Physician director" means the medical director of a comprehensive hemophilia treatment center who is directly responsible for an individual's maintenance program. The physician director must be a physician licensed in Wisconsin, certified by the American board of internal medicine or American board of pediatrics or equivalent certifying body, with specialized training in hematology, as determined by the department.

(11) "Provider" means a comprehensive hemophilia treatment center or a source approved by the center.

History: Cr. Register, June, 1979, No. 282, eff. 7-1-79; renum. from H 53.01, r. (5), renum. (6) to (12) to be (5) to (11) and am. (10), Register, May, 1982, No. 317, eff. 6-1-82.

HSS 153.02 Patient eligibility and certification. (1) PATIENT ELIGIBILITY. (a) Patients eligible for this program shall be those permanent residents of the state who have hemophilia or a related inherited plasma factor defect. A resident of Wisconsin is any individual who is living in the state for purposes of employment or is living in Wisconsin with the intention to remain permanently or for an indefinite period. The state of residence of any individual under age 21 shall be determined in accordance with the rules governing residence under the aid to families with dependent children program. For an individual who becomes incapable of indicating intent at or after age 21, the state of residence shall be the state in which the individual most recently established residence before becoming incapable of indicating intent.

(b) Patients are required to enter into a written agreement with a comprehensive hemophilia treatment center for compliance with a maintenance program. This agreement shall also be required as a condition for continued eligibility.

(c) Patient eligibility based on net worth shall be established by the department.

(d) Patients are responsible for providing to the department or its delegated agent full, truthful and correct information necessary to determine eligibility. Necessary information includes but is not limited to information concerning coverages under medicare, medicaid, health insurance plans, government or private benefit plans, or any real or potential third party coverage, and information regarding income, changes in income, resources or other circumstances which may affect eligibility status. Patients will be denied reimbursement if they refuse to provide information necessary to determine eligibility.

(2) PATIENT CERTIFICATION. (a) The department shall certify reimbursement upon completion of all required forms and written recommendation of the physician director following successful participation in a home care or self-infusion training program. The physician director shall be responsible for reviewing the maintenance program every 6 months and shall verify in writing that the patient is complying with the program.

(b) A statewide list of certified home care hemophilia patients shall be maintained by the department or by an agency designated by the department. Information deemed necessary and appropriate by the department to determine eligibility and facilitate reimbursement shall be provided by the comprehensive hemophilia treatment center.

History: Cr. Register, June, 1979, No. 282, eff. 7-1-79; renum. from H 53.02, Register, May, 1982, No. 317, eff. 6-1-82.

HSS 153.03 Reimbursement. (1) TERMS. An individual may claim reimbursement for covered blood products and infusion supplies as defined in hemophilia home care program policies and procedures when such materials are furnished by an approved comprehensive hemophilia treatment center or source approved by the center. Reimbursement shall be allowed if:

(a) The patient was eligible to receive benefits from the program on the date that the blood products and supplies were furnished;

(b) The comprehensive hemophilia treatment center or approved source complied with all applicable state procedural requirements relating to furnishing such blood products and supplies, and;

(c) The supplies and blood products were medically necessary.

(1m) Nothing in this rule shall preclude the comprehensive hemophilia treatment center from providing non-covered blood products and supplies, if before providing such materials the center advises the patient that such blood products and supplies are not covered under the program and that the patient shall be responsible for payment for the non-covered items.

(2) THIRD PARTY OR OTHER COVERAGE. (a) The comprehensive hemophilia treatment center or approved source shall identify third party resources legally liable to contribute in whole or in part to the cost of blood products and infusion supplies provided to the patient under this program.

(b) If a third party source of insurance or payment is identified, the comprehensive hemophilia treatment center or approved source shall, before submitting a claim to the department, seek to obtain from that third party, payment for the blood products and supplies. If the third party coverage is denied for all or a part of the cost of the blood products and supplies, the comprehensive hemophilia treatment center or approved source may then submit a claim, with a copy of the denial, to the extent of the unpaid amount.

(3) CLAIM FORMS. (a) The comprehensive hemophilia treatment center or approved source shall utilize claim forms provided by the department.

(b) The comprehensive hemophilia treatment center or approved source shall make all reasonable attempts to insure 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 authorized agent of the comprehensive hemophilia treatment center or approved source.

(4) TIMELINESS. (a) A claim may not be submitted until the patient has received the blood products and supplies which are the subject of the claim and payments from all other third party or other sources have been received.

(b) A claim shall be submitted within 12 months of the date such blood products and supplies were provided. Payment shall not be made for any claim submitted after the 12 month period, except where the comprehensive hemophilia treatment center demonstrates to the department that unusual circumstances beyond the center's control prevented timely submission of the claim.

(5) PAYMENT. (a) The department shall establish reasonable costs for blood products and infusion supplies as a basis for reimbursement.

(b) Reimbursement shall not be made for any blood products and supplies which are not purchased from or provided by a comprehensive he-

mophilia treatment center or a source approved by the center. Reimbursement shall not be made for any portion of the cost of blood products and supplies which are payable under any other state or federal program, grant, contract, or any other contractual arrangement.

(c) The department shall pay only for the portion of the reasonable cost of blood products and supplies remaining after all health insurance and other payments have been received and the patient liability has been ascertained. These payments, regardless of total amount, are not subject to recovery by the state, are not subject to estate settlements, and may not be used for "spend-down."

(d) Payment for blood products and supplies shall be made directly to the comprehensive hemophilia treatment center or approved source that furnishes them. The department shall reimburse the center or approved source for covered blood products and supplies according to the payment schedule "Terms of Hemophilia Program Reimbursement."

(e) If a comprehensive hemophilia treatment center or approved source 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 to the department the amount of such erroneous or excess payment.

(6) PATIENT'S LIABILITY. (a) The amount of patient's liability for reasonable costs of blood products and home care supplies shall be based on income and family size.

(b) Individual liability shall be determined at the time of certification for eligibility or upon the patient's notification to the department of a change in family size or financial condition.

History: Cr. Register, June, 1979, No. 282, eff. 7-1-79; renum. from H 53.03, Register, May, 1982, No. 317, eff. 6-1-82.

HSS 153.04 Comprehensive hemophilia treatment center standards. (1) STAFFING. The following staffing is required for a comprehensive hemophilia treatment center for management of home care patients:

(a) *Physician director.* The responsibilities of the physician director shall include but not be limited to organizing and coordinating the administrative functions of the comprehensive hemophilia treatment center, delegating duties as authorized and establishing a formal means of accountability for those involved in patient care; participating in the development, negotiation and implementation of agreements into which the center may enter; maintaining and submitting required reports; providing medical supervision and developing written home care training policies and procedures and their implementation.

(b) *Multidisciplinary staff.* The multidisciplinary staff, including the physician director, shall develop the comprehensive health maintenance program and shall provide, but not be limited to, the training of patients in home care, access to the necessary psychosocial evaluations and referrals, and assistance in reimbursement. The staff must include, at a minimum, access to a hematologist, internist, pediatrician (except that if the hematologist is also an internist or pediatrician, an additional internist or pediatrician is not required), orthopedic surgeon, oral surgeon or dentist, radiologist, physical therapist, registered nurse, social worker and financial counselor.

(c) *Additional specialties.* The comprehensive hemophilia treatment center must also insure the availability of a nutritionist, psychiatrist or psychologist, and an educational/vocational or rehabilitation counselor.

(2) FACILITIES AND SERVICES. (a) *Facilities.* The comprehensive hemophilia treatment center shall be a facility approved under the Hospital Regulation and Approval Act, ss. 50.32 to 50.39, Stats. and shall meet all of the requirements of Section 1861 (e) of the Social Security Act, including an agreement to participate in the Medicare program or shall have a written agreement with a facility qualifying under this section.

(b) *Services.* The comprehensive hemophilia treatment center shall provide the following services:

1. Home care training program. Training in home care self-infusion techniques shall be available to hemophilia patients, parents, guardians or assistants served by the center. This training shall include instruction to the patient and assistant utilizing the products, equipment and supplies necessary in home care treatment.

2. Maintenance program. There shall be a written maintenance program for each home care hemophilia patient which is reviewed by the multidisciplinary staff every 6 months. The maintenance program must accompany the patient in interfacility transfer.

3. Emergency medical services. The comprehensive hemophilia treatment center shall insure the availability of emergency medical services on a 24-hour, 7 day-per-week basis for home care patients who need medical assistance.

4. Recognition of patient rights and responsibilities. Patients must be assisted in recognizing their rights and responsibilities. A grievance mechanism shall be available to all patients under which they may participate without fear of reprisal.

5. The comprehensive hemophilia treatment center shall also provide the following services directly or under agreement:

a. Laboratory. There shall be access to a state-approved laboratory capable of testing for plasma factor deficiency and the presence of inhibitors to one or more clotting factors.

b. Blood products. The comprehensive hemophilia treatment center shall insure the availability of blood products and home care supplies, including but not limited to plasma factor concentrate, cryoprecipitate and fresh frozen plasma.

(3) DOCUMENTATION. All providers must maintain the following records:

(a) Contracts or agreements with persons or organizations for the furnishing of blood products and supplies, payment for which may be made in whole or in part, directly or indirectly, by the hemophilia home care program;

(b) Billings and records of supplies and blood products which are the subject of such billings, as are necessary fully to disclose the nature and extent of such blood products and supplies, and;

(c) Any and all prescriptions necessary to disclose the nature and extent of blood products and supplies provided and billed under the program.

(4) CERTIFICATION AGREEMENT. (a) Each comprehensive hemophilia treatment center, upon meeting the requirements under this section, shall execute a written agreement with the department in order to become an approved center and thereby eligible for state reimbursements. This agreement shall, unless terminated, remain in full force and effect from the date of execution. The date on which it was signed on behalf of the department by its authorized representative shall be considered the effective date.

(b) The comprehensive hemophilia treatment center and its approved source shall affirm in writing that, with respect to each service for which reimbursement is sought, for the purpose of providing the service, it holds all licenses or similar entitlements or is under agreement with such a facility, as specified in this rule and required by federal or state law, rule or regulation for provision of the service.

(c) The provider shall, upon request by the department, furnish in writing the names and addresses of all vendors of blood products and infusion supplies furnished to home care hemophilia patients under this program.

(5) CONTIGUOUS OUT-OF-STATE CENTERS. A border state facility whose normal practice includes providing services and supplies to Wisconsin residents may be certified as a comprehensive hemophilia treatment center if it meets the requirements for approval under this rule. Such out-of-state centers shall be subject to the same regulations and contractual agreements as Wisconsin facilities.

(6) TERMINATION OF PROGRAM PARTICIPATION. (a) *Voluntary.* 1. A comprehensive hemophilia treatment center may elect at any time to terminate participation in the program and shall within 30 days notify the department in writing of such election and of the effective date of such termination.

2. A provider may not claim reimbursement for blood products and supplies furnished to patients on or after the effective date specified in the termination notice.

(b) *Involuntary termination, suspension or denial of certification.* 1. The department may suspend or terminate the certification of a comprehensive hemophilia treatment center or approved source participating in the program if after 60 days' written notice and opportunity for hearing within 30 days the department finds:

a. The comprehensive hemophilia treatment center or approved source has repeatedly and knowingly failed or refused to comply with federal or state statute, rule or regulation applicable to the delivery of or billing for blood products and supplies under the program.

b. The comprehensive hemophilia treatment center or approved source has repeatedly and knowingly failed or refused to comply with the conditions and terms of any agreement with the department.

c. The comprehensive hemophilia treatment center or approved source has provided or claimed reimbursement for blood products and supplies

under the program which where either inappropriate, unnecessary or in excess of the patient's needs, or of grossly inferior quality.

d. The licensure, certification, authorization or other official entitlement required under state or federal law as a prerequisite to the provider's certification to participate in the program has been suspended, terminated, expired or revoked.

e. The comprehensive hemophilia treatment center or approved source has knowingly made or caused to be made false statements or misrepresentations of material fact in a claim or report submitted to the department for purposes of establishing reimbursements or reimbursement rates under the program.

(7) HOME HEALTH CARE AGREEMENT. The agreement between the patient and the comprehensive hemophilia treatment center for a home maintenance program must be in writing and must designate:

(a) Services to be provided;

(b) Responsibilities of the patient and the center relating to developing the plan of treatment and conforming to the applicable policies of the center;

(c) The manner in which services are to be controlled, coordinated and evaluated by the center;

(d) The procedure for periodic medical evaluations, and;

(e) The procedure for determining charges and reimbursements.

History: Cr. Register, June, 1979, No. 282, eff. 7-1-79; renum. from H 53.04, Register, May, 1982, No. 317, eff. 6-1-82.

HSS 153.05 Patient rights and responsibilities. (1) The patient or parent or guardian shall inform the department within 30 days of any change in address, eligibility, income, net worth or family size.

(2) Patients are responsible for providing to the comprehensive hemophilia treatment center full, truthful and correct information which is necessary for the submission of correct and complete claims under the program. Failure to provide information in the above manner may result in limitation or termination of benefits. Eligibility will not be granted under the program if the patient refuses to provide information necessary to determine eligibility.

(3) The patient has the right to a full and fair hearing and appeal in the event benefits are terminated under the program.

(4) All information provided by patients shall remain confidential and may not be used for any purpose other than determination of eligibility for benefits under the program. Statistical analyses of program data shall not reveal patients' identity.

(5) The patient has the right not to be discriminated against and not to be denied benefits on the basis of race, sex, age, national origin, marital status, creed or handicap.

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