

1. The applicant shall demonstrate that it has at least one year of experience in the management of bleeding episodes, with at least one year of experience with home treatment of bleeding episodes associated with hemophilia, addressing the needs of at least 10 individuals diagnosed with hemophilia;

2. The applicant shall demonstrate its ability to actively participate in both Class I and Class II drug recalls, both in terms of receiving or obtaining information from multiple sources and disseminating information to clients, including covered persons to whom services have been rendered;

3. The applicant shall have a policy of accepting assignment of benefits when the applicant is not under contract with a carrier or other payer and assignment of benefits is an available option;

4. The applicant shall have knowledge and experience in third party billing of carriers, Medicare, Medicaid and other payers, and in obtaining successful reimbursement;

i. The applicant may rely upon the demonstrated experience of a billing agent under contract with the applicant;

ii. The applicant's knowledge and experience shall include coordination of benefits between and among government programs and other forms of health benefits plans and self-funded agreements;

5. The applicant shall have a policy against presentation of any bill to or the collection of any monies from a covered person of a carrier with which the applicant has an agreement for the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia, except as may be appropriate to collect the copayments, deductibles or coinsurance amounts the covered person is required to pay under the terms of his or her health benefits plan(s), and the applicant shall agree not to hold such a covered person liable for any monies (other than copayments, deductibles or coinsurance amounts) for which the carrier is responsible pursuant to the terms of the covered person's health benefits plan(s) and the agreement between the carrier and the applicant, regardless of whether the applicant believes the carrier has fulfilled its obligations;

6. At a minimum, the applicant's written policy regarding discontinuation of services shall specify that:

i. The applicant shall continue to provide services and supplies to an individual, notwithstanding that the individual ceases to be able to assure payment for some or all of the costs of services and supplies, until the individual obtains an alternate source of services and supplies, up to at least four months after the occurrence of one of the following: loss of coverage under a health benefits plan; ineligibility for benefits or exhaustion of benefits under a health benefits plan; a requirement to satisfy deductibles, coinsurance, co-payments or other

cost-sharing requirements or liability for excess costs or excluded items of expense;

ii. The applicant shall continue to provide services and supplies to an individual in the event the applicant and the covered person's carrier terminate the agreement which includes among its terms, the provision of services and supplies to a covered person for home treatment of bleeding episodes associated with hemophilia, for at least four months, or until the individual obtains an alternate source of services and supplies, whichever occurs first, except when termination is the result of the health care provider losing designation as a home treatment health care provider, or for breach, fraud or a determination by the carrier's medical director that the health care provider is an imminent danger to one or more covered persons, whether such breach, fraud or imminent harm is related to the provision of services or supplies for home treatment of bleeding episodes associated with hemophilia, or other services and supplies for which the carrier and health care provider have an agreement;

iii. The applicant shall refer the individual to the Hemophilia Association of New Jersey to obtain help and information about resources as soon as possible following the occurrence of the situations described in (e)6i or ii above; and

iv. The applicant shall provide the policies and procedures to a covered person in writing prior to the applicant's initial provision of services to the covered person, and to covered persons and carriers upon request; and

7. The applicant's staff credentialing program shall require primary source verification of licenses and permits, and shall require recredentialing at least every three years.

(f) If, in the Department's opinion, the applicant does not meet the standards for designation, the Department shall provide a written notice of that determination, with an explanation therefor, to the applicant.

1. An applicant may appeal the Department's determination, and request a hearing in accordance with the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, but shall not be entitled to enter into any agreement with a carrier for the provision of home treatment for bleeding episodes associated with hemophilia until and unless a final decision in favor of the applicant has been obtained.

2. An applicant shall have the right to make a new application consistent with the requirements of N.J.A.C. 8:38C-2.4 without regard to whether the applicant has requested a hearing and the request has been granted.

(g) If, in the Department's opinion, an applicant meets the standards for designation, the Department shall provide written notice to the applicant, confirming the applicant's designation.

8:38C-2.9 Renewal of designation as a health care provider of home treatment of bleeding episodes associated with hemophilia

(a) Designation as a health care provider for home treatments of bleeding episodes associated with hemophilia shall be effective until the end of the third September following the date of the health care provider's most recent designation, unless there is a change in the status of the designated health care provider that makes the health care provider ineligible for the designation at an earlier date.

(b) In order to avoid loss of designation, a designated health care provider shall submit an application to maintain its designation at least 30 days prior to the date on which its designation is scheduled to expire.

(c) A designated health care provider shall comply with the requirements of N.J.A.C. 8:38C-2.4 and 2.5, or its renewal application shall be considered incomplete.

(d) The Department shall apply the same standards to renewal applications for designation as it applies to initial applications for designation.

(e) In the event that a designation expires due to inaction or late action by the designated health care provider or any of its agents, the health care provider shall not have a right to request a hearing on the loss of the designation, and the health care provider and carrier shall end their relationship regarding the provision of services and supplies for the home treatment of hemophilia in accordance with N.J.A.C. 8:38C-2.10.

8:38C-2.10 Loss of designation as a home treatment provider

(a) A designated health care provider may lose its designation as the result of one or more of the following:

1. Revocation, suspension or surrender of a registration with respect to a health care service firm;
2. Revocation, suspension or surrender of a license with respect to health care providers;
3. Revocation, suspension or surrender of a pharmacy permit, including a specialized permit, unless the specialized permit was surrendered in order to be replaced by another form of pharmacy permit;
4. Failure of the health care provider to meet one of the standards on which designation was originally issued, other than maintenance by the health care provider and/or its subcontractors of registration(s), license(s) or permit(s) in good standing;

5. Failure of the health care provider to submit a timely request for renewal of its designation; or

6. Failure of a designated health care provider to report material changes in accordance with N.J.A.C. 8:38C-2.12.

(b) With respect to a revocation, suspension or surrender of a registration, license or permit, as set forth in (a)1, 2 and 3 above, loss of the health care provider's designation shall be immediate upon occurrence of the event, and shall not be contingent upon notification, verbal or written, being sent from the Department.

(c) When a designated health care provider has failed to timely submit an application to renew its designation, and the loss of designation results solely on that basis, the loss of designation shall be effective as of October 1 in the designation renewal year for that health care provider, and shall not be contingent upon notification, verbal or written, being sent from the Department to the health care provider.

(d) Except as (b) and (c) above applies, loss of designation shall be effective upon the date that written notice of the loss of designation is sent by the Department to the designated health care provider.

(e) In the event that a designated health care provider loses its designation, the health care provider shall be entitled to request a hearing regarding the loss of the designation in accordance with the provisions of the Administrative Procedures Act, N.J.S.A. 52:14B-1 et seq., and the Uniform Administrative Procedure Rules, N.J.A.C. 1:1, except when loss of the designation results from (a)1, 2 or 3 above.

(f) Upon receipt of notice of loss of its designation, a health care provider shall notify all of the carriers with which it has an agreement to provide home treatment for bleeding episodes associated with hemophilia of the loss of the designation, and all of the covered persons to whom such services have been or currently are being rendered, and shall cease offering home treatment services, at a minimum, in accordance with N.J.A.C. 8:38C-2.11.

1. Verbal notification shall be acceptable for purposes of expediency; however, the health care provider shall send written notification of the loss of designation to carriers and covered persons.

(g) No health care provider shall advertise or otherwise hold itself out to any carrier, covered person or any other person as a designated health care provider in any medium following the loss of designation.

8:38C-2.11 Cessation of services

(a) When loss of designation results from a situation set forth at N.J.A.C. 8:38C-2.10(a)1, 2 or 3, the health care provider shall cease providing home treatment for bleeding episodes associated with hemophilia immediately.