

**INSURANCE
DEPARTMENT OF BANKING AND INSURANCE
DIVISION OF INSURANCE**

Managed Care Plans

Proposed Readoption with Amendments: N.J.A.C. 11:24C

Proposed Repeal and New Rules: N.J.A.C. 11:24C-2.9

Proposed Repeals: N.J.A.C. 11:24C-2.14 and 3.9

Authorized By: Steven M. Goldman, Commissioner, Department of Banking and Insurance.

Authority: N.J.S.A. 17:1-8.1 and 17:1-15(e), 26:2S-7.1 through 7.3 and 26:2S-10.3.

Calendar Reference: See Summary below for explanation of exception to calendar requirement.

Proposal Number: PRN 2008-413

Submit comments by February 13, 2009 to:

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20 West State Street
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The agency proposal follows:

Summary

The Department of Banking and Insurance (Department) proposes to readopt N.J.A.C. 11:24C governing managed care plans. Pursuant to N.J.S.A. 52:14B-5.1c, the rules in this chapter are scheduled to expire on December 1, 2008. In accordance with N.J.S.A. 52:14B-5.1c, the submission of this notice of proposal to the Office of Administrative Law extended that expiration date 180 days to May 30, 2009.

The chapter originally appeared in Title 8 of the New Jersey Administrative Code, as rules promulgated by the Department of Health and Senior Services (DHSS), Office of Managed Care (OMC). As part of Reorganization Plan No. 005-2005 (A Plan to Provide for the Transfer, Consolidation and Reorganization of the Office of Managed Care from the Department of Health and Senior Services to the Department of Banking and Insurance) issued by Governor Richard J. Codey on June 30, 2005 (see 37 N.J.R. 2737(a)), the chapter was recodified in Title 11 (see 38 N.J.R. 4721(a)). The chapter includes

rules implementing P.L. 2001, c. 88 (codified at N.J.S.A. 26:2S-7.1 through 7.3), which mandated that carriers offering managed care plans accept a universal application form and renewal form developed by the Commissioner of the DHSS for credentialing physicians seeking to participate in a carrier's provider network. The rules also establish alternative, acceptable means by which carriers offering managed care plans may credential and recredential physicians.

The chapter also contains rules at N.J.A.C. 11:24C-2 implementing P.L. 2000, c. 121 (principally codified at N.J.S.A. 26:2S-10.1 through 10.3), which establish certain standards for carriers' provision of benefits or coverage of services for hemophilia treatment. The rules establish a process for health care providers to become designated to provide hemophilia treatment, as well as a process for renewal or modification of such designation. The rules further define or establish additional standards for designation as a health care provider eligible to contract for the provision of home treatment of bleeding episodes associated with hemophilia and standards for handling treatment when a health care provider loses the designation or the provider's contract with a carrier terminates.

The rules at N.J.A.C. 11:24C-3 require that carriers' managed care plans provide certain benefits or services for hemophilia treatment, and require the Department to maintain a list of designated home treatment health care providers and State-recognized outpatient regional hemophilia care centers.

The Department has reviewed these rules and determined them to be reasonable, necessary and proper for the purpose for which they were originally promulgated. The Department believes that the original purpose for each rule, as set forth in the rules itself, continues to exist. Moreover, the Department continues to believe that the rules proposed for readoption are necessary to provide guidance and a regulatory framework to implement the legislation authorizing them. The Department has also determined to amend certain rules in the chapter and to repeal others, to eliminate requirements no longer deemed necessary and to streamline the oversight process. A summary of the proposed amendments and repeals follows:

The Department proposes to amend Subchapter 2 of the chapter (Designation of Hemophilia Health Care Providers). At N.J.A.C. 11:24C-2.4(a), the Department is proposing to delete language requiring that applications to become a designated health care provider of home treatment services be

submitted to the Department by February 4, 2005 or during the month of September in each calendar year thereafter. The February 4, 2005 reference is outdated, and the Department has determined that the September only submission requirement is no longer necessary. Reference to this requirement in the Subchapter Appendix is also being deleted. The Department is further proposing to recodify existing N.J.A.C. 11:24C-2.4(c) as (b) and to delete from that subsection the items listed at paragraphs 1 and 2 that are to be included with an application. Those items are being added to the Instructions and Checklist appearing in the Appendix.

The Department is further proposing to delete most of the provisions in existing N.J.A.C. 11:24C-2.9, Renewal of designation as a health care provider of home treatment of bleeding episodes associated with hemophilia, and to propose a new section, "Annual report." The Department has determined that it is unnecessary for providers to file an annual renewal application. Therefore, the new section will require providers to file an annual report with the Department in lieu of a renewal application, which will be less burdensome on providers and the Department. The new rule identifies the information to be provided to the Department on the annual report, and notifies providers that the report form and instructions for submission will be available on the Department's website. The proposal also deletes existing sections (c) through (e), which reference renewal applications for continued designation as a hemophilia health care provider.

Because the Department is proposing to repeal N.J.A.C. 11:24C-2.9 referring to a renewal process and application for continued designation as a hemophilia health care provider, references to such a renewal process and application are being deleted at N.J.A.C. 11:24C-2.10. In addition to the existing reasons listed at N.J.A.C. 11:24C-2.10 for which a provider may lose its designation, the Department is adding a provider's failure to file an annual report with the Department as an additional reason. The Department is further proposing to recodify existing subsections (d) through (g) therein as (c) through (f).

The Department is proposing to repeal N.J.A.C. 11:24C-2.14, Effect of Bulletin OMC 2001-04. This section addressed the interrelationship of these rules when they were originally proposed by the DHSS in November 2003 and Bulletin OMC 2001-04 issued by the DHSS in August 2001 as they related to

providers of home treatment services for hemophilia. The bulletin provided carriers with an interim list of home treatment health care providers with whom it was acceptable for them to contract, or to whom covered persons could be referred within the spirit of the statute, and the list of facilities participating in the Federally funded hemophilia treatment center network. Upon adoption, the rules provided that use of those providers would continue to be acceptable for a period of time following the effective date of the rules, but that thereafter providers were required to file for designation in accordance with the requirements of the rules. Because the specified period of time has passed, this section has become outdated and is no longer necessary.

For the same reasons discussed above regarding the repeal of N.J.A.C. 11:24C-2.14, the Department is also proposing to amend certain provisions at N.J.A.C. 11:24C-3.8, Effect of Bulletin OMC 2001-04. This section addresses the interrelationship of these rules as originally proposed by the DHSS in November 2003 and Bulletin OMC 2001-04 issued by the DHSS in August 2001, as they related to carriers having agreements with providers of home treatment services for hemophilia.

The Department is also proposing to repeal N.J.A.C. 11:24C-3.9, Identification of hemophilia health care providers by carrier, because the requirement contained therein that carriers file certain information with DHSS by February 4, 2005 is outdated.

As the department has provided a 60-day comment period on this notice of proposal, this notice is excepted from the rulemaking calendar requirement pursuant to N.J.A.C. 1:30-3.3(a)5.

Social Impact

The rules proposed for readoption with amendments, repeals and new rule will continue to provide a streamlined physician credentialing process whereby carriers are able to identify and contract with competent physicians, encourage high standards of health care and retain physicians with the most desirable credentials. The process will continue to have a positive impact on physicians and carriers. Consumers will also continue to be favorably indirectly impacted because continuation of this process will further reduce the administrative burdens involved in credentialing, thereby allowing resources to be redirected to enhanced or more focused patient care. The rules proposed for readoption with

amendments, repeals and new rule will also continue to favorably impact consumers in that the rules' home health care designation standards assure that covered persons with hemophilia have access within managed care networks to high caliber, qualified health care providers with specific expertise in treating bleeding episodes associated with hemophilia. The proposed amendments, repeals and new rule will likewise impact providers favorably because, rather than requiring an annual application process for renewal of their hemophilia home treatment provider designation, providers need only file an annual report with the Commissioner to maintain such a designation. Finally, the rules proposed for re-adoption with amendments, repeals and new rule will ensure that carriers continue to provide benefits or coverage of services for hemophilia treatment under managed care health benefits plans. The proposed amendments, repeals and new rule eliminate outdated or unnecessary requirements, and provide for the efficient ongoing regulation of carriers' credentialing of physicians seeking to participate in a carrier's provider network, of designated hemophilia health care providers, and of carriers' provision of benefits or coverage of services for hemophilia treatment.

Economic Impact

Carriers and physicians should continue to be positively impacted by continued use of the physician credentialing standards and process established pursuant to this chapter, whether a carrier elects to use its own credentialing form or a national database for this purpose. At the time these rules were originally adopted, those carriers who had not been using a universal credentialing form may have experienced a slightly unfavorable impact because of certain system changes required to be made. However, these initial costs were not expected to be ongoing. On the other hand, physicians who had previously been required to complete a number of carrier-specific credentialing and recredentialing application forms were favorably impacted at the outset. Over the long term, both carriers and physicians have been favorably impacted by the credentialing process established by these rules.

Carriers and providers may have experienced some adverse economic impact when the rules regarding designation of hemophilia health care providers were initially adopted. At that time, providers who had been providing home treatments for hemophilia bleeding episodes under contract or other

arrangement with carriers may have elected not to seek designation and continue to provide such services, thereby reducing their revenue to some extent. Those providers who elected to become designated incurred some costs related to the submission and review of their applications and renewals. Carriers may also have incurred some administrative costs either in adding a designated home treatment health care provider(s) to their network or making other arrangements to assure that their covered persons accessed services from such a provider at full benefits or coverage of services.

The proposed amendments, repeals and new rule eliminate the annual renewal application process for providers seeking to maintain their designation and require instead that providers submit an annual report to the Department. This will eliminate unnecessary filings and should lower providers' costs by reducing the amount of time spent on complying with the renewal application requirements. Moreover, the information proposed to be included in the annual report should be readily available to a provider seeking to maintain his or her designation. The Department does not believe that any professional services will be required to be employed by either carriers or providers in order to comply with the rules proposed for readoption with amendments repeals and new rule.

Federal Standards Statement

A Federal standards analysis is not required because the rules proposed for readoption with amendments, repeals and new rule are not subject to any Federal requirements or standards.

Jobs Impact

The Department does not anticipate that any jobs will be lost or generated in New Jersey as a result of the rules proposed for readoption with amendments, repeals and new rule.

Agriculture Industry Impact

The Department does not expect any agriculture industry impact from the rules proposed for readoption with amendments, repeals and new rule.

Regulatory Flexibility Analysis

The rules proposed for re-adoption with amendments, repeals and new rule will apply to “small businesses” as that term is defined in the Regulatory Flexibility Act, N.J.S.A. 52:14B-16 et seq. However, the rules proposed for re-adoption with amendments, repeals and new rule do not impose any new recordkeeping or reporting requirements, or any requirements necessitating professional services, on carriers or providers who will be affected by the re-adopted rules. The statute setting forth the standards and procedures for carriers to follow in credentialing and recredentialing physicians seeking participation in a carrier’s provider network did not specify that different standards should be used based on the size of the carriers involved. Further, there is no indication that the Legislature intended that physicians should be subject to different standards of data collection based on whether they were seeking to become a part of the network or a larger or smaller carrier. Accordingly, no accommodation for carriers that may be small businesses have been made.

Providers seeking to become designated as health care providers for the home treatment of hemophilia must file an initial application to obtain such designation, and are required to file annual reports with the Commissioner to maintain the designation. The statute requiring such designation established minimum standards that providers must meet in order to be designated, and did not provide any regulatory flexibility regarding compliance with those standards. Further, the Department does not believe those standards should be compromised based on business size. The rules seek to protect the health and welfare of a particularly vulnerable population, and the interests and needs of this population should not be compromised based on the size of a company interested in providing health care services. Accordingly, no accommodation for entities that may be small businesses has been made.

Smart Growth Impact

The rules proposed for re-adoption with amendments, repeals and new rule will have no impact on the achievement of smart growth and implementation of the State Development and Redevelopment Plan (State Plan).

Housing Affordability Impact

The rules proposed for readoption with amendments, repeals and new rule will have no impact on housing affordability. The rules proposed for readoption with amendments, repeals and new rule affect managed health care plans.

Smart Growth Development Impact

The rules proposed for readoption with amendments, repeals and new rule will have no impact on housing production in Planning Areas 1 and 2, or within designated centers, under the State Plan. The rules proposed for readoption with amendments, repeals and new rule affect managed health care plans.

Full text of the rules proposed for readoption may be found in the New Jersey Administrative Code at N.J.A.C. 11:24C.

Full text of the rules proposed for repeal may be found in the New Jersey Administrative Code at N.J.A.C. 11:24C-2.9, 2.14 and 3.9.

Full text of the proposed amendments follows (additions indicated in boldface **thus**; deletions indicated in brackets **[thus]**):

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

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)] **(b)** The applicant shall comply with **the** "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.]

Recodify existing (d) and (e) as **(c) and (d)** (No change in text.)

11:24C-2.9 Annual report

(a) No later than April 1 of each year, a designated health care provider shall submit an annual report for the immediately preceding calendar year, which shall include the following:

1. The number of patients served with the number of units of blood clotting factors shipped;

2. Proof of all required licenses and certifications needed to conduct business in the State of New Jersey, including waste disposal contracts;

3. Proof of inventory available that will also verify access to all products, assays and contractual agreements with pertinent manufacturers and/or distributors;

4. Information demonstrating the provider's nursing expertise in servicing these patients;

5. Patient intake, evaluation and follow-up policies and procedures, including initial information on fee/reimbursement structure and emergency delivery procedures; and

6. All insurance reimbursement, billing and assistance procedures.

(b) The annual report described in (a) above shall be submitted on a form and pursuant to instructions determined by the Commissioner and available on the Department's website at www.state.nj.us/dobi/formlist.htm.

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. – 3. (No change.)

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; or

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

[6.] **5.** (No change in text.)

(b) (No change.)

[(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)] **(c)** 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.]

Recodify existing (e) - (g) as (d) – (f) (No change in text.)

SUBCHAPTER 3.. BENEFITS OR COVERAGE OF SERVICE FOR HEMOPHILIA TREATMENT

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 **of the following** occurs first:

[1. February 5, 2005, if the health care provider does not submit an application for designation;]

[2.] **1.** 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;

Recodify existing 3. and 4. as **2. and 3.** (No change in text.)

(b) (No change.)

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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 **that includes the following: (1) a statement that the information contained in the application is accurate and true to the knowledge of the signatory; (2) a statement that the signatory is authorized to make the certification and submit legal documents on behalf of the applicant company; and (3) the signatory's printed title, printed name and the printed date the certification was signed.**

- 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**] **Notarized copies** of all **current** 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.]