

HOUSE BILL 949

C3

11r2450

By: **Delegate Holmes**

Introduced and read first time: February 11, 2011

Assigned to: Health and Government Operations

A BILL ENTITLED

1 AN ACT concerning

2 **Health Insurance – Coverage for the Treatment of Bleeding Disorders**

3 FOR the purpose of requiring certain insurers, nonprofit health service plans, and
4 health maintenance organizations to provide coverage for certain pharmacy
5 care, home nursing services, treatment at a hemophilia treatment center, and
6 clinical laboratory services that an insured's or enrollee's treating physician
7 determines are necessary to prevent, diagnose, or treat a bleeding disorder;
8 requiring the insurers, nonprofit health service plans, and health maintenance
9 organizations to preapprove or preauthorize a prescription for a blood clotting
10 product in a certain manner, under certain circumstances; requiring the
11 insurers, nonprofit health service plans, and health maintenance organizations
12 to provide to an insured or enrollee a choice of a certain number of certain
13 full-service home care providers; authorizing the imposition of a copayment or
14 coinsurance requirement or deductible for certain coverage under certain
15 circumstances; defining certain terms; providing for the application of this Act;
16 and generally relating to coverage for bleeding disorders under health insurance
17 policies and contracts.

18 BY adding to

19 Article – Health – General

20 Section 19-706(kkkk)

21 Annotated Code of Maryland

22 (2009 Replacement Volume and 2010 Supplement)

23 BY adding to

24 Article – Insurance

25 Section 15-845

26 Annotated Code of Maryland

27 (2006 Replacement Volume and 2010 Supplement)

28

Preamble

EXPLANATION: CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.

[Brackets] indicate matter deleted from existing law.



1 WHEREAS, Hemophilia is a rare, hereditary bleeding disorder that affects
2 hundreds of residents of the State; and

3 WHEREAS, Hemophilia is a chronic, lifelong, and incurable disease; and

4 WHEREAS, Until the 1970s, individuals afflicted with severe hemophilia
5 suffered from uncontrollable internal bleeding, crippling orthopedic deformities, and a
6 diminished lifespan; and

7 WHEREAS, The scientific discovery of highly purified blood clotting factors has
8 enabled many individuals with hemophilia and other bleeding disorders to lead
9 normal lives free of pain and crippling arthritis; and

10 WHEREAS, The blood clotting factors are expensive and must be injected
11 intravenously several times a week, but this medicine can be administered in an
12 individual's home, which is the preferred method of treatment; and

13 WHEREAS, In addition to blood clotting factors, individuals with hemophilia
14 require expert, specialized medical care at regional hemophilia treatment centers; and

15 WHEREAS, Individuals with hemophilia and other bleeding disorders need
16 access to health insurance coverage for blood clotting products, medical care, home
17 health services, and laboratory services necessary to enable them to lead healthy,
18 productive lives; now, therefore,

19 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
20 MARYLAND, That the Laws of Maryland read as follows:

21 **Article – Health – General**

22 19–706.

23 **(KKKK) THE PROVISIONS OF § 15–845 OF THE INSURANCE ARTICLE**
24 **APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.**

25 **Article – Insurance**

26 **15–845.**

27 **(A) (1) IN THIS SECTION THE FOLLOWING WORDS HAVE THE**
28 **MEANINGS INDICATED.**

29 **(2) (I) “ANCILLARY INFUSION EQUIPMENT AND SUPPLIES”**
30 **MEANS THE EQUIPMENT AND SUPPLIES REQUIRED TO INFUSE A BLOOD**
31 **CLOTTING PRODUCT INTO A HUMAN VEIN.**

1 (II) “ANCILLARY INFUSION EQUIPMENT AND SUPPLIES”
2 INCLUDES SYRINGES, NEEDLES, STERILE GAUZE, ALCOHOL SWABS,
3 TOURNIQUETS, MEDICAL TAPE, SHARPS OR EQUIVALENT BIOHAZARD WASTE
4 CONTAINERS FOR THE REMOVAL AND DISPOSAL OF HAZARDOUS WASTE, AND
5 COLD COMPRESSION PACKS.

6 (3) (I) “BLEEDING DISORDER” MEANS A MEDICAL CONDITION
7 THAT IS CHARACTERIZED BY A SEVERE DEFICIENCY OR ABSENCE OF ONE OR
8 MORE ESSENTIAL BLOOD CLOTTING PROTEINS IN THE HUMAN BLOOD, OFTEN
9 REFERRED TO AS FACTORS.

10 (II) “BLEEDING DISORDER” INCLUDES:

- 11 1. ALL FORMS OF HEMOPHILIA;
12 2. VON WILLEBRAND DISEASE; AND
13 3. ANY OTHER BLEEDING DISORDER THAT RESULTS
14 IN UNCONTROLLABLE BLEEDING OR ABNORMAL BLOOD CLOTTING.

15 (4) (I) “BLOOD CLOTTING PRODUCT” MEANS AN
16 INTRAVENOUSLY ADMINISTERED MEDICINE THAT IS:

- 17 1. MANUFACTURED FROM HUMAN PLASMA OR
18 RECOMBINANT BIOTECHNOLOGY TECHNIQUES;
19 2. APPROVED FOR DISTRIBUTION BY THE FDA; AND
20 3. USED FOR THE TREATMENT AND PREVENTION OF
21 SYMPTOMS ASSOCIATED WITH BLEEDING DISORDERS.

22 (II) “BLOOD CLOTTING PRODUCT” INCLUDES:

- 23 1. FACTOR VIIA, FACTOR VIII, AND FACTOR IX
24 PRODUCTS;
25 2. VON WILLEBRAND FACTOR PRODUCTS;
26 3. PROTHROMBIN COMPLEX CONCENTRATES;
27 4. ACTIVATED PROTHROMBIN COMPLEX
28 CONCENTRATES; AND

1 **5. ANY OTHER PRODUCT APPROVED BY THE FDA**
2 **FOR THE TREATMENT OF BLEEDING DISORDERS AND ASSOCIATED INHIBITORS.**

3 **(5) (I) “CLINICAL LABORATORY SERVICES” MEANS SERVICES**
4 **THAT ARE:**

5 **1. PROVIDED AT A CLINICAL COAGULATION**
6 **LABORATORY LOCATED AT A HEMOPHILIA TREATMENT CENTER; AND**

7 **2. DETERMINED BY AN INSURED’S OR ENROLLEE’S**
8 **TREATING PHYSICIAN TO BE MEDICALLY NECESSARY, INCLUDING**
9 **CIRCUMSTANCES DEEMED URGENT BY THE TREATING PHYSICIAN, FOR THE**
10 **SCREENING, DIAGNOSIS, PROVISIONAL DIAGNOSIS, OR TREATMENT OF A**
11 **BLEEDING DISORDER OR SUSPECTED BLEEDING DISORDER.**

12 **(II) “CLINICAL LABORATORY SERVICES” INCLUDES**
13 **SCREENING FOR VON WILLEBRAND DISEASE OR OTHER BLEEDING DISORDER**
14 **CONDUCTED BEFORE AN INSURED OR ENROLLEE UNDERGOES ANY INVASIVE**
15 **UTERINE SURGICAL PROCEDURE FOR THE TREATMENT OF MENORRHAGIA.**

16 **(6) “FDA” MEANS THE U.S. FOOD AND DRUG ADMINISTRATION.**

17 **(7) “FULL-SERVICE HOME CARE PROVIDER” MEANS A PERSON**
18 **THAT SELLS OR PROVIDES BLOOD CLOTTING PRODUCTS, ANCILLARY INFUSION**
19 **EQUIPMENT AND SUPPLIES, HOME NURSING SERVICES, AND ASSISTANCE TO AN**
20 **INDIVIDUAL FOR THE MANAGEMENT OF BLEEDING DISORDERS IN A HOME**
21 **SETTING.**

22 **(8) “HEMOPHILIA” MEANS A HUMAN BLEEDING DISORDER**
23 **CAUSED BY A HEREDITARY DEFICIENCY OF THE FACTOR VIII, FACTOR IX, OR**
24 **FACTOR XI BLOOD CLOTTING PROTEIN IN HUMAN BLOOD.**

25 **(9) “HEMOPHILIA TREATMENT CENTER” MEANS A**
26 **FEDERALLY FUNDED ENTITY THAT:**

27 **(I) SPECIALIZES IN TREATING PATIENTS WITH BLEEDING**
28 **DISORDERS; AND**

29 **(II) HAS AT LEAST A HEMATOLOGIST, A NURSE, A SOCIAL**
30 **WORKER, AND A PHYSICAL THERAPIST WORKING AS A TEAM TO DELIVER**
31 **COMPREHENSIVE CARE TO PATIENTS AND FAMILIES.**

1 **(10) “HOME NURSING SERVICES” MEANS SPECIALIZED NURSING**
2 **CARE PROVIDED IN AN INDIVIDUAL’S HOME TO ASSIST THE INDIVIDUAL IN THE**
3 **RECONSTITUTION AND ADMINISTRATION OF BLOOD CLOTTING PRODUCTS.**

4 **(11) “PHARMACY CARE” MEANS A BLOOD CLOTTING PRODUCT OR**
5 **ANCILLARY INFUSION EQUIPMENT AND SUPPLIES THAT IS:**

6 **(I) PRESCRIBED BY A LICENSED PHYSICIAN; AND**

7 **(II) USED IN THE TREATMENT OF A BLEEDING DISORDER.**

8 **(12) “VON WILLEBRAND DISEASE” MEANS A BLEEDING DISORDER**
9 **CAUSED BY A HEREDITARY DEFICIENCY OR ABNORMALITY OF THE VON**
10 **WILLEBRAND FACTOR IN HUMAN BLOOD.**

11 **(B) THIS SECTION APPLIES TO:**

12 **(1) INSURERS AND NONPROFIT HEALTH SERVICE PLANS THAT**
13 **PROVIDE HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR**
14 **GROUPS ON AN EXPENSE–INCURRED BASIS UNDER HEALTH INSURANCE**
15 **POLICIES THAT ARE ISSUED OR DELIVERED IN THE STATE; AND**

16 **(2) HEALTH MAINTENANCE ORGANIZATIONS THAT PROVIDE**
17 **HOSPITAL, MEDICAL, OR SURGICAL BENEFITS TO INDIVIDUALS OR GROUPS**
18 **UNDER CONTRACTS THAT ARE ISSUED OR DELIVERED IN THE STATE.**

19 **(C) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE**
20 **FOR ALL MEDICALLY NECESSARY AND APPROPRIATE PHARMACY CARE, HOME**
21 **NURSING SERVICES, TREATMENT AT A HEMOPHILIA TREATMENT CENTER, AND**
22 **CLINICAL LABORATORY SERVICES THAT AN INSURED’S OR ENROLLEE’S**
23 **TREATING PHYSICIAN DETERMINES ARE NECESSARY TO PREVENT, DIAGNOSE,**
24 **OR TREAT A BLEEDING DISORDER.**

25 **(D) (1) IF AN ENTITY SUBJECT TO THIS SECTION REQUIRES**
26 **PREAPPROVAL OR PREAUTHORIZATION OF A PRESCRIPTION FOR A BLOOD**
27 **CLOTTING PRODUCT BEFORE IT IS DISPENSED, THE ENTITY SHALL COMPLETE**
28 **PREAPPROVAL OR PREAUTHORIZATION WITHIN THE LATER OF 24 HOURS OR 1**
29 **BUSINESS DAY.**

30 **(2) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE**
31 **COVERAGE FOR FDA–APPROVED BRANDS OF BLOOD CLOTTING PRODUCTS IN**
32 **MULTIPLE ASSAY RANGES, LOW, MEDIUM, AND HIGH, AS APPLICABLE,**
33 **INCLUDING BLOOD CLOTTING PRODUCTS MANUFACTURED FROM HUMAN**

1 PLASMA AND THOSE MANUFACTURED WITH RECOMBINANT BIOTECHNOLOGY
2 TECHNIQUES.

3 (3) IF AN ENTITY SUBJECT TO THIS SECTION HAS A DRUG
4 FORMULARY, INCLUDING A DRUG FORMULARY RELATING TO SPECIALTY
5 PHARMACEUTICAL THERAPIES, ALL FDA-APPROVED BLOOD CLOTTING
6 PRODUCTS SHALL BE INCLUDED IN THE FORMULARY.

7 (E) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE TO AN
8 INSURED OR ENROLLEE A CHOICE OF AT LEAST THREE FULL-SERVICE HOME
9 CARE PROVIDERS THAT MEET THE REQUIREMENTS SET FORTH IN THE
10 NATIONAL HEMOPHILIA FOUNDATION, MEDICAL AND SCIENTIFIC ADVISORY
11 COUNCIL (MASAC), MASAC DOCUMENT NUMBER 188.

12 (F) (1) SUBJECT TO PARAGRAPH (2) OF THIS SUBSECTION, THE
13 COVERAGE REQUIRED UNDER THIS SECTION MAY BE SUBJECT TO A COPAYMENT
14 OR COINSURANCE REQUIREMENT OR DEDUCTIBLE THAT AN ENTITY SUBJECT TO
15 THIS SECTION IMPOSES FOR SIMILAR COVERAGES UNDER THE SAME HEALTH
16 INSURANCE POLICY OR CONTRACT.

17 (2) THE COPAYMENT OR COINSURANCE REQUIREMENT OR
18 DEDUCTIBLE IMPOSED UNDER PARAGRAPH (1) OF THIS SUBSECTION MAY NOT
19 BE GREATER THAN THE COPAYMENT OR COINSURANCE REQUIREMENT OR
20 DEDUCTIBLE IMPOSED BY THE ENTITY FOR SIMILAR COVERAGES.

21 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to
22 all health insurance policies and contracts issued, delivered, or renewed in the State
23 on or after October 1, 2011.

24 SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect
25 October 1, 2011.