

Chapter HFS 153

REIMBURSEMENT FOR BLOOD PRODUCTS AND SUPPLIES USED IN THE HOME CARE OF HEMOPHILIA

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Note: Chapter HSS 153 as it existed on December 31, 1994 was repealed and a new chapter HSS 153 was created effective January 1, 1995. Chapter HSS 153 was renumbered to chapter HFS 153 under s. 13.93 (2m) (b) 1., Stats., and corrections made under s. 13.93 (2m) (b) 6. and 7., Stats., Register, September, 1999, No. 525.

HFS 153.01 Authority and purpose. This chapter is promulgated under the authority of ss. 49.685 (8) (c), 49.687 (1) and 227.11 (2), Stats., to implement a program of reimbursement for the cost of blood products and supplies for use in the home care of residents of Wisconsin who have hemophilia.

History: Cr. Register, December, 1994, No. 468, eff. 1-1-95.

HFS 153.02 Definitions. In this chapter:

(1) "Approved source" means a provider who has an agreement with a comprehensive hemophilia treatment center for distribution of blood products and supplies to program participants.

(1m) "BadgerCare" means the medical assistance-related program established under s. 49.665, Stats., and chs. HFS 101 to 108.

(2) "Case management services" means services essential for effective use of blood products and supplies, namely, home care initial training, nurse monitoring for participant compliance and annual comprehensive evaluation of a participant.

(3) "Comprehensive hemophilia treatment center" means a center, including its satellite facilities, certified by the department under this chapter to provide services, including development of maintenance programs, to persons with hemophilia and other related congenital bleeding disorders.

(4) "Current year" means the 12-month period beginning with the month of a patient's first application to the hemophilia home care program, or beginning with the month of a participant's subsequent annual recertification for the program.

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

(6) "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.

(7) "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.

(8) "Hemophilia" means a bleeding disorder resulting from a genetically determined clotting factor, protein or platelet function abnormality or deficiency.

(9) "Home care" means a patient's self-infusion of blood products on an outpatient basis, or the infusion of blood products to a patient on an outpatient basis by a person trained in that procedure.

(10) "Income" 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.

(11) "Maintenance program" means a patient's therapeutic and treatment regimen, including medical, dental, social and vocational rehabilitation services and home health care.

(11g) "Medical assistance" has the meaning specified in s. 49.43 (8), Stats., and chs. HFS 101 to 108.

(11r) "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.

(12) "Participant" means a patient who has been found eligible by the department under s. 49.685, Stats., and this chapter for reimbursement for the costs of blood products and supplies used in the home care of hemophilia.

(13) "Patient" means a person diagnosed as having hemophilia.

(14) "Physician director" means the medical director of the comprehensive hemophilia treatment center which is directly responsible for a patient's maintenance program.

(15) "Program" means the hemophilia home care program under s. 49.685, Stats., and this chapter.

(16) "Provider" means a comprehensive hemophilia treatment center, an approved source of blood products and supplies or a provider of case management services for program participants.

(17) "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.

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

History: Cr. Register, December, 1994, No. 468, eff. 1-1-95; **CR 04-051: cr. (1m), (11g), (11r) and (18) Register November 2004 No. 587, eff. 12-1-04.**

HFS 153.03 Eligibility. To be eligible for the hemophilia home care program, a patient shall:

- (1) Be a resident of Wisconsin;
- (2) Be diagnosed by a comprehensive hemophilia treatment center as having hemophilia;
- (3) Enter into a written agreement with a comprehensive hemophilia treatment center for compliance with a maintenance program. The agreement shall specify:
 - (a) The services to be provided;
 - (b) Responsibilities of the patient and the center relating to development of the plan of treatment and conformance of the patient to applicable center policies;

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

(d) Procedures for semi-annual evaluation of the maintenance program and for verification that the patient is complying with the established treatment regimen; and

(4) Provide to the department or its designated agent full, truthful and correct information necessary for the department to determine eligibility and liability on forms specified by the department. A patient shall be ineligible for financial assistance if he or she refuses to provide information, withholds information, refuses to assist the department in verifying the information or provides inaccurate information. The department may verify or audit an applicant's total family income.

(5) Complete one of the following actions:

(a) 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.

(b) Apply for and receive from the department a waiver from par. (a) for religious reasons. If the department does not approve the request for a waiver, the applicant shall meet the requirements of par. (a).

Note: Persons desiring a waiver from the requirements under par. (a) should submit their request to the Wisconsin Chronic Disease Program, Attention: Eligibility Unit, P.O. Box 6410, Madison, WI 53716-0410, or call 608-221-3701. Requests must describe the basis of the religious belief that precludes application for benefits under one or more of the programs listed under par. (a).

History: Cr. Register, December, 1994, No. 468, eff. 1-1-95; CR 04-051: cr. (5) Register November 2004 No. 587, eff. 12-1-04.

HFS 153.035 Termination of eligibility. Eligibility under the hemophilia home care program is terminated if any of the following events occur:

(1) The patient dies.

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

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

HFS 153.037 Retroactive eligibility. Retroactive eligibility is not available under the hemophilia home care program. Patients who are found to be eligible under s. HFS 153.03 become eligible for benefits on the date the application was received.

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

HFS 153.04 Patient certification. (1) APPLICATION. To apply for assistance in paying for the costs of blood products and supplies used in the home care of hemophilia, a patient shall complete a form available from a comprehensive hemophilia treatment center, and shall submit the completed form either to the center or directly to the department. The completed form shall include a signed certification by the physician director of the center that the patient has successfully participated in a home care program, and that the physician director will review the patient's maintenance program every 6 months and, on request of the department, will verify that the patient is complying with the program.

(2) **NOTIFICATION OF APPLICANT.** The department shall certify a patient as eligible for reimbursement for part of the costs of blood products and supplies used in the home treatment of hemophilia if all requirements under s. HFS 153.03 are met. The department shall notify the patient, in writing, of its decision within 60 days after the department receives an application for assistance. If the application is denied, the notice shall include the reason for denial with information that the patient may request a hearing under sub. (7) on that decision.

(3) **RECERTIFICATION.** Certification is for one year. To be recertified, a participant shall complete, sign and submit to the department a financial statement form received from the department. The participant shall provide to the department full, truthful and correct information necessary for the department to determine eligibility and liability.

(4) **REVOCATION OR NONRENEWAL OF CERTIFICATION.** The department may revoke or not renew a participant's certification

if the department finds that the participant is no longer eligible for the program. The department shall send written notice of revocation or nonrenewal to the participant, stating the reason for it and with information that the participant may request a hearing under sub. (7) on that decision.

(5) **PARTICIPANT RESPONSIBILITY TO PROVIDE INFORMATION.** (a) A participant shall inform the department within 30 days of any change in address, other source of health care coverage or family size, or any change in income of more than 10%.

(b) The department may verify or audit a participant's total family income. The department may redetermine a participant's estimated total family income for the current year based on a change in the family's financial circumstances.

(6) **CONFIDENTIALITY OF PATIENT INFORMATION.** All personally identifiable information provided by or on behalf of a patient to the department shall remain confidential and may not be used for any purpose other than to determine program eligibility, patient liability and the payment of claims. Statistical analyses of program data may not reveal patient identity.

(7) **APPEAL.** A patient denied assistance under sub. (2) or a participant whose certification is revoked or not renewed under sub. (4) may request a hearing on that decision under ss. 227.44 to 227.50, Stats., by the department of administration's division of hearings and appeals. The request for a hearing shall be in writing and shall be sent to the division of hearings and appeals so that it is received there within 30 days after the date of the notice of denial, revocation or nonrenewal of certification.

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

History: Cr. Register, December, 1994, No. 468, eff. 1-1-95.

HFS 153.05 Provider approval. (1) COMPREHENSIVE HEMOPHILIA TREATMENT CENTERS. (a) *Condition.* 1. To be reimbursed by the program for blood products and supplies, including case management services, provided to program participants, a center treating hemophilia patients shall submit an application to the department and shall comply with the standards in s. HFS 153.08. Within 60 days after receiving a complete application for certification, the department shall either approve or deny the application. If the application is denied, the department shall give the applicant reasons, in writing, for the denial.

2. As part of its application for certification under par. (a), a hemophilia treatment center shall execute a written agreement with the department to be a comprehensive hemophilia treatment center and to receive state reimbursement. This agreement shall, unless terminated by either party, remain in full force and effect from the date of execution.

(b) *Border state treatment centers.* The department may approve a hemophilia treatment center in a state bordering on Wisconsin as a comprehensive hemophilia treatment center if the center is within 100 miles of the Wisconsin border, has a practice which includes providing blood products and supplies to Wisconsin residents and meets the requirements for certification specified in s. HFS 153.08. A border state treatment center is subject to the same rules and contractual agreements as comprehensive hemophilia treatment centers located in Wisconsin.

(c) *List of approved sources.* A comprehensive hemophilia treatment center shall, upon request of the department, furnish in writing the names and addresses of all vendors of blood products and supplies provided to participants in the hemophilia home care program.

(2) **OTHER PROVIDERS.** To receive reimbursement, a source approved by a comprehensive hemophilia treatment center shall either:

(a) Provide a copy of a signed agreement with the treatment center to provide blood products or supplies; or

(b) Be limited to reimbursement for provision of case management services.

History: Cr. Register, December, 1994, No. 468, eff. 1-1-95.

HFS 153.06 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 submission 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 instructions 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 12 months after the date that services for which the claim is made are provided, except that a claim may be submitted later if the department is notified within that 12 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 taken delivery of the blood products and supplies.

(3) PAYMENT. (a) The department shall establish allowable costs for blood products and supplies as a basis for reimbursing providers.

(b) Reimbursement may not be made for any cost of blood supplies and equipment payable under any other state or federal program or any grant or contract.

(c) Before submitting a claim to the hemophilia home care program, a provider shall seek payment for services provided to a participant from medicare, medical assistance or another health care plan if the participant 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 hemophilia home care 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 hemophilia home care 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) 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, December, 1994, No. 468, eff. 1-1-95; CR 04-051: cr. (3) (g) Register November 2004 No. 587, eff. 12-1-04.

HFS 153.07 Participant liability. (1) CALCULATION. A participant's liability to contribute toward the cost of treatment shall be calculated in accordance with subs. (2) to (4). If there are 2 or more participants in the same family, the family's liability shall be limited to the liability of one member of the family.

(2) INCOME DEDUCTIBLE. A participant 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 condition before the hemophilia home care 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) PARTICIPANT COINSURANCE. (a) A participant shall pay a coinsurance amount to cover part of the cost of blood products and home care supplies.

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

(c) The amount of a participant's coinsurance shall be related to family size and to family income rounded to the nearest whole dollar, in accordance with the schedule in Table 153.07.

(d) The amount that a patient pays in coinsurance annually may not exceed the following applicable percentage of the family's income, rounded to the nearest whole dollar:

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

(4) PARTICIPANT COPAYMENT. When a pharmacy directly bills the hemophilia home care program for a prescription received by a program participant, the participant is responsible for a \$7.50 copayment amount for each generic drug and a \$15.00 copayment amount for each brand name drug.

(5) ESTATE RECOVERY. (a) An heir or beneficiary of the estate of a participant or a participant'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 867.035, Stats. The criteria for granting waivers in s. HFS 108.02 (12) (b) shall apply to applications under this subsection. All of the procedures and rights in s. HFS 108.02 (12) (b) to (e) shall apply to this subsection.

(b) For purposes of applying s. HFS 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 participant or the deceased surviving spouse of a participant who received benefits that are subject to recovery under s. 49.682 or 867.035, 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 participant who received reimbursement under s. 49.685, Stats.; and
5. "Waiver applicant" means a beneficiary or heir of a decedent

dent who requests the department to waive an estate claim filed by the department pursuant to s. 49.682 or 867.035, Stats.

(c) The department may make adjustments to and settle estate claims filed under s. 49.682 or 867.035, Stats., to obtain the fullest amount practicable.

**TABLE 153.07
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	3	2	1	0	0	0	0	0	0	0
15,001-20,000	4	3	2	1	0	0	0	0	0	0
20,001-25,000	5	4	3	2	1	0	0	0	0	0
25,001-30,000	14	5	4	3	2	1	0	0	0	0
30,001-35,000	17	13	5	4	3	2	1	0	0	0
35,001-40,000	20	16	6	5	4	3	2	1	0	0
40,001-45,000	24	19	15	6	5	4	3	2	1	0
45,001-50,000	29	24	20	17	6	5	4	3	2	1
50,001-55,000	34	29	25	21	7	6	5	4	3	2
55,001-60,000	39	34	29	25	23	7	6	5	4	3
60,001-65,000	44	39	34	30	28	25	7	6	5	4
65,001-70,000	49	44	39	35	32	29	8	7	6	5
70,001-75,000	55	49	44	40	37	34	32	8	7	6
75,001-80,000	61	55	50	46	43	40	37	35	7	6
80,001-85,000	67	61	56	52	49	46	43	40	7	6
85,001-90,000	74	68	63	59	56	53	50	47	45	6
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. (5), eff. 11-1-95; cr. (5), Register, April, 1996, No. 484, eff. 5-1-96; CR 02-070: am. (4) Register October 2002 No. 562, eff. 11-1-02; CR 04-051: am. (2) and (4), cr. (2) (f) to (h) Register November 2004 No. 587, eff. 12-1-04.

HFS 153.08 Standards for comprehensive treatment centers. (1) COMPLIANCE. A comprehensive hemophilia treatment center shall comply with the standards in this section.

(2) STAFFING. A comprehensive hemophilia treatment center shall have the following staff:

(a) *A physician director.* 1. The physician director shall be a physician licensed in Wisconsin and certified by the American board of internal medicine or American board of pediatrics or equivalent certifying body, with specialized training in hematology.

2. The responsibilities of the physician director shall include organizing and coordinating the administrative functions of the comprehensive hemophilia treatment center; delegating duties 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 records and submitting any required reports to the department; providing medical supervision; and developing written home care training policies and procedures and supervising their implementation.

(b) *Specialists on staff.* 1. The center shall have a multidisciplinary staff which shall include a hematologist, internist, pediatrician, orthopedic surgeon, oral surgeon or dentist, radiologist, physical therapist, registered nurse, social worker and financial counselor.

2. The multidisciplinary staff and the physician director shall develop patient maintenance programs and shall provide services, including the training of patients in home care, access to the neces-

sary psychosocial evaluations and referrals and assistance in securing reimbursement.

(c) *Specialists available.* The center shall arrange for the availability of a nutritionist, psychiatrist or psychologist, and an educational, vocational or rehabilitation counselor, as needed.

(3) FACILITIES. A comprehensive hemophilia treatment center shall be approved under ss. 50.32 to 50.39, Stats., and ch. HFS 124, and shall meet all of the requirements of s. 1861 (e) of the Social Security Act of 1935, as amended, including having an agreement to participate in the federal Medicare program.

(4) SERVICES. A comprehensive hemophilia treatment center shall provide all of the following:

(a) Training in home care self-infusion techniques for hemophilia patients and their parents or guardians. This training shall include instructing the patient and whoever assists the patient in how to use the products, equipment and supplies necessary for home care treatment;

(b) A written maintenance program for each home care hemophilia patient. The maintenance program shall be reviewed by the multidisciplinary staff every 6 months and shall accompany the patient in inter-facility transfer;

(c) Blood products and home care supplies, including plasma factor concentrate, cryoprecipitate and fresh frozen plasma. Blood products and supplies may be provided directly or under agreement;

(d) Emergency medical services 24-hours a day and 7 days a week for home care patients who need medical services; and

(e) Services of a laboratory certified under ch. HSS 165 capable of testing for plasma factor deficiency and for the presence of inhibitors to one or more clotting factors. Laboratory services may be provided directly or under agreement.

(5) AVAILABILITY OF A GRIEVANCE MECHANISM FOR PATIENTS. A center shall have a written grievance procedure and shall provide a copy to each patient. A patient shall be permitted to file a grievance.

(6) DOCUMENTATION. All comprehensive hemophilia treatment centers and other providers shall maintain the following records:

(a) Agreements with individual patients regarding home care, as described under s. HFS 153.03 (3);

(b) Agreements with persons or organizations for payment which may be made, directly or indirectly, by the hemophilia home care program;

(c) Billings and records which are the subject of the billings, as are necessary to disclose fully the nature and extent of the billings; and

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

History: Cr. Register, December, 1994, No. 468, eff. 1-1-95.