REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

Senate Bill 1265
Mandated Coverage of Menorrhagia

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA

COMMONWEALTH OF VIRGINIA
RICHMOND
2004

December 19, 2003

To: The Honorable Mark Warner
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 2.2-2504 and 2.2-2505 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits to assess the social and financial impact and the medical efficacy of Senate Bill 1265 regarding a proposed mandate of coverage for menorrhagia.

Respectfully submitted,

Stephen H. Martin
Chairman
Special Advisory Commission on
Mandated Health Insurance Benefits

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EXECUTIVE SUMMARY

The Senate Committee on Commerce and Labor referred Senate Bill 1265 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 2003 Session of the General Assembly. Senate Bill 1265 was introduced by Senator Yvonne B. Miller.

The Advisory Commission held a public hearing on July 9, 2003, in Richmond to receive public comments on Senate Bill 1265. In addition to the patron, Senator Miller, three speakers addressed the proposal. A representative from the United Virginia Chapter of the National Hemophilia Foundation spoke in favor of Senate Bill 1265. Representatives from the Virginia Association of Health Plans (VAHP) and the Health Insurance Association of America (HIAA) spoke in opposition to the bill.

In addition, written comments in support of the bill were provided by the United Virginia Chapter of the National Hemophilia Foundation (NHF). Written comments in opposition to Senate Bill 1265 were provided by the VAHP and the HIAA.

Senate Bill 1265 would add menorrhagia to the hemophilia and congenital bleeding disorders mandate that requires insurers to provide coverage for these bleeding disorders. The mandate is applicable to insurers proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing subscription contracts; and HMOs providing health care plans.

The bill defines “menorrhagia” as menstrual blood loss greater than 80 milliliters per menstrual cycle. The bill also adds menorrhagia to the current requirement that benefits be provided for expenses incurred in connection with the treatment of routine bleeding episodes associated with hemophilia, and other congenital bleeding disorders. The benefits in the current section are to include coverage for the purchase of blood products and blood infusion equipment required for home treatment of routine bleeding episodes when the home treatment program is under the supervision of the state-approved hemophilia treatment center.

The Advisory Commission voted unanimously (9 – No, 0 – Yes) on August 13, 2003 to recommend that Senate Bill 1265 not be enacted. The Advisory Commission believes that based on the information presented, coverage for the cost of diagnostic tests and the treatment of menorrhagia is currently available, and a mandate is not necessary at this time

INTRODUCTION

The Senate Committee on Commerce and Labor referred Senate Bill 1265 to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) during the 2003 Session of the General Assembly. Senate Bill 1265 was introduced by Senator Yvonne B. Miller.

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SUMMARY OF PROPOSED LEGISLATION

Senate Bill 1265 would add menorrhagia to the hemophilia and congenital bleeding disorders mandate that requires insurers to provide coverage for these bleeding disorders. The mandate is applicable to insurers proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical coverage on an expense-incurred basis; corporations providing subscription contracts; and HMOs providing health care plans.

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THE CODE OF VIRGINIA

Section 38.2-3418.3 requires accident and sickness insurance policies to provide coverage for hemophilia and congenital bleeding disorders. The section applies to individual and group policies providing hospital, medical and surgical or major medical coverage on an expense-incurred basis and subscription contracts and health care plans provided by health maintenance organizations. The section applies to policies, contracts and plans delivered or issued for delivery or renewal after July 1, 1998.

The section defines “blood infusion equipment” as including, but not being limited to, syringes and needles. “Blood products” as used in the bills include but are not limited to Factor VII, Factor VIII, Factor IX and cryoprecipitate. “Hemophilia” is defined as a lifelong hereditary bleeding disorder usually affecting males that results in prolonged bleeding primarily into joints and muscles. “Home treatment program” means a program where individuals or family members are trained to provide infusion therapy at home in order to achieve optimal health and cost effectiveness. “State-approved hemophilia treatment center” means a hospital or clinic which receives federal or state Maternal and Child Health Bureau, and/or Centers for Disease Control funds to conduct comprehensive care for persons with hemophilia and other bleeding disorders.

MENORRHAGIA

According to the National Organization for Rare Disorders (NORD), menorrhagia is defined as excessively heavy or prolonged uterine bleeding that may be caused by medical problems or hormone imbalances.[1] Heavy bleeding (menorrhagia) affects many women. In some cases, bleeding may be so severe that daily activities become interrupted. Persistent heavy bleeding can lead to thinning of the blood (anemia) that may cause tiredness, shortness of breath, faintness, and even angina.[2]

An average amount of blood loss during a menstruation is 30 to 40 milliliters (six to eight teaspoons).[3] Bleeding is considered excessive when a woman soaks through enough sanitary products (napkins or tampons) to require changing every hour.[4] Bleeding is prolonged when a woman experiences a menstrual period that lasts longer than seven days per menstrual cycle. Symptoms may also include spotting, bleeding during pregnancy or between menstrual periods.

According to the Virginia Department of Health (VDH), the causes of menorrhagia may be identified by the appropriate diagnostic procedures. Possible causes may include the following: infections such as pelvic inflammatory disease; uterine fibroids; hormonal imbalances; abnormal pregnancy (ectopic) or miscarriage; certain birth control devices (intrauterine devices); liver, kidney, or thyroid dysfunctions; chronic disorders such as Lupus; bleeding or platelet disorders; precancerous or cancerous conditions; and tumors or polyps in the pelvic cavity.[5]

According to the Baptist Health System Website, the first step to diagnose a patient with menorrhagia begins with a gynecologist evaluating a patient's medical history and a complete physical examination that includes a pelvic examination. A diagnosis of menorrhagia can only be confirmed when the physician rules out other menstrual disorders, medical conditions, or medications that may be causing or aggravating the condition. The diagnostic procedures most commonly used for determining the specific physiological causes of menorrhagia include the following: blood tests for anemia, thyroid, reproductive hormones, blood clotting protein (von Willebrand's disease), other platelet disorders and vitamin K deficiency; pap tests, to determine if abnormal or precancerous cells are present on the cervix; ultrasound, to identify abnormalities such as fibroids; biopsy, to identify cancerous of other abnormal cells; hysteroscopy, to visually examine the cervix an interior of the uterus; and dilation and curettage (D&C), scrapping of the internal lining of the uterus to allow resumption of normal functioning of the uterus lining.[6]

The United Virginia Chapter of the National Hemophilia Foundation (NHF) and the NHF of New York, NY expressed their concerns over the misdiagnosis and under-treatment of women with von Willebrand disease (VWD) factor. VWD is a genetic condition characterized by the reduction in the quantity of von Willebrand factor (VWF), a protein required for normal blood clotting. If a person has an altered VWF protein or low levels of VWF, it takes longer for the bleeding to stop.[7] According to the information provided the VDH, NHF estimated that 20% of women with menorrhagia have VWD and 23% of women diagnosed with VWD eventually have a hysterectomy.[8] Symptoms of VWD include easy bruising, frequent nosebleeds, and prolonged bleeding from dental work and surgery. Other symptoms affecting a woman's health may include postpartum hemorrhaging and heavy periods. The NHF reported that as many as 2 people in 100 have VWD, making it more common than any other bleeding disorder, including hemophilia.[9]

SOCIAL IMPACT

The VDH stated that menorrhagia is especially prevalent among premenopausal women between 35-45 years of age when hormonal imbalances can develop. Because hormonal imbalances can also occur with the onset of menstruation, menorrhagia sometimes occurs in adolescent women. According to the information provided by the VDH, the U.S. Centers for Disease Control and Prevention estimated that approximately 28,000 women per year have hysterectomies due to menorrhagia.[10]

FINANCIAL IMPACT

The NHF of New York, NY reported that treatments are currently available for patients that are diagnosed with VWD. The NHF and its Project Red Flag can provide information regarding hemophilia treatment centers (HTC), federally-supported health centers that specialize in the testing and treatment of bleeding disorders, so that women with VWD can receive proper diagnosis and treatment.[11]

Information was provided by the Virginia Commonwealth University Richmond Hemophilia Treatment Center. The center provided information on four blood tests that were commonly ordered to determine if a patient has von Willebrand disease. The tests include Factor VIII level that costs $177, APTT costs $51, von Willebrand Activity costs $200 and von Willebrand Antigen costs $197. According to the information, the center would need to perform all four tests to make a diagnosis. It was noted that the Hemophilia Treatment Center is unaware of any cases where a patient was denied insurance coverage for these blood tests as long as the diagnosis code reflects a coagulation disorder work-up.[12]

MEDICAL EFFICACY

The Baptist Health System website states that a physician will determine the specific treatment for patients diagnosed with menorrhagia based on their overall health and medical history, extent and cause of the condition, and their tolerance for medications, procedures, or therapies. Treatment for menorrhagia may include the following: iron supplements, when the condition is joined with anemia that consists of a blood disorder caused by a deficiency of red blood cells or hemoglobin; prostaglandin inhibitors, nonsteroidal anti-inflammatory medications that help reduce cramping and the amount of blood expelled; oral contraceptives, to act as both an ovulation and hormonal regulator; progesterone, to reestablish hormonal balance with estrogen; endometrial ablation, a procedure used to destroy the lining of the uterus; and hysterectomy, surgical removal of the uterus.[13]

CURRENT INDUSTRY PRACTICES

The State Corporation Commission Bureau of Insurance surveyed 60 of the top writers of accident and sickness insurance in Virginia regarding each of the bills to be reviewed by the Advisory Commission. Fifty companies responded by June 16, 2003. Thirteen indicated that they have little or no applicable health insurance business in force in Virginia and, therefore, could not provide the information requested. Of the 37 respondents that completed the survey, 34 reported that they currently provide the coverage required by Senate Bill 1265.

Eleven respondents to the Bureau of Insurance survey provided cost figures that ranged from less than $.01 to $1.35 per month, per standard individual policyholder and from $.01 to $.75 per month, per standard group certificate to provide the coverage required by Senate Bill 1248. Fifteen insurers provided cost figures of $.63 to $5.00 per month per individual policyholder and from $.53 to $1.34 per month per group certificate holder for the coverage required by Senate Bill 1265 on an optional basis.

SIMILAR LEGISLATION IN OTHER STATES

According to information published by the National Association of Insurance Commissioners and the National Insurance Law Service, no state mandates coverage for menorrhagia.

REVIEW CRITERIA

SOCIAL IMPACT

a. *The extent to which the treatment or service is generally utilized by a significant portion of the population.*

The VDH stated that menorrhagia is extremely prevalent among premenopausal women between 35-45 years of age when hormonal imbalances start to develop. Because hormonal imbalances can also occur with the onset of menstruation, menorrhagia sometimes occurs in adolescent women.[14]

b. *The extent to which insurance coverage for the treatment or service is already available.*

In a 2003 State Corporation Commission’s Bureau of Insurance survey of the top 60 writers of accident and sickness insurance in Virginia, 37 companies currently writing applicable business in Virginia responded. Of the 37, 34 companies (92%) already provide the coverage required by Senate Bill 1265.

c. *If coverage is not generally available, the extent to which the lack of coverage results in persons being unable to obtain necessary health care treatments.*

Information was not presented on the number of people that have not been treated because of a lack of coverage. However, according to the information provided by the VDH, the U.S. Centers for Disease Control and

Prevention, estimated that 28,000 women per year have hysterectomies due to menorrhagia.[15]

d. If the coverage is not generally available, the extent to which the lack of coverage results in unreasonable financial hardship on those persons needing treatment.

A representative from the United Virginia Chapter of the NHF testified in favor of Senate Bill 1265 at the public hearing. The representative had been informed by the community and by treatment centers that some insurance companies are reluctant to cover the cost of blood tests to determine whether a patient is diagnosed with an inherited bleeding disorder. The proponent explained that some people suffer chronic anemia and have to take time off from their jobs approximately 3 to 5 days a month. The United Virginia Chapter of the NHF affirmed that under the existing law, once the disorder is diagnosed, menorrhagia is covered. Its main concern was the cost of the diagnostic tests. Many people cannot afford to pay several hundreds of dollars to determine if they have the bleeding disorder. The proponent concluded that in the long run, proper treatments for these disorders are needed to prevent financial hardships and to maintain a healthy body.[16]

The NHF of New York, NY reported that treatments are currently available for patients that are diagnosed with VWD. The NHF and its Project Red Flag can provide information regarding hemophilia treatment centers (HTC), federally-supported health centers that specialize in the testing and treatment of bleeding disorders, so that women with VWD can receive proper diagnosis and treatment.[17]

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e. The level of public demand for the treatment or service.

A representative from the United Virginia Chapter of the NHF testified at the public meeting that the community has very little knowledge about von Willebrand's disease. Von Willebrand's disease affects approximately 1% to 2%

of men and women equally. She explained that without proper treatment, life is very challenging for a person with von Willebrand's disease. For some female patients, the only treatment option offered is a hysterectomy. The representative testified that according to the Centers for Disease Control, 1 out of every 100 persons diagnosed with von Willebrand's disease is between the ages of 18 to 25 years old.[19]

f. The level of public demand and the level of demand from providers for individual and group insurance coverage of the treatment or service.

In written comments, the HIAA stated that according to the National Institutes of Health (NIH), there are several causes of menorrhagia and myriad treatments ranging from anti-inflammatory drugs to surgerical procedures, such as a hysterectomy. HIAA stated that many of these procedures are already covered services under their members' health insurance policies. HIAA noted that insurers are required to cover medically necessary services and that there is little evidence that women with menorrhagia are being denied adequate coverage. [20]

g. The level of interest of collective bargaining organizations in negotiating privately for inclusion of this coverage in group contracts.

No information was received from collective bargaining organizations addressing potential interest in negotiating privately for inclusion of this coverage in group contracts.

h. Any relevant findings of the state health planning agency or the appropriate health system agency relating to the social impact of the mandated benefit.

The Advisory Commission is not aware of any findings of a state health planning agency or appropriate health system agency relating to the social impact of this proposal.

FINANCIAL IMPACT

a. *The extent to which the proposed insurance coverage would increase or decrease the cost of treatment or service over the next five years.*

No information was provided by either proponents or opponents that would suggest that the cost of treatments would increase or decrease in the next five years because of insurance coverage.

b. *The extent to which the proposed insurance coverage might increase the appropriate or inappropriate use of the treatment or service.*

The appropriate use of treatment could possibly increase if the insurance policy provided coverage for the treatment of menorrhagia and there previously was no coverage.

The VAHP, which represents 24 managed health care plans that provide coverage for approximately 3.8 million Virginians, reported that a study commissioned by the American Association of Health Plans and conducted by Price WaterhouseCoopers in 2002 attributed a 15% increase in health care costs to government mandates and regulations. VAHP stated that its members are unaware of any situations or set of circumstances under which treatment for the condition of menorrhagia would not be covered.[21]

c. *The extent to which the mandated treatment or service might serve as an alternative for more expensive or less expensive treatment or service.*

According to a representative of the United Virginia Chapter of the NHF, untreated menorrhagia can lead to serious problems. An early diagnosis of menorrhagia may appropriately decrease the number of hysterectomies. The representative stated that early and proper treatments may decrease the number of days off from work and medical visits.[22]

d. *The extent to which the insurance coverage may affect the number and types of providers of the mandated treatment or service over the next five years.*

Coverage for the treatment of menorrhagia is not expected to affect the number or types of providers over the next five years.

e. *The extent to which insurance coverage might be expected to increase or decrease the administrative expenses of insurance companies and the premium and administrative expenses of policyholders.*

An increase in the administrative expenses of insurance companies, in premiums, and in the administrative expenses for policyholders is anticipated because of the expenses associated with such things as policy redesign, form filings, claims processing systems, and marketing.

Eleven respondents to the Bureau of Insurance survey provided cost figures that ranged from less than $.01 to $1.35 per month, per standard individual policyholder and from $.01 to $.75 per month, per standard group certificate to provide the coverage required by Senate Bill 1248. Fifteen insurers provided cost figures of $.63 to $5.00 per month per individual policyholder and from $.53 to $1.34 per month per group certificate holder to provide the coverage required by Senate Bill 1265 on an optional basis.

f. *The impact of coverage on the total cost of health care.*

In written comments, the HIAA opposed legislation that mandates specific benefits to be provided in health insurance policies. HIAA noted that mandates lock into law what should be a flexible decision about levels of coverage made in the context of rapidly advancing medical knowledge and evolving medical technologies. HIAA noted that studies have continually indicated that mandated benefits do increase the cost of health insurance, resulting in higher premiums and more uninsured people. Health care costs and insurance premiums are constantly rising at double digit rates, and almost 15% of Virginians lack health insurance coverage. It was noted that additional mandates will serve only to exacerbate these trends.[23]

MEDICAL EFFICACY

a. *The contribution of the benefit to the quality of patient care and the health status of the population, including the results of any research demonstrating the medical efficacy of the treatment or service compared to alternatives or not providing the treatment or service.*

According to a representative of the United Virginia Chapter of the NHF, untreated menorrhagia can lead to serious problems. An early diagnosis of menorrhagia may appropriately decrease the number of hysterectomies. The representative stated that early and proper treatments may decrease the number of days off from work and medical visits.[24]

b. *If the legislation seeks to mandate coverage of an additional class of practitioners:*

1) *The results of any professionally acceptable research demonstrating the medical results achieved by the additional class of practitioners relative to those already covered.*

Not applicable.

2) *The methods of the appropriate professional organization that assure clinical proficiency.*

Not applicable.

EFFECTS OF BALANCING THE SOCIAL, FINANCIAL AND MEDICAL EFFICACY CONSIDERATIONS

a. *The extent to which the benefit addresses a medical or a broader social need and whether it is consistent with the role of health insurance.*

Senate Bill 1265 addresses the medical need of treating individuals diagnosed with menorrhagia. The benefit is consistent with the role of health insurance.

b. *The extent to which the need for coverage outweighs the costs of mandating the benefit for all policyholders.*

Eleven respondents to the Bureau of Insurance survey provided cost figures that ranged from less than $.01 to $1.35 per month, per standard individual policyholder and from $.01 to $.75 per month, per standard group certificate to provide the coverage required by Senate Bill 1248. Fifteen insurers provided cost figures of $.63 to $5.00 per month per individual policyholder and from $.53 to $1.34 per month per group certificate holder to provide coverage required by Senate Bill 1265 on an optional basis.

In written comments, HIAA noted that the individual and small group insurance markets could be substantially harmed by the proposed mandates because they will further limit insurers ability to provide affordable products.[8]

c. *The extent to which the need for coverage may be solved by mandating the availability of the coverage as an option for policyholders.*

In the case of group coverage, the decision whether to select the optional coverage or not would lie with the master contract holder and not the individual insured.

RECOMMENDATION

The Advisory Commission voted unanimously (9 – No, 0 – Yes) on August 13, 2003 to recommend that Senate Bill 1265 not be enacted.

CONCLUSION

The Advisory Commission believes that based on the information presented, coverage for the cost of diagnostic tests and the treatment of menorrhagia is currently available, and a mandate is not necessary at this time.

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[1] Menorrhagia. April 2003. National Organization for Rare Disorders, Inc.

[2] Heavy Periods (Menorrhagia). March 2002. Medinfo. www.medinfo.co.uk/conditions/heavyperiods.

[3] Heavy Periods (Menorrhagia). March 2002. Medinfo. www.medinfo.co.uk/conditions/heavyperiods.

[4] Menorrhagia. April 2003. National Organization for Rare Disorders, Inc.

[5] Menorrhagia: Overview, Treatment and Prevention. Virginia Department of Health, Office of Health Policy and Planning.

[6] Menorrhagia. April 2003. Baptist: The One Word in Healthcare Website: www.baptistoneword.org/healthinfo.

[7] Heavy Periods or a Bleeding Disorders? 2001. National Hemophilia Foundation's Project Red Flag, New York, NY.

[8] Menorrhagia: Overview, Treatment and Prevention. Virginia Department of Health, Office of Health Policy and Planning.

[9] Heavy Periods or a Bleeding Disorders? 2001. National Hemophilia Foundation's Project Red Flag, New York, NY.

[10] Menorrhagia: Overview, Treatment and Prevention. Virginia Department of Health, Office of Health Policy and Planning.

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[14] Menorrhagia: Overview, Treatment and Prevention. Virginia Department of Health, Office of Health Policy and Planning.

[15] Menorrhagia: Overview, Treatment and Prevention. Virginia Department of Health, Office of Health Policy and Planning.

[16] DeRatto, Patricia of the United Virginia Chapter of the National Hemophilia Foundation. "Public Meeting." Richmond, Virginia. 9 July 2003.

[17] Heavy Periods or a Bleeding Disorders? 2001. National Hemophilia Foundation's Project Red Flag, New York, NY.

[18] Virginia Commonwealth University, MCV Coagulation Disorders Center. July 2003.

[19] DeRatto, Patricia of the United Virginia Chapter of the National Hemophilia Foundation. "Public Meeting." Richmond, Virginia. 9 July 2003.

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[20] Health Insurance Association of America, June 2003.

[21] Virginia Association of Health Plans, July 2003.

[22] DeRatto, Patricia of the United Virginia Chapter of the National Hemophilia Foundation. "Public Meeting." Richmond, Virginia. 9 July 2003.

[23] Health Insurance Association of America, June 2003.

[24] DeRatto, Patricia of the United Virginia Chapter of the National Hemophilia Foundation. "Public Meeting." Richmond, Virginia. 9 July 2003.