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HUMAN RESOURCES
DIVISION

B-164031(2)

June 4, 1979

The Honorable H. John Heinz III
United States Senate

Dear Senator Heinz:

As requested in your November 30, 1978, letter, we are reviewing federally funded activities concerning the research and control of diabetes mellitus. In our work to date, we have focused primarily on the activities of the National Institutes of Health and the Center for Disease Control of the Department of Health, Education, and Welfare.

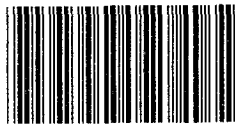
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On April 27, 1979, you asked for the results of our work to date for your use in the Senate's consideration of possible changes to the Medicare program. Therefore, as agreed, enclosures I, II, and III contain information on

- biomedical research related to diabetes;
- diabetes control; and
- benefits for diabetes control services provided by Medicare, Medicaid, and private health benefit plans.

Because our review is incomplete, our observations must be considered as tentative. We have not fully explored all the aspects of these matters, nor have we formed conclusions or recommendations pertaining to them.

HRD-79-90
(103940)



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Letter Report

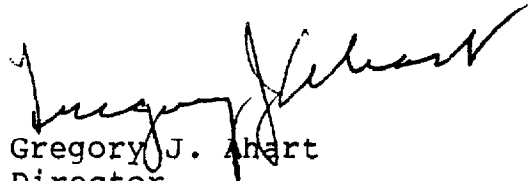
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Unless you publicly announce its contents earlier, we plan no further distribution of this report for 30 days. At that time we will send copies to interested parties and make copies available to others upon request.

Sincerely yours,



Gregory J. Ahart
Director

Enclosures - 3

AN OVERVIEW OF BIOMEDICAL RESEARCHACTIVITIES INVOLVING DIABETES

Despite substantially increased Federal funding for diabetes research in recent years, diabetes remains a serious problem. Some advances have been made in treating complications caused by diabetes; however, treatments do not always eliminate complications. Furthermore, the cause of diabetes remains unknown, and scientists believe that neither a cure nor a significant treatment advance is imminent.

Diabetes mellitus is the most common of several types of medical problems generally referred to as diabetes; it is the type of diabetes referred to in this report. Diabetes mellitus may impair the insulin production process of the islets of langerhans in the pancreas, or may prevent the body from efficiently using the insulin that it produces. In either case, the body's ability to break down food substances into energy is reduced and blood sugar levels are elevated. If left uncontrolled, diabetes can be fatal.

With the discovery of insulin in 1921, some believed that diabetes was cured. While insulin is still considered essential for helping to control possibly fatal complications in diabetics who depend on medication, it is generally recognized that insulin does not eliminate the risk of a variety of complications which can lead to blindness, kidney failure, heart attack, stroke, and lower extremity amputations. In recent years, scientists have become increasingly aware that morbidity and mortality among diabetics is substantially higher than among nondiabetics. Also, current information indicates that the prevalence of diabetes is increasing in the United States.

FEDERAL FUNDING FOR DIABETES-RELATED RESEARCH ACTIVITIES

Enactment of the National Diabetes Mellitus Research and Education Act (42 U.S.C. 289c-2) in 1974 resulted in substantially increased Federal funding for research identified as diabetes related. Within the National Institutes of Health (NIH), the National Institute of Arthritis, Metabolism and Digestive Diseases (NIAMDD) is primarily responsible for diabetes research activities. NIAMDD funding for research which was described to us as directly concerned with diabetes, or with diabetes-associated complications, increased from about \$14 million in fiscal year 1974 to about \$59 million in fiscal year 1978.

Federal organizations (including NIAMDD) provided funding of about \$120 million for diabetes-related research activities in fiscal year 1978--about 90 percent of which was funded through programs supported by NIH. The following table shows estimates of funding provided by various Federal organizations for diabetes-related research activities during fiscal year 1978.

Estimated Funding During Fiscal Year 1978
Of Research Relating To Diabetes
By Federal Organization

	<u>Funding</u> (millions)
NIH organizations:	
National Institute of Arthritis, Metabolism, and Digestive Diseases	\$ 58.6
National Heart, Lung, and Blood Institute	13.4
National Eye Institute	12.1
Division of Research Resources	8.2
National Institute of Child Health and Human Development	6.1
National Institute of Neurological and Communicative Diseases and Stroke	3.3
National Institute of Allergy and Infectious Diseases	2.4
National Institute on Aging	1.3
National Institute of Dental Research	.8
National Institute of General Medical Sciences	<u>.2</u>
NIH total	<u>106.4</u>
Other organizations:	
Department of Agriculture	a/7.3
Veterans Administration	4.1
National Science Foundation	2.4
National Institute of Mental Health	<u>.3</u>
Total	<u>\$120.5</u>

a/This represents an estimate for fiscal year 1977. An official at the Department of Agriculture stated that the amount for fiscal year 1978 would be approximately the same as that for the previous year.

The following table compares estimated funding for fiscal years 1976 and 1978 by Federal organization for diabetes-related research activities by general research category:

Estimated Funding Reported By Federal Organization
For Diabetes Research

<u>Research category</u>	<u>Fiscal year 1976</u>	<u>Fiscal year 1978</u>
	(millions)	
General research (basic research, genetics, viruses, artificial devices, general clinical research centers, etc.)	\$47.9	\$101.9
Multidisciplinary programs (diabetes research and training centers and diabetes endocrinology research centers)	2.5	9.0
Manpower development (training, career awards, fellowships)	1.3	7.0
Epidemiology (morbidity, mortality, incidence studies)	1.0	1.5
Workshops and conferences, publications, NIH intramural activities	<u>1.1</u>	<u>1.1</u>
Total Federal diabetes research-related funding	<u>\$53.8</u>	<u>\$120.5</u>

TYPES AND OBJECTIVES OF
FEDERALLY SUPPORTED RESEARCH

Most federally supported research relating to diabetes is directed toward gaining a better general understanding of the disease. The previous table lists the various categories of diabetes research that are being funded by the Federal Government. An official at NIH stated that, within these categories, they have recently established several research objectives dealing with diabetes. Between August and October 1978, NIH announced that it was seeking grant applications concerning diabetes mellitus and related problems which mentioned these objectives. Following is a brief discussion of these research objectives:

- Determination of whether strict control of blood glucose levels affects the secondary vascular problems associated with diabetes. NIH is currently determining if a full-scale clinical trial is feasible for this problem. An NIH official stated that, if carried out, the results of such a trial would not be available for at least 5 years.

- Further clarifying the relationship between pregnancy and diabetes. Recent research supported by NIH has clarified some aspects of the relationship between pregnancy and diabetes. The researchers reported that the application of this information to clinical practice has reduced the high rate of infant mortality occurring near the time of birth. The National Institute of Child Health and Human Development funded basic research in this area with about \$4.8 million in fiscal year 1978.

- Improving knowledge about photocoagulation (treatment of blood vessels in the eye involving laser beams) to treat diabetic retinopathy, a problem of the retina often caused by diabetes and a leading cause of blindness. An NIH official stated that, during the 1950s and 1960s, a German scientist and a scientist supported by NIH applied photocoagulation technology as a therapy for diabetic retinopathy. An official of the National Eye Institute stated that in the early 1970s NIH sponsored clinical trials which showed that photocoagulation is a safe and effective treatment for diabetic retinopathy. An NIH official estimated that savings to the economy as a result of this advance exceeded \$6 billion over a recent 5-year period. Research is continuing toward refining treatment methods.

- Learning to produce synthetic human insulin through recombinant DNA research. This activity will not lead to a cure for diabetes; however, scientists hope that, by the turn of the century, research in this area will lead to the production of synthetic human insulin, which will not cause allergic reactions--such reactions sometimes occur with the currently used animal insulins.

- Development of artificial devices. Scientists hope that practical artificial devices can be developed that will continuously feed the body with the proper amount of insulin to mimic the insulin production of nondiabetics. They hope that such devices will restore the normal metabolic state and reduce the rate of diabetic complications. Such devices are currently being tested on a few patients, but numerous problems must be overcome before a device will be available for general use.
- Increasing knowledge about transplanting pancreatic islet cells, the source of the body's insulin. An NIH-supported researcher recently reported a major advance in this area which may overcome the problem of the rejection and destruction of islet tissue transplanted into diabetic animals. Nevertheless, many problems remain with such transplantations, and knowledge may be insufficient for attempting transplants in humans for many years.
- Finding the cause or causes of diabetes. In recent years scientists have detected a possible relationship between viruses and diabetes. Also, scientists have concluded that diabetes can be inherited. Scientists are continuing to perform research to better understand the causes of diabetes.

DIABETES RESEARCH AND TRAINING CENTERS

According to the National Diabetes Mellitus Research and Education Act, the establishment of regional diabetes research and training centers throughout the Nation is essential for developing scientific information and appropriate therapies to deal with diabetes. The act requires NIH to establish diabetes research and training centers to (1) conduct research in diabetes and related disorders and (2) develop training and information programs for physicians and allied health personnel. The act requires that, insofar as practicable, the centers shall be located geographically on the basis of population density throughout the United States.

NIAMDD has established eight centers to date. These centers are not distributed evenly on a geographic basis; there are no centers located west of St. Louis or south of Nashville. An NIAMDD official explained that applications have been received from other geographic locations but were not funded, primarily because of scientific or other questions

about the applications. The official stated that NIAMDD is aware that the centers are not well dispersed and plans to improve the geographic distribution of the centers in the future as new centers are funded. He stated that NIAMDD plans to fund up to 7 more centers, making a total of 15 NIAMDD-supported centers.

NONFEDERAL FUNDING FOR DIABETES-
RELATED RESEARCH ACTIVITIES

While most research on diabetes is funded by the Federal Government, the National Diabetes Advisory Board, in its March 26, 1979, report to the Congress, indicated that private organizations also support a limited amount of research. It reported that the largest national voluntary organizations devoted entirely to diabetes are the American Diabetes Association and the Juvenile Diabetes Foundation. Also, many other national organizations and their local chapters and affiliates support research programs and provide services to diabetic patients and their families. The report indicated that private organizations which submitted information on their diabetes activities reported that they provided about \$16 million in 1977 to support diabetes research programs and services to diabetics.

The Board reported that the American Diabetes Association provided about \$1.68 million for research in 1977. This included about \$1 million in research grants and about \$680,000 in research training-related activities. In addition, the Juvenile Diabetes Foundation reported funding for research-related activities totaling about \$1.2 million in that year.

The Board reported that the following non-Federal organizations also support diabetes efforts:

- The American Association of Diabetes Educators.
- The Howard Hughes Medical Institute.
- The Joslin Diabetes Foundation, Inc.
- The Kroc Foundation.
- The National Foundation--March of Dimes.
- The American Heart Association.
- The National Society to Prevent Blindness.

--Research to Prevent Blindness, Inc.

--Fight for Sight, Inc.

The amounts provided for diabetes research by these organizations were not available.

COORDINATION OF NATIONAL DIABETES ACTIVITIES

Various groups have been established to promote the coordination of diabetes activities. Federal coordination activities include the Diabetes Mellitus Coordinating Committee and the NIH Coordinating Committee. NIAMDD's Associate Director for Diabetes chairs both of these committees and, according to NIH officials, reports directly to the Director of NIH in discharging his coordination responsibilities. The Executive Director of the National Diabetes Advisory Board told us that the Board has a coordination function which includes non-Federal diabetes activities.

The Diabetes Mellitus Coordinating Committee was established by NIH in response to the National Diabetes Mellitus Research and Education Act. It is made up of representatives of NIH organizations involved in diabetes-related research and other Federal organizations whose programs involve health functions. While several Federal officials told us that this Committee has no authority over Federal organizations to require action pertaining to their diabetes-related programs, it does obtain Government-wide information on programs relating to diabetes. The Committee publishes an annual report which contains financial and project information on Federal diabetes-related activities by agency.

NIH is composed of 11 institutes, and each has specific biomedical research responsibilities and programs. Diabetes and its associated complications extend beyond the program interests of any single institute; therefore, the Director of NIH has established an NIH Coordinating Committee. This Committee is composed of representatives from eight NIH institutes, two NIH divisions, and the Office of the Director. The Director of NIH has charged the Committee with acting as an information resource for all NIH institutes and helping develop the NIH diabetes budget. Its other responsibilities include (1) promoting communication among the institutes regarding the implementation of the Long-Range Plan to Combat Diabetes, prepared by the National Commission on Diabetes, (2) evaluating existing diabetes programs supported by NIH, and (3) identifying promising research areas in diabetes.

A function of the National Diabetes Advisory Board, according to its Executive Director, is to coordinate national diabetes activities. Its membership consists of individuals representing both Federal and non-Federal organizations and private individuals who have an interest in the diabetes area. Its annual reports to the Congress have included sections on diabetes efforts in both the Federal and private sectors.

DIABETES CONTROL

The Diabetes Control Activity of the Center for Disease Control (CDC) is the only Federal activity that is specifically geared toward demonstrating the effectiveness of improved diabetes control programs. The term "diabetes control" in public health, according to a Diabetes Control Activity official, means achieving the lowest possible levels of diabetes morbidity and mortality through use of currently available knowledge and resources in managing the disease. We have not yet assessed the effectiveness of the control programs funded by the activity. However, we were advised, but have not yet verified, that they reach only a small percentage of the Nation's diabetics and that funding is a problem.

Experts in diabetes told us that the best hope for minimizing medical complications among today's diabetics is to make the greatest use of currently known control techniques. As discussed in enclosure I, many years of research may be needed before a cure for diabetes is discovered, or major advances are made in treating the disease. Diabetes experts also said that current control techniques include a combination of diet, exercise, monitoring of blood and urine sugar levels, and the use of medication, when necessary. Normally the patient must perform these functions; thus, a well-educated patient is a key to effective control. Also, the diabetic needs access to health care personnel trained in providing technical advice or other assistance related to the disease.

According to the National Commission on Diabetes, encouraging patient education and other disease control techniques should be an important aspect of the Federal interest in diabetes. The Commission emphasized in its December 1975 long-range plan to combat diabetes that:

- Patient-administered treatment is crucial to the diabetic.
- Education of the diabetic should be considered treatment.
- Federal emphasis on the control of diabetes should be increased.

The National Diabetes Mellitus Research and Education Act and reports of the National Diabetes Advisory Board also indicate a need for increased Federal emphasis on diabetes

control. Although Federal research on diabetes has increased greatly in recent years, little funding has gone to diabetes control.

DIABETES CONTROL MEASURES CAN REDUCE
COMPLICATION RATES AND MEDICAL COSTS

Reports we examined indicate that diabetes control measures can reduce complications as well as medical care costs. For instance, recent studies discussed below show that, where diabetics have access to proper preventive medical services, there is a significant decline in lower extremity amputations and emergency treatment for ketoacidosis (a potentially life-threatening condition caused by elevated blood sugar). Other papers indicate that cardiovascular problems associated with diabetes can also be reduced by effective control. Also, several reports indicate that good control measures result in a net reduction in health care costs--Diabetes Control Activity personnel have estimated that at least \$25 can be saved for each dollar invested in a diabetes control program.

One study we reviewed, which was headed by a physician at Grady Memorial Hospital in Atlanta, reported a marked decrease in the number of emergency hospital admissions for diabetes-related conditions after opening a diabetes clinic. Before the clinic's opening in 1971 this hospital, which primarily serves Medicare and Medicaid patients, annually averaged 502 admissions for ketoacidosis. Because of the improved control service offered by the clinic, the annual average is now only 122 admissions for this problem.

Experts we contacted told us that diabetics are prone to having circulatory problems as well as nerve problems which can cause added complications, particularly with the lower legs and feet. The nerve problems impair feeling and, if the diabetic is not knowledgeable of this condition, injuries may go unnoticed. As a result, injuries or other problems that are ordinarily considered minor (such as ingrown toenails or improperly managed calluses) can result in infections and subsequent lower extremity amputations. The physician at Grady Hospital reported a marked decrease in lower extremity amputations after adding a podiatrist to the diabetes clinic staff in 1973. Before adding the podiatrist, the hospital was averaging 172 diabetes-related lower extremity amputations per year. The amputation rate steadily declined after 1973, so that only 86 diabetes-related lower extremity amputations occurred during 1978. According to the physician

who headed the study, these reductions in admissions for ketoacidosis and amputations resulted in a net savings in health care costs of about \$260,000 in 1978.

In a June 29, 1972, New England Journal of Medicine report, two individuals from the University of Southern California reported substantially reduced hospitalization for diabetics at that University's medical center in Los Angeles County, after introducing special provisions for them. These new provisions included (1) a direct-dial, hot-line telephone answering service for diabetics and (2) a requirement that a nurse practitioner or diabetes-services resident screen all patients before hospital admission (previously, those in the emergency room often decided whom to admit). From 1968 to 1970, while the number of diabetics using the outpatient clinic increased from about 4,000 to about 6,000, officials reported that annual hospital admissions of diabetics decreased from 2,680 to 1,250. Also during this period, hospital admissions for ketoacidosis dropped from 300 to 100 annually.

Another report, in the January 1975 Journal of The American Medical Association, indicated that patient access to nearby health maintenance services may result in reduced hospital utilization for diabetes-related complications. The report showed that annual hospital days per 1,000 patients was reduced from 3,318 to 1,680 after specially trained nurses began to provide maintenance health care outside of hospital clinics. Previously, patients were required to come to hospital outpatient clinics. After the nurses began to provide health maintenance services in other locations, the total number of outpatient visits at all locations increased, which probably resulted in the reduction of hospital days among diabetics.

Scientific papers we reviewed stated that a relationship may exist between lower rates of heart disease among diabetics and good diabetes control programs. Physicians at the University of Chicago reported that evidence is increasing that good control improves post-heart-attack survival chances and may result in lowered heart disease rates. They reported that more than half of the diabetic patients die from heart disease, which is twice the rate of nondiabetics. Although there is little scientific evidence to clearly show the tie between good control and lowered heart disease rates, several studies have shown that (1) no difference exists in post-heart-attack mortality between diabetics with good control and nondiabetics and (2) post-heart-attack mortality is very high among diabetics who have poor control of their disease.

NATIONAL EFFORTS TO CONTROL DIABETES

Reports we reviewed and individuals we contacted indicated that there is a national need for increased emphasis on improving the availability of adequate health services to diabetics. However, little information was available on what geographical areas need improvements most, what specific services need to be upgraded, and how to go about improving the services.

The National Commission on Diabetes reported in its December 1975 long-range plan to combat diabetes that, although control by patient-administered treatment is crucial to a diabetic, diabetic patients often do not receive instruction in self therapy. The Commission also reported that few followup programs exist, manpower knowledgeable of diabetes is severely short, the use of allied health personnel is significantly limited, and ignorance of diabetes too often prevails among health professionals responsible for delivering health care to the diabetic.

Physicians, including those specializing in the treatment of diabetics and those involved in diabetes research, told us that a need exists to (1) improve the diabetic's access to health services, especially in rural areas, and (2) train health personnel in recently developed methods of managing diabetes. For example, a 1974 medical school graduate who is now a diabetes researcher stated that he was taught in medical school to give substantially more insulin for treating ketoacidosis than is now known to be the best treatment. He also indicated that physicians who graduated from medical school 10 to 15 years ago were likely taught to rely much too heavily on insulin for controlling obese diabetics, who make up the majority of the newly diagnosed cases.

THE DIABETES CONTROL ACTIVITY AT CDC
SPONSORS LIMITED DEMONSTRATION
PROGRAMS TO ASSESS DIABETES CONTROL NEEDS

CDC's Diabetes Control Activity has been funding demonstration programs to assess the health care needs of diabetics since September 1977. The Congress chose CDC for this responsibility after the National Commission on Diabetes recommended in its report to the Congress in December 1975 that CDC implement such an activity. Ten States have been involved in the CDC-sponsored demonstration programs. These programs have covered less than one-fourth of the U.S. population.

The December 1975 report of the National Commission on Diabetes indicated a need for a diabetes control program. Among other things, such a program should include identifying and strengthening available health resources and making health services more accessible to the diabetic patient and family. The Commission concluded that CDC had the interest, competence, and experience to develop such a program. The Commission report further stated that the CDC program should foster State or local diabetes control programs and CDC headquarters staff should provide technical consultation and administrative support.

An update on November 30, 1976, by the Commission reported that implementing the CDC Diabetes Control Activity was contingent upon the appropriation of additional money and the authorization of additional staff to CDC. The Commission urged implementation of its previous recommendations to establish a diabetes control program at CDC.

The Congress appropriated \$1.5 million for fiscal year 1977 for use by CDC in starting the Diabetes Control Activity. In that fiscal year, CDC announced the availability of these funds for use in conducting programs to demonstrate the effects of diabetes control techniques and the best methods for delivering them. Twenty-nine States applied for contracts to assess their health care needs for diabetes. In September 1977, after technical and financial reviews of State applications by Federal experts, CDC awarded contracts to 10 State health departments. The States were to (1) collect and assess baseline morbidity, mortality, and health care resource data, (2) find out the major problems of diabetics and the contributing factors, (3) coordinate community resources that could be made available to diabetics, and (4) develop an implementation plan for improving the control of diabetes. These States subsequently completed their implementation plans and were awarded a total of \$2.3 million in additional funds to begin the implementation process, according to Diabetes Control Activity officials. The following table shows information provided by Diabetes Control Activity personnel, which we have not yet verified, on the amount initially awarded to each State, the amount subsequently provided to implement their diabetes control plans, and the date the implementation process began.

<u>State</u>	<u>Amount of contract award</u>		<u>Date implemen- tation began</u>
	<u>Planning</u>	<u>Implemen- tation</u>	
Colorado	\$ 294,000	\$ 253,000	a/6/15/79
Georgia	141,000	188,000	1/16/79
Illinois	121,000	198,000	9/28/78
Maine	155,000	243,000	9/29/78
Michigan	158,000	251,000	1/16/79
Mississippi	122,000	162,000	9/29/78
Nebraska	63,000	211,000	9/29/78
New York	214,000	339,000	1/16/79
Rhode Island	119,000	195,000	9/29/78
South Carolina	115,000	269,000	9/28/78
Total	<u>\$1,502,000</u>	<u>\$2,309,000</u>	

a/Funding is expected to start on the date indicated.

The Diabetes Control Activity
funds programs in 10 States

Diabetes Control Activity officials stated that, at current funding levels, the demonstration programs they support can reach only a small percentage of the Nation's diabetics. They currently fund programs in 10 States which have about 25 percent of the Nation's population and, according to CDC, about 1.3 million diabetics. They recognize that more information is needed on how best to promote optimum control programs before programs they support can be expanded to cover the entire Nation. However, they believe that they could reach more diabetics in the States they cover and expand their activities to additional States with more funding.

Programs currently supported by the Activity do not reach all diabetics in the States in which they operate. Activity officials estimate that \$4.4 million per year for 5 years would be needed to establish a coordinated diabetes control program in these 10 States. The officials stated that, in contrast, the Activity was appropriated \$1.5 million for fiscal year 1978 and \$2.6 million for fiscal year 1979.

Reports by the Appropriations Committees of both the House and the Senate on the HEW Appropriations Bill for fiscal year 1979 allow for CDC to expand coverage of its Diabetes Control Activity to 10 additional States; Activity officials stated that the Congress, however, had not provided enough funds to extend programs to 10 more States. An

official stated that \$330,000 of the \$2.6 million appropriation for fiscal year 1979 has been earmarked to fund up to three additional State diabetes demonstration projects and, as of April 1979, CDC had received applications from 19 States interested in obtaining funds for diabetes control programs.

Both the National Commission on Diabetes and the National Diabetes Advisory Board have recommended increased funding for the Activity. In its November 30, 1976, report, the Commission recommended funding of \$11.6 million for fiscal year 1979--more than four times the Activity's actual funding in that year. The Commission also stated that, since a cure for diabetes does not appear imminent, a need exists to increase efforts in the area of prevention and treatment. It expressed alarm at the Government's severe lack of progress with implementing its recommendations pertaining to health care, education, and control programs. Later, a National Diabetes Advisory Board report of March 1979 stated that it has given its highest priority to encouraging the development of the Activity's programs. Referring to the Activity, the report stated that:

"A significant step toward a national program is underway with the implementation of the current series of Community-Based Diabetes Control Demonstration Projects."

The Board recommended that funding levels of the Activity for future years be increased substantially over the fiscal year 1979 level.

DIABETES CONTROL SERVICES COVEREDBY MEDICARE, MEDICAID, AND PRIVATEHEALTH BENEFIT PLANS

Although the health benefit plans we reviewed cover patient costs relating to the treatment of diabetic complications (such as lower extremity amputations), they do not cover many services specifically for control (such as educating the diabetic in proper health maintenance techniques). Research studies indicate that medical complications and health care costs can be reduced through the use of good diabetes control techniques. (See pp. 10 and 11.) CDC is now supporting programs in four States aimed at demonstrating to insurers that they can reduce claims by reimbursing for diabetes control services.

HEALTH BENEFIT PLANS WE REVIEWED DO
NOT COVER CHARGES SPECIFICALLY FOR
CERTAIN DIABETES CONTROL SERVICES

Although the National Commission on Diabetes and diabetes experts we contacted consider the education of the diabetic to be the key to any diabetes control program, none of the health benefit plans we reviewed cover charges specifically for teaching the diabetic disease control techniques. While some plans covered the cost of routine foot care and medication supplies for diabetics, others provided limited or no coverage for these costs. Our review of benefit coverage for diabetes control services included nine plans: Medicare, two major health insurance plans for Federal employees--the Blue Cross and Blue Shield Service Benefit Plan, and the Aetna Life Insurance Company Indemnity Benefit Plan--and the Medicaid Plans in the District of Columbia and 5 States (Illinois, Maryland, Michigan, Rhode Island, and Virginia).

Health benefit plans probably pay for some education-related services provided to diabetics as part of general treatment-related services. An appendix to the Medicare Regulations states that the enabling law for this program does not identify patient education programs as covered services. However, according to the appendix, reimbursement may be made to the extent that the programs are considered reasonable and necessary for treating an individual's illness or injury. A Medicare official stated that a specific charge for education services would be disallowed. However, this provision allows payment for instructing the diabetic in

insulin administration and following a diet when they are part of covered inpatient routine care, home health care nurse visits, or clinic visits. Other health benefit plan officials told us that they too would not reimburse for education services. However, they probably do pay for such services when they are included in general treatment-related services.

Routine foot care is also a diabetes control service which is important to certain diabetics. Officials of the nine health benefit plans we reviewed told us that they normally will not cover these needs, but six make a special exception for diabetic patients. Another two (Medicaid of Maryland and the Aetna Government-wide Indemnity Benefit Plan) make a special exception only if the patient has peripheral vascular disease (a disease of the body's blood circulatory system which affects the lower portions of the legs and feet). While this disease is present in many diabetics who need routine foot care, an expert in diabetes at NIAMDD stated that some diabetics do not have this disease but do have other complications which are associated with diabetic neuropathy. Diabetics with neuropathy have an impaired function of the nerves and are subject to developing calluses, corns, and infections which can lead to the amputation of the toes or feet. One source of infection can be injuries that diabetics unknowingly incur while removing calluses or otherwise caring for their own feet. The table on page 18 summarizes health benefit plan policies' coverage of the cost of routine foot care for diabetics.

None of the health benefit plans will reimburse for corrective shoes for diabetics. Physicians sometimes recommend the use of such shoes to help prevent or alleviate foot deformities which are associated with diabetic neuropathy. These deformities, which can occur simply from the stresses of walking, make problems with corns, calluses, and infections harder to control. Deformation of the feet makes it difficult to find properly fitting shoes, and a deformed foot with an improperly fitted shoe will undergo increasing trauma, wear and tear, and worsening of corns and calluses.

Diabetics often must purchase insulin, syringes, and medical supplies to monitor and control their blood sugar levels. The cost of all this, based on a limited survey of physicians and druggists in the Washington, D.C., area, is likely to be about \$150 a year for the average diabetic who uses insulin. A Medicare official stated that Medicare

does not cover charges for medication that is self-administered; therefore, insulin and related supplies are covered only when used in an institutional setting or when provided by health personnel to disabled patients under an approved home health care program. Under Medicare and many of the other health benefit plans, the patient is responsible for part of the cost of covered services.

Based on information obtained from health benefit plan officials, the following table shows the extent to which the costs of certain services are covered by the plans we reviewed.

Health benefit plan	Charges specifically for teaching control techniques	Routine foot care	Correc- tive shoes	Medication and supplies such as insulin and syringes
Blue Cross and Blue Shield Service Benefit Plan for Federal Employees	No	No	No	Yes
Aetna Govern- ment-wide Indemnity Benefit Plan	No	a/Limited	No	Yes
Medicare	No	Yes	No	No
Medicaid of: The Dis- trict of Columbia Illinois Maryland Michigan Rhode Island Virginia	No	Yes	No	Yes
	No	Yes	No	Yes
	No	a/Limited	No	Yes
	No	Yes	No	Yes
	No	Yes	No	Yes
	No	Yes	No	Yes

a/Coverage is provided only if the patient has peripheral vascular disease. See discussion of routine foot care on page 17.

CDC IS STUDYING THE COST EFFECTIVENESS
OF PROVIDING INSURANCE REIMBURSEMENTS
FOR DIABETES CONTROL SERVICES

A CDC official stated that 4 of the 10 State health department programs funded through CDC's Diabetes Control Activity include efforts to assess whether health insurers will incur a net reduction in claims by covering diabetes control services. These States are Nebraska, Maine, New York, and Rhode Island. We discussed these assessment efforts with program officials in New York and Rhode Island. Officials in both of these programs have been in contact with major health insurance companies for assistance in their assessment efforts.

Program officials in New York told us about their coordination efforts with Blue Cross and Blue Shield in that State. Their project activities include diabetes demonstration programs at four locations throughout the State which are designed to show the effect of education combined with preventive care on the well being of diabetic patients. All of the programs are to be in operation by July 1, 1979. Two of the officials stated that, through their encouragement, officials of Blue Cross and Blue Shield have recently agreed to provide reimbursement for subscribers who participate in a diabetes control program at a hospital in Utica, New York. The agreement is for at least a 1-year experimental period. Blue Cross and Blue Shield will also participate in the diabetes control demonstration program at this hospital.

New York project officials also expressed concern about the effect of the cutoff of State Medicaid payments to podiatrists several years ago. These officials are considering a study to find out if lower extremity amputations increased since this action. An official of the Podiatry Society of the State of New York expressed concern that this cutoff may have an adverse effect on diabetics in the State. However, he doubted that any such effect has occurred so far. He explained that the New York College of Podiatric Medicine has continued to provide services to diabetics who are covered by Medicaid at little or no charge, and hospitals which provide podiatric services bill Medicaid for this service under a general category such as clinic visit. He stated that the Society tries to encourage the providing of podiatric services to Medicaid recipients. However, he was doubtful about the future of such services for Medicaid recipients under current State laws.

A project official in Rhode Island told us of that State's efforts to secure insurance reimbursement for diabetics in education programs. Its program supports studies to show whether providing education to diabetics reduces diabetes-related morbidity and mortality. He also said that the State is working with Blue Cross and Blue Shield in Rhode Island to convince them to provide reimbursement for education services to diabetics, at least on a trial basis. He indicated that Blue Cross is now waiting for the results of the Rhode Island studies on the education of diabetics before further considering reimbursement for such programs.