

Standards of Care for Hemophilia Home Care

In 2004, the New Jersey Department of Health & Senior Services (DHSS) completed implementation of a new “Standards of Care in Hemophilia Homecare Law” that was passed in 2000 (Senate Bill 786) at the urging of the Hemophilia Association of New Jersey (HANJ).

The new standards resulted from problems with the quality of hemophilia care being provided by home care companies (HCCs) in New Jersey that were identified by HANJ. Most of the problems with the quality of treatment being received by people with hemophilia were the result of insurers and payers that forced people with hemophilia to switch to HCCs with whom the insurers and payers have exclusive contracts. Often times, the new HCC that the individual with hemophilia was required to use was unfamiliar with hemophilia care, needs, and complications. Patients were required to leave HCCs that they dealt with for years with little or no time to appeal the decision. More specifically; the HCCs:

- Placed limitations on choice of hemophilia therapy and the amount of factor that an individual with hemophilia was allowed to store at home;
- Did not make ancillary supplies (i.e., needles and syringes) available;
- Did not provide factor therapies to people with hemophilia in a timely manner;
- Did not provide medically necessary preventative devices, disposal of medical waste, or nursing care; and
- Did not have trained staff to help clients with third party reimbursement issues.

Under the new standards, New Jersey now requires all insurance carriers (including individual and group health insurers, small employer plans, hospital, medical, and health services corporations, and health maintenance organizations) that provide coverage for the home treatment of hemophilia to contract with home care providers that comply with certain minimum Standards of Care (SOC) developed by the Department of Health & Senior Services in consultation with HANJ.

These Standards of Care include, but are not limited to:

- Prohibitions on substitution of blood products without prior approval of the attending physician;
- The ability to provide all brands of clotting factor products and all needed ancillary supplies;
- The ability to deliver prescribed blood products within three hours for emergent situations and maintain 24-hour on-call service to accommodate this requirement;
- Demonstrated experience with and knowledge of bleeding disorders and the management thereof;
- Demonstrated record keeping ability, and the ability to expedite product recall notifications;
- The ability to assist covered persons in obtaining third party reimbursement; and
- Providing for the proper removal and disposal of hazardous waste pursuant to State and federal law.

New Jersey also requires the state Department of Health and Senior Services to compile a list of providers who meet the minimum standards and to make the list available to insurance carriers and their policy holders. Insurers must now provide payment for laboratory services at all hemophilia treatment centers regardless of whether or not the laboratory is a participating provider with the insurer.

The draft Act in this SSL volume is based on New Jersey law.

Submitted as:
New Jersey
Chapter 121 of 2000
Status: Enacted into law in 2000.

Suggested State Legislation

(Title, enacting clause, etc.)

1 Section 1. [*Short Title.*] This Act may be cited as “An Act Concerning Health Care
2 Coverage for Treatment of Hemophilia.”

3

4 Section 2. [*Definitions.*] As used in this Act:

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a. “Blood Product” includes, but is not limited to, Factor VIII, Factor IX and
6 cryoprecipitate; and

7

b. “Blood Infusion Equipment” includes, but is not limited to, syringes and needles.

8

9 Section 3. [*Home Treatment For Bleeding Episodes Associated With Hemophilia:*
10 *Required Coverage.*]

11

a. A carrier which offers a managed care plan that provides benefits or health care
12 services, as applicable, for the home treatment of bleeding episodes associated with hemophilia,
13 including the purchase of blood products and blood infusion equipment, shall comply with the
14 provisions of this section. For the purpose of providing home treatment services for bleeding
15 episodes associated with hemophilia, the carrier shall be required to contract with, and
16 exclusively use, providers that comply with standards adopted by regulation of the [state
17 Department of Health and Senior Services] in consultation with the [Hemophilia Association of
18 this state]. At a minimum, the standards shall require that each provider:

19

(1) provide services pursuant to a prescription from the covered person’s
20 attending physician and not make any substitutions of blood products without prior approval of
21 the attending physician;

22

(2) provide all brands of clotting factor products in low, medium and high-assay
23 range levels to execute treatment regimens as prescribed by a covered person’s attending
24 physician, and all needed ancillary supplies for the treatment or prevention of bleeding episodes,
25 including, but not limited to, needles, syringes and cold compression packs;

26

(3) have the ability to deliver prescribed blood products, medications and nursing
27 services within [three hours] after receipt of a prescription for an emergent situation, and
28 maintain 24-hour on-call service to accommodate this requirement;

29

(4) demonstrate experience with and knowledge of bleeding disorders and the
30 management thereof;

31

(5) demonstrate the ability for appropriate and necessary record keeping and
32 documentation, including the ability to expedite product recall or notification systems and the
33 ability to assist covered persons in obtaining third party reimbursement;

34

(6) provide for proper removal and disposal of hazardous waste pursuant to State
35 and federal law;

36

(7) provide covered persons with a written copy of the agency’s policy regarding
37 discontinuation of services related to loss of health benefits plan coverage or inability to pay; and

38

(8) provide covered persons, upon request, with information about the expected
39 costs for medications and services provided by the agency that are not otherwise covered by the
40 covered person’s health benefits plan.

41 b. The [Department of Health and Senior Services] shall compile a list of providers who
42 meet the minimum standards established pursuant to this section and shall make the list available
43 to carriers and covered persons, upon request.

44 c. The [Department of Health and Senior Services], pursuant to [insert citation], shall
45 adopt regulations to carry out the provisions of this section.

46
47 Section 4. [*Clinical Laboratory Services At Outpatient Regional Hemophilia Care*
48 *Center: Required Coverage.*]

49 a. A carrier which offers a managed care plan shall provide payment for services to the
50 clinical laboratory at a hospital with a State-designated outpatient regional hemophilia care
51 center regardless of whether the hospital's clinical laboratory is a participating provider in the
52 managed care plan, if the covered person's attending physician determines that use of the
53 hospital's clinical laboratory is necessary because:

54 (1) the results of laboratory tests are medically necessary immediately or sooner
55 than the normal return time for the carrier's participating clinical laboratory; or

56 (2) accurate test results need to be determined by closely supervised procedures
57 in venipuncture and laboratory techniques in controlled environments that cannot be achieved by
58 the carrier's participating clinical laboratory.

59 b. The carrier shall pay the hospital's clinical laboratory for the laboratory services at the
60 same rate it would pay a participating clinical laboratory for comparable services.

61 c. The carrier shall retain the right to review all services provided pursuant to this section
62 for medical necessity.

63 d. The [state Department of Health and Senior Services], pursuant to [insert citation],
64 shall adopt regulations to carry out the provisions of this section.

65
66 Section 5. [*Coverage for Hemophilia by Individual Health Insurers.*] Notwithstanding the
67 provisions of [insert citation] to the contrary, no policy shall be delivered, issued, executed or
68 renewed on or after the effective date of this Act unless the policy meets the requirements of
69 Sections 3 and 4 of this Act and the regulations adopted thereto. The provisions of this section
70 shall apply to all policies in which the insurer has reserved the right to change the premium.

71
72 Section 6. [*Coverage for Hemophilia Services by Group Health Insurers.*] Notwithstanding
73 the provisions of [insert citation] to the contrary, no policy shall be delivered,
74 issued, executed or renewed on or after the effective date of this Act unless the policy meets the
75 requirements of Sections 3 and 4 of this Act and the regulations adopted thereto. The provisions
76 of this section shall apply to all policies in which the insurer has reserved the right to change the
77 premium.

78
79 Section 7. [*Coverage for Hemophilia Services by Small Employer Plan.*] Notwithstanding
80 the provisions of [insert citation] to the contrary, no policy or contract shall be delivered, issued,
81 executed or renewed on or after the effective date of this Act unless the policy or contract meets
82 the requirements of Sections 3 and 4 of this Act and the regulations adopted thereto. The
83 provisions of this section shall apply to all policies or contracts in which the carrier has reserved
84 the right to change the premium.

85
86 Section 8. [*Coverage for Hemophilia Services by Individual Health Policy.*] Notwithstanding
87 the provisions of [insert citation] to the contrary, no policy or contract shall be
88 delivered, issued, executed or renewed on or after the effective date of this Act unless the policy
89 or contract meets the requirements of Sections 3 and 4 of this Act and the regulations adopted

90 thereto. The provisions of this section shall apply to all policies or contracts in which the carrier
91 has reserved the right to change the premium.

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93 Section 9. [*Coverage for Hemophilia Services by Hospital Service Corporations.*]
94 Notwithstanding the provisions of [insert citation] to the contrary, no individual or group
95 contract shall be delivered, issued, executed or renewed on or after the effective date of this Act
96 unless the contract meets the requirements of Sections 3 and 4 of this Act and the regulations
97 adopted thereto. The provisions of this section shall apply to all contracts in which the hospital
98 service corporation has reserved the right to change the premium.

99

100 Section 10. [*Coverage for Hemophilia Services by Medical Services Corporation.*]
101 Notwithstanding the provisions of [insert citation] to the contrary, no individual or group
102 contract shall be delivered, issued, executed or renewed on or after the effective date of this Act
103 unless the contract meets the requirements of Sections 3 and 4 of this Act and the regulations
104 adopted thereto. The provisions of this section shall apply to all contracts in which the medical
105 service corporation has reserved the right to change the premium.

106

107 Section 11. [*Coverage for Hemophilia Services by Health Service Corporation.*]
108 Notwithstanding the provisions of [insert citation] to the contrary, no individual or group
109 contract shall be delivered, issued, executed or renewed on or after the effective date of this Act
110 unless the contract meets the requirements of Sections 3 and 4 of this Act and the regulations
111 adopted thereto. The provisions of this section shall apply to all contracts in which the health
112 service corporation has reserved the right to change the premium.

113

114 Section 12. [*Coverage for Hemophilia Services by HMO.*] Notwithstanding the
115 provisions of [insert citation] to the contrary, a certificate of authority to establish and operate a
116 health maintenance organization in this State shall not be issued or continued on or after the
117 effective date of this Act unless the health maintenance organization meets the requirements of
118 Sections 3 and 4 of this Act and the regulations adopted thereto. The provisions of this section
119 shall apply to all enrollee agreements in which the health maintenance organization has reserved
120 the right to change the schedule of charges.

121

122 Section 13. [*Severability.*] [Insert severability clause.]

123

124 Section 14. [*Repealer.*] [Insert repealer clause.]

125

126 Section 15. [*Effective Date.*] [Insert effective date.]