SENATE BILL 908

C3 0lr3347
CF 0lr1718

By: **Senator Stone**
Introduced and read first time: February 16, 2010
Assigned to: Rules

A BILL ENTITLED

AN ACT concerning

Health Insurance – Coverage for the Treatment of Bleeding Disorders

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

BY adding to
Article – Health – General
Section 19–706(cccc)
Annotated Code of Maryland
(2009 Replacement Volume)

BY adding to
Article – Insurance
Section 15–845
Annotated Code of Maryland
(2006 Replacement Volume and 2009 Supplement)

EXPLANATION: **CAPITALS INDICATE MATTER ADDED TO EXISTING LAW.**
[Brackets**]** indicate matter deleted from existing law.

Preamble

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

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

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

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

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

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

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

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

Article – Health – General

19–706.

(CCCC) THE PROVISIONS OF § 15–845 OF THE INSURANCE ARTICLE APPLY TO HEALTH MAINTENANCE ORGANIZATIONS.

Article – Insurance

15–845.

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

(2) (I) "ANCILLARY INFUSION EQUIPMENT AND SUPPLIES" MEANS THE EQUIPMENT AND SUPPLIES REQUIRED TO INFUSE A BLOOD CLOTTING PRODUCT INTO A HUMAN VEIN.

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

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

(II) "BLEEDING DISORDER" INCLUDES:

1. ALL FORMS OF HEMOPHILIA;

2. VON WILLEBRAND DISEASE; AND

3. ANY OTHER BLEEDING DISORDER THAT RESULTS IN UNCONTROLLABLE BLEEDING OR ABNORMAL BLOOD CLOTTING.

(4) (I) "BLOOD CLOTTING PRODUCT" MEANS AN INTRAVENOUSLY ADMINISTERED MEDICINE THAT IS:

1. MANUFACTURED FROM HUMAN PLASMA OR RECOMBINANT BIOTECHNOLOGY TECHNIQUES;

2. APPROVED FOR DISTRIBUTION BY THE FDA; AND

3. USED FOR THE TREATMENT AND PREVENTION OF SYMPTOMS ASSOCIATED WITH BLEEDING DISORDERS.

(II) "BLOOD CLOTTING PRODUCT" INCLUDES:

1. FACTOR VIIA, FACTOR VIII, AND FACTOR IX PRODUCTS;

2. VON WILLEBRAND FACTOR PRODUCTS;

3. PROTHROMBIN COMPLEX CONCENTRATES;

4. ACTIVATED PROTHROMBIN COMPLEX CONCENTRATES; AND

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

(5) (I) "CLINICAL LABORATORY SERVICES" MEANS SERVICES THAT ARE:

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

2. DETERMINED BY AN INSURED'S OR ENROLLEE'S TREATING PHYSICIAN TO BE MEDICALLY NECESSARY, INCLUDING CIRCUMSTANCES DEEMED URGENT BY THE TREATING PHYSICIAN, FOR THE SCREENING, DIAGNOSIS, PROVISIONAL DIAGNOSIS, OR TREATMENT OF A BLEEDING DISORDER OR SUSPECTED BLEEDING DISORDER.

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

(6) "FDA" MEANS THE U.S. FOOD AND DRUG ADMINISTRATION.

(7) "FULL–SERVICE HOME CARE PROVIDER" MEANS A PERSON THAT SELLS OR PROVIDES BLOOD CLOTTING PRODUCTS, ANCILLARY INFUSION EQUIPMENT AND SUPPLIES, HOME NURSING SERVICES, AND ASSISTANCE TO AN INDIVIDUAL FOR THE MANAGEMENT OF BLEEDING DISORDERS IN A HOME SETTING.

(8) "HEMOPHILIA" MEANS A HUMAN BLEEDING DISORDER CAUSED BY A HEREDITARY DEFICIENCY OF THE FACTOR VIII, FACTOR IX, OR FACTOR XI BLOOD CLOTTING PROTEIN IN HUMAN BLOOD.

(9) "HEMOPHILIA TREATMENT CENTER" MEANS A FEDERALLY FUNDED ENTITY THAT:

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

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

(10) "HOME NURSING SERVICES" MEANS SPECIALIZED NURSING CARE PROVIDED IN AN INDIVIDUAL'S HOME TO ASSIST THE INDIVIDUAL IN THE RECONSTITUTION AND ADMINISTRATION OF BLOOD CLOTTING PRODUCTS.

(11) "PHARMACY CARE" MEANS A BLOOD CLOTTING PRODUCT OR ANCILLARY INFUSION EQUIPMENT AND SUPPLIES THAT IS:

(I) PRESCRIBED BY A LICENSED PHYSICIAN; AND

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

(12) "VON WILLEBRAND DISEASE" MEANS A BLEEDING DISORDER CAUSED BY A HEREDITARY DEFICIENCY OR ABNORMALITY OF THE VON WILLEBRAND FACTOR IN HUMAN BLOOD.

(B) THIS SECTION APPLIES TO:

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

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

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

(D) (1) AN ENTITY SUBJECT TO THIS SECTION:

(I) SHALL PROVIDE COVERAGE FOR THE BLOOD CLOTTING PRODUCT PRESCRIBED BY THE TREATING PHYSICIAN OF AN INSURED OR ENROLLEE; AND

(II) MAY NOT REQUIRE AN INSURED OR ENROLLEE TO USE A SUBSTITUTE BLOOD CLOTTING PRODUCT WITHOUT PRIOR APPROVAL OF THE INSURED'S OR ENROLLEE'S TREATING PHYSICIAN.

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

(3) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE COVERAGE FOR:

(I) FDA–APPROVED BRANDS OF BLOOD CLOTTING PRODUCTS IN MULTIPLE ASSAY RANGES, LOW, MEDIUM, AND HIGH, AS APPLICABLE, INCLUDING BLOOD CLOTTING PRODUCTS MANUFACTURED FROM HUMAN PLASMA AND THOSE MANUFACTURED WITH RECOMBINANT BIOTECHNOLOGY TECHNIQUES; AND

(II) BLOOD CLOTTING PRODUCTS AS PRESCRIBED BY THE INSURED'S OR ENROLLEE'S TREATING PHYSICIAN FOR INPATIENT CARE, OUTPATIENT CARE, AND HOME TREATMENT OF BLEEDING DISORDERS.

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

(E) AN ENTITY SUBJECT TO THIS SECTION SHALL PROVIDE TO AN INSURED OR ENROLLEE A CHOICE OF AT LEAST THREE FULL–SERVICE HOME CARE PROVIDERS THAT:

(1) SUPPLY BLOOD CLOTTING PRODUCTS AND HOME NURSING SERVICES AS PRESCRIBED BY THE INSURED'S OR ENROLLEE'S TREATING PHYSICIAN, WITHOUT SUBSTITUTION OF A BLOOD CLOTTING PRODUCT UNLESS APPROVED IN ADVANCE BY THE TREATING PHYSICIAN;

(2) SUPPLY ALL FDA–APPROVED BRANDS OF BLOOD CLOTTING PRODUCTS IN MULTIPLE ASSAY RANGES, LOW, MEDIUM, AND HIGH, AS APPLICABLE, INCLUDING BLOOD CLOTTING PRODUCTS MANUFACTURED FROM HUMAN PLASMA AND THOSE MANUFACTURED WITH RECOMBINANT BIOTECHNOLOGY TECHNIQUES;

(3) SUPPLY ALL NECESSARY ANCILLARY INFUSION EQUIPMENT AND SUPPLIES;

(4) PROVIDE, DIRECTLY OR THROUGH A RELIABLE THIRD–PARTY, HOME NURSING SERVICES THAT ARE PRESCRIBED AND DEEMED NECESSARY BY THE INSURED'S OR ENROLLEE'S TREATING PHYSICIAN;

(5) ON RECEIPT OF A PRESCRIPTION, SEND WITHIN 3 BUSINESS DAYS AND IN A SINGLE SHIPMENT, THE PRESCRIBED BLOOD CLOTTING PRODUCT AND ANCILLARY INFUSION EQUIPMENT AND SUPPLIES TO THE INSURED OR ENROLLEE;

(6) PROVIDE A PHARMACIST ON CALL, 24 HOURS A DAY, 7 DAYS A WEEK, TO FILL A PRESCRIPTION FOR A BLOOD CLOTTING PRODUCT;

(7) IF AN INSURED OR ENROLLEE NEEDS A BLOOD CLOTTING PRODUCT ON AN EMERGENCY BASIS, IMMEDIATELY NOTIFY THE INSURED'S OR ENROLLEE'S TREATING PHYSICIAN AND, IN CONSULTATION WITH THE TREATING PHYSICIAN, ENSURE ACCESS TO THE BLOOD CLOTTING PRODUCT AS SOON AS PRACTICABLE, AND IN NO EVENT MORE THAN 12 HOURS AFTER NOTICE OF THE EMERGENCY SITUATION;

(8) NOTIFY THE INSURED OR ENROLLEE, AS SOON AS PRACTICABLE, OF ANY RECALL OR WITHDRAWAL OF A BLOOD CLOTTING PRODUCT OR ANCILLARY INFUSION EQUIPMENT AND SUPPLIES; AND

(9) PROVIDE SHARPS CONTAINERS OR THE EQUIVALENT FOR THE REMOVAL AND DISPOSAL OF MEDICAL WASTE.

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

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

SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall apply to all health insurance policies and contracts issued, delivered, or renewed in the State on or after October 1, 2010.

SECTION 3. AND BE IT FURTHER ENACTED, That this Act shall take effect October 1, 2010.