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MEDICARE THERAPEUTIC SHOES DEMONSTRATION: WAS THE DEMONSTRATION COST-EFFECTIVE? FINAL COMPREHENSIVE REPORT

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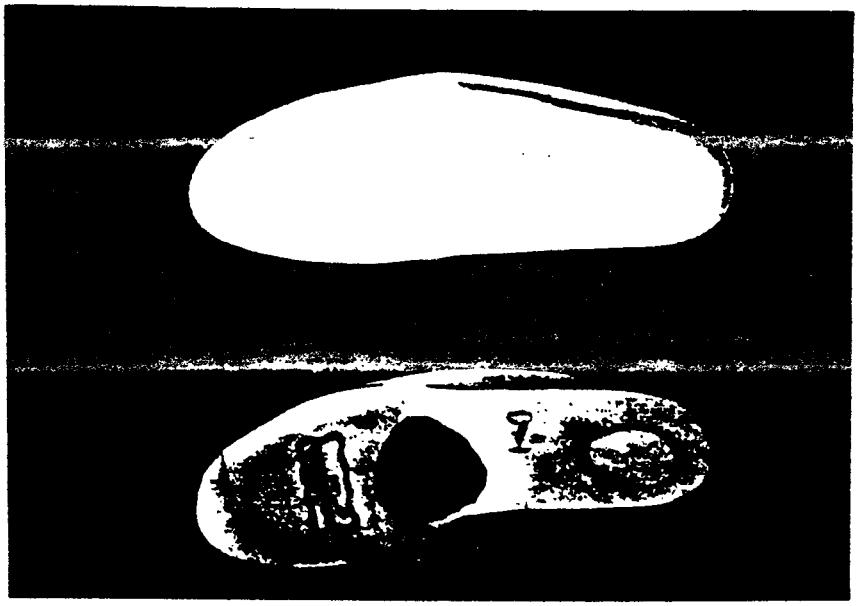

ABSTRACT

The Medicare Therapeutic Shoe Demonstration. which ran from August 1989 through October 1992 in California, Florida. and New York. expanded Medicare Part B to cover therapeutic (special protective) shoes for beneficiaries with severe diabetic foot disease. The demonstration was enacted by the Omnibus Budget Reconciliation Act of 1987 (P.L. l(K)-203. Section 4072) to evaluate whether the benefit would be cost-effective if it were included in the regular Medicare program. Because the evaluation produced no evidence that the benefit was not cost-effective (the Congressional criterion for adding the benefit)? the benefit was introduced into the Medicare program on May 1, 1993.

The demonstration was implemented according to the legislative requirements (which covered beneficiary eligibility criteria. requirements for physician certification of beneficiary eligibility and physician prescription of the shoes, requirements for shoe suppliers, and shoe types and prices). Because of the temporary nature of the benefit, the demonstration was publicized to beneficiaries, physicians, and shoe suppliers.

Participation was lower than expected, and participants were sicker than expected. During a 3-year period. the demonstration enrolled 4,373 Medicare beneficiaries with diabetes and evidence or risk of foot disease. This population had considerable evidence of foot disease: one-fourth had already had a lower-extremity amputation and nearly two-thirds had had a lower-extremity ulcer. The Medicare payments for this group were about four times that of the average Medicare beneficiary in the year before enrollment in the demonstration.

To test the cost-effectiveness of the benefit, participants were randomly assigned to two equal-size groups. One (the treatment group) was offered payment for the shoe benefit. Among the treatment group, only two-thirds acquired the shoes through Medicare in the first year. and only one-fourth renewed the shoes in the following year. However, a survey of the participating treatment and control group beneficiaries showed that the treatment group was significantly more likely to own and wear therapeutic shoes than the control group.

In a test of whether the benefit increased total Medicare payments during a l-year period after enrollment in the demonstration, the results were inconclusive. We could show neither that the benefit increased Medicare costs, nor that it decreased Medicare costs. In accordance with the legislation (which stated that, after a test period of 4 years, the shoe benefit would be introduced unless it were shown that it was not cost-effective), the shoe benefit was introduced into the Medicare program.

EXECUTIVE SUMMARY

The Medicare Therapeutic Shoe Demonstration produced no definitive evidence that expanding Medicare Part B to cover therapeutic (special protective) shoes for beneficiaries with severe diabetic foot disease would increase total Medicare costs. The demonstration. which ran from August 1989 to October 1992, offered Medicare Part B coverage for therapeutic shoes on a trial basis in three States. Our findings indicate that the demonstration was implemented largely as intended, was successful at increasing therapeutic shoe ownership. and was instrumental in increasing beneficiaries' use of the shoes when walking outdoors. We based these findings on the experiences of 4,373 Medicare beneficiaries who enrolled in the demonstration and were randomly assigned to either the demonstration group, which received the shoe-coverage benefit, or the control group, which received only standard Medicare coverage. A therapeutic shoe benefit was added to Medicare Part B as of May I, 1993 as a result of the demonstration findings.

A. PREVALENCE AND COMPLICATIONS OF FOOT DISEASE

Persons with diabetes are at high risk of developing foot problems that may lead to amputation. an experience with high personal, medical, and social costs. Persons with diabetes can develop ulcers and infections as a result of, for example, wearing ill-fitting shoes and socks, stepping on sharn objects, or stubbing their toes. Untreated. these ulcers and infections become gangrenous, and amputation of part or all of a foot or leg may become necessary. Clinicians who treat diabetic foot problems usually advise their patients to practice careful foot hygiene and wear special shoes to protect their feet from damage.

Diabetes is widespread among all three groups of individuals who have coverage for Medicare Part B services (which includes physician care. primarily). Among the *aged*, approximately IO percent have diabetes: among the *disabled*, approximately 21 percent have diabetes; and among *end stage renal disease program beneficiaries,* approximately 33 percent have diabetes. Nationwide; we estimate that there were 3.5 million Medicare beneficiaries with diabetes in 1990. There are few estimates of the prevalence of foot disease among diabetic populations. Using the findings from one study of older-onset diabetes in Wisconsin. we estimated that about 563.000 beneficiaries with Medicare Part B coverage have foot disease. measured by ever having had a foot ulcer (about one of every six beneficiaries with diabetes). The incidence of foot disease increases with the duration of diabetes.

Estimates of lower extremity amputations among aged diabetic Medicare beneficiaries nationally range from 12,400 in 1984 (American Diabetes Association 1986) to 38,000 in 1987 (Centers for Disease Control 1990). Mortality rates for persons who have had lower extremity

amputations are high. Reported mortality rates 5 years after amputation range from 41 to 70 percent (Palumbo and Melton 1985: Steer et al. 1983; and Most and Sinnock 1983).

If therapeutic shoes are clinically effective (for which there is no firm evidence). they may prevent ulcers and help to avert costly hospital stays for ulcer treatment and amputation. Jacobs et al. (1991) estimated the average cost per hospital stay for diabetic diseases of the arteries (including skin ulcers and gangrene) at $12,730. Reiber (1992) estimated average Medicare payments for lower extremity amputations at $12,230.

Because sensation in diabetic persons' feet may be reduced, it is imperative that these people wear shoes to protect their feet from trauma. Clinicians believe that therapeutic shoes are important in preventing the chafing and trauma that often precede ulcerations, yet diabetic persons do not universally own and wear therapeutic shoes. Clinicians report that diabetic persons do not buy the shoes for three reasons:

- They are expensive and insurance does not cover them.
- They are unattractive.
- Many diabetic persons are unaware of the importance of specially fitted shoes in preventing foot damage.

The Medicare Therapeutic Shoe Demonstration provides the first estimates of the rates of ownership of therapeutic shoes by a diabetic population that knows about the importance of the shoes. When they entered the demonstration, almost one-third of participating beneficiaries already owned either depth-inlay (off-the-shelf shoes manufactured with extra depth to accommodate an insert) or custom-molded shoes.

The demonstration was designed to encourage therapeutic shoe purchase and use among diabetic Medicare beneficiaries by including shoes as a covered benefit. Our evaluation of the demonstration estimated the effects of the shoe coverage on Medicare costs, but did not estimate the clinical effectiveness of therapeutic shoes.

B. PURPOSE OF THE LEGISLATION AND LEGISLATIVE MANDATES

In 1987, Congress mandated a demonstration of a Medicare Part B therapeutic shoe benefit for diabetic Medicare beneficiaries under the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203, Section 4072), and required that the demonstration be evaluated to determine whether the benefit was cost-effective. The legislation specified the beneficiary eligibility requirements. the types of shoes to be covered, the prices Medicare would pay. and the types of physicians and suppliers who might participate in the demonstration.

The legislation specified the clinical criteria, medical history, and comprehensive care plan requirements for Part B covered beneficiaries to qualify for the benefit, and the process by which eligibility would be established. A physician who was managing a patient's diabetes was to certify that the patient was in a comprehensive care plan for his or her diabetes, met the clinical eligibility criteria (a diagnosis of diabetes and evidence of peripheral neuropathy with calluses, prior ulceration. prior amputation, foot deformity, or poor circulation), and needed the shoes.

Congress left the determination of which physicians were qualified to prescribe the therapeutic shoes to the Secretary of the Department of Health and Human Services. but mentioned podiatrists in the legislation.

The initial demonstration benefit consisted of Medicare Part B payment for one pair of shoes annually. Two types of therapeutic shoes were covered: depth-inlay shoes with customized inserts and custom-molded shoes.[1] In the Omnibus Budget Reconciliation Act of 1989 (Public Law 101-239, Section 6131) Congress expanded the demonstration benefit to cover up to two pairs of replacement inserts per year, or modifications to shoes up to the price of two pairs of replacement inserts.

The legislation established the maximum allowed prices for fitting and furnishing therapeutic shoes in the demonstration, with a provision that these prices be adjusted annually according to the change in the price index for durable medical equipment. The statutory prices at the start of the demonstration (August 1989) were in effect until the end of 1990. These prices were increased (to $316 for custom-molded shoes, $105 for depth-inlay shoes. and $53 for customized inserts) at the beginning of 1991 and remained at that level until the end of the demonstration in October 1992.

Congress specified that shoes were to be fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist). Further requirements for qualified individuals were once again to be identified by the Secretary of the Department of Health and

[1] The legislation refers to "extra-depth" shoes (a trademark) rather than to depth-inlay shoes (the generic name). We referred to depth-inlay shoes throughout the demonstration.

Human Services. But Congress precluded physicians who certified the need for the shoes from fitting and furnishing the shoes. to avoid conflicts of interest.

The Health Care Financing Administration (HCFA) required authorized shoe suppliers in the demonstration to accept assignment of Medicare benefits for furnishing therapeutic shoes to participants (that is. they agreed to accept the maximum allowed price, or a lower price. as the full charge for the service). The maximum payment that authorized suppliers could receive from Medicare Part B was equal to 80 percent of the lowest of the following:

- The current statutory price
- The price that the supplier had agreed to accept during the demonstration
- The actual charge, less any annual Medicare Part B deductible not yet met by the beneficiary ($75 maximum in 1989 and 1990 and $100 in 1991 and 1992)

The shoe recipients were responsible for the remaining 20 percent copayment plus any outstanding annual Part B deductible.

Before introducing the therapeutic shoe benefit into the regular Medicare program. Congress wanted to determine whether the benefit was cost-effective.' Two years after the demonstration started (that is. by October 1, 1990) the Department of Health and Human Services was to submit a report to Congress addressing whether the benefit was cost-effective. If it was not cost-effective, the demonstration was to continue for 2 more years and another report was to be submitted on April 1, 1993. Unless that report showed that the benefit was clearly not cost-effective, the benefit was to be introduced into the regular Medicare program on the first day of the month following the month the report was actually submitted.

C. THE DEMONSTRATION WAS IMPLEMENTED AS INTENDED

The demonstration was implemented largely according to the legislative specifications and operated from August 1, 1989, to October 31, 1992, in California, Florida. and New York. The three states selected for the demonstration had large numbers of beneficiaries. sufficient shoe suppliers, and represented three different geographic regions. To provide a meaningful test of the cost-effectiveness of a national benefit, the demonstration was implemented with

[2]The Health Care Financing Administration awarded a contract to Mathematica Policy Research, Inc., (MPR) to evaluate the effectiveness of the therapeutic shoe benefit (contract number HCFA 500-87-0028-9).

procedures that corresponded as closely as possible to those that would be used in a national program. However. some special procedures were necessary because of evaluation requirements and the short operational period of the demonstration.

The Demonstration Was Publicized

Because the demonstration was to operate for a short period of time (initially 2 years. with the potential of 2 further years), publicity was required to initiate and encourage participation by beneficiaries, physicians, and suppliers. In the 2 months before the demonstration began, the demonstration contractor (MPR) sent publicity materials directly to all physicians and shoe suppliers in the demonstration states who provided services to diabetic Medicare beneficiaries and to Medicare beneficiaries who appeared to be eligible for the benefit, based on readily identifiable characteristics from Medicare claims.

The publicity materials included form letters describing the benefit. who was eligible. the limited term for which it was available, the fact that eligible beneficiaries would have a 50 percent chance of receiving the benefit, and the procedures for applying. Each of tne 56.000 targeted physicians in the three demonstration states also received a postcard for requesting the demonstration's application form (the certification and prescription form). About 6.300 potential shoe suppliers were sent an application to become authorized shoe suppliers. Beneficiaries were instructed to ask their physician to enroll them (43.000 beneficiaries were notified),

Additional predemonstration publicity included articles about the demonstration in Medicare carriers' newsletters to providers and beneficiaries. and in patient group newsletters. such as those issued by local chapters of the American Diabetes Association. Diabetes clinics that were identified by state and local chapters of the American Diabetes Association also were sent copies of all the publicity materials. MPR met with interested state and national professional associations before the demonstration began to discuss plans for the demonstration design and implementation.

Because it quickly became clear that fewer beneficiaries than expected were applying for the benefit (see discussion of enrollment later), a second round of publicity was implemented 1 year after the demonstration began. After consultation with representatives of several professional associations and the American Diabetes Association, MPR mounted a 6-month publicity campaign that attempted primarily to educate physicians about the value of the benefit to their diabetic Medicare patients. New materials were developed and sent to generalist and specialist physicians in the three demonstration States. State physician associations sent the materials with a cover letter endorsing the benefit. Other professional associations. such as diabetes educators. who treat or work with diabetic patients also received the new materials in quantity for distribution to their members.

The Evaluation Requirements Led to Restrictions on Who Could Receive the Shoe Benefit

Although all Medicare beneficiaries who met the clinical and Medicare eligibility criteria and needed therapeutic shoes would receive the benefit under a national program. the benefit was limited during the demonstration to beneficiaries who:

- Resided in the three demonstration States
- Were not enrolled in a Medicare HMO
- Were assigned to the treatment group

To provide the most precise estimate of the cost-effectiveness of the benefit. the demonstration used an experimental design to assign eligible applicants randomly in equal numbers to either the treatment group, which received the extra therapeutic shoe coverage. or the control group, which received only standard Medicare coverage. (Control group memoers could still' purchase the shoes with 'their 'own' 'money.) Medicare beneficiaries enrolled in Medicare HMOs were excluded from participation because Medicare claims. which were the main source of data for the evaluation, do not exist for HMO members.

Enrollment Procedures Worked Smoothly, but Beneficiary and Physician Participation Was Lower than Expected

The research design called for about 27,500 beneficiaries to apply for the shoe benefit. in order to evaluate the effect of the benefit on Medicare costs (see Section D). However. only 4.373 beneficiaries actually applied. Only 887 (20 percent) were from the group notified about the demonstration before it began. The second publicity campaign increased enrollment only slightly. Thus. only about 0.6 percent of the estimated number of eligible diabetic Medicare beneficiaries in the three demonstration States enrolled. This lower than anticipated enrollment rate greatly reduced our ability to identify statistically small cost increases (or decreases) that might have resulted from the shoe benefit.

The demonstration certification and prescription form was used to initiate the enrollment process, which consisted of four steps:

- The beneficiary visited the physician managing his or her diabetes, who then certified the beneficiary as clinically eligible for the demonstration (either the

beneficiary or the physician may have initiated discussion of participating in the demonstration).

- The physician either prescribed the shoes or referred the beneficiary to another physician who prescribed the shoes.
- The beneficiary signed the informed consent agreement, signifying his or her understanding of the temporary nature of the benefit and the 50 percent chance of receiving it.
- The beneficiary mailed the completed form to MPR for eligibility assessment and randomization.

On the basis of our analysis of the enrollment procedures for the 4.373 enrolled beneficiaries. we drew the following conclusions.

The enrollment procedures met legislative requirements, with the exception that many certifying physicians were not the diabetes managers. Many certifying physicians were podiatrists or orthopedic surgeons, reflecting the reality that footcare specialists are most likely to initiate shoe use among diabetic beneficiaries and may be appropriate certifiers of medical eligibility and need for shoes. Only about nine percent of the participating physicians were general and family practitioners.

Participating beneficiaries exhibited a wide range of clinical severity, but on average they were more severely affected than expected. One quarter of participating beneficiaries had a previous amputation of part or ail of one or both feet, and nearly 60 percent had experienced foot ulcers before they applied for the demonstration benefit.

Consistent with the legislative requirement that beneficiaries receiving the benefit have a comprehensive plan of care for their diabetes, a survey of beneficiaries enrolled during the first 2 years of the demonstration found that ***very high proportions of participating beneficiaries reported having had glucose tests and foot examinations in the 6 months before the interview, indicating that their diabetic condition was being monitored.*** Over 96 percent said that their urine or blood had been checked for glucose, and 91 percent said that their feet had been checked.

The randomization procedure in the demonstration probably reduced participation. Both before and during the demonstration, professional groups and individual physicians criticized random assignment, stating that it affected physicians'wiiiingness to prescribe the shoe benefit. Only 3,525 physicians ever certified or prescribed shoes for applicants for the demonstration benefit, although 56,000 physicians practicing in the demonstration states had been notified about the benefit and could have certified beneficiaries or prescribed the therapeutic shoes.

The random assignment procedures produced treatment (extra-coverage) and control (standard-coverage) groups that were comparable on measurable characteristics at the time of enrollment. The two groups were similar in prevalence of prior foot problems (including amputations), age. Medicare payments in the previous year, and reason for entitlement to Medicare.

The centralized processing of demonstration applications was more complex than a national benefit would require and may have discouraged participation. Centralized processing (necessary for randomization) introduced a delay in furnishing patients with shoes. a lag that was unpopular with physicians. On average, beneficiaries received the shoes 9 weeks after they were randomized. which could have been reduced to an average of 4 weeks if the S-week average period between application and randomization had not been necessary.

Over 400 Shoe Suppliers Were Authorized to Supply the Shoes

Four types of health professionals were eligible to fit and furnish (that is. supply) shoes in the demonstration: podiatrists. certified pedorthists, certified orthotists. and certified prosthetists. These professionals are trained to take casts of feet; prepare customized. multiple-density inserts: fit shoes: and modify shoes. To be authorized to supply the shoes. eligible individuals or companies that employed eligible individuals were required to apply to the demonstration. agree to accept assignment of Medicare benefits. and be assigned a supplier number.

More than 400 shoe suppliers were authorized, and 61 percent were podiatrists. However, podiatrists supplied only 23 percent of shoes. Certified pedorthists supplied 29 percent: orthotists. prosthetists. and orthotist/prosthetists provided 22 percent: and suppliers employing more than one type of professional supplied 26 percent of the shoes.

The process of authorizing suppliers and supplying the shoes in the demonstration complied with legislative requirements. with the exception that the inserts to shoes were not always customized and multiple-density, which may have reduced their clinical effectiveness.

About half of the authorized shoe suppliers supplied shoes at some time during the demonstration. This number of suppliers was adequate for the volume of participating beneficiaries and does not appear to have constrained beneficiary participation. (Most of the suppliers who were authorized but never supplied shoes were podiatrists who appear to have believed that they had applied for approval to *prescribe* shoes in the demonstiation rather than to supply them.)

Podiatrists furnished mostly custom-molded shoes (three-quarters of the shoes they supplied), but other suppliers furnished much lower proportions of custom-molded shoes (43 to 57 percent. depending on the profession).

Therapeutic Shoes Were Supplied to More than Two-Thirds of Those Offered the Benefit

The majority of the applicants assigned to the treatment group acquired therapeutic shoes. although the acquisition and renewai rates were lower than expected.

Even though Medicare would pay for the shoes, under 70 ***percent of those authorized to receive the shoes purchased them within 9 months a&r being authorized.*** The rate is lower than expected given that the beneficiaries had therapeutic shoes prescribed for them. took the trouble to request the benefit by mailing the form, and were eligible to have Medicare pay 80 percent of the cost of the shoes. The most common reasons that treatment group beneficiaries gave for not acquiring the shoes after authorization were that they:

- Lost the paperwork (14 percent)
- No longer needed or wanted the shoes (12 percent)
- Found the shoes too hard to get (11 percent)

Among beneficiaries who received the shoes, 59 percent were supplied with custom-molded shoes and 41 percent with depth-inlay shoes. A much higher proportion of custom-molded shoes was supplied than was anticipated--perhaps because of the severity of patients' clinical conditions. current patterns of prescribing (physicians prescribed custom-molded shoes more often than depth-inlay ones--% percent compared with 44 percent) or the relatively higher price allowed for custom-molded shoes.

Only 23 ***percent of the treatment group eligible to renew the benefit 1 year after initial shoe purchase did so.*** The most common reasons that beneficiaries gave for not renewing the benefit were that they:

- Did not need new shoes (33 percent of nonrenewers. including those who said the original shoes were not worn out).
- Did not realize that they could renew the benefit (14 percent--consistent with procedures that would be used in a national program, beneficiaries were not reminded that they could renew the shoes)
- Did not find the shoes comfortable (13 percent)

Only six percent of beneficiaries who acquired the shoes also received shoe modifications, and only six percent received replacement customized inserts. Low use rates for these benefits may be related to the high rate of use of custom-molded shoes for which modifications are not necessary. Coverage for shoe modifications and customized inserts was added to encourage use of the less expensive depth-inlay shoes.

Medicare Paid Over $350,000 for Therapeutic Shoes in the Demonstration

During the demonstration. Medicare Part B paid just over $353.000 for shoes. inserts. and modifications supplied by authorized shoe suppliers to 1,459 beneficiaries. Medicare paid an average of $240.80 per pair for custom-molded shoes (76 percent of the maximum price) during the demonstration. when the maximum price was $316, and $73.75 for depth-inlay shoes (70 percent of the maximum price). when the maximum price was $106. Although Medicare would pay up to 80 percent of the maximum prices, participating beneficiaries first had to meet their annual deductibles.

The Demonstration Increased Use of Therapeutic Shoes

In order for the demonstration benefit to be cost-effective, the proportion of beneficiaries purchasing the shoes had to be higher in the treatment group than in the control group (if the shoes had not been covered. fewer treatment group members would have purchased them). The owners of the shoes also had to wear them. and the shoes had to be clinically effective.

A survey of participating beneficiaries who were enrolled in the first 2 years of the demonstration and who were still alive in May 1992 showed that the demonstration increased ownership of therapeutic shoes among the treatment group. At the time they applied to the demonstration, 32 percent of beneficiaries already owned therapeutic shoes: 14 percent had custom-molded shoes. 15 percent had depth-inlay shoes, and 4 percent had other types of therapeutic shoes. By the time of the survey! a substantially larger proportion of the treatment group (85 percent) than the control group (55 percent) owned therapeutic shoes.

Furthermore. the survey showed that ***a much higher proportion of the treatment group than the control group wore therapeutic shoes to walk outside*** (61 ***percent compared with 3 7 percent).***

The evaluation was not intended to measure the clinical effectiveness of the therapeutic shoes: hence. we cannot be sure whether the shoes purchased in the demonstration were clinically effective. However. on the basis of reported health status, there appears to be no measurable difference between the treatment and control groups in the survey sample. despite the greater use of the shoes by the treatment group.

D. WHAT WAS THE TEST OF COST-EFFECTIVENESS?

How Was Cost-Effectiveness Defined?

The legislation that authorized the demonstration mandated an assessment of the cost-effectiveness of expanding Medicare Part B coverage to include therapeutic shoes for diabetic persons with severe foot disease. It did not define the term "cost-effectiveness." In the evaluation, we adopted a narrow definition of cost-effectiveness that focused on cost neutrality from the perspective of Medicare payments. rather than a comprehensive cost-effectiveness analysis. This focus was consistent with the tenor of the authorizing legislation and the resources available for the demonstration.

Our principal measure of Medicare costs was total Medicare payments over a follow-up period of 1 year for the sample of 3,428 beneficiaries who enrolled in the demonstration by September 30, 1991 (just over 2 years after the demonstration began). We supplemented this measure of Medicare costs with total Medicare payments for follow-up periods of 6 months for a sample that included later entrants. and 18 months for a sample restricted to those entering by March 31, 1991. We also constructed a measure of the Medicare costs that we could identify as being for footcare services.

How Was Cost-Effectiveness Tested?

Congress mandated a two-phase evaluation of the cost-effectiveness ot the therapeutic shoe benefit. In the first phase, the evaluation was to look for evidence that the shoe benefit was cost-effective (that it lowered total Medicare payments for participating beneficiaries) and report to Congress on the findings. That report (submitted on September 21, 1990)' found no evidence to support a conclusion of cost-savings. Hence, in accordance with the Congressional mandate, the demonstration was extended for a second 2-year phase. After 2 years. following the Congressional mandate. a Second Report to Congress was issued. examining whether the demonstration *increased* costs. That report (submitted to Congress on April 26, 1993) found no statistical basis for concluding that costs had increased.[4] The current report summarizes a final and more comprehensive evaluation of whether the shoe benefit was cost-effective. In terms of formal hypothesis testing, we test (as we did for the Second Congressional Report) whether we can reject the null hypothesis that, under the demonstration, costs were lower than or equal to what they would have been without the intervention. For purposes of the evaluation, the benefit will not be cost-effective if the net cost to Medicare of providing the therapeutic shoes significantly exceeds zero--that is. if the

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[3]This report was based on Wooldridge et al. (1990).

'That report was based on Wooldridge et al. (1992).

gross cost of covering the shoes exceeds any savings from a reduction in the use of other Medicare services (such as hospital stays) that might arise if the therapeutic shoes help prevent new foot problems.

This approach is contrary to the usual approach of statistically testing for evidence of program impacts. in which the null hypothesis is no *difference* in outcomes in *either* direction. The usual approach is conservative. because the analysis will not conclude that the program is truly effective unless there is a *very low probability* that this conclusion, based on the sample data. is incorrect. Because of the wording of the Congressional mandate (enact the benefit nationally unless it is shown not to be cost-effective), however, it was necessary to reverse the usual approach. The null hypothesis is that costs are lower or equivalent under the demonstration--thus ensuring a low probability of concluding that the benefit ***increased*** costs if it really did not. The usual approach, by being careful to avoid concluding that desirable effects exist when they really do not, also means that an analyst may conclude that a program is ineffective even if it did have desirable impacts of moderate size (that is, this approach has a low probability--or statistical power--to detect small effects). Correspondingly, our analysis ensures a low probability of asserting that costs increased because of the new benefit if they really did not. However. it also runs the risk of failing to conclude that costs truly increased under the new benefit if the cost increase is small (compared with the overall average Medicare payments for this population).

The costs of the therapeutic shoe benefit in the demonstration include the costs of the shoes. any physician costs that would not otherwise have been incurred (such as a special visit to ask a physician to prescribe or fit the shoes), and any costs of care received under a comprehensive plan of care for diabetes that exceed those that would have been incurred in the absence of the demonstration. The benefits expected from the therapeutic shoe demonstration are a reduction in footcare costs (from a reduction in the number of infections and amputations) and. consequently, an increase in the quality and length of life. However. the evaluation was not intended to measure improvements in the quality and length of life for beneficiaries that might occur if the shoe benefit were clinically effective. The purpose of the evaluation was not to determine whether therapeutic shoes are clinically effective. although the shoe benefit would probably not be cost-effective if the shoes were not clinically effective.

The cost-effectiveness of shoe benefit coverage also depends on the extent to which it alters the behavior of beneficiaries. We are concerned with ***net*** changes in Medicare payments for the treatment group, relative to what Medicare payments would have been if the benefit had not existed, which are in turn determined by ***net*** changes in underlying behavior. Thus. the key determinants of whether the expanded coverage is cost-effective are the extent to which beneficiaries increase their purchase and use of therapeutic shoes and the extent to which the shoes enable beneficiaries to reduce their use of other Medicare-covered footcare services. Reductions in use of Medicare-covered footcare services will depend, in turn, on the clinical effectiveness of the shoes at reducing the adverse consequences of severe diabetic foot

disease. which requires that they be fitted properly by skilled clinicians, modified as necessary. maintained in good condition. and worn by beneficiaries.

The evaluation compared the Medicare costs for two equivalent groups. In designing the evaluation. we estimated that a sample of 27,500 beneficiaries would be needed to have an 80 percent chance of detecting a 6 percent increase in Medicare costs. This 6 percent target was chosen because it was our estimate of the percentage increase in the total Medicare payment per beneficiary that would occur if the shoe benefit had no effect on other Medicare services and if 75 percent of the beneficiaries received the shoes. We assumed that the total Medicare payment per beneficiary without the shoe benefit would be 20 percent higher than the average Medicare beneficiary payment of $2,500 in 1986. In fact, only 4,373 beneficiaries enrolled, substantially reducing our ability to identify moderate increases in costs. Data gathered during the evaluation also showed that total Medicare payments per beneficiary were four times larger than the average Medicare beneficiary in the year before applying for the benefit, presumably because they were much sicker than the average beneficiary.[5] Had we known the actual payments, and if the shoe benefit had no effect on other Medicare services and 75 percent of the beneficiaries received the shoes. we would have estimated that the percentage increase in the total Medicare payment per beneficiary was 15 percent. We know now that to detect such a small effect confidently, we would have needed to enroll nearly 250,000 beneficiaries.

E. WAS THE BENEFIT COST-EFFECTIVE?

Findings of the Congressional Report and the Final Comprehensive Report

The evaluation estimated the impact of the therapeutic shoe benefit on total Medicare payments over a l-year period by comparing the average Medicare payments for the treatment group. which was offered the extra coverage, to the average payments for the control group. which received standard coverage. If therapeutic shoes were cost-effective, the total Medicare payments for the extra-coverage group should be no more than the payments for the standard-coverage group (the payments for the shoes would be offset by savings from reduced frequency or severity of foot problems). If the benefit were not cost-effective, the total Medicare payments for the extra-coverage group would exceed the payments for the standard-coverage group.

Congressional Reports. Two reports to Congress were prepared before this final comprehensive report. The first report, submitted in September 1990, was unable to draw any

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‘Five years before their death, diabetic Medicare beneficiaries have total Medicare payments 1.6 times the national average payment. By the year of their death, this rises to four times the national average payment (Riley and Lubitz 1989).

conclusions about the therapeutic shoe benefit because it was due too soon after the demonstration began for any effects to be measurable. ***The Second Report to Congress, submitted in April 1993, was based on a smaller sample than that used in this final comprehensive report, hut came to the same conclusions.*** -The principal finding was **that total** Medicare payments in the year after enrollment in the demonstration were $432 higher among the group which was offered the benefit than among the control group that was not offered the benefit. The confidence interval around this estimate was **-$497** to **+$1,362.** This difference was not statistically significant. Comparable results were found for **footcare** payments only, and when we looked at differences between treatment and control group payments among subgroups of the sample.

Final Comprehensive Report. The shoes were expected to reduce Medicare costs through reduced hospital admissions for lower extremity amputations and other **footcare** procedures. We evaluated differences in total hospital admissions and admissions for lower extremity amputations and other **footcare** procedures. However, the sample was too small for moderate effects on hospital use to be identified with confidence. For example, we would be confident of detecting reductions in the proportion with hospital admissions only if the true effect were a decrease of about 4 percentage points (about 10 percent) in the 45 percent rate observed.

The overall rate of hospital utilization among participating beneficiaries was high--about 45 percent of both groups of beneficiaries were admitted to a hospital during their first year in the demonstration. and about one-third of these admissions were for footcare. Treatment group members had slightly fewer hospital admissions and hospital days, **but slightly more** admissions for footcare. However, the differences between the two groups are not statistically significant.

The percentage of participating beneficiaries having a lower extremity amputation during their first year in the demonstration hovered around 2 percent--about 2.6 percent of the treatment group beneficiaries and 1.8 percent of the control group beneficiaries. The difference is not statistically significant. As expected, mortality was high among those who experienced an amputation--two-thirds of the control group and half the treatment group who had an amputation in their first year in the demonstration died within 12 months after entering the demonstration. Although large, this difference is not statistically significant, because so few beneficiaries were involved (about 40 or 50 in each group).

Consistent with participating beneficiaries' high hospital use, their Medicare payments were about $13,000 per year--about five times the payment for the average Medicare recipient

in the national population in 1989.[6] Certain groups of beneficiaries had higher Medicare payments than others. Beneficiaries who had originally enrolled in Medicare because of end-stage renal disease had unadjusted average Medicare payments for all services over the 12 months after randomization that were 3.5 times the payments for those who had originally enrolled because of old age, and their payments for footcare were 2.2 times larger. Similarly. the severity of foot problems at randomization correlated with Medicare payments over the subsequent year. Those who had already had a lower extremity amputation had total Medicare payments that were 2.5 times the payments for those who had experienced neither an amputation nor an ulcer, and their footcare payments were 7 times larger.

Differences between members of the treatment and control groups reveal no consistent evidence of demonstration effects on either total Medicare payments or footcare payments. During the treatment group's first year in the demonstration, Medicare payments for all services were $451 higher (3.8 percent) than payments for all services provided to the control group. Medicare payments for Part A services only and Part B services only were also higher for the treatment group. Similarly, payments for all footcare services were $318 higher (14.6 percent) for the treatment than the control group. a figure that considerably exceeds the average cost of the shoe benefit ($118) In none of these comparisons are. the differences statistically significant at the conventional levels adopted in this report. The lack of evidence on cost differences is consistent with the indistinguishable rates of hospital admissions among the treatment and control groups.

To assess whether the therapeutic shoe benefit was more effective for some types of Medicare beneficiaries than for others, we reviewed differences in Medicare Payments for a!!. services and for footcare services by subgroups of treatment and control group beneficiaries. The objective was to assess whether the shoe benefit was cost-effective for more precisely targeted subgroups of the demonstration's population. The subgroups were defined by the age of the beneficiary at enrollment, States of residence. specialties of the physicians who certified eligibility, duration of diabetes, presence of three clinical foot conditions at the time of benefit application (including prior amputation), and reason for original Medicare entitlement.

The higher Medicare payments for all services and for footcare services for the treatment group relative to those in the control group persisted across most subgroups. In only one instance were the differences statistically significant from either each other or from zero: treatment group beneficiaries who were originally entitled to Medicare for reasons other than old age--that is, because of disability, end-stage renal disease, or both--had lower Medicare payments relative to similar individuals in the control group for all services and for footcare

[6]The average reimbursement for hospital insurance and supplementary medical insurance for 1989 was $2,704 per beneficiary enrolled in the program (U.S. House of Representatives 1992, Table 31).

services. The difference. however, is only statistically significant at the five percent level on a two-tail test for payments for all services for beneficiaries originally entitled because of end-stage renal disease ($p=0.006$), who represent about three percent of our sample. Given the inconsistency with other findings and the small sample size in this subgroup, the large difference observed is probably due to chance rather than program effects.

Implications and Limitations of the Findings

The results of the demonstration left us with substantial uncertainty. The findings did not permit us to state confidently that the Medicare therapeutic shoe benetit is not cost-effective. or that the coverage is cost-effective. In essence, this inconclusiveness was made irrelevant by the Congressional mandate that the coverage be introduced "unless the Secretary finds that such coverage is not cost-effective." This wording suggests that Congress wanted to introduce a benefit that might save money (or provide better outcomes for beneficiaries at no increase in cost)? as long as there was no clear evidence to the contrary.

In designing the demonstration, we followed this Congressional intent by establishing a sample design and testing process that would have a very low probability of concluding that the shoe benefit was not cost-effective, if the shoe benefit did. in fact, save money or was cost neutral. Furthermore. we designed the demonstration to provide assurance that if the benefit *increased* costs. we would have a reasonable chance of correctly detecting that result. Finally. we defined cost-effectiveness to mean that the introduction of the shoe benefit would not increase overall Medicare costs per beneficiary in the year after the benefit was received. This definition reflects the implicit assumption of Congress that if the benetit were cost-effective. the costs of providing the therapeutic shoes would be offset by short-run reductions in the Medicare costs for footcare treatments. A limitation of the study was the short period over which cost-effectiveness could be measured. We have no information about the longer-term effects of therapeutic shoes. for example, their ability to prevent ulcerations in those who had never had a foot problem but were at risk.

The design for conducting these tests had two key components. First, in order to ensure that we would not incorrectly reject the shoe benefit if it were actually cost-effective. we specified a statistical test with a very low probability of this type of error. Specifically, we said that unless a positive treatment-control difference in Medicare costs were statistically significant at the five percent level (using a one-tail test), we would not reject the hypothesis that the benefit was cost-effective. Our procedures ensured that we would be unlikely (a 1 in 20 chance) to fail to introduce a cost-effective benefit. Second. to guard against the chance that we would mistakenly find the shoe benefit cost-effective when it was not, we sought to enroll 27.500 eligible beneficiaries in the demonstration, This number would have given us enough precision to have an 80 percent chance of correctly concluding from our sample that the shoe benefit was not cost-effective, if, in fact, it was not.

We were not able to reject the hypothesis that the shoe benefit is cost-effective. While we estimated that beneficiaries with the shoe coverage had slightly higher Medicare payments than those in the control group. the estimated increase was not sufficiently large for us to be confident that the higher costs of the treatment group were attributable to the shoe benefit rather than to chance. Thus. we could not conclude confidently that the benefit was not cost-effective.

However, because enrollment in the demonstration fell short of the target. we do not have sufficient precision in our estimates to be sure that if the benefit is not cost-effective. we would correctly identify it as such. When the Congressional report was prepared. the l-year follow-up records of only 2,440 beneficiaries were available. Even this final comprehensive report included follow-up records for only 3,428 beneficiaries. Because of this shortfall in enrollment. (and because the beneficiaries who participated were much sicker than anticipated and hence had very much higher total Medicare payments than anticipated) it is highly likely that statistical tests would be unable to reject the hypothesis that costs increased as a result of the benefit expansion. even if costs really did increase. For example, if the effect of the shoe benefit were an increase in Medicare costs by the observed difference between the treatment and control groups, the available sample of beneficiaries and the difference observed would provide only a seven percent chance (about I in 14) of correctly detecting that the benefit was not cost-effective. There was no way of reducing the probability-of making this type of error without enrolling more beneficiaries or increasing the chance that we would violate the Congressional mandate to ensure that a potentially cost-effective benefit would be implemented.

Given this uncertainty, conclusions about the cost-effectiveness of the shoe benefit depended on the type of error decision makers prefer to avoid. If they preferred to avoid rejecting a benefit that might be cost-effective. as Congress indicated, then they would proceed with introducing the shoe benefit because we found no strong evidence that it is not cost-effective. This was in fact the outcome of the demonstration. If Congress had preferred to avoid implementing a benefit that might not be cost-effective (that might ***increase*** total Medicare payments), then they would have set different criteria for introducing the benefit and would not have implemented the shoe benefit. (For example, suppose Congress had specified that the benefit would become law only if the Secretary found clear evidence of cost-effectiveness. Because the demonstration did not provide such evidence, the benefit would not have been introduced.) As noted. however, Congress clearly wanted to avoid rejecting a potentially beneficial expansion in coverage, so the findings of the demonstration resulted in the shoe benefit being introduced (as of May 1, 1993).

F. WHAT WOULD A NATIONAL BENEFIT COST?

National Costs Can Be Estimated, Assuming No Changes in the Benefit and Participation

The demonstration and evaluation results have two major implications for procedures and costs of a national program covering therapeutic shoes for diabetic beneficiaries under Medicare Part B. First, the demonstration was implemented as intended, and it increased therapeutic shoe purchases by 54 percent and shoe use by 70 percent. If the shoes were clinically effective, they had the potential to affect costs, although these potential impacts could be experienced only by those who would not have purchased and worn the shoes in the absence of the demonstration. Second, our analysis of the therapeutic shoe benefit's impact on Medicare costs produced inconclusive results. Although we did not reject the hypothesis that the shoe benefit increased Medicare costs. the confidence interval around the point estimates of the impact was wide. We estimated a cost increase in the treatment group of $451, with a confidence interval of -$701 to +$1,604. This is comparable to the estimate and confidence interval developed from a smaller sample for the Second Report to Congress on the basis of which the benefit was introduced: a cost increase in the treatment group of $432. with a confidence interval of -$497 to +$1,362. The single best point estimate of the net change in Medicare costs from introducing the benefit ($451 per applicant per year) is about four times greater than the cost of the shoes.

Given these equivocal results, precise estimates of the cost of introducing a national benefit are not possible., We developed our estimates using varying assumptions to reflect the, likely range of the costs (or savings) that would be produced by introducing therapeutic shoe coverage nationwide.

The estimates from the demonstration provide a starting point for estimating national costs. However, they reflect the fact that the demonstration lasted only 3 years and only provide a basis for estimating short-term start-up costs, rather than long-term "steady-state" costs. Here we present the range of estimates developed for the Report to Congress on the basis of which the benefit was introduced, and our revised estimates based upon an increased sample and a longer period of demonstration operations. These estimates of first-year and steady-state national benefit costs can only be illustrative as they are very sensitive to the assumptions used to extrapolate from the demonstration.

The Congressional Report included a first-year midpoint estimate of increased national costs of $14.6 million, with a range from savings of $17 million to increased costs of $46 million. This estimate assumed that enrollment build up would be accelerated and that demonstration shoe purchase rates and prices would prevail. However, we also believed that in the absence of demonstration-specific procedures such as random assignment and central prior authorization of benefits, that participation would increase--we assumed an increase to twice the demonstration rate. HCFA's Office of the Actuary estimated that first year costs

would be $15 million. By contrast. in the comprehensive report, we have assumed more conservatively, that in the first year, enrollment build up would resemble that of the first year of the demonstration. rather than being accelerated. Assuming that participation would double yielded a midpoint estimate of $22 million with a range from savings of $10 million to increased costs of $22 million,

Our estimate of the annual costs of the national benefit in the period after enrollment build-up (the steady-state period) assumed demonstration participation rates, shoe purchase rates and prices, but a much higher rate of renewing participants relative to new participants. These assumptions yielded a midpoint estimate of $4 million a year using the sample available for the Congressional report and $5 million a year using the final report sample. We also estimated annual costs assuming that higher cost assumptions would prevail (double the participation, and increased use of the benefit). These assumptions yielded a midpoint estimate of $18 million a year using the Congressional Report sample and $21 million a year using the final sample. HCFA's Office of the Actuary estimated annual costs of $20 million in fiscal 1996 and $25 million in fiscal 1997.

Some Aspects of the Benefit Should Change if It Is Enacted Nationally

A national benefit could differ from that offered in the demonstration. In the short run. the benefit could only be modified in ways that are consistent with the enabling legislation. On the basis of the demonstration experience and the comments of participating health professionals. we recommend the following short term changes:

- Cover additional shoe modifications: flared heels, extended steel shanks, leg-length modifications, Velcro closures, rigid heel counters, and accommodations to inserts for missing toes (toe blocks)
- Use a simple form for certifying eligibility (medical necessity) and prescribing shoes (consistent with Medicare Part B requirements for orthotic devices)
- Do not require suppliers to accept assignment of Medicare benefits (consistent with Medicare Part B requirements for orthotic devices)

By varying assumptions about the benefit and the procedures for beneficiaries to receive it (a process we assume will affect both the prescription rate and the shoe acquisition rate). we generated alternative annual national costs in a steady-state period. These estimates, which are very sensitive to the assumptions used, illustrate only the range of possible costs. Our medium-cost assumptions assume that, relative to the demonstration, 50 percent more

prescriptions are written. and new and renewing applicants increase acquisition of shoes by 10 and 100 percent, respectively. Our high-cost assumptions assume that 100 percent more prescriptions are written, and that new and renewing applicants increase acquisition of shoes by 25 percent and 200 percent, respectively. The medium-cost assumptions yield a midpoint estimate that annual costs would increase by $11.7 million, while the high-cost assumptions yield an estimated midpoint cost increase of $21.2 million. (These estimates should be compared to the midpoint "steady-state" estimate of $5.3 million, using the demonstration participation rate.) These cost estimates are based on the assumption that the acquisition rate and the renewal rate will both increase sharply in a national program. However. if a higher proportion of depth-inlay shoes were provided in a national program (as a result of changed price incentives), the midpoint costs would probably be slightly smaller than these estimates (for example, $10.9 million and $19.8 million, respectively, if 54 percent of the shoes supplied were depth-inlay instead of the 43 percent rate that occurred in the demonstration).

Lessons learned from the evaluation suggest that Congress may also want to consider some longer-term changes in the benefit and the procedures? which are not consistent with the enabling legislation:

- Cover shoe repairs (to be consistent with the coverage of repairs for other durable medical equipment items under Medicare Part B)

- Cover two pairs of shoes in the first year a beneficiary receives the benefit (because of the importance to foot hygiene of alternating pairs of shoes from day to day)

- Allow therapeutic shoes to be replaced more often than annually-that is, when a clinician certifies that major structural foot changes have occurred

- Because footcare specialists are the most likely to initiate shoe use, allow podiatrists and other physicians who are not managing a beneficiary's diabetes to certify the beneficiary's eligibility, a change from the demonstration requirement that the physician managing the diabetes must certify eligibility. (Physician visits would likely be reduced by this change, and patients could be fitted with shoes more quickly.)

- Change Medicare payments in the demonstration to bring the method of payment in line with other Part B services, and alter the relative payment for depth-inlay and custom-molded shoes. One of the reasons for providing the coverage was the high cost of the shoes, which many beneficiaries could not afford (a situation supported by our survey of control-group participants in the demonstration). Increasing Medicare-allowable prices would increase the proportion of shoe

suppliers that accept assignment of benefits (thus limiting beneficiaries' out-of-pocket costs). We also recommend pricing per shoe for custom-molded shoes. rather than pricing per pair, to accommodate patients who only need one shoe.

- Allow HCFA to introduce competitive bidding for the manufacture of custom-molded shoes from positive foot casts, in order to obtain advantageous wholesale prices

Certain regulatory changes could also help ensure that the shoes fitted were of high quality:

- Require that, to be authorized to supply depth-inlay shoes, a supplier has to carry a stock of depth-inlay shoes (which would help ensure that these shoes can be fitted properly and without excessive delays)

- Require that facilities supplying either type of shoe meet the specifications of the relevant professional body--for example, the Board for Certification in Pedorthics

Introducing these longer-run changes would probably increase annual costs relative to the cost of the benefit in the demonstration. (The estimates are highly sensitive to assumptions about the size of price changes and the reduction in number of physician visits required.) However, if competitive bidding could reduce the price of custom-molded shoes substantially. it would also offset the increased costs to Medicare from covering repairs and additional pairs of shoes. Furthermore, with these changes, the shoes may be more effective and beneficiaries may wear them more often, which could decrease the costs to Medicare for foot-related medical care.

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FIGURES

I. DEMONSTRATION GOALS AND CONTEXT

Diabetic patients are at high risk of developing foot problems that may lead to amputation. an event with high personal, medical, and social costs. Clinicians who treat diabetic foot problems include special shoes in the plan of care to avert amputation. The U.S. Congress mandated a demonstration of Medicare Part B coverage for therapeutic shoes for diabetic Medicare beneficiaries to test whether the benefit is cost-effective (Omnibus Budget Reconciliation Act of 1987, Section 4072). The demonstration ran from August 1, 1989, to October 31. 1992.

Congress stated that it would introduce the therapeutic shoe benefit on the first day of the first month after it received a Report to Congress unless the benefit was shown not to be cost-effective.' The benefit is *not* cost-effective if the net cost to Medicare of providing the therapeutic shoes is greater than zero--that is, the gross cost of covering the shoes exceeds any savings from a reduction in the use of other Medicare services (such as hospital stays) that occurs because the therapeutic shoes help prevent new foot problems.

An evaluation of the demonstration was designed and implemented. To provide precise. unbiased impacts that could be attributed with certainty to the demonstration itself. the evaluation relied on a randomized design in which half of the eligible applicants received the shoe benefit, and half did not. This comprehensive final report on the demonstration

'The Report to Congress was due on April 1, 1993. It was submitted on April 26. 1993. and therapeutic shoe coverage was added, effective May 1, 1993. See Volume II, Appendix A.

describes how it was implemented and, for a larger sample than was available for the Congressionally mandated report, evaluates whether offering therapeutic shoe coverage (the "shoe benefit") is cost-effective for the Medicare program.

A. THE DIABETIC FOOT AND THERAPEUTIC SHOES

Persons with long-term diabetes are at risk of developing severe foot problems. Diabetic patients typically develop ulcers on the soles of their feet, which if not treated promptly and successfully can progress to serious infections and gangrene; in turn, these conditions may necessitate amputating the toe, foot, or leg. When a lower extremity has been amputated. patients are at high risk of further amputations. Worse, these patients also have high death rates. Any treatment that reduces foot infections and amputations may save Medicare costs and improve the quality and length of life.

1. Prevalence of Severe Diabetic Foot Disease, Amputation, and Mortality among Medicare Beneficiaries Enrolled in Part B

The overall net cost (or savings) of the therapeutic shoe benefit to Medicare depends in part on the number of beneficiaries who would be eligible for it. Since eligible beneficiaries must have diabetes and severe foot problems, the number of eligible beneficiaries depends on both the prevalence of diabetes among Medicare beneficiaries and the prevalence of severe foot problems among this group. Although the prevalence of diabetes among different population groups is reasonably well established, few good estimates of the prevalence of foot disease among the diabetic population are available.

Prevalence of Diabetes. Medicare beneficiaries are drawn from three eligibility categories: the aged (age 65 and older), the disabled, and those with end-stage renal disease. Each category is associated with different rates of the prevalence of diabetes. The largest group of Medicare beneficiaries enrolled in Part B is the aged population, comprising 90.4 percent of Medicare beneficiaries enrolled in Part B (U.S.' House of Representatives 1992, p. 139). Two estimates of the prevalence of diabetes among the aged are available: 9.7 percent, from the Centers for Disease Control (1990); and 10 percent, from Huse et al. (1989) (see Table I. 1). The next largest category of Medicare beneficiaries enrolled in Part B is the disabled population, comprising 9.1 percent (U.S. House of Representatives 1992. p. 139). The prevalence of diabetes among the disabled Medicare population was drawn from Manton and"' Liu (1990), who estimate that 21.2 percent of the disabled Medicare population living in the community are diabetic. Those eligible for Medicare Part B through the end-stage renal disease program comprise ii.5 percent of the Medicare population.. The U.S. House of Representatives (1992, p. 150) reports that 33 percent of new enrollees each year in the end-stage renal disease program have a diagnosis of diabetes.

We estimate that the prevalence of diabetes among persons enrolled in Medicare Part B in 1990 is 10.7 percent (or 3.5 million Medicare beneficiaries nationwide). We generated this

TABLE I.1

PREVALENCE OF DIABETES, FOOT DISEASE, AND LOWER-EXTREMITY AMPUTATIONS AMONG THE MEDICARE POPULATION

Characteristics	Rate (Percent)	Estimated Number
Number of Medicare Part B Enrollees, 1990		
Aged		29,426,000 [a]
Disabled		2,907,000 [a]
End-Stage Renal Disease Program		148,351 [a]
Total Medicare Part B Enrollees, 1990		32,481,351 *
Diabetes Prevalence		
Aged Part B Enrollees	9.5 [b]	2,795,470 *
Disabled Part B Enrollees	21.22 [c]	616,865 *
End-Stage Renal Disease Program Enrollees	33.33 [d]	49,445 *
Combined Prevalence Rate	10.7 *	3,461,781 *
Diabetic Foot Disease		
History of Sores and Ulcers Among a Diabetic Population		
Age 65 to 75	15.6 [e]	252,934 [f]
Age 75 or older	17.34 [e]	203,588 [f]
Disabled	17.34 [g]	10,964 *
End-Stage Renal Disease Program Enrollees	17.34 [g]	8,574 *
Total		572,060 *
Four-Year Incidence of Foot Ulcers and Sores in an Older Onset Diabetic Population	10.3 [h]	356,563 *
Lower-Extremity Amputation		
Annual Rate Among Diabetic Among Persons Age 65 or Older, 1987	1.01 [i]	28,234 *
Prevalence Rate Among Those Age 65 or Older	1.4 [b]	38,000 [b]
Prevalence Rate Among Those Age 60 to 69 with Early Onset Diabetes	13.3 [h]	--
Prevalence Rate Among Those Age 60 to 69 with Older Onset Diabetes	4.9 [h]	--

*Indicates that the estimate was generated from the data shown in the table.

[a] U.S. House of Representatives 1992 *(Greenbook)*, pp. 139, 149.

[b] Centers for Disease Control (1990), as described in footnote 1 in Chapter I.

[c] Manton and Liu (1990).

[d] U.S. House of Representatives (1992), p. 150.

[e] Palumbo and Melton (1985).

[f] Assumes that the distribution of the aged Medicare Part II population is as follows (U.S. Bureau of the Census, 1993, p. 14):

65-74 years: 58 percent of aged Medicare beneficiaries
75 years or older: 42 percent of aged Medicare beneficiaries

[g] Assumes same as (e).

[h] Moss et al. (1992).

[i] American Diabetes Association (1983), cited by Pylling and Knighton (1989).

estimate by combining separate estimates of the prevalence of diabetes among aged, disabled. and end-stage renal disease program Medicare beneficiaries enrolled in Part B.[2]

Prevalence of Diabetic Foot Disease. The prevalence of diagnosed diabetes has been growing, and. hence. the prevalence of foot disease may also be growing. However, few estimates of the prevalence of foot disease are available. Using two sources. both based on the Wisconsin epidemiological study of Diabetic Retinopathy, we estimate that. in 1990. between 356,563 and 572,060 diabetic Medicare beneficiaries had foot disease. These are crude estimates of the prevalence of foot disease. but are the best available.'

One estimate was drawn from Palumbo and Melton (1985), who provide risk rates for elderly persons in Wisconsin with older onset diabetes with a *history* of ulcers or sores on the foot or ankle--direct evidence of foot disease. They found that 156 per 1,000 persons with older onset diabetes age 65 to 74 and 173 per 1,000 persons with diabetes age 75 and older

[2]Our estimate of the prevalence of diabetes among aged Medicare beneficiaries in 1990 was 9.5 percent. We obtained this estimate by applying regional diabetes prevalence figures for the aged (adjusted for race and gender) (Centers for Disease Control. 1990) to the number of aged beneficiaries enrolled in Part B in each specific region in 1990 (Social Security Administration. 1991). We assumed that the prevalence of diabetes among disabled beneficiaries in 1990 was 21.2 percent (from Manton and Liu 1990), and that the percentage of end-stage renal disease program enrollees with diabetes was the same as for new enrollees--33.3 percent (U.S. House of Representatives 1992). Applying these three rates to the number of Medicare beneficiaries eligible for Part B in 1990 yields an overall rate ot 10.7 percent, or 3.5 million Medicare beneficiaries nationwide (see Table 1.1).

[3]A British study of all known diabetic patients in an area (1,150) found that 7.8 percent had ever had a foot ulcer. Among those younger than age 60, the rate was 2.6 percent: among those older than age 60. it was 9.1 percent. These rates are somewhat lower than the rates in the U.S. population (Walters et al. 1992).

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showed evidence of ever having had foot disease." Applying these rates to the aged Medicare Part B diabetic population in 1990 (2.79 million) yields 456.522 persons with a history of foot ulcers or sores. Assuming that the rate for the disabled and end-stage renal disease program populations is the same as for the 75-year-old and older population yields 106,964 disabled and 8,574 end-stage renal disease diabetic Medicare beneficiaries enrolled in Part B with a history of ulcers or sores. Thus, the Palumbo and Melton foot disease rates yield a combined estimate of 572,060 aged. disabled. and end-stage renal disease program persons in the Medicare Part B program who have diabetic foot disease.

The other estimate was drawn from Moss et al. (1992) for the same population. who estimate that during the subsequent 4-year period the incidence of ulcers and sores among the population of persons with older onset diabetes (at age 30 or older) was 10.3 percent.' A 4-year incidence (new case) rate is not the same as the prevalence rate (it is presumably lower than the prevalence rate, which is the cumulative rate), but it provides a lower-bound estimate. Applying this 4-year incidence rate to the aged, disabled. and end-stage renal disease program diabetic Medicare Part B population in 1990 yields 356,563 Medicare Part B beneficiaries with diabetic foot disease.

Amputation Rates and Mortality. If foot disease is not treated, or if treatment is unsuccessful, the amputation of a toe, foot, or leg may be necessary. Estimates of the annual

[4]The sample was a stratified random sample of 1,780 older onset diabetic persons who were examined between 1980 and 1982.

'Seventy-three percent of this population were older than age 60. Incidence of foot sores was not available by age category.

number of lower-extremity amputations among diabetic Medicare beneficiaries range from the American Diabetes Association's (1986) estimate of 12,400 in 1984 to the Centers for Disease Control's estimate of 38,000 nontraumatic lower-extremity amputations in 1987 among diabetic persons age 65 and older (Centers for Disease Control 1990). The Centers for Disease Control estimate of 38,000 lower-extremity amputations annually among the aged implies an annual amputation rate of 1.4 percent among aged Medicare beneficiaries with diabetes, but 8.3 percent among those with foot disease (an estimated 456,000 aged persons)."

Moss et al. (1992) provide estimates of the prevalence of lower-extremity amputation in an early onset and an older onset diabetic population in Wisconsin which show that amputation rates increased with the duration of diabetes. Among persons age 60 to 69, the prevalence rate was higher among those with early onset diabetes (13.3 percent) than among those with older onset diabetes (4.9 percent). The Centers for Disease Control and Moss et al. show that the risk of lower-extremity amputation is considerably higher among men than women and among blacks than whites. and that risk increases with age.

Mortality is higher among diabetic persons who have had a lower-extremity amputation than among those who have not. Palumbo and Melton (1985) report that 50 percent of a sample of diabetic persons who had a lower-extremity amputation were still alive 3 years after amputation. but that only 40 percent were alive 5 years after an amputation. Other authors have shown that the probability of survival among diabetic persons who have extensive

[6]The Centers for Disease Control estimate of the prevalence of amputation is derived from the National Hospital Discharge Survey.

amputations ranges from 30 to 59 percent 5 years after surgery (Steer et al. 1983; and Most and Sinnock 1983).

Costs. The costs of treating the complications of diabetic foot disease are high. Reiber (1992) reports an average Medicare reimbursement of $12,230 for hospital stays for lower-extremity amputations (with an average length of stay of 18.7 days). Jacobs, Sena, and Fox (1991) estimate that the average cost of a hospital stay for diabetic diseases of the arteries (which include skin ulcers and gangrene) is $12,730 (with an average length of stay of 14.4 days). Given the high mortality rates among persons with lower-extremity amputations and the fourfold increase in Medicare costs for all diabetic Medicare beneficiaries in the calendar year prior to death (Riley and Lubitz 1989), the Medicare costs for persons who have a lower-extremity amputation will be much higher on average than the Medicare costs for those who do not.

2. The **Use and Effectiveness of Therapeutic Shoes**

Because diabetic patients often have reduced sensation in their feet. it is extremely important that they wear shoes at all times. Due to poor sensation. patients may wear shoes that are too tight or may walk unknowingly on foreign objects, thus unknowingly damaging their feet. Due to altered weight-bearing in the diabetic foot, ordinary shoes will not provide adequate protection or weight redistribution. Properly fitted therapeutic shoes protect against

external injuries, do not rub or chafe. and provide the necessary weight redistribution to prevent damage to foot tissue.'

Clinicians have argued that properly fitted shoes are a necessary part of the plan of care for diabetic patients, but they also stress that shoes must be part of a *comprehensive* plan of care that includes blood-sugar monitoring and foot hygiene. comprising inspecting the feet for damage, washing the feet, and wearing clean hose every ***day. (See*** the extensive citations in Cavanagh 1992.) Some clinicians also recommend preventive surgery to correct deformities that can lead to severe problems in the diabetic foot.

The two principal types of therapeutic shoes prescribed by physicians for diabetic patients are ***depth-inlay shoes*** and ***custom-molded shoes.*** Depth-inlay shoes are off-the-shelf shoes manufactured in a variety of styles, sizes, and materials, with sufficient depth to accommodate an insert. Clinicians recommend these shoes for patients whose feet are not grossly deformed. Inlays or inserts can be made from a variety of materials that provide cushioning or support. and may be off-the-shelf, customized, or custom-made from a cast of the patient's foot. Custom-molded shoes are manufactured from total contact casts of the patients' feet. Clinicians recommend these shoes for patients who have had major structural changes to their feet.

Clinicians who work with patients with diabetic foot disease encourage their patients always to wear protective shoes. Yet protective shoes are by no means owned or worn

[7]Apelqvist et al. (1990) found that among 3 14 consecutive patients with a diabetic foot ulcer the most common external precipitating factor was ill-fitting shoes or socks (39 percent), and next most common was an accident, such as stubbing the toe (18 percent).

universally by the patients. Clinicians give three reasons why patients do not own or wear therapeutic shoes: the first is that they are expensive and are not covered by insurance (for instance. the shoes are covered only in 11 State Medicaid programs at present. according to Commerce Clearing House 1993); the second reason is that patients are unaware of the importance of the shoes in preventing foot damage; and the third reason is that the shoes are unattractive (see the photographs in the frontispiece).

Aside from the data collected in the Medicare Therapeutic Shoe Demonstration. no estimates are available of the rates at which diabetic persons purchase or wear therapeutic shoes. As discussed further in Chapters III and V, almost one-third of the demonstration participants already had therapeutic shoes when they applied for the shoe payment benefit. Over two-thirds of all the applicants who received the demonstration benefit used the benefit to purchase therapeutic shoes during the subsequent 12 months. Three years after the demonstration began, 85 percent of those assigned to receive the benefit owned therapeutic shoes, and 61 percent wore them to walk outside. Among applicants who did not receive the benefit. 55 percent owned therapeutic shoes, and 37 percent wore them to walk outside.

If therapeutic shoes are effective at preventing ulcers and delaying amputations (for which no definitive evidence is available from controlled clinical trials), then the hospital and other health care costs for those who wear them may be lower. The demonstration was designed to test whether Medicare payments were lower or higher for at-risk beneficiaries for whom Medicare covers therapeutic shoes. However, the demonstration was not evaluated for its clinical effectiveness.

The demonstration encourages shoe purchases and use by including therapeutic shoes as a covered Medicare benefit. The demonstration may also have increased awareness of the importance of a comprehensive plan of care for diabetes and foot conditions, and. if shoe coverage encourages more people to buy therapeutic shoes when prescribed by their physicians, then the demonstration will likely increase compliance.

B. THE LAW AUTHORIZING THE THERAPEUTIC SHOE DEMONSTRATION

The demonstration of a Medicare Therapeutic Shoe benefit was mandated in 1987 only after a long period of debate about the potential costs and benefits of covering therapeutic shoes under Medicare.[3]

1. Legislative History Before 1987

Under the Omnibus Budget Reconciliation Act of 1980, Congress mandated a comprehensive study of methods for providing coverage for therapeutic shoes under the Medicare Part B program. The study was to recommend what the benefit should cover. methods for controlling costs and ensuring the quality of care, and equitable and efficient administration. The Department of Health and Human Services submitted a Report to Congress in 1981 (summarized in Young 1981) which recommended that the benefit not be implemented because it was expected to add $85 million to Medicare Part B program costs

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[3] Until May 1, 1993, therapeutic shoes could be covered under the national Medicare Part B program only if attached as an integral part to an orthotic or prosthetic device. in the presence of a substantial or total amputation of the foot.

in fiscal 1982 and was thought to be difficult to target at the individuals who could derive the greatest benefit from the coverage.

In 1985, a new bill was introduced into Congress to provide Medicare coverage for therapeutic shoes for individuals at risk of severe diabetic foot disease. Despite a background paper by the American Diabetes Association which estimated that the annual savings from a therapeutic shoe benefit would be between $2.4 million and $23.6 million, the bill was not passed into law."

2. The **Omnibus Budget Reconciliation Act of 1987**

The value of a therapeutic shoe benefit to diabetic Medicare beneficiaries continued, to be of interest to Congress, the American Diabetes Association, and other organizations concerned with preventing severe foot disease and lower-extremity amputation. In 1987, Congress mandated a demonstration of a Medicare Part B therapeutic shoe benefit under the Omnibus Budget Reconciliation Act of 1987 (Public Law 100-203, Section 4072), and required that the demonstration be evaluated to determine whether the benefit was cost-effective.

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[9]The American Diabetes Association estimated that if the benefit averted 20 percent of lower-extremity amputations the net annual savings to Medicare would be approximately $2.4 million, and that if it averted 40 percent of amputations the savings would be as high as $23.6 million (based on its estimate of 12,400 lower-extremity amputations annually). However, these estimates of savings are probably too high, even if the assumed impacts on amputation were correct, because, whiie taking into account the costs of the shoes and the savings from fewer amputations, the study ignored the possibility that some beneficiaries would already have therapeutic shoes and would not derive any additional clinical benefit from coverage. Furthermore, the American Diabetes Association study did not include the costs associated with the requirement that patients be in a comprehensive plan of care. The demonstration reported here (which was implemented in 1989) was designed to take all these costs and savings into account.

The legislation specified the clinical criteria, medical history, and comprehensive care plan required for beneficiaries to qualify for the benefit. Thus, the benefit was targeted at those who could benefit most from the therapeutic shoes:

> The individual has peripheral neuropathy with evidence of callus formation. a history of pre-ulcerative calluses, a history of previous ulceration, foot deformity, or previous amputation, or poor circulation, and ... the individual needs such shoes under a comprehensive plan of care related to the individual's diabetic condition.

The legislation specified the types of therapeutic shoes to be covered and their costs (depth-inlay shoes with customized inserts at $150; and custom-molded shoes at $300), and stipulated that shoes could be replaced annually.[12] Finally, the law described the types of physicians and shoe suppliers who could participate:

> The physician who is managing the individual's diabetic condition documents [the clinical conditions] ... and certifies [the need for shoes].
>
> The types of shoes are prescribed by a podiatrist or other qualified physician (as established by the Secretary).
>
> The shoes are fitted and furnished by a podiatrist or other qualified individual (such as a pedorthist or orthotist, as established by the Secretary) who is not the physician [who documents the clinical conditions and certifies the need for shoes], (unless the Secretary finds that the physician is the only such qualified individual in the area).

The legislation did not specify how cost-effectiveness would be measured. The presumption was that if the shoes were clinically effective at reducing the incidence of ulcers

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[12] The legislation refers to "extra-depth" shoes (a trademark) rather than to depth-inlay shoes (the generic name). Throughout the demonstration, we referred to depth-inlay shoes rather than to extra-depth shoes.

and infections. the use of other Medicare-covered services, such as hospital stays and physician visits. would be lower. Thus, as discussed in subsequent chapters, we based the evaluation of cost-effectiveness on whether Medicare payments were higher among eligible beneficiaries who were offered the therapeutic shoe benefit, compared with an equivalent group of eligible beneficiaries who were not offered the benefit.

Congress specified a 2-year operating period for the demonstration. ending on October 1, 1990. A Report to Congress was mandated for October I, 1990, which was to specify whether the benefit was cost-effective. Since inadequate information was available for determining the cost-effectiveness of the benefit when the Department of Health and Human Services submitted that Report to Congress on September 21, 1990, the demonstration was extended for 2 more years under a provision of the law which stipulated that if the benefit was not shown to be cost-effective after 2 years it should operate for another 2 years." The Congress mandated a second Report, due on April 1, 1993. If the evaluation did not find net cost increases. the benefit would become effective on the first day of the first month after Congress received the Report. If the benefit increased net costs, the coverage would not he introduced. That report did not find evidence of increased net costs.[12]

[11]The Report to Congress was based on Wooldridge, Handwerger, and Sing 1990.

'*The Report to Congress was based on Wooldridge et al. 1992. The findings of Wooldridge et al. 1992 are summarized in this report.

3. The Omnibus Budget Reconciliation Act of 1989

In November 1989, Congress amended the demonstration benefit in the Omnibus Budget Reconciliation Act (Public Law 101-239, Section 6131). The benefit was expanded to include two pairs of replacement inserts per year (for either type of shoe) or shoe modifications that may be substituted for one or both pairs of replacement inserts.

This amendment was introduced to address the concerns of the clinical community that the clinical effectiveness of shoe inserts declines with wear (and thus the benefits of the shoes would be lost if the patients did not replace their inserts regularly), and that. in the absence of coverage for modifications to depth-inlay shoes, an unnecessarily large number of patients would be prescribed the more expensive custom-molded shoes (because special modifications can be built into these shoes at no additional cost). High rates of prescriptions for custom-molded shoes could have two undesirable effects: less compliance by patients due to the unattractive appearance of the shoes, and higher-than-necessary Medicare costs. Allowing the depth-inlay shoes to be modified would ameliorate these adverse outcomes, and the demonstration would be more likely to yield findings of savings to the Medicare program.

II. HOW WAS THE DEMONSTRATION DESIGNED?

The demonstration benefit consisted of Medicare Part B payment for therapeutic shoes for clinically eligible Medicare beneficiaries with diabetes for a limited time period in three States. This chapter describes the benefit and who was eligible to receive it, the timing of and sites in which the demonstration benefit was made available, and the roles of health care providers and shoe suppliers. Because Congress mandated an evaluation of the cost-effectiveness of the demonstration, the evaluation measured the costs incurred (or the savings accrued) by Medicare under the demonstration. This chapter also describes how some evaiuation requirements affected the demonstration design.

A. THE DEMONSTRATION BENEFIT

Congress specified the demonstration benefit in the Omnibus Budget Reconciliation Act of 1987, clearly delineating its intentions about who was eligible to receive the benefit. what the benefit encompassed, and the role that health care providers would play. (Appendix A presents the legislation that enacted the demonstration.)

1. Definition of the Benefit

The demonstration benefit consisted of Medicare Part B payment for one pair of therapeutic shoes each year. Two types of shoes were covered: ***depth-inlay shoes*** (off-the-shelf shoes manufactured to accommodate inserts) and ***custom-molded shoes*** (which are manufactured from a cast of the patient's foot and supplied with inserts). These two types of

shoes are illustrated in the photograph in the frontispiece. When depth-inlay shoes were prescribed, the benefit also covered a pair of customized inserts. Regardless of the type of shoe that was prescribed, up to two pairs of replacement inserts or certain shoe modifications of the same value were covered each year.[1] Table II.1 summarizes the items covered and the frequency with which they could be renewed.

2. Eligible Beneficiaries, Physicians, and Shoe Suppliers

To be eligible for the demonstration, beneficiaries had to meet Congressionally specified clinical criteria. certified by the physicians managing their diabetes. First, to be certified as eligible for the demonstration &id:‘ in need of therapeutid shoes, beneficiaries had to be diagnosed with diabetes and show clinical evidence of foot disease, such as an amputation. ulceration, callus formation and peripheral neuropathy, foot deformity, or poor circulation. Second, beneficiaries had to be under a comprehensive plan of care for managing their diabetes. A comprehensive plan of care for diabetes includes recommendations for diet and exercise. education, monitoring, a plan for preventing complications, and, if indicated, an oral hypoglycemic or insulin. Table 11.2 presents the clinical eligibility criteria and definition of comprehensive care.

Additional, operational eligibility criteria were also applied to participants. Congress required that participants have Medicare Part B coverage. Participants also had to reside in the geographic areas where the demonstration was implemented. A further operational

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‘The Omnibus Budget Reconciliation Act of 1989 added replacement inserts and modifications retroactively to the benefit.

TABLE II.1

ITEMS COVERED BY MEDICARE PART B UNDER THE THERAPEUTIC SHOE DEMONSTRATION

Item Covered	Frequency of Rcncwal
Shoes	
One pair of depth-inlay shoes with customized inserts[a]	Annual
OR	
One pair of custom-molded shoes[b]	Annual
Replacement Inserts or Modifications	
Two pairs of replacement customized inserts	Annual
OR	
Shoe modifications[c]	Annual: up to the maximum allowable charge for two pairs of replacement inserts
Replaccmcnt customized inserts and shoe modifications	Annual: any combination of replacement inserts and modifications up to the maximum allowable charge for two pairs of replacement inserts

SOURCE: Medicare Therapeutic Shoe Demonstration Shoe Supplier Manual. (See Volume II. Appendix D.)

Nom: Medicare allowable charges are shown in Table 11.3.

"Depth-inlay shoes were covered only if shoes were closed (that is, slip-on styles were not covered). The inserts covered were total contact. customized, multiple density, removable inlays molded directly to the patient's feet or to a positive cast of the patient's feet.

"Custom-molded shoes were covered if molded to a positive cast of the patient's feet. The shoes included custom inserts and built-in modifications. Some form of shoe closure was rcquircd.

'Shoe modifications included rigid rocker bottoms. roller bottoms, metatarsal bars, wedges, and offset heels. Other modifications were covered only with prior authorization, which was never requested.

TABLE II.2

CLINICAL CRITERIA FOR BENEFICIARY ELIGIBILITY AND THEIR DEFINITIONS IN THE DEMONSTRATION

Criterion	Definition
1. Diagnosed as Having Diabetes	Self-explanatory
2. Diagnosed as Having One or More of the Following Conditions:[a]	
• Previous amputation of the foot or part of the foot	Self-explanatory
• History of previous foot ulceration	A history of an open foot ulcer due to diabetic neuropathy or to vascular disease which penetrates the skin, often associated with tissue disintegration and infection, not solely produced by traumatic injury.
• Callus formation or a history of callus formation with peripheral neuropathy	Thick, hardened, dried skin, particularly over metatarsal heads, toes, or heels, plus loss of normal protective sensation. The latter is best assessed by testing for loss of normal vibratory sensation (128 cps tuning fork), light touch (using the deformable Semmes-Weinstein monofilaments), or other appropriate formal sensory testing that can be measured quantitatively.
• Foot deformity with potential for ulceration	Inherited-- or acquired - (as, for example, from motor neuropathy) abnormal foot and or toe shape which creates excessive pressure or mechanical force with normal weight bearing. The deformity must be combined with loss of protective sensation or significantly impaired arterial circulation to constitute a significant potential for ulceration. Charcot joint, large bunions, exostoses, hammertoes, pes cavus, and hallux valgus deformities combined with sensory neuropathy are some examples in diabetic patients.
• Poor circulation	Patients with severe ischemic feet characterized by marked atrophic skin changes of the feet and dependent rubor or with history of ischemic ulceration not treatable by vascular surgery.

TABLE II.2 *(continued)*

Criterion	Definition
3. The physician must also certify that the patient is being treated under a comprehensive plan of care for his or her diabetes and that he or she needs therapeutic shoes.	Comprehensive care is defined as follows. The therapy of diabetes mellitus includes diet, cxercisc. and if indicated. an oral hypoglycemic or insulin. Comprehensive care implies three added elements: education, monitoring, and prevention of complications. First, education informs patients about the treatment and complications of diabetes. Subjects for instruction include diabetes monitoring with urine and capillary blood testing, sick day rules, diet. and behavior modification such as smoking cessation, foot inspection, and regular exercise to reduce long-term complications. Second. diabetes monitoring encompasses assessment of glycemic control, diabetic complications (kidney, eye, and foot) and risks for cardiovascular disease. Glyccmic control is evaluated by self glucose monitoring and glycohcmogiobin tests. Diabetic renal complications arc evaluated by yearly tests for proteinuria. BUN. and creatininc. Eye complications are assessed by regular lunduscopic exam and referral to ophthalmologists every year. Diabetic foot disorders arc evaluated by examination of the feet, peripheral pulses, signs of arterial insufficiency and evidence of peripheral neuropathy, for cxnmple, tests for pain and touch sensitivity, vibratory sensation, and reflexes. Cardiovascular disease risk assessment includes measuring blood lipids. blood pressure and other known risk factors. Last, prevention of complications combines these aspects of monitoring with both therapy modification and educational intervention to avert complications. Comprehensive care should be implemented by primary physicians in conjunction with other caretakers (podiatrists. dieticians, nurses, orthotists, pcdorthists. prosthetists. etc.).

NOTES: These criteria were worded slightly differently from the legislation to reflect the recommendations of the demonstration's clinical advisory panel. For example, the potential for ulceration was added to the foot deformity category because the panel felt that "fool deformity" was too broad a category, which could encourage participation by Medicare beneficiaries who would not derive a clinical benefit from the shoes. The definitions developed for the demonstration were included in the "Instructions for Physicians" shown in Volume II, Appendix C.

The physician responsible for managing the patient's diabetes was required to certify that the patient met these clinical criteria.

[a] Physicians were instructed not to prescribe therapeutic shoes to patients with the following conditions: (1) intact protective foot sensation; (2) minor foot deformities, for example corns. with intact protective foot sensation and adequately preserved circulation: (3) minimally impaired circulation with intact foot sensation: (4) patients with active (open, draining) ulceration of the feet.

criterion was added: Medicare health maintenance organization (HMO) members were excluded because it would not have been possible to collect their Medicare claims records, which were necessary for evaluating cost-effectiveness.

Congress specified that physicians should play a central role in enrolling beneficiaries in the demonstration. First, physicians were to certify that beneficiaries met the clinical eligibility criteria presented in Table 11.2. Only physicians who managed the systemic diabetic condition were eligible to certify the clinical eligibility of beneficiaries. Second, physicians were to prescribe the therapeutic shoes. Any physician wishing to prescribe therapeutic shoes was eligible to do so, although podiatrists were the only physicians mentioned specifically in the legislation. A single physician could certify eligibility and prescribe therapeutic shoes for a beneficiary, or one physician could certify and another prescribe.

Congress also specified the types of professionals who could furnish therapeutic shoes in the demonstration. The legislation specified that podiatrists and other qualified individuals could fit and supply therapeutic shoes in the demonstration; pedorthists and orthotists were also mentioned. However, physicians who certified the clinical eligibility of beneficiaries for the demonstration were excluded from supplying shoes to the beneficiaries whom they certified. HCFA determined the process by which shoe suppliers could be authorized to supply the shoes. This process, described more fully in Chapter III, required that suppliers employ appropriately qualified personnel and agree on a price that they would bill Medicare for the shoes.

Chapter III describes how these legislative requirements were made operational; it also describes how potential participants were notified of the demonstration benefit through a publicity campaign.

3. Shoe Prices and Assignment of Benefits

The statutory maximum prices for furnishing therapeutic shoes in the demonstration were set by Congress in the legislation, with a provision that prices be adjusted annually according to the change in the price index for durable medical equipment. The statutory prices at the start of the demonstration were operational until the end of 1990. Prices were increased at the beginning of 1991 and continued at that level until the end of the demonstration in October 1992. The two price levels are shown in Table II.3.

HCFA required that authorized shoe suppliers in the demonstration accept assignment of Medicare benefits for dispensing therapeutic shoes to beneficiaries in the demonstration (that is, that they agree to accept the maximum allowed price, or a lower price, as the full charge for the service). The payment received by authorized suppliers from Medicare Part B was equal to 80 percent of the lowest of (1) the current statutory price, (2) the price that the supplier had agreed to accept during the demonstration. or (3) the actual charge, less any annual Medicare Part B deductible not yet met by the beneficiary.[2] Beneficiaries in the demonstration were responsible for the remaining 20 percent copayment plus any outstanding annual Part B deductible.

[2]As was the case with all Medicare payments. the demonstration payments were reduced by 2.092 percent during fiscal 1990 to comply with Section 256(d) of the Balanced Budget and Emergency Deficit Control Act of 1985 (Public Law 99-177).

TABLE 11.3

MEDICARE PART B DEDUCTIBLES AND ALLOWABLE CHARGES FOR THERAPEUTIC SHOES, CUSTOMIZED INSERTS, AND SHOE MODIFICATIONS DURING THE DEMONSTRATION

	August 1, 1989 to Dccemhcr 31, 1990	January 1. 1991 to October 31, 1992
Medicare Part B Deductible (Annual)	$75	$100
Depth-Inlay Shoes (Pair)	$102	$105
Custom-Molded Shoes (Pair)	$305	$316
Customized Inserts (Pair)	$51	$53
Modifications		
Rigid rocker bottoms (pair)	$75	$79
Roller bottoms (pair)	$75	$79
Metatarsai bars (pair)	$25	$26
Wedges (pair)	$25	$26
Offset heels (pair)	$51	$53

NOTES: The prices specified in the legislation ($100 for depth-inlay shoes, $300 for custom-molded shoes, and $50 for customized inserts) were adjusted once before the demonstration began.

Modifications were not part of the original benefit but were introduced retroactively in 1990.

Payments were reduced by 2.092 percent due to Gramm-Rudman-Hollings cutbacks for services rendered on or after October 17, 1989 to September 30, 1990.

The participation of the Medicaid (Medical) programs in the demonstration was sought in the three demonstration States (California, Florida, and New York), so that dually entitled Medicare and Medicaid (Medical) beneficiaries participating in the demonstration would not have to make copayments. Arrangements were made with the Florida and California programs to cover beneficiary copayments for therapeutic shoes supplied in the demonstration. New York declined to cover demonstration copayments.[3]

4. Demonstration Schedule

The Medicare Therapeutic Shoe Demonstration was authorized by the Omnibus Budget Reconciliation Act of 1987, with an expected start of October 1, 1988. The Health Care Financing Administration awarded a contract to Mathematica Policy Research. Inc., on June 30, 1988, to design, implement, and evaluate the demonstration.[4] The demonstration and evaluation were designed over the subsequent 13 months, and the demonstration began on August 1, 1989 in California, Florida, and New York. The demonstration was to operate until October 1, 1990.

The legislation mandated an evaluation of the cost-effectiveness of the benefit and a Report to Congress. A national benefit was to supersede the demonstration benefit if the Report to Congress showed that the benefit was cost-effective. If the report did not show that the demonstration benefit was cost effective, the demonstration would be extended through

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[3]The Medicaid programs of both New York and California cover therapeutic shoes: the Florida program does not.

'Under contract number HCFA 500-87-0028-9.

October 1, 1992. The Report to Congress (based on Wooldridge, Handwerger, and Sing 1990) did not show that the benefit was cost-effective (it was too early to draw conclusions). Hence, the demonstration was extended for 2 more years. The sequence of demonstration and evaluation activities is summarized in Table 11.4.

The legislation also mandated that unless a second Report to Congress, due on April 1. 1993, showed that the benefit was not cost-effective a national benefit would be introduced on the first day of the first month after the report was submitted. That Report to Congress. delivered on April 26, 1996 (based on Wooldridge et al. 1992) found no evidence that the benefit was not cost-effective (nor did it show that the benefit *was* cost-effective). Accordingly, therapeutic shoes became a covered benefit on May 1, 1993. In this final comprehensive report. we use a larger sample than was available for the Report to Congress to evaluate the evidence on the cost-effectiveness of the shoe benefit (our sample is discussed more fully in Chapter IV.)

B. THE EVALUATION DESIGN AFFECTED THE DEMONSTRATION DESIGN

1. The Demonstration States Contained Large Medicare Populations

The demonstration was implemented statewide in California, Florida, and New York on August 1, 1989. These States were selected because statistical power tests suggested that the evaluation would require a sample of 27,500 participating Medicare beneficiaries in order to test whether the shoe benefit was cost effective. (That is, this sample size was necessary to ensure a high probability of correctly concluding that the benefit was not cost-effective if the only true effect was an increase in expenditures for shoes.) In addition to the requirement

TABLE II.4

SCHEDULE OF MAJOR DEMONSTRATION EVENTS

Event	Date
OBRA 1987 Legislation Mandated Demonstration	12/87
HFCA Awarded Contract to Design Demonstration	06/88
Final Operational Protocol Report Accepted	05/89
Final Demonstration Design Report Accepted	06/89
Demonstration Operations Began	08/01/89
Demonstration Benefit Modified by Omnibus Budget Reconciliation Act of 1989	11/89
New Publicity Campaign Began	07/90
Preliminary Report to Congress Due	10/01/90
Preliminary Report to Congress Delivered on the Basis of Which the Demonstration was Extcndcd 2 Years	9/21/90
Demonstration Ended	10/31/92
Report to Congress Due	4/11/93
Report to Congress Delivered on the Basis of Which the Benefit Was Added	4/26/93
Benefit Effective	5/01/93

SOURCE: Medicare Therapeutic Shoe Demonstration.

that the demonstration states contain a large number of Medicare beneficiaries, they were to contain a sufficient volume of physicians and shoe suppliers to ensure that participating beneficiaries would have access to the shoe benefit. Based on data from 1986, California, Florida, New York, New Jersey, Illinois, and Texas ranked the highest of the 50 States across these variables. Since the resources for the demonstration would allow only three demonstration States, California, Florida, and New York were selected from the six highest-ranked States, thus representing three geographic regions.

2. Randomization Required Centralized Pre-Authorization

The evaluation design called for randomizing eligible beneficiaries into either a treatment group of beneficiaries who would receive payment for therapeutic shoes or an equal-size control group. Assigning beneficiaries randomly to the two groups for the evaluation required that eligible beneficiaries apply to and be approved by the evaluation contractor at a central location before they could receive the shoes. Thus, ail paperwork had to be processed through the evaluation contractor, rather than the Medicare carrier, before beneficiaries could receive shoes. (The application, randomization. and pre-authorization processes are described fully in Chapter III.)

3. The **Evaluation Required Clinical Information as of the Time that Beneficiaries Applied to the Demonstration**

The evaluation required clinical information on the severity of diabetes as of the time that beneficiaries applied to the demonstration and information on the previous ownership and use of therapeutic of shoes in order to increase the precision of the estimates of the cost-

effectiveness of therapeutic shoes. Therefore, the Certification and Prescription Form included three items that were not required by the legislation: the duration of diabetes, whether a physician had prescribed therapeutic shoes in the past 12 months, and whether the beneficiary currently owned depth-inlay or custom-molded therapeutic shoes.

4. The **Data Needs of the Evaluation Precluded Members of HMOs and Health Care Prepayment Plans from Participating in the Demonstration**

The evaluation required data on the costs of medical care after enrollment in the demonstration to determine the cost-effectiveness of the therapeutic shoe benefit. However. HMOs and Health Care Prepayment Plans usually do not maintain records on the costs of medical care for members, because they automatically receive a monthly payment for each member regardless of the medical services that members use. Thus, members of HMOs and prepaid plans were excluded from the demonstration because the data necessary for evaluating the cost-effectiveness of the therapeutic shoe benefit would not have been available for them. However, when beneficiaries were assigned to the treatment group, they were not denied benefit renewal if they subsequently joined an HMO or prepaid plan. No treatment or control group member was dropped from the analysis if they joined a prepaid plan.

III. WAS THE DEMONSTRATION IMPLEMENTED AS INTENDED?

For the demonstration to provide a meaningful test of the cost-effectiveness of a national benefit, it should have been implemented both according to the legislation and in a way that closely matched the procedures and the number and types of beneficiaries, physicians, and shoe suppliers that would be found in a national program. ***The demonstration was implemented largely according to the legislation, and operated from August I,*** 1989 ***to October*** 31, 1992. ***However, though the demonstration procedures matched as closely as possible those that would apply in a national program, some differences were necessary because of evaluation requirements. Moreover, the numb& and types of participants differed somewhat from e&&ions: beneficiaries were more severely ill, far fewer physicians were primary care practitioners, and the participation of beneficiaries and physicians was considerably lower than anticipated.***

Given the short period of time in which the demonstration was to operate (2 years initially, with the potential of 2 further years), publicity was required to encourage participation. Hence, this chapter first addresses how beneficiaries, physicians, and potential shoe suppiiers were notified about the demonstration benefit (Section A). The chapter then reviews how the demonstration was implemented, focusing on detailed answers to the two major questions:' whether the demonstration was implemented according to the legislation, and whether the operational components and rates of participation were comparable to those that would occur under a national benefit. The answers to these two questions are addressed in the context of beneficiary participation (Section B), physician participation (Section C), shoe

supplier participation (Section D), the use of the shoe benefit (Section E), and conclusions about the generaiizability of the demonstration results (Section F). The detailed questions posed in each of these sections are as follows:

Section B

- What was the process by which beneficiaries were enrolled?
- Were the intended number of beneficiaries enrolled?
- Did participating beneficiaries exhibit the expected characteristics?
- Did randomization generate equivalent treatment and control groups?
- Were participating beneficiaries representative of those who would participate in a national program?

Section C

- What was the role of physicians in the demonstration?
- Which specialties were represented by the physicians who participated?
- Did the expected number of physicians participate?
- What were the barriers to physician participation?

Section D

- How were shoe suppliers authorized for the demonstration?
- Did different disciplines furnish shoes at different rates, and different types of shoes?
- Did demonstration procedures inhibit the participation of shoe suppliers?

Section E

- What proportion of authorized beneficiaries used the benefit?
- How much did Medicare pay for the demonstration-supplied shoes?
- What types of technical assistance were provided to participating beneficiaries and shoe suppliers to facilitate using the demonstration benefit?
- Was the shoe benefit used as much as it could have been, and, if not, why not?

Section F

- What are the implications of the demonstration for a national therapeutic shoe benefit?

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The chapter draws on four types of demonstration materials to address these questions: (1) publicity notices and information (presented in Appendix B); (2) the Certification and Prescription Form that was used to enroll beneficiaries, as well as the instructions to physicians on how to complete the form (found in Appendix C); (3) the supplier agreement all suppliers had to accept in order to participate in the demonstration and the Medicare supplier agreement and manual that described the regulations governing shoe supply and claims filing (found in Appendix D); and claims for therapeutic shoes supplied in the demonstration.

To supplement our understanding of how the demonstration procedures worked, we held structured discussions during the last 8 months of the demonstration with a sample of participating beneficiaries, physicians, and shoe suppliers in the three demonstration States. staff from the American Diabetes Association, and representatives of three professional associations: the American Podiatric Medical Association, the American Orthopaedic Foot

and Ankle Society (a group of orthopedic surgeons who specialize in foot and ankle care), and the Prescription Footwear Association. We met in person with physicians, shoe suppliers, and association staff to identify the aspects of the demonstration that worked well and those that they would change in a national program.[1] We interviewed 10 podiatrists, 2 medical doctors, 6 pedorthists, 1 orthotist, and 1 orthotist-prosthetist.[2] Appendix E provides details on site visits. Eight beneficiaries who had received shoes through the demonstration were interviewed by telephone to determine how the demonstration procedures and benefit had worked for them.

A. TWO PUBLICITY CAMPAIGNS NOTIFIED POTENTIAL PARTICIPANTS OF THE DEMONSTRATION BENEFIT

In the 2 months before the demonstration began, the demonstration contractor sent publicity materials about the demonstration directly to readily identifiable Medicare beneficiaries who appeared to meet the eligibility requirements, and to all physicians and shoe suppliers that provided services to diabetic Medicare beneficiaries in the three demonstration States. The objective of the notification was to encourage participation by describing the purpose and importance of the demonstration, application and enrollment procedures, and the availability of Medicare coverage. Because fewer beneficiaries enrolled in the first few months

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[1] We spoke with a representative of the American Orthopaedic Foot and Ankle Society by telephone.

[2] The 10 podiatrists assumed several professional roles: 5 of them prescribed the shoes. 4 of them prescribed and supplied the shoes, and 1 of them only supplied shoes. The two medical doctors--a family practitioner and an endocrinologist--certified the eligibility of and prescribed shoes for beneficiaries. The six pedorthists, the orthotist, and the orthotist-prosthetist supplied shoes.

of the demonstration than expected, a second publicity campaign was mounted. which generated only a small. short-term increase-in enrollment.

1. The Original Publicity Campaign Targeted Numerous Beneficiaries, Physicians, and Shoe Suppliers

Based on Medicare claims data, the beneficiary publicity campaign targeted Medicare beneficiaries who had hospital stays for diabetic foot conditions in the 3 years prior to the demonstration. In July 1989, 43,064 Medicare beneficiaries (16,584 in New York. 15,495 in California, and 10,985 in Florida) were mailed third-class leaflets that explained the purpose and limitations of the benefit, and instructed beneficiaries to ask their physician to enroll them in the demonstration at their next visit. (Appendix B contains an example of the leaflet.)

The physician publicity campaign targeted physicians who were likely to provide care to diabetic Medicare beneficiaries: general and family practitioners; internists; endocrinologists; orthopedic, vascular, and general surgeons; and podiatrists. Using addresses supplied by the four Medicare carriers in the three demonstration States, the demonstration contractor mailed notification letters to 56,236 physicians. The letter described the benefit and explained the demonstration procedures, and included a return postcard for requesting materials for enrolling beneficiaries. (Appendix B contains an example of the notification letter.) Of these 56,236 physicians, two-thirds were internists or general or family practitioners, the specialties that see 80 percent or more of diabetic beneficiaries. Orthopedic, general, and vascular surgeons--specialties likely to provide surgical care for severe diabetic foot conditions--

comprised about 13 percent of the physicians who were notified. Ten percent of the physicians who were notified were podiatrists, who are foot and ankle specialists.

Finally, the supplier publicity campaign was targeted at members of the four professions that supply shoes and orthoses. A total of 6,312 professionals in the demonstration States were sent a notification letter: 83 percent of them were podiatrists, 15 percent were orthotists or prosthetists, and 2 percent were pedorthists. (Appendix B contains an example of the letter to potential shoe suppliers.) The Medicare carriers in demonstration States provided addresses for podiatrists; the Board for Certification in Pedorthics, the American Board for Certification of Orthotists and Prosthetists, and the Prescription Footwear Association provided mailing labels for certified pedorthists, orthotists, and prosthetists.[3] The notification letter described the demonstration and explained the procedures for applying to be an authorized shoe supplier. and contained two copies of the blank supplier agreement form. as well as instructions for providing the information necessary for payment.

Before the demonstration began, the demonstration contractor also met with or mailed a notification to a variety of professional associations, clinics, and special interest groups to explain the purpose of the demonstration, the schedule for its implementation, and the random-assignment and other operational procedures. The physician and beneficiary notification materials and a short article about the demonstration for inclusion in newsletters were sent to national and state professional associations of generalist and specialist physicians.

[3]Within 3 months after the start of the demonstration, the New York Board of Certified Orthotists also provided a list of certified orthotists. These orthotists were sent supplier information.

the local chapters of the American Diabetes Association, hospitals and clinics that operate diabetes treatment or education programs, and the Medicare carriers in the three demonstration States. Several of these groups also reviewed and commented on draft versions of the notification materials.

2. Lower-than-Expected Participation Necessitated More Publicity

Within a few months after the demonstration began, it became clear that far fewer beneficiaries were applying for the therapeutic shoe benefit than had been anticipated. The enrollment target for the first 3 months of the demonstration was 6,875 beneficiaries: the demonstration enrolled only 577 from August 1, 1989 through October 1989.[4] Without a greater number of applications, the evaluation might not have been able to measure the effect of the therapeutic shoe benefit on Medicare payments with sufficient precision to form a conclusion about the direction of the effect.

After meeting with representatives of several professional associations and the American Diabetes Association. the demonstration contractor developed a plan for another publicity campaign. Because the initial notification materials were text only, and the groups consulted believed that more eye-catching materials were required in order to grab the attention of beneficiaries, the demonstration contractor developed posters, brochures, and pictorial charts of demonstration procedures (see Appendix B), and launched the second publicity campaign

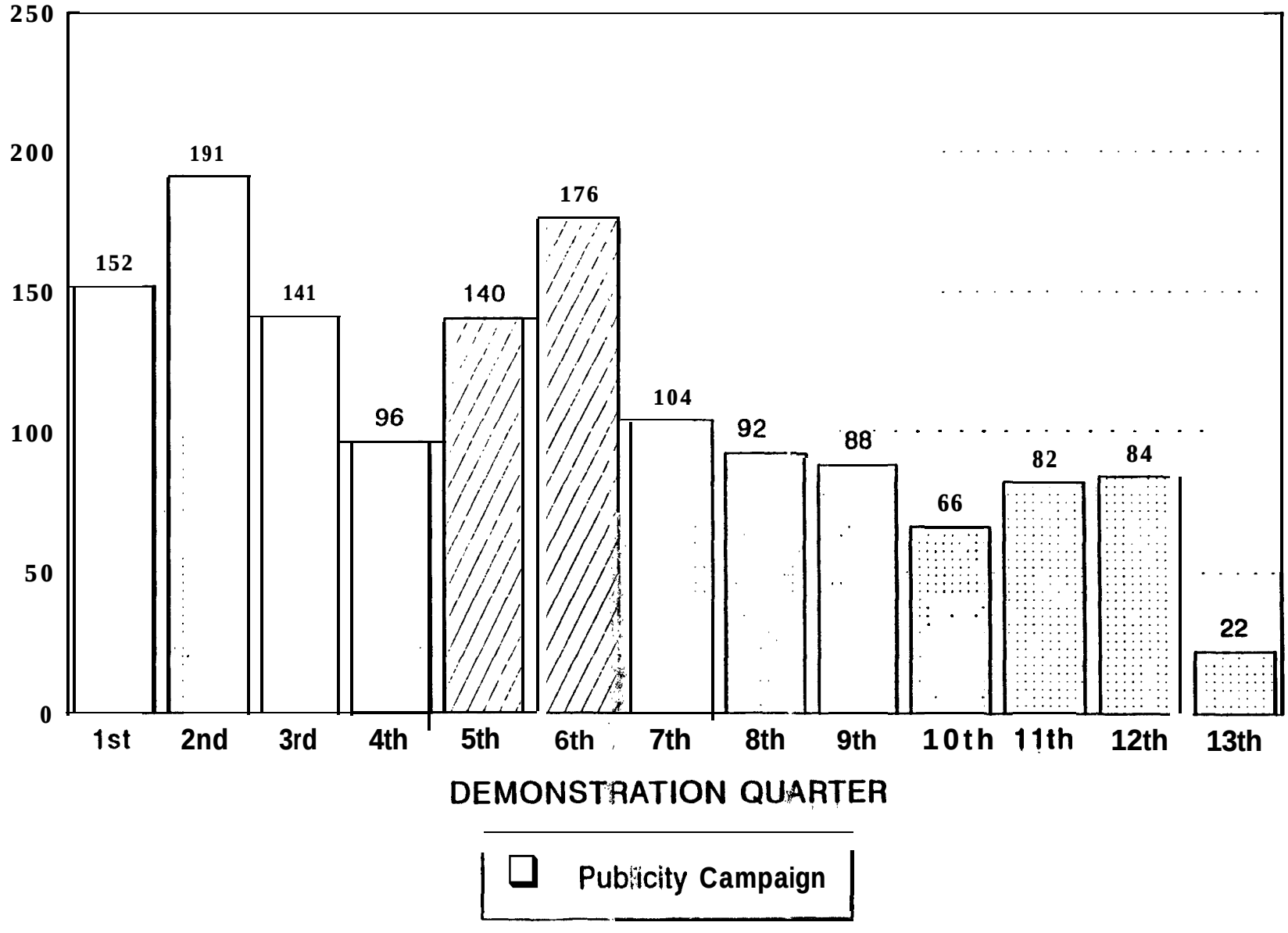
[4]The targeted number is based on a target of 27,500 enrollees during the originally scheduled l-year enrollment period.

in July 1990, 11 months after the demonstration began. The campaign lasted 7 months, until February 1991.

The purpose of the campaign was to prompt health care professionals who treat diabetes to enroll more beneficiaries in the demonstration. The prime target was physicians. To reach them. the demonstration contractor requested that state physician associations, including specialist associations, mail an endorsement of the demonstration and its objectives to their members on their own letterhead. The contractor also requested that the professional associations include an article on the demonstration in newsletters to members. Other professional groups were also targeted, including diabetes educators and those practicing in clinical settings in which a high proportion of diabetic foot care beneficiaries are treated (wound treatment centers and renal dialysis centers). The demonstration contractor also sought to attract more beneficiaries to the demonstration by publicizing the demonstration more extensively in the newsletters of the local chapters of the American Diabetes Association. (Appendix B, Table B.l, summarizes the professional associations and groups contacted, the materials provided to them, and the number of members who received endorsement letters and information packets on the demonstration.) Section C of this chapter discusses the number and type of physicians who were contacted and who participated.

The second publicity campaign had only a temporary effect on enrollment in the demonstration. New enrollment in the demonstration program in California rose in the quarters in which the publicity campaign was in progress (approximately the fifth and sixth quarters) and one quarter thereafter (Figure III.1.A). However, by the eighth quarter, new

FIGURE III.1.A
ENROLLMENT OF BENEFICIARIES BY QUARTER: CALIFORNIA



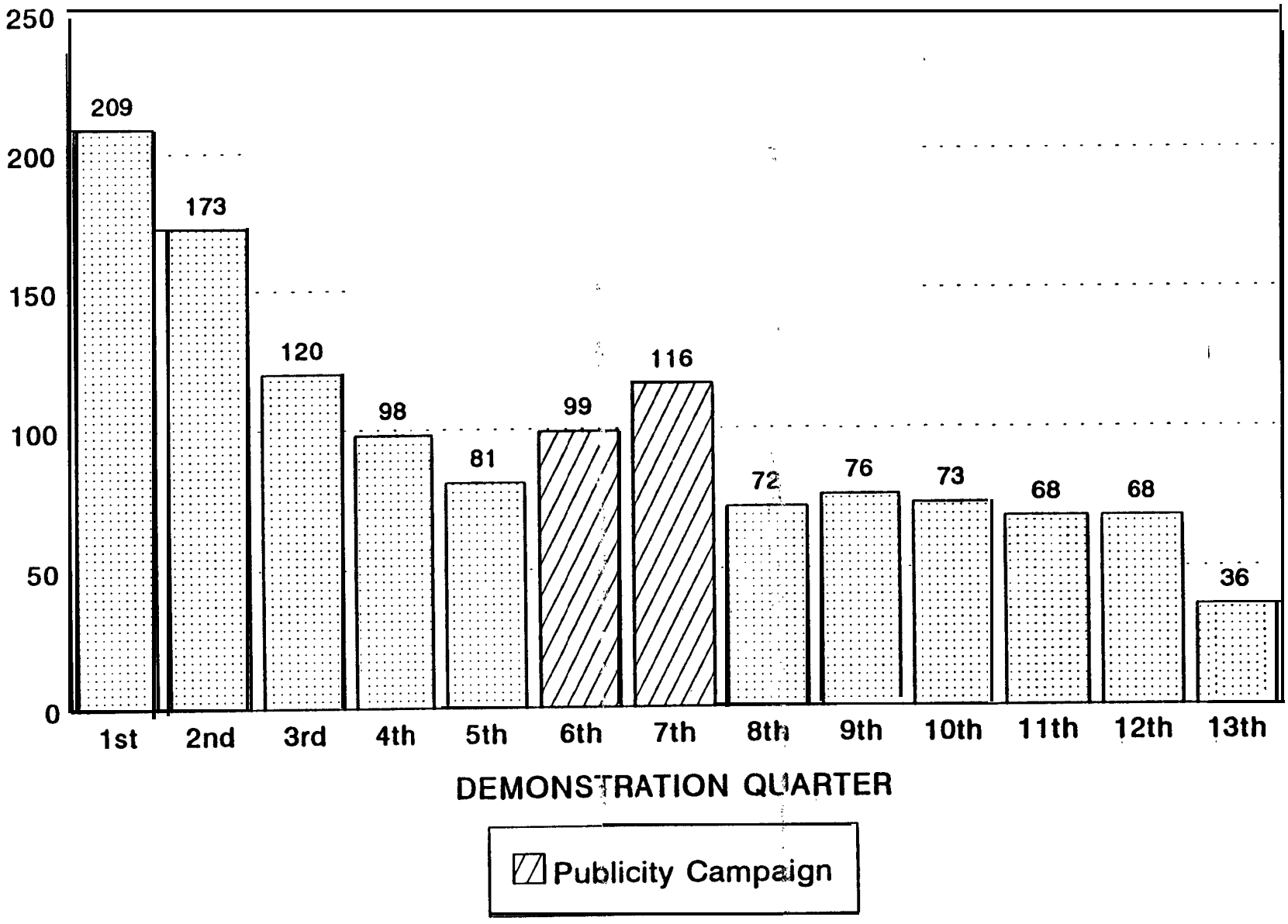
enrollment in the demonstration program in California fell below the enrollment level reached prior to the second publicity campaign. The same trend occurred in the two other demonstration States, but to a smaller degree; the publicity campaigns in Florida (Figure III.1.B) and New York (Figure III.1.C) spurred a slight increase in new enrollment in the sixth and seventh quarters when it was underway. In Florida, new enrollment fell sharply in the eighth quarter; in New York, new enrollment in the demonstration was stable in the first quarter after the publicity campaign, but then fell sharply in the ninth quarter.

Reorienting physicians toward care that seeks to prevent severe diabetic foot disease is a difficult task. The second publicity campaign showed that, even when physicians are contacted by their professional associations about the availability and importance of a therapeutic shoe benefit, they do not necessarily respond aggressively to calls to adopt the shoe benefit to prevent severe diabetic foot disease.

B. FORMAL BENEFICIARY ENROLLMENT PROCEDURES WERE ADOPTED AND THE PARTICIPATING BENEFICIARIES SHOWED MUCH EVIDENCE OF DIABETIC FOOT DISEASE

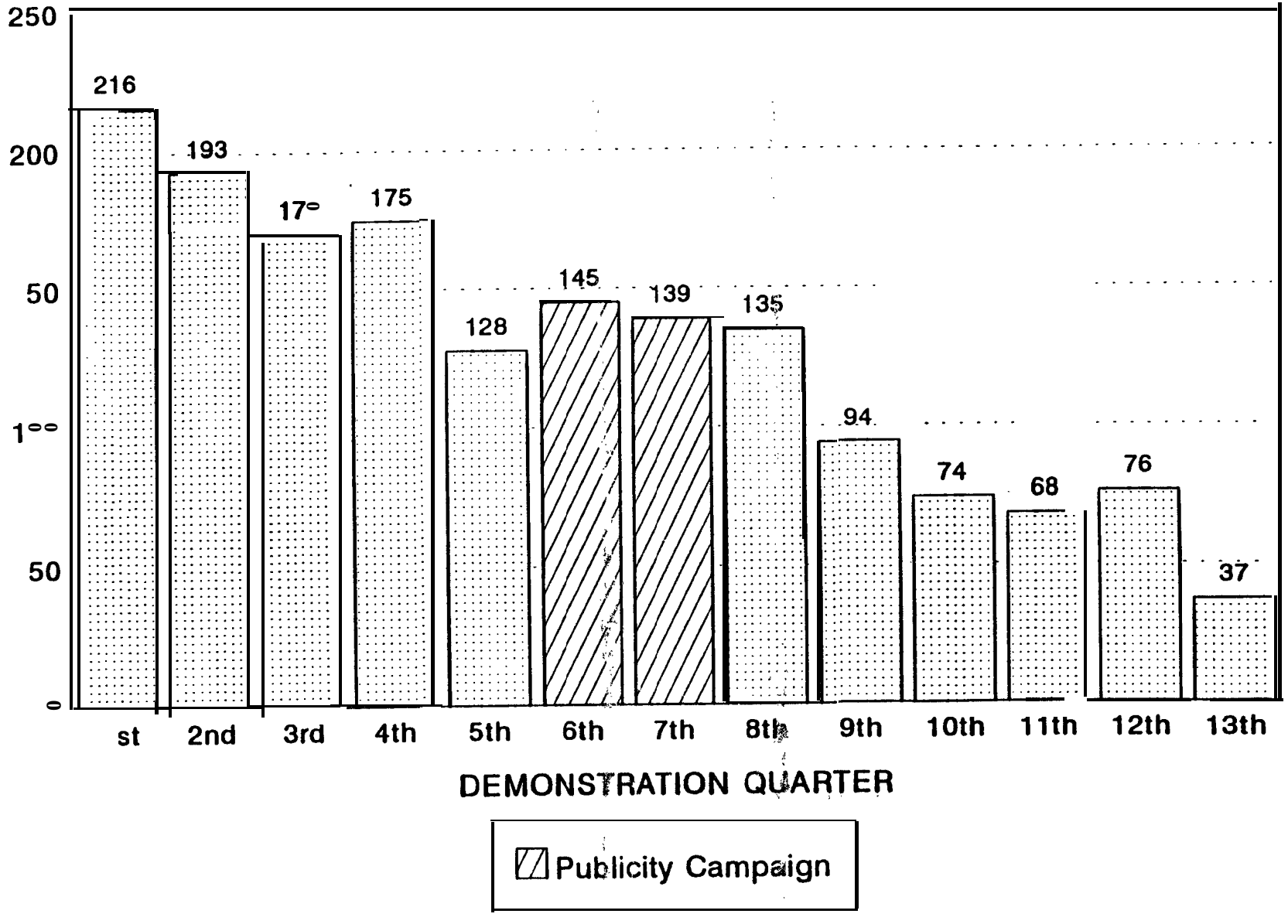
The demonstration enrollment process included some elements that were legislatively required, others that were operational decisions made by the Health Care Financing Administration, and others that were introduced in response to the analytical objectives of the evaluation. An application form was developed to collect the certification and prescription information that Congress mandated to determine eligibility. Applications were processed at a central location because the evaluation design called for randomizing beneficiaries after

FIGURE III.1.B
ENROLLMENT OF BENEFICIARIES BY QUARTER: FLORIDA



Enrollment in the demonstration began on August 1, 1989, and ended on September 8, 1992.

FIGURE III.1.C
ENROLLMENT OF BENEFICIARIES BY QUARTER: NEW YORK



Enrollment in the demonstration began on August 1, 1988, and ended on September 8, 1992

eligibility was determined to ensure that only ***currently eligible*** Medicare beneficiaries were offered the benefit. Central processing ensured the integrity of the randomization process.[5]

This section describes the enrollment process, the characteristics and number of beneficiaries who enrolled, and the effectiveness of the randomization process.

1. A Special Form Was Used to Initiate the Enrollment Process, Which Was then Mailed to the Demonstration Contractor for Centralized Processing

The demonstration contractor developed a one-page Certification and Prescription Form to meet the legislative requirement that one or more physicians certify the eligibility of beneficiaries and prescribe therapeutic shoes. This form was mailed to physicians who requested it. The enrollment process consisted of four steps:

- The beneficiary visited the physician who was managing his or her diabetes to be certified as clinically eligible for the demonstration.
- The physician either prescribed the shoes or referred the beneficiary to another physician who prescribed the shoes.
- The beneficiary signed the informed-consent agreement on the prescription form.[6]
- The beneficiary mailed the completed form to the demonstration contractor for eligibility assessment and randomization.

---

[5] Central processing also made it possible to issue payment authorization forms to those who were offered the benefit. The payment authorization forms committed Medicare payment to shoe suppliers who furnished the benefit.

[6] The informed consent agreement stated that the applicant understood that the therapeutic shoe coverage was being offered as a temporary benefit, and that half of the eligible applicants would be chosen randomly to receive the coverage. A large-type version and Spanish translation were provided on the back of the Certification and Prescription Form.

The process is shown in Figure 111.2; this pictorial explanation was distributed to potential and actual participants after it had been developed for the second publicity campaign.

The demonstration contractor checked whether the form was complete and whether the beneficiary was eligible, and then, within each State, assigned half of the eligible beneficiaries at random to either the benefit-recipient (treatment) group or the nonrecipient (control) group. The demonstration contractor determined eligibility by checking Medicare records with HCFA to ensure current Part B entitlement, residence in a demonstration State, and no current enrollment in a Medicare HMO. The demonstration contractor also checked that the beneficiary had not previously been randomized and that he or she met the clinical eligibility criteria (described in Chapter II).[7] Incomplete and ineligible Certification and Prescription Forms were returned to the sender, accompanied by a form letter that requested missing information or explained the reason for ineligibility. Beneficiaries were invited to complete or correct and resubmit forms, and many did so.[8]

'Applicants were ineligible if they were not currently covered under Medicare Part B. were enrolled in a Medicare HMO, lived in a State that was not in the demonstration, did not meet the clinical eligibility criteria, or had already been randomized. During the demonstration. 172 applicants were rejected because they lacked Medicare Part B coverage or could not be matched to Part B records, 136 because they belonged to a Medicare HMO, 28 because they lived outside a demonstration State, and 106 because they did not have diabetes.

[8]During the demonstration, 893 forms were returned to applicants because they were ineligible or incomplete, of which 707 were completed and returned by the applicants. The majority of the forms were rejected initially because the physician(s) had not signed the form to certify eligibility or to prescribe shoes. In addition, many forms were initially rejected because they were missing Medicare numbers and patient consent signatures. If applications were missing data required only for the evaluation, they were not returned to applicants.

STEPS TO MAKE A DIFFERENCE

Step 1. How to Get Enrolled

a. The doctor treating your diabetes gets the certification and prescription forms.

b. The doctor carefully fills out the certification and prescription form for you.

c. The doctor gives the completed form to you.

d. You sign the form.

e. You mail the form to Mathematica Policy Resea (address at bottom of this p

Step 2. How You Find Out

a. If you are selected to receive the benefit, you will receive a [illegible] authorization, and a list of authorized shoe suppliers.

b. If you are selected to be in the control group, you will receive a letter saying that you will NOT receive this Medicare benefit at this time.

Step 3. How To Get Your Shoes

a. Pick an authorized shoe supplier from the list.

b. Go to the authorized shoe supplier to get your new shoes fitted.

c. When your shoes are ready, go to the shoe supp and pick them up.

Step 4. How to Cover Costs

a. The shoe supplier will file the Medicare claim paperwork which will cover 80 percent of the costs.

b. Once you have met your annual Medicare Par deductible, you pay shoe supplier 20 percent of the c which should be no more than $31 for depth-inl shoes, and no more than $61 for custom-molded sh (these are 1990 prices, your actual costs may be slig more).

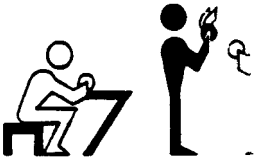
Step 5. How to Get Replacement Inlays or Shoe Modifications

a. After you have your shoes, you may need replacement inlays, if your first inlays are worn, or shoe modifications, if your feet change. Your doctor will give you a written referral to a shoe supplier to get these items.

b. You take the written referral to your authorized shoe supplier.

c. The shoe supplier will make new inlays for your shoes or will modify your shoes based on the doctor's referral note and your present foot condition.

d. You will return to the shoe supplier to pick up the replacement inlays or your modified shoes.



e. Paying for the replacem inlays or modifications follows the same procedu as in Step 4.

Step 6. Next Year

a. Once you have been selected to receive the benefit, you may receive payment for a new pair of shoes and replacement inlays or modifications each year of the demonstration. To get the shoes: Follow Step 1 again.

b. You will receive a new payment authorization, a new list of suppliers, and a set of instructions.

This chart is a brief overview of the process for more information, contact:

Medicare Therapeutic Shoe Demonstrati
Mathematica Policy Research inc
P.O. Box 2393
Princeton, New Jersey 08543-2393

Treatment group members were mailed a copy of their completed Certification and Prescription Form, a form authorizing payment for the prescribed shoes (the Payment Authorization Form, presented in Appendix C), instructions on how to obtain the shoes (Instructions to Medicare Beneficiaries, presented in Appendix C), and a list of authorized shoe suppliers in their States (also presented in Appendix C). Beneficiaries assigned to the control group were mailed a letter to indicate that they were not selected for the benefit, and a copy of their Certification and Prescription Form was returned to them. The eligibility determination process--from the receipt of the Certification and Prescription Form by the demonstration contractor to the mailing of the assignment information--ranged from 3 to 7 weeks."

Applications to the demonstration were accepted from August 1, 1989 through September 8, 1992. The first beneficiaries were notified that they were accepted in September 1989, and the final notifications of acceptance were mailed on September 17, 1992. Shoes were supplied through October 1992.

To obtain the shoes, the beneficiary selected and visited an authorized shoe supplier from the list. Beneficiaries gave the Certification and Prescription Form and the Payment Authorization to the shoe supplier. Beneficiaries were fitted with either depth-inlay or custom-molded shoes, whichever had been prescribed. The shoe suppliers fitted and furnished the shoes, and then billed Medicare with a standard Medicare claim form (Form HCFA-1500), attaching the Payment Authorization. Beneficiaries were responsible for the usual Part B

'Medicare eligibility checks and random assignment required 3 weeks. This process occurred once each month.

coinsurance of 20 percent of the allowed costs of the shoes after meeting their annual Medicare Part B deductibles. (Sections III.D and III.E provide details on shoe fitting and the use of the shoe benefit.)

Treatment group members were eligible for new shoes once each year on the anniversary of their random assignment, but had to reapply for the benefit. Because the demonstration was designed to be as similar as possible to a national program, in which renewal reminders would not be sent, the demonstration did not remind beneficiaries that they were eligible to renew the benefit. Treatment group members who applied for renewal were subject to the same Medicare eligibility check that was imposed during the initial application. If these treatment group members continued to be eligible for Medicare Part B, they received the same packet of materials sent originally to them.

The demonstration contractor provided technical assistance to beneficiaries who inquired about enrollment in the demonstration and to those who called on behalf of the beneficiaries. such as physicians and Congressional staff. The majority of the technical assistance needs of beneficiaries pertained to how they could enroll to receive the benefit or how their application was progressing. Beneficiaries who requested information on enrollment procedures were mailed a brochure about the demonstration and a Certification and Prescription Form that they could take to their physicians. Physicians who requested information about how to enroll patients were mailed a physician information packet (see Section iII.C.l). Beneficiaries who were anxious about the progress of their enrollment application were informed of the necessary processing and administrative time lags (which could take from 3 to 7 weeks). Some

called the demonstration contractor to question the eligibility criteria (especially the HMO exclusion). These beneficiaries were mailed a letter that explained the limited availability and temporary nature of the benefit. Beneficiaries who had been assigned randomly to the control group and who requested that they be reconsidered for the treatment group were mailed a letter to explain that control group designations could not be changed.

2. Fewer Beneficiaries Enrolled than Expected

The original goal was to enroll 27,500 beneficiaries during a 12-month intake period, divided evenly between the treatment and control groups. This goal was calculated on the assumption that the average shoe cost to Medicare would be $200, and that three-quarters of those offered the benefit would use it. Assuming that only half of those eligible would apply. this required an eligible population of 55,000. A sample of 27,500 would have been sufficient for detecting a 6 percent impact of the demonstration benefit on Medicare expenditures over a l-year follow-up period with 80 percent power.[10] One year after the demonstration was implemented, only 1,934 eligible beneficiaries had enrolled, only 7 percent of the original goal: by the end of the demonstration in October 1992 (39 months after the demonstration was implemented), 4,373 beneficiaries had enrolled, 16 percent of the original enrollment goal (Table III.1).[11]

---

[10]The assumptions to support this estimate are discussed in Chapter IV.

[11]The 4,373 beneficiaries who enrolled constituted only 0.61 percent of the estimated number of diabetic Medicare beneficiaries in the demonstration States.

TABLE III.1

NUMBER AND PERCENTAGE OF BENEFICIARIES NOTIFIED AND ENROLLED

	California	Florida	New York	Total
Size of Beneficiary Pool				
Estimated Number of Diabetic Beneficiaries	255,458	212,281	252,082	719,821[a]
Beneficiaries Hospitalized with Foot Problems in the 3 Years Prior to the Demonstration--Notified in July 1989	15,495	10,985	16,584	43,064
Enrollment in Demonstration				
Number of Beneficiaries Enrolled in First Year (Through July 1990)	580	600	754	1,934
Beneficiaries Who Were Notified in July 1989 Who Ever Enrolled[b]	290	207	391	888
Total Beneficiaries Enrolled (Through September 17, 1992)	1,434	1,289	1,650	4,373
Enrollment as a Percentage of Beneficiary Pool				
Enrolled Beneficiaries as a Percentage of the Estimated Number of Diabetic Beneficiaries	0.56	0.61	0.65	0.61
Percentage of Beneficiaries Notified in First Campaign Who Ever Enrolled[b]	1.87	1.88	2.36	2.06

SOURCE: Demonstration data. See Chapter I for an explanation of the estimated number of diabetic beneficiaries.

NOTE: The first publicity campaign notified all diabetic Medicare beneficiaries who were hospitalized for foot problems during the 3 years prior to the demonstration, based on Medicare claims data.

[a]These figures are based on Table I.1 and Table VI.1. HMO enrollees are excluded.

[b]Most of the beneficiaries who enrolled in the demonstration in the first year had not been notified about the demonstration in July 1989 because they had not had a Medicare Part A claim for a hospital stay for diabetic foot problems in the past 3 years. The "Beneficiaries Who Were Notified in July 1989 Who Ever Enrolled" and the "Percentage of Beneficiaries Notified in First Campaign Who Ever Enrolled" indicates those individuals who enrolled after being so notified.

Given the short timeframe of the demonstration, notifications about the demonstration were sent to 43,064 beneficiaries who appeared to be eligible (based on their claims history) in the month before the demonstration began (see section III.A.1).[12] The first year of the 3-year demonstration was the most successful one for beneficiary enrollment: 44 percent of participating beneficiaries enrolled during that year. However, this higher first-year enrollment cannot be attributed to the previous notification, since only 2 percent of those who were notified ever enrolled. Enrollment numbers and rates per 1,000 diabetic Medicare beneficiaries were very similar across States; New York had the highest enrollment (1,650) and the highest rate, (0.65 percent, or 6.5 per 1,000), Florida had the lowest enrollment (1,289), but California had the lowest enrollment rate (at 0.50 percent, or 5.0 per 1,000). (See Table III.1.)

The disparity between the number of eligible beneficiaries who were notified and the number who enrolled illustrates the difficulty in implementing preventive care. Although the notification was targeted at beneficiaries who had been hospitalized for diabetic foot problems in the 3-year predemonstration period. 98 percent of this group did not participate. either because they had died, or did not perceive that they needed the demonstration benefit.

3. **Participating Beneficiaries Were Sicker than Diabetic Medicare Beneficiaries Nationwide**

Broad clinical eligibility criteria were used to target the demonstration at all diabetic Medicare beneficiaries who could benefit from protective shoes. The targeted beneficiaries

[12]Beneficiaries who were notified about the demonstration the month before it began had been hospitalized with diabetic foot problems during the 3 years prior to the demonstration, as determined from Medicare claims data.

included both those who had never had foot problems but were at risk of foot problems (because, for example, they had insensate and deformed feet or poor circulation) and those who were at high risk of lower-extremity amputation, including beneficiaries who had a history of ulcers or amputation. The characteristics of the 4,363 treatment and control group members who were alive at enrollment are described in this section.[13] First, we compare the characteristics of participating beneficiaries with the characteristics of all Medicare beneficiaries to determine the representativeness of our sample. Then, in subsection 4. we compare the characteristics of beneficiaries who were assigned to the treatment group with the characteristics of beneficiaries who were assigned to the control group, to determine whether randomization yielded comparable samples.

a. Demographic Characteristics and the Reasons for Medicare Entitlement (Table 111.2)

Participating beneficiaries were 70 years old on average, although 19 percent of beneficiaries in the demonstration were younger than age 65 (they were entitled to Medicare because they were disabled or had end-stage renal disease).[14] Two-thirds of all beneficiaries in the demonstration were originally entitled to Medicare because they had reached the statutory age--that is, 65 years. Thirty percent were originally entitled to Medicare because they were disabled, and a small proportion (nearly 4 percent) were entitled to Medicare

[13]Eight beneficiaries died between the time they applied to the demonstration and the date on which they were assigned randomly either to the treatment group or to the control group. The Medicare numbers for two additional beneficiaries could not be matched to the file of beneficiary characteristics.

[14]The Health Insurance Skeleton Eligibility Write-Off (HISKEW) file provided the data on these characteristics.

TABLE III.2

AGE. ORIGINAL REASON FOR MEDICARE ENTITLEMENT. AND TOTAL MEDICARE PAYMENTS IN THE 12-MONTH PERIOD BEFORE ENROLLMENT AMONG ALL BENEFICIARIES PARTICIPATING IN THE DEMONSTRATION. AND TREATMENT-CONTROL DIFFERENCES

Chatactenstic	All Beneficiaries	Treatment Group	Control Group	Difference	Probability of Difference Occurring by Chance
Average Age at Enrollment (Yeats)	70.2	70.0	70.2	0.2	.47
Percentage Age Distribution at Enrollment (Years)					.77
Perantage younger than 65 years	19.2	19.2	19.2	0.0	
Percentage 65-69 years	25.3	25.9	24.6	1.3	
Percentage 70-74 years	25.5	25.7	25.4	0.3	
Percentage 75-79 years	17.1	16.3	17.9	-1.6	
Percent 80-84 years	8.6	8.8	8.5	0.3	
Percent 85 or older	4.2	4.1	4.4	-0.3	
Percentage Distribution of Original Reason for Medicare Entitlement					.60
Old age	66.3	65.9	66.7	-0.8	
Disability	30.0	38.7	29.3	1.4	
End-stage renal disease	1.6	1.4	1.7	-0.3	
Disability and end-stage renal disease	2.2	2.1	2 2	-0.1	
Average Medicare Payment in the 12-Month Period Before Enrollment	$10,883	f10.784	$10,981	-$197	.67
Percentage Who Were Dually Eligible for Medicare and Medicaid	20.7	213	20.1	1.2	.33
Sample Size	4,363	2.179	2.184		

SOURCE: HCFA Medicare Automated Data Retrieval file. National Claims History file. and HISKEW file for all beneficiaries who were enrolled by September 17. 1992, the final day for enrolling in the demonstration.

NOTE: Percentage distributions may not add to 100 percent due to rounding.

The total sample size is 10 less than the total number of enrolled beneficiaries because 2 beneficiaries could not be matched to the HISKEW file. and 8 beneficiaries died before randomization and were excluded.

because they had end-stage renal disease. Nationwide, about 90 percent of Medicare beneficiaries are entitled because they have reached the statutory age, and 10 percent are entitled because they are disabled or have end-stage renal disease (see Chapter I). The demonstration beneficiaries thus overrepresented the disabled and end-stage renal disease population, reflecting the higher prevalence rates of diabetes among these groups.

b. Total Medicare Payments in the Prerandomization Period (Table 111.2)

In the 12-month period before beneficiaries enrolled in the demonstration, their average Medicare payment was $10,883." This figure compares with national average annual Medicare expenditures of $2,440 per aged beneficiary, $2,896 per disabled beneficiary, and $24.831 per end-stage renal disease beneficiary in 1988, the year before the demonstration began (U.S. House of Representatives 1992). Even when we account for the fact that the Medicare costs of aged diabetic Medicare beneficiaries 5 years before they die are about 1.6 times the costs for the average beneficiary (Riley and Lubitz 1989), as well as account for inflationary increases in Medicare payments since 1988 and the fact that the demonstration States have higher Medicare costs than the national average,[16] the annual average Medicare payment for enrolled beneficiaries is considerably higher than would be expected. The most

[15]The payment estimate for the 12-month period before randomization is based on data from the Medicare Automated Retrieval System (MADRS) file (see Appendix J). The pre-randomization period is defined as the 12 months immediately preceding the date on which a participant was assigned to the treatment or control group. The conventions adopted for quantifying total payments during this period are reported in Chapter IV and Appendix H.

[16]Medicare reimbursements per aged beneficiary in 1989 were higher than the national average by a factor of 1.02 in Florida, 1.15 in New York, and 1.22 in California (U.S. House of Representatives 1992, Table 39).

likely explanation is that the beneficiaries who enrolled in the demonstration were disproportionately sicker than Medicare beneficiaries overall, perhaps because a high proportion of them were in the last few years of their lives, when Medicare payments are known to be considerably higher than average (Riley and Lubitz, 1989).[17]

c. **Dual Medicaid and Medicare Eligibility** (Table 111.2)

About 21 percent of all participating beneficiaries were entitled to both Medicare and Medicaid benefits. This proportion is considerably higher than the nationwide rate of about 10 percent of beneficiaries enrolled in Medicare Part B under state buy-in agreements in 1988, and the average rate of 13 percent across the three demonstration States (U.S. House of Representatives 1991).

d. Clinical Characteristics and Therapeutic Shoe Prescriptions (Tables III.3 and III.4)

Slightly more than 40 percent of the participating beneficiaries had diabetes for 15 or more years, and only approximately 9 percent had diabetes for 5 or fewer years (see Table III.3).[18] This distribution was consistent with expectations, since it is well documented that foot problems increase with the duration of diabetes (Centers for Disease Control 1991).

Participating beneficiaries had relatively severe foot problems. One-quarter of the beneficiaries had previously had an amputation of part or all of one or both feet--the most

---

"One year after enrollment, between 8 and 9 percent of participating beneficiaries had died.

"Note that we do not have information on the duration of diabetes for about 9 percent of all beneficiaries, either because the beneficiaries did not report it to the physician or because the physician did not enter it on the form.

TABLE III.3

CLINICAL CHARACTERISTICS OF ALL BENEFICIARIES PARTICIPATING IN THE DEMONSTRATION. AND TREATMENT-CONTROL DIFFERENCES
(Percent)

Charactctistic	All Participants	Treatment Grow	Control Group	Difference	Probability of Difference Occumng by Chance
When Diabetes Was First Recognized					.77
Less than 5 Years Ago	9.2	9.7	8.7	1.1	
5 to 10 Years Ago	23.0	23.0	229	0.1	
11 to 15 Yeats Ago	18.5	18.4	18.S	-0.1	
More Than 15 Yeats Ago	40.5	40.3	40.8	-0.5	
Missing	8.8	8.5	9.1	-0.6	
Diabetic Fool Conditions					
Foot Deformity with Potential for Ulceration (percent)	74.4	74.1.	74.7	-0.6	.62
Callus Formation or History of Callus Formation with Peripheral Neuropathy (percent)	72.3	73.3	71.2	2.1	.12
Poor Circulation (percent)	73.8	13.7	73.9	-0.2	.88
Previous Foot. Ulceration (percent)	59.2	58.2	60.3	-2.1	.15
Previous Amputation of Foot or Pan of Foot (percent):					
Either foot	25.4	24.7	26.1	-1.4	.29
One foot	19.5	19.0	20.0	-1.0	.56
Both feet	5.9	5.8	6.1	-0.3	
Sample size	4.363	2,179	2,184		

SOURCE: Medicare Therapeutic Shoe Demonstration--Certification and Prescription Form completed for all demonstration beneticiaries who were enrolled by September 17, 1992.

TABLE III.4

PRESCRIPTIONS FOR THERAPEUTIC SHOES AMONG ALL BENEFICIARIES PARTICIPATING IN THE DEMONSTRATION, AND TREATMENT-CONTROL DIFFERENCES PRERANDOMIZATION PERIOD. AT ENROLLMENT, AND DURING THE DEMONSTRATION

Type of Prior Therapeutic Shoe Use	All Participants	Treatment Group	Control Group	Difference	Probability of Difference Occurring by Chance
Percentage of Beneficiaries Receiving Physician Prescription or Recommendation for Therapeutic shoes in the Past 12 Months					.52
Yes	25.9	26.2	25.6	0.6	
No	65.2	64.4	65.9	-1.5	
Missing	9.0	9.4	8.5	0.9	
Percentage of Beneficiaries who Had Therapeutic Shoes as of Their Enrollment Date					
Any therapeutic shoes[a] (N=4,061)	31.9	32.1	31.7	0.4	.77
Depth-Inlay Shoes (N=4,085)	15.4	15.6	15.2	-0.4	.79
Custom-Molded Shoes (N=4,084)	14.1	14.0	14.2	-0.2	.85
Other (N=4,082)	4.3	4.2	4.3	-0.1	.80
Percentage of Therapeutic Shoes Prescribed in the Demonstration[b]					
Depth-Inlay Shoes with Inserts	45.8	44.9	46.7	-1.8	.25
Custom-Molded Shoes	55.0	55.8	54.1	1.7	.26
Sample Size	4,363	3.179	2,184		

SOURCE: Medicare Therapeutic Shoe Demonstration--Certification and Prescription Form completed for all demonstration beneficiaries who were enrolled by September 17. 1992.

[a]The Certification and Prescription Forms for 282 beneficiaries were missing information on whether they had therapeutic shoes at enrollment.

[b]Percentages do not add to 100 because more than one type of shoe could have been prescribed.

serious of the risk factors for future amputation--indicating that participating beneficiaries include a relatively large proportion of this highest-risk group. Nearly 60 percent had foot ulcerations prior to demonstration enrollment--the next most serious risk factor for future amputation. Almost three-quarters of all participating beneficiaries had a foot deformity with potential for ulceration, circulatory problems, or callus formation with peripheral neuropathy. These findings indicate that beneficiaries had an average of at least three prior foot conditions. any one of which would have made them eligible for the demonstration.

Consistent with the high rate of foot problems among participating beneficiaries, one-quarter had received a physician prescription or recommendation for therapeutic shoes in the previous 12 months, and nearly one-third owned therapeutic shoes as of their enrollment (see Table III.4). These rates are higher than had been anticipated, and diminished the probability that the demonstration benefit would be cost-effective, since so many beneficiaries had already obtained shoes in the absence of the shoe benefit. As of the time that beneficiaries applied to the demonstration, a similar proportion had custom-molded shoes as had depth-inlay shoes (about 15 percent). Yet, during the demonstration, physicians were 20 percent more likely to prescribe custom-molded shoes (55 percent) than depth-inlay shoes (46 percent).[19] Because the cost of custom-molded shoes is twice the cost of depth-inlay shoes, the likelihood that the benefit would be cost-effective would decrease as the proportion of custom-molded shoes prescribed increases (assuming that clinical conditions do not vary). Three factors may explain

[19]The prescription rates for the two types of shoes under the demonstration are counter to expectations: based on clinical consultation, we had expected that the prescription rates would be about 70 percent depth-inlay and 30 percent custom-molded shoes.

why more custom-molded shoes were prescribed: the severity of foot problems among the beneficiaries, the prescribing patterns of the participating physicians (especially podiatrists), and the fact that the demonstration prices provided larger differences between wholesale and allowable charges for custom-molded shoes than for depth-inlay shoes.

4, **Randomization** Procedures Were **Effective**

Despite the overriding analytic strengths of the experimental design, it raised procedural issues. First, we addressed how an easily followed randomization process could be designed and implemented without presenting opportunities for gaming, and with procedures that would notify applicants promptly about their experimental status and expedite furnishing the shoes. Second, we had to ensure that the random assignment process did not create ethical problems. Addressing this issue was fairly straightforward, since Congress had mandated that the demonstration provide the expanded coverage to some, but not all, eligible Medicare beneficiaries. Thus, random assignment within three States seemed to be as fair a way to allocate the coverage as would any alternative--for example, offering the coverage only in specific substate areas. In essence, the random assignment process gave all eligible beneficiaries within the three States an equal chance of obtaining the extra coverage of the demonstration. Since Medicare coverage remained the same for all beneficiaries assigned to the control group, the demonstration did not take away any benefits to which they had previously been entitled.

The experimental approach was necessitated by the dearth of rigorous clinical literature on whether therapeutic shoes were clinically effective in community settings. Without a widely

accepted basis for knowing whether shoe use could be justified by clinical outcomes, the random assignment of eligible beneficiaries to the two groups is a reasonable procedure.[20]

As described in Chapter II, the experimental design of the demonstration called for randomly assigning eligible Medicare beneficiaries who applied to the demonstration equally to a treatment group (which was eligible for the shoe benefit) and to a control group (which was ineligible for the shoe benefit, but remained eligible for all currently available Medicare coverage). This research design was expected to yield two groups whose measured and unmeasured characteristics would be similar at the time of enrollment.

To test whether this presumption of comparability was justified, we relied on statistical tests of the equivalence of the two randomly assigned groups.[21] We assessed differences in the proportion of sample beneficiaries in the two study groups with specific characteristics using a t-test. and whether the percentage distribution for a given characteristic was the same for the two groups using a Chi-square test. (Appendix F describes the method used to compare treatment and control groups.) We performed the tests for demographic and entitlement characteristics, the prevalence of foot problems, the number of previous

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"Even without rigorous clinical evidence on the effectiveness of the shoes, a large body of literature is available on the indications for therapeutic shoe prescriptions among the diabetic population (Cavanagh 1992), and many physicians presume that shoes are effective at mitigating the adverse consequences of severe diabetic foot disease, creating an apparent advantage for the group who received the expanded coverage. However, being offered the shoe benefit may lead to adverse outcomes--for example, if patients who are offered the shoe develop a false sense of security and do not follow good footcare practices, or visit their physician less often.

[21]The centralized randomization procedures at the demonstration contractor ensured the integrity of the process by preventing "gaming" by applicants. The procedures ensured that all applicants had been prescribed therapeutic shoes before they were randomized.

prescriptions for therapeutic shoes, and the recent use of health services--measured by the average Medicare payment in the year prior to randomization.

The results of these tests (reported in Table III.2 to Table 111.4) indicate that the random assignment process yielded comparable treatment and control groups. That is, at enrollment, the treatment and control group members had similar demographic and entitlement characteristics, clinical conditions, Medicare payments, and therapeutic shoe prescription rates. Because these factors did not differ significantly between the two groups when beneficiaries entered the demonstration, we can confidently attribute any subsequent differences in Medicare payments to the intervention (that is, to the therapeutic-shoe benefit).

5. Would More or Different Types of Beneficiaries Enroll in a National Program?

Only 0.6 percent of the entire population of diabetic Medicare beneficiaries in the three demonstration States and only 2 percent of the beneficiaries who were notified about the demonstration because they were hospitalized for footcare problems in the 3 years prior to the demonstration actually applied for the benefit. The low application rate appears to have two roots--a lack of awareness among beneficiaries, and a lack of awareness among or objections to the demonstration procedures by physicians.

The small group of physicians and shoe suppliers whom we interviewed offered several explanations for why physicians had enrolled so few beneficiaries: physicians did not know about the demonstration, they were confused by it, they disliked the randomized design, they felt that they had no incentive to handle the demonstration paperwork, and felt that an insufficient volume of suppliers was available to provide the shoes had they enrolled

beneficiaries.[22] None of the interviewed physicians made special efforts to increase enrollment, though some shoe suppliers went out of their way to do so. In a national program. randomization and prior authorization would not be necessary, removing impediments to physician participation. Thus, more physicians would enroll patients in a national program, thus increasing the enrollment rate relative to the eligible population.

We asked the professional associations to comment on whether the severity of the problems of beneficiaries in a national program would likely differ from those of the demonstration participants--an important issue for interpreting the cost-effectiveness impacts. Most respondents said that without more effective outreach and education, the same types of beneficiaries would apply--that is, a high proportion of diabetic persons who have already had an amputation or an ulcer who are thus at highest risk of repeated problems and subsequent amputation. The reason that they would be more likely to apply is that, in experiencing an amputation or the threat ot an amputation, they have been forced to overcome denial and have recognized the danger of severe diabetic foot disease, thus affecting their behavior toward wearing shoes and practicing foot hygiene and inspection.

[22]We discussed the enrollment process in detail with 12 physicians who were selected because they had been active in the demonstration--certifying eligibility, prescribing shoes. or supplying shoes. We also spoke with 8 nonphysician, authorized shoe suppliers. These providers were not a representative sample from the demonstration States, since, by definition, all of them participated. However, other than their willingness to speak with us. we had no prior knowledge about their attitude toward the demonstration.

6. Summary

Beneficiaries were enrolled by a process that required physicians to certify eligibility and prescribe therapeutic shoes using a standardized form that beneficiaries mailed to the demonstration contractor. Enrollment by beneficiaries was considerably less than the intended goal (4,373 after 3 years and 2 months, compared with a target of 27,500 after 1 year), thus reducing the power of the test of cost-effectiveness. Participating beneficiaries were assigned randomly to the treatment and control groups in equal-size groups, and exhibited comparable characteristics. The centralized processing of the beneficiaries' applications--to ensure the integrity of the random assignment process--was more complex than a national benefit would require and may have discouraged participation among physicians, and thus among eligible beneficiaries.

The participating beneficiaries exhibited a wide range of clinical severity, though on average they were more severely affected than expected. Professional associations believed that these patterns would likely be found in a national program; the beneficiaries who participated in the demonstration are probably representative of the population that would apply for a national benefit.

C. THE PARTICIPATION OF PHYSICIANS DIFFERED FROM EXPECTATIONS

1. Physicians Played Two Major Roles in the Demonstration

Physicians certified the eligibility of beneficiaries for the demonstration benefit. and prescribed the shoes for beneficiaries. The same or different physicians could certify and prescribe shoes in the demonstration. In a few cases, the physician was also the supplier of

the therapeutic shoes (the legislation did not prohibit physicians from prescribing and supplying shoes: the restriction was that those who *certified eligibility* could not supply the shoes).

When physicians were notitied about the demonstration. those who wished to enroll beneficiaries applied to the demonstration contractor for demonstration information packets that included the Certification and Prescription Forms, instructions on completing the form, and an explanation of beneficiary enrollment procedures (Appendix C provides examples of each).

An extensive outreach effort was made to inform physicians about the demonstration. without marked effect. Relatively few of the 56,236 physicians who were notified about the demonstration prior to July 1989 requested demonstration materials. During the demonstration. only 4,245 physicians or other health professionals formally requested intormation packets. This figure underestimates the actual number of physicians who received materials, because many physicians received information directly from professional societies or informally from other physicians and shoe suppliers. Only 3,535 (or 6 percent) certified eligibility or prescribed shoes during the demonstration (Table 111.5).

2. Specialties that Certified Eligibility and Prescribed Shoes Differed from Expectations

Most of the physicians participating in the demonstration were podiatrists and internists. which is not surprising, since podiatrists specialize in foot care, and internists are likely to manage diabetes. Slightly more than one-third of the physicians who certified the eligibility of beneficiaries or prescribed shoes were podiatrists, and slightly over one-quarter were

TABLE III.5

NUMBER AND PERCENTAGE DISTRIBUTION OF NOTIFIED PHYSICIANS AND PARTICIPATING PHYSICIANS. BY SPECIALTY. IN DEMONSTRATION STATES

Specialty	Notified Physicians		Physicians Who Certified Eligibility or Pmctibed Shoes in the Demonstration	
	Number	Percent	Number	Percent
Internal Medicine	19.071	33.9	903	25.5
General or Family Practice	16.741	29.8	316	8.9
Podiatry	5.703	10.1	1.199	33.9
General or Vascular Surgery	3.722	6.7	171	4.8
Orthopedic Surgery	3.717	6.6	369	10.4
Other or Unspecified	7.232	12.9	577	16.3
Total	56.236	100.0	3.535	100.0

SOURCES: The first and second columns come from Medicare carriers in the three demonstration States 1989: the third and fourth columns come from the demonstratton Certification and Prescnption Forms for beneficiaries randomized by September 17, 1992.

NOTE: All of the physicians in these specialties who were Medicate-certified according to the fiscal intermediary in each demonstratton state were notified. Hence. the number and percentage notified represent the population of physicians in the three demonstration States.

internists (see Table 111.5). Orthopedic surgeons accounted for slightly more than 10 percent of certifying or prescribing physicians. At 9 percent of the participating physicians. general and family practitioners were seriously underrepresented in the demonstration relative to the proportion of physicians in these specialties in the three demonstration States (30 percent), and podiatrists were equally overrepresented (34 percent of participating physicians but only 10 percent of all physicians). The lack of participating general and family practitioners may be a partial determinant of the low demonstration enrollment, since most diabetic Medicare beneficiaries see primary care physicians for their care.

Although the legislation mandated that only the physicians who were managing the beneficiaries' diabetes could certify eligibility, almost half of the physicians who certified eligibility were podiatrists and surgeons (orthopedic, vascular, and general). In recognition that such physicians do serve diabetic beneficiaries even if they do not manage their diabetes. HCFA decided to accept their certifications. and thus to keep enrollment rates as high as possible. Otherwise, it would have been necessary to return a high proportion of applications to beneficiaries. These physicians knew that they were serving diabetic beneficiaries. even if they were not managing their diabetes.[23] The reality of current practice is that footcare specialists (podiatrists and orthopedic surgeons) usually recommend and prescribe therapeutic

[23]Although diabetic management is clearly outside the practice scope of podiatrists (the largest group of physicians who certified patients), a large proportion of their patients are diabetic Medicare beneficiaries, who are among the limited group of Medicare beneficiaries for whom routine podiatry services are covered. Moreover, before podiatrists can provide those routine services, a comprehensive plan of care must be established by the patient's primary care physician. Furthermore, many podiatrists test the blood-sugar levels of their diabetic patients before performing routine footcare services.

shoes. Thus, in the demonstration, they either certified the beneficiaries themselves or referred the beneficiaries back to their primary care physicians or endocrinologists for the certification. thus slowing up the process of enrollment and requiring a second visit.

3. Physician Participation Was Low Because They Knew Little About Therapeutic Shoes and Did Not Like the Demonstration Procedures

Before the demonstration began, we received numerous comments on the proposed enrollment process. both from professional societies and from individual practitioners. Eight months before the end of the demonstration, we sought comments on the physician-initiated enrollment process from physicians and shoe suppliers who had participated in the demonstration and from relevant professional associations.

Before the demonstration, we received two main suggestions on the enrollment process from professional associations and individual physicians: to keep the process simple. and to abandon the random assignment of eligible applicants because it would be unacceptable to physicians. One of the State podiatric associations was outspoken against a randomized design and was unwilling to publicize the demonstration to its membership at that time.

The demonstration information disseminated through the initial notification and subsequent publicity campaigns did not appear to "reach' the primary care physicians who could have enrolled a large number of beneficiaries (as evidenced by the small number of primary care physicians who actually enrolled beneficiaries). Many of the physicians whom we interviewed informed us that the low rate of involvement in the demonstration by primary care physicians was due to the fact that, aside from foot specialists (podiatrists and some

orthopedic surgeons), most physicians know little about foot management and therapeutic shoes for diabetic beneficiaries, and hence would be unwilling to prescribe therapeutic shoes.

Even physicians who participated in the demonstration were confused about the purpose of the demonstration and the enrollment procedures. For example, some physicians thought that the demonstration required that physicians have prior authorization to certify beneficiaries or prescribe shoes. Another physician said that, because he thought that the cost-effectiveness of the demonstration was to be measured by the total costs of the shoes, he enrolled far fewer beneficiaries than he could **have in order to** hold down costs. Several respondents criticized the complexity of the process by which beneficiaries were enrolled (particularly the centralized processing).

By far the greatest problem was randomization, as had been noted by several physicians prior to the demonstration. Randomization was generally misunderstood and disliked. Physicians disliked the "lottery" aspect of the process because it inevitably meant that some beneficiaries would not receive the benefit (some of whom were perceived to be the sicker beneficiaries, though, as shown in Section B of this chapter. the random assignment procedures generated groups who were indistinguishable on average); however, they also disliked having to deal with the disappointment of the beneficiaries who were assigned to the control group. Thus, although the randomized approach provided the strongest approach for evaluating the demonstration, it appeared to be the factor that had the greatest limiting effect on the number of beneficiaries who enrolled.

The physicians also criticized various aspects of the demonstration "paperwork." and said that they had no incentive to complete the form. We do not believe that the one-page form to be completed by physicians (see Appendix C) **could have** been simplified. since it contained the information required by Congress for certifying and prescribing the shoes, required merely that physicians checkmark the necessary information and sign the form, and included carbon copies to allow the physician to retain a copy with the medical record. This form would have been required in the demonstration even in the absence of randomization, and a comparable form will be required for the national benefit." Although the physicians and professional associations would have preferred a, simpler enrollment process. none thought that the certification and prescription process was too complicated (most thought it was necessary): indeed. they proposed more stringent prescribing and more precise certifying requirements than were used in the demonstration. (These proposals are described in Chapter VI when we discuss how the national benefit might be modified.)

Podiatrists were very active in enrolling beneficiaries. As we know from the technical assistance that we provided in the demonstration, podiatrists frequently initiated the enrollment process by explaining it to the beneficiary and providing them with the Certification and Prescription Form. But among the 10 podiatrists whom we interviewed (which is not a representative sample, since all had participated in the demonstration), 3 mentioned having difficulties in prompting the physicians who managed the beneficiaries' diabetes to certify eligibility. One even visited an endocrinologist's office to request her signature.

[24] As noted earlier, the form also included three items required for the evaluation but not for the demonstration, all of which were check-box items.

Some demonstration shoe suppliers made aggressive efforts to enroll beneficiaries. Among the 13 whom we interviewed, 2 made mass mailings to area physicians. 1 mailed materials to previous customers who appeared to be eligible, 1 reprinted the Certification and Prescription Forms and gave them to beneficiaries to take to their physicians," and 1 (who was also a custom-molded shoe manufacturer) sent out a copy of the Act of Congress and an information card to area suppliers. Despite these efforts, these suppliers (who were among those who supplied the greatest number of shoes in the demonstration) did not believe that their efforts had a substantial effect on enrollment, and they concurred that few physicians knew about or understood the purpose of the demonstration.

4. Summary

Beneficiary enrollment depended on physicians to play two roles: certifying patient eligibility and prescribing shoes. Footcare specialists played those roles disproportionately and primary care physicians were least likely to play these roles. Outreach in the demonstration did not effectively reach primary care physicians. In a national program. participation would likely increase over time as more primary care physicians learned about foot management and prescribed the covered therapeutic shoes.

Some physicians and professional associations objected to randomizing beneficiaries into treatment and control groups. The randomized demonstration design that ensured an effective evaluation of cost-effectiveness probably reduced physician participation somewhat relative to

[25]These forms were available free in bulk from the demonstration contractor.

the absence of randomization. Only 3,525 physicians ever certified beneficiaries or prescribed shoes, although about 56.000 might have done so.

The enrollment procedures met the legislative requirements, with the exception that many certifying physicians were not the managers of the beneficiaries' diabetes. Many physicians who certified eligibility were podiatrists and surgeons. Since footcare specialists are most likely to initiate shoe use among diabetic beneficiaries, it may be appropriate for them to certify medical eligibility.

D. THE PARTICIPATION OF SHOE SUPPLIERS

1. Shoe Suppliers Were Authorized Before They Could Supply Therapeutic Shoes in the Demonstration

Four types of health professionals were eligible to fit and supply shoes in the demonstration: podiatrists, certified pedorthists, certified orthotists. and certified prosthetists. Congress had identified these groups as those that are trained to fit therapeutic shoes. which required that they be able to take casts of feet. prepare customized, multiple-density inserts. fit shoes. and modify shoes as necessary. To supply the shoes. eligible professionals or companies that employed eligible professionals were required to apply to the demonstration. using the materials sent to them before the demonstration began, or subsequently upon request (see Appendix D). Application to the demonstration was necessary because the suppliers had to agree to accept assignment for the Medicare shoe benefit (and to file the claims for therapeutic shoes with the demonstration carrier for the beneficiaries) and wet-e required to indicate the prices they would accept for covered items (at or below the prices set

by Congress)." Before the demonstration 6,312 professionals were notified and during the demonstration 442 (7 percent) applied for authorization to supply shoes." (See Table III.6.)

Quality assurance standards in the demonstration were implicit in the types of professionals who could supply the shoes. Previous experience in fitting shoes to the diabetic foot was not required, under the presumption that requiring professional certification would ensure that the suppliers would have the necessary training.[28] The demonstration did not require that authorized suppliers maintain stocks of depth-inlay shoes (to optimize the fit of shoes), nor that they have specific equipment available on the premises for modifying shoes and making or customizing inserts for the shoes. Although beneficiaries had to be authorized for payment before the supplier could supply the shoes, a review of medical necessity was not required. since one or more physicians had already certified eligibility and prescribed therapeutic shoes.

HCFA authorized 442 suppliers of therapeutic shoes, 402 of them in the first year of the demonstration. These suppliers were fairly evenly distributed across the three demonstration

[26]The shoe suppliers filed claims with the Health Care Financing Administration (HCFA) (the demonstration carrier) by completing Form HCFA-1500, and attaching a copy of the demonstration payment authorization form issued to the participating beneficiary. A supplier manual was developed for the demonstration, a copy of which was provided to each authorized supplier (see Appendix D).

[27]We subsequently notified orthotists certified by the New York Board for Orthotist Certification about the demonstration.

[28]In order to handle the isolated complaints received from beneficiaries about the quality of shoes supplied, the demonstration contractor established a procedure for issuing a new payment authorization to beneficiaries whose physicians wrote a letter to the demonstration contractor to indicate that the shoes did not fit. Four such re-authorizations were provided during the demonstration.

TABLE III.6

NUMBER AND PERCENTAGE DISTRIBUTION OF POTENTIAL SHOE SUPPLIERS. AUTHORIZED SHOE SUPPLIERS. AND AUTHORIZED SHOE SUPPLIERS WHO SUPPLIED SHOES, AND THE QUANTITY OF SHOES THEY FURNISHED IN THE DEMONSTRATION

Professional Discipline	Number and Percentage Notified in 1989[a]	Number and Percentage Authorized[b]	Number Who Supplied any Shoes'	Pairs of Shoes supplied to Beneficiaries[d]
Podiatrists	5.264 83 %	271 61.3 %	115 45.5 %	450 23.0 %
Orthotists. Orthotist-Prosthetists, and Prosthetists	922 15 %	79 17.8 %	61 24.1 %	433 22.1%
Pedorthists	126 2 %	35 7.9 %	30 11.9 %	564 28.8 %
Combination'	--	57 12.9 %	47 18.6 %	513 26.2 %
Total Number Total Percent	6.312 100.0 %	442 100.0 %	253 100.0 %	1.960 100.0 %

SOURCE: Demonstration claims data.

NOTE: Two beneficiaries bought only inserts in the demonstration. and are not included in the table.

[a]Notifications were sent to members of four professions that supply shoes and orthoses.

[b]Number of shoe suppliers who applied to be authorized to supply shoes in the demonstration.

'Number of shoe suppliers who filed any shoe claims that were processed by December 31, 1992.

[d]Number of shoe claims processed by December 31, 1992. for beneficiaries authorized by September 17. 1992.

[c]Suppliers with staff from more than one discipline.

States, although Florida (with the fewest diabetic Medicare beneficiaries among the three States) contained the most suppliers (36 percent of all authorized suppliers). Florida had 1 participating supplier for every 8 participating beneficiaries. compared with about 1 supplier for every 13 participating beneficiaries in New York.[29]

State-specific lists of authorized suppliers were given to physicians and authorized beneficiaries. During the demonstration, several beneficiaries requested using a shoe supplier that was not authorized. In these cases, we sent information on authorization for the demonstration to the requested supplier. Some beneficiaries who tried to use a shoe supplier on the authorized list found that the shoe supplier had moved, gone out of business. or retired. or no longer wanted to participate in the demonstration. When beneficiaries informed us that authorized suppliers were not at the address we had provided, we attempted to find the new address (if there was one). We provided any new information to the beneficiaries. and updated our address list. When beneficiaries informed us that suppliers no longer wished to take part in the demonstration, we contacted the suppliers to encourage their participation. Sometimes, suppliers merely required information about outstanding claims. and were then willing to continue as demonstration suppliers.

[29]Florida had the highest number of participating suppliers per 10,000 diabetic Medicare beneficiaries (8 percent), but the second highest number of participating beneficiaries as a percentage of diabetic Medicare beneficiaries (0.6 percent). New York, with the lowest number of participating suppliers per 10,000 of diabetic Medicare beneficiaries (5 percent). had the highest number of participating beneficiaries as a percentage of diabetic Medicare beneficiaries (0.7 percent).

2. **Authorized Suppliers Participated and Furnished Shoes at Different Rates by Discipline**

More shoe suppliers were authorized to suppiy shoes than actually supplied them during the demonstration. Only about 57 percent of authorized suppliers (253 of 442 suppliers authorized) supplied shoes (Table 111.6). Eighty percent of the authorized suppiiers who did not actually supply shoes were podiatrists who appeared to have applied to be shoe suppliers in the demonstration in the mistaken belief that they were required to do so in order to prescribe shoes for any beneficiaries. We assume that a sufficient number of suppliers participated in the demonstration. because beneficiaries and physicians did not complain of delays in obtaining shoes due to a backlog from demonstration suppliers.

The four types of suppliers (podiatrists, pedorthists, onhotists and prosthetists, and suppliers in which a combination of these professionals furnish shoes) each supplied about one-fourth of the shoes under the demonstration, but accounted for very different proportions of the authorized or participating suppliers. For example, podiatrists accounted for 61 percent of the authorized suppliers, but represented only 46 percent of the suppliers who ever supplied therapeutic shoes: moreover, they supplied only 23 percent of all shoes supplied. based on claims processed through December 31, 1992 (see Table 111.6). In contrast, certified pedorthists were much more active in the demonstration; they comprised 8 percent of authorized suppliers and 12 percent of the suppliers who supplied shoes, but supplied 29 percent of the shoes.

On average, each shoe supplier who supplied any shoes furnished only about seven or eight pairs during the 39 months of the demonstration. Suppliers furnished between 1 pair

and 95 pairs of therapeutic shoes. The 10 most active suppliers furnished between 34 and 95 pairs of shoes. Five of the top 10 suppliers (including the supplier who furnished the greatest number of shoes) were pedorthists, three were combinations of professions, one was an orthotist, and one was a prosthetist.

The different professional groups supplied different types of shoes (see Table 111.7). Three-quarters of the shoes supplied by podiatrists were custom-molded shoes--which is not surprising, since most podiatrists prefer not to carry a stock of depth-inlay shoes. Pedorthists also supplied custom-molded shoes more than half of the time (57 percent). Orthotists and prosthetists were most likely to supply depth-inlay shoes (57 percent of shoes supplied).

3. A Sample of Suppliers Largely Followed Demonstration Procedures, but Held Varying Opinions about Them

The 13 shoe suppliers whom we interviewed in the last 8 months of the demonstration about demonstration procedures were selected because they were the highest-volume suppliers in their geographic areas. They felt that the demonstration procedures for supplying shoes were straightforward, although they recommended changing some of the procedures in a national program.

Most of these 13 suppliers would see beneficiaries on the same day that they called for an appointment to obtain the shoes. All six pedorthists and the orthotist-prosthetist maintained a stock of depth-inlay shoes, and only occasionally had to order shoes for a beneficiary, primarily because they did not have a particular color or style in stock. The

TABLE III.7

TYPES OF SHOES SUPPLIED BY AUTHORIZED SUPPLIERS IN THE DEMONSTRATION TO ALL BENEFICIARIES AUTHORIZED FOR SHOE COVERAGE

Professional Discipline	Number of Pairs Supplied	Types of Shoe Supplied (Percent)		
		Custom-Molded	Depth-Inlay	Total
Podiatrists	450	75.1	24.9	100.0
Orthotists, Orthotist-Prosthetists, and Prosthetists	433	43.4	56.6	100.0
Pedorthists	564	57.3	427	100.0
Combination[a]	513	50.7	49.3	100.0
Total	1,960	56.6	43.4	100.0

SOURCES: Demonstration claims data.

NOTES: Shoes must have been supplied by October 31, 1992. The table presents data from claims that were processed by December 31, 1992, for beneficiaries authorized by September 17, 1992.

Two beneficiaries bought only inserts in the demonstration. and are not included in the table.

[a]Suppliers with staff from more than one discipline.

other suppliers either did not supply the depth-inlay shoes or had to order them specially. which, as one of them pointed out, was problematic because the shoes did not always fit and would have to be reordered.[30] One supplier would send a cast of the foot to a wholesaler for fitting a depth-inlay shoe. All of the suppliers made customized inserts in-house, although one did not follow the demonstration requirement that the inserts be multiple-density; he supplied a single-density piastazote inlay. For custom-molded shoes, all the suppliers made the casts in-house and sent them to a shoe laboratory to be made, a process which took from 2 to 7 weeks, but averaged 4 to 5 weeks.

The suppliers were required to accept assignment of Medicare benefits in the demonstration, and to file claims for the shoes (which might not necessarily be a requirement in a national benefit). The 13 suppliers whom we interviewed had different interpretations about accepting assignment. Some suppliers specified a "basic" shoe that they felt would be covered by Medicare, and then charged extra for other types of shoes. Another accepted assignment for covered items, but charged full price for items that were not covered specifically (such as a toe-block as part of an insert when the toe had been amputated). Two suppliers recommended against requiring Medicare assignment in a national program. and a third recommended that it be required. The 13 suppliers felt that the shoe claims had been processed smoothly in the demonstration, with the exception that several suppliers mentioned long lags in payment early in the demonstration and errors in deductibles that occurred when Part B processing was modified in 1991.

[30]This supplier, a podiatrist with a pedorthist employee, said that he would purchase the necessary inventory (at a cost of about $50,000) if the benefit were introduced nationally.

The demonstration's only quality assurance requirement was that minimum professional qualifications be fulfilled. Some of the suppliers were concerned that the quality of shoes supplied in a national program might not be adequate unless new quality assurance procedures were introduced. They suggested that additional requirements (such as maintaining a stock of depth-inlay shoes) be established in a national program.

Several suppliers were concerned about the ethics of having the same physician prescribe and supply shoes to the same beneficiary (which was implicitly allowed in the demonstration because the legislation did not specifically exclude it), and recommended that this practice not be allowed in a national program.[31]

4. Summary

We found that:

- Shoe suppliers were authorized to participate in the demonstration if they agreed to the demonstration prices. agreed to accept assignment of Medicare benefits, and were podiatrists or certified orthotists, prosthetists, or pedorthists.
- The process of authorizing suppliers and supplying the shoes in the demonstration complied with legislative and HCFA requirements. with the exception that the inserts supplied were not always multiple-density and customized.
- About one-quarter of the podiatrists and three-quarters of the other suppliers who were authorized ever supplied shoes (253 suppliers). Yet this number was adequate for the volume of participating beneficiaries.

[31]The legislation precluded certifying physicians from supplying shoes but did not preclude prescribing physicians from supplying shoes. Since the certifying physicians were supposed to be medical doctors (who rarely fit or furnish shoes), this rule seems to have been entirely unnecessary. On the other hand, the law did not preclude physicians from prescribing and supplying shoes (which often occurs in podiatry practices and in clinics where patients are seen by multidisciplinary teams).

- Podiatrists mostly furnished custom-molded shoes (three-quarters of the shoes they supplied), but other suppliers furnished much lower proportions of custom-molded shoes.

- In a national program, Medicare assignment would not be required (see Chapter VI for a discussion).

E. THE SHOE BENEFIT: USE AND COST TO MEDICARE

1. Two-Thirds of Beneficiaries Used the Demonstration Benefit

Purchase of First Pair of Shoes. By the last day on which shoes could be supplied in the demonstration (October 31, 1992), 3 years and 3 months after the demonstration began, 4,373 beneficiaries had enrolled in the demonstration, of whom 2,183 were authorized to receive Medicare payment for therapeutic shoes (that is, were in the treatment group). About two-thirds (69 percent) of the authorized group were supplied with at least one pair of shoes.[32] The shoe purchase rate of 69 percent is lower than expected, since all these beneficiaries had therapeutic shoes prescribed for them, they took the trouble to request the benefit by mailing the form, and they were eligible to have Medicare pay 80 percent of the cost of the shoes.

In order to investigate whether claims-processing lags led to an underestimate of the actual rate at which the benefit was used, we recomputed the shoe purchase rate for a sample for whom a 5-month or more processing time was available. (Although suppliers have an

[32]This figure is based on claims processed through December 31, 1992, for beneficiaries who enrolled by September 17, 1992 (the last enrollment date). The 85 percent rate of shoe ownership obtained from survey results reported in Chapter V is higher (1) because the survey sample excludes beneficiaries who died and includes beneficiaries enrolled through May 1992 and (2) because it includes shoes that were bought independently of the demonstration.

incentive to request payment promptly, they may not have done so.) The claims data for this report were processed by December 31, 1992; if we allow 5 months for claims to be submitted and processed, the sample of authorized Medicare beneficiaries would be 2,107, only slightly smaller than the full sample of 2,183 (as shown in Table III.8).[33] This 5-month lagged sample produces a 69.2 percent rate at which authorized beneficiaries had their shoe prescriptions filled. Thus, since few claims are expected to take longer than 5 months to be submitted to and processed by HCFA, the true rate of shoe purchase appears to be about 69 percent. as suggested by the entire treatment sample.

Figure III.3 depicts the disparity between the total number of beneficiaries who enrolled in the demonstration, the number of treatment group members who were offered the therapeutic shoe benefit, the number of beneficiaries who received therapeutic shoes, and the number of shoes furnished in the demonstration. The fact that nearly one-third of the beneficiaries in the treatment. group did not receive demonstration-supplied shoes reduces the likelihood that the therapeutic shoe benefit will affect Medicare costs. The sharp increase in the number of shoes supplied in the demonstration in October 1992 reflects the fact that. in August 1992, treatment group members who had not renewed their authorizations were notified that the demonstration was about to end, and that they would have to have their shoe prescriptions filled by October 1992 if Medicare was to cover 80 percent of the cost.

We ruled out the possibility that beneficiaries did not purchase shoes because their authorization expired. The authorization form was dated to be used within 3 months after

[33]Based on claims processed through December 3 1, 1992, for beneficiaries who enrolled by July 31, 1992 (2,107 beneficiaries).

TABLE III.8

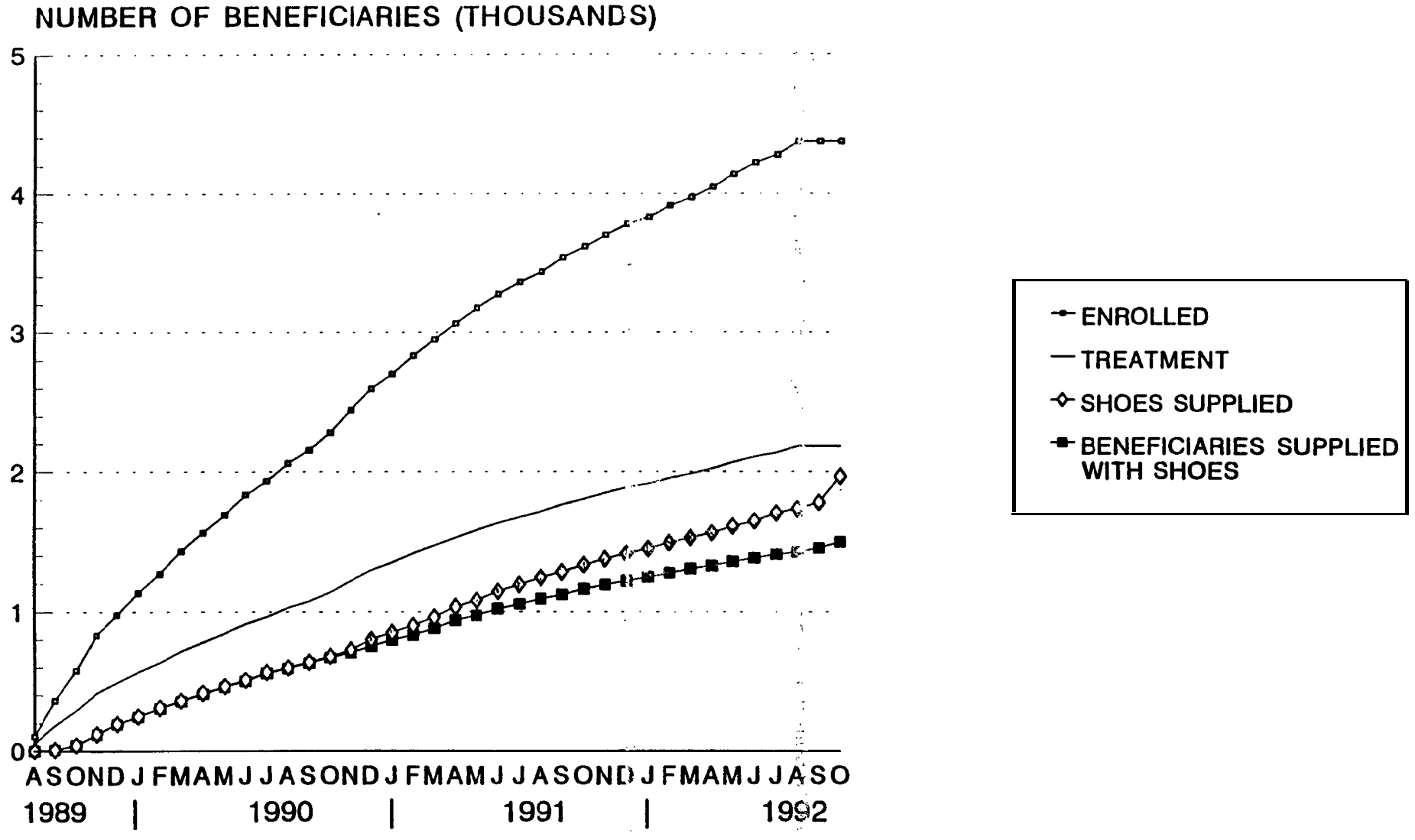
NUMBER AND PERCENTAGE OF TREATMENT GROUP BENEFICIARIES AUTHORIZED TO RECEIVE PAYMENT FOR SHOES AND SUPPLIED WITH SHOES, BY STATE

	Total	State					
		California		Florida		New York	
	Number	Number	Percent	Number	Percent	Number	Percent
Beneficiaries Authorized to Receive Payment for Shoes	2,107	693	32.9	619	29.4	795	37.8
Beneficiaries Supplied with Shoes	1,457	464	31.8	455	31.2	538	36.9
Beneficiaries Supplied with Replacement Inserts	94	39	41.5	30	31.9	25	26.6
Beneficiaries Supplied with Modifications	90	23	25.6	41	45.6	26	28.9

SOURCE: Demonstration claims data.

NOTE: Sample includes 2,107 beneficiaries who were enrolled by July 31, 1992, and whose claims were processed by December 31, 1992. Shoes had to be supplied by October 31, 1992.

FIGURE III.3
CUMULATIVE NUMBER OF BENEFICIARIES ENROLLED AND SUPPLIED WITH THERAPEUTIC SHOES IN THE DEMONSTRATION



Treatment members had to be supplied with shoes by October 3., 1992.
Figure presents data from claims processed by December 31, 1992.
Total number of beneficiaries originally notified was 43,064.

The number of shoes supplied exceeds the number of beneficiaries supplied with shoes starting in August 1990 because beneficiaries could renew the benefit for additional pairs of shoes each year after the anniversary of their enrollment in the demonstration.

authorization. But some beneficiaries were unable to use their payment authorization form within the 3-month period, usually because they had been in the hospital. Beneficiaries were informed upon enrollment that their authorization could be extended if it expired. Through October 31, 1992, 62 of these re-authorizations were provided.

In a telephone survey in 1992, the most common reason that beneficiaries gave for not having purchased the shoes after authorization was that they had lost the paperwork (14 percent) or did not want or need the shoes (12 percent); another 8 percent said the shoes were too hard to get.[34,35]

Replacement Inserts and Shoe Modifications. The shoe benefit also covered replacement inserts or shoe modifications (Table III.8). Only 94 (6.5 percent) of the 1,437 beneficiaries who were supplied with shoes in the demonstration received replacement inserts (see Table III.8). This low proportion of beneficiaries with replacement inserts is surprising, given that the health and professional societies who lobbied for Medicare coverage of replacement inserts did so because they believed that the inserts are not durable enough to last an entire year. Only **90 (6.2** percent) of the beneficiaries who were supplied with shoes were supplied with shoe modifications. Most of these modifications were rigid rocker bottoms. The rationale for covering shoe modifications was that an unnecessarily high proportion of the more expensive

[34]Treatment group members who did not own shoes at all most often said the reason was that the shoes were too expensive despite Medicare coverage (57 percent of those who did not own therapeutic shoes). Another 19 percent said they did not want or did not need the shoes, and 11 percent each said that the shoes would not be comfortable or were too hard to get.

[35]The beneficiary survey was administered in May and June 1992; 1,120 of the treatment group members responded. (Chapter V and Appendix K describe the survey.)

custom-molded shoes would be prescribed and supplied if modifications to depth-inlay shoes were not covered, thus potentially affecting the cost-effectiveness of the demonstration benefit.

Renewal of the Benefit Annually. **The** beneficiaries were entitled to renew the demonstration shoe benefit each year, following the same procedures required for the first pair of shoes. Of the 1,633 beneficiaries who were eligible for shoe renewals, only 504 (31 percent) sent in another Certification and Prescription Form to renew the benefit (see Table 111.9). Of the 1,633 eligible beneficiaries, only 380 (23.3 percent) actually purchased a second pair of shoes. The rates of application for the renewal and purchase of a third pair of shoes are even lower. Of 914 eligible beneficiaries, only 99 (11 percent) applied for renewal, and 81 (9 percent) purchased a third pair of shoes."

The reasons for the low rate of application for shoe renewal varied. The most common reason that beneficiaries gave for not renewing the shoe benefit was that they did not need the shoes (33 percent of those 'eligible for renewal had not renewed either because they no longer walked or because their shoes had not worn out). The next most common reasons were that they were unaware that they could get a second pair of shoes (14 percent), that the shoes were uncomfortable (14 percent), and that they were waiting for the paperwork (10 percent).[37]

[36]However, among those who applied for the benefit, shoe purchase rates increased from 69 percent for the first pair, to 75 percent for the second pair, and 87 percent for the third pair.

[37]These figures are based on responses to the beneficiary survey, May and June 1992. Another 44 percent of beneficiaries gave 15 different reasons for not renewing the shoe benefit (multiple responses were allowed).

TABLE III.9

SHOE ACQUISITION AND RENEWALS

	Initial Shoes		First Renewal (Second Pair of Shoes)		Second Renewal (Third Pair of Shoes)	
	Number	Percent	Number	Percent	Number	Percent
Eligible and Benefit-Using Beneficiaries						
Eligible Beneficiaries	2,107	108.0	1,633	100.0	914[b]	100.0
Beneficiaries Who Applied (Percentage of Eligible Beneficiaries)	2,107	100.0	504	30.9	99	IO.8
Bcneficiarics Who Actually Used Benefit (Percentage of Eligible Beneficiaries)	1,457	69.2	380	23.3	81	8.9
Items Covered						
Depth-Inlay Shoes with Customized Inserts'	635	43.6	155	40.8	32	39.5
Custom-Molded Shoes	822	56.4	225	59.2	49	60.5
Replacement Inserts	76	5.2	27	7.1	3	3.7
Modifications	64	4.4	48	12.6	7	8.6
Rigid rocker bottoms	32	2.2	23	6.1	6	7.4
Roller bottoms	12	0.8	15	3.9	0	0.0
Metatarsal bars	6	0.4	I	0.3	0	0.0
Wedges	6	0.4	7	1.8	1	1.2
Offset heels	8	0.5	2	0.5	0	0.0

SOURCE: Demonstration claims data.

NOTE: Sample includes 2,107 beneficiaries who were enrolled by July 31,1992 and whose claims were processed by December 31, 1992

● Two beneficiaries received inserts under the demonstration, but did not receive shoes.

[b] The number of beneficiaries eligible for renewal is estimated on the basis of the originai date of application. Some of these beneficiaries may have died or moved to a State not in the demonstration.

Given that shoe ownership is a requirement for the shoes to be clinically effective, it is useful to examine the participation of all treatment group members in the demonstration by the proportion of time they spent with and without shoes (Figure 111.4). Each participating beneficiary spent a different amount of time in the demonstration, according to his or her date of enrollment and according to when either he or she died or the demonstration ended. During that time, each treatment group member spent a portion of that time waiting for paperwork to be completed and for the shoes to be supplied (7 percent of the days in the demonstration were spent waiting for the first pair of shoes).[38] Each spent another portion of the demonstration with shoes (56 percent of the time with his or her first pair, and 8.5 percent of the time with subsequent pairs). The proportion of demonstration time attributed to treatment group members who never received shoes is 28 percent. The proportion of time in the demonstration with shoes (65 percent) is slightly lower than the proportion of treatment group members who received shoes (69 percent).

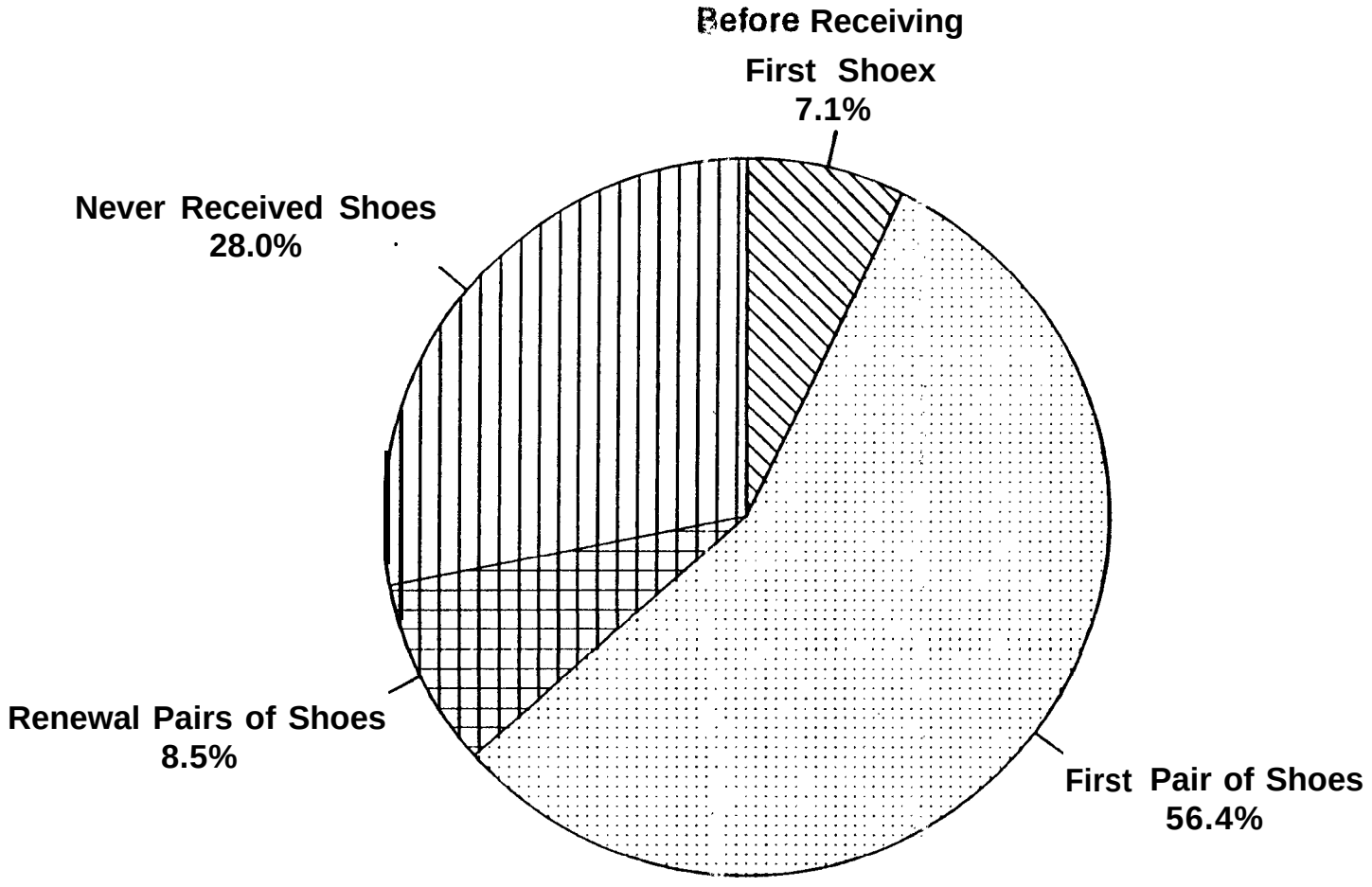
2. **Suppliers Were Paid About $350,000 in Payments for Shoes**

Shoe claims were processed according to standard Medicare Part B procedures. with two exceptions. First, HCFA served as the carrier for the demonstration. Second, authorized suppliers were required to attach a copy of the payment authorization form to the standard health insurance claim form (HCFA 1500) for payment. Suppliers mailed the two forms to HCFA for processing. Reimbursement checks and an Explanation of Medicare Benefits were

[38]The mean time between randomization (enrollment) and shoe receipt (the date of service on claims) for those who used the benefit was 64.5 days.

FIGURE III.4

PERCENTAGE OF POTENTIAL TIME IN THE DEMONSTRATION "THAT ALL TREATMENT GROUP MEMBERS SPENT WITHOUT SHOES, WITH THE FIRST PAIR OF SHOES, AND WITH RENEWAL SHOES



For beneficiaries who died during the demonstration, the date of death was used as end of demonstration date.
Two individuals received only inserts in the demonstration, and appear under 'Never Received Shoes.'
One individual received only inserts for the second authorization.
Figure is based on all 2.183 treatment group members.

mailed directly to authorized shoe suppliers. The Explanation of Medicare Benefits showed the amount billed, the amount approved, the Medicare payment (80 percent of the approved amount), and the annual deductible and co-insurance amounts owed by the beneficiary, which the shoe supplier was expected to collect from the beneficiary. The approved amount was the charge indicated on the claim, the rate indicated by the shoe supplier on the Participating Supplier Agreement, or the maximum allowable rate, whichever was lowest.

The total payment received by the shoe supplier for services covered under the demonstration could not exceed the amount approved, because suppliers agreed to accept benefit assignment. The shoe supplier could collect from the beneficiary any amount for services that were not covered under the demonstration.

As of December 31, 1992, 2,874 items had been claimed under the demonstration: 1,918 pairs of shoes, and 956 pairs of removable inserts and modifications (Table III.10).[39] As of December 31, 1992, $353,172 had been paid to shoe suppliers (an average of $242 per beneficiary); $254,852 of that amount was for custom-molded shoes ($233 per pair), $57,770 was for depth-inlay shoes ($70 per pair), $34,505 was for inserts ($41 per pair), and $6.044 was for modifications ($5 1 per modification). Because two different prices were operating during the demonstration, Table 111.10 also shows the number of items and the associated Medicare payments for both periods.

[39]Because the legislation mandated that depth-inlay shoes were to be supplied with inserts, most of the inserts were supplied with depth-inlay shoes.

TABLE III.10

NUMBER. TOTAL COSTS. AND AVERAGE COSTS OF ITEMS PURCHASED UNDER THE DEMONSTRATION. TOTAL AND BY TIME PERIOD

	Total			
	Number	Cost to Medicare Program	Average Cost to Medicare Program per Beneficiary[a]	Average Cost to Medicare Program per Item
Total				
AU Beneficiaries	1,459	353.17152	242.06	
Beneficiaries' Initial Claims	1.459 [b]	260.972.37	178.87	--
Beneficiaries' Renewal Claims	381 [c]	92,199.15	241.99	--
Shoes (Pain) Supplied	1,918	312,622.66	214.57	162.99
Custom-molded	1,096	254,852.27	300.89	23253
Depth-inlay	822	57.77039	88.20	70.28
Removable Inserts (Pain) [d]	837	34505.03	51.97	41.22
Modifications	[illegible]	5,045.63	67.23	50.79
Rigid rocker bottoms	61	3,746.88	68.13	61.42
Roller bottoms	27	1,492.80	59.71	55.29
Metatarsal bars	7	145.60	20.80	20.80
Wedges	14	269.59	20.74	19.26
Offset heels	10	388.96	38.90	38.90
From 8/89 to 12/90 (Original Prices and $75 Deductible)				
All Beneficiaries	757	140.44222	185.52	
Beneficiaries with Initial Claims	757	132,772.59	175.39	--
Beneficiaries with Renewal Claims	44	7,669.63	174.31	--
Shoes (Pairs) Supplied'	800	127,263.10	168.34	159.08
Custom-molded[e]	480	106517.39	233.08	221.91
Depth-inlay	320	2Q.745.71	68.24	64.83
Removable Inserts (Pairs)	322	12874.17	4263	39.98
Modifications	7	304.95	60.99	43.56
Rigid rocker bottoms	2	117.60	58.80	58.80
Roller bottoms	2	117.60	58.80	58.80
Metatarsal ban	0	0.00	0.00	0.00
Wedges	1	19.99	19.99	19.99
Offset heels	2	49.76	24.88	24.88
From 1/91 to 10/92 (New Prices and $100 Deductible)				
All Beneficiaries	715	212729.30	297.52	
Beneficiaries with initial Claims	715	128,199.78	179.30	--
Beneficiaries with Renewal Claims	348	84,529.52	242.90	--
Shoes (Pairs) Supplied	1.118	185.359.56	20280	165.80
Custom-molded	616	148.334.88	291.42	240.80
Depth-inlay	502	37,024.68	88.15	73.75

TABLE 111.10 *(continued)*

	Total			
	Number	Cost to Medicare Program	Average Cost to Medicare Pmgtam per Beneficiary[a]	Average Cost to Medicate Program per Item
Removable Inserts (Pairs)	515	21,630.86	49.84	42.00
Modifications	112	5,738.88	66.73	51.24
Rigid rocker bottoms	59	3,629.28	67.21	61.51
Roller bottoms	25	1,375.20	59.79	55.01
Metatarsal bars	7	145.60	20.80	20.80
wedges	13	249.60	20.80	19.20
Offset heels	8	339.20	42.40	42.40

SOURCE: Sample includes 2.107 beneficiaries who were enrolled by July 31.1992 and whose claims were processed thmugh December 31. 1992.

NOTE: Dates represent the date of service recorded on the demonstration claim file. The costs of beneficiaries' renewal chums represent the costs for renewals only. Numbers of beneficiaries in each time period do not sum to the total because the same beneficiary could submit claims in each time pertod, and would be counted only once in the total.

[a]Tables III.8 and III.9 provide the total number of items provided under the demonstration.

[b]This figure cotresponds to the number of benefictanes who actually used the initial shoe benefit in 'fable III.9 if the two bcncliciancs who purchased only inserts with their first authorization are subtracted.

'This figure corresponds to the number of beneficiaries who actually used the first renewal benefit in Table III.9 if the beneficiary who purchased only inserts with his renewal authorization is subtracted.

[d]Removable inserts tn this table include all claims submttted for inserts. This differs from 'fable 111.9 because Table III.9 shows only inserts that were purchased independently of shoes as replacements for the original inserts that came with shoes. The number of depth-inlay shoes and replacement inserts in Table III.9 does not equal the number of removable inserts in Table III.10 because original inserts were not always claimed with depth-inlay shoes on the claim file.

[e]One beneficiary has a date of service that appears to have been keyed incorrectly from the birthdate. The second pair of shoes purchased for this beneficiary were purchased in February 1991; thus, the first pair of shoes were placed in the first lime pcnod.

3. Beneficiaries, Shoe Suppliers, and Others Required Technical Assistance for Shoe Claims Processing

Beneficiaries or their representatives called the demonstration contractor to inquire about such reimbursement issues as deductibles, copayments, and discrepancies on the Explanation of Medicare Benefits. Some beneficiaries did not realize that they were responsible for the 20 percent copayment and any unmet Part B deductible, and questioned the amounts they owed.

Shoe suppliers often asked when their claim would be processed or questioned the amount paid for claims. Claims processing during the first two quarters of the demonstration was slow: as claims processing times improved, the number. of complaints from suppliers fell. Subsequent delays in claims processing were caused by missing payment authorization forms or supplier identification numbers, unauthorized supplier names on claim forms, or nondemonstration procedure codes on claim forms. If the payment authorization was missing, the demonstration contractor sent a copy of the authorization to HCFA. We then contacted the shoe supplier to obtain the other missing information. Starting in the third demonstration quarter, the deductible shown on the Explanation of Medicare Benefits for the shoe claims was wrong in many cases, due to an error in claims processing. After receiving complaints from beneficiaries and suppliers, the demonstration contractor alerted the Medicare carrier of the problems and monitored the problems until they were resolved.

One problem with claims processing pertained to the imposition of the California state tax on therapeutic shoes. Under California Regulation 1591, ***Prescription Medicines.*** therapeutic shoes that are not attached to a brace or an artificial leg are subject to a state

sales tax, but items that are issued under a doctor's prescription are not. The California Board of Equalization determined that therapeutic shoes are not exempt from the state sales tax. The demonstration contractor mailed a description of the ruling to authorized shoe suppliers in California in March 1991.

Occasionally, the demonstration contractor received claims for therapeutic shoes that had been sent to the regular Medicare carriers, and were then forwarded to the demonstration. Some of these claims were authorized for the demonstration, and some were independent of the demonstration. If the claim was ready to be processed through the demonstration carrier, the shoe supplier who submitted the claim was telephoned to clarify the claims-submissions procedures. Claims that were completed incorrectly were returned to the shoe supplier with a letter that provided the correct address for claims submissions and the proper claims-submission procedures. Claims that were independent of the demonstration were returned to the carrier as ineligible, and the beneficiary, physician, and shoe supplier were sent information on the demonstration. However, if the claim indicated an extensive lower-extremity amputation, we pointed out to the carrier that the claim could be eligible for coverage under regular Medicare Part B.

Some beneficiaries who were eligible for renewed benefits (those who were enrolled for more than 12 months) had not submitted new Certification and Prescription Forms, but submitted a second claim for shoes. The demonstration carrier identified these claims by checking whether the authorization number had already been used. If the authorization number had already been used, the claim was flagged and held, and the carrier called the

demonstration contractor. The contractor notified the beneficiary that he or she was required to renew the Certification and Prescription Form for coverage under the demonstration. When the renewal forms had been processed and received at HCFA, these claims were processed. In some cases, shoe suppliers contacted the demonstration contractor about how beneficiaries would receive their next pair of shoes, and demonstration procedures were explained to them.

4. **Reactions to the Benefit and Suggestions for Modifying the Benefit**

a. Beneficiaries' Reaction to the Benefit

We spoke in depth with eight beneficiaries who had received shoes; all were enthusiastic about the benefit and had no problems in obtaining their shoes under the demonstration. They wanted the benefit to be made available to others because it had been "a blessing" to them, and had given them "peace of mind." Two of the eight had not been helped by the shoes; in one case, the beneficiary could not wear the shoes (her feet were exceptionally sensitive and painful), and in the other the beneficiary had been wearing carefully fitted shoes for years and received no extra help from the demonstration shoes; the other six were very happy with the shoes, and five of them attributed higher activity levels to the demonstration shoes. Five of the eight said that the demonstration had helped them understand more about footcare--an important educational effect.

b. Reasons Why the Benefit Was Nat Used

The relatively low rate of shoe purchase in the program after authorization surprised us: only 69 percent received the shoes, and only 23 percent renewed the shoes in the second year. The three principal reasons given by authorized beneficiaries for not using the authorization to buy the shoes: they lost the paperwork (14 percent), the beneficiaries did not need or want the shoes (12 percent), and they had difficulty in obtaining the shoes (8 percent); the primary factors behind benefit nonrenewal were that beneficiaries did not need it (33 percent), they were unaware that renewal was allowed (14 percent), and they felt that the shoes were uncomfortable (14 percent).[40] There is no reason to suspect that these reasons were related to the demonstration design or procedures, or that beneficiaries in a national program would behave differently.

The low rate at which replacement inserts were purchased (106 pairs for 94 beneficiaries of the 1,457 beneficiaries receiving shoes) is surprising, given the importance placed on the replacement of inserts by the professional associations that lobbied successfully (in 1989) for modifying the demonstration benefit to include them. However, the low rate was less surprising in light of the comments made by one-fourth of the 18 physicians and shoe suppliers visited in the last 8 months of the demonstration that one pair of inserts a year is sufficient.

[40] These figures are based on responses from the beneficiary survey, May and June 1992. Another 44 percent of the beneficiaries gave 15 different reasons for not renewing the shoe benefit (multiple responses were allowed).

c. Suggestions for Mudifying the Benefit

The physicians, shoe suppliers, and professional associations with whom we spoke both before the demonstration began and 8 months before it ended had numerous suggestions for modifying the shoe benefit in ways that would be inconsistent with the legislative requirements. These recommendations included (1) covering two pairs of shoes a year under certain circumstances, (2) covering deep athletic shoes, (3) covering off-the-shelf and custom-made inserts, (4) covering shoe repairs, and (5) increasing the Medicare-allowed prices for therapeutic shoes." However, the same group also provided comments and suggestions on the demonstration benefit that are consistent with the legislative requirements.

The shoe suppliers and professional associations with whom we spoke largely concurred that both types of shoes should be covered. Some suppliers rarely use custom-molded shoes (for example, only for beneficiaries with Charcot's foot) and recommend limiting their use. This recommendation is consistent with the practice of physicians with whom we spoke who limit custom-molded shoes to beneficiaries with chronic problems or gross deformities. suggesting that depth-inlay shoes are appropriate for most beneficiaries. This practice recommendation is in sharp contrast to the demonstration experience, in which nearly 60 percent of the shoes that were prescribed and supplied were custom-molded.

The demonstration coverage of up to two pairs of replacement inserts per year was acceptable to most respondents. The modifications covered by the demonstration were

[41] As summarized in Table 11.1, the demonstration benefit covered custom-molded and depth-inlay shoes, customized multiple-density inserts molded to the foot or a cast of the foot, replacement customized multiple-density inserts, and certain modifications.

accepted (though two suppliers felt that metatarsal bars were unnecessary), but several suppliers proposed augmenting the list of modifications with: flared heels, extended steel shanks, leg-length modifications, velcro closures, rigid heel counters, and accommodations to inserts for missing toes (toe blocks).

The Medicare allowable charges for the demonstration-covered shoes during 1991 and 1992 were $316 for custom-molded and $105 for depth-inlay shoes. The shoe suppliers whom we interviewed recommended higher allowable charges: the average minimum prices recommended were $400 for the custom-molded shoes (with a range of $300 to $500), $154 for men's depth-inlay shoes, and $121 for women's depth-inlay shoes (with a range from $110 to $180). Some suppliers suggested regional or local variation in prices. These current market prices are between 27 and 47 percent above the demonstration maximum allowable charges, and cover (as in the demonstration price) casting, fitting, and return visits. Universally, the demonstration prices were considered to be too low, especially for depth-inlay shoes,[42] and some physicians said that the low prices prompted some of the best suppliers not to apply to be authorized suppliers in the demonstration.[43]

[42]Demonstration allowable charges were about 1.4 times the average wholesale prices quoted by suppliers interviewed for both types of shoes.

[43]We also reviewed Medicaid prices in 1992 in the 11 States that cover either type of therapeutic shoe. In States with fee schedules or maximum prices, custom-molded shoe prices range from $200 to $380 per pair, and depth-inlay shoe prices range from $80 to $150 per pair. Telephone calls were made to the 11 States.

5. Summary

We conclude that:

- Fewer of the beneficiaries than anticipated purchased the shoes, even though they were authorized for payment (almost 70 percent of those enrolled by July 31, 1992). The most common reasons that beneficiaries gave for not purchasing the shoes was that they had lost the paperwork, that they no longer needed the shoes. and that they had difficulty in obtaining the shoes.

- Fewer of the beneficiaries than anticipated renewed the benefit (23 percent of those eligible). The most common reasons that beneficiaries gave for not renewing the benefit were that they no longer needed the shoes or did not need replacements, were unaware that they could renew them, and felt that the shoes were uncomfortable.

- Very few beneficiaries received shoe modifications or replacement inlays, possibly due to the high rate at which custom-molded shoes were supplied.

- The lower than anticipated rate of shoe purchase- and benefit renewal does not appear to be due to features of the demonstration that would differ from a national program.

- A much higher proportion of custom-molded shoes was supplied than was anticipated based on clinicians' recommendations--due perhaps to the severity of the beneficiaries' clinical condition, or perhaps to the relatively higher price allowed for custom-molded shoes (it is not clear whether this pattern would change in a national program).

- Participating shoe suppliers would like to change the benefit in a national program. Additional types of modifications would be consistent with the legislative requirements, but some of the other proposals--higher prices, two pairs of shoes per year, and coverage for other types of shoes and inserts--would not be consistent with the legislative requirements.

- For the most part, claims and payment processing worked smoothly in the demonstration. In total Medicare paid just over $350,000 for shoes, inlays, and modifications.

F. APPLICABILITY OF DEMONSTRATION OPERATIONS AND PROCEDURES TO A NATIONAL BENEFIT

The demonstration incorporated the following beneficiary enrollment procedures:

- Physicians certified the eligibility of beneficiaries.
- Physicians prescribed the shoes.
- Beneficiaries received pribr authorization from a central location.
- Beneficiaries were assigned randomly to receive the shoe benefit (the treatment group) or to continue receiving standard coverage (the control group).

The last two features of the demonstration would not be required in a national benefit. As we discussed earlier in the chapter, these two special features may have reduced participation in the demonstration relative to actual participation in a national program. However, we do not believe that the demonstration operations enrolled a group of atypical or unrepresentative beneficiaries.

The demonstration included the following procedures for supplying therapeutic shoes:

- Suppliers were authorized to assign supplier identification and to check credentials.
- Quality was assured through professional certification requirements.
- A fee schedule was followed for the covered benefit.
- Suppliers accepted Medicare benefit assignment.

The last supplier procedure in the demonstration would not be required in a national benefit. We do not know whether requiring that Medicare assignment be accepted had any effect on

the types or quality of shoe suppliers who participated in the demonstration, although we believe that this requirement prevented some suppliers from participating, and some beneficiaries did not fill their prescriptions because it was too hard to get the shoes. Thus, in a national program. a slightly higher rate of filling prescriptions might be expected.

costs of all treatment group members identified from the claims history screen, plus half of those identified through the claims but who had not applied for participation. were to be compared with those of the screened group in the comparison sites. This comparison would have yielded an estimate of the total effects of the intervention, including the effects due to an increase in physicians' knowledge.[3]

Due to the small number of beneficiaries who enrolled in the demonstration, this design could not be implemented. Yet the fact that so few beneficiaries enrolled in the demonstration itself suggests that the educational effect of the demonstration was negligible. and thus the absence of the supplementary study to assess the impact of the educational effect is not a major constraint on the rigor of our analysis.

c. Low Participation

The original sample size target for the evaluation (27,500 participants) was set to provide an 80 percent chance of detecting a 6 percent increase in average Medicare expenditures.' The total sample that was enrolled in the demonstration over a 37-month period was only 4,373 beneficiaries--about 16 percent of the original sample-size target. The actual sample size gave us only a 1 in 14 chance of detecting cost-increases equivalent to the actual cost of the

[3]This design is described more fully in Brown et al. (1989).

[4]The calculation was made under the assumption that the annual average Medicare payment for the target group would be $2,500 (20 percent above the national average in 1986), with a coefficient of variation (ratio of the standard deviation of payment to the mean payment) of 2 (Brown et al. 1989, pp. 57-60). Under these assumptions, we would be able to detect an increase of $200 per shoe recipient, $150 per participating beneficiary (assuming 75 percent of participants receive shoes), or the assumed approximate cost of the shoe benefit, with 80 percent power.

therapeutic shoe coverage relative to the actual annual average payments for Medicare beneficiaries. ***We had 80 percent power for detecting differences larger than $1,381 per eligible beneficiary.'***

Given the small number of beneficiaries who enrolled in the demonstration, and thus the constraint it imposed on our ability to identify cost differences even if they did exist, we expanded our evaluation of the demonstration with a survey of the beneficiaries in May and June 1992. The purpose of the survey was to determine the effects of the demonstration on direct measures of behavioral change. In other words, the survey allowed us to study the conditions ***necessary*** for there to be an effect on costs and service use, rather than having to rely only on the measures of cost differences. The results are described in Chapter V.

"Note that the sample size necessary for maintaining 80 percent power for detecting a reduction in average Medicare costs of 6 percent (assuming that only 75 percent of treatment group members purchased the shoes, and that the average cost to Medicare for the shoes was only $200 per recipient) was calculated on the basis of a conservative estimate of the annual average Medicare payments for beneficiaries with diabetes (the basis was 20 percent above the national average Medicare payment in 1986 per beneficiary). Because the sample of 4,373 beneficiaries who enrolled in the demonstration had severe medical problems, their Medicare payments were $10,800 in the year preceding randomization. almost 4 times higher than the estimate used in the design report (see footnote 4). In contrast, the coefficient of variation for Medicare payments for all beneficiaries enrolled in the demonstration was 1.4, rather than 2.0, implying that these beneficiaries were more homogeneous than originally assumed. Had we known these estimates of Medicare payments in the year prior to randomization when we estimated sample requirements, we would have calculated that the sample size required to detect an effect of 1.4 percent (= 0.75 x ($200/$10,800)) with 80 percent power would have been about 247,000 Medicare beneficiaries, 9 times the sample size targeted for the demonstration.

B. THE DESIGN OF THE COST-EFFECTIVENESS ANALYSIS

1. How Would the Shoe Coverage Affect Casts?

The purpose of the evaluation was to determine whether implementing the shoe benefit coverage nationwide would generate a net increase in costs for the Medicare program. The evaluation was not intended to determine whether therapeutic shoes reduced the risk of amputation and other serious foot problems among participants. Furthermore, since the intervention was to provide shoe benefit coverage, the evaluation was not to assess whether the intervention changed the knowledge, attitudes, or prescribing practices of physicians.

Although the evaluation goal was narrow, it was important that a research strategy be formulated to capture all of the effects on Medicare costs, including those due to the effects of factors other than the demonstration. Two sets of factors could have reduced Medicare costs to offset the cost of the shoe benefit:

Changes in the Behavior and Knowledge of Beneficiaries

- Participating beneficiaries (both treatment and control group members) who would not have been able or willing to purchase prescribed therapeutic shoes in the absence of Medicare coverage for 80 percent of the cost did purchase the shoes when offered demonstration coverage, and some proportion of the group who benefitted from coverage avoided amputation or other serious foot problems (an impact on the treatment group).

- Having been notified about the new benefit coverage, diabetic beneficiaries learned more about their disease and proper self-care and physician care. This enhanced knowledge may have led to fewer diabetic-related health problems (particularly foot problems) and thus to lower Medicare costs (an impact on both the treatment and the control groups)

Changes in the Behavior of Physicians

- Physicians who in the absence of the cost coverage that helped defray the high out-of-pocket expenses of beneficiaries would not have prescribed shoes for their patients did prescribe shoes because the demonstration reduced the costs that beneficiaries would have incurred. Some proportion of the prescribed shoes may have averted serious foot problems (an impact on the treatment group)

These two sets of impacts could also have interacted. For example, an increase in the awareness of beneficiaries may have prompted them to ask questions of their physicians.

The experimental design captured the effects due to changes in the behavior and knowledge of participating beneficiaries because the control group did not receive either the pecuniary benefits or the possible accompanying educational benefits provided by the shoe suppliers."

2. **What Constitutes Cast-Effectiveness?**

The legislation that authorized the demonstration mandated that the cost-effectiveness of expanding Medicare Part B coverage to include therapeutic shoes for diabetic persons with severe foot disease be assessed. It did not define the term "cost-effectiveness." In the evaluation, we adopted a narrow definition of cost-effectiveness that focused on cost-neutrality from the perspective of Medicare payment, rather than a comprehensive cost-effectiveness analysis. This focus was consistent with the limited resources available for the demonstration and with the tenor of the authorizing legislation.

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[6]The experimental design did not capture any effects on Medicare costs due to an increase in physicians' knowledge from having been notified about the shoe coverage benefit (see subsection A.3.b), nor the increased awareness or behavioral changes among control group members because they may have expected to receive the therapeutic shoe benefit.

3. Analytic Approach for Measuring the Impact of the Demonstration Benefit

The demonstration was implemented in the expectation that therapeutic shoes would reduce the rate of lower-extremity amputations and related procedures among persons with severe diabetic foot disease, and that persons who could benefit from the shoes had not purchased them because they could not afford them. Thus, the demonstration provided Medicare Part B coverage for the shoes in the expectation that this expanded coverage would enable beneficiaries who would not otherwise be able to afford therapeutic shoes to obtain those shoes. In addition, the expanded Medicare coverage and demonstration publicity may have heightened awareness about the role of therapeutic shoes in dealing with severe diabetic foot disease. Together, the coverage and educational effects were expected to:

- Increase the purchase and use of therapeutic shoes by Medicare beneficiaries with severe diabetic foot disease
- Reduce the incidence of lower-extremity amputations and related procedures among Medicare beneficiaries with severe diabetic foot disease
- Reduce the number of hospital admissions and hospital days among Medicare beneficiaries with severe diabetic foot disease
- Reduce the overall Medicare expenditures for beneficiaries with severe diabetic foot disease
- Have potentially different effects for subgroups of beneficiaries differentiated by the stage of disease, the type of clinical care, and social and demographic characteristics

The key expectation for the cost-effectiveness analysis was a reduction in overall Medicare costs. This cost reduction was expected because the cost of the therapeutic shoes was

anticipated to be less than the reduction in Medicare costs for treatment of foot problems. Specifically, the authorizing legislation mandated a test of the following hypothesis:

> ***Beneficiaries eligible far the shoe-coverage benefit will not have higher average Medicare expenditures than beneficiaries not eligible for the shoe-coverage benefit.***

Congress intended that the therapeutic shoe benefit be offered to all eligible beneficiaries unless this hypothesis was rejected-that is, unless the demonstration benefits were shown to ***increase*** costs to Medicare.'

We assessed the cost-effectiveness of the Medicare therapeutic shoes benefit by comparing the total Medicare payments of treatment group members with those of control group members. We also compared footcare payments, service use, and amputation rates, to help interpret the differences in total Medicare payments. We used regression analysis to control for the concomitant characteristics of the beneficiaries (for example, their age and the clinical condition of their feet at randomization) in deriving estimates of the impact of the demonstration (that is, of being in the randomized treatment group) on Medicare payments. The regression analysis enabled us to increase the precision of our estimates of the effect on the outcomes of the treatment group by reducing the error variance. in addition, we tested whether the demonstration's effects differed for individuals with selected characteristics. To

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'In our report to HCFA that was the basis of the second Report to Congress, we "did not find the benefit to be not cost-effective and, thus, expected that the shoe benefit will be made part of Medicare" (Wooldridge et al. 1992). This comprehensive final report provides a more extensive analysis of cost-effectiveness, encompassing a larger sample and a longer follow-up period.

do this, we used regression analysis that included interactions between the treatment group indicator and the characteristics. (Appendix L provides a detailed discussion of the approach.)

We use a one-tail test of statistical significance to assess the null hypothesis that Medicare payments for the treatment were less than or equal to payments for the control group. We also used a one-tail test to assess whether the null hypothesis that the service use and amputation rates for the treatment group were ***greater than or*** **equal** ***to*** the rates for the control group. Note that the direction of the null hypothesis for Medicare payments is opposite to the direction of the null hypothesis for service utilization. Though the direction of the former test was mandated by Congress, the direction of the latter test was based on our intention to disprove the hypothesis that the shoe benefit would result in beneficiaries using Medicare services more frequently than the beneficiaries in the control group. The rejection of this hypothesis would lead us to believe that the shoe benefit reduces service utilization--which is what clinicians suggest is the effect of the shoes.

Finally, we considered whether the loss of some individuals from the experimental intervention (through enrollment in an HMO) in a potentially nonrandom fashion, or ***attrition bias***, may have negated the effects of randomization. (Appendix G provides a broader discussion of this issue.)

4. Outcomes Evaluated: Total Medicare Payments, Medicare Footcare Payments, Hospital Stays, Amputations, and Mortality

We studied the differences in the total Medicare payments (for both Part A and Part B covered services) of the treatment and control groups for a defined period after they had

applied for the therapeutic shoe benefit. The samples used and their follow-up periods are discussed in Section B.5 in this chapter. In order to understand the source of any observed differences in total Medicare payments, we also compared the treatment-control differences in Medicare payments for Part A covered services only and Part B covered services only. We also distinguished payments for footcare services from payments for other services and compared the total, Part A only, and Part B only footcare payments for the treatment and control groups. (Appendix H describes the conventions used to define total and footcare payments.)

Since hospital admissions are the highest-cost services, we also compared hospital service use (admissions and days) by the two groups for ail reasons for admission and for footcare admissions. In addition, since therapeutic shoes are expected to prevent lower-extremity amputations, we analyzed the difference in the proportion of treatment and control group members who had a lower-extremity amputation during the follow-up period. Finally, we also examined whether the proportion of individuals who died during the follow-up period was associated with the study group to which beneficiaries were assigned. Table IV.1 lists the outcomes analyzed in this report.

The demonstration sample resembles other samples of diabetic patients with foot problems described in published epidemiological studies in several respects but appears to have more severe foot problems. For instance, as shown in the first column of Table IV.2.

TABLE IV.1

OUTCOMES STUDIED IN THE EVALUATION

Outcome Measure
Costs
Medicare payment: Part A services
Medicare payment: Part B services
Medicare payment: all services[a]
Medicare payment: Part A footcare services
Medicare payment: Part B footcare services[b]
Medicare payment: all footcare services[c]
Services
Number of hospital admissions
Number of hospital admissions for footcare
Whether beneficiary was admitted to a hospital
Whether beneficiary was admitted to a hospital for footcare
Number of hospital days
Number of hospital days for footcare
Whether beneficiary had a lower-extremity amputation
Number of lower-extremity amputations
Mortality
Whether beneficiary died[d]

[a]Includes all Part A and Part B services, including the therapeutic shoe benefit.

[b]No footcare services could be identified from Part B records for physician office visits and other services provided in the office. Thus, the only Part B footcare services included here are for physician services rendered in a hospital setting and in a setting "other than an office" (see Table IV.4).

'Includes footcare services identified from Part A and Part B records, including the therapeutic shoe benefit.

[d]We did not expect mortality to be affected by the demonstration, but mortality rates were estimated for evidence of chance differences that could distort impact estimates for other outcomes.

TABLE IV.2

COMPARISON OF SELECTED OUTCOME MEASURES FOR THE DEMONSTRATION SAMPLE AND OTHER AT-RISK SAMPLES

Sample	Lower-Extremity Amputation Rate (per hundred)	Severe Foot Disease Rate (per hundred)	Total Medicare Cost per Year (dollars)	Cost of Lower-Extremity Amputation (dollars)
Medicare Therapeutic Shoe Demonstration	216 [a]	59.28 [d]	510,883 [f]	$14,158 [h]
Reiber (1992)				$12,230 [i]
Centers for Disease Control (1991), 1987-1988	1.32 [b]		--	--
Gupta and Veith (1988)				$27,255 [j]
American Diabetes Association (1986)	--		$8,600 [g]	--
Mackey et al. (1986)			--	s19.468 [k]
Palumbo and Melton (1985), 1980-1982	--	15.61 [e]	--	..
Most and Sinnock (1983)	1.00 [c]	--	--	--

[a] Refers to an average annual rate of having a lower-extremity amputation among all demonstration participants over the course of the demonstration.

[b] Refers to annual lower-extremity amputation rates among diabetic Medicare beneficiaries older than 65. Estimates are based on the National Hospital Discharge Survey for 1986.

'Refers to an annual rate among diabetic Medicare beneficiaries based on hospital abstracts from Illinois. Maine, Minnesota, Ohio. Rhode Island. and South Carolina during the period 1976-1986.

[d] Refers to the percentage of all beneficiaries in the demonstration who reported having previously had a foot ulceration as of the time they applied to the demonstration.

[e] Corresponds to older-onset diabetic patients age 65-74 with a history of ulcers or sores on feet or ankles based on the Wisconsin Epidemiology Study of Diabetic Retinopathy.

[f] Refers to the average annual Medicare payment for all demonstration participants in the year before they enrolled in the demonstration. (See Table 111.2.)

[g] Based on standardized national payments, weighted for a diabetes diagnosis.

[h] Refers to the average annual Medicare payments for the 155 beneficiaries who had at least one lower-extremity amputation between their date of enrollment in the demonstration and September 30, 1992 or their date of death, whichever occurred earlier.

[i] Refers to Medicare payments per amputation. Excludes toe amputations.

[j] A below-knee amputation.

[k] Refers to the average costs for a single hospitalization involving an amputation.

the reported annual rate of lower-extremity amputation (of unspecified extent) among Medicare beneficiaries with diabetes ranges from 1 to 2.2 percent, with the demonstration sample having the highest rate. The reported ranges of the prevalence rates for severe foot disease (defined as a history of ulcerations) are much broader, with 59 percent of the demonstration sample reporting a **previous ulceration** when they entered the demonstration compared to 16 percent in an elderly diabetic sample in Wisconsin. The payments associated with severe diabetic foot disease and amputation are shown in the fourth column of this table.

Based on annual Medicare payments reported in different studies, the demonstration sample appears to have much more severe problems than all diabetic Medicare beneficiaries. Table IV.2 shows the annual Medicare payments for diabetic beneficiaries. Here, our estimate of $10,883 substantially exceeds the estimate reported by the American Diabetes Association in 1986 ($8,600). Even with corrections for inflation since 1986, the demonstration sample's Medicare payments are still high. However, our estimate of the total Medicare payments during the year in which a lower-extremity amputation occurred ($14,158)[8] is similar to Reiber's estimate (1992)--$12,230, which refers to the Medicare payments only for any amputation except toe amputation. Our estimate is lower than that reported by Mackey et al. (1986)--$19,460--and almost half of that found by Gupta and Veith (1988)--$27,255. However, Mackey et al. do not specify whether they are referring to costs or charges, nor the

[8]This estimate refers to the average annual Medicare payment for the 155 beneficiaries who had at least one lower-extremity amputation between their date of enrollment in the demonstration and September 30, 1992 or their date of death, whichever occurred earlier.

period to which they refer. Also, the relatively small samples of amputees and large variances make it difficult to assess how different the estimates really are.

5. The Samples Used and Their Fallow-Up Periods

For this report, we analyzed the Medicare payment and service use of several different samples of demonstration participants, each allowing a different length of follow-up (see Table IV.3). Because the problems associated with improper footwear occur over time, depending on the severity of the patient's foot problems, we selected an l&month follow-up period to support longer-term findings on the effects of the therapeutic shoe benefit. However, we also analyzed a 6-month follow-up period because, though it provided a shorter time interval for determining the effects of the therapeutic shoe benefit, it yielded a sample size large enough to provide greater statistical power to discriminate differences in the outcomes of the two study groups. In addition, we also considered the 12-month follow-up period because it was the interval proposed in the design of the demonstration for analyzing the effects of the therapeutic shoe benefit (Brown et al. 1989), and because it offers a longer follow-up than the 6-month period with only moderate loss in sample size.

The 6-month follow-up sample included beneficiaries who applied between August 1, 1989 and February 25, 1992 and were randomized by March 31, 1992 (3,916 beneficiaries, who were enrolled in the demonstration for at least 6 months). This sampling period permitted us to

TABLE IV.3

NUMBER OF MEDICARE BENEFICIARIES INCLUDED IN THE SAMPLES USED FOR ANALYSIS OF OUTCOME MEASURES, BY FOLLOW-UP PERIOD AND STUDY GROUP

Follow-Up Period	Definition	Treatment Group	Control Group	All Beneficiaries
6 Months	Beneficiaria who enrolled and were randomized between August 1.1989 and March 31, 1992	1.950	1,956	3,906[a]
12 Months	Beneficiaries who enrolled and were randomized between August 1.1989 and September 30, 1991	1,711	1,717	3,428[b]
18 Months	Beneficiaries who enrolled and were randomized between August 1.1989 and March 31, 1991	1,412	1,415	2,827[c]
Variable	Beneficiaries who enrolled and were randomized between August 1, 1989 and September 17, 1992. This is also called the "demonstration sample"	2179	2,184	4,363[d]
Telephone Survey Sample	Beneficiaries who enrolled and were randomized between August 1, 1989 and June 30.1991. and survived to the date of interview (May or June of 1992)	1,120	1,099	2.219[e]

SOURCES: Demonstration Claims File, and Survey of Therapeutic Shoe Demonstration Participants.

[a]The 6-month sample excludes eight individuals who died after applying for the benefit but just before randomization. as well as two individuals for whom no Medicare claims records were found. Four beneficiaries were assigned to the treatment group. and six were assigned to the control group.

[b]The 12-month subsample excludes six individuals who died after applying for the benefit but just before randomization. as well as two individuals for whom no Medicate claims records were found. Three were assigned to the treatment group, and five were assigned to the control group.

[c]The 18-month subsample excludes six individuals who died after applying for the benefit but just before randomization. as well as one individual for whom no Medicare claims records were found. Two beneficiaries were assigned to the treatment group, and five were assigned to the control group.

[d]The number of individuals acluded from this sample is identical to the number acluded from the 6-month sample (that is. four beneficiaries in the treatment group and six beneficiaries in the control group).

[e]Among the 3.173 beneficiaries who had been randomized by June 30, 1991, 338 beneficiaria died before the survey was administered. and 74 beneficiaries were determined to have died during the course of the study. Among the survivors, the survey had an 80 percent response rate.

IV. HOW WAS THE EVALUATION DESIGNED?

A. FRAMEWORK AND ISSUES

Congress mandated a two-phased evaluation of the therapeutic shoe demonstration. In the first phase, the evaluation was to look for evidence that the shoe benefit was cost-effective and report to Congress on the findings. That Report to Congress was unable to find evidence of cost-effectiveness, and, hence, the demonstration was extended for a second 2-year phase. At the end of that period, following a Congressional mandate, a new report was issued which failed to reject the hypothesis that the demonstration was cost-effective. This report summarizes a final and more comprehensive evaluation of whether the shoe benefit was cost-effective (or, in terms of formal hypothesis testing, whether we could reject the null hypothesis that under the demonstration costs were lower than or equal to what they would have been without the intervention).

1. Cost Effectiveness

The term "cost-effectiveness" is central to the demonstration and its evaluation. For purposes of the evaluation, the benefit will be shown not to be cost-effective if the net cost to Medicare of providing the therapeutic shoes exceeds zero--that is, if the gross cost of covering the shoes exceeds any savings resulting from reduced use of other Medicare services (such as hospital stays) because the therapeutic shoes help prevent new foot problems. The purpose of the evaluation was not to determine whether the therapeutic shoe benefit was clinically effective (though it would be unlikely that the therapeutic shoes would be cost-

effective without being clinically effective), nor was it to address larger questions associated with the well-being of beneficiaries or social costs.'

This approach is contrary to the usual approach of statistically testing for evidence of program impacts, in which the null hypothesis is that there is no ***change*** in outcomes. The usual approach is conservative in that the analysis will not conclude that the program is truly effective unless there is a very low probability that this conclusion is incorrect (due to sampling variability). Because of the wording of the Congressional mandate, however, it was necessary to reverse this approach and frame the null hypothesis as costs being lower or equivalent under the demonstration to ensure a low probability of concluding that the benefit ***increased*** costs if it really had not. However, the usual approach also implies that the analyst may well conclude that the program was ineffective, even if it did have modest impacts (that is. there is a low probability--statistical power--to detect small effects).

The costs of the therapeutic shoe demonstration include the costs of the shoes themselves. any physician costs that would not otherwise have been incurred (such as a special visit to ask the physician to prescribe or fit the shoes), and any costs of care received under a comprehensive plan of care for the diabetes that exceed those that would have been incurred in the absence of the demonstration. The benefits expected from the therapeutic shoe demonstration are a reduction in footcare costs (from a reduction in the number of infections and amputations) and, consequently, an increase in the quality of and length of life. However.

'As noted in Chapter I, there is no definitive evidence that therapeutic shoes are clinically effective at preventing diabetic foot problems.

the evaluation of the demonstration was not intended to measure improvements in the quality of and the length of life among beneficiaries.

The cost-effectiveness of shoe benefit coverage will depend on the extent to which the shoe benefit alters the behavior of beneficiaries. In essence, we want to compare Medicare expenditures under the demonstration coverage with expenditures under the current Medicare program. We are concerned with net changes in Medicare payments, which are in turn determined by *net* changes in underlying behavior. Thus, the key determinants of whether the expanded coverage is cost-effective are the extent to which beneficiaries increase their purchase and use of therapeutic shoes and the extent to which the shoes enable beneficiaries to reduce their use of Medicare-covered footcare. Cost-effectiveness will depend, in turn, on the clinical effectiveness of the shoes at reducing the adverse consequences of severe diabetic foot disease, which requires that they be fitted properly by skilled clinicians, that they be modified as necessary and maintained in good condition, and that the beneficiaries wear them.

2. Issues Associated with Selecting the Evaluation Design

In designing the evaluation of the Medicare Therapeutic Shoe Demonstration. we considered both the internal and external validity of the demonstration. Internal validity asks whether what we observe--for example, a change in the average Medicare expenditures for persons with Medicare coverage for shoes--is in fact caused by the demonstration intervention. External validity asks whether the observed impacts of the demonstration would be replicated if implemented more widely--in this case, as a nationwide Medicare benefit. Policymakers are

interested in both concepts: the failure of either measure of validity weakens the relevance of the evaluation findings to policy decisions.

In designing the evaluation, we chose a randomized experiment, an evaluation design whose internal validity is clearly superior over the internal validity of comparison group and other evaluation designs for estimating the impacts of interventions. Only with random assignment do we have a basis for attributing what we observe to the impact of an intervention with a known degree of statistical precision. With respect to external validity, we sought to implement the demonstration on a large scale in the three States that contained the largest populations of diabetic Medicare beneficiaries, using procedures that were, as far as possible. likely to be used in a nationwide program. Along both dimensions of validity, we designed the demonstration as a fair test of the nationwide expansion of the Medicare Part B program to cover therapeutic shoes.

Our evaluation indicated two concerns about the internal and external validity of the demonstration as it was fielded. First, the enrollment of beneficiaries in the demonstration fell far short of the desired levels, leaving the evaluation with less statistical precision for detecting impacts than planned (a threat to internal validity). Second, although the shoe benefit was implemented in the demonstration quite smoothly overall, the demonstration enrollment process necessarily differed from the process that would be used in a national program. This difference appears to have influenced the participation of both physicians and beneficiaries, and thus will affect the external validity of the demonstration.

Given these concerns about validity, the evaluation closely examined the limitations of the conclusions that could be drawn from the demonstration. We conducted a survey of all the demonstration participants to determine their footcare and therapeutic shoe ownership and use in more depth. We examined the small body of clinical literature on the effectiveness of the shoes and compared the characteristics of demonstration participants with those of the broader population of diabetic Medicare beneficiaries. And we discussed the demonstration with participating physicians and authorized shoe suppliers in all three demonstration States.

Overall, our assessment of validity indicated that internal validity was still strong, although. in effect, the small sample size made it unlikely that we would detect small or moderate increases in Medicare payments (for example, there is only a 7 percent a priori probability that our sample would exhibit a statistically significant treatment-control difference in total Medicare costs if the true increase in Medicare costs were $118, the average annual actual cost of the shoe benefit per treatment group member). An additional discussion of this issue is provided in subsection 3.c. in this chapter. Similarly, both the beneficiary survey and the discussions with physicians, shoe suppliers, and beneficiaries enabled us to make reasoned judgments about the impacts of a nationwide shoe benefit, although the estimates for a national program are inherently less precise than those specific to the demonstration. A broader discussion of the costs of the shoe benefit if it were implemented nationwide is offered in Chapter VI.

3. Background to the Evaluation

a. Randomized Design

With a randomized design, we need not be concerned about whether observed differences in the outcomes of the treatment and control groups are due to inherent differences in other factors that could be related to those outcomes--for example, the underlying behavior of the two groups. Thus, an experimental design creates far fewer sources of differences between the two demonstration groups than does a quasi-experimental design or an observational study.

Because the randomized design was implemented as intended and was effective. the two groups of participants are comparable in terms of their observable characteristics (see Chapter III, Section B.4) and, presumably, their unobservable characteristics (for example, their willingness to see a doctor and whether they faithfully follow a prescribed footcare regimen). Furthermore, the two groups were exposed to the same set of prescribing physicians, practice patterns, and shoe suppliers because it was the individual beneficiaries rather than physicians or suppliers who were randomized. Hence, the statistical assessment of differences in postdemonstration outcomes can be attributed to the effects of the demonstration with a high degree of confidence. Estimates of program effects are unbiased and this unbiasedness is not dependent upon any statistical modeling assumptions.

b. Educational Effect

One design problem peculiar to this evaluation was that the demonstration might have affected participants through its ***educational*** effect on the prescribing behavior of physicians in addition to the direct effect to the shoes benefit itself. Although the intervention was the

Medicare coverage of therapeutic shoes, the necessary process of notifying the physicians about the shoe benefits may have enhanced their knowledge about the clinical benefits of the shoes (and about footcare for diabetic persons in general), which in turn could have affected the health of and Medicare payments incurred by all of their patients--control group members included. Hence, any effects of the intervention that may have been due to the demonstration-induced changes in physicians' knowledge would not be reflected in differences between the treatment and control groups. if these effects were sizeable, the overall effects of the demonstration (that is, the combined effect of shoe coverage and the enhanced education) could have been underestimated by treatment-control differences. While this could be viewed as a strength, in that any difference between the two groups should reflect only the direct effect of the benefit rather than the combined effect of education and benefit, the combined effect is actually the true impact of the program for assessing cost-effectiveness.

In order to overcome this problem, we initially proposed a supplementary study in which the group of all demonstration State beneficiaries would be compared with an *external comparison group,* both identified from Medicare claims. Our proposal was to select a set of comparison States that matched the demonstration States as closely as possible in terms of average Medicare payments and lower-extremity amputation rates in previous years.[2] Then. in both sets of States, we would have identified beneficiaries whose Part A Medicare claims indicated serious diabetic foot problems in the predemonstration period. The total Medicare

[2]Other matching criteria were also considered: the number of podiatrists per 10,000 beneficiaries and other observable criteria that reflect the availability of foot care.

study the experience of 3,906 Medicare beneficiaries over a 6-month follow-up period.' The 12-month follow-up sample included the subset of beneficiaries who applied by August 25, 1991 and were randomized by September 30, 1991 (3,436 beneficiaries, who were enrolled in the demonstration for at least 12 months). This sampling period permitted us to study the payments and service experience of 3,428 beneficiaries over a 12-month follow-up period." In addition, we studied the experience of the subset of demonstration participants who applied by February 25, 1991 and were randomized by March 31, 1991 (2,834 beneficiaries, who were enrolled in the demonstration for at least 18 months). This sampling period permitted us to study the payments and service use experience of 2,827 beneficiaries over an 18-month period."

In addition to the three nested samples defined by follow-up periods of fixed duration, we analyzed a sample in which the study period for each beneficiary varied according to the month of enrollment (and randomization) in the demonstration. We call this group the

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[9]The 6-month sample excludes eight individuals who were randomized (three into the treatment group and five into the control group), but who were later determined to have died after applying for the benefit but just before randomization, as well as two individuals for whom no Medicare claims records were found (one in the treatment group and one in the control group).

[10]The 12-month sample excludes six individuals who died after applying for the benefit but just before randomization, as well as two individuals for whom no Medicare claims records were found. Three of these beneficiaries were in the treatment group, and five were in the control group.

[11] The l&month sample excludes six individuals who died after applying for the benefit but just before randomization, as well as one individual for whom no Medicare claims records were found. Two of these beneficiaries were in the treatment group, and five were in the control group.

variable follow-up period sample. This sampling period permitted us to study the experience of 4,363 Medicare beneficiaries over an average follow-up period of 20 months." This sample yielded the largest sample size of all study groups, since it includes all persons who applied for coverage, which permitted us to estimate the average annual effects of the therapeutic shoe benefit over the entire demonstration period.[13] The number of beneficiaries in this sample by month of randomization and the number of person-months of participation in the demonstration are reported in Appendix I.

C. DATA SOURCES FOR AND THE LIMITATIONS OF THE COST-EFFECTIVENESS ANALYSIS

1. Medicare Part A and B Claims

The Medicare Automated Data Retrieval System (MADRS) file and the National Claims History (NCH) file are the sources of data on bills and claims for all Part A and Part B covered services for beneficiaries enrolled in the demonstration. We used these claims data to construct the outcome variables (for example, Medicare payment for the year after randomization) and control variables (for example, the Medicare payment for the year preceding randomization) that were used in the analysis. We drew data for calendar years

[12]The number of individuals excluded from this sample is identical with those excluded from the B-month sample (that is, four beneficiaries in the treatment group and six beneficiaries in the control group).

[13]This sample includes all persons who applied by September 8, 1992 and were randomized by September 17, 1992--that is, the entire demonstration population.

1988 through 1991 from the MADRS file and data for calendar year 1992 from the NCH database.[14] Table IV.4 summarizes the contents and limitations of claims data extracted from MADRS and NCH.

2. **Demonstration Claims**

The demonstration therapeutic shoe claims file contains identifying information on all beneficiaries who were supplied with shoes in the demonstration, the type of shoes they purchased, the type of shoe supplier, and the claim amount, as well as the amount actually paid by Medicare for shoes, inserts, and modifications. The claims used in this analysis were processed between the start of the demonstration in August 1989 and December 31, 1992, 2 months after the last therapeutic shoes eligible for demonstration coverage were provided."

3. **Demonstration Certification and Prescription Form**

The demonstration's Certification and Prescription Form provided identifying and demographic information on the beneficiary, a description of the patient's foot conditions (on the basis of which the physician certified the eligibility of the individual for the demonstration benefit), the estimated duration of diabetes, previous prescriptions or recommendations for

[14]**The** NCH database replaced the MADRS file as of 1992.

[15]**The** claims for shoes supplied in the last few months of the demonstration may not be complete, but because shoe suppliers (who accepted assignment of benefits) had an incentive to claim promptly, there are probably few missing claims.

TABLE IV.4

CONTENTS OF CLAIMS DATA EXTRACTED FROM THE MEDICARE AUTOMATED DATA RETRIEVAL SYSTEM AND THE NATIONAL CLAIMS HISTORY DATABASE

Type of Medicare Service	Type of Information Available: Payment in Dollars	Date of Service	Diagnosis/ Procedural code	Limitations
Part A				
inpatient hospital services	Yes	Yes	Diagnosis and procedure[a]	
Inpatient skilled nursing services	Yes	Yes	Diagnosis only	
Home health agency services	Yes	Yes	Diagnosis only	
Hospice services	Yes	Yes	Diagnosis only	
Rehabilitation services	Yes	Yes	Diagnosis only	
Part B				
Outpatient hospital services	Yes	Yes	Diagnosis and procedure[b]	
Physician services for "office-medical care"	Yes	No	None	Summary of payments for calendar year classified by maximum allowable charge[c]
Physician services for "office-other than medical care"	Yes	No	None	Summary of payments for calendar year classified by maximum allowable charge[c]
Physician services for visits provided in a setting "other than office"	Yes	Yes	None	Classified by maximum allowable charge
Other Part B[d]	Yes	Yes	None	

SOURCE: Medicare/Medicaid Statistical Files Manual. HCFA, Division of Documentation and Release. March 1990.

[a]Both diagnosis and procedure codes are based on a selection of International Classification of Disease (ICD-9CM) codes.

[b]Procedure codes are based on HCFA's Common Procedure Coding System (HCPCS).

[c]The National Claims History (NCH) extract file provide *all* payment records for Part B physician services provided in an office during a calendar year.

[d]For example, durable medical equipment.

therapeutic shoes, the type of shoes currently owned, and the specialty of the prescriber. (Appendix B includes a copy of the prescription form.)

4. **Medicare Eligibility History Files**

The Health Insurance Skeleton Eligibility Write-Off **(HISKEW)** file provided data on certain demographic and Medicare-entitlement characteristics at the time of **randomization.**[16] In addition to providing the age and sex of all individuals who are covered by Medicare, it provides the original reason for Medicare entitlement, indicates dual entitlement to both Medicare and Medicaid, and provides dates of death."

5. Beneficiary Survey

Because ***the purchase and use of therapeutic shoes*** is a precondition for clinical effectiveness and a reduction in use of other **footcare** services, we examined whether shoe use differed among the demonstration participants. The only valid and feasible way to obtain this information was to ask the beneficiaries directly about their shoe use during the demonstration period. For this purpose, we administered a telephone survey in May and June 1992 to all surviving Medicare beneficiaries who enrolled between August 1, 1989 and June 30, 1991. This survey provides a follow-up period that varies across beneficiaries, depending on when

[16]The HISKEW file is an extract of **HCFA's** main membership file of Medicare beneficiaries--the Health Insurance Master file.

"Although the Certification and Prescription Form provides information on date of birth and sex, these data were missing for many individuals. Because the **HISKEW** file had complete data on these two variables for almost all beneficiaries, we used data from this file only.

they enrolled. It provides approximately 34 months of follow-up on the earliest beneficiaries to enroll in the demonstration and 12 months of follow-up on beneficiaries who enrolled in June 1991. The survey yielded 2,219 completed interviews (a response rate of 80 percent; see Table IV.3). (Appendix K describes the interviewing procedures and the completion rates.)

The questionnaire contained items that measure whether respondents had special shoes, the circumstances under which they wore the shoes, the other types of footwear they owned. the extent of foot problems they had experienced since acquiring the shoes, and whether and the extent to which beneficiaries adhered to the clinical management of diabetes. This information enabled us to:

- Establish the shoe ownership rates for the treatment and control groups
- Determine whether those who own shoes wear them
- Determine the reasons that beneficiaries did not purchase and did not wear therapeutic shoes
- Establish whether foot problems are less common among those who wear therapeutic shoes

Thus, the data allow us to determine the effects of the program on the conditions necessary for there to be an 'effect on costs and service use, and provide an indication of the proportion of the treatment group whose costs and use might have been influenced by the shoe benefit. The results are discussed in the next chapter.

V. WAS THE DEMONSTRATION BENEFIT COST-EFFECTIVE?

This chapter assesses whether offering diabetic Medicare beneficiaries coverage for the therapeutic shoes was a cost-effective intervention; that is, did total Medicare payments decline, remain constant, or increase as a result of the benefit? First, we use data from a survey of beneficiaries to determine whether treatment and control group members differed in their purchase and use of therapeutic shoes and their diabetes management. Shoe ownership and use, and the monitoring of diabetic and foot problems, are all necessary conditions to reduce total Medicare costs. We then provide evidence of differences in hospital use, lower-extremity amputation, and mortality between treatment and control group members, since these differences are likely to be the major sources of any cost differences between the two groups. We then discuss the evidence on the differences between treatment and control group members in Medicare costs for several samples (and related follow-up periods). We close with a discussion of the implications of these results. This final section also presents the findings of the two Reports to Congress on the impacts of therapeutic shoes on Medicare costs.

A. DID THE DEMONSTRATION INCREASE SHOE PURCHASE AND USE?

Based on the data from the survey of beneficiaries, in this section we discuss whether shoe ownership and acquisition differed between study groups, whether beneficiaries who were in the treatment group used therapeutic shoes more frequently than their counterparts in the control group, and the reasons given by the beneficiaries for not using therapeutic shoes. We

also present a brief discussion of differences in monitoring of glucose levels and foot problems between the study groups.

1. Shoe Ownership and Purchase

The survey results indicate that Medicare coverage for therapeutic shoes increased the ownership of these shoes among participating beneficiaries, especially ownership of the more expensive type of custom-molded shoes. At the time they entered the demonstration, 32 percent of both the treatment group and the control group owned therapeutic shoes.* By the time of our follow-up survey, almost 3 years after the demonstration began, 85 percent of the treatment-group members reported owning therapeutic (either custom-molded or depth-inlay) shoes, compared with 55 percent of control group members (Table V.1).[2] This difference is significant (with a p value of essentially zero) and can be attributed confidently to the effect of the demonstration.[3] Of the specific types of therapeutic shoes owned, treatment-group members were twice as likely to own custom-molded shoes as were

*Both the demonstration sample discussed in Chapter III and the smaller survey sample reported therapeutic shoe ownership at enrollment of between 32 and 33 percent, in both the treatment and control groups.

[2]The shoe ownership rate in the treatment group is 16 percentage points higher than that reported in Chapter III. The reason for the difference is that the survey results include shoes that were not purchased using the demonstration benefit.

[3]As discussed in-depth in Chapter IV, the experimental design of the demonstration enables us to attribute observed differences between the treatment and control groups to the effect of the Medicare shoe coverage with a known degree of statistical precision. In essence, random assignment produced groups whose predemonstration (observed) characteristics were similar. Thus, differences that emerge between the groups after randomization can be attributed confidently to the impact of the demonstration.

TABLE V.1

PERCENTAGE OF PARTICIPATING BENEFICIARIES WHO OWNED VARIOUS TYPES OF SHOES AT THE TIME OF THE INTERVIEW, BY STUDY GROUP

Type of Shoe Owned	All	Treatment Group	Control Group	Difference	p[c]
Therapeutic					
Either Custom-Molded or Depth-Inlay Shoes	70.4	85.4	55.2	30.2	0.000
Custom-Molded Shoes	43.3	57.0	29.1	27.9	0.000
Depth-inlay Shoes	36.3	40.4	32.1	8.3	0.000
Non-Therapeutic					
Special Plastic Protective Shoes or Sandals	5.3	4.9	5.7	-0.8	0.441
Athletic Walking or Running Shoes	33.7	32.2	35.3	-3.1	0.126
Other Regular Closed Shoes with Fastenings[a]	51.4	48.4	54.4	-6.0	0.005
Other Regular Non-Prescription Sandals or Shoes[b]	48.1	49.1	47.1	2.0	0.351
Sample Size	2,219	1,120	1,099		

SOURCE: Survey of Therapeutic Shoe Demonstration Participants.

NOTE: Beneficiaries may have owned more than one type of shoe.

[a]Such as laces, velcro or buckles.

[b]Includes the few instances where a person reported having custom-made shoes.

[c]Refers to a two-tailed test.

control-group members (57 percent, compared with 29 percent), and 25 percent more likely to own depth-inlay shoes (40 percent, compared with 32 percent). Both of these differences are statistically significant.[4] Thus, the demonstration was especially effective at increasing the ownership of custom-molded shoes, which are about twice as expensive as depth-inlay shoes. The rate of ownership of nontherapeutic shoes--that is, special plastic protective shoes or sandals, athletic walking or running shoes, and other regular nonprescription sandals or shoes--was similar between the two groups. Note, however, that a higher proportion of the control group (54 percent) owned other closed shoes than did the treatment group (48 percent), a difference that is statistically significant.

Reports from control group members about their purchase of therapeutic shoes provide further evidence that Medicare coverage encouraged beneficiaries to obtain therapeutic shoes (Table V.2). About 48 percent of control group members in the survey sample reported purchasing therapeutic shoes in the last 3 years (which is approximately the timeframe of the demonstration). In comparison, 71 percent of the treatment-group members in the survey sample filled their prescriptions for therapeutic shoes in the demonstration. While this comparison may be subject to data limitations (we relied on control group members to recall their purchases, while we used demonstration records to determine purchases among treatment group members), the magnitude of the difference suggests that Medicare coverage was an important determinant of the acquisition of therapeutic footwear. Again, the effect was particularly large for custom-molded shoes, which are considerably more expensive than

[4]Some beneficiaries own both custom-molded and depth-inlay shoes.

TABLE V.2

PERCENTAGE OF PARTICIPATING BENEFICIARIES WHO PURCHASED THERAPEUTIC SHOES DURING THE DEMONSTRATION, BY STUDY GROUP

Type of Shoe Purchased	Percentage of Treatment-Group Members Who Filled Their Demonstration Shoe Prescription	Percentage of Control-Group Members Who Reported Buying Therapeutic Shoes in the Last 3 Years
Custom-Molded or Depth-Inlay Shoes	71.0	48.2
Custom-molded shoes	48.8	23.7
Depth-inlay shoes	32.7	29.3
Sample Size	1,120	1,099

SOURCE: Survey of Therapeutic Shoe Demonstration Participants and Demonstration Claims file.

depth-inlay shoes. Furthermore, 61 percent of the beneficiaries who had not bought therapeutic shoes said that they had not bought them because they were too expensive.

2. Shoe Use

Although the therapeutic shoe benefit provided the economic resources necessary to enable Medicare beneficiaries to purchase the shoes, any cost impact of the demonstration benefit--that is, whether shoe use among the beneficiaries in the treatment group actually reduced the incidence of foot-related problems and hence Medicare footcare costs--depended on whether the beneficiaries wore them. To identify whether the demonstration had the intended effect of increasing therapeutic shoe use, we measured when and where individuals wore the prescribed shoes.

In assessing therapeutic shoe use, we first examined the extent to which the beneficiaries in the demonstration walked outdoors. Survey data indicate that approximately 6 percent in each group ***could not walk at all***, and that another 10 percent in both groups reported only walking indoors. See Table V.3.

Among the 84 percent of the sample members who did walk outdoors, we see a striking (and statistically significant) difference in therapeutic shoe use. Treatment-group members were 66 percent more likely to use therapeutic shoes when walking outdoors than were control-group members (61 percent of the treatment group, compared with 37 percent of the control group, reported wearing their therapeutic shoes when they walked outside of the house). This difference appears to be due largely to the higher proportion of treatment group members who owned therapeutic shoes.

TABLE V.3

PERCENTAGE OF PARTICIPATING BENEFICIARIES, BY CATEGORY OF THERAPEUTIC SHOE USED FOR WALKING OUTDOORS, AND PERCENTAGE OF BENEFICIARIES WHO DID NOT USE THEIR THERAPEUTIC SHOES, BY REASON AND STUDY GROUP

	All		Treatment Group		Control Group	
Category	Number	Percent	Number	Percent	Number	Percent
Therapeutic Shoe Use for Walking Outdoors						
Does Not Walk Outdoors	36.5	16.4	168	15.0	197	17.9
Walks Outdoors but Does Not Own Therapeutic Shoes	538	23.9	127	11.3	403	36.7
Walks Outdoors and Wears Therapeutic Shoes Outdoors	1,993	49.3	688	61.4	405	36.Y
Walks Outdoors, Owns Therapeutic Shoes, but Does Not Wear Them Outdoors	220	9.9	133	11.8	87	7.Y
Missing	11	0.5	4	0.4	7	0.6
Sam ple Size	2,219	100.0[b]	1,120	100.0[b]	1,099	100.0
Reasons For Not Using Therapeutic Shoes For Those Who Owned Such Shoes and Walked Outdoors[a]						
Shoes Were Not Comfortable	115	52.5[c]	71	53.8[c]	44	50.8[c]
Fit Poorly/Not Made Properly	32	14.6[c]	25	18.9[c]	7	8.1[c]
Shoes Not Appmpriste--New Foot Problem	21	9.6[c]	12	9.1[c]	Y	10.3[c]
Did Not Like the Way They Look	15	6.8[c]	12	9.1[c]	3	3.4[c]
Doctor Recommended Not Wearing Them	13	5.9[c]	4	8.3[c]	2	2.3[c]
Shoes Need to Be Repaired/Worn Out	8	3.7[c]	23	3.0[c]	4	4.7[c]
Ocher	39	17.8[c]		17.4[c]	16	18.4[c]
Do Not Know	3	1.4[c]	2	1.5[c]	1	1.2[c]
Sample Size	220		133		87	

SOURCE: Survey of Therapeutic Shoe Demonstration participants.

[a]Multiple responses were allowed.

[b]Numbers and percents do not add to total due to rounding.

[c]Percent refers to all beneficiaries who walked outdoors. owned therapeutic shoes as of the interview, but did not wear them outdoors.

Approximately 10 percent (220) of all beneficiaries who owned therapeutic shoes and walked outdoors did not wear the therapeutic shoes outdoors. The primary reason that beneficiaries did not wear their therapeutic shoes outdoors is that the shoes were uncomfortable.[5] More than half of these 220 beneficiaries gave this reason, and the difference between the study groups is not statistically significant. Another reason was that the shoes fit poorly or were not made properly; almost 19 percent of treatment group members, compared with 8 percent of control group members, gave this reason. Other reasons were that the shoes were not appropriate because the beneficiary had developed a new foot problem (10 percent), that the beneficiary thought that the shoes were unattractive (7 percent), that the beneficiary's doctor recommended not wearing them (6 percent), and that the shoes needed to be repaired or were worn out (4 percent).

Treatment group members who owned the shoes and walked outdoors increased their use of custom-molded shoes but not of depth-inlay shoes (see Table V.4). Almost 47 percent of the beneficiaries in the treatment group reported wearing custom-molded shoes "most often" when they walked outdoors in the 2 weeks prior to the interview, over 30 percent the rate observed (36 percent) in the control group. In contrast, more control group beneficiaries wore depth-inlay shoes most often in the 2-week reference period than their counterparts in the

[5] In analyzing why beneficiaries did not use their therapeutic shoes, we concentrate on the group who actually walked outdoors (84 percent of the sample). This analysis also excludes beneficiaries who were able to walk outdoors but did not own therapeutic shoes (11 and 37 percent for the treatment and controls group, respectively), and those who owned the shoes and wore them when they walked outdoors (61 and 37 percent, respectively). Thus, 133 beneficiaries in the treatment group and 87 in the control group (12 and 8 percent of all beneficiaries in the treatment and control groups, respectively) provided information on why they did not wear their therapeutic shoes outdoors (see Table V.3).

TABLE V.4

TYPES OF SHOES WORN BY PARTICIPATING BENEFICIARIES WHO WALK OUTDOORS AND REPORTED OWNING THERAPEUTIC SHOES

Type of Shoe Worn to Walk Outdoors	Percentage of Ail Sample Members	Percentage of Treatment Group Members	Percentage of Control Group Mcmbcrs
Wore Custom-Molded Shoes	42.6	46.6	36.1
Wore Depth-Inlay Shoes	33.2	29.7	38.9
Wore Nonprescription Shoes"	22.7	22.6	23.1
Did Not Wear Shoes	0.3	0.0	0.5
Do Not Know	1.2	1.1	1.4
Sample Size	1,324	825	499

SOURCE: Survcy of Thcrapcutic Shoe Dcmonstration Participants.

Non: This table is based on responses to the interview question: "During the past 2 weeks, which shoes did you wear most often when you walked outdoors?" The sample includes only those persons who owned therapeutic shoes.

'Nonprescription shoes include special plastic protective sandals, athletic walking/running shoes, other regular nonprescription, closed shoes with fastenings, and other nonprescription sandals.

treatment group: 39 percent of the control group, compared with about 30 percent of the treatment group. Almost one-quarter of the beneficiaries who walked outdoors and owned therapeutic shoes either wore'nonprescription shoes or did not wear shoes outdoors.

Note that these differences in shoe use could be attributed to the different rate of therapeutic shoe ownership between the study groups, since the proportion of treatment group and control group beneficiaries who walked outdoors is very similar (85 and 82 percent in the treatment and control groups, respectively; the difference between these two figures is not statistically significant at conventional levels ($p = 0.063$)). In summary, the demonstration was especially effective at increasing the use of custom-molded shoes--the more expensive type of specialized shoes--among the beneficiaries who needed them to walk outdoors.

3. **Diabetes Monitoring**

Because clinicians concur that for therapeutic shoes to be effective, the patients' diabetes must be controlled, requiring that they have their diabetes and feet monitored regularly, Congress required demonstration beneficiaries to be in a comprehensive plan of care. To determine whether participating beneficiaries were being monitored, we asked them about glucose and foot checks by a doctor.

We found that the rate at which treatment and control group members were monitored for glucose and foot problems was similar and that in both groups monitoring was nearly universal. For instance, less than 4 percent of each group of beneficiaries did not have their glucose levels checked during the 6 months prior to the interview (Table **V.5). Also, for** beneficiaries who received glucose-level testing, differences between treatment and control

TABLE V.5

PERCENTAGE OF PARTICIPATING BENEFICIARIES WHOSE URINE OR BLOOD WAS CHECKED FOR GLUCOSE IN THE 6 MONTHS PRIOR TO THE INTERVIEW, BY STUDY GROUP

Number of Times Checked	All	Treatment Group	Control Group	Difference
Zero	3.2	2.8	3.6	-0.8
Less than Three	26.9	26.1	27.8	-1.7
Three through Five	24.6	25.5	23.7	1.8
Six through Ten	30.4	30.6	30.1	0.5
Greater than Ten	13.6	13.2	14.1	-0.9
Don't Know	1.2	1.7	0.7	1.0
Sample Size	2,219	1.120	1.099	

SOURCE: Survey of Therapeutic Shoe Demonstration Participants.

NOTE: The p-value for the Chi-square test (.278) indicated no statistically significant differences between the treatment and control groups in the frequency of glucose-level testing.

group members were small, statistically insignificant, and varied in either direction. Only 9.6 percent of control group members did not have their feet checked at all during the 6 months prior to the interview while 8.2 percent of treatment group members did not have their feet checked during that time (see Table V.6). Although treatment group members were slightly more likely to have had a foot examination, the small difference was not statistically significant.

4. Summary of the Survey Findings

In summary, the survey of therapeutic shoe use among the Medicare beneficiaries who enrolled and were randomized between August 1, 1989 and June 30, 1991 and survived to the date of interview (May or June of 1992) showed that:

- A larger proportion of the beneficiaries in the treatment group purchased and owned therapeutic shoes than their counterparts in the control group. The demonstration was particularly effective at increasing ownership of custom-molded shoes. ***The difference in purchase and ownership rates can be attributed to the demonstration.*** However, the proportion of control group members who owned therapeutic shoes rose from 32 percent at enrollment to more than 50 percent at the survey.

- As a result of the increased therapeutic shoe ownership, a higher proportion of the treatment group wore therapeutic shoes when walking outside than the control group.

- Among those 220 beneficiaries who were able to walk outdoors but who did not wear their therapeutic shoes, most of them reported not wearing them because they were uncomfortable or did not fit properly. Those who received the shoe benefit were twice as likely to complain about the fit as were control group members who acquired the therapeutic shoes on their own.

- Among beneficiaries who could walk outdoors and reported having therapeutic shoes, a larger proportion of beneficiaries in the treatment group wore custom-molded shoes, the more expensive type of specialized shoes, probably because they were more likely to own this type of shoe.

TABLE V.6

PERCENTAGE OF PARTICIPATING BENEFICIARIES WHOSE FEET WERE CHECKED IN THE 6 MONTHS PRIOR TO THE INTERVIEW, BY STUDY GROUP

Number of Times Checked	All	Treatment Group	Control Group	Difference
None	8.9	8.2	9.6	-1.4
Less than Three	20.6	21.0	20.3	0.7
Three through Five	29.8	30.8	28.8	2.0
Six through Ten	24.1	24.5	23.7	0.8
Greater than Ten	16.0	15.0	17.1	-2.1
Don't Know	0.6	0.5	0.6	-0.1
Sample Size	**2,219**	1,120	1,099	

SOURCE: Survey of Therapeutic Shoe Demonstration Participants.

NOTE: The p-value for the Chi-square test (.577) indicated no statistically significant differences between the treatment and control groups in the frequency of checking their feet.

- Very few participants had not had their glucose monitored in the past 6 months, and only 10 percent had not had their feet checked, indicating that most of them were receiving care for their diabetes and their feet. Treatment and control group members received a similar level of monitoring in the 6 months preceding the interview for glucose levels in their urine or blood, and for foot problems. These results are consistent with Congress' intention that the therapeutic shoes be supplied to beneficiaries receiving comprehensive care for their diabetes.

B. DID COVERAGE REDUCE HOSPITAL ADMISSIONS, AMPUTATIONS, AND MORTALITY?

The expected mechanism for shoes to reduce Medicare costs was through reduced hospital admissions for lower extremity amputations and other footcare procedures. Therefore, we evaluated differences in total hospital admissions, admissions for all footcare-related problems, and admissions for lower-extremity amputations.

1. Overview of Results[6]

The overall rate of hospital utilization among participating beneficiaries was high, although the difference between treatment and control group members was not statistically significant. A summary of the results of our analysis of the service-use experience of the Medicare beneficiaries enrolled in the demonstration throughout three follow-up periods of fixed length (f&month, 12-month, and l&month periods) and one follow-up period of variable length is shown in Table V.7. These results can be highlighted as follows:

[6]All the results presented in this and the following sections are based on estimated ordinary least squares (OLS), logit, and Poisson regression models which are used to compute adjusted treatment and control group means (or probabilities) for the outcome variable by varying study group but keeping constant age at randomization, gender, race or ethnicity, State of residence, original reason for entitlement, dual entitlement for Medicaid and Medicare. duration of diabetes, clinical impairment at enrollment, and Medicare payments in the year prior to randomization. (For more details, see Appendix L.)

TABLE V.7

SUMMARY OF DIFFERENCES IN SERVICE USE, LOWER-EXTREMITY AMPUTATIONS AND MORTALITY BETWEEN BENEFICIARIES IN TI IE TREATMENT AND CONTROL GROUPS FOR FIXED FOLLOW-UP AND VARIABLE FOLLOW-IJP SAMPLES

	Sample			
Outcome Measure	6-Month Follow-Up	12-Month Follow-t Jp	18-Month Follow-Up	Variable Follow-Up
All Admissions				
Average Number of Hospital Admissions	−			+
Percent of Beneficiaries with a Hospital Admission	−	+	+	NA
Average Number of Hospital Days	−			
Footcare Admissions				
Average Number of Hospital Admissions	+	+	+	+
Percent of Beneficiaries with a Hospital Admission	+	+	+	NA
Average Number of Hospital Days	+	+		
Percent of Beneficiaries Who Had a Lower-Extremity Amputation in Period	+	+	+	
Percent of Beneficiaries Who Died in Period	+	+	+	+
Sample Size	3,906	3,428	2,827	4,363

SOURCE: Tables V.R. V.9, V.10, and V.11.

NOTES: +(-) indicates that the beneficiaries in the treatment group had a higher (lower) rcgrcssion-adjusted value for the outcome measure than did beneficiaries in the control group.

• denotes that the difference in outcomes is statistically significant at the 5 percent level for a one-tail test to assess the null hypothesis that service use, lower-extremity amputation or mortality were greater than or equal to those for the control group.

NA = Not applicable.

- In most cases, the average number of hospital admissions, the proportion admitted to the hospital, and the number of days in the hospital for ***all services*** were lower among beneficiaries in the treatment group than among those in the control group, although these differences are not statistically significant.

- The number of hospital admissions for ***footcare*** *services* was higher among beneficiaries in the treatment group than among those in the control group, although in no instance was the difference statistically significant.

- The proportion of treatment group beneficiaries who had a lower-extremity amputation or who died was higher than the proportion among the control group, although these differences are not statistically significant.

We studied the service-use experience of beneficiaries throughout three fixed-length follow-up periods and a variable-length follow-up period; the longest follow-up period (18 months) had the smallest sample (2,827) and the shortest follow-up period (6 months) had the largest sample (3,906). Thus, the samples involved trade-offs between sample size and longer periods of follow-up for evaluating the problems that can arise over time without proper footcare (see Chapter IV, section B). However, because we can study only the experience of individuals who can potentially be observed for at least the duration of the fixed study period. the outcomes of these samples represent the experience of limited numbers of beneficiaries enrolled in the demonstration over a fixed-length period of time after randomization. In contrast, the results for the variable follow-up period represent the average annual service-use experience of ***all*** beneficiaries who enrolled in the demonstration, and should be interpreted as a broad measure of annual service use for all the Medicare beneficiaries who participated in the demonstration. Tables V.8 through V.10 present the results for the 6-month, 12-month, and l&month follow-up periods, and Table V. 11 presents our findings for the variable follow-up sample. In the remainder of this section. we review the most relevant findings of our

TABLE V.8

SERVICE USE DURING THE FIRST 6 MONTHS AFTER SHOES WERE PRESCRIBED

Outcome Measure	Treatment Group	Control Group	Difference[a]	p-Value[b]
Average Number of Hospital Admissions				
Total	0.44	0.47	-0.03	0.065
Footcare	0.13	0.11	0.02	0.982
Percent of Beneficiaries with a Hospital Admission				
Total	27.96	29.69	-1.73	0.109
Footcarc	9.94	9.12	0.82	0.815
Average Number of Hospital Days				
Total	4.87	5.29	-0.42	0.154
Footcarc	1.92	1.67	0.25	0.842
Percent of Beneficiaries Who Had a Lower-Extremity Amputation in Period	1.49	1.12	0.37 [c]	0.790
Percent of Beneficiaries Who Died in Period	4.84	4.02	0.82	0.090
Sample Size	1,950	1,956		

SOURCE: MADRS file extracts for 1989, 1990, and 1991 and NCH file extracts for 1992 for beneficiaries with complete HISKEW file records who enrolled between August 1, 1989 and March 31, 1992.

[a]Treatment and control group means or probabilities were calculated from an OLS, Poisson. or logit regression model varying study group but keeping the following factors: age at randomization. gender, race, duration of diabetes, State of rcsidencc, original reason for cntitlcmcnt. dual entitlement, duration of diabetes, clinical impairment at enrollment, and Medicarc reimbursemcnt in the year prior to randomization, constant (see Appendix L).

[b]For a one-tail test to assess the null hypothesis that service use was greater than or equal to the service use for the control group.

'Simple difference in means (see Appendix L).

TABLE V.9

SERVICE USE DURING THE FIRST 12 MONTHS AFTER SHOES WERE PRESCRIBED

Outcome Measure	Treatment Group	Control Group	Difference[a]	p-Value[b]
Average Number of Hospital Admissions				
Total	0.86	0.89	-0.03	0.227
Footcare	0.22	0.20	0.02	0.887
Percent of Beneficiaries with a Hospital Admission				
Total	44.78	44.67	0.11	0.526
Footcare	15.09	14.21	0.88	0.537
Average Number of Hospital Days				
Total	9.67	10.06	-0.39	0.287
Footcare	3.06	2.98	0.06	0.594
Percent of Beneficiaries Who Had a Lower-Extremity Amputation in Period	2.57	1.80	0.77 [c]	0.935
Percent of Bcneficiarics Who Died in Period	9.13	8.03	1.10	0.884
Sample Size	1,711	1,717		

SOURCE: MADRS file extracts for 1989, 1990, and 1991, and NCH tile extracts for 1992 for beneficiaries with complete HISKEW file records who enrolled between August 1, 1989 and September 30, 1991.

"Treatment and control group means or probabilities were calculated from an OLS, Poisson, or logit regression model varying study group but keeping the following factors: age at randomization. gender, race, duration of diabetes, State of residence, original reason for entitlement, dual entitlement, duration of diabetes, clinical impairment at enrollment, and Medicare reimbursement in the year prior to randomization, constant (see Appendix L).

[b]For a one-tail test to assess the null hypothesis that service use was greater than or equal to the service use for the control group.

'Regression-adjusted only by age at randomization (see Appendix L).

TABLE V.10

SERVICE USE DURING THE FIRST 18 MONTHS AFTER SHOES WERE PRESCRIBED

Outcome Measure	Treatment Group	Control Group	Difference[a]	p-Value[b]
Average Number of Hospital Admissions				
Total	1.30	1.31	-0.01	0.449
Footcare	0.31	0.30	0.01	0.805
Percent of Beneficiaries with a Hospital Admission				
Total	56.84	53.95	2.89	0.947
Footcare	20.26	18.81	1.45	0.847
Average Number of Hospital Days				
Total	14.25	15.53	-1.28	0.101
Footcare	4.31	4.65	-0.34	0.253
Percent of Beneficiaries Who Had a Lower-Extremity Amputation in Period	3.67	2.98	0.69	0.847
Percent of Beneficiaries Who Died in Period	12.96	11.88	1.08	0.818
Sample Size	1,412	1,415		

SOURCE: MADRS file extracts for 1989, 1990, and 1991 and NCH file extracts for 1992 for beneficiaries with complete HISKEW file records who enrolled between August 1, 1989 and March 31, 1991.

[a]Treatment and control group means or probabilities were calculated from an OLS, Poisson, or logit regression model varying study group but keeping the following factors: age at randomization, gender, race, duration of diabetes, State of residence, original reason for entitlement, dual entitlement, duration of diabetes, clinical impairment at enrollment, and Medicare reimbursement in the year prior to randomization, constant (see Appendix L).

[b]For a one-tail test to assess the null hypothesis that service use was greater than or equal to the service use for the control group.

'Regression-adjusted only by age at randomization (see Appendix L).

TABLE V. 11

SERVICE USE BETWEEN RANDOMIZATION AND SEPTEMBER 30.1992

Outcome Mcasurc	Treatment Group	Control Group	Difference"	p-Valuc[b]
Annual Average Rate of Hospital Admission (per 100 Persons at Risk)				
Total	98.99	98.63	0.36	0.53 1
Footcare	23.59	22.38	1.21	0.830
Annual Average Number of Hospital Days				
Total	10.33	11.10	-0.77	0.099
Footcare	3.26	3.27	-0.02	0.480
Annual Lower-Extremity Amputation Rate (per 100 Persons at Risk)	2.61	2.67	-0.06 [c]	0.424
Annual Mortality Rate (per 100 Persons at Risk)	9.20	8.72	0.48	0.573
Sample Size	2,179	2,184		

SOURCE: MADRS file extracts for 1989, 1990, and 1991 and NCH file extracts for 1992 for beneliciarics with complete HISKEW file records who enrolled between August 1, 1989 and September 17, 1992.

"Treatment and control group average rates were calculated from a Poisson regression model varying study group but keeping the following factors: age at randomization, gcndcr. race, duration ol diabetes, State of residence, original reason for cntitlcment, dual entitlcment, duration of diabetes, clinical impairment at enrollment, and Medicare reimbursement in the year prior to randomization. constant (see Appendix L).

'For a one-tail test to assess the null hypothesis that service use was greater than or equal to the service use for the control group.

'Regression-adjusted only by age at randomization (see Appendix L).

analyses, focusing on the results for the 12-month sample, and comment on the comparability of results across the other samples.

2. **Hospital Admissions**

About 45 percent of both groups of beneficiaries were admitted to a hospital during their first year in the demonstration, about one third (14 to 15 percent) of whom received Medicare reimbursed footcare services. Beneficiaries were admitted to a hospital an average of just less than one time **(0.9)** during their first year in the demonstration, and about 0.2 times for footcare. Note, however, that the difference in the average number of admissions between treatment and control group members is about 0.02 admissions per beneficiary for all three fiied follow-up period samples and is not statistically significant in any instance.

Both groups of beneficiaries spent about 10 days in the hospital on average over the 12-month follow-up period, with the average number of days for those with 1 or more admissions being about 23 days. For footcare admissions, the results were comparable--3 days in a hospital on average among both groups of beneficiaries, but close to 21 days for beneficiaries who were admitted one or more times during their first year in the demonstration. The differences between treatment and control groups are not statistically significant in any of the samples, nor is there a clear pattern of higher service use among treatment group members than among the control group across different lengths of follow-up.

3. **Lower-Extremity Amputations**

Approximately 2.6 percent of treatment group beneficiaries had at least one lower-extremity amputation within the first 12 months after randomization, compared to 1.8 percent

of control group members, a difference which is not statistically significant for this or any of the other three samples (Table V.9). Furthermore, note that the variable follow-up period. *control* group beneficiaries had a higher annual rate of amputation than their counterparts in the treatment group. However, this difference is neither large nor statistically significant.'

Among those beneficiaries who had a lower-extremity amputation during the follow-up period, a substantial proportion died during the first year after randomization. Almost two-thirds of those in the control group and about half of those in the treatment group who had an amputation in the period died before the end of the 12-month period. The difference is not statistically significant, however, and the small number of observations hinders our ability to ascertain the robustness of these estimates. Note also that, because this demonstration was not designed to assess whether the therapeutic shoe benefit averted deaths due to a reduction in the number of lower-extremity amputations, no inferences should be drawn about the clinical effectiveness of therapeutic shoes from these results.

4. Mortality

Approximately 8 to 9 percent of all beneficiaries died within a year after the date of randomization. In each of the four samples, a higher proportion of beneficiaries in the treatment group than in the control group died during the study period. However, the

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'The annual lower-extremity amputation rate for the variable length follow-up period is slightly higher than the corresponding estimate for the participants' first year in the demonstration because the variable follow-up result is an annualized measure of the experience of the demonstration beneficiaries until September 30, 1992 or their date of death, whichever occurred earlier (see Tables V.9 and V.ll). In contrast, the measures based on a fixed follow-up period are derived for only those beneficiaries who were alive throughout the study period.

differences are small in each case and not significantly different from zero statistically at conventional levels.

C. WERE THERE ANY DIFFERENCES IN MEDICARE PAYMENTS?

1. Overview of Results

Consistent with their high hospital use for footcare and amputation rates, the Medicare payments for participating beneficiaries were about $13,000 per year--about five times the payment for the average Medicare recipient in the national population in 1989.[8] Among the participating beneficiaries, risk group--defined in terms of the original reasons for Medicare entitlement--and Medicare payments are related. Beneficiaries who enrolled in Medicare because of end-stage renal disease had unadjusted average Medicare payments for all services over the 12 months after randomization 3.5 times the payments for those who enrolled because of old age, and their payments for footcare were 2.2 times larger. Similarly, the severity of foot problems at randomization correlates with Medicare payments over the subsequent year. Those who had already had a lower extremity amputation had Medicare payments 2.5 times the payments for those who had experienced neither an amputation nor an ulcer, and their footcare payments were 7 times larger.

Treatment-control differences reveal no consistent evidence of program effects on either total Medicare payments or footcare payments. The Medicare payments for all services and for Part A and Part B services separately were higher for treatment group beneficiaries than

[8]The average reimbursement for hospital insurance and supplementary medical insurance for 1989 was $2,704 per beneficiary enrolled in the program (U.S. House of Representatives 1992, Table 31).

for control group beneficiaries, but the difference is not statistically significant in any of the samples.[9] The Medicare payments for footcare also were higher for beneficiaries in the treatment group in all but one instance (that is, Part A footcare payments in the 18-month sample). The difference in Medicare payments for footcare is statistically significant only for the 6-month sample. Table V.12 summarizes the results of our regression analysis of Medicare payments for beneficiaries for the four study samples. Actual estimates are provided in Table V.13 through V.16. Below, we describe the most relevant findings of our analyses by focusing on the results for the 12-month sample, and comment on the comparability of results across samples.

2. **Annual Medicare Payments**

For their first year in the demonstration, Medicare payments for all services among the treatment group were $451 (3.8 percent) higher than those for all services among the control group, as shown in Table V.14. Medicare payments for both Part A services and Part B services were higher among the treatment group. Similarly, payments for all footcare services were $318 (14.6 percent) higher among beneficiaries in the treatment group, considerably exceeding the cost of the shoe benefit ($118). In none of these comparisons are the differences statistically significant at the conventional levels adopted in this report. Part A services comprise the largest component of payments for all services and for footcare services (about 80 percent). These findings are comparable across the other samples considered.

[9] As discussed in the final section of this chapter on page 167, these results are very similar to those which were the basis for the April 26, 1993 Report to Congress, which resulted in a therapeutic shoe benefit being added to the Medicare program.

TABLE V.12

SUMMARY OF DIFFERENCES IN MEDICARE PAYMENTS FOR ALL SERVICES AND FOOTCARE SERVICES BETWEEN BENEFICIARIES IN THE TREATMENT AND CONTROL GROUPS FOR FIXED AND VARIABLE FOLLOW-UP SAMPLES

	Sample			
Outcome Measure	6-Month Follow-Un	12-Month Follow-Un	18-Month Follow-Un	Variable Follow-Un
Average Medicare **Payment**				
Part A	+	+	+	+
Part B	+	+	+	+
All Services	+	+	+	+
Average **Medicare Footcare Payment**				
Part A	+	+	-	+
Part B	+	+	+	+
All Services	+*	+	+	+
Sample Size	**3,906**	**3,428**	**2,827**	**4363**

SOURCE: Tables V.13, V.14, V.15, and V.16.

NOTES: +(-) denotes that the beneficiaries in the trcatmcnt group had a higher (lower) value for the outcome measure than did bcneticiarics in the control group.

*denotes that the difference in outcomes is statistically significant at the 5 percent level for a one-tail test to assess the null hypothesis that Medicare payments for the trcatmcnt were less than or equal to payments of the control group.

TABLE V.13

MEDICARE PAYMENTS DURING THE FIRST 6 MONTHS AFTER SHOES WERE PRESCRIBED

Outcome Mcasurc	Treatment Group	Control Group	Difference[a]	p-Valuc[b]
Average Medicare Payment (Dollars)				
Part A	3,714.86	3,696.63	18.23	0.472
Part B	2,633.75	2,564.09	69.66	0.242
Shoe Benefit	113.24	--	--	--
All Services[c]	6,46 1.92	6,260.64	201.28	0.268
Average Medicare Footcare Payment (Dollars)				
Part A	1.246.19	1,056.78	189.41	0.086
Part B[d]	244.18	199.48	44.70	0.072
Shoe Bcncfit	113.24	--	--	--
All Services[d]	1,603.67	1.256.18	347.49	0.013
Sample Size	**1,950**	**1,956**		

SOURCE: MADRS file extracts for 1989, 1990, and 1991 and NCH Iilc extracts for 1992 for hcneficiarics with complete HISKEW file records, and HCFA shoe-claim file for beneficiarics who enrolled hctween August 1, 1989 and March 31. 1992.

NOTE: The sum of payments for Part A and Part B services may not add up to the payment for all services due to rounding.

"Treatment and control group means were calculated from an OLS regression model varying study group but keeping the following factors: age at randomization, gcndcr, race, State of rcsidcncc. original reason for entitlement, dual entitlement, duration of diabetes, clinical impairment at enrollment, and Medicare reimbursement in the year prior to randomization. constant (see Appendix L).

"For one-tail test of the null hypothesis that Medicare payments for the treatment were less than or equal to payments for the control group.

'Includes all Part A and Part B services, including the therapeutic shoe benefit.

[d]No footcare services could be identified from records for Part B physician office visit and other services provided in the office.

TABLE V.14

MEDICARE PAYMENTS DURING THE FIRST 12 MONTHS AFTER SHOES WERE PRESCRIBED

Outcome Measure	Treatment Group	Control Group	Difference[a]	p-Value[b]
Average Medicare Payment (Dollars)				
Part A	7,184.46	6,957.32	227.14	0.293
Part B	5,055.61	4,949.62	105.99	0.280
Shoe Benefit	117.75	--	--	--
All Services[c]	12,358.06	11,906.70	451.36	0.199
Average Medicare Footcare Payment (Dollars)				
Part A	1,968.92	1,818.71	150.21	0.222
Part B[d]	409.30	359.66	49.64	0.147
Shoe Benefit	117.75	--	--	--
All Services	2.496.2 1	2,178.13	318.08	0.085
Sample Size	1,711	1,717		

SOURCE: MADRS file extracts for 1989, 1990, and 1991 and NCH file extracts for 1992 for beneficiaries with complete HISKEW file records, and HCFA shoe-claim file for beneficiaries who enrolled hetwcen August 1. 1989 and September 30, 1991.

NOTE: The sum of payments for Part A and Part B services may not add up to the pnymcnt for all services due to rounding.

"Treatment and control group means were calculated from an OLS regression model varying study group but keeping the following factors: age at randomization, gender, race, State of residence, original reason for entitlement, dual entitlement, duration of diabetes, clinical impairment at enrollment, and Medicare reimbursement in the year prior to randomization, constant (see Appendix L).

*For a one-tail test of the null hypothesis that Medicare payments for the treatment were less than or equal to payments for the control group.

'Includes all Part A and Part B services, including the therapeutic shoe benefit.

[d]No footcarc services could be identified from Part B records for physician office visit records and other services provided in the office.

TABLE V.15

MEDICARE PAYMENTS DURING THE FIRST 18 MONTHS AFTER SHOES WERE PRESCRIBED

Outcome Measure	Treatment Group	Control Group	Difference[a]	p-Value[b]
Average Medicare Payment (Dollars)				
Part A	10,578.52	10,482.30	96.22	0.435
Part B	7,424.05	731.85	42.20	0.441
Shoe Benefit	139.33	--	--	--
All Services[c]	18,141.90	17,864.10	277.80	0.360
Average Medicare Footcare Payment (Dollars)				
Part A	2,706.15	2.718.23	-12.08	0.482
Part B[d]	621.41	567.87	53.54	0.23
Shoe Benefit	139.33	--	--	--
All Services[d]	X466.91	3,286.07	180.84	0.286
Sample Size	**1,412**	**1,415**		

SOURCE: MADRS file extracts for 1989, 1990, and 1991 and NCH file extracts for 1992 for beneficiaries with complete HISKEW file records, and HCFA shoe-claim file for beneficiaries who enrolled between August 1. 1989 and March 31, 1992.

NOTE: The sum of payments for Part A and Part B services may not add up to the payment for all services because of rounding.

[a]Treatment and control group means were calculated from an OLS regression model varying study group but keeping the following factors: age at randomization, gender, race, State of residence, original reason for entitlement, dual entitlement. duration of diabetes, clinical impairment at enrollment. and Medicare reimbursement in the year prior to randomization, constant (see Appendix L).

[b]For a one-tail test of the null hypothesis that Medicare payments for the treatment were less than or equal to payments for the control group.

'Includes all Part A and Part B services, including the therapeutic shoe benefit.

[d]No footcare services could be identified from records for Part B physician office visit and other services provided in the office.

TABLE V. 16

MEDICARE PAYMENTS BETWEEN RANDOMIZATION AND SEPTEMBER 30, 1992

Outcome Measure	Treatment Group	Control Group	Difference[a]	p-Value[b]
Annual Average Medicare Payment (Dollars)				
Part A	$018.25	7.97 1.84	46.41	0.45 1
Part B	5,239.30	5,134.28	105.02	0.261
Shoe Benefit	87.71	--	--	--
All Services[c]	1 X345.20	13,106.14	239.06	0.3 1 1
Annual Average Medicare Footcare Payment (Dollars)				
Part A	2,094.61	2,091.47	3.14	0.493
Part B[d]	423.39	403.04	20.35	0.299
Shoe Benelit	87.71	--	--	--
All Services	2.605.60	2,494.50	111.10	0.287
Sample Size	2.179	2,184		

SOURCE: MADRS file extracts for 1989, 1990, and 1991 and NCH file extracts for 1992 for beneficiaries with complete HISKEW file records, and HCFA shoe-claim file for beneficiaries who enrolled between August 1. 1989 and September 17. 1992.

NOTE: The sum of payments for Part A and Part B services may not add up to the payment for all services because of rounding.

[a]Treatment and control group means were calculated from an OLS regression model varying study group but keeping the following factors: age at randomization, gender, race, State of rcsidcncc. original reason for entitlement, dual entitlement, duration of diabetes, clinical impairment at enrollment, and Medicare reimbursement in the year prior to randomization, constant (see Appendix L).

[b]For a one-tailed test of the null hypothesis that Medicare payments for the treatment were less than or equal to payments for the control group.

'Includes all Part A and Part B services, including the therapeutic shoe benefit.

[d]No footcare services could be identified from Part B records for physician office visit records and other services provided in the office.

Note that the average annual Medicare payment derived from the variable follow-up sample is higher than the payment during the first 12 months after the shoes were prescribed--about $1,000 more for ail services, and $200 more for footcare services (Tables V.14 and V.16). As discussed earlier, because the average annual estimates reflect the actual experience of all demonstration beneficiaries over the demonstration period (that is, until September 30, 1992 or the date of death, whichever occurred earlier), the estimates from the variable follow-up sample would more likely reflect the impact of the therapeutic shoe benefit for a cross-section of Medicare beneficiaries in a given calendar year. Still, the payment estimates derived from the first 12 months of experience among participating beneficiaries are more adequate measures foi assessing the impact of the demonstration than annualized estimates of payments. In any case, the conclusions are unchanged regardless of which sample is used--there is no evidence that the demonstration affected Medicare costs.

3. Footcare Payments

Although estimated cost effects were statistically significant only for one of the cost measures examined--for footcare services in the 6-month sample--the consistently higher estimates of payments for the treatment group led us to investigate whether the results could be explained by the experience of a few cases with extreme values. For instance, we estimated the difference between the two study groups excluding both observations on beneficiaries who had a lower-extremity amputation during the follow-up period--an expensive surgical procedure, as described earlier--and observations that were outliers.[10] In neither case did

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"Anomalous observations, or *outliers*, are defined here as those cases in which the (continued...)

our conclusion change, although removing the beneficiaries who had a lower-extremity amputation reduced the magnitude of the difference in Medicare payments between the two study groups from $318 to $291. Hence, we feel that the Medicare payments for treatment group beneficiaries were larger in the first 6 months because their service use was high at the beginning of the demonstration, possibly because their treatment group status prompted them to seek medical attention more frequently (a common occurrence in clinical trials). Note that there was no evidence based on their foot problems or prior year service use that the treatment group members were any sicker than the control group, but because we do not have a measure of the overall clinical condition of the participating beneficiaries *as of the rime they were randomized, we* cannot determine whether those in the treatment group were sicker on average than those in the control group *at that time.*

Because the preventive effects of therapeutic shoes may increase over time, we also explored in more detail whether the difference in the average Medicare footcare payments for treatment and control group beneficiaries widened or narrowed as the follow-up period increased. When we exclude the shoe benefit from the average payment for ail footcare costs. the difference in average payments for the two groups narrowed as individuals were studied for a longer period of time ($234, $201, and $41 for the 6-, 12-, and 18-month follow-up samples, respectively). This narrowing of differences in payments as the follow-up period increases could be due to the higher service use among treatment group members at the

[10](. ..continued)
standardized residual from the regression model (McCullagh and Nelder 1983) exceeds two standard deviations (in absolute value). For example, we found that about 164 observations (4 percent of the sample) in the 6-month sample were classified as outliers in the analysis of payments for footcare services.

beginning of the demonstration, again because their treatment group status may have prompted them to seek medical attention more frequently than did their counterparts in the control group at that stage of the demonstration. However, after this initial utilization of medical services, treatment group members renewed the shoe benefit at a low rate (see Chapter III, Table 111.9, page 85), and consequently, their service utilization became similar to that of their control group counterparts. Thus, after an l&month follow-up period, the level of Medicare payments for treatment and control beneficiaries became almost indistinguishable. Overall, however, the small samples involved in our calculations make it difficult to distinguish whether these trends are statistically significant or are due to chance.

4. **Differences Across Subgroups**

In order to assess whether the therapeutic shoe benefit is more effective for some types of Medicare beneficiaries than for others, we reviewed differences in Medicare payments for all services and for footcare services by subgroups of treatment and control group beneficiaries in the It-month follow-up sample. The objective was to assess whether the shoe benefit was cost-effective for more precisely targeted subgroups of the demonstration's population, for example, among beneficiaries who had a lower-extremity amputation prior to randomization. The subgroups were defined by the age of the beneficiary at enrollment, States of residence, the specialties of the physicians who certified eligibility, the duration of diabetes, three clinical conditions of the foot at the time of the benefit application (including prior amputation), and the reason for original entitlement to Medicare. We conducted two types of statistical tests. First, we used an F-test to assess whether the treatment-control difference was constant *across* subgroups for a specific characteristic. Second, we used an F-test to assess whether the

treatment-control difference in Medicare payments was equal to zero *within* each of the subgroups of a specific characteristic. In this instance, we used a two-tail test." The results are shown in Table V.17.

The higher Medicare payments for all services and for footcare services for the treatment group relative to those in the control group persisted across most subgroups, and only in one instance were the differences statistically significant from either each other or from zero. For instance, treatment group beneficiaries who were originally entitled to Medicare for other reasons than old age--that is, because of disability, end-stage renal disease, or both--had *lower* Medicare payments relative to those in the control group for all services and for footcare services. The difference, however, is only statistically significant at the 5 percent level on a two-tail test for payments for all services for beneficiaries originally entitled because of end-stage renal disease (p=0.006), who represent about 3 percent of our sample. The large difference is probably due to the small sample size in this subgroup. Moreover, note that the treatment-control difference for all services is about 20 times the difference for footcare services. This suggests that the disability condition of these beneficiaries and not the shoe benefit is responsible for the high Medicare payments for this risk category. In contrast, note that for beneficiaries who were entitled to Medicare because of old age, Medicare payments for the treatment group were ***higher*** than for their counterparts in the control group. For payments for all services, the difference was significant at the 10 percent level but not at the

*'F-tests are two-tailed by definition. We used one-tail tests of differences for the entire sample, because we were testing a directional hypothesis (see Chapter IV, Section A). For the subgroups, we had no such directional hypothesis.

TABLE v. 17

MEDICARE PAYMENTS DURING THE FIRST 12 MONTHS AFTER SHOES WERE PRESCRIBED, BY BENEFICIARY CHARACTERISTIC

	Medicare Payments							
	All Services[a]				Footcare Services[b]			
Characteristic	Treatment	Control	Difference	p-Value[c]	Treatment	Control	Difference	p-Value[c]
Age at Enrollment								
Younger than 65	12270	13,987	-1,717	0.159	3.087	4.009	-922	0.08 1
65 to 69 Years	11,676	10,355	1.321	0.222	2.550	1.800	750	0.110
70 to 74 Years	12.125	11.160	965	0.353	2133	1.729	404	0.369
75 lo 79 Years	12,924	11,545	1.379	0.287	2,253	1,719	534	0.342
80 to 84 Years	13.643	14,635	992	0.576	3.070	1.837	1,233	0.109
85 or Older	13.193	11,739	1.454	0.593	1,421	1,054	367	0.756
(Test of Equality of Differences)				(0.374)				(0.159)
State of Residence								
New York	11.468	15021	553	0.520	2.571	2,456	114	0.758
California	12,656	11.618	1,038	0.268	2.354	1.919	435	0.285
Florida	13,208	12,092	1.116	0.262	2,576	2.082	493	0.252
(Test of Equality of Differences)				(0.332)				(0.963)
Certifying Physician Specialties								
General/Family Ptactia	12.663	11,423	1,240	0.489	2,739	1,968	771	0.321
Internal Medicine/Endocrinology	12.340	15362	-22	0.982	2,274	1,962	312	0.467
General. Orthopedic, or Vascular Surgery	10.797	10.840	43	0.975	2,374	2,287	85	0.887
Podiatry	12,958	12,016	942	0.287	5573	2.193	380	0 . 3 2 1
Other Specialty, Other Medical, Group Practice, or Unspecified	12,491	12.077	414	0.805	2,870	2.754	116	0.873
(Test of Equality of Differences)				(0.930)				(0.762)
Type of Shoe Supplier (First Purchase)								
Pedorthist	12.217	--	--	--	2.100	--	--	--
Orthotist. Prosthetist. or Both	10.979	--	--	--	2.130	--	--	--
Podiatrist	11.625	--	--	--	1.972	--	--	--
Combination of Above Categories	11.876	--	--	--	2.5X-l	_	--	--
No Shoe Purchase	13.478	--	--	--	2.47 l	--	--	--

TABLE V.17 *(continued)*

Characteristic	Medicate Payments							
	All Services[a]				Footcare Services[b]			
	Treatment	Control	Difference	p-Value[c]	Treatment	Control	Difference	p-Value[c]
When Diabetes **Was First** Recognized								
Less than 5 Years Ago	11,519	11.228	291	0.911	2.488	1,943	545	0.512
5 to 10 Years Ago	10,762	10.557	205	0.793	1,631	2,130	-499	0.258
11 to 15 Years Ago	13,107	12,631	476	0.705	2,382	2,048	334	0.539
Mote than 15 Years Ago	12,547	12,558	-110	0.989	2,647	2535	112	0.757
Missing	13,850	10.612	3,238	0.076	3,071	1.131	1.643	0.038
(Test of Equality of Diffetences)				(0.612)				(0.343)
Most Severe **Clinical Impairment at Enrollment**[d]								
Previous Amputation	33,496	12,711	785	0.894	3,700	3.113	587	0.823
Previous Ulceration	12,833	12,059	774	0.458	3,095	2,702	393	0.201
Other	11,102	11.219	-117	0.377	1,085	1,000	85	0.301
(Test of Equality of Differences)				(0.722)				(0.687)
Reason **for** Original **Entitlement**								
Old Age	il.826	10,705	1,121	0.088	2,789	2.029	770	0.008
Disability	11,743	11,766	23	0.981	2.009	2,548	-539	0.203
Other Reasons'	26,226	33,801	-7.575	0.006	1.352	1.702	280	0.778
(Test of Equality of Diffetences)				(0.008)				(0.033)
All Beneficiaries	12,358	11,907 .	451	0.199	2,496	2.178	318	0.085
Sample Size	1.71 I	1.717			1.71 I	I.717		

SOURCE: MADRS fik extracts for 1989,1990, and 1991 and NCI I file extracts for 1992 for beneficiaries with complete I HSKEW file records. and I ICFA shoe-claim file for beneficiaries who enrolled between August 1, 1989 and September 30, 1991.

NOTE: Treatment and control group means were calculated front an OLS regression model varying study group but keeping the following factors: age at randomization. gender. race. State of residence. original reason for entitlement. dual entitlement. duration of diabetes. clinical impairment at enrollment. and Medicare reimbursement in the year prior to randomization. constant (see Appendix L). In addition. they include the (first-order) interaction coefficients for tlte characteristic under consideration.

[a] Inc ludes all Part A and Part B services. including the therapeutic shoe benefit.

[b] No footcare services could be identified from records for Part B physician office visits and other services in the office.

TABLE V.17 *(continued)*

[c]For a two-tail test. We used one-tail tests of differences for the entire sample. because we were testing a directional hypothesis. For the subgroups. we had no such directional hypothesis.

[d]Beneficiaries are classified in the category which indicates the greatest severity of experience in the following order: amputation, ulceration, and other problems (that is. poor circulation. callus formation, or foot deformity with potential for ulceration).

[e]Other reasons are: end-stage renal disease, and disability and end-stage renal disease.

5 percent level (p=0.088).[12] Note that the treatment control difference is about $1.120. almost 2.5 times that for all beneficiaries in the 12-month sample (that is, $451). For footcare services, the-treatment-control difference far the aged is about $770, which was statistically significant at conventional levels (p=0.008), and about 2.5 times that for the entire sample (that is, $318).[13] In the aggregate, the treatment-control group difference in Medicare payments for all services and for footcare services varied across the subgroups defined by reason for original entitlement to Medicare (p=0.008, and p=0.033, respectively), although the erratic pattern of the treatment-control differences across the subgroups of this characteristic should be attributed to the small sample size in the subgroup of beneficiaries originally entitled because of end-stage renal disease.

Beneficiaries who reported having previously had an amputation as of the time that the shoes were prescribed had the highest level of payment for footcare services among the categories of the severity of illness at randomization--three times that of beneficiaries who had never had an amputation or ulceration.[14] Beneficiaries who had a previous ulceration (of

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[12]In a one-tail test of the null hypothesis that Medicare payments for the treatment group were less than or equal to payments for the control group, this difference would be statistically significant at the 5 percent level, that is, p=0.044.

[13]Note the correspondence of these results with those across the age categories. For instance, the subgroup with the highest footcare service payments were those beneficiaries younger than 65 (exactly those entitled because of disability or end-stage renal disease), and the payments for beneficiaries in the control group were also higher than for beneficiaries in the treatment group for both overall and footcare only services.

[14]We found some inconsistencies in the data. Based on the claims data, about 6 of the 43 beneficiaries who had a lower-extremity amputation in the year preceding randomization did not report previous amputations on the demonstration's Certification and Prescription Form. However, we used the reports on the demonstration's Certification and Prescription Form rather than the information reported in the MADRS record.

(continued...)

unspecified seriousness) but no amputation had the next highest Medicare payments. None of the treatment-control differences in Medicare payments across the three clinical severity subgroups was significant, but the difference was smaller for those with "other" types of impairment than for those with an amputation or ulceration at the time of randomization.

For the other subgroups, we found the expected patterns. For example, Medicare footcare payments were higher for individuals who had diabetes longer, indicating higher service use due to an increased level of severity of diabetes. However, there was no indication that the pattern of payments by the duration of diabetes differed between the treatment and control group. Note that the difference between treatment and control group beneficiaries was statistically significant among those beneficiaries for whom the duration of their diabetes was not recorded in the Certification and Prescription Form. However, the small number of cases in this subgroup might be responsible for the instability of the parameter estimates. The average Medicare payment (either for all services or for footcare services) did not differ significantly by State of residence, or by the specialty of the physician who certified the shoes. In all instances, the differences between groups were not statistically significant from each other or from zero.

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[14](...continued)

These inconsistencies in the reports of the beneficiaries suggest that the data on clinical impairment at enrollment might also have been reported erroneously by physicians for beneficiaries who did not have an amputation during the follow-up period. However, we did not validate the reports on the Certification and Prescription Form.

5. Discussion of Results

Our data suggest that the therapeutic shoe benefit did not have a significant effect on Medicare payments for footcare services or overall, despite a preponderance of positive treatment-control differences on various cost measures examined. However, the sample sizes were not large enough to make it likely that we would detect a true effect equal to the cost of the shoes. We find no consistent evidence across time periods or outcome measures of an effect on the payments or utilization of other footcare or Medicare covered services in general. Thus, it seems likely that Medicare payments were increased, but only by the direct cost of the shoe benefit. The results indicate that the benefit may have increased the Medicare payments for footcare among beneficiaries in the treatment group beyond the annualized cost of the shoes and inserts ($88) by about 5 percent of the annual average Medicare payment for footcare among beneficiaries in the treatment group ($111.10/$2,494.50). However. the difference in Medicare payments for all services or footcare services--and its components--was statistically significant only in one instance--payment for footcare services during the 6-month follow-up period.

D. SUMMARY OF THE IMPACTS OF THE BENEFIT

In the Omnibus Budget Reconciliation Act of 1987, Congress mandated the Medicare Therapeutic Shoe Demonstration in order to assess the cost-effectiveness of providing Medicare Part B coverage for therapeutic shoes. Four prerequisites for the shoe coverage to be cost-effective were: that the demonstration was implemented as planned, that beneficiaries received the shoes, that they wore the shoes after acquiring them, and that the shoes were clinically effective. In Chapter III we showed that the demonstration was implemented largely

as legislated, though participation among beneficiaries was lower than planned. In this chapter, we showed that the benefit prompted a larger proportion of the treatment group to acquire therapeutic shoes and to wear them outdoors (at least the more expensive type of custom-molded shoe). We did not collect systematic evidence on clinical effectiveness though there was a suggestion (inconclusive) that foot problems may have been reduced among those who wore therapeutic shoes.[15] Thus, if the benefit is cost-effective, the demonstration created the conditions for this effect to have occurred, excepting that a very low participation rate may make measurement of this effect impossible, even if it occurred.

The legislation contained two criteria for determining whether the shoe coverage would be made permanent. First, the benefit would become permanent after 2 years if at that time the Secretary found that the shoe coverage was cost effective. If such a finding could not be made at that time, the demonstration would run for 2 more years. Second, at the end of this second period, the benefit would become permanent as long as the Secretary did *not* find that the benefit was *not* cost-effective. The first Report to Congress provided *no* evidence that the demonstration was cost-effective. The second Report to Congress failed to reject the hypothesis that the demonstration is cost-effective. In this comprehensive final report. we repeated the analyses presented in the second Congressional report by using a larger sample--

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"Some information on the possible clinical effectiveness of the therapeutic shoes was available from the survey of beneficiaries. For instance, we studied the demonstration participants who did not have therapeutic shoes when they enrolled in the demonstration, even though they had prior foot ulcerations or an amputation. These beneficiaries either obtained their shoes through the demonstration (the treatment group) or purchased therapeutic shoes within 3 years prior to the interview (the control group). Almost two-thirds of beneficiaries who had not previously owned therapeutic shoes reported no sores after having acquired the therapeutic shoes. Most of the beneficiaries who had open sores after acquiring shoes reported having those sores less of the time.

that is, ***all*** beneficiaries enrolled in the demonstration--and a longer follow-up period (2 years. on average) and confirmed our earlier findings. Below, we describe the most relevant conclusions of these three reports.

1. Findings from the First Report to Congress

Because the demonstration did not begin until August 1, 1989, at the time this report was prepared (February 1990) only a few months had elapsed since the demonstration had been made available to Medicare beneficiaries--barely enough time for the participants to have the therapeutic shoes supplied. Hence it was too early to assess whether the benefit was cost-effective. That report focused on the design and implementation of the demonstration and the characteristics of those who enrolled in the first 4 months of the demonstration.

2. Findings from the Second Report to Congress

Our analysis of total Medicare payments of a sample of 2,440 beneficiaries over a I-year period after beneficiaries applied for the benefit showed that the treatment group had Medicare payments that were $432 per applicant higher than the control group, but the difference between the groups is not statistically significant. The confidence interval around this estimate is - $497 to + $1,362. Given our single best point estimate of the net change in Medicare costs from introducing the benefit, we failed to reject that the benefit was cost-effective.

3. **Findings from the Comprehensive Final Report**

As in the second Congressional Report, we addressed the second criterion for determining whether the demonstration was cost-effective. We have defined cost-effectiveness as meaning

that the introduction of the benefit would not increase overall Medicare payments per beneficiary for the year after the benefit was provided (Brown et al. 1989). This definition reflects the implicit assumption of Congress that, if the benefit were cost-effective. then the costs of providing the therapeutic shoes would be offset by reductions in the Medicare payments for footcare treatments.

In order to apply the criterion, we formalized the Congressional statements into a testable research hypothesis (Chapter IV, Section B):

> ***The average Medicare expenditures for beneficiaries eligible for the shoe-coverage benefit will not be higher than those for beneficiaries not eligible for the shoe-covemge benefit.***

The standard statistical approach for testing this hypothesis is to conduct a ***classical hypothesis testing*** procedure, which we adopted in our design report (Brown et al. 1989). This approach relies on a conceptual framework that permitted us to ascertain whether the outcomes of the demonstration supported the belief that the demonstration is cost-effective. This conceptual framework encompasses different elements of uncertainty inherent in testing a hypothesis, which we present in Table V. 18 for the Congressional criterion described before.

The framework explicitly recognizes that even with the demonstration we will not know ***with certainty*** whether the shoe benefit is cost-effective. We can, however, make an informed estimate of its cost-effectiveness. If in fact the benefit leads to lower average Medicare payments and we do not reject the hypothesis that the benefit is cost-effective, the correct decision is made--namely, a cost-effective benefit is introduced. However, if the benefit is cost effective, and we reject the hypothesis that it is cost-effective, then there will be an error. In the design report for the demonstration (Brown et al. 1989), we established a test that would

TABLE V.18

POSSIBLE ERRORS STEMMING FROM DECISIONS ABOUT THE SHOE BENEFIT

State of the World	Decision and Implication	
	Do Not Reject Hypothesis of Cost-Effectiveness	Reject Hypothesis of Cost-Effectiveness
Beneficiaries Eligible for the Shoe-Coverage Benefit ***Will Not Have*** Higher Average Medicare Expenditures than Beneficiaries Not Eligible for the Shoe-Coverage Benefit (Null Hypothesis Is True)	**Correct decision:** Introduce a benefit that is costeffective	**Incorrect** decision **(Type I error):** Do not introduce a benefit that is cost-effective
Beneficiaries Eligible for the Shoe-Coverage Benefit ***Will Have*** Higher Average Medicare Expenditures than Beneficiaries Not Eligible for the Shoe-Coverage Benefit (Null Hypothesis is False)	**Incorrect** decision (Type II error): **Introduce** a benefit that is not cost-effective	**Correct decision:** Do not introduce a benefit that is not cost-effective

have a very low probability of making this type of error. Specifically, we stated that, unless a positive treatment-control difference in Medicare payments was statistically significant at the 5 percent level, we would not reject the hypothesis that the benefit was cost-effective. Thus, our procedures ensure that we will be unlikely to fail to introduce a cost-effective benefit.

Alternatively, if the shoe benefit in fact leads to an increase in Medicare payments, we would make an incorrect decision if we failed to reject the hypothesis that the benefit is cost-effective. We are less able to avoid this type of error than to avoid the first type of error. Essentially, the probability of making this type of error is determined by the number of beneficiaries included in the demonstration and by the underlying variation of Medicare payments for those beneficiaries. Our design called for 27,500 beneficiaries to be included, but, in fact, only 4,373 beneficiaries enrolled over the demonstration period. Given this shortfall in enrollment, the probability that we will make an error of this second type if the true impact were an increase in costs equal to the actual average cost of the shoes is approximately 93 percent--in other words, if the shoe benefit actually increases costs because there are no savings to offset the costs of the shoes, we have only a 7 percent chance (about 1 in 14) of correctly detecting that the benefit is not cost-effective. There is no way to improve our odds of avoiding this type of error without enrolling more beneficiaries or increasing the chance of making the first (most serious) type of error.

In summary, we conducted the test set out in our design report--and addressed in the second Report to Congress--and again failed to reject the hypothesis that the demonstration is cost-effective. While Medicare payments for the treatment group were slightly higher than

for the control group, the difference was not large enough for us to be confident that the benefit is not cost-effective. Essentially, we found that there is a reasonable chance that the benefit was actually cost-effective and that the estimates we observed for the demonstration arose from chance differences between the two groups. This final report confirms the findings of our second Report to Congress: ***that we did not detect evidence for the benefit to be not cast-effective.*** Based on the policy implications of these findings, the shoe benefit was made part of Medicare, effective May 1, 1993.

VI. IMPLICATIONS AND RECOMMENDATIONS FOR THE NATIONAL BENEFIT

The demonstration and evaluation results have two major implications for the procedures and costs of the national program that covers therapeutic shoes for diabetic beneficiaries under Medicare Part B. First, the demonstration was implemented as intended, and it increased therapeutic shoe purchases by 54 percent and shoe use by 70 percent. Thus, if the shoes were clinically effective, they would have had an opportunity to have an impact on costs, although the potential impacts would be limited to those who would not have purchased and worn the shoes in the absence of the demonstration. Second, the results of our analysis of the impact of the therapeutic shoe benefit on Medicare costs were inconclusive. Although we did not reject the hypothesis that the shoe benefit increased Medicare costs, the confidence interval around the point estimate of the impact ranges from an increase of just over $1,600 to a reduction of just over $700 per applicant per year, and the single best (point) estimate of the net change in Medicare costs from introducing the benefit ($451 per applicant per year) is about four times greater than the cost of the shoes themselves.

This chapter discusses the likely costs of the national benefit. In Section A, we elucidate the two major implications more fully and explain how they would affect costs. in Sections B and C, we explore how modifying procedures whereby beneficiaries acquire the shoes (in a manner consistent with the original legislation) may affect shoe purchase rates and Medicare costs, respectively, under the national program. Section D then presents alternative costs of therapeutic shoe coverage under these changed assumptions. In Section E, we discuss the

potential implications of changes to how the benefit is administered that would require a change in the legislation; these changes were proposed by physicians and shoe suppliers who participated in the demonstration and by interested professional associations. The section also discusses the likely costs of adopting their proposals.

A. FRAMEWORK FOR DISCUSSING COST-EFFECTIVENESS

1. The Demonstration Was Implemented as Intended and Had the Intended Effect on Shoe Use

As implemented, the demonstration was a fair test of a national therapeutic shoe benefit. We conclude that:

- Inadequately targeting the population who could benefit most from the coverage could increase costs. The demonstration clearly targeted Medicare beneficiaries at high risk of infection and amputation according to their baseline characteristics, as well as those for whom the shoes could have prevented the first occurrence of an ulcer. Hence, the demonstration probably did not increase costs by targeting the benefit inappropriately.

- The demonstration might have increased the knowledge of physicians about the importance of therapeutic shoes in a comprehensive plan of care. If it did so, it would have reduced the impact of the benefit. The small number of physicians who enrolled their patients and the small impact of an additional publicity campaign on enrollment rates suggests that the impact of the demonstration on physicians' knowledge was slight.

- Extensive prior ownership of the therapeutic shoes, so that the benefit could not augment therapeutic footcare, would have increased costs. The demonstration provides evidence that therapeutic shoes are not purchased nearly as frequently when they are not available as a Medicare benefit (though one-third of the applicants already had therapeutic shoes); hence, the demonstration did not increase costs by providing coverage only to persons who would have bought the shoes anyway.

On balance, if the demonstration benefit were cost-effective, little in the demonstration procedures would have prevented the benefit from having its intended effects. Furthermore. the survey of demonstration participants shows that the group who received the therapeutic shoe benefit wore the shoes when they walked outdoors much more often than did the control group when they walked outdoors. If no difference in shoe use had been observed, the benefit could only have had the effect of increasing costs.

2. Inconclusiveness of the Cost-Effectiveness Analysis

If therapeutic shoes are not clinically more effective than are regular shoes, the demonstration would have increased costs by the annual cost of the shoes (about $118 per treatment group member in the first year). While the demonstration did not endeavor to test clinical effectiveness, limited postenrollment information on lower-extremity amputation rates (from claims) and the occurrence of foot sores and ulcers (from the survey of participating beneficiaries) suggests that the clinical outcomes of the treatment and control groups were similar.

The analysis of impacts on costs was inconclusive because the low rate of participation in the demonstration, combined with the extreme variability of Medicare payments among participating beneficiaries and the absence of evidence of clinical effectiveness of the shoes, created a large confidence interval around the estimate of the impact on cost-effectiveness, making it impossible to indicate whether the demonstration benefit was or was not cost-effective overall. (This was true both for the findings of this final comprehensive report and the Second Report to Congress, which was the basis for the decision to add the shoe benefit

to the Medicare program.) Because the 95 percent confidence interval around the estimate of the impact on beneficiaries over 12 months ranged from -$701 to +$1,604, we cannot determine with much certainty whether costs would increase or decrease if the benefit were introduced nationally (because a zero cost impact lies inside the confidence interval around the estimate). We can' conclude only that costs would neither increase substantially nor decrease substantially.

Given this uncertainty, we developed estimates of the ***range*** of possible costs or savings of a national benefit identical to the demonstration benefit according to various participation assumptions. These estimates (described in Section D) show that ***during ifs first year*** the benefit could reduce Medicare costs by nearly $5 million or increase them by as much as over $11 million; our best estimate is an increase of $3.2 million, if the application rate and shoe benefit and prices were the same as in the first year of the demonstration. However, the range of costs and savings in the first year could expand to a savings of nearly $15 million or to a cost of $34 million a year if the application rate tripled (equivalent to assuming that the proportion of eligible beneficiaries for whom shoes are prescribed each year would be **equal** to the cumulative proportion of beneficiaries who enrolled during the 3 years of the demonstration). Section D.4, page 197 compares these final results with those underlying the earlier Report to Congress.

We also developed alternate cost estimates by varying the mix of applicants in a "steady-state" rather than in a "start-up" phase of program activities. During a steady-state phase. participation would have built up and stabilized, and a large proportion of the applicants

would be renewing their benefit rather than initiating it. In the demonstration, the renewal rate was less than half the receipt rate for a first pair of shoes. Assuming that this demonstration behavior would be true under a national benefit, the steady-state estimate reduces annual costs by about 44 percent per beneficiary. However, in a steady state, an increase in shoe-renewal rates relative to the demonstration renewal rate would increase the cost estimates proportionately.

B. THE POPULATION WHO WOULD USE THE THERAPEUTIC SHOE BENEFIT: POTENTIAL DIFFERENCES FROM THE DEMONSTRATION POPULATION

Demonstration participants could differ from participants using the national benefit due either to the features of the demonstration design or to the characteristics of the three demonstration States. In this section we review the differences in the demonstration participant group that could be due to the States chosen to implement the demonstration.

The demonstration States were selected primarily because they contain a large population of eligible beneficiaries. About one-fourth of the national population of diabetic Medicare beneficiaries reside in California, Florida, and New York (about the same proportion as Medicare beneficiaries enrolled in Part B).[1] By simple extrapolation, four times more participants could be expected in the national program than in the demonstration. In the demonstration, applicants were assigned randomly to equal-size treatment and control groups,

[1] Based on enrollment in Supplementary Medical Insurance and diabetes surveillance estimates prepared by the Centers for Disease Control, we estimate that the three demonstration States contain about 822,000 diabetic Medicare beneficiaries, of a total of about 3.4 million in the 50 states (Social Security Administration, 1991; and Centers for Disease Control, 1990).

which will obviously not be the process for providing the national benefit. We believe that randomization created a participation disincentive for physicians, and that the participation rate for the national benefit is likely to be greater than the demonstration participation rate if physicians start prescribing the benefit. Finally, HMO enrollees were excluded from the demonstration, but are under the national benefit, which will also increase the number of participants in the national benefit.2

Furthermore, the demonstration States differ from the nation as a whole along dimensions that also have implications for a therapeutic shoe benefit: the demonstration States are more urbanized and have a higher concentration of podiatrists, and are thus likely to exhibit proportionately higher predemonstration and postdemonstration therapeutic shoe use than would occur nationwide. A very high proportion of the population within the demonstration States live in metropolitan areas (93 percent, compared with 78 percent of the U.S. population). Metropolitan areas tend to contain a higher proportion of physicians, especially podiatrists (who specialize in foot care). The population of the demonstration States has more active physicians per capita (239 per 100,000 population, compared with 204 nationally) and more licensed podiatrists per capita (6.9 per 100,000 population, compared with 5.1 nationally). Indeed, the demonstration States have one-third of the nation's podiatrists, but only one-fourth of the eligible beneficiaries.

The availability of certified pedorthists (who supplied one-fourth of depth-inlay shoes in the demonstration) is currently very limited both in the three demonstration States and in the

[2]The average rate of Medicare HMO enrollment among beneficiaries in the demonstration States is 15.4 percent.

nation. The relative scarcity of pedorthists both in and beyond the demonstration States is, in the short-run, likely to keep the use and availability of the lower-price depth-inlay therapeutic shoes in the national benefit at a level similar to the demonstration level. Table VI.1 shows selected population and health-service characteristics of the demonstration States and the nation, and the expected direction (and, when we have an estimate, the size) of the effects of differences between the demonstration States and the nation on the participation rate in the national benefit.

C. POTENTIAL DIFFERENCES BETWEEN THE NATIONAL BENEFIT AND THE DEMONSTRATION BENEFIT

The national benefit will be implemented in the same way that it was offered in the demonstration (based on the legislative requirements). That is to say, no changes will be made in the beneficiary eligibility criteria, the benefit itself, the prices paid by Medicare, the requirement that physicians certify the eligibility of patients and prescribe the shoes, or the procedures for supplying the shoes. However, the following aspects of the demonstration benefit and procedures could change:

- The types of shoe modifications covered (which were at the discretion of the Secretary)
- The prior authorization requirement of the demonstration (which was linked to the randomization process)
- The requirement that suppliers accept assignment of Medicare benefits

TABLE VI.1

POPULATION AND HEALTH-SERVICE CHARACTERISTICS OF THE DEMONSTRATION STATES AND THE UNITED STATES

Demographic or Health Resource Characteristic	Demonstration States	United States	Ratio of Shoe Purchase Rates: National Benefit: Demonstration Benefit
Number of Diabetic Medicare Part B-Enrolled Beneficiaries. 1990	719,821 [a]	X461.781 [b]	+ increased participation: • Five times greater due to the inclusion of all States and no HMO exclusion • Increase due to the absence of random assignment
Percent Metropolitan Population. 1990[c]	93 %	78 %	- Lower participation rate
Active Physicians per 100.000 Population. 1988[d]	239	204	- Lower participation rate
Podiatrists per 100,000 Population. 1991[e]	6.9	5.14	- Lower participation rate
Certified Pedorthists per 100.000 Population'	0.15	0.17	+ More depth-inlay shoes prescribed

[a]The number in demonstration States excludes 15.4 percent of beneficiaries who were enrolled in Medicare HMOs.

[b]Aged, disabled. and end stage renal disease program Part B enrolled diabetic Medicare beneficiaries.

[c]Metropolitan population: *Statistical Abstract of the United States*, 1991.

[d]Number of active physicians: American Medical Association. cited in *Statistical Abstract of the United States, 1991.*

[e]Number of podiatrists: American Podiatric Medical Association membership estimate for 3/31/91.

[f]Board for Certification in Pedorthia: *List of Certified Pedorthists in the United States*, May 1992.

This section reviews the effects of these changes, and the effects of a shift to a nationwide program on participation rates and the cost per user.

1. Beneficiary Eligibility Criteria

The personal characteristics of applicants for the national benefit could differ from those of demonstration applicants in the future if practice patterns changed and if physicians stressed the potential benefits of therapeutic shoes to their diabetic patients. Foot disease among the demonstration applicants was more severe than we had anticipated before the demonstration: 25 percent of applicants had already had a lower-extremity amputation, and another 38 percent had had a foot ulcer (without amputation). When patients have had an amputation or ulceration, they are at very high risk of further adverse events. Only 37 percent of the applicants had not had a previous amputation or ulceration, and thus could still benefit from primary prevention. We would expect comparable characteristics among participants in the national program in its early years, but, as knowledge of the benefit spread. we would expect that less severely affected beneficiaries would start to use the benefit. Should this happen. the overall short-run costs of the benefit would increase, but the long-run benefits would also increase if the benefit were clinically effective. Given the short time frame of the evaluation. estimates of long-term benefits could not be derived, and we could not determine with certainty the net effects of an increase in participation by less severely affected beneficiaries.

2. The Covered Benefit

As indicated earlier, the Secretary has the discretion to extend coverage to additional modifications. Based on the recommendations of practitioners and their associations, we recommend that the national benefit cover the following additional shoe modifications:

- *Flared heels, extended steel shanks, leg-length modifications, velcro closures, rigid heel counters, and accommodations to inserts for missing toes (toe blocks)*

As proposed, the coverage of additional modifications would not add to the maximum annual cost of the benefit for any individual because the annual cost of modifications is capped at the price of two pairs of replacement inlays. However, if expanding coverage of these modifications adds to the proportion of beneficiaries who receive arty modifications, it would add to the average cost per user, since in the demonstration the optional replacement shoe inserts and modifications were not purchased up to the maximum available (indeed, only about 6 percent of beneficiaries who received shoes in the demonstration purchased these options).

3. Physician Certification and Prescription and Prior Authorization

The demonstration used a Certification and Prescription Form that contained checkboxes for physicians to certify the medical eligibility of beneficiaries and to prescribe shoes, as required by the legislation. We recommend revising this form to make it conform to Part B regulations for orthotic devices. Medicare Part B regulations require that physicians certify 'the medical necessity for orthotic devices prescribed; the certification must include the patient's diagnosis and prognosis, and the physician's estimate of the duration of need for the

device. Carriers are allowed to develop and require customized medical-necessity certification forms. Figure VI.1 shows a draft of a medical-necessity certification and prescription form that includes the regulatory minimum information, and incorporates the suggestions we received from physicians, suppliers, and professional associations about therapeutic shoe prescriptions. Specifically, we recommend the following change to the demonstration process:

- ***That the form in Figure VI.1, or its equivalent, be required for certifying eligibility (medical necessity) and prescribing shoes in the national benefit***

Although the demonstration included prior authorization before shoes were supplied. we do not believe that prior authorization is necessary for the national program. Because the demonstration authorization process ensured that the applicant had Part B coverage, the authorization to the suppliers (who were required to accept assignment of benefits) was a meaningful commitment that Medicare would pay for the prescribed shoes. This centralized process (which included randomizing applicants after their eligibility was determined) added an average of 5 weeks before beneficiaries could initiate the shoe-fitting process. We believe that excluding this process would increase participation among physicians and would prompt more eligible beneficiaries to obtain prescriptions and have them filled, because they would not have to wait several weeks before taking the form to a shoe supplier.

FIGURE **VI.1**

ILLUSTRATIVE CERTIFICATION OF MEDICAL NECESSITY
AND PRESCRIPTION FORM

Patient Name _____ **Medicare Number** _____

Diabetes Dx _____

In Comprehensive Care Plan for Diabetes? _____

Description of Foot Problem To Be Addressed by Therapeutic Shoes (for example: Charcot's Foot)

_____

_____

Check Conditions Present:

_ **Prior Amputation**
_ **History of Ulceration**
_ **Foot Deformity and Peripheral Neuropathy (includes Charcot's foot)**
_ **Callus Formation and Peripheral Neuropathy**
_ **Poor Circulation**
_ **Peripheral Neuropathy**

Prescription for Therapeutic Shoes:

_ **Depth Inlay Shoes:** indicate special accommodations required to shoe or insert and goals of the shoes

_____

_____

_ **Custom-Molded Shoes:** indicate any special accommodations required and goals of the shoes

_____

_____

PhysicianNameandAddress _____

_____

Physician Signature _____

4. Supplying the Shoes

a. Supplier Authorization and Quality Assurance

In the demonstration, shoe suppliers were authorized to supply shoes if they applied to do so and if they met the requirements that they had certified staff available to fit the shoes (podiatrists, or certified pedorthists, certified orthotists, or certified prosthetists). The authorization process had several functions: to provide a supplier number for billing purposes, to ensure that the supplier agreed to accept assignment of Medicare benefits and Medicare maximum allowable charges, and to provide evidence of minimum quality standards--that is. that they employ one or more of the designated professionals. Since suppliers will need Medicare provider identification numbers, the authorization process would presumably remain largely unchanged in the national benefit, although the requirement of accepting assignment should probably be changed (see below).

b. Medicare Assignment of Benefits

In the demonstration, authorized shoe suppliers were required to accept assignment of Medicare benefits. In the national program, we recommend that the policy on assignment be consistent with comparable orthotic benefits under Medicare Part B. Hence, we recommend

- ***That suppliers need not accept assignment of Medicare benefits***

If this recommendation were followed, the availability of shoe suppliers would be less constrained, since they could balance-bill their patients, and would not be required to file claims with Medicare. Furthermore, a higher proportion of depth-inlay shoes might he

supplied if suppliers were able to increase their markup for these lower-price shoes. Such an increase in depth-inlay shoes supplied could happen if suppliers recommended physicians to change prescriptions for custom-molded shoes to depth-inlay shoes when applicable.

c. Relationship among Certifiers, Prescribers, and Suppliers

The demonstration legislation stipulated that the physician who certified the eligibility of the participating beneficiary for coverage could not supply shoes to that beneficiary, but that the prescribing physician could. Because the physicians who certified clinical eligibility were supposed to be those who managed the diabetes (for example, internists and family practitioners), they were extremely unlikely ever to have supplied shoes; hence, precluding them from supplying shoes was somewhat meaningless. On the other hand, podiatrists were allowed both to prescribe shoes and to supply shoes, which could be seen as a conflict of interest. Some podiatrists who were authorized suppliers were so uncomfortable with this arrangement that, although they supplied shoes to the patients of other physicians, they did not supply shoes to their own patients. And some clinics that employed certified pedorthists did not enroll as suppliers because they were concerned that the anti-kickback provisions of the Medicare and Medicaid Patient and Program Protection Act of 1987 precluded them from sending their patients to their in-house supplier, notwithstanding the language of the legislation that mandated the therapeutic shoe demonstration.

Inasmuch as multi-disciplinary teams commonly deliver diabetic health care and deliver it effectively, we recommend that the regulations governing the nationwide benefit specify that

clinics and practices with multi-disciplinary teams be allowed to supply shoes to the patients whom they certify as eligible and for whom they prescribe shoes.

D. THE COST OF THE NATIONAL BENEFIT

Based on the demonstration results and the effects of the assumptions and recommendations about the national benefit discussed in the previous section, we present a range of estimates of the potential costs of a national therapeutic shoe benefit, and discuss the potential for a cost-effective national benefit. Two sets of estimates are presented. First, we present a range of national cost estimates based on the final impact estimates from the demonstration, but we vary the participation rate (the prescription and shoe purchase rates). Second, we modify the national cost estimate to take into account two factors:

- Differences in shoe purchase rates between the start-up and steady-state phases
- Variation in the cost per user according to the proportion of depth-inlay to custom-molded shoes supplied, and adding additional modifications to the benefit

We discuss the implications and effects of changes in these parameters on the costs of the national benefit.

1. Assumptions for Costing Out the National Benefit

a. The Cost-Effkxtiveness of the National Benefit

The net costs of the national therapeutic shoe benefit to the Federal government would be greater than zero only if we assume that the therapeutic shoe benefit is not cost-effective. Because we have not shown that the benefit is not cost-effective, we have assumed that. for

purposes of developing ranges of national cost estimates, costs range from -$701 to $1,604 (the confidence interval around the point estimate of $451 of the impact on Medicare costs over a 12-month period). (The comparable range given in the letter Report to Congress was -$497 to $1,362, with a point estimate of $432.) For comparison, we also present the cost of the shoe benefit only.

b. Participation Rate

The two elements of the participation rate are the number of eligible applicants who receive a prescription for therapeutic shoes from their physicians and the rate at which those prescriptions are filled by a shoe supplier and Medicare is billed.

In the demonstration, only 3 percent of the estimated number of beneficiaries with diabetic foot disease in the demonstration States applied for the benefit over the 3-year period (0.6 percent of the estimated number of diabetic Medicare beneficiaries). By "applied for" we mean that the beneficiary received a physician prescription for shoes and sent it to the demonstration contractor. We have assumed that, alternately, annual physician prescription rates ("eligible applicant" rates) for the national benefit would (1) resemble the demonstration. (2) be 50 percent higher, and (3) be 100 percent higher. These alternate rates are shown in Table VI.2. We do not really know how much the evaluation procedures inhibited participation by physicians, and it is possible that the rates at which physicians prescribed shoes would increase by far more than these alternate rates.

TABLE VI.2

DEMONSTRATION AND NATIONAL COST ASSUMPTIONS

Assumption	Demonstration Assumptions	Alternate Assumptions	
		Medium	High
First-Year Number of Eligible Applicants	6.998	IO.497	13,997
Steady-State Number of Eligible Applicants Annually	20.997 [c]	31.4% [d]	41.994 [e]
Percentage of Applicants Who Are New	333 %	33.3 %	33.3 %
Percentage Using the Benefit Each Year[a]			
New users	69.2 %	76.1 % [f]	86.5 % [g]
Renewal users	23.371,	46.6 % [h]	69.9 % [i]
Percentage of Users Using Each Type of Shoe			
Depth-inlay	42.9 %	42.9 % [j]	42.9 % [j]
Custom-molded	57.1 %	57.1 %	57.1 %
Percentage of Users Using:			
Replacement inserts	5.5 %	6.9 % [g]	11.0 % [h]
Modifications	6.2 %	7.8 % [g]	12.4 % [h]
Cost per User (1992 prices)[b]			
Depth-inlay shoes with inserts	$115.75	$115.75	$115.75
Custom-molded shoes	$240.80	$240.80	$240.80
Replacement inserts	$42.00	$42.00	$42.00
Modifications	$51.24	S51.24	$51.24
Implied Annual Shoe Benefit Cost per Applicant	$74.06 [k]	$109.31	$149.34
Implied Total Annual Cost of Shoes	$1.555.134	S3.442.764	f6.271.579

"See Table 111.9 for derivation.

'Demonstration cost per item; see Table III.10, third panel.

[c] Number is based on 0.6 percent of diabetic Medicare beneficiaries from an estimated population of 3.461.781 (see Table I.1).

[d] Assumes a 50 percent increase over the demonstration number.

'Assumes a 100 percent increase over the demonstration rate.

[f] Assumes a IO percent increase over the demonstration rate.

[g] Assumes a 25 percent increase over the demonstration rate.

[h] Assumes a 100 percent increase over the demonstration rate.

[i] Assumes a 200 percent increase over the demonstration rate.

[j] Assumes the same rate as the demonstration. Costs for alternate rates that are 10 and 25 percent higher are also provided (thnt is. 47 percent depth-inlay to 53 percent custom-molded, and 54 percent depth-inlay to 46 percent custom-molded).

[k] If all applicants were new, the cost per applicant would be S133.31.

Moreover, we have assumed that, alternately, these rates are for a start-up and a steady-state period (varying the percentage of renewals to new participants in a given year). The steady-state period is defined as a l-year period 3 or more years after the benefit is introduced, in which 0.6 percent of all diabetic Medicare beneficiaries seek the therapeutic shoe benefit--one-third for the first time and two-thirds for a second or more time?

Among demonstration participants whose physicians certified that they were eligible and wrote a prescription, 69 percent were supplied with the shoes in their first year. We assume that in the national benefit the annual shoe-supply rate for new participants would alternatively be (1) the same as in the demonstration (69.2 percent), (2) 10 percent higher (76.1 percent), and (3) 25 percent higher (86.5 percent). It would be unlikely that every person who received a prescription would have it filled. However, it would be reasonable to expect that the rate would exceed the demonstration rate, if only because some of the prescribing physicians would also be suppliers; we have thus assumed that the rate at which physicians prescribe shoes would increase.

The renewal of shoe prescriptions by demonstration participants in the second year was markedly lower than in the first-year; only 23 percent of those who had applied in the previous year renewed their prescription a year later and were supplied with shoes. Our assumed alternative rates of shoe-supply renewal in the national benefit alternatively include (1) the demonstration rate (23.3 percent), (2) a rate 100 percent higher (46.6 percent), and (3) a rate

"We assume that newly eligible beneficiaries exactly replace previously eligible beneficiaries who die. Thus, we may slightly underestimate the true steady-state rate if the proportion of beneficiaries with diabetes were growing.

200 percent higher (69.9 percent). The alternate rates of renewal that we have selected are considerably higher than the demonstration rate because we believe that suppliers may be more active in informing clients about the benefit than they were in the demonstration. Assuming that they would no longer have to accept assignment of Medicare benefits, more of them are likely to play this more active role.

c. The Covered Benefit

The covered benefit in the demonstration included one pair of shoes each year and replacement inserts and modifications. Two types of shoes were covered. We assume that in the national benefit the ratio at which the different types of shoes would be used would be alternatively (1) the same ratio as in the demonstration (42.9 percent depth-inlay to 57.1 percent custom-molded), (2) a 10 percent higher rate for depth-inlay shoes (47.2 percent depth-inlay to 52.8 percent custom-molded), and (3) a 25 percent higher rate for depth-inlay shoes (53.6 percent depth-inlay to 46.2 percent custom-molded). Furthermore, we assume that the rate at which replacement inserts and shoe modifications would be used in the national benefit could be higher than the low demonstration rates (6 percent or less), and we assume alternately that the rate at which replacement inlays and modifications would be used would increase by 25 percent and 100 percent, respectively. The alternative rates at which depth-inlay shoes would be supplied reflect clinicians' expectations about the proportions of the participating beneficiaries who could actually have worn such shoes. If the types of patients who received the benefit in the national program changed specifically--for example, more patients without previous ulcerations--the rate at which depth-inlay shoes could be provided

could be much larger. We have assumed that the clinical conditions of those who receive the prescriptions would not change from the demonstration experience.

d. Medicare Prices

In the demonstration, Medicare set maximum allowable charges and paid 80 percent of those charges after the beneficiary had met the annual Medicare Part B deductible. For purposes of costing out the benefit, we have assumed that the national benefit will use the demonstration prices prevailing in 1992, the last year of the demonstration.

2. Range of the Likely Costs of the National Benefit in Its First Year Based on Demonstration Assumptions

Given the alternate assumptions described, an enormous number of different cost estimates could be presented. Instead, for each of the three annual cost-impact estimates per beneficiary from the demonstration (-$701.46, or the low bound of the confidence interval: $45 1.36, the point estimate; and $1,604.17, or the high bound of the confidence interval), we present only three alternate estimates that assume the same prices as in the demonstration but alternate participation rates, plus an estimate based solely on the cost of the shoe estimate.

Since the cost-impact estimate is a net annual cost per applicant, we can simply multiply the estimated number of applicants by the estimated cost impact. The number of applicants we have assumed for the first year of the benefit is extrapolated from the demonstration experience. After 3 years, the demonstration had enrolled 0.6 percent of all eligible diabetic beneficiaries in the demonstration States. Thus, we assume that one-third of 0.6 percent of eligible beneficiaries nationwide would enroll in the first year (6,998). Alternately, we assume

rates of 50 percent and 100 percent above that rate (10,497 and 13,997, respectively). The product of these estimates of annual Medicare costs ranges from nearly -$10 million to just over $22 million with a midpoint estimate of $6.3 million, as shown in Table VI.3. These estimates are for the first year of the national benefit. As shown in the note to Table VI.3, the estimate based only on the shoe costs lies between $1 million and $1.8 million in the first year.

3. **Range of the Likely Casts of the National Benefit in a Steady-State Period**

We also estimated the net cost of a national benefit by assuming that it occurs in a steady-state period (with only one-third of initial applicants in a given year) and alternately by using the medium and high participation and shoe-supply assumptions for a national benefit from Table VI.2.

The impact of each alternative assumption on costs is shown as a percentage relative to the demonstration assumptions in Table VI.4. The impacts are driven by our assumptions about the likely size of changes. Thus, the single most important factor in net costs or savings is the number of beneficiaries who use the benefit. The next most important factor is the proportion of beneficiaries who receive depth-inlay shoes.

First, we assume that the point estimate from the demonstration is the best estimate of the effect of the benefit on costs, and, furthermore, that the estimate of $451 per applicant per year is essentially the cost of the therapeutic shoes and does not include additional medical

TABLE VI.3

RANGE OF ESTIMATED COSTS FOR THE FIRST YEAR OF THE NATIONAL BENEFIT. ASSUMING NO CHANGES IN THE THERAPEUTIC SHOE BENEFIT

	Annual Cost per Applicant		
	Lower Bound	Best Estimate	Upper Bound
Participation Rate	-$701.46	$451.36	$1.604.17
Demonstration Extrapolation (6,998)[a]	-$4,908,817	$3,158,617	$11.225,982
50% Over Demonstration (10,497)	-$7,363,226	$4,737,926	$16838.972
100% Over Demonstration (13,997)	-$9.818.336	$6.317.686	$22.453.567

NOTE: If the cost of the shoe benefit *only* is calculated, the first-year cost is $133.3 1per applicant. Multiplying this rate by the alternate participation rates yields costs of bctwccn $932.903 (6,998 participants) and $1,865,807 (13,997 participants) in the first year. The $ 133.31 rate is derived from the national cost assumptions in Table VI.2 with one change: rather than 33 percent of applicants being new. all are assumed to bc new.

[a]Estimated as 0.6 percent of the national estimate of diabetic Medicare bcneficiarics (X461.781). divided by 3--to parallel the demonstration experience of 0.6 percent of eligible bcneficiarics enrolling over 3 years.

TABLE VI.4

INCREASE IN THE COSTS OF THE NATIONAL THERAPEUTIC SHOE BENEFIT OVER THE DEMONSTRATION COSTS ATTRIBUTABLE TO SPECIFIC ASSUMPTIONS

Changing Assumption	Estimated Increase fmm Each Assumption Independently (1) Medium-Cost Assumptions	(2) Ifigh-Cost Assumptions
Number of Eligible Applicants	+50.0 %	+100 %
Percentage Using the Benefit		
New users	5.9 %	+14.9 %
Renewal users	49.6 %	+81.2 %
Percentage Using Depth-Inlay Shoes		
42.9% (Basic assumption)	0.0 %	0.0 %
47.2% (Medium assumption)	-2.8 %	-2.8 %
53.6% (High assumption)	-7.0 %	-7.0 %
Percentage Using:		
Replacement inserts	+0.3 %	+1.2 %
Modifications	+0.4 %	+1.7 %
Combining All Assumptions		
Total Cost per Applicant[3]	+47.6 %	+ 101.6 %
Total Costs[a]	+ 121.4 %	+303.3 %

NOTE: The increase in costs attributable to each assumption is calculated by substituting one-by-one the assumptions in Table VI.? for the demonstration assumptions in the following formula:

# of applicants • ((% new applicants • % of new users using) + (% renewal applicants • % of renewal users using)) • (% using depth-inlay shoes • $115.75) + • (% using custom-molded shoes • $240.80) + • (% using replacement inserts • 542.00) + • (% using modifications • S51.24).

Additional effects per assumption will not add to the total.

"Total costs under the demonstration with the basic assumption about the proponion of depth-inlay to custom-molded shoes.

care.[4] Thus, we have assumed that the covered benefit or the allowable charges do not change. Second, we apply the steady-state demonstration participation assumptions from Table VI.2 to this estimate, which has two contradictory effects on the estimate of national costs. The cost per participant declines due to the low rate of shoe purchase (23 percent) among beneficiaries who are eligible to renew the benefit (who comprise two-thirds of the applicants in the steady state) (a reduction by a factor of 0.556). However, we also assume three times more participants each year in the steady state, which drives the annual costs above the cost for the first year--annual net costs to Medicare of $5.3 million, rather than $3.2 million.' The derivation of this estimate is shown in Table VI.5.

Next, we estimate national costs under the "medium" assumptions from Table VI.2--that is, we increase both the number who receive a prescription and the number who fill it. These changes increase the costs by a factor of 2.214, increasing the estimate from $5.3 million to $11.7 million. If the national benefit increased the rate at which depth-inlay shoes are used.

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[4]In fact, the cost of the shoe benefit was considerably less than the impact estimate of $451 per applicant. In a steady-state period, when only one-third of the participants are new, we estimate that annual participant costs would range from $74 to $149 (see Table VI.2). The main reason that the impact estimate is higher than the costs of the shoes alone is that it includes physician visits associated with the benefit. For example. some beneficiaries probably had an extra visit to have their Certification and Prescription Form completed. Others may have made extra visits to check how the shoes fit after they had been supplied by this or another practitioner.

"The ratio of costs per user in a l-year period in which one-third of users are new to the costs per use in any l-year period in which all users are new is 1: 1.8. Thus, the ratio of steady-state to start-up costs is 0.556. However, participation will have built up to a greater level than in the first year. Based on the experience of the demonstration, we have assumed that participation reaches a steady state of three times the annual average demonstration rate after 3 years. Thus, compared with the first year of the national benefit, costs in the steady state would be 1.667 times higher (3 * 0.556).

the net cost would be lower: $10.9 million if 54 percent of the shoes supplied were depth-inlay.

Finally, we estimate national costs under the "high" assumptions from Table VI.2--that is, we again increase the participation rate. As shown in Table VI.5, the high-cost assumptions yield an annual cost estimate of $21.3 million. If a higher purchase rate for depth-inlay shoes could be achieved, this estimate would drop to $19.8 million if 54 percent of the shoes supplied were depth-inlay. If our participation assumptions are too modest and participation in a national benefit more than doubles, these costs would expand proportionately.

4. **Comparison with Earlier** Reports

In the Report to Congress on the basis of which the shoe benefit was introduced nationally, slightly different national cost estimates were provided. The differences between that Report and this Final Comprehensive Report are the result of several factors. First. the sample available for the earlier report was smaller than that available for this final comprehensive report. Thus the point estimate of the impact differed:

- Earlier report $432 (with a confidence interval of -$497 to $1,362)
- Current report $451 (with a confidence interval of -$701 to $1,604)

Second, the assumptions drawn from the demonstration differed because of the larger sample and longer experience in the final report. Most importantly, in the earlier report we assumed. for the start-up period cost estimates, that the demonstration participation rate could he achieved in one year. This yielded higher first year costs than we are now estimating.

TABLE VI.5

RANGE OF NATIONAL COST ESTIMATES UNDER VARIED PARTICIPATION ASSUMPTIONS

Assumption	Net Annual Cost to Medicare
Demonstration Assumptions, First Year	$3,158,617
Demonstration Assumptions, Steady-State Period (First Year * .556 x 3)"	$5,269,326 [b]
Medium Changes to Assumptions (Steady-State * 2.214)'	$11,666,288 [d]
High Participation Changes to Assumptions (Steady-State * 4.033)[e]	$21.251.193 [f]

NOTE: Estimates are based on a point estimate of $45 per applicant per year, adjusted for changes in participation and shoe-use assumptions.

"The ratio of costs per user in steady-state period to costs in the first year start-up period is 1:1.8, or 0.556. The basis of this ratio is a computation using the p&-applicant cost assumption in Table VI.2. and assuming alternately that one-third of all applicants in a one-year period arc new, and that they purchase the shoes at the rates shown for new and renewing users (68 pcrccnt and 19 pcrccnt. respectively). This ratio is multiplied by three to account for the increased participation in a steady-state period compared with the first year.

'The alternate costs For depth-inlay shoe-use rates of 47 percent and 54 percent arc $5.1 million and $4.8 million.

The ratio of shoe costs in a national program when demonstration assumptions are increased moderately relative to the demonstration is 2.214 (see Table VI.2), a ratio of $3,442,764:$1,555,134).

[d]The alternate costs for depth-inlay shoe-use rates of 47 percent and 54 percent arc $1 1.3 million and $10.9 million.

[e]The ratio of shoe costs in a national program when demonstration assumptions arc incrcnscd substantially relative to the demonstration is 4.033 (see Table VI.2), a ratio of $6,271,579:$1,555,134).

'The alternate costs for depth-inlay shoe-use rates of 47 percent and 54 percent are $20.7 million and $ 19.8 million.

However, the steady-state period estimates are very similar.

- Second Report to Congress: first year cost range based on demonstration assumptions, but accelerated enrollment:

  savings $8 million
  increased costs $23 million
  midpoint estimate $7 million

- HCFA Office of the Actuary: estimate of first year costs (fiscal 1994)
  $15 million

- Current report: first year cost range based on demonstration assumptions:

  savings $5 million
  increased costs $11 million
  midpoint estimate $3 million

- Current report: using the accelerated enrollment assumptions of the Second Report to Congress yields:

  savings $15 million
  increased costs $34 million
  midpoint estimate $10 million

Doubling the start-up period participation rate assumptions yielded the following cost ranges:

- Second Report to Congress; first year; accelerated enrollment and doubled participation:

  savings of $17 million
  increased costs $46 million
  midpoint estimate $14.6 million

- Current report; first year; cost range for doubled participation:

  savings of $10 million
  increased costs $22 million
  midpoint estimate of $6 million

- Current report: using the accelerated participation assumptions of the earlier report yields:

  savings $30 million
  increased costs $66 million
  midpoint estimate $18 million

For the steady-state period estimates of costs the only differences in the estimates derive from the differences in the demonstration results between the two reports:

- Second Report to Congress; steady-state period, midpoint estimate for demonstration assumptions:

  midpoint estimate $4 million

- Current report; steady-state period, midpoint estimate for demonstration assumptions:

  midpoint estimate $5 million

- Second Report to Congress; steady-state period, midpoint estimate for high cost assumptions:

  midpoint estimate $18 million

- HCFA Office of the Actuary: estimate $20 million in fiscal 1996 and $25 million in fiscal 1997

- Current report; steady-state period, midpoint estimate for high cost assumptions:

  midpoint estimate $21 million

5. Potential for a Cost-Effective Benefit

Weighing the factors that affect the cost-effectiveness of a national program and the evidence provided by the demonstration on those factors suggests that, although we cannot

determine whether the benefit is or is not cost-effective? it may be. If it is implemented as recommended in this chapter, it is slightly less likely to be cost-effective than in the demonstration given the additional costs of the added modifications. The most obvious way to increase its cost-effectiveness would be to increase the rate at which depth-inlay shoes are prescribed (and thus reduce the rate at which custom-molded shoes are prescribed). If the major suppliers of depth-inlay shoes became more aggressive about promoting the prescription of depth-inlay shoes, the average cost per user would decline. The suppliers might become more aggressive if they were no longer bound to accept assignment of Medicare benefits. However, without the requirement that assignment of Medicare benefits be accepted. the costs to beneficiaries would rise, and fewer beneficiaries would purchase the shoes.

E. LONG-TERM CHANGES TO THE NATIONAL BENEFIT

In the long run, it may be advantageous to modify the demonstration benefit and the procedures that are used to supply therapeutic shoes in order to maximize the access of beneficiaries to the shoes, to improve the quality of the shoes supplied. and to contain the costs to Medicare. This section draws on the findings from the demonstration and the suggestions of physicians, suppliers, and professional associations to recommend longer-term changes to the structure of and the procedures that govern the benefit. The cost implications of these recommendations are also explored.

1. Potential Changes and Recommendations

Several changes may be beneficial in the long run if therapeutic shoes are to be covered by Medicare, including changes in the beneficiary eligibility criteria, the shoe benefit (the number and type of shoes, inlays, and modifications covered), the physician certification and prescription requirements, the prices paid by Medicare, and the procedures used to supply the shoes. Below, we **discuss changes proposed by some of the professionals** involved in prescribing and supplying shoes to diabetic patients in the demonstration. We then recommend long-term changes to the benefit, based on an evaluation of their recommendations.

a. Beneficiary Eligibility Criteria

The demonstration imposed three clinical eligibility criteria on beneficiaries: the presence of diabetes, the presence of specific clinical foot conditions, and the existence of a comprehensive plan of care for the diabetes.

The physicians interviewed in visits to the demonstration States accepted the necessity of imposing clinical eligibility criteria and had only one suggested change.' The exception was that the presence of Charcot's foot be made an explicit eligibility criterion (in fact, it was included under the general criterion of foot deformity).[7,8]

"Appendix E describes the site visits.

'The benefit was clearly intended to cover patients with Charcot's foot. In Charcot's foot, the metatarsal bones may collapse, producing new pressure points. With these gross structural changes, plantar ulcers may develop.

The professional associations suggested several modifications to the clinical eligibility criteria. One association suggested that a clinical panel be formed to establish the criteria for a national benefit, because the demonstration eligibility criteria were not related to risk. Another suggested making patients eligible earlier in the progression of the disease (even though the current criteria do not appear to have limited early enrollment in the demonstration). Others suggested that the degree of neuropathy be indicated, and that foot management (including the type of footwear) be related to the level of neuropathy, deformity. and ulceration history.

Three options are available for a revised national benefit:

1. To use the demonstration clinical eligibility criteria--they do not appear to have excluded anybody whom the Congress intended to cover.

2. To convene a clinical panel to recommend clinical eligibility criteria

3. To follow the recommendations of the American Orthopaedic Foot and Ankle Society to relate clinical conditions to foot management requirements, including the types of shoes required. These recommendations represent the current teaching at the American Academy of Orthopaedic Surgeons and are used in the Complete Foot Care Course of the American Orthopaedic Foot and Ankle Society (see Appendix M).

Recommendations. The evaluation did not show that the effectiveness of the demonstration benefit differed for beneficiaries with different foot problems. The criteria as currently stated are sufficiently broad that patients at risk of problems--who need the shoes to prevent a first occurrence of ulcers and sores--can receive the benefit (and did in the

[8]Several of the physicians suggested that the benefit be made available to other types of patients, such as those with arthritis.

demonstration), and that patients who have already had severe problems can be included as benefit recipients. Hence, we do not believe that changes to the eligibility criteria are pressing. However, the proposal of the American Orthopaedic Foot and Ankle Society for relating clinical conditions to appropriate footwear merits further consideration.

b. The Covered Benefit

The demonstration benefit included two types of shoes (custom-molded and depth-inlay), customized multiple-density inserts, and certain modifications. The shoes were renewable annually, and two pairs of replacement inserts, or modifications of the same value. were allowed each year.

All of the physicians, beneficiaries, and professional associations and all but one of the suppliers with whom we spoke, strongly supported Medicare coverage of therapeutic shoes. both because they believe that the shoes help prevent foot problems and because the high cost of the shoes implies that beneficiaries need the benefit in order to afford them (a view supported by the survey of participants). The respondents commented on the types and number of shoes that should be covered, the frequency with which they should be renewed. and the price of the shoes. One podiatrist was certain that the benefit would be abused by patients and physicians, and thus recommended against introducing it.

Most respondents felt that one pair of shoes annually was insufficient, for three reasons: when the foot structure changes dramatically (as, for example, with Charcot's foot), new shoes are necessary; active patients need two pairs of shoes, although inactive patients may be able

to manage with one pair; and, in the first year of coverage, two pairs are required to ensure that pairs of shoes are alternated, thus improving foot hygiene and increasing shoe wear.

As discussed in Section C, an expanded list of modifications was also suggested hy respondents, which we recommended be incorporated in the national benefit immediately, since it is consistent with the legislation.[9]

Although opinions differed, most suppliers recommended that repairs be covered, because the shoes might not otherwise remain clinically effective. The coverage of repairs to durable medical equipment under Medicare Part B was cited as an appropriate precedent for covering shoe repairs.

Based on these suggestions, the following options for changes to the benefit should be considered in the long term:

1. Cover two pairs of shoes each year, or allow some tlexibility, such as covering two pairs of shoes in the first year, and allow replacements when major structural changes occur to the foot, even if a full year has not elapsed since the last shoes were supplied

2. in conformance with coverage for repairs for durable medical equipment under Medicare Part B, allow shoe repairs to be covered

Recommendations. We recommend that the demonstration configuration of shoe benefits be offered in the national program, with one addition:

[9]The list of additional modifications includes flared heels, extended steel shanks. leg-length modifications, velcro closures, rigid heel counters, and accommodations to inserts for missing toes (toe blocks).

- *Coverage for shoe repairs (to be consistent with the coverage of repairs for other durable medical equipment items).* [10]

The national benefit would then provide annual coverage for the following items:

1. One pair of either custom-molded shoes OR depth-inlay shoes, AND
2. One pair of customized, multiple-density inlays with depth-inlay shoes. AND A CHOICE OF:
   a. Up to two pairs of replacement customized, multiple-density inlays, OR
   b. Modifications *(the expanded list)* of therapeutic shoes up to the price of two pairs of replacement inlays, OR
   c. Repairs to the shoes up to the price of two pairs of replacement inlays, OR
   d. Any combination of a, b, or c

Clinicians argued convincingly for covering more than one pair of shoes in the national benefit, again because alternating the shoes worn daily improves both foot hygiene and shoe life. Beneficiaries who need therapeutic shoes should not wear ordinary shoes. Thus. beneficiaries need more than one pair of therapeutic shoes. We recommend that Congress consider:

- *Coverage for two pairs of shoes in the first year in which any beneficiary receives the benefit.*

"Medicare Carriers Manual, Section 4105.2, described in Commerce Clearing House (1993), paragraph 10281.02.

Obviously. this recommendation could double the first-year costs of the benefit if all beneficiaries used the full benefit. Furthermore, some diabetic patients experience major structural changes in their feet, necessitating new shoes. Clinicians would also like the flexibility of being able to put the patient in new shoes when such changes occur. We recommend that:

- ***Congress allow therapeutic shoes to be replaced more often than annually--that is, when a clinician certifies that major structural changes have occurred.***

c. The Certification and Prescribing Procedures

The demonstration certification and prescription process for therapeutic shoes required one or two physicians: the primary diabetes manager, to certify the eligibility of the beneficiary; and a physician, to prescribe the shoes. Most of the physician, supplier. and professional association staff interviewed in the last 8 months of the demonstration recognized that both the certification of medical eligibility and a prescription for therapeutic shoes were necessary to meet the legislative requirements of the demonstration and to ensure clinical and fiscal responsibility in a national program. But they suggested that the certification and prescribing processes be modified.

Congress required that the medical physician responsible for managing the care of the diabetes certify that the beneficiary had diabetes and was in a comprehensive plan of care, in an effort to target the therapeutic shoes benefit at those who had a specific need for them and for whom they would be clinically effective. Most of the podiatrists whom we interviewed felt that they, too, should have been allowed to certify that their patients had diabetes, since they

know which of their patients have the disease. A few respondents recommended that podiatrists not be allowed to certify patients, though one professional association suggested a compromise--that they be allowed to certify the ***need*** for therapeutic shoes. The dilemma here is between the practice paradigm in which primary care physicians would certify diabetes and refer the patient to a footcare specialist, who would then prescribe the shoes, and the practical reality that footcare physicians are most likely to initiate shoe use.

The prescription process in the demonstration was simple; the physician was required only to check the type of shoes to be supplied (either custom-molded or depth-inlay) on the Certification and Prescription Form. Several respondents recommended that a shoe prescription include a detailed diagnosis (such as Charcot's foot), that it describe the accommodations required in the shoes, and that it be goal-oriented (see the proposed certification and prescription form in Figure VI.1). The implication of this prescription process (voiced by a few) is that shoes should be prescribed only by those experienced in footcare and therapeutic footwear. Again, this is the paradigm, which must be posed against the reality recognized by most respondents--that it is not practical to restrict the specialties of physicians who may prescribe therapeutic shoes, even if most of them do not know how to prescribe them. Table VI.6 summarizes the options for procedural changes in a national program.

Recommendations. If the shoe benefit is introduced nationally, we recommend changing the demonstration requirement that the physician who manages the diabetes certify the

TABLE VI.6

SOME OPTIONS FOR CHANGES IN PROCEDURES IN THE NATIONAL PROGRAM

Demonstration Procedure	Required in the National Program?	Options in the National Program
Prior Authorization/Medical Necessity Certification		
1. Physician Certification of Beneficiary Eligibility	Yes[a]	1. Require that primary care physician certify. 2. Allow any physician to certify. 3. Combine with prescribing procedure.
2. Physician Prescription for Therapeutic Shoes	Yes[a]	1. Require that a footcare specialist prescribe.[b] 2. Allow any physician to prescribe.[b] 3. Combine with certifying procedure'
Supplying Shoes		
1. Quality Assurance	Yes	1. Use demonstration approach of requiring specified disciplines and certifications. 2. Develop shoe standards: (a) Detailed descriptions and lists of covered shoes. (b) Certify or authorize shoe manufacturers and laboratorics. (c) Require facility certification. 3. Use utilization review.
2. Set Fee Schedule for Shoes	Yes[a]	1. Allow carriers to set prices according to local and regional variation. 2. Set minimum national prices.

[a]Required under Medicare Part B regulations for durable medical equipment, ***Medicare Carriers Manual,*** Section 4105.2.

[b]Claims for prosthetics and orthotics under Medicare Part B are required to include a physician prescription that includes diagnosis, prognosis. reason required, and an estimate of the duration of need. Carriers may develop customized. medical necessity certification forms ***(Medicare Carriers Manual,*** Section 4105.2).

patient's eligibility for the benefit. Because footcare specialists are those most likely to initiate shoe use, we recommend that:

- ***Podiatrists and other physicians who are not managing the diabetes be allowed to certify the clinical eligibility of the beneficiary.***

Thus, the process of acquiring the shoes could be accelerated, and the cost of an additional visit to the medical physician may be avoided. Allowing podiatrists and other nonmedical physicians to certify eligibility may also increase the rate at which beneficiaries, receive prescriptions from physicians.

d. Medicare Prices

The Medicare prices for the two types of shoes covered in the demonstration drew criticism from the industry because they were low compared with the prices charged by shoe suppliers to privately paying customers, and because the markup over the wholesale price was larger for the more expensive custom-molded shoes than for the depth-inlay shoes.

Some shoe suppliers did not seek authorization to supply shoes under the demonstration, due supposedly to the low Medicare shoe prices (combined with the requirement that suppliers accept assignment of Medicare benefits). A revised pricing structure could increase the number of authorized suppliers, which would probably increase the participation rate among eligible beneficiaries (increased shoe payments are likely to increase the number of patients whom suppliers refer to a physician for coverage). If the quality of suppliers who would choose to enroll at the demonstration prices differed from the quality of those who

would enroll at higher prices, higher prices might also change clinical outcomes (it is not clear in which direction).

Due perhaps to the differential markups, custom-molded shoes were prescribed and supplied more often in the demonstration than were depth-inlay shoes (more often than had been anticipated based on the input of clinicians during the design of the demonstration). Increased markups for depth-inlay shoes could increase the proportion of depth-inlay shoes supplied, assuming that some proportion of those who received custom-molded shoes in the demonstration could have worn depth-inlay shoes. Should this occur, it would reduce the relative cost of the benefit.

Recommendations. Shoe suppliers incur several types of costs: taking casts of the feet (for custom-molded shoes), supplying the shoes, customizing the shoe inserts (for depth-inlay shoes), and fitting the shoes, which should include follow-up checking after wear to determine whether the fit is good or whether modifications are required. We recommend that prices he adequate to cover all these aspects of supplying shoes. Specifically, we recommend that:

- ***Medicare payments be changed from the demonstration rates to bring the method of payment into line with other Part B services, and that the relative prices of depth-inlay and custom-molded shoes be altered. Furthermore, we recommend that custom-molded shoes be priced per shoe, rather than per pair, to accommodate patients who need only one shoe.'*** [1]

"Note that when a podiatrist supplies the shoes, he or she should not be charging Medicare for a routine visit when the purpose of the visit is solely for casting or fitting. the cost of which is included in the shoe price.

One of the reasons for providing the coverage was the high cost of the shoes. which beneficiaries could not afford (a view supported by the results of our survey of control group participants in the demonstration). Because we recommended that Medicare assignment not be required of suppliers, which could increase the out-of-pocket costs to beneficiaries, we also recommend that:

- ***Medicare prices be increased to ensure that an adequate number of shoe suppliers will accept assignment of benefits. With this change, beneficiaries would be less likely to be discouraged from purchasing the shoes because their out-of-pocket cost was too high.***[12]

Furthermore:

- ***Congress may also wish to consider allowing competitive bidding for a limited number of custom-molded shoe manufacturers nationally to produce custom-molded shoes from the positive foot carts taken by shoe suppliers, in order to obtain advantageous wholesale prices from high-quality manufacturers.***

e. Procedures for Supplying the Shoes

Physicians, suppliers, and professional associations also suggested increasing the quality standards for supplying shoes. One professional association preferred setting shoe standards over setting professional standards, and thought that it might be useful for the American Diabetes Association's foot council to set the shoe standards. Another professional association

[12]The Medicare allowable charge for custom-molded shoes was set at $316 at the end of the demonstration. Assuming that suppliers would accept assignment only if the Medicare allowable charge were set at, say, $340, they would not accept assignment at $316, but instead would charge the beneficiary $340, and the beneficiary out-of-pocket cost would be 20 percent of $316 ($63.20) plus the difference between $316 and $340 ($24), a total of $87.20. On the other hand, if the Medicare allowable charge were set at $340, the beneficiary would pay only $68.

suggested that the Prescription Footwear Association be asked to describe the appropriate types of shoes. Other suggestions included requiring that the shoe laboratories that make the custom-molded shoes covered by Medicare be certified, and that shoe suppliers have an adequate inventory of depth-inlay shoes.[13] Increasing the training of the professionals who fit shoes was also recommended. (See Table VI.6.)

Recommendations. We recommend some regulatory changes to ensure quality standards for shoe fitting. We recommend distinguishing suppliers who are authorized to supply custom-molded shoes from those authorized to supply depth-inlay shoes. We recommend that:

- ***To be authorized to supply depth-inlay shoes, the supplier carry a stock of depth-inlay shoes (which would help ensure that depth-inlay shoes can be fitted properly and without excessive delays).***

Furthermore, we recommend that:

- ***Facilities that supply either type of shoe should be required to meet the specifications of the relevant professional body-for example, the Board for Certification in Pedorthics for pedorthists (Board for Certification in Pedorthics, 1992).***

The effect of these changes on Medicare costs is unclear. The higher standards might lower the number of authorized suppliers, and hence might mean that fewer shoes would be supplied. However, these standards may also lower Medicare costs if they improve the quality of shoe-fitting. However, Medicare administrative costs would increase if the qualifications of facilities had to be verified.

[13] A stock of depth-inlay shoes would include shoes of varying styles, lengths, and widths. One supplier estimated that the inventory would cost $50,000.

2. Cost Implications of the Recommendations

Changes to the benefit have two types of impacts: those that affect the cost per user, and those that affect the beneficiary participation rate. These effects may be direct or indirect and are likely to interact. Both the short-run changes recommended in Section D and the long-run changes recommended in this section are listed in Table VI.7, with the expected direction of the impact of the change on the cost per user and beneficiary participation rates. This section describes assumptions about the size of these impacts and estimates the costs of a national program that includes them.

a. Assumptions about Cost impacts

The costs of the benefit would increase if several recommendations in this section were adopted: covering repairs, covering more than one pair of shoes each year under certain circumstances, and increasing Medicare-allowable prices for the shoes. These increases would augment the cost increase from the short-run recommendation (discussed in Section D) that additional shoe modifications be covered.

Allowing physicians other than the primary diabetes manager to certify the eligibility of beneficiaries would reduce costs (due to a reduction in the number of visits), and engaging in competitive bidding for the manufacture of custom-molded shoes would also reduce costs.

For the purposes of estimating national costs, we assumed the following impacts on prices:

- *Repairs.* Cost per user: $42 (the same as the average Medicare payment for replacement inlays in 1992); alternate rates of use: 5 percent or 10 percent of users

TABLE VI.7

DIRECTION OF THE IMPACTS OF RECOMMENDED CHANGES TO THE MEDICARE THERAPEUTIC SHOE BENEFIT

Aspect of Demonstration Benefit	Change in National Benefit	Impact on Cost per Beneficiary	Impact on Prescription and Shoe Purchase Hales
1. Beneficiary Eligibility Criteria			
• Medicare Part B enrollment • Diabetes diagnosis • In plan of comprehensive care for diabetes • Clinical conditions present: - Previous tower-extremity amputation - Foot deformity with potential for ulceration (neuropathy) - Callus formalion or a history of callus formation with peripheral neuropathy - Poor circulation - History of previous foot ulceration	No change	No change	No change
2. The Covered Benefit			
a. Cuslom-molded shoes (i) One pair per year	No change	No change	No change
	OR (ii) Two pairs of shoes in the first year that beneficiaries are covered or if fool structure changes	Increase	No change
OR			
b. Depth-inlay shoes (i) One pair per year	No change	No change	No change
	OR (ii) Two pairs of shoes in the first year that beneficiary is covered	Increase	No change
AND			
c. Customized. multiple-density inserts for deplh-inlay shoes (one pair with shoes)	No change	No change	No change
AND			
d. Customized. multiple-density replacement inserts for either type of shoe (up to two pair per year)	No change	No change	No change

TABLE VI.7 *(continued)*

Aspect of Demonstration Benefit	Change in National Benefit	Impact on Cost per Eteneficiaty	Impact on Prescription and Shoe Purchase Rates
OR			
e. Modifications to shoes up to the cost of two pairs of customized, multipledensity replacement inserts	Additional modifications	Increase	No change
	OR		
	f. Repairs to shoes up to the cost of two pairs of customized, multipledensity teplaament inserts	Increase	No change
3. Certification of Medical Necessity			
Physician who is managing the beneficiary's diabetes certifies eligibility (diabetes diagnosis, in plan of care, and clinical conditions)	Any physician certifies medical eligibility	Possible reduction	Increase in prescription rate
Any physician prescribes shoes	No change	No change	No change
Prior authorization & randomization	No prior authorization or randomization	No changes	Increase in prescription and shoe-purchase rates
4. Supplying the Shoes			
a. Supplier authorization			
(i) Supplier has employee(s) from among: - Podiatrist - Certified Pedorthist - Certifii Orthotist - Certified Prosthetist - Certified Orthotist/Prosthetist	No change	No change	No change
	(ii) If supplier is a nonmedical provider, it meets the facility specifications of the relevant profession	Unknown	Unknown
	(iii) To be a supplier of depth-inlay shoes, supplier must stock an inventory of depth-inlay shoes	Unknown	Unknown
b Supplier accepts assignment of Medicare benefits	Supplier need not accept assignment of Medicare benefits	Unknown	Reduction in shoe-purchase rate unless allowable charges increase

TABLE VI.7 *(continued)*

Aspect of Demonstration Benefit		Change in National Benefit	Impact on Cost per Beneficiary	Impact on Prescription and Shoe Purchase Rates
c. Medicare payment levels (in 1992) (allowable charges)				
Custom-molded shoes	$316	Increase[b]	increase	Increase in prescription rate. Possible decrease in shoe purchase rate.
Depth-inlay shoes	$105	Increase[b]	Increase	Increase in prescription rate. Possible decrease in shoe purchase rile.
Customized multiple-density inserts	$53	No change	No change	No change
Modifications:				
Rigid rocker bottom	$79	No change	No change	No change
Rigid roller bottom	S79	No change	No change	No change
Metatarsal bars	$26	No change	No change	No change
Wedges	$26	No change	No change	No change
Offset heels	$53	No change	No change	No change
Flared heels	--	Increase[c]	Increase	No change
Extended steel shanks	--	Increase[c]	Increase	No change
Leg-length modifications	--	Increase[c]	increase	No change
Velcro closures	–	Increase[c]	Increase	No change
Rigid heel counters	--	Increase[c]	increase	No change
Accommodations to inserts for missing toes	–	Increase[c]	Increase	No change
Repairs	–	Increase[c]	Increase	No change,

[a]This excludes the administrative costs of the demonstration.

[b]For the purpose of the cost estimates discussed in this chapter, we assumed $340 per pair of custom-molded shoes and $111 per pair of depth-inlay shoes,. These prices are 150 percent of the average whoksak price quoted by interviewed suppliers.

[c]Prices for these items would have to be set. possibly based on discussions with industry representatives. For lhe purpose of the cost estimates discussed in this chapter. we assumed an annual cost per user for repairs of $42.00.

- ***Increased allowable charges.*** 150 percent of the average wholesale prices quoted by suppliers (custom-molded shoes, $340; depth-inlay shoes, $111)
- ***Increased pairs of shoes covered.*** A rate of use of two pairs each year during a steady-state period: 20 percent of new users, and 5 percent of renewing users
- ***Competitive bidding for custom-molded shoes.*** Alternate price reductions of 10 percent and 15 percent
- ***Reduced physician visits for certification.*** Savings of one visit at an allowable charge of $50 for 10 percent of users

b. National Cost Estimates

Based on these cost-impact assumptions, we developed two estimates of the cost of the national benefit that incorporated the changes. The first estimate used the lower cost of any two new assumptions, and the second used the higher cost of any two new assumptions. (All other assumptions were held at demonstration levels.)

Relative to the estimated national costs for the demonstration benefit presented in Section D (Table **VI.5),** the changes recommended in this chapter would increase costs by between 17 and 25 percent. If the allowable charges were not increased, then costs would increase by only 3 to 11 percent.

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