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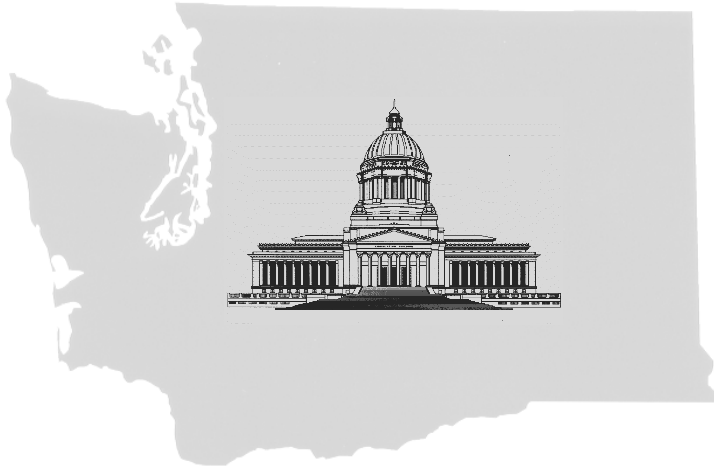
Joint Legislative Audit and Review Committee (JLARC)



# Diabetes Cost Reduction Act Sunset Review

## Briefing Report 2000-1

January 6, 2000

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Established by Chapter 44.28 RCW, the Joint Legislative Audit and Review Committee (formerly the Legislative Budget Committee) provides oversight of state funded programs and activities. This joint, bipartisan legislative committee consists of eight senators and eight representatives equally divided between the two major political parties.

Under the direction of the Legislative Auditor, committee staff conduct performance audits, program evaluations, sunset reviews, and other policy and fiscal studies. Studies focus on the efficiency and effectiveness of agency operations, impact of state programs, and compliance with legislative intent. As appropriate, recommendations to correct identified problem areas are included. The Legislative Auditor also has responsibility for facilitating implementation of effective performance measurement throughout state government.

## DIABETES COST REDUCTION ACT SUNSET REVIEW

## BRIEFING REPORT 2000-1

REPORT DIGEST

JANUARY 6, 2000

STATE OF WASHINGTON

JOINT LEGISLATIVE AUDIT AND REVIEW COMMITTEE

**PREPARED BY**

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# DIABETES COST REDUCTION ACT

## BACKGROUND

This briefing report is in response to a mandated sunset review of the Diabetes Cost Reduction Act. The Act was passed during the 1997 Legislative Session and became effective on January 1, 1998. It requires that health plans provide self-management education and training, and medically necessary equipment and supplies to patients with diabetes. Health plans have discretion over the kinds of education programs they offer.

## MAJOR FINDINGS

Studies conducted nationally and abroad have shown that access to supplies and equipment, coupled with self-management training and motivated patients, can improve health outcomes for diabetics both in the short-term and the long-term. However, these improvements come at a cost. Some education and self-management strategies have been shown to produce or have the potential for cost-savings, but they depend on specific, prescriptive approaches.

Given the flexibility and discretion provided in Washington's Act, health plans have implemented the Act in different ways. Some plans may be achieving cost-savings while others may be experiencing cost increases.

The major clinical studies suggest that the full impact of Washington's Act might not be felt for six to ten years. Washington's Act did not go into effect until January 1998, and only one year of statewide data is currently available. Even this set of data is incomplete for measuring the impact of the Act.

## RECOMMENDATION

*The 2000 Legislature should rescind sunset termination of the Diabetes Cost Reduction Act so that the Act will continue; and direct the Washington State Department of Health to evaluate the impact of the Act and to present a final report by 2007 to the Joint Legislative Audit and Review Committee.*

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# BRIEFING REPORT

## BACKGROUND

The Joint Legislative Audit and Review Committee (JLARC) is mandated to complete a sunset review of the **Diabetes Cost Reduction Act** by June 30, 2000. The Act was passed during the 1997 Legislative Session as 2SSB 5178 and became effective on January 1, 1998. It became Chapter 276, Washington Laws of 1997. In the absence of legislative action, the Act will terminate on June 30, 2001.

The Act requires that health plans provide medically necessary equipment and supplies to patients with diabetes, and that patients have access to self-management training and education.[1]

The preamble to the Act states that the provision of these benefits "is crucial to prevent or delay the short- and long-term complications of diabetes and its attendant costs."

Thirty-six other states have mandated diabetes benefits coverage. Most of their Acts are similar to Washington's.[2]

RCW 48.47 provides for a process by which a proposed mandated health benefit be assessed based on criteria specified in RCW 48.47.030. Such an assessment, however, is discretionary and was not applied in the case of the Diabetes Cost Reduction Act. Apart from a sunset review, no evaluation of the Act was mandated.

## FACTS ON DIABETES

Diabetes is a chronic disease that so far has no cure. It is characterized by high levels of blood glucose resulting from defects in insulin secretion and/or insulin action. Diabetes can be associated with serious complications and premature death, but people with diabetes can take measures to reduce the likelihood of such occurrences.

It is the sixth leading cause of death by disease in the United States.

According to the Washington State Department of Health, diabetes affects 317,000 people in Washington and was associated with 49,643 hospital admissions in 1997. Most of these admissions are a result of diabetes complications, including coronary heart disease, stroke, blindness, and lower extremity amputations.

The two most prevalent types of diabetes are:[3]

**Type 1**—occurs when the pancreas no longer produces any (or produces very little) insulin. The body needs insulin to use sugar for energy. Type 1 diabetes accounts for 5 to 10 percent of people with diabetes. It was previously called *insulin-dependent diabetes mellitus*, or *juvenile-onset diabetes*.

**Type 2**—occurs when the pancreas does not produce enough insulin or when the body does not effectively use the insulin that is produced. Type 2 represents from 90 to 95 percent of people with diabetes. It used to be called *non-insulin dependent diabetes mellitus*, or *adult-onset diabetes*.

## RELEVANT STUDIES

At the time Washington enacted the Diabetes Cost Reduction Act, advocates for the Act, such as the American Diabetes Association, provided information from clinical trials and evaluations of other states' diabetes education and self-management programs.

The information from a well-regarded clinical trial showed that a rigorous program of education and self-management—aimed at controlling blood sugar levels—could reduce some of the long-term complications of Type 1 diabetes. At the same time, studies by some other states' diabetes care programs further suggested that short-term savings from fewer hospital stays were also possible for diabetic patients in general.

Since the passage of Washington's Act in 1997, more studies have been published showing the value of controlling blood sugar levels in Type 2 diabetes. A recent study of a program in five managed health care organizations has found that a specific approach to diabetes education and self-management has a potential for savings, depending on the number of patients served.

A more detailed discussion of the aforementioned studies is included in the Technical Appendix to this report.

## IMPLICATIONS OF THE STUDIES FOR WASHINGTON STATE

It would be problematic and misleading to extrapolate from existing national and international studies to produce an estimate of the cost impact of Washington's Act.

Although studies have shown that access to supplies and equipment, coupled with self-management training and motivated patients, can improve health outcomes for diabetics both in the short-term and the long-term, these improvements come at a cost.

Some education and self-management programs have been shown to produce or have the potential for cost-savings, but they depend on specific, prescriptive approaches that vary in their costs. The cost-savings may also depend on economies of scale. That is, what may work for a large health plan that can spread fixed costs over a large number of patients may not be as cost-effective for smaller plans.

Given the flexibility and discretion provided in the Act, health plans have implemented the Act in different ways. Some plans may be achieving cost-savings while others are not. Furthermore, some health plans in Washington were already providing such benefits before they became mandated in January 1998.

## LIMITATIONS OF THE DATA AND THE TIME HORIZON FOR THE SUNSET REVIEW

More definitive information concerning the impact of the Act will not be available by the end of June 2000, which is the statutory deadline for this sunset review.

Although some studies suggest that savings are possible in the short-term (one to two years), the major impact of the Act might not be known for six to ten years. Washington's Act did not go into effect until January 1998, and only one year of data is currently available.

Available data are incomplete for purposes of isolating the impact of the Act from other changes that might affect health outcomes and costs.[4]

## APPLICATION OF SUNSET CRITERIA

In conducting sunset reviews, JLARC considers a number of factors. Two that would pertain to a mandated health benefit would include:

- Does the Act operate in the public interest by effectively providing a needed service that should be continued rather than modified or eliminated?
- Would termination or modification of the Act adversely affect the public health, safety, or welfare?

## Effectiveness in Providing a Needed Service

Given the flexibility and discretion provided in the Act, and the relatively short time it has been in effect, we do not have a sufficient basis for reaching a conclusion as to the Act's cost-effectiveness.

Clinical studies have shown that the types of benefits mandated by the Act, when utilized by diabetic patients, can result in improved health outcomes. The extent to which such improved outcomes may have occurred statewide since the implementation of the Act, and whether the outcomes are cost-effective, cannot be determined at this time or before June 2000.

## Termination

We do not have a basis for recommending termination of the Act.

Elimination of the mandated benefits could result in more restricted access by diabetic patients to the supplies, equipment, and education that would assist them in self-managing their disease. Clinical studies have shown that access to such benefits can have positive health outcomes for persons with diabetes. However, the extent to which restricted access would occur is unknown, as some health plans would continue to offer the benefits in the absence of the Act.

An evaluation component, with baseline information collected on cost impacts, was not included in the Act. Existing statewide data do not permit a determination of the net costs or savings from implementation of the Act.

## Continuation or Modification

Neither an elimination of the sunset provision nor an extension without modification would address the issue of whether the Act has been cost-effective. Unless enough time elapses and an agency is directed to collect data and report on outcomes, there is no guarantee that better information will be available in the future.

Two options could address the issue of cost-effectiveness:

1. *Extend the sunset date* and modify the Act by including an evaluation with periodic reports and a final report by a specific date.
2. *Rescind the sunset termination* but include a mandate for an evaluation with periodic reports and a final report by a specific date.

Under either option, for an evaluation component itself to be both useful and cost-effective, several conditions would apply:

- Data would need to cover a multi-year period in order to reflect the full impact of the Act. The two major clinical studies mentioned in this briefing report (see the Technical Appendix), the Diabetes Control and Complications Test (DCCT) and the United Kingdom Prospective Diabetes Study (UKPDS), followed patients for an average of six and a half and ten years, respectively.
- The evaluation should focus not only on health and cost outcomes on an aggregate statewide basis, but also on identifying particular programs and practices that are cost-effective and that are achieving success. (Note: A complete *best practices* evaluation would entail multi-state and multi-health plan comparisons—a matter of national interest that might best be addressed on the national level. A Washington State evaluation could focus on in-state practices and, if possible, be linked to a national study.)
- The evaluation should collect enough data to achieve its objectives, but with an emphasis on limiting additional reporting by, or administrative burdens on, the health plans.

- The design phase of the evaluation should include a process by which stakeholders, such as the health plans, advocacy organizations, purchasers, and practitioners, have an opportunity to comment.
- The evaluation should, to the extent possible,[5] follow the criteria specified in RCW 48.47.030 for assessing the impact of proposed mandated health benefits.

## DISCUSSION OF THE RECOMMENDATION

Option 1 would provide for an evaluation and would automatically require a sunset review, while Option 2 would leave to legislative consideration whether an additional review should be conducted and the kind of review it should be.

*We recommend Option 2: Rescind the sunset termination but include a mandate for an evaluation.* This option provides the most flexibility for action on the part of the legislature, while at the same time requiring an evaluation process to inform future decisions and to ensure accountability.

*We recommend a due date by the year 2007.* Based on the time frames that have been used by clinical studies, and the fact that some baseline information may not be generated until the evaluation begins, a due date for the final report of at least seven years may be required. A due date by 2007 would not preclude having a shorter evaluation period if conclusive information becomes available at an earlier date.

*We recommend that the Washington State Department of Health be assigned responsibility for carrying out the evaluation and be directed to report its findings to JLARC.* The Department of Health (DOH) already plays a central role in diabetes health and education.

DOH could address issues such as the cost of the evaluation and the advisability of contracting with outside evaluators as part of its fiscal note in response to proposed legislation. DOH could also seek resources for such an evaluation from federal and private sources. Since the costs of evaluations vary depending on their scope and expected outcomes, the legislature may wish to ask the agency to identify alternatives that would have different costs.

Having DOH report its findings to JLARC would preserve the Committee's oversight role regarding the cost-effectiveness of the Act.

## RECOMMENDATION

In summary, our recommendation is as follows. ***The 2000 Legislature should rescind sunset termination of the Diabetes Cost Reduction Act so that the Act will continue; and direct the Washington State Department of Health to evaluate the impact of the Act and to present a final report by 2007 to the Joint Legislative Audit and Review Committee.***

## AGENCY RESPONSE

The Department of Health has responded that it recognizes the importance of the evaluation that is recommended in this briefing report. The Department cannot support the recommendation, however, unless funds for an evaluation are appropriated. The Department's complete response in included in Appendix 2 – Agency Response.

## ACKNOWLEDGMENTS

We appreciate the assistance provided by the staff of the Diabetes Control Program within the Washington State Department of Health, the Washington State Health Care Authority and the Office of the Insurance Commissioner; and by the American Diabetes Association; the State of Maine Bureau of Health; the Division of Diabetes Control of the Maryland Department of Health & Mental Hygiene; the Center for Health Program Development and

Management of the University of Maryland, Baltimore County; Milliman & Robertson, Inc.; the Lewin Group; the Rhode Island Diabetes Outpatient Education Program; the Benaroya Diabetes Center at Virginia Mason; the Center for Health Studies of Group Health Cooperative; and Thomas M. Wickizer, Professor, Department of Health Sciences, School of Public Health and Community Medicine of the University of Washington.

Thomas M. Sykes
Legislative Auditor

On January 6, 2000, this report was approved for distribution by the Joint Legislative Audit and Review Committee.

Senator Georgia Gardner
Chair

# ENDNOTES

[1] The requirement to provide equipment and supplies pertains to plans that include pharmacy as a covered benefit. The Act's requirements do not apply to Washington State's Basic Health Plan.

[2] American Diabetes Association: http://www.diabetes.org/advocacy/states.asp.

[3] Other types of diabetes are: **Gestational,** which is a temporary condition that occurs during pregnancy. It affects 2 to 5 percent of all pregnancies with an increased risk of developing diabetes for both mother and child; and **Other specific types,** which result from specific genetic syndromes, surgery, drugs, malnutrition, infections, and other illnesses. Such types of diabetes may account for 1 to 2 percent of all diagnosed cases of diabetes. See: Centers for Disease Control and Prevention. National Diabetes Fact Sheet: National Estimates and General Information On Diabetes in the United States. Revised edition. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 1998: http://www.cdc.gov/diabetes/pubs/facts98.htm; National Institute of Diabetes and Digestive and Kidney Disease of the National Institutes of Health: http://www.niddk.nih.gov/health/diabetes/pubs/dmstats/dmstats.htm.

[4] If the Act were having a cost reduction impact in the near term, it might be occurring due to decreases in outpatient visits rather than in hospital stays. Information on outpatient visits does not exist on a statewide basis.

[5] Some of the baseline data may be lost by now due to the fact that a mandated health benefit review was not required prior to the passage of the Act, and to the fact that an on-going evaluation was not required.

# TECHNICAL APPENDIX 1—DIABETES STUDIES

## OVERVIEW

There is a growing literature of studies related to the cost-effectiveness of diabetes treatment, education, and self-management programs. This Technical Appendix focuses on a selection of studies that are frequently cited concerning the cost-effectiveness of mandated diabetes benefits.

## THE STUDIES

At the time of the passage of Washington's Diabetes Cost Reduction Act, notable among the available clinical trials was the Diabetes Control and Complications Test (DCCT) published in 1993. In the DCCT, 1,441 patients with Type 1 diabetes were randomly assigned to intensive therapy and conventional therapy groups. Those in the intensive group received frequent blood glucose monitoring and insulin injections to control blood glucose levels. The patients were followed on average for six and a half years. Results showed that intensive therapy delays the onset and slows the progression of some of the long-term complications of Type 1 diabetes.

At the same time, studies from such states as Maine and Maryland showed cost-savings potential from programs that emphasize prescriptive approaches to education and self-management for all types of diabetes.

Since the passage of Washington's Act in 1997, more information has become available. One of the most important recent clinical trials is the United Kingdom Prospective Diabetes Study (UKPDS), published in 1998. Similar in design to the DCCT, the UKPDS confirmed that rigorous control and lowering of glucose levels is important in reducing some of the long-term complications of the disease for patients with Type 2 diabetes.

Several recent studies have focused on the cost-effectiveness of diabetes management programs within individual health plans and managed healthcare organizations. A widely cited study by the Lewin Group, published in 1998, examined a program utilized in five managed care organizations. This program was modeled, in part, on the DCCT. The Lewin Group's study found that the program breaks even at approximately 1,265 diabetic members, and that savings would occur and would increase as the number of diabetic members increased beyond 1,265.

Other studies conducted on behalf of the American Diabetes Association and of individual states such as California, Pennsylvania, and Virginia, have evaluated potential cost-savings from mandated benefits, such as those that exist in Washington State, for diabetes patients. These studies have made estimates of potential cost-savings based on research conducted elsewhere (such as the DCCT, Lewin Group, Maryland, and Maine studies mentioned here). They have the same study limitations as those of the other research, as well as additional limitations that may come with their own methods used to make estimates.

For example, in a study conducted by Milliman & Robertson (M&R) on behalf of the American Diabetes Association, the consultants used information their firm had gathered to estimate low, medium, and high additional benefit costs. In addition, they used information from other studies to

estimate utilization savings characterized as optimistic, base (or neutral), and pessimistic. While such a methodology can help set the parameters for estimates of net costs or savings, the results are highly sensitive to some of the assumptions.

Some assumptions, in particular the costs of education and nutritional training, were set as constants instead of variables in the analysis. The values applied were lower, or even far lower, than the cost of such benefits associated with some of the approaches (such as the DCCT) that have been shown to reduce and delay the complication of diabetes and their attendant costs.

Taking M&R's approach, but substituting higher values for the cost of education and nutritional training, yields results that are inconclusive concerning the likely cost-effectiveness of a mandated diabetes health benefit such as exists in Washington State under the Diabetes Cost Reduction Act.

Two fundamental problems with any extrapolation from these studies to produce an estimate of the impact of Washington State's Diabetes Cost Reduction Act would be the following:

- The Act has not been in effect long enough for its full impact to be measured.
- Available research concerning cost-effectiveness has focused on specific, prescriptive approaches to education and self-management. Washington's Act is not prescriptive in this regard.

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# APPENDIX 2—AGENCY RESPONSE

- **Department of Health**

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December 28, 1999

Robert Thomas, Supervisor
Joint Legislative Audit and Review Committee
Post Office Box 40910
Olympia, Washington 98504-0910

Dear Mr. Thomas:

Thank you for asking the Department of Health to comment on the Joint Legislative Audit and Review Committee (JLARC) draft sunset review of the Diabetes Cost Reduction Act, which requires health plans to cover diabetes education and supplies. We understand that the staff recommendation is to remove the June 2001 sunset clause, to request the department to conduct a study to evaluate the impact of the act, which is to be presented to JLARC by 2006.

The department recognizes the importance of the study as described in the review. Health care dollars should be invested in interventions that prevent the progression of costly diabetes complications. However, the department cannot support the recommendation of a study if the funds for the study are not appropriated for that purpose.

Please contact Jan Norman with the Diabetes Control Program, Office of Community Wellness and Prevention, at (360) 236-3686, for additional information on our response to the JLARC recommendation.

Sincerely,

MARY C. SELECKY
Secretary

cc: Jan Norman