

**CHAPTER 24C
MANAGED CARE PLANS**

Authority

N.J.S.A. 26:2S-7.1 through 7.3 and 26:2S-10.3.

Source and Effective Date

R.2003 d.456, effective December 1, 2003 (operative May 29, 2004).
See: 35 N.J.R. 355(a), 35 N.J.R. 5378(a).

Chapter Expiration Date

In accordance with N.J.S.A. 52:14B-5.1c, Chapter 24C, Managed Care Plans, expires on May 30, 2009. See: 40 N.J.R. 6922(a).

Chapter Historical Note

Chapter 38C, Managed Care Plans, was adopted as R.2003 d.456, effective December 1, 2003 (operative May 29, 2004). See: Source and Effective Date.

Subchapter 2, Designation of Hemophilia Health Care Providers, and Subchapter 3, Benefits or Coverage of Service for Hemophilia Treatment, were adopted as new rules by R.2004 d.437, effective December 6, 2004. See: 35 N.J.R. 4963(a), 36 N.J.R. 5337(b).

Pursuant to Reorganization Plan No. 005-2005, Chapter 38C of Title 8, Managed Care Plans, was recodified as Chapter 24C of Title 11, effective October 6, 2006. See: 37 N.J.R. 2737(a), 38 N.J.R. 4721(a).

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SUBCHAPTER 1. PHYSICIAN CREDENTIALING

11:24C-1.1 Scope and purpose

(a) This subchapter applies to all carriers offering managed care plans, and the agents that carriers may use for purposes of credentialing or recredentialing physicians on behalf of the carriers.

(b) This subchapter establishes a credentialing and recredentialing form pursuant to the authority set forth at N.J.S.A. 26:2S-7.1, to be accepted by all carriers offering managed care plans for the purpose of credentialing and recredentialing physicians who seek to participate in a carrier's provider network, including physicians employed by hospitals or other health care facilities.

(c) This subchapter establishes alternative, acceptable means by which carriers offering managed care plans may credential and recredential physicians.

11:24C-1.2 Definitions

The following words and terms, when used in this subchapter, shall have the following meanings, unless the context clearly indicates otherwise.

“Carrier” means an insurance company authorized to transact the business of insurance in this State and doing a health insurance business in accordance with N.J.S.A. 17B:17-1 et seq., a hospital service corporation authorized to do business pursuant to N.J.S.A. 17:48-1 et seq., a medical service corporation authorized to do business pursuant to N.J.S.A. 17:48A-1 et seq., a health service corporation authorized to do business pursuant to N.J.S.A. 17:48E-1 et seq., or a health maintenance organization authorized to transact business pursuant to N.J.S.A. 26:2J-1 et seq.

“Credentialing” means the process of collecting and validating the professional qualifications of a physician and evaluating those qualifications against a carrier’s standards of qualifications for participation in the carrier’s health care provider network for the carrier’s managed care plans.

“Credentials data” means information, attachments, or answers to questions required by a carrier to complete the credentialing or recredentialing of a physician.

“Department” means the Department of Banking and Insurance.

“Managed care plan” means a health benefits plan (as health benefits plan is defined at N.J.S.A. 26:2S-1 et seq.), that integrates the financing and delivery of appropriate health care services to covered persons by arrangement with participating providers, who are selected to participate on the basis of explicit standards, to furnish a comprehensive set of health care services and financial incentives for covered persons to use the participating providers and procedures provided for in the plan.

“New Jersey Universal Physician Application” means the form developed by the Department and set forth in the Appendix to this subchapter as Exhibit 1.

“New Jersey Physician Recredentialing Application” means the form developed by the Department and set forth in the Appendix to this subchapter as Exhibit 2.

“Physician” means a person who is licensed by the State Board of Medical Examiners in accordance with the provisions of Title 45 of the Revised Statutes.

“Prepopulate” means to pre-print requested information derived from a database on a form prior to distributing the document to the target population for review, completion and correction, as appropriate.

“Recredentialing” means the process by which a physician’s information related to his or her credentials is updated and re-verified for purposes of determining whether the physician shall continue to participate in the carrier’s health care provider network.

11:24C-1.3 Credentialing standards

(a) Carriers that offer managed care plans shall accept the New Jersey Universal Physician Application, as set forth in Exhibit 1 of the Appendix to this subchapter and incorporated herein by reference, for the purpose of credentialing physicians who seek to participate in the carrier’s network(s).

(b) Carriers that offer managed care plans may continue to use another physician credentialing application form but shall inform physicians that a downloadable version of the New Jersey Universal Physician Application is available through the Department’s website www.state.nj.us/dobi or indicate

where physicians may obtain a hard copy of the New Jersey Universal Physician Application.

1. When a physician makes an oral inquiry concerning a credentialing application, then a carrier’s response concerning the availability of the New Jersey Universal Physician Application may be oral; however, any mailing of the carrier’s credentialing application form as a follow-up to the oral request shall include a written notice referencing the availability of the New Jersey Universal Physician Application, and information on how to access the application.

2. When a physician inquires in writing concerning a credentialing application, then the carrier shall include with its credentialing application form a written notice referencing the availability of the New Jersey Universal Physician Application and information on how to access the application.

3. Carriers shall not require providers to use the carrier’s credentialing form in lieu of the New Jersey Universal Physician Application in order to participate in the carrier’s network(s).

(c) As an alternative to the requirements set forth in (a) or (b) above, carriers may access information about a physician from a recognized, national credentialing database, data bank or repository of health care providers subject to the following conditions:

1. Carriers shall not require providers to use a national database in lieu of one of the forms set forth in (a) or (b) in order to participate in the carrier’s network(s).

2. The database shall include credentialing data commonly requested by carriers, hospitals and other health care entities and credentials verification organizations for purposes of credentialing and shall minimize the need for the collection of additional credentials data.

3. The database shall be accessible to physicians at no cost.

4. The database shall be accessible to physicians through multiple methods including electronic and paper formats.

5. The database shall incorporate adequate security features to ensure that credentials data submitted by physicians and provided for review shall remain confidential, as provided by law, and shall not be released without the written consent of the physician.

i. An electronic signature or other similar alternative that acknowledges the physician’s consent to the release of credentials data shall satisfy the written consent requirement.

6. The database shall, at a minimum, collect the following physician credentialing information:

i. Education and degrees;

(b) Carriers with an aggregate enrollment of 50,000 covered persons or more in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least two designated health care providers, unless there are fewer than two designated health care providers designated in New Jersey, in which event, the carrier shall arrange for the provision of home treatment services with the lone designated health care provider, regardless of the carrier's enrollment.

(c) Carriers with aggregate enrollment of fewer than 50,000 covered persons in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least one designated health care provider.

(d) Nothing in this subchapter shall be construed to limit or eliminate any carrier's obligation to credential and re-credential health care providers with which the carrier arranges for the provision of home treatment of hemophilia with respect to such treatments or any other services that the health care provider may render to a carrier's covered persons.

11:24C-2.4 Application: procedure to become a designated health care provider of home treatment services

(a) A person seeking to become a designated health care provider shall submit an application to the Department by February 4, 2005, or during the month of September in each calendar year thereafter.

(b) A person seeking to become a designated health care provider shall submit an original and at least one copy of the application to the Department in accordance with (a) above to:

Attn: Hemophilia Treatment Designation
Application
Valuation Bureau
NJ Department of Banking and Insurance
20 West State Street
PO Box 325
Trenton, NJ 08625-0325

(c) The applicant shall comply with "Instructions and Checklist" set forth in the Appendix to this subchapter, incorporated herein by reference, when submitting the application, in addition to the following:

1. The application shall include notarized copies of all current registrations, licenses and permits held by the applicant that have been issued by a New Jersey regulatory agency; and
2. The application shall include a certification signed by an officer of the applicant company, which shall include:

- i. A statement that the information contained in the application is accurate and true to the knowledge of the signatory;

- ii. A statement that the signatory is authorized to make the certification and submit legal documents on behalf of the applicant company; and

- iii. The signatory's printed title, printed name, and the printed date the certification was signed.

(d) Applicants may submit copies of the application in paper or electronic format, or both, subject to the requirement that at least one copy of the application be in paper format, and that the original and copy(ies) be set forth in the same order and contain the same content.

(e) The applicant shall submit a response to each of the requirements set forth in N.J.A.C. 11:24C-2.5.

11:24C-2.5 Application: demonstration of qualifications for becoming a designated health care provider of home treatment services

(a) The applicant shall submit copies of all registrations, licenses and permits issued to the applicant by the State of New Jersey pursuant to Title 45 and Title 26 of the New Jersey Statutes, and shall demonstrate that the applicant is in good standing with respect to such licenses, registrations and permits.

(b) The applicant shall demonstrate each of the following:

1. Its ability to provide services and to maintain and provide all brands of blood product, including low, medium and high-assay range levels to execute treatment regimens as prescribed by a covered person's attending physician, without making substitutions of blood products except upon prior approval of the attending physician;

2. Its ability to maintain and provide all needed ancillary supplies for the treatment or prevention of bleeding episodes, including blood infusion equipment and cold compression packs;

3. Its ability to deliver any and all prescribed blood products, medications, nursing services and blood infusion equipment within three hours after receipt of a prescription for a covered person's emergent situation, 24-hours per day, seven days per week;

4. Its experience in management of bleeding disorders;

- i. Experience may be demonstrated by performance of services in other states;

- ii. Experience shall include, at a minimum, the provision of services for the home treatment of hemophilia;

5. Its ability to perform appropriate recordkeeping and maintain appropriate records, consistent with the medical and health record standards for home health agencies at N.J.A.C. 8:42;

6. Its ability to monitor and actively participate in product recall and notification systems, both drug-related and otherwise;

7. Its ability to assist covered persons in obtaining third party reimbursements when necessary or appropriate;

8. Its ability to comply with proper removal and disposal of hazardous waste, in accordance with the standards applicable to home health agencies at N.J.A.C. 8:42;

9. That it has written policies and procedures regarding the discontinuation of services when an individual is no longer able to pay for or assure payment of the costs associated with the services rendered by the applicant;

i. The applicant shall submit its written policies and procedures to the Department;

ii. The applicant's written policies and procedures shall address the issue of dissemination of the policies and procedures to covered persons upon request;

10. Its ability to disseminate information to covered persons regarding probable costs for services that the applicant may provide that are not covered by a covered person's health benefits plan; and

11. Its program for credentialing and recredentialing the health care practitioners or other health care providers contracted with or employed by the applicant.

11:24C-2.6 Application: process for incomplete applications

(a) The Department shall review applications to determine whether they are complete.

(b) If the Department determines that an application is incomplete, the Department shall provide a written notice to the applicant of this determination with an explanation of why the application is incomplete, and shall return all documentation and electronic files submitted with the incomplete applications to the applicant.

(c) Within 45 days after the Department sends notice to the applicant that the application is incomplete, an applicant may resubmit the application with the information necessary to make the application complete. The Department shall not consider perfected applications outside of the specified 45-day time frame, nor shall the Department retain the perfected application.

1. The Department shall return the application to the applicant only if the resubmitted application includes prepaid return mail packaging.

11:24C-2.7 Application: complete applications and additional information

(a) The Department may request additional information from the applicant notwithstanding a determination that the

application is complete, if the Department believes such information is relevant to the Department's review of the application.

(b) The Department may consider additional information received from the applicant or from other sources if the Department believes the information is relevant to the Department's review of the application, notwithstanding a determination that the application is complete.

11:24C-2.8 Department review: minimum standards for designation

(a) An applicant shall possess a pharmacy permit issued by the New Jersey Board of Pharmacy pursuant to N.J.A.C. 13:39-4, which may be a specialized permit issued in accordance with N.J.A.C. 13:39-4.16.

1. With respect to the applicant's pharmacy permit, at least some portion of the applicant's pharmacy services shall be dedicated to the provision of services and supplies specifically for the treatment of hemophilia.

(b) If the applicant's blood products include cryoprecipitate, the applicant shall possess a blood bank license issued by the Department in accordance with N.J.S.A. 26:2A-2 et seq., and rules promulgated pursuant thereto, specifically N.J.A.C. 8:8.

(c) An applicant shall be either a health care service firm registered with the New Jersey Department of Law and Public Safety, Division of Consumer Affairs, in accordance with N.J.A.C. 13:45B-14, or a health care provider licensed pursuant to N.J.S.A. 26:2H-1 et seq., or the applicant shall have a contract with one or more other persons having such a registration or license that has the ability to assure the provision of in-home nursing services when needed by a covered person.

(d) The applicant shall be in good standing with respect to all of its registrations, licenses and permits, as shall be the pharmacists employed by or contracted with the applicant, and other persons, if any, contracted with the applicant in accordance with (c) above.

(e) The applicant shall demonstrate to the Department's satisfaction that the applicant meets the requirements of N.J.A.C. 11:24C-2.5(b), including, but not limited to, the following:

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. 11:24C-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.

11:24C-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. 11:24C-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. 11:24C-2.10.

Public Notice: Legislative and Regulatory Affairs; Hemophilia Home Care Provider Designation: designation of providers eligible to provide home treatment services for bleeding episodes associated with Hemophilia, and correction to duration of designation statement for all designees.

See: 38 N.J.R. 1602(b).

11:24C-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. 11:24C-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. 11:24C-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.

11:24C-2.11 Cessation of services

(a) When loss of designation results from a situation set forth at N.J.A.C. 11:24C-2.10(a)1, 2 or 3, the health care provider shall cease providing home treatment for bleeding episodes associated with hemophilia immediately.

1. The health care provider shall coordinate with the carrier to arrange for another designated health care provider, whether or not in the carrier's network, to provide services to covered persons, prior to withdrawal of any nursing services or supplies from the home of any covered person.

(b) When the loss of designation results from any other reason not specified in N.J.A.C. 11:24C-2.10(a)1, 2 or 3, the health care provider shall continue to provide services and supplies to covered persons that have been receiving services and supplies from the health care provider, at the option of the covered person, for four months following the loss of designation, or until the covered person is able to obtain services and supplies from another designated health care provider, whichever occurs first, but shall not provide services to any other covered person for the home treatment of bleeding episodes associated with hemophilia.

1. The health care provider shall coordinate with the carrier to arrange for another designated health care provider, whether or not in the carrier's network at that time, to provide services to covered persons.

(c) A health care provider that continues to provide services for home treatment of bleeding episodes associated with hemophilia following loss of its designation shall continue to abide by all aspects of its agreement with the carrier for the provision of such services, except those that would otherwise cause it to be in violation of this section.

(d) A health care provider shall comply with the requirements of (a) or (b) above, as appropriate to the health care provider's situation, notwithstanding that the health care provider may have requested, and the Department may have granted the request, for a hearing.

11:24C-2.12 Obligation of designated health care provider to notify Department of material changes

(a) Every designated health care provider shall have an affirmative obligation to provide notice to the Department about any material change in the information provided to the Department on which the health care provider's designation was based.

1. Health care providers shall report changes in writing at least 30 days prior to the expected date of change, or within no more than 10 days following the date of a change that was unexpected.

2. In providing notice of a change, expected or unexpected, a health care provider shall specify what action it plans to take to assure that it remains in compliance or comes back into compliance with the standards for designation.

i. With respect to providing information regarding a plan to bring the health care provider back into compliance with the standards for designation, the plan shall be structured to assure that the health care provider is in compliance within no more than 45 days following the material change.

3. If the plan of correction is acceptable and implemented, no loss of designation will occur, except when the material change is revocation or surrender of a license,

permit or registration, or a suspension that cannot be remedied in 45 days.

(b) Failure of a designated health care provider to submit a notice of material change to the Department shall be grounds for the Department to revoke the health care provider's designation.

11:24C-2.13 Designation list

(a) The Department shall maintain a written list of designated home treatment health care providers, which shall be made available to any person upon request made to the Department, and shall be maintained on the Department's Internet site.

(b) The list for general distribution, whether in paper or electronic format, shall be updated as frequently as necessary, but shall be published as a public notice in the New Jersey Register no more frequently than annually.

11:24C-2.14 Effect of Bulletin OMC 2001-04

(a) Those persons identified in Bulletin OMC 2001-04 as acceptable providers of services for home treatment of bleeding episodes associated with hemophilia for purposes of carriers making agreements and fulfilling their obligations pursuant to N.J.S.A. 26:2S-10.1 prior to adoption of this subchapter, shall continue to be considered acceptable until February 5, 2005, except as (b) below applies.

(b) A person identified in Bulletin OMC 2001-04 as an acceptable provider of services for home treatment of bleeding episodes associated with hemophilia that submits an application for designation by February 4, 2005 shall continue to be considered acceptable for purposes of carriers making agreements to fulfill their obligations pursuant to N.J.S.A. 26:2S-10.1 until such time as it is determined that the person does not meet the requirements for designation.

(c) A person identified in Bulletin OMC 2001-04 as an acceptable provider of services for home treatment of bleeding episodes associated with hemophilia shall comply with N.J.A.C. 11:24C-2.10 and 2.11 if the person:

1. Elects not to submit an application for designation;
2. Submits an application that is determined incomplete and does not resubmit the application; or
3. Submits a complete application but receives notice that it will not be designated by the Department.

(d) A carrier that has an agreement with a person identified as an acceptable provider of services for home treatment of bleeding episodes associated with hemophilia that does not become designated shall comply with N.J.A.C. 11:24C-3.8.

APPENDIX

APPLICATION FOR DESIGNATION AS A HEMOPHILIA HOME TREATMENT HEALTH CARE PROVIDER—INSTRUCTIONS AND CHECKLISTS

INSTRUCTIONS: New and renewal applications should be submitted in September each year; applications submitted at other times will not be considered.* Applications must be complete. If a question or requirement does not apply to an applicant's particular circumstances, the applicant must so indicate that, rather than ignoring the question or requirement.

PART A: Form

The following checklist is provided to help applicants complete their applications properly. However, completion of the checklist shall not result in an application being deemed complete or approved. Applicants shall refer to N.J.A.C. 11:24C-2 for details.

- The application is being submitted in duplicate
- At least one copy of the application is being submitted in paper format
- The paper copy is being submitted in one or more two-or three-ring binders
- Binders are labeled to indicate the number of binders included in the submission
- Disks, if any, are labeled to indicate the number of disks included in the submission
- The application is being sent to:
 - Hemophilia Treatment Designation Application
 - Valuation Bureau
 - NJ Department of Banking and Insurance
 - PO Box 325
 - Trenton, NJ 08625-0325
 (if by other than U.S. Postal, 20 West State Street substitutes for PO Box 325)
- All copies of registrations, licenses and permits are enclosed
- The application includes a certification signed by an officer of the applicant company
- The officer's name and title is printed in the certification
- The application contains a Table of Contents
- The application is tabbed consistent with the Table of Contents
- The pages of the application are numbered, and pages intentionally left blank are so indicated

PART B: Content

The following checklist is provided to help applicants complete their applications properly. However, completion of the checklist shall not result in an application being deemed complete or approved. Applicants shall refer to N.J.A.C. 11:24C-2 for details.

- Copies of all registrations, licenses and permits issued to the applicant by the State of New Jersey pursuant to Titles 45 and 26 of the New Jersey statutes or N.J.A.C. 13:45B-14 are enclosed
- The application includes evidence of the applicant's ability to provide all blood products, including low, medium and high-assay levels
- The application includes evidence of the applicant's ability to provide all needed ancillary supplies for the treatment of bleeding episodes, including blood infusion equipment and cold compression packs
- The application includes evidence of the applicant's ability to deliver prescribed services and supplies within three hours after receipt of a prescription, 24 hours per day, year-round
- The application includes evidence of the applicant's experience in management of bleeding disorders
- The application includes evidence of the applicant's ability to perform appropriate recordkeeping and to maintain appropriate records
- The application includes evidence of the applicant's ability to monitor and participate in product recall notification systems
- The application includes evidence of the applicant's willingness to assist, and experience in assisting, individual clients in addressing third party reimbursement issues
- The application includes evidence of the applicant's compliance with safe handling standards with respect to biological products, including removal and disposal of hazardous waste products
- The application includes evidence of the applicant's policies and procedures regarding discontinuation of services and supplies when individual clients are no longer able to assure payment for services and supplies, and willingness to share these policies and procedures with individual clients and carriers
- The application includes evidence of the applicant's ability and willingness to disseminate information to individual clients regarding the applicant's schedule(s) of costs, including projections of probable costs to individual clients based on an individual client's health benefits plan(s)

[] The application includes evidence of the applicant's credentialing and recredentialing program for health care practitioners and other health care providers employed by or with which the applicant contracts for services and supplies.

* Applications will be accepted initially by February 4, 2005.

SUBCHAPTER 3. BENEFITS OR COVERAGE OF SERVICE FOR HEMOPHILIA TREATMENT

11:24C-3.1 Scope and applicability

(a) This subchapter shall apply to all carriers offering health benefits plans that are managed care plans, and to all such health benefits plans offered by a carrier.

(b) This subchapter applies only with respect to the provision of services for treatment of hemophilia, and does not have a direct bearing on the relationship between a carrier and a health care provider for the provision of any other services or supplies.

(c) Nothing in this subchapter shall be construed to limit the obligation of any carrier to comply with other laws regarding the provision of benefits or services for the treatment of hemophilia.

11:24C-3.2 Definitions

For the purposes of this subchapter, the words and terms set forth below shall have the following meanings, unless the context clearly indicates otherwise.

"Carrier" means an insurance company authorized to transact the business of insurance in this State and doing a health insurance business in accordance with N.J.S.A. 17B:17-1 et seq., a hospital service corporation authorized to do business pursuant to N.J.S.A. 17:48-1 et seq., a medical service corporation authorized to do business pursuant to N.J.S.A. 17:48A-1 et seq., a health service corporation authorized to do business pursuant to N.J.S.A. 17:48E-1 et seq., or a health maintenance organization authorized to do business pursuant to N.J.S.A. 26:2J-1 et seq.

"Covered person" means the natural person on whose behalf a carrier is obligated to pay benefits or provide health care services pursuant to the health benefits plan.

"Department" means the New Jersey Department of Banking and Insurance.

"Designation" or "designated" means that a health care provider has been approved by the Department to contract with carriers for the purposes of rendering service for the home treatment of bleeding episodes associated with hemophilia.

"Health benefits plan" means a policy or contract for the payment of benefits for hospital and medical expenses or the provision of hospital and medical services, that is delivered or issued for delivery in this State by a carrier. The term "health benefits plan" specifically includes:

1. Medicare supplement coverage and risk contracts for the provision of health care services covered by Medicare to the extent that State regulation of such contracts or policies is not otherwise preempted by Federal law; and
2. Any other policy or contract not otherwise specifically excluded by statute or this definition.

The term "health benefits plan" specifically excludes:

1. Accident only policies;
2. Credit health policies;
3. Disability income policies;
4. Long-term care policies;
5. TRICARE/CHAMPUS coverage, and supplements thereto;
6. Hospital confinement indemnity coverage;
7. Coverage arising out of a workers' compensation law or similar such law;
8. Automobile medical payment insurance or personal injury protection insurance issued pursuant to N.J.S.A. 39:6A-1 et seq.; and
9. Coverage for medical expenses contained in a liability insurance policy.

"Health care provider" means a person licensed to deliver one or more health care services pursuant to Title 45 or Title 26 of the New Jersey Statutes, or a health care service firm as that term is defined at N.J.A.C. 13:45B-14.2.

"Managed care plan" means a health benefits plan that integrates the financing and delivery of appropriate health care services to covered persons by agreement with participating health care providers, who are selected to participate on the basis of explicit standards, to furnish a comprehensive set of health care services and financial incentives for covered persons to use the participating health care providers and procedures set forth in the plan.

"Person" means both legal and natural person except as otherwise specified.

"State-recognized outpatient regional hemophilia care center" means a health care facility participating in the Federally funded hemophilia treatment center network, as determined by the United States Department of Health and Human Services, that is located within New Jersey's geographic borders, without regard to the hemophilia treatment center's Federally designated region.

11:24C-3.3 Carrier's obligation to provide benefits or services for the home treatment of bleeding episodes associated with hemophilia

(a) Every carrier shall provide for, in its managed care plans, in-network benefits or services for the home treatment of bleeding episodes associated with hemophilia.

(b) No carrier shall arrange with any person for the provision of home treatment of bleeding episodes associated with hemophilia unless that person shall be a designated provider of such services, nor shall a carrier refer any covered person or cause a covered person to be referred to a person that is not a designated health care provider of services and supplies for the home treatment of bleeding episodes associated with hemophilia.

(c) Carriers with an aggregate enrollment of 50,000 covered persons or more in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least two designated health care providers, unless there are fewer than two designated health care providers designated in New Jersey, in which event, the carrier shall arrange for the provision of home treatment services with the lone designated health care provider, regardless of the carrier's enrollment.

(d) Carriers with aggregate enrollment of fewer than 50,000 covered persons in managed care plans shall arrange for the provision of home treatment of bleeding episodes associated with hemophilia with at least one designated health care provider.

(e) Nothing in this subchapter shall be construed to limit the obligation of a carrier to provide out-of-network benefits for home treatment services accessed at the option of the covered person through a health care provider that is not designated, when the managed care plan has an out-of-network benefits component.

(f) Nothing in this subchapter shall be construed to limit the obligation of a carrier to provide benefits or services on an in-network basis when a covered person accesses home treatment services from a health care provider, designated or not, because the carrier fails to have an agreement with a designated health care provider to provide services for the home treatment of bleeding episodes associated with hemophilia to the covered person at the time that such services are prescribed.

11:24C-3.4 Loss of designated status

(a) When a designated health care provider with which the carrier has arranged for the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia loses designation, the carrier shall not continue to refer covered persons to the services and supplies of that health care provider for home treatment of bleeding episodes associated with hemophilia.

(b) With respect to covered persons that have been receiving services and supplies from a health care provider that has lost its designation, the carrier shall continue to provide services or benefits to or on behalf of the covered person at an in-network level for home treatment services and supplies, until such time as arrangements are made for the covered person to receive home treatment services and supplies from another in-network designated health care provider, or for four months following the date of the loss of designation, whichever occurs first.

1. Notwithstanding (b) above, the carrier shall not be required to continue to provide services or benefits to a covered person at an in-network level when the health care provider's loss of designation is the result of revocation or surrender of a license, permit or registration, or is the result of a suspension of a license, permit or registration that cannot be corrected by reinstatement within 45 days following the date of the suspension, except as may be necessary for the carrier and health care provider to transition the covered person's care to another designated health care provider, consistent with N.J.A.C. 11:24C-2.11(a).

(c) Nothing in this subchapter shall be construed to necessarily require termination of the agreement between the carrier and health care provider, or otherwise affect the agreement to the extent that it addresses the provision of services or supplies to covered persons by the health care provider, or the performance of other functions under the terms of the agreement, separate from those related to the home treatment of bleeding episodes associated with hemophilia.

(d) Nothing in this section shall be construed to require a carrier to provide more extensive benefits for covered services than that which is specified in the underlying health benefits plan.

11:24C-3.5 Termination of the agreement for services and supplies for home treatment of bleeding episodes associated with hemophilia

(a) In the event that a carrier or a designated health care provider terminate their agreement for, or which includes among its terms, the provision of services and supplies to a carrier's covered person for home treatment of bleeding episodes associated with hemophilia, the carrier shall continue to provide services or benefits to or on behalf of a covered person at an in-network level until the end of four months following the date of termination, or until arrangements are made for the covered person to obtain home treatment services and supplies from another in-network designated health care provider, whichever occurs first.

(b) The requirements of (a) above shall not apply when the agreement terminates on the basis of 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.

1. The carrier shall arrange to pay for services through another designated health care provider.

(c) Nothing in this subchapter shall be construed to limit the statutory or other regulatory obligations that may apply to an agreement between a carrier and a hospital, physician or other health care provider, pursuant to N.J.S.A. 26:2J-11.1 and 26:2S-9.1, for instance, as appropriate to the type of carrier and the type of health care provider.

(d) Nothing in this section shall be construed to require a carrier to provide more extensive benefits for covered services than that which is specified in the underlying health benefits plan.

11:24C-3.6 List of designated home treatment health care providers and State-recognized outpatient regional hemophilia care centers

(a) The Department shall maintain and make available a list of designated health care providers in accordance with N.J.A.C. 11:24C-2.13, and a list of State-recognized outpatient regional hemophilia care centers.

(b) Notwithstanding the Department's maintenance of a list of designated health care providers, nothing in this subchapter shall be construed to limit a carrier's responsibility to assure that a health care provider is designated and remains designated while providing services and supplies to covered persons for the home treatment of bleeding episodes associated with hemophilia.

(c) Nothing in this subchapter shall be construed to limit or eliminate any carrier's obligation to credential and recreational health care providers with which the carrier arranges for the provision of home treatment of hemophilia with respect to such treatments or any other services that the health care provider may render to a carrier's covered persons.

(d) The Department adopts and incorporates herein the standards and procedures used by the United States Department of Health and Human Services to designate regional hemophilia treatment centers in accordance with Federal laws.

1. Information regarding the Federally funded regional hemophilia centers (and grants therefor) may be obtained by contacting the Maternal and Child Health Bureau of the Health Resources and Services Administration within the United States Department of Health and Human Services, or a list of hemophilia treatment centers by state currently is available through the Centers for Disease Control at www.cdc.gov/ncidod/dastlr/hematology/htc_list.htm.

2. In the event that there is any discrepancy between the Department-generated list of State-recognized outpa-

tient regional hemophilia care centers and the hemophilia treatment centers included in the United States Department of Health and Human Service's regional network(s) for the State of New Jersey, the information provided by the United States Department of Health and Human Services shall take precedence.

11:24C-3.7 Clinical laboratories at State-recognized outpatient regional hemophilia care centers

(a) When a covered person's attending physician determines that a covered person needs to use the services of a clinical laboratory at a State-recognized outpatient regional hemophilia care center because of timing or the need for closely supervised procedures in venipuncture and laboratory techniques, and the carrier does not have an agreement for the provision of services at any clinical laboratory of a State-recognized outpatient regional hemophilia care center, the carrier shall approve the use of such services at the clinical laboratory of a State-recognized outpatient regional hemophilia care center determined appropriate by the attending physician.

1. The center shall provide services or benefits to or on behalf of the covered person as if the covered person had accessed services in-network when the services are accessed in accordance with (a)1 above.

2. A refusal by a carrier or its agent to provide benefits or services as if in-network under the circumstances set forth in (a)1 above shall be considered a utilization management denial, and subject to the utilization management appeal process set forth at N.J.A.C. 11:24-8 or 11:24A-4.12, as appropriate to the type of carrier.

(b) When a covered person's attending physician determines that a covered person needs to use the services of a clinical laboratory at a State-recognized outpatient regional hemophilia care center because of timing or the need for closely supervised procedures in venipuncture and laboratory techniques, and the carrier has an agreement for the provision of services at a clinical laboratory of one or more State-recognized outpatient regional hemophilia care centers, the carrier may require use of such services at its contracted facility(ies) in order to obtain in-network benefits or provision of services at the in-network level; however, the carrier shall treat a denial to approve use of the clinical laboratory determined appropriate by the attending physician as a utilization management denial, not an administrative denial, and shall treat any appeal of the denial as a utilization management appeal in accordance with the rules at N.J.A.C. 11:24-8 or 11:24A-4.12, as appropriate to the type of carrier.

1. If the covered person is covered under a health benefits plan with out-of-network benefits, the carrier may provide services or benefits to or on behalf of the covered person as if the covered person had accessed services out-of-network.

2. If the covered person is covered under a health benefits plan without out-of-network benefits, the carrier shall pay for the laboratory services at the same rate it would pay for comparable services at the State-recognized outpatient regional hemophilia care center(s) in the carrier's network.

(c) Nothing in (a) and (b) above shall be construed to otherwise limit a covered person's rights in obtaining services or a carrier's obligations with respect to providing benefits in an emergency.

(d) Treatment by the carrier of a covered person as in-network when accessing the services of a clinical laboratory at a State-recognized outpatient hemophilia care center shall not be contingent upon the status of the attending physician as an in-or out-of-network health care provider with respect to the managed care plan covering the covered person.

(e) Nothing in this subchapter shall be construed to prevent the carrier from reviewing the services provided and making a determination as to whether the services were medically necessary.

11:24C-3.8 Effect of Bulletin OMC 2001-04

(a) Carriers that have agreements for the provision of services and supplies for home treatment of bleeding episodes associated with hemophilia with one or more persons identified in Bulletin OMC 2001-04 as acceptable health care providers of such services may continue to refer covered persons to such health care providers, and the carrier shall be considered in compliance with these rules until whichever occurs first:

1. February 5, 2005, if the health care provider does not submit an application for designation;
2. The Department makes a determination and provides written notice to the person in writing that the person does not meet the standards for designation, if the person files an application for designation in accordance with N.J.A.C. 11:24C-2.4;
3. The person loses designation pursuant to N.J.A.C. 11:24C-2.10; or

4. The carrier and person otherwise terminate their agreement, or amend one or more terms thereof, with respect to the provision of services for home treatment of bleeding episodes associated with hemophilia.

(b) In the event that a person identified in Bulletin OMC 2001-04 as an acceptable health care provider of services and supplies for the home treatment of bleeding episodes associated with hemophilia elects not to file an application for designation, or files an application but does not receive designation, the carrier shall comply with the requirements of N.J.A.C. 11:24C-3.4, as if the person had lost designation.

11:24C-3.9 Identification of hemophilia health care providers by carrier

(a) Carriers shall, by February 4, 2005, submit written identification to the Department of the person(s) with which the carrier has an agreement for the provision of services and supplies for the home treatment of bleeding episodes associated with hemophilia.

(b) Carriers shall submit the information required in (a) above by mail or by facsimile as follows:

Attn: Hemophilia Health Care Provider
 Identification
 Office of Managed Care
 NJ Department of Health and Senior Services
 PO Box 360
 Trenton, NJ 08625-0360
 Fax: (609) 633-0660

11:24C-3.10 Violations

A carrier that violates any provisions of this subchapter shall be subject to fines and other penalties available pursuant to N.J.S.A. 26:2S-16; however, a carrier shall not be determined to be in violation of the provisions of the subchapter that require contracting with and referral to designated health care providers if there are no designated health care providers in New Jersey on the date that services for the home treatment of bleeding episodes related to hemophilia are sought by or for a covered person.