REPORT OF THE
SPECIAL ADVISORY COMMISSION ON MANDATED
HEALTH INSURANCE BENEFITS

# Coverage for Medication for Diabetes

TO THE GOVERNOR AND
THE GENERAL ASSEMBLY OF VIRGINIA


## SENATE DOCUMENT NO. 21

COMMONWEALTH OF VIRGINIA
RICHMOND
2001

# COMMONWEALTH OF VIRGINIA

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PRIVILEGES AND ELECTIONS

SENATE

December 28, 2000

To: The Honorable James S. Gilmore, III
Governor of Virginia
and
The General Assembly of Virginia

The report contained herein has been prepared pursuant to §§ 9-298 and 9-299 of the Code of Virginia.

This report documents a study conducted by the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) to assess the social and financial impact and the medical efficacy of Senate Bill 466, regarding a proposed mandate of coverage for medication for diabetes.

Respectfully submitted,

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

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## INTRODUCTION

Senate Bill 466 was referred to the Special Advisory Commission on Mandated Health Insurance Benefits (Advisory Commission) by the Senate Committee on Commerce and Labor in the 2000 Session of the General Assembly. Senator Charles J. Colgan introduced the bill.

The Advisory Commission held a public hearing to receive comments on the bill in Richmond on August 3, 2000. The patron, Senator Colgan, spoke in support of the bill. Representatives of the Virginia Association of Health Plans (VAHP) and the Health Insurance Association of America spoke against the bill. Written comments in support of the bill were received from the Virginia Affiliate of the American Diabetes Association, along with information from the national association and a proponent of the legislation. Written comments in opposition to the bill were received from the VAHP.

The Advisory Commission concluded its review of the bill on August 30, 2000.

## SUMMARY OF PROPOSED LEGISLATION

The bill amends and reenacts § 38.2-3418.10 in the accident and sickness provisions chapter. The section applies to insurers proposing to issue an individual or group hospital policy or major medical policy in this Commonwealth; each corporation proposing to issue an individual or group hospital, medical or major medical subscription contract; and each health maintenance organization (HMO) providing a health care plan for such services.

The bill requires benefits for medications approved by the federal Food and Drug Administration (FDA). This is in addition to equipment, supplies, and outpatient self-management training and education, including medical nutrition therapy for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes, and non-insulin-using diabetes, if prescribed by a health care professional legally authorized to prescribe such items under law, which is already required by the section.

The current language in § 38.2-3418.10 requires that any insurer 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; each corporation providing individual or group accident and sickness subscription contracts; and each health maintenance organization providing a health care plan for health care services provide coverage for diabetes as provided in this section.

The coverage must include benefits for equipment, supplies, and outpatient self-management training and education, including medical nutrition therapy for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes, and non-insulin using diabetes, if prescribed by a health care professional legally authorized to prescribe such items under law. Diabetes outpatient self-management training and education must be provided by a certified, registered, or licensed health care provider to qualify for coverage under the section.

Insurers, corporations, or HMOs cannot impose upon any person receiving benefits pursuant to this section any co-payment, fee, or condition that is not equally imposed upon all individuals in the same benefit category. The section does not apply to short-term travel, accident only, limited or specified disease, or individual conversion policies or contracts, nor to policies or contracts designed for issuance to persons eligible for similar coverage under state or federal governmental plans. The section applies to all insurance policies, contracts, and plans delivered, issued for delivery, reissued, or extended on and after July 1, 1999, or at any time thereafter when any term of the policy, contract, or plan is changed or any premium adjustment is made.

The bill, as introduced, appears to mandate coverage for prescription drugs in policies and plans that do not otherwise provide prescription drug coverage. Prescription drug coverage is usually provided separately by rider for all covered pharmaceuticals and not for a particular medication.

Senator Colgan proposed amended language at the August 3 meeting. The new language stated: "Coverage by those entities described in subsection A that provide prescription drug benefits shall also include coverage of medications approved by the federal Food and Drug Administration for diabetes treatment, if prescribed by a health care professional legally authorized to prescribe such medication under law. Coverages under this subsection may be provided in accordance with §38.2-3407.90:01." This amended language is found in Appendix B.

## SOCIAL IMPACT

According to information provided by the United States Department of Health and Human Services (HHS) in the "National Diabetes Fact Sheet," diabetes mellitus (diabetes) is a group of diseases characterized by high levels of blood glucose resulting from defects in insulin secretion, insulin action, or both. The American Diabetes Association (ADA) states that diabetes is a chronic illness that requires continual medical care and education to prevent acute complications and to reduce the risk of long-term complications. Diabetes can be associated with serious complications and premature death, but persons with diabetes can take measures to reduce the likelihood of such occurrences. The

HHS estimates that 15.7 million people (or 5.9% of the population) have diabetes. Using 1996 population estimates, the Virginia Department of Health (VDH) estimates that there are 220,000 diabetics in Virginia. There are approximately 75,000 additional diabetics who are not diagnosed.

There are generally four types of diabetes. The HHS reports that Type I diabetes (previously called "juvenile-onset" diabetes or "insulin-dependent" diabetes) may account for 5% to 10% of all diagnosed cases of diabetes. Type II diabetes (previously known as "adult-onset" diabetes or "non-insulin-dependent" diabetes) may account for 90% to 95% of all diagnosed cases of diabetes. According to the HHS, gestational diabetes develops in 2% to 5% of all pregnancies but disappears when a pregnancy ends. Other specific types of diabetes result from specific genetic syndromes, surgery, drugs, malnutrition, infections, and other illnesses. The HHS reports that such types of diabetes may account for 1% to 2% of all diagnosed cases of diabetes.

Diabetes can cause both short-term and long-term health complications. Short-term complications include problems associated with inadequate control of blood sugar levels, which can lead to coma; infectious, metabolic, or neurological complications; hospitalization; a need for emergency room care; and even death. Long-term complications can include blindness, kidney disease, amputations, heart disease, stroke, and death.

The lack of insulin production by the pancreas makes Type I diabetes difficult to control. The American Diabetes Association (ADA) also notes that treatment of Type I diabetes includes insulin, a meal plan developed by a registered dietician, an exercise regimen developed by a health care practitioner, and daily blood and urine testing equipment. Treatment for Type II diabetes typically includes diet control, exercise, home glucose testing, and in some cases, oral medication and/or insulin. The HHS reports that approximately 40% of people with Type II diabetes require insulin injections.

## FINANCIAL IMPACT

Proponents of Senate Bill 466 estimate that on a daily basis, the cost of FDA-approved medications for the treatment of diabetes ranges from $.40 to $4.00. Two other sources provided cost estimates of medications ranging from $8.97 per month up to $143 per month and from $15.85 to $148.70 per month.

## MEDICAL EFFICACY

The primary treatment tools for diabetes are weight control, diet, exercise, and medication. The more overweight a person is, the more his or her cells become resistant to his or her own insulin. Losing weight decreases that

resistance. A loss of weight may sometimes be enough to bring blood sugar into the normal range.

It is currently recommended that diabetics eat a healthful, balanced diet, the same that is generally recommended for most people. A recommended diet would include whole grains, legumes, vegetables, and fruits. These foods can help with blood sugar control and are high in fiber. It is recommended that fat intake and cholesterol intake be controlled by eating lean meats, poultry, fish, and low fat dairy products.

According to the Mayo Foundation for Medical Education and Research, exercise is important in controlling diabetes. Exercise can help prevent development of Type II diabetes for people who are high risks for developing the condition. The need for insulin may be reduced, or sometimes eliminated, for those with Type II diabetes. For some individuals whose diabetes is not sufficiently controlled by weight control, diet, and exercise, the addition of medication may be helpful.

## Medications

Individuals with Type I diabetes usually take insulin. Those who have Type II diabetes who are not able to control the disease through diet and exercise may be helped by medications. According to the Mayo Foundation for Medical Education and Research, the medications include:

1. **Sulfonylurea drugs** - This class of drugs lowers the blood sugar by increasing the amount of insulin released by the pancreas. Sulfonylureas commonly prescribed are Glipizide and Glyburide. Newer drugs include Amaryl.

2. **Non-Sulfonylurea secretagogues** - These drugs also stimulate the pancreas to produce and release more insulin. They are chemically different from sulfonylureas.

3. **Metformin** - Decreases the release of glucose stored in the liver.

4. **Acarbose (Precose)** - This drug helps decrease the after-meal spike in the blood sugar by slowing the digestion and absorption of carbohydrates in the intestine.

5. **Rosiglitazone** - This drug improves insulin action. Regular tests to monitor liver function are initiated at the start of therapy.

6. **Pioglitazone** - This drug is similar to Rosiglitazone in its action.

7. **Insulin** - The drug was discovered in 1921. Prior to its discovery, most people with Type I diabetes died within two years. Most people use synthetic insulin that is chemically identical to human insulin.

## Drug Approval through the Food and Drug Administration

The Food and Drug Administration (FDA) is a public health agency. It was designed to protect American consumers by enforcing the federal Food, Drug, and Cosmetic Act and several related public health laws. The FDA has approximately 1,100 investigators and inspectors to visit nearly 95,000 businesses that are subject to the FDA.

The FDA's Center for Drug Evaluation and Research was designed to ensure that safe and effective drugs are available to the American people. The FDA Modernization Act, enacted on November 21, 1997, amended the original Act. This modernization enhanced the mission of the agency to recognize increased technological, trade, and public health complexities. The Act streamlined regulatory procedure. A flow chart describing the procedure for drug approval is found in Appendix C.

## CURRENT INDUSTRY PRACTICES

The Bureau of Insurance surveyed 60 of the top writers of accident and sickness insurance in Virginia in March and May 2000. Fifty companies responded to the survey by July 18, 2000. Twenty-four companies do not write the type of coverage to which the mandate would apply. Twenty-six companies completed the survey. Nine companies do not provide the coverage required by the bill. One company covers only insulin derivatives, and one provides the coverage only if there is coverage for prescription drugs, then limits coverage to $1,000 per year. One insurer provides the coverage only in group contracts. The other fourteen respondents (or 54%) indicated that they provide the coverage required by the bill.

## REQUIREMENTS IN OTHER STATES

Information from the National Insurance Law Service and the National Association of Insurance Commissioners (NAIC) indicates that at least 35 states have some type of requirement for coverage for diabetes. At least fifteen states require coverage for insulin and/or "oral hypoglycemic agents or pharmacological agents.

Connecticut, Georgia, Kentucky, Maine, New Hampshire (with prescription drug rider), New Jersey, New York, North Carolina, Oklahoma, Rhode Island,

Tennessee, Texas, Washington, West Virginia and Wisconsin require some type of coverage for insulin and/or other medications.

## REVIEW CRITERIA

SOCIAL IMPACT

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

According to estimates from the Virginia Department of Health, in 1996, there were approximately 220,000 diabetics in Virginia. An additional 75,000 diabetics were not yet diagnosed.

Proponents of the legislation estimate that 1,000 to 2,000 Virginians have Type I diabetes, and most take insulin several times a day. The proponents estimate that 80% to 90% of the 264,000 Virginians with Type II diabetes will take medications, including insulin, at some point.

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

Twenty-six insurers completed the Bureau of Insurance's survey regarding Senate Bill 466. Nine companies do not provide the coverage required by the bill. One company covers only insulin derivatives, and one provides the coverage only if there is coverage for prescription drugs, then limits coverage to $1,000 per year. One insurer provides the coverage only in group contracts. The other fourteen respondents (or 54%) indicated that they provide the coverage required by the bill.

The VAHP states that comprehensive coverage for diabetes medications is currently available in the market. They state that most health plans in Virginia offer an open, three-tiered formulary. Most, if not all, FDA-approved medications are available to the covered persons at different co-payments for each tier.

The VAHP further states that health plans that offer a restricted formulary still provide access to many diabetes medications. Access is limited to a pre-approved list of medications.

When a specific drug is not included in the plan formulary, the covered person can obtain his or her medicine by paying a higher out-of-pocket cost or when the formulary drug is not appropriate, a non-formulary drug can be obtained as required by Virginia law.

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 who go without medications because of a lack of coverage. Proponents make the argument that some people may go without their medications because of the absence of coverage.

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.*

Information from three separate sources indicates that the cost of FDA-approved medications for diabetes treatment on a monthly basis could range from $12.00 to $120.00; $8.97 to $143.00; and $15.85 to $148.70. The degree of financial hardship on an individual without coverage would be dependent upon the percentage of the individual's income available to meet the projected cost of up to $149.00 per month.

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

Proponents believe that 80% to 90% of the 260,000 Virginians with Type II diabetes will need medications, or insulin alone, to control their blood glucose. All diabetics do not need medication. Some individuals are able to control the condition with diet and exercise. All of the people with Type I diabetes are expected to need insulin (1,000 to 2,000).

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

Provider demand for insurance coverage for diabetes medications is not known. However, it could be assumed that providers would not oppose this requirement. Public demand was demonstrated by support of the bill by the Virginia Diabetes Association and proponents of the bill in local chapters of the association.

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

The interest of collective bargaining organizations in negotiating for inclusion of diabetes medication coverage in group contracts is not known.

*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 Virginia Diabetes Task Force was founded to coordinate diabetes related efforts of the public health system with private health care providers and payors, along with government and volunteer organizations and professional and academic institutions. The task force membership included over 40 Virginia organizations. The task force's purpose was to advise and coordinate state efforts that would reduce the burden of diabetes in Virginia. The 1998 state plan focuses on four key issues: surveillance, reimbursement, education, and access to care. In the area of reimbursement, the goal of the plan is to prevent costly complications and to allow diabetics to have healthy and productive lives. The plan summary states that diabetes self-management education and medical supplies must be available, accessible, and affordable to everyone with diabetes.

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.*

Coverage for medications for diabetes is not expected to significantly increase or decrease the cost of the medications over the next five years.

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

Coverage for medications might appropriately increase the use of medications if, in fact, people are currently not taking their medications because coverage is not available. Inappropriate use of medications is not expected to occur because a physician must prescribe the medications.

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

Proponents believe that a lack of consistent insurance coverage for diabetes education, supplies, and medication affects the mortality and morbidity rates in Virginia. They noted that the National Institutes of Health Diabetes Control and Complications Trial (DCCT) confirmed that regular monitoring, self-management training, access to health care professionals, and medications reduced the incidence of diabetes eye disease by 76%, diabetes kidney disease by 54%, and diabetes nerve disease by 60%.

*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 diabetes medications is not expected to affect the number or types of providers of the medications in 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.*

There are administrative expenses associated with the implementation of any new mandated benefit because of requirements for forms redesign and approval. Eight responses to the Bureau of Insurance's survey on the cost that this coverage would add to an individual standard contract ranged from $.12 to $25.00 per month. One company estimated less than 1% and another company estimated 10%. Sixteen companies provided responses to the cost of coverage for a standard group contract. The responses ranged from $.08 to $25.00. One insurer estimated 0% increase in the premium cost, another estimated less than 1%, and a third, 10%. Two insurers supplied answers on a per member per month basis with one estimating $l.02 and the other $14.00.

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

Proponents of the mandate cite information from a 1997 Black and Decker Corporation program that provides diabetes education and supplies. According to the William M. Mercer, Inc. analysis of the program, Black and Decker saved $1.4 million. The savings were experienced in large part because of reduced hospital stays and emergency room visits. Proponents cited state spending of $2.8 billion per year for diabetes treatment from the surveillance report in 1996 through the Diabetes Control Project of the Department of Health and the U. S. Bureau of the Census. Ninety-eight billion dollars was cited as the national cost in 1997.

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.*

The medical efficacy of medications for the treatment of diabetes was not challenged in any information presented to the Advisory Commission. Medications are recognized as appropriate treatment for individuals with diabetes when diet and exercise alone cannot control the disease.

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 organi- zation that assure professional efficiency.*

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.*

The proposal addresses medical need and is consistent with the role of health insurance. The VAHP comments that requiring coverage for medications for diabetes even when there is no other prescription drug coverage in the policy is not consistent with the way prescription drug coverage is provided through insurance.

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

The VAHP stated that mandating coverage for all FDA-approved medications would weaken the ability of health plans to establish and maintain prescription drug formularies. They believe that formularies are one of the most effective mechanisms for controlling the impact of pharmaceutical costs.

They point to the double-digit growth for expenditures for prescription drugs over the past 20 years. They cited a recent study by the National Institute of Health Care Management Research and Education Foundation, which stated that newer drugs cost, on average, twice as much as older drugs.

The VAHP believes that weakening health plans' ability to control pharmaceutical costs will lead to higher health coverage premiums, higher out-of-pocket costs, lower benefits, or more restricted access to drugs.

Proponents of the bill believe that the amended language addresses the concerns regarding health plan formularies.

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

Insurers made the argument that coverage for diabetes medications is available along with coverage for other medications by riders to policies or contracts.

Coverage is basically available as an option for many contracts. The coverage is available to the individual for an individual policy and to the group policyholder, usually the employer, for group coverage.

## RECOMMENDATION

The patron of the bill indicated, on August 28, 2000, that if there would be no gap in coverage for diabetes medications, he would put the legislation aside. He indicated that if future problems developed, he would renew his efforts to mandate this coverage.

The Advisory Commission unanimously voted (8-0), on August 30, 2000, to recommend that Senate Bill 466 not be enacted. The testimony and written submissions indicated that coverage for FDA-approved medications for diabetes is available, although it is acknowledged that coverage must often be purchased in the form of a rider to the contract.

## CONCLUSION

The Advisory Commission believes that a mandate of coverage for medications approved by the Food and Drug Administration for the treatment of diabetes is not necessary at this time. Most insurers currently offer coverage for diabetes medications and other medications by rider. There was also some concern that the legislation could possibly create difficulties in the use of an insurer's formulary because the original wording of the bill required coverage for all FDA-approved medications.

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# SENATE BILL NO. 466

Offered January 24, 2000

*A BILL to amend and reenact § 38.2-3418.10 of the Code of Virginia, relating to accident and sickness insurance: coverage for diabetes.*

Patron—Colgan

Referred to Committee on Commerce and Labor

**Be it enacted by the General Assembly of Virginia:**

**1. That § 38.2-3418.10 of the Code of Virginia is amended and reenacted as follows:**

§ 38.2-3418.10. Coverage for diabetes.

A. Each insurer proposing to issue an individual or group hospital policy or major medical policy in this Commonwealth, each corporation proposing to issue an individual or group hospital, medical or major medical subscription contract, and each health maintenance organization providing a health care plan for health care services shall provide coverage for diabetes as provided in this section.

B. Such coverage shall include benefits for equipment, *medications approved by the federal Food and Drug Administration,* supplies and outpatient self-management training and education, including medical nutrition therapy, for the treatment of insulin-dependent diabetes, insulin-using diabetes, gestational diabetes and noninsulin-using diabetes if prescribed by a health care professional legally authorized to prescribe such items under law.

C. To qualify for coverage under this section, diabetes outpatient self-management training and education shall be provided by a certified, registered or licensed health care professional.

D. No insurer, corporation, or health maintenance organization shall impose upon any person receiving benefits pursuant to this section any copayment, fee or condition that is not equally imposed upon all individuals in the same benefit category.

E. The requirements of this section shall apply to all insurance policies, contracts and plans delivered, issued for delivery, reissued, or extended on and after July 1, 1999, or at any time thereafter when any term of the policy, contract or plan is changed or any premium adjustment is made.

F. This section shall not apply to short-term travel, accident only, limited or specified disease, or individual conversion policies or contracts, nor to policies or contracts designed for issuance to persons eligible for coverage under Title XVIII of the Social Security Act, known as Medicare, or any other similar coverage under state or federal governmental plans.

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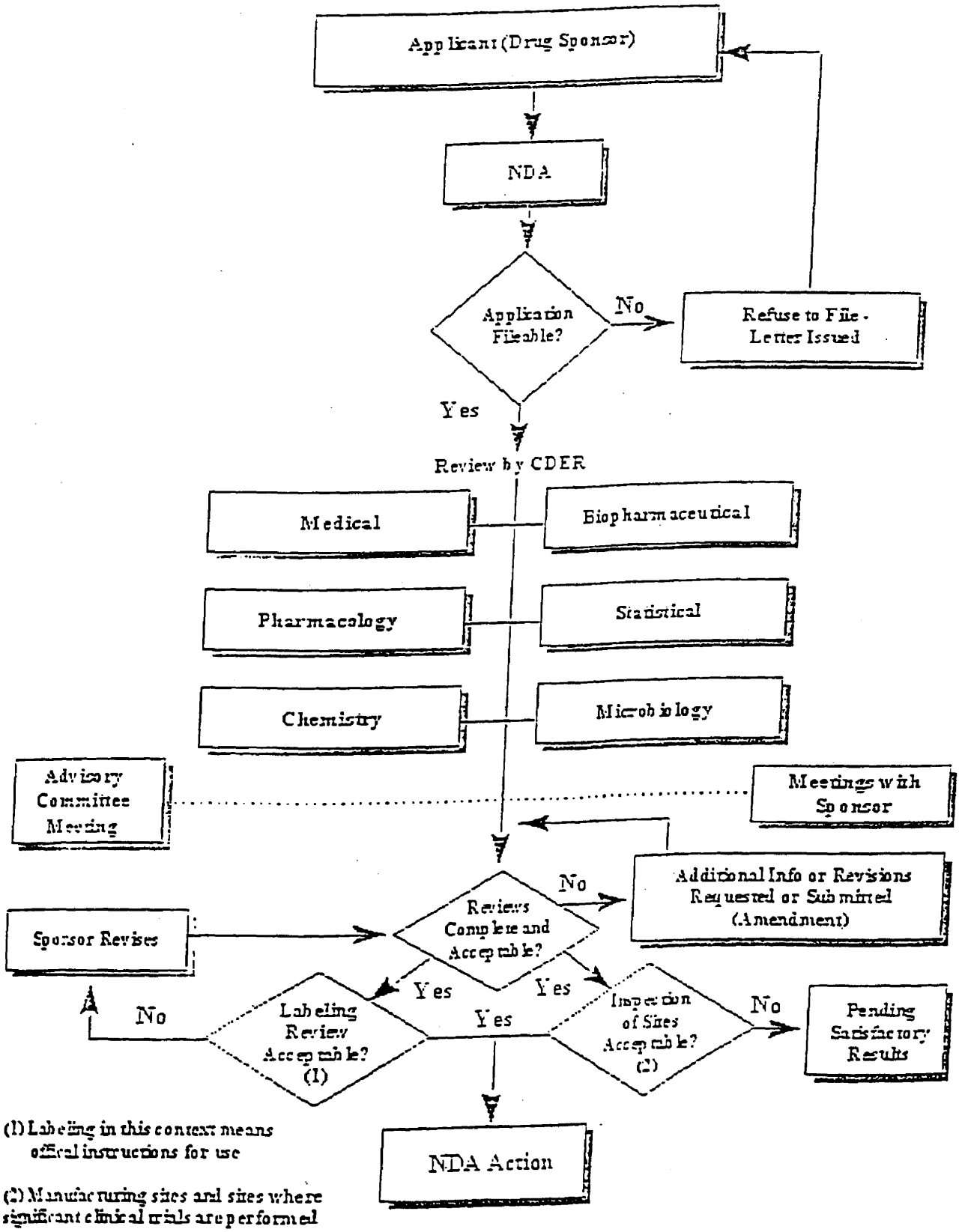
SB466

Proposed new language for SB 466, deleting the new language in the bill as introduced, and creating the following new subsection:

D. Coverage by those entities described in subsection A that provide prescription drug benefits shall also include coverage of medications approved by the federal Food and Drug Administration for diabetes treatment, if prescribed by a health care professional legally authorized to prescribe such medication under law. Coverages under this subsection may be provided in accordance with §38.2-3407.9:01.

## PROCEDURE FOR DRUG APPROVAL

# *NDA Review Process*




(1) Labeling in this context means offical instructions for use

(2) Manufacturing sites and sites where significant clinical trials are performed