The Role of Community Pharmacies in Diabetes Care: Eight Case Studies

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The Role of Community Pharmacies in Diabetes Care: Eight Case Studies

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About the Foundation

The California HealthCare Foundation, based in Oakland, is an independent philanthropy committed to improving California’s health care delivery and financing systems. Formed in 1996, our goal is to ensure that all Californians have access to affordable, quality health care. For more information, visit us online (www.chcf.org).

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I. Introduction

**Community pharmacies are accessible and already linked to care because of diabetes patients’ continuous need for medications and supplies.**

**Millions of Americans with diabetes could benefit from the clinical skills of their community pharmacists and the accessibility of their local pharmacies. This is the premise behind a variety of programs around the nation that are enabling community pharmacists to help diabetics maintain their health.**

A recent commentary in the *American Journal of Health-System Pharmacy* recommended that chronic care pharmacy programs be evaluated in terms of quality outcomes as described in the Institute of Medicine’s *Crossing the Quality Chasm* report.¹,²

This report describes eight community pharmacy-based diabetes care programs. They are diverse geographically and serve a wide variety of patients—rich and poor, rural and urban, English-speaking and otherwise. Although programs of this type are not yet common, there is increasing interest in matching the care needs of diabetes sufferers with the professional skills available in their community pharmacies.

The case study examples can serve as models for pharmacists interested in starting clinical programs for diabetes patients. For diabetic patients and others with a stake in improved diabetes care, the case studies explore a new avenue for health support—one that is accessible and already linked to care because of patients’ continuous need for diabetes medications and supplies.

An expert panel of clinicians and researchers with broad experience in diabetes care selected the eight case study programs based on criteria related to quality of care and sustainability. While the programs differ in terms of location, patient demographics, and reimbursement strategies; all offer assessment, education, and monitoring services to a significant number of diabetes patients. All use national guidelines from the American Diabetes Association, the American Diabetes Educators Association, or other widely accepted organizations.

This report highlights the unique innovations or special qualities of particular programs in a number of areas: clinical activities and outcomes; technology and communication; reimbursement strategy; relationships with physicians; and logistics—including the physical layout and its impact on pharmacy operations. These analyses should be helpful to
those seeking to resolve challenges commonly encountered when community pharmacies attempt to implement clinical services that are integrated into the patient’s broader health care picture.

**Background: Why Community Pharmacies?**

Of the 207,000 active, licensed pharmacists in the United States, about 134,000 work in some 55,200 community pharmacies that are well-distributed throughout the country. Community pharmacies include: chain drug stores (37 percent); independent pharmacies (36 percent); units of supermarkets (16 percent); and units of mass merchandisers such as Wal-Mart (11 percent).

Several features of community pharmacies make them well suited to provide services for people with chronic diseases. These include the large number and convenient placement of pharmacies, their long hours of daily operation, and the availability of pharmacists without a prior appointment. Pharmacists in low-income ethnic communities often speak the same language as their customers. Additionally, the training for pharmacists is now both longer and more directed toward clinical activities. Professional training programs are four years in length after two to four years of pre-pharmacy college coursework. All include at least one year of clinical training. In addition, the pharmacist workforce is increasingly inclined to participate in clinical activities. A recent study showed that more than 61.9 percent of pharmacists would like to be involved in more patient consultation, 58.5 percent in more drug management activities, and 94.1 percent in less medication dispensing activity.

Strong links between chronically ill persons and their pharmacies already exist. Most diabetes patients, for example, visit their pharmacies at least once each month to purchase medications and supplies. In fact, generally, there is no other health facility (physician’s office, community health center or clinic) that is visited this frequently. These monthly visits provide opportunities for monitoring, education, and data-gathering that could improve patient self-management and health outcomes and reduce costs related to complications. Pharmacies also strive to employ staff who share the language and culture of the community in which they are located. This makes them especially well suited to work with non-English-speaking populations and people who have emigrated from other nations.

More and more pharmacies are offering health services other than prescription dispensing. The most common example is providing immunizations—especially for flu. Pharmacies increasingly sponsor blood pressure screening, blood lipid assessment, and osteoporosis screening along with patient education and encouragement to visit physicians. In recent years, there has been a national movement toward pharmacists offering clinical services to patients with chronic illnesses, particularly for diabetes mellitus, asthma, hypertension, and hyperlipidemia. The Asheville Project in North Carolina is an example of a chronic illness care program for patients with diabetes. Paid for by the City of Asheville, the six-year-old program has reported beneficial clinical, economic, and humanistic outcomes.
II. Project Design

The researchers created a case report on each program and sent it to an expert panel, a multidisciplinary group of physicians, pharmacists, nurses, and other experts associated with diabetes care.

National pharmacy organizations, including the National Association of Chain Drug Stores (NACDS), the American Pharmacists Association (APhA), and the California Pharmacists Association (CPhA), were contacted to identify best-practice models of community-pharmacy-based clinical services for patients with diabetes.

These sources contributed to an initial contact list of 20 pharmacies or pharmacy organizations with strong diabetes programs. Of these, four could not be contacted or currently had no programs; one didn’t meet the criterion of having a community pharmacy as part of the program; and three declined to participate for proprietary reasons. At each of the remaining 12 programs, an involved pharmacist was interviewed by telephone to gather the following information:

- Pharmacy name;
- Pharmacy type (independent or chain);
- Pharmacy setting (urban or rural);
- Pharmacy specifics: Number of staff pharmacists per day; number of prescriptions filled per day; physical description of the pharmacy; case mix; special education or credentials of the pharmacy staff; patient demographics;
- Type program (education only, collaborative practice, etc.);
- How the program works;
- Logistics: advertising and promotion; reimbursement and pricing;
- Use of technology and other resources in establishing and running the program;
- Assessment of documented outcomes that are associated with the program (clinical, economic, and humanistic);
- Challenges and success factors in setting up and maintaining the program; and
- Advice on establishing new programs.

At least two investigators were present for each data collection session. They used a standardized telephone script to increase consistency. After collection and tabulation, the data were sent back to each interviewee to be reviewed for accuracy.
The researchers created a case report on each program and sent it to an expert panel, a multidisciplinary group of physicians, pharmacists, nurses, and other experts associated with diabetes care (see Appendix A). The panelists used an ordinal scale to evaluate each program on the basis of several criteria (see Best Practices Criteria section). Program characteristics the panel looked for included: clinical activities; patient education; patient incentives; the presence of a multidisciplinary team; technology innovations; reimbursement strategy; program replicability; training of pharmacists; physical environment; collection of outcomes data; and the presence of collaborative practice agreements.

The expert panel met with the project team members and a representative from the California HealthCare Foundation (CHCF) for a day-long session. At this meeting, each program was reviewed and discussed. Based on these discussions, the group identified features that seemed to be present in the strongest programs. These included:

- Recognition of the program or providers through the ADA, APhA, or NABP;
- CDE training or other certification;
- Incentives for patients;
- Economic viability;
- Program maturity and volume of patients;
- Patient follow-up; and
- Connectedness—use of the forums of the ADA, AADE, or the APhA for education, certification, and communication with other programs.

Following the discussion, the expert panel voted on whether to include each program in the final report as a case study. Of the 12 programs under consideration, eight were selected as best meeting the best practices criteria. There was strong consensus for all eight programs.
III. Best Practices Criteria

In assessing program quality, the researchers and expert panel built upon several nationwide standards as guidelines. The National Standards of Diabetes Self-Management Education (DSME), defines quality diabetes self-management education that can be implemented in diverse settings. Programs that meet the national standards are eligible for recognition by the American Diabetes Association (ADA). The ADA’s Education Recognition Program is the only accrediting body that is currently approved by the Centers for Medicare and Medicaid Services (CMS). This recognition of quality can be used to promote the program to prospective customers. Programs that receive recognition from the ADA are also eligible for reimbursement from Medicare.

The researchers and the expert panel looked for the following specific program characteristics and features in selecting best practice models:

Collaborative practice agreements with physicians. These agreements allow pharmacists autonomy in the management of patient care, as well as helping them build good customer relations with patients, and serving as a reliable source of information. Under collaborative practice agreements, pharmacists usually have ongoing communication with physicians and make significant contributions to treatment. In this way, pharmacists serve as the bridge between patients and their health care providers and help to ensure continuity of care.

Connectedness. Pharmacists involved in DSME programs should give presentations and share success stories at local and national organizations such as the American Diabetes Association. It is also important to participate in provider’s day functions at local hospitals, attend community events where patients will see them, and build an alliance with pharmaceutical representatives in order to market their program and learn innovative ways to improve patient outcomes.

Documented organizational structure, mission statement, and goals. Programs must understand their customers’ needs and develop ways to communicate how the diabetes program could help meet them. To accommodate the community being served, the program should conduct an assessment of demographics, including age, type of diabetes, payer mix, educational background, ethnicity, and literacy. Its mission statement should
set out the philosophy and scope of the program, as well as clear, specific patient goals.

**Reimbursement strategies.** Programs must develop reimbursement strategies based on realistic budgeting in order to remain financially independent and sustainable. Those with recognition from the ADA can be reimbursed by public payers (federal and state programs such as Medicare and Medicaid), as well as private payers including insurance companies and self-insured employers. Establishing a contractual arrangement with commercial payers is another option.

**Physical environment.** Successful DSME programs should have adequate space, staff, office equipment, and patient education materials. Programs that offer services to Medicare beneficiaries are required to provide most of the services in a small group format that offers space for the patient and also for a family member.

Ideally, a program should have a room that accommodates 10-20 people as well as storage space for patient education materials and insulin teaching supplies. An office area is also needed for members of the team to meet individually with patients. The decision to offer classes or individual consults or a combination may be influenced by who pays for the services. Medicare and some other insurers require that most educational services be provided in a small-group format.

Hand-washing facilities are required if glucometer training and insulin skills are taught. Local and federal requirements concerning syringe disposal and appropriate cleaning of areas where blood products are used should be checked.

**Patient education.** Patients with diabetes require extensive education in order to manage their disease. The achievement of glycemic control places an enormous impact on a patient’s lifestyle, requiring regular glucose monitoring, diet, lifestyle modifications, and frequent medical visits. Self-management of diabetes includes nutrition, foot care, physical activity, insulin injection and glucometer skills, and management of medications.

**Diabetes education and multidisciplinary teams.** Studies show that patients who receive care from a diabetes specialist have higher rates of self-care and quality of life than patients cared for by a generalist. The benefits of an interdisciplinary approach to diabetes care and education have also been indicated in studies. Team-teaching benefits include: knowledge from professionals with multidisciplinary expertise; better coordination of care and education; multiple reinforcement of the same educational objectives; and consistency of approach to treatment.

DMSE standards specify that such a team may include a behaviorist, pharmacist, physician, registered nurse, and dietitian. Each member brings expertise in a specific area of diabetes management and the team is collectively qualified to teach all content areas—especially when it includes an RN and Registered Dietitian (RD). All instructors must be either a Certified Diabetes Educator (CDE) or have recent didactic and experiential preparation in education and diabetes management.

**Training in diabetes management.** Since diabetes education involves more than pharmacotherapy, pharmacists who wish to start a DSME program must receive training in other aspects of diabetes management. Pharmacists can receive formal training in diabetes education and certification from one of the following: National Community Pharmacist Association, LifeScan, APhA Institute, Board of Pharmaceutical
Curriculum. Patient education materials should be designed to fit a particular setting and group of patients. They should be selected based on disease type (Type 1 or Type 2 diabetes), education, experience, needs, ability, and cultural background. The national guidelines recommend the following content areas for a DSME curriculum: description of the disease, treatment options, nutrition, exercise, blood glucose monitoring, insulin delivery (if applicable), detection and prevention of complications, management of gestational diabetes (if applicable), and goal-setting.

Replication. Programs should be designed in a way that can be replicated in other pharmacies with adequate resources to establish a program. To encourage replication, programs should gather outcomes data and disseminate them through national pharmacy meetings and peer-reviewed professional journals.

Continuous quality improvement (CQI). A CQI process should be in place to assess whether customers are benefiting from the services and if the services are provided in the most effective way. Important outcomes measures include changes in HbA1C, blood pressure, and lipid profile, as well as changes in a patient’s knowledge, attitudes, skills, and quality of life. Useful data collection tools include quality-of-life surveys, charts, or computerized medical records.

Outcomes data pooling. Combining outcomes data from many patients is useful in determining program effectiveness and identifying processes or practices that can improve patient care. The data can also be used to inform payers about the program’s effectiveness.

Effective database. Retrievable data should be stored in a proper database containing a large amount of clinical information that can be accessed by dietitians, nurses, physicians, pharmacist, and other health care providers. The database structure should allow for extensive data analysis. Extracting data in a format that can be analyzed using an external statistical software package is ideal.

Innovative technology. Programs should creatively use technology to foster efficiency, program-building, and communication among physicians, pharmacists, and patients. Areas for innovation include: use of the Web; computer technology for data analysis; and computer-based tools such as form letters, patient release forms, and educational materials.

Program maturity. To be considered a best practice model, programs must have been in operation for at least six months and have supporting data reflecting this length of operation.
VI. Case Studies

Independent Community Pharmacy  
Larkspur, CA

Paul Lofholm, Pharm.D.  
Ross Valley Pharmacy

ROSS VALLEY PHARMACY IS LOCATED IN LARKSPUR, CALIFORNIA, AN affluent, suburban community with a population of approximately 10,000. The pharmacy is close to medical offices and a community hospital. A psychiatric facility and a large prison in the area (San Quentin) influence the prescription mix at the pharmacy.

A second pharmacy with the same owner focuses more on consulting for skilled nursing facilities and hospices. Together, the two pharmacies offer a range of medication management services beyond the diabetes program, including:

- Compounding medications—primarily hormone replacement.
- Pain, anti-emetic, and other medications for about 100 hospice patients.
- Medication regimens for about 45 HIV patients—most of whom are young, gay men with expensive medications.
- Psychiatric medications for patients of a nearby clinic.

In addition, the lead pharmacist is working to develop other clinical services using the diabetes model.

Patients. About 65 percent of the pharmacy patients are over age 65. Although the community is primarily Caucasian, affluent, and highly educated, there is also a significant underserved population. Obesity is not an obvious problem. The payment structure is 30 percent Medi-Cal (due to a federally supported clinic and psychiatry facility nearby), 85 percent third-party payer, and 15 percent self-pay. Currently, there are 24 patients in the program, 20 of whom have participated for over six months. The 24 patients have progressed through the program in three groups.

Pharmacy. The professional staff includes two full-time equivalent (FTE) pharmacists, two part-time pharmacists (0.8 FTE), one pharmacist working only Saturday mornings (0.1 FTE), and a dietitian who is a certified diabetes educator (CDE). The dietitian coordinates the diabetes program and works half-time (0.5 FTE). In addition, there are four technicians, three clerks, two delivery staff, and 1.5 FTE bookkeepers.

The pharmacy dispenses about 270 prescriptions each day. With 3.7 FTE pharmacists, each fills an average of about 73 prescriptions per day, which is somewhat lower than the national average of about 100. Two of the pharmacists have been involved in the diabetes program and other clinical activities, while the two part-time pharmacists have primarily dispensing responsibilities. The pharmacy is recognized by the American Diabetes Association and has also been a community pharmacy residency site.
Pharmacist background. The lead pharmacist received a Pharm.D. from University of California, San Francisco in 1964 and is a clinical professor for that institution. He is also an adjunct professor for University of the Pacific.

This pharmacist holds several certifications related to asthma (American College of Apothecaries), anticoagulation, diabetes, women’s health, compounding, nutrition, and infectious disease. He has been a preceptor to pharmacy students and residents, and has been active in pharmacy associations. Engaged in developing the concept of clinical pharmacy in the community setting for many years, he is currently working on the development of pharmacy networks that can offer clinical services through the California Pharmacists Association.

Diabetes Program

The pharmacy’s involvement with diabetes services began as a gestational diabetes support group. Eventually services for newly diagnosed diabetes patients were developed with new patients coming from physician referrals.

In 2002, the program was upgraded to an American Diabetes Association Medicare-Certified program. The current program involves patient assessment, education, goal-setting, monitoring, and documentation of outcomes. Services are delivered by a multidisciplinary team that includes pharmacists, a nurse practitioner who is a CDE, a health educator, and the CDE dietitian. The program has an advisory board that includes team members, community members, and health practitioners.

Protocols

- **Enrollment.** To gain ADA recognition, the pharmacy was required to demonstrate a record of patients completing the program—a pilot project. To this end, 21 patients were invited to enroll in the program without charge. These patients identified a contact physician, who was then sent a letter about the program and the patient’s enrollment. This process was handled by the program coordinator. Three additional patients were enrolled on a fee-for-service basis. Future patients can self-enroll or be referred by physicians. Generally, because of the relatively high number of physicians in the area, physicians have not been referring heavily to the pharmacy-based program.

- **Initial visit.** The first session includes a history, risk assessment, and review of the patient’s knowledge about diabetes and its management by the program coordinator. A record of clinical data is also established. The pharmacist completes a medication history. Qualifying patients (usually Medi-Cal) are referred to the Marin Community Clinic for problems related to hypertension and diabetes; in turn, the clinic refers patients to the pharmacy program for diabetes management.

- **Educational classes.** Nine topics defined by ADA guidelines are covered by the team in nine weekly two-hour sessions. Topics include: the diabetes disease process; treatment options; nutrition; the benefits of physical activity; appropriate medication use; self-
monitoring; preventing, detecting, and treating acute and chronic complications; goal-setting; and psychosocial adjustments in daily life. Patients are pre- and post-tested.

Follow-up. After the educational programs, patients and their follow-up lab values are monitored for six months. Patients who use the pharmacy for medications and supplies are easier to monitor. Pharmacists and dietitians can bill for these interventions.

Advertising/promotion. The program is publicized through flyers, prescription receipts, letters to physicians, and a local employer.

Reimbursement and pricing. The current charge for the program is $510. Now that the program is Medicare-recognized, both Medicare and third-party reimbursement are anticipated. To date, three patients have paid out-of-pocket to participate.

Technology. Computers are used to maintain aggregate patient data. Individual patient records are paper-based. Software is used to download glucose meter data.

Physician participation. Collaborative practice protocol agreements are in place. Physician participation through referral has been sparse and pharmacists are trying to build a track record with physicians. The slow progress may be due to the high number of physicians in the area.

Outcomes. Outcomes have been tracked for the first 24 patients. Although clinical data are generally not complete, trends for HDL and LDL are generally favorable. Trends for HbA1c are positive and negative but initial values were below 9 percent except in four cases. Evaluations of the educational program were very positive. Knowledge gains through pre- and post-testing were generally positive, often reaching 100 percent, although some data were missing.

Physical set-up and materials. Three offices within the pharmacy are available for taking patient histories. Space was rented for the education program, which is based on ADA guidelines.

Observations from the lead pharmacist:

- Difficulty with getting reimbursed is the biggest problem, although this should improve now that ADA-recognition has been achieved.
- Cost of staffing. At current reimbursement levels, the program can’t afford a full-time coordinator.
- Frustration because of the obvious gap between need and availability of services. For example, there are many Hispanic residents in the area, but current systems don’t meet their needs. Although physicians may not have time for so many patients, pharmacists working in a multidisciplinary environment may.
- Historically, CDEs have been connected to hospital-based programs; their employment in a community pharmacy is a new model.
- A local IPA hasn’t been very interested in the program.
Success factors:

- The fact that diabetic patients need better care continues to be a motivating factor. According to diabetes incidence data, there should be 10,000 diabetes patients in the county. Of these, about half are likely to be receiving treatment at Kaiser Permanente. The others may benefit from a program like this.

- Perseverance has been important.

- The lead pharmacist has been working closely with a California Pharmacists Association project to create pharmacy networks that will facilitate dissemination of this type of program.
Chain Pharmacy Program
Milpitas, CA

Christina Ly, Pharm.D.
Rite-Aid Pharmacy

This pharmacy is located in an urban area near San Jose in Northern California, where there is a high percentage of Vietnamese residents.

Patients. This program is focused on non-English-speaking patients with diabetes. The principal group is over age 45; there are only a few pediatric patients. Turnover of patients coming into the pharmacy is high. Ethnicity of patients is mostly Asian (about 50 percent are South Vietnamese), Asian Indian, and Hispanic. The education level of the patients is mostly high school with some college.

Pharmacy. There are two pharmacists, two technicians, and numerous clerks and staff. The pharmacy dispenses 150 prescriptions per day. There are more new prescriptions than refills (90 new versus 60 refills). The pharmacy is open for long hours seven days a week. Clinical services are available when there is overlap with staff pharmacists. Diabetes patients are seen Monday, Tuesday, and Friday 1-4 p.m. by appointment. Three patients are seen per day for about 30-60 minutes each. The corporate office provides guidelines and tools for the program.

Pharmacist background. The lead pharmacist received her Pharm.D. in 1989 and began working with her present employer in 1990. She was certified as a diabetes specialist (2003) and also in the area of asthma (2002). The training required a two-day certification course provided by the American Pharmacists Association (APhA). She also holds an immunization certification (2004) through her corporate employer.

Diabetes Program

The diabetes program includes patient education and monitoring services. The site is not an American Diabetes Association (ADA)-recognized program, although the Rite-Aid Corporation is working toward that. Pharmacist consultations are provided free of charge; the program is provided as a value-added service. There is no collaborative practice agreement, but physician referrals do occur.

Protocols

- Initial visit. During the first visit, which ranges from 45 minutes to an hour, the pharmacist collects information on a form developed by Rite-Aid. Patient data include: demographics, physician in charge, medication history, co-morbidities, major surgeries, dates of eye and dental exams, and whether or not the patient has a glucose monitor. Patients are asked to bring in their most recent lab data for HbA1c; if they don’t have it, their physician office is asked to fax it to the pharmacy. Patient education is conducted.
Second visit. Two weeks later, patients come back for follow-up, monitoring, patient questions, goal-setting, and an assessment of their understanding of their disease and its management. This session usually lasts 20-30 minutes. If the glucose levels are consistently high, the pharmacist phones the physician with a recommendation on medication adjustment. A monofilament test is conducted to assess foot health.

Follow-up. After the second visit, patients are seen every month to continue assessment of lab data and patient skills in managing the disease.

Advertising and promotion. Patients are recruited via pharmacy promotions (i.e., placing flyers in prescription bags and working through community and senior centers). Events such as a Diabetes Day are conducted to offer diabetes and blood pressure screens and demonstrate meters. The pharmacist provides diabetes education for about six hours at Mission College as a form of advertising. Additional enrollment occurs through physician referrals, primarily endocrinologists.

Reimbursement and pricing. The program is currently free to patients. Patient satisfaction is the corporate motivation for the program.

Outcomes. A total of 50 patients have been seen, and 25 patients are active in the program at any given time. Clinical outcomes such as HbA1c are monitored as well as weight loss and eye exams. Patient satisfaction is measured after the third visit; most have reported being satisfied with the program.

Physical set-up and materials. The Rite-Aid store has a small office next to the pharmacy with a table and chair, which serves as the consultation area. Patients receive educational materials obtained from LifeScan. Equipment is provided through Aventis and Roche. Handbooks are available in various languages, including Vietnamese, Spanish, and Chinese. Patients go through nutritional education including “carb counting,” and are shown how to monitor and record blood sugars in a logbook.

Challenges:

- Having the time required to provide clinical services. There needs to be more overlap time between pharmacists.
- Incorporating these services into clinical practice.

Success factors:

- Growing support from the Rite-Aid corporate office.
- More traffic in the store and increased sales of over-the-counter products.

Advice on establishing new programs:

- Be patient; time and effort are needed to develop and run a program. Clinical services in retail settings are still in a primitive stage.
- Need to be aggressive to get corporate support.
Supermarket-based Program
St. Louis, MO

Nicole Petersen, Pharm.D.
Schnucks Pharmacy

These two pharmacies are located in supermarkets in an urban, blue-collar area of St. Louis. Both have long hours seven days a week. Clinical services are available from 9 a.m. to 5 p.m., Monday through Friday. Appointments are structured for patient convenience. Current demand results in about two appointments per day. Plans are underway to add immunization services and a blood pressure control program, as well as to publish a newsletter.

The advantage of the supermarket pharmacy is that some patients are seen as often as every day and usually every week as they come in to buy food. Based on this frequency, the patients’ relationship with the pharmacy staff has become very personal. The supermarket location also offers pharmacists the opportunity to take patients on educational “food tours.”

The program has two sites. One has two full-time staff pharmacists, a clinical pharmacist, and 2.5 FTE pharmacy technicians. At the other site, there are two full-time pharmacists. Altogether, the program has six pharmacists with advanced diabetes training. In addition, there is one dietitian, one nurse, and one CDE working in the diabetes program.

Patients. These pharmacies are located in an urban area with a generally low-income population.

Pharmacies. The supermarket chain has 100 stores in six states: Indiana, Illinois, Tennessee, Mississippi, Wisconsin, and Missouri. The pharmacies with diabetes programs are American Diabetes Association (ADA)-registered sites, which allows the pharmacists to bill for services.

The chain benefits not only from the additional income opportunity, but also by making participating pharmacists feel better about their jobs. The program is used as a recruitment tool in attracting pharmacists. The time required for meeting with diabetic patients and running the program does not hinder the pharmacy operation, which is considered a customer convenience and not the principal corporate focus.

Pharmacist background. The lead pharmacist received a Pharm.D. from the University of Iowa and completed clerkship work under faculty members who have been pioneers in bringing clinical services into community pharmacies. She completed a one-year, accredited community pharmacy residency at the University of Illinois at Chicago. She has community pharmacy experience at Dominick's Supermarket, where a number of disease management programs are in place. The pharmacist is an assistant professor at St. Louis College of Pharmacy. She does not hold a CDE certification, citing its extensive requirement for patient care hours.
Diabetes Program

The program includes patient assessment, education, interactive goal-setting, and monitoring services.

Protocols

- **Enrollment.** Patients are self-enrolled through the pharmacy or are referred by physicians. Prior to the first session, the pharmacy conducts a telephone interview to establish a patient record. The patient’s history and medications are recorded. Based on the interview, a paper chart is set up that resides in the store.

- **Initial visit.** The initial session includes physical assessment (height, weight, blood pressure, and HbA1c, which is determined by sending a blood sample to an outside laboratory), and introduction to the curriculum. HbA1c values are available about two weeks later.

- **Educational classes.** Groups with ten to 15 patients go through a curriculum that includes ten hours of instruction over four nights (about 2.5 hours per night). The series takes two weeks to complete (two sessions per week). The curriculum is drawn from the University of Michigan Diabetes Education Program, which includes a book, “Life with Diabetes.” This general curriculum is suitable for Type 1 or Type 2 diabetics. There are separate curricula for gestational diabetes, pre-diabetes, and out-of-control diabetes.

  The first group session focuses on medication, diet, and co-morbidities such as cardiovascular disease. Patient-based activities such as “carb counting” are introduced. The second session is led by a dietitian who explains nutritional aspects of diabetes care. The dietitian works with patients to make a personalized meal plan. The results of patients’ HbA1c tests are explained. At the last group session, each patient selects three goals from a long list that includes: blood sugar control; nutrition and weight-loss; exercise regimen; and health maintenance goals such as having an eye exam.

- **Follow-up.** At the end of six months, there is an individual session to measure outcomes and goal achievement. At this visit, each patient goes through the physical assessment again, including HbA1c determination. As an incentive to keep their six-month follow-up appointment, patients are given a $10 gift certificate that can be used in the pharmacy.

Advertising and promotion. The program is marketed to customers (personal marketing) and to physicians by explaining the program (physician detailing) and inviting referrals.

Reimbursement and pricing. In this fee-for-service program, patients pay $1 per minute for services. The staff is talking with three health plans about adding the program to their service package.

Physician participation. A physician serves as the medical director for the program, and there is a collaborative practice agreement between the participating physicians and pharmacists. Participating physicians can refer patients to the program and provide data for the pharmacy-based patient record. The pharmacist’s notes from the patient record kept at the pharmacy are sent to the patient’s physician.
Outcomes. Four groups of ten to 15 people—about 60 patients altogether—have completed the educational and goal-setting part of the program. Currently, about 30 patients are active in this part of the program. The pharmacy is proud of its high follow-up rate: 80 percent of program participants returned for the six-month outcomes assessment. The national average for this type of program is about 40 percent. Clinical outcomes data were being compiled at the time of the interview.

Physical set-up and materials. Each pharmacy has two service windows—one for dropping off prescriptions and one for counseling. For patient care services, the lead pharmacist uses an office that has three chairs, a desk, and a computer. The other site uses a back room for classes and physical assessment. The curriculum is based on the University of Michigan Diabetes Education Program, which is endorsed by the ADA.

Challenges:
- Pharmacists’ interest in participating was not high in the beginning. The lead pharmacist has “piggybacked” office visits onto pharmaceutical company representatives’ visits in order to gain access to some physicians. Physician relationships have not always been smooth. One asked the pharmacists not to do the HbA1c test. The pharmacist noted that providing feedback to the physicians is important in gaining their support.
- Patient recruitment has been a challenge.
- Detailing physicians is a time-consuming effort.
- Payment, other than fee-for-service, remains a challenge.

Success factors:
- Having pharmacists who are motivated and excited about the program. This helps motivate patients, which makes it more likely they will achieve their goals.
- Having a collaborative physician/pharmacist team.
- Following up on patients’ goals and providing incentives to reach them.

Advice on establishing new programs:
- Be sure that the corporation is committed to the program.
- Set concrete goals tailored to specific areas. For example, establish goals for marketing to employers or to health plans.
Pharmacy-based Network
Asheville, NC

Barry Bunting, Pharm.D.
Asheville Pharmacy Network

Asheville, North Carolina, with a population of approximately 70,000, is surrounded by rural areas. There are currently 18 pharmacists in the citywide Asheville Pharmacy Network, based in several community pharmacies (both independent and chain-owned). The network provides contracted services on a fee-for-service basis to diabetics, as well as those with a variety of other chronic health problems.

The largest participating employers are Mission Hospitals, with 5,000 employees (8,000 covered lives), and the City of Asheville, with 1,200 employees (2,000 covered lives). There are several smaller employers as well. In each case, the employer is self-insured for employee health benefits.

Patients. All diabetic employees and dependents of participating employer organizations are eligible and encouraged by the employer to enroll in the diabetes care program. Employee participation is voluntary. About 400 employees are enrolled in the diabetes program, and another 400 in programs for other diseases.

Pharmacies. All the pharmacies are located in Asheville in close proximity to their clientele. Patients in the program are seen by appointment in the pharmacies, and some also accommodate walk-ins. In most cases there is only one network pharmacist in a particular pharmacy, and clients are aware that they must arrange to see that pharmacist when he or she is on duty. In each case, the pharmacy manager (if someone other than the network pharmacist) is strongly supportive of the program and helps publicize the service.

Pharmacist background. The program director for the network is certified in diabetes care by the American Pharmacists Association. He holds a Pharm.D. and has had six years of professional practice experience subsequent to graduation, in both inpatient and ambulatory settings. The other network pharmacists have varying degrees of professional experience. All participating network pharmacists receive special training from physician-trainers. Proof of training is provided to the program director. Pharmacists completing the training are certified by the American Pharmacists Association as diabetes care providers.

Diabetes Program

This program, founded in 1997, includes patient education and monitoring services, which are provided as an elective benefit to employees of participating organizations under a contractual arrangement. The goal is to improve the health and quality of life of individuals with certain chronic health problems. From the employer’s standpoint, the aim is to foster healthier, more productive employees and decrease overall health care costs. The program has been replicated in five sites and an article documenting its success was recently published.
Protocols

- **Enrollment.** All employees receive a letter from their employer describing the program and encouraging any employee or dependent who has been diagnosed with diabetes to enroll. (In some instances, employees have been encouraged by their physicians to enroll.) Prospective participants are informed about patient consent forms, benefits and services, and the expectations for continued participation. Patients must sign a consent form to enroll, and each is assigned a unique identifying number. These features allow HIPAA-compliant exchange of patient information. Enrolling patients select a network pharmacist (from among the 18 participating network members). Pharmacists in the program manage anywhere from two or three patients to 150. (One pharmacist devotes full time to this type of practice.)

- **Initial visit.** The pharmacist: (1) assesses the patient’s knowledge about diabetes and his or her current medications; (2) reviews the role of nutrition and meal planning in management of diabetes, and provides other relevant education; (3) assesses the patient’s health status based on a medical history and laboratory data (HbA1c, lipid panel, etc.). During this initial visit, each patient is required to identify a few specific goals related to diabetes management (such as weight reduction); the patient is prompted by a list of goals derived from materials provided by APhA. These goals serve as reference points to be reviewed in subsequent visits.

- **Educational classes.** After the initial visit, patients participate in five group educational sessions on self-care; each session is approximately two hours.

- **Follow-up visits.** Following completion of the self-care group sessions, patients are seen individually once a month for assessment of lab values, application of skills they have been taught, and review of their progress toward their goals. During these follow-up sessions, consideration is given to foot and vision care. The pharmacist refers patients for eye and foot examinations as appropriate.

- **Compliance incentives.** Patient compliance (keeping appointments, adopting appropriate behavior modifications, and taking medications correctly) is encouraged and rewarded by the employer. If compliance is satisfactory, the employer waives the co-pay for prescriptions (i.e., the employer pays the full price of any prescriptions the employee requires). Compliant patients also receive a free blood glucose meter and routine diabetes supplies. If patients become noncompliant, they may receive a letter from the employer notifying them that they are no longer eligible for a co-pay waiver or other benefits they have been receiving.

**Advertising and promotion.** The program has been publicized in the pharmacy literature and has attracted considerable attention within the pharmacy field. Since many physicians in the area have become aware of this program, they often recommend it to their patients who work for participating employers.
Reimbursement and pricing. The participating employers are all self-insured for employee health care, and are invoiced on a fee-for-service basis. The fee is negotiated as part of the contract between the employer and the network.

Technology. A computer is used for patient records.

Outcomes. Clinical measures include reports of goal achievement for HbA1c, low-density lipoproteins, and blood pressure. Outcome measures are being established in the areas of nutrition, exercise, weight, immunizations, eye exams, and foot exams. Patient satisfaction was used as an outcome measure at one point, but the response was overwhelmingly positive, so this is not assessed anymore. The SF-12 and a locally developed diabetes-specific instrument are used to measure overall health status. Economic outcomes are calculated based on all costs in medical and prescription claims and attendance at work (days worked), but not the cost (to the employer) of co-payments.

Physical set-up and materials. Each network pharmacy has a semi-private or completely private consultation area equipped with diabetes educational and demonstration materials. Literature provided by APhA is used to reinforce the pharmacist’s educational interventions.

Observations from lead pharmacist. Some pharmacists have difficulty finding the time to meet with patients. For many pharmacists, the diabetes program is a relatively small part of their overall duties, and some see it as taking a disproportionate amount of their time. The relatively small number of pharmacists is a concern to the network, which believes that if more pharmacists participated, the program could conceivably be expanded to include other employers, thereby strengthening the credibility of pharmacists as health care providers.

Success factors:
- Strong support and cooperation from the American Pharmacists Association and the North Carolina Association of Pharmacists.
- Receptivity among key employer groups (especially the City of Asheville).
- Willingness and desire among a core group of pharmacists to become more directly involved in patient care.
- Ability to demonstrate good clinical outcomes.
- Patient satisfaction.

Advice on establishing new programs:
- Before making such a commitment, carefully examine your motivation and “staying power.” Motivation is a vital requirement.
- Make realistic projections about the number of pharmacists needed and assess whether an adequate number can be recruited.
- Do not underestimate the amount of time required per patient.
Coalition of Independent Pharmacists
Greensboro, NC

Frank Burton, B.S.Pharm.
Burton’s Valu-Rite Pharmacy

Greensboro, North Carolina, with a population of some 224,000, is the setting for Piedmont Pharmacy Care Network (PPCN), a coalition of independent pharmacists. The network was created when 25 pharmacists organized to market their clinical services to self-insured employers.

PPCN’s current focus is providing diabetes care on a fee-for-service basis under a contractual arrangement with local employers. The network serves one major self-insured employer in Greensboro. Although members of PPCN are all based in independently owned community pharmacies, they see clients primarily in the client’s workplace, using a space set aside by the employer.

Patients. All employees and their dependents at the participating companies who are diabetic—or thought to be at risk—are eligible. They are encouraged by their employer to enroll in the PPCN diabetes care program, although participation is voluntary. The largest participating organization, a textile manufacturing company, employs primarily blue-collar workers.

Pharmacies. Most PPCN services are provided in the employee’s workplace, although some member pharmacists also see clients in their pharmacies evenings and weekends. The PPCN member who was interviewed for this report devotes the majority of his time to managing his pharmacy. He also serves a panel of five diabetic patients through the PPCN contract, and expects to increase this to about ten patients in the near future. Most of these patients are also regular clients of his pharmacy, so he sees many of them for follow-up appointments in the pharmacy. This appears to be typical of the situation with other PPCN members.

Pharmacist background. PPCN members are licensed pharmacists who received training either through the North Carolina Area Health Education Program program or the North Carolina Association of Pharmacists (NCAP). These programs draw heavily on materials provided by the American Pharmacists Association (APhA) and the American Diabetes Association. The educational background and level of professional experience varies among members of the network, but all are trained in diabetes patient care services.

Diabetes Program
This three-year-old program, modeled on the one in Asheville, NC (see page 20), identifies previously undiagnosed diabetics and provides follow-up care to patients already known to have diabetes. It includes patient screening, education, and monitoring services, all offered as an elective benefit to employees of participating organizations.
Protocols

**Enrollment.** All employees of participating organizations receive a letter from their employer, notifying them about the program and inviting their participation. Employees are given information about PPCN’s schedule and onsite location, patient consent forms, benefits and services of the program, and the expectations for continued enrollment/participation. Enrolling patients select a pharmacist from a list of PPCN members and schedule an appointment in the workplace setting. Some may be seen in the pharmacy.

**Initial visit.** Both diagnosed and undiagnosed individuals come in for an initial visit. For those who have not been diagnosed, the purpose of the visit is diabetic screening through assessment of the person’s medical history and laboratory data (HbA1c, lipid panel, etc.). Those found to be in need of a complete diagnostic work-up are encouraged to see a physician for that purpose. For patients who are already known to have diabetes, the initial visit includes: assessment of their knowledge about the disease and their current medications; education about behavior modifications and self-monitoring; and counseling on the importance of keeping all scheduled appointments.

**Follow-up visits.** Two additional appointments are scheduled at one-month intervals. The APhA Foundation's standardized checklists are used for each visit. (There is a separate checklist for the first visit, second visit, and third visit, as well as for any subsequent appointments that may be scheduled.)

**Communication with physician.** At the conclusion of a patient visit, the pharmacist generates a progress note and sends it to the patient’s physician. The interviewed pharmacist says he seldom receives any acknowledgment from the physician, but he does notice that his recommendations are often reflected in subsequent prescriptions.

**Advertising and promotion.** Eligible participants are notified in writing by their employers. Since many physicians in the area have become aware of this program, they sometimes recommend it to their patients.

**Reimbursement and pricing.** Employers are all self-insured for employee health care benefits, and they are invoiced for the services on a fee-for-service basis. The fee is negotiated as part of the contract between the employer and the network.

**Technology.** Patient records are maintained on a computer. A Cholestech glucose level analyzer is available in some of the member pharmacies.

**Outcomes.** Network pharmacists use a standard APhA outcomes reporting form.

**Physical set-up and materials.** The employer usually designates a conference room, office, or other private space for visits. Educational materials provided by APhA, ADA, and the pharmaceutical industry are used to reinforce the pharmacist’s instructions. The interviewed pharmacist maintains a private patient consultation room, and it is assumed that most of the other pharmacies also have designated consultation areas. Most of the pharmacies have diabetes education printed matter and equipment for demonstration.
Challenges:
- Building a relationship with physicians.
- Finding the time to provide patient services while having full-time responsibilities managing a pharmacy.

Success factors:
- Strong support from the APhA Foundation and the North Carolina Association of Pharmacists.
- Cooperation by key employer groups.
- Strong commitment by members of the PPCN coalition.
- Emphasis on “patient credentialing,” ensuring that patients are adequately educated about their disease, their needed behavior modifications, appropriate medication use, and the importance of keeping appointments. The assumption is that “credentialed” patients are more likely than others to have good outcomes.

Advice on establishing new programs:
- Get the requisite education and training to do the job well.
- Take advantage of existing support systems (such as the APhA Foundation).
- Make sure you have the time to devote to the program.
Community Pharmacy
Darlington, SC

Kathy Shuler, R.Ph.
Pee Dee Medical Group Pharmacy

Darlington is a city of less than 10,000 in a rural area with a high unemployment rate. The pharmacy is an integral part of a multidisciplinary health care organization owned by a five-member family practice physician group. The medical group decided about three years ago to be proactive rather than reactive in treating chronic diseases. They created a team of employees that includes nurses, nurse practitioners, pharmacists, laboratory personnel, and others. The pharmacists are employees of the medical group, and the pharmacy is located in the organization’s medical office building, where the pharmacists have access to patient records and laboratory data.

The site includes onsite laboratories; equipment for radiological, cardiological, and gastrointestinal procedures; and is a training site for nursing and doctor of pharmacy students. The medical group offers comprehensive services in one location because many patients don’t have ready access to transportation. For example, internal medicine specialists from two cardiology groups, a gastroenterologist, and a nephrologist use space for patient visits and procedures several days a week.

Patients. The health care organization serves about 60,000 patients, mostly adults; about 35-40 percent are over 65. Half of the patients are African-American and more than half are covered by Medicaid. The local area has the one of the highest incidences of cardiovascular disease per capita in the United States. Obesity is prevalent and most diabetic patients have Type 2.

Pharmacy. There are two full-time pharmacists, one providing clinical services and the other primarily handling dispensing and business matters. There are also three full-time pharmacy technicians and a full-time nurse manager. The pharmacy averages about 125 prescriptions per pharmacist per day, which is close to the national average. This pharmacy is not prescription-driven; rather it is offered as a convenience for medical-group patients.

The pharmacy offers clinical services related to metabolic syndromes including diabetes, as well as asthma and coumadin management. The Smart Care program is a chronic disease management service that uses protocols and guidelines for patient care involving multidisciplinary teams. Through the Smart Care program, the organization is able to bill Medicare, Medicaid, and other third-party payers for services. There are some restrictions on Medicare charges—there is no incidental billing allowed—because, as a federally designated rural health care area, the physicians already are reimbursed at a higher level. The pharmacy does rather extensive compounding; and the revenues compounding—particularly from nebulizers—subsidize other clinical service programs. The organization employs a full-time, non-pharmacist staff member who manages indigent care programs for patients who qualify.

The pharmacists participate in the organization’s community outreach program, which provides free clinics and health screenings throughout the year. Health fairs are also sponsored during
NASCAR races and held nearby. Wellness and other programs are often held in churches and schools. The pharmacy also provides contracted asthma services for local schools.

The pharmacy has access to a centralized, computerized data system that includes patient charts and laboratory data. The organization is starting to integrate pharmacy information into the centralized database. This gives pharmacists access to all chart, laboratory, and prescription drug data, and allows them to obtain additional medication and compliance information from local retail drugstores for inclusion in the medical record. Local pharmacies are willing to provide these data because this pharmacy is not considered to be in competition with them—but rather a convenience for patients of the medical group.

**Pharmacist background.** The lead pharmacist for the diabetes programs is also the pharmacist in charge for the asthma nebulizer compounding service. The revenues from the compounding service help to financially support the multiple clinical services offered through the pharmacy. The lead pharmacist received her B.S. in pharmacy from the University of South Carolina in Columbia, and has been in community pharmacy practice about 30 years. She is a certified geriatric pharmacist through the American Society of Consultant Pharmacists. The training for this certification emphasizes the management of medications for seniors who frequently have more than one diagnosis and take multiple medications. She completed coursework on measuring health outcomes through the Medical University of South Carolina in Charleston.

**Diabetes Program**

The ADA-recognized diabetes program includes screening, patient education, and monitoring services for the medical group’s patients.

**Protocols**

- **Enrollment.** Patients enter the comprehensive diabetes program, including the pharmacist component, through referral from a member of the physician group.

- **Initial visit.** A medical and pharmacy work-up is done, and a management plan is created. The work-up includes all current medications and whether the patient is taking them correctly, as well as the patient’s record of compliance.

- **Follow-up.** Thereafter, patients are seen every three months by group physicians (based on South Carolina Medicaid guidelines). HbA1c is also tested by the clinical laboratory every three months. Additionally, patients are seen by the pharmacist every month, usually coinciding with obtaining their medications and supplies. These sessions, typically 15-60 minutes, include patient education and monitoring for related problems such as obesity and foot care. Typically, the pharmacist provides the patient with reading materials appropriate for that individual’s level of knowledge and particular problems. During the next session, they discuss what the patient has read. The pharmacist can also refer patients to the certified diabetes educator. Treatment of related problems such as obesity and foot care, ordering laboratory tests, and arranging for periodic eye examinations is coordinated among physicians, nurses, and pharmacists.
Advertising and promotion. Advertising has not been necessary because the medical group has been in place for 30 years and everyone knows one another in the small, local area. Over 80 percent of the group’s patients live within ten miles of the medical complex.

Reimbursement and pricing. Reimbursement comes from three sources: Medicaid (50 percent of patients), third-party payers (40 percent), and fee-for-service (less than 10 percent). For Medicaid and third-party payers like Blue Cross/Blue Shield, pharmacy service reimbursement is incidental to the physician billing.

Technology. Patient records and laboratory data are available to physicians, nurses, and pharmacists. The pharmacy medication profile database is not yet fully integrated with the patient record and laboratory database but they are working toward this goal. The pharmacist updates medication information from local pharmacies every three months (medication use review), including information about compliance, and makes notes to the medical record.

Outcomes. The organization is setting up a system to capture financial and clinical outcomes such as HbA1c and other clinical measures, including: loss of limbs, requirement for dialysis, loss of eyesight, cardiovascular events, hospitalizations, and the need for coronary artery procedures.

Physical set-up and materials. The pharmacists see patients in examination rooms when physicians are not using them. The principal reading tool is a book on living with diabetes that is produced by Eli Lilly. After the patient reads it, the pharmacist uses patient-driven questions rather than measuring knowledge with a test.

Success factors:
- A visionary and committed medical group.
- The rural setting where everyone knows everyone else in the community.
- The multidisciplinary approach.
- The existence of a model, the Asheville Project (see page 20), that provided the main inspiration for the pharmacist role.
- Efforts to collect data and establish outcomes will be important for the sustained success of the program.

Advice on establishing new programs:
- Academic preparation is important. The CDE credential is hard for pharmacists to achieve because it requires 1,000 hours of patient experience. Other credentials such as the certified diabetes manager require less education and provide good preparation. The Pharm.D. alone is not sufficient for this role. Pharmacist training at the residency level would be highly desirable, but South Carolina has few pharmacists with residency training for this type of role.
Mix of Chain and Independent Pharmacies
Two Rivers, WI

Brian Jensen, R.Ph., FACA
Medicine Shoppe Pharmacy
Lakeshore Apothecare, Inc.

This program is based in a suburban Wisconsin community of 14,000 located southeast of Green Bay. Some 85,000 people live in the greater area of suburban and rural environments. The network of eight pharmacies includes two Medicine Shoppe pharmacies, a chain pharmacy, four independent pharmacies, and a health systems site. It was organized to offer the diabetes (and other) programs widely, making it convenient for patients. The network has been in operation for 18 months and has contracts with seven self-insured employer groups. It is seeking to extend contracted services to an HMO and to implement a pilot study with the Wisconsin Employees Trust Fund of Wisconsin and the Wisconsin Medicaid program. They want to find out if currently used incentives will work in a Medicaid program. Network leaders are working with pharmacists at two other sites in Wisconsin to set up similar networks, using a scalable model.

The patients. The patient population is skewed to older patients; 45 percent are age 50 or older. The population is almost 100 percent Caucasian, and about 26 percent have completed post-high school education.

The pharmacies. The network’s 18 pharmacists and one full-time site coordinator provide services related to hypertension, asthma, lipid control, immunizations, compounding, and weight loss, in addition to diabetes. For all these services, there is a defined standard of care and focus on documentation.

The Medicine Shoppe pharmacies, which are part of the network, have a total of five full-time pharmacists, a community pharmacy resident, and 23 pharmacy technicians. One pharmacist works full-time providing patient services. The high technician-to-pharmacist ratio allows the pharmacists to move away from dispensing activities. Each of the two pharmacies dispenses about 200-350 prescriptions per day—higher than the national average of about 100 per pharmacist per day.

Pharmacist background. The lead pharmacist is the owner of the two Medicine Shoppe sites. He received a B.S in pharmacy from the University of Wisconsin in 1980, and spent several years directing a hospital pharmacy. He is the past president of the Pharmacists Society of Wisconsin and is a leader within the network group. He holds an APhA certification for diabetes and has completed skill-building coursework through the College of Pharmacy at the University of Wisconsin.
Diabetes Program

The diabetes program—an elective employee benefit—includes screening, patient education, and monitoring services based on employer contracts.

Protocols

- **Enrollment.** Employers drive enrollment; they send letters to employees explaining the program or invite network representatives to go to the worksites. Prospective participants learn about consent forms, benefits, services, and patient responsibilities. Patients who wish to enroll return the signed consent form (which may be done online). They receive a personal identification number, which allows HIPAA-compliant exchange of patient information and the creation of a database for research and outcomes reporting. Enrollees select a pharmacy site for receiving services, and network personnel then match patients and pharmacists based on patient preferences and pharmacist availability. An effort is made to spread the patients evenly across available pharmacists. Pharmacies may also enroll patients on a walk-in basis.

- **Initial visit.** Information is gathered about the patient’s disease knowledge, current medications, the role of nutrition and meal planning, and other aspects of managing diabetes. Health status is assessed through a medical history and laboratory data. The information is used to classify the patient in one of three categories: beginner, proficient, or advanced. The program from this point is customized to their status. Patients identify goals such as weight loss, which are discussed at future sessions. The list of goals is derived from APhA materials.

- **Follow-up visits.** Monthly visits are scheduled for the first six months; there are eight visits per year thereafter. The role of the pharmacist is not to teach but to coach, assess, and refer. If the patient needs more education, the pharmacist “prescribes” educational services at a formal education center where educators are reimbursed for their services based on the prescription. This prescribing relationship has reduced competition between the pharmacy and the education center, since they are not competing for the same patients. As patients gain knowledge and disease management skills, they move from beginner to proficient to advanced status.

- **Compliance incentives.** If enrolled patients are compliant, the co-pay for medications for diabetes and related conditions is waived. In addition, compliant patients receive a free blood glucose meter and supplies, as well as professional coaching services by trained pharmacists. Noncompliant patients receive up to two warnings and then can be dropped from the program. The incentives for the employer are related to healthier, more productive employees and a decrease in overall health care costs. The incentives program has been in place for seven months.

Advertising and promotion. Employers are responsible for providing employees with information about the program. Sometimes pharmacists make presentations about the program at the employment site.
Reimbursement and pricing. The program is supported by employer contributions. The network has received funding from Aventis Pharmaceuticals and support from APhA. Periodically, clinical events such as grand rounds and social events such as dinners bring employers and providers together to review the process and achievements of the program. Future plans include achieving greater penetration of employers in the local areas and expanding outside the local area with new networks.

Technology. The program uses Web-based tools developed by APhA for patients and providers. Web-based elements include enrollment forms, sample letters, care plans, forms for documenting services, HIPAA information, data sets that can be accessed by researchers, information for patients and providers, and an appointment-making capability. The software can also generate patient reports that show the patient's status, a review of what was learned, and a “to do” list.

Physician participation. This program has no mandate for collaborative practice agreements. Some physicians are enthusiastic participants and access patient data using the Web.

Outcomes. Seventy-five patients of a total of 7,000 lives are enrolled in the program. Quarterly and annual outcomes reports are generated. Clinical outcomes include: goal achievement for HbA1c, low-density lipoproteins (LDL), and blood pressure. Other clinical goals are in the areas of nutrition, exercise, weight, immunizations, eye exams, and foot exams. Humanistic goals include patient satisfaction with the program and perceptions about care. Economic goals include increased attendance at work and lower worker compensation claims.

Physical set-up. Network pharmacies all have a counseling area and computers with high-speed Internet connection.

Challenges:
- Since the APhA program required at least one employer with 5,000 covered lives, the pharmacists who initiated the program had to develop a coalition of employers to reach that number.
- The pharmacists had to build the network.
- The medical community has not yet strongly embraced the program.
- The network had to coordinate elements from APhA, the University of Wisconsin, and the Wisconsin Pharmacists Association to make the program work.

Success factors:
- Perseverance and the building of a support group based on the belief that this was the right thing to do.
Independent Pharmacy  
Crystal Springs, MS

Tommy Spell, Pharm.D.  
Biggs Pharmacy

Biggs Pharmacy is located in the rural community of Crystal Springs, Mississippi, 20 miles south of Jackson. It works with two other businesses on the same site to provide diabetes services through a multidisciplinary team that includes pharmacists and registered dietitians.

Patients. Most patients live in the Crystal Springs area, are 65 or older, and receive Medicare benefits. Initially, the patients were customers of the pharmacy who were identified on the pharmacy database of patients taking diabetes medications.

Pharmacy. The business has two full-time pharmacists—one clinical and one dispensing—as well as two full-time registered dietitians (who are also CDEs). There is no set amount of time allotted for the diabetes care program. Using its diabetes program as a model, the pharmacy intends to expand clinical services to include weight management, high blood pressure, high cholesterol, and asthma.

Pharmacist background. The lead pharmacist received a B.S. in pharmacy in 1991 from University of Mississippi and recently completed a Pharm.D. program at the same institution. He is credentialed as a certified diabetes manager by the National Institute of Pharmacist Care Outcomes and is currently working on his certified diabetes educator credentials. He has been in community pharmacy since 1991, and has been a preceptor to pharmacy students since 1993. He serves on the Dean’s Advisory Board for the University of Mississippi.

Diabetes Program

Three interrelated business units are involved in this practice model: (1) the Biggs Pharmacy; (2) a specialty diabetes supply unit housed in the same building; and (3) a patient education/patient care unit known as DREAM, Inc. (Diabetes-Related Education and Management), located in an adjoining building.

This three-part professional operation serves as a rotation site for pharmacy internship students from the University of Mississippi. The two CDE/RDs provide diabetes patient education in six physician offices on a referral basis. (Since physicians receive a capitated payment under Medicare, it makes economic sense for them to refer patients to another provider for patient education and follow-up monitoring. In this case, the referral is to CDEs, who can bill Medicare separately for their services.)

Protocols

- Enrollment. Patients are referred by their physician and are required to make an appointment with the CDE. Self-referred patients are also accepted.
Initial visit. The CDE assesses the goals of the patient and helps in setting new goals (from a list of 20-25) to achieve during the program. Baseline measures are collected, including a pretest covering the patient’s knowledge of diabetes, quality of life, HbA1c, kidney function, liver function, and cholesterol. Copies go to the patient and the physician.

Educational classes and follow-up. Patients go through four diabetes education classes of two to four hours each. These are held in the offices of DREAM, Inc., adjacent to the pharmacy site. Classes usually have ten patients, and are conducted twice a week. After an initial education session in the physician’s office, patients are seen quarterly on a follow-up basis in the DREAM unit. A summary of each visit is given to the physician to sign and agree to recommendations and changes provided by the pharmacist.

Advertising and promotion. The program is driven by physician referral.

Reimbursement and pricing. The program serves primarily Medicare patients, although others can be seen on a fee-for-service basis. Medicare provides compensation of $60 for an individual diabetes education session, and $35 per patient when the education is provided in a group setting. Currently, the lead pharmacist is also working with Blue Cross/Blue Shield of Mississippi on a pilot project to provide services to their employees. Twenty employees currently receive services at their worksite. The pharmacist hopes this pilot will demonstrate the program benefits to Blue Cross/Blue Shield, and that the insurers will subsequently provide coverage for such services.

Technology. The program has used hand-held computers for patient charting since 1998. During classes, participants use a wireless network to respond instantly to questions. The results, displayed in seconds, allow the educator to track the progress of the patients. If patients do not provide correct answers, the educator goes over the topic again.

Physician participation. The level of physician support for this program has been good. Physician referral is the primary means of patient recruitment.

Outcomes. Clinical outcomes collected include HbA1c, liver and kidney function tests, and cholesterol. Humanistic outcomes that are gathered include diabetes knowledge and quality-of-life measures (using a modified questionnaire based on the SF-36 and SF-12). So far, the program has reported an average drop in HbA1c of 1.5 percent.

Challenges:

- There were no existing models for this type of program. It required considerable trial and error, and patience. The lead pharmacist recommends that APhA provide a business tool kit for pharmacists who want to provide disease state management services.

- Building understanding and acceptance among physicians proved difficult in the beginning; however those problems have since been overcome. Still, there is no viable network of pharmacists who are interested in developing, promoting, or sustaining this type of practice model.
There were no established compensation models; they had to be developed.

The lack of good outcomes data is a deterrent.

There are not enough payers, as yet, to make such programs economically viable on a widespread basis.

The lack of provider status for pharmacists is a major deterrent.

Success factors:
- The three-part business model (retail pharmacy, medical supplies, reimbursable patient care services) has been key to success. Each part of the model reinforces demand for the other parts.
- Pharmaceutical manufacturers’ interest in the program has led to speaking invitations (compensated) and funds for materials and supplies.

Advice on establishing new programs:
- The practice model has to be tied to the local economic situation.
- The pharmacist has to know how to make the third-party payment system work. This includes collaborating with others who have provider status.
- Be patient, and be willing to set long-term goals for success.
- Be careful to not seem a threat to local physicians. Work with them; cultivate their patients; make the physicians look good to their patients.
Key factors in the success of diabetes care programs in a pharmacy setting.

IN THE PROCESS OF CONDUCTING THE PROJECT, the researchers formed certain impressions that are discussed here. These observations fed into the specific recommendations provided at the end of this section.

Observations

- A pharmacist’s basic clinical education provides an adequate foundation on which to build the specific skills necessary to carry out a diabetes care program. With only a modest investment in continuing professional development, many more community pharmacists could become qualified to provide such services.

- Because community pharmacists are not usually in direct day-to-day contact with physicians, it requires a major effort to establish and maintain the type of relationship with physicians that is needed for collaborative disease state management. Pharmacists who have been successful in establishing a diabetes practice cultivated relationships with physicians in a number of ways: through formal integration into a medical group; giving presentations at meetings that physicians regularly attend; scheduling individual appointments with physicians to explain what services they can offer patients; and voluntarily sending progress reports to patients’ physicians.

- There are few viable economic models for diabetes care services in community pharmacies. Only a small percentage of the public appears willing to pay for these services out-of-pocket. Many insurance plans pay for services provided by certified diabetes educators (CDEs), but very few pharmacists hold this type of certification. Pharmacists may need to become CDEs, or hire a CDE, in order to bill for services. The most promising economic model may be the pharmacist networks that contract with self-insured employers to provide services for employees on a fee-for-service basis. The Asheville, Greensboro, and Wisconsin programs represent such a model. The perceived benefits to employers include: (1) cost-avoidance for preventing the complications of unmanaged diabetes; (2) a healthier workforce; and (3) employee satisfaction.
For patients, the relief from co-pay for diabetes medications and supplies seems to be a significant incentive for their active participation in the program.

Most pharmacists find it difficult to make time available for personalized patient services. Two major factors contribute to this situation. First, there has been a national pharmacist shortage, dating from 1999 (and earlier in some sections of the country). Although this shortage has abated somewhat in certain areas of California (Orange County, for example), the shortage is still pronounced in most of the state and throughout the United States. Increased numbers of prescriptions are a major contributing factor. Furthermore, the profit margins on prescriptions have steadily declined over several years in response to pressures to reduce costs of drug benefit programs. In order to survive economically, community pharmacists (both independent and corporate-owned) must fill more prescriptions per hour or per day.

Compared to some sections of the country, few comprehensive community pharmacy models were found in California. The researchers are aware of a number of California pharmacists who provide diabetes care services in other types of environments, including managed care settings, physician offices, and hospitals or hospital-affiliated clinics. However, these services were not considered for the project if they did not include a community pharmacy component. The researchers speculate that the degree of managed care penetration in a given region affects the demand for disease-management services in community pharmacies because the need for these services may be met in other settings.

Useful tools are available to community pharmacists who decide to pursue a practice in diabetes care. Particularly impressive is the maturity and robustness of the Asheville Project that is being disseminated through the APhA Institute. Invaluable support is also available from ADA and ADEA. The interviews illustrate how a few pharmacists have been able to succeed using these tools. It is reasonable to assume that other pharmacists, with appropriate coaching and mentoring, could replicate these models.

Pharmacists who were interviewed in this study, but who were not included in the case studies, tended to base their practice on point-of-sale contact with patients who come in to have prescriptions filled or to purchase diabetes-care products. The researchers were not able to identify any consistent standards of practice, such as routine health assessment interviews, maintaining a patient record, or providing routine monitoring services. Some of these services may be provided in specific cases, but not on a consistent basis. The researchers were left with the impression that many pharmacists who seem genuinely motivated to provide diabetes care services lack a standard practice model.
Recommendations
Based on project findings, the researchers recommend the following:

- Community pharmacists who wish to engage in diabetes care services would benefit from:
  - Taking professional development programs offered by the American Pharmacists Association, the American Diabetes Association, the American Diabetes Educators Association, and others;
  - Becoming credentialed as a CDE or an APhA-certified diabetes practitioner;
  - Building a strong professional relationship with physicians in order to obtain patient referrals;
  - Establishing a formal collaborative practice arrangement with specific physicians;
  - Joining a pharmacist provider network; and
  - Adopting a standard practice model with a standardized protocol.

- A nationally recognized certification or credential should be required for pharmacists who want to provide billable diabetes care services.

- A survey of the type represented by this report should be conducted periodically to document changes in the status of pharmacist-provided diabetes care. These studies should document trends such as the growth in the numbers of pharmacists providing these services; prescription drug plans that provide payment for pharmacist providers; and diabetic patients receiving services from pharmacists.

- Employers who are amenable to contracting with pharmacists or networks to provide diabetes-care services for their employees.

- Pharmacists should document the outcomes of the diabetes-care services they provide, in order to substantiate their effectiveness.
Appendix A: Expert Panel

Ann Albright, Ph.D., senior health policy fellow, Office of the Surgeon General; chief of the California Diabetes Prevention Control Program. Dr. Albright is a registered dietitian with a doctorate in exercise physiology from Ohio State University. Her focus is on the prevention of diabetes and the beneficial effects of exercise and nutrition on diabetes.

At the time of this project, Dr. Albright was working with the Office of the Secretary of Health & Human Services (HHS) and the Office of the Surgeon General. She served as a lead for the Secretary's Diabetes Detection Initiative, briefing the surgeon general on diabetes-related topics, consulting on the Secretary's National Diabetes Action Plan, representing the Office of the Surgeon General on the HHS Prevention Steering Committee, and consulting on the surgeon general's speeches and correspondence. She is permanently affiliated with the Institute for Health and Aging, University of California, San Francisco, and the California Department of Health Services.

Peter R. Baginsky, M.D., associate professor, Touro University College of Osteopathic Medicine; associate clinical professor, UCSF School of Medicine; director, Diabetes Clinic, Sutter Medical Center Family Practice Center, Santa Rosa, CA.

Dr. Baginsky, a diabetologist, is a board-certified family practice physician with fellowship training in diabetes and nutrition. He received his medical degree at the Harvard Medical School, and did his residency and fellowship at UCSF.


Mr. Campbell has been a national and international leader in pharmacist participation in diabetes education and care. He is the recipient of many honors, including the R. Keith Campbell Endowed Chair in Diabetes Care at Washington State University College of Pharmacy (2002) and was named as Outstanding Health Professional Educator in the Field of Diabetes in the United States by the American Diabetes Association (1989).

Dale Christensen, Ph.D., F.A.Ph.A., Mescal S. Ferguson distinguished professor, Division of Pharmaceutical Policy and Evaluative Sciences, School of Pharmacy, University of North Carolina, Chapel Hill.

Dr. Christensen is a leading pharmacy practice researcher at the University of North Carolina. He served, until recently, as chair of the Division of Pharmaceutical Policy & Evaluative Sciences in the School of Pharmacy. Dr. Christensen co-authored a set of three papers about the Asheville Project, a community pharmacy diabetes project in Asheville, North Carolina, that has received national attention.

Daniel Garrett, B.pharm., M.S., F.A.S.H.P., senior director for Medication Adherence Programs for the American Pharmacists Association (APhA) Foundation.

Mr. Garrett was instrumental in establishing the Asheville Project for community-based pharmaceutical care services, which has become a model for diabetes care in community pharmacies. From 1998 to 2001 he was executive director of the North Carolina Association of Pharmacists. In 2001, he joined the APhA Foundation where he works to provide programs, support, and tools for pharmacists to offer diabetes services in community pharmacies.

Eva Marie Vivian, Pharm.D., associate professor, College of Pharmacy, Western University of Health Sciences.

Dr. Vivian completed two pharmacy residencies in Veterans Administration (VA) facilities in San Francisco and San Diego. During her residencies, she worked in VA diabetes clinics. Dr. Vivian is a certified diabetes educator, is board certified in Advanced Diabetes Management, and is a board certified pharmacotherapy specialist.

At the time of this project, Dr. Vivian was affiliated with the Harriman Jones Medical Group of Long Beach, CA.
Appendix B: Resources

American Pharmacists Association (APhA)
2215 Constitution Avenue, NW, Washington, DC 20037-2985
Telephone: (202) 628-4410
Web site: www.aphanet.org

APhA is the oldest and largest professional association of pharmacists in the United States. The organization supports the provision and justification of clinical pharmacy services in all practice settings, and provides tools necessary to accomplish this goal.

American Pharmacists Association (APhA) Foundation
2215 Constitution Avenue, NW, Washington, DC 20037
Telephone: (202) 429-7565
Email: info@aphafoundation.org
Web site: www.aphafoundation.org

APhA Foundation provides innovative programs and projects that contribute to new information for pharmacists to use in retooling their practices to satisfy the health needs of their patients. It is affiliated with the American Pharmacists Association.

American Association of Diabetes Educators (AADE)
100 W. Monroe, Suite 400, Chicago, IL 60603
Telephone: (800) 338-3633
Email aade@aadenet.org
Web site: www.aadenet.org

AADE is a multi-disciplinary membership organization dedicated to advancing diabetes self-management training and care as integral components of the treatment and prevention of diabetes.

American Diabetes Association (ADA)
1701 North Beauregard Street, Alexandria, VA 22311
Telephone: (800)-DIABETES (342-2383)
Email: AskADA@diabetes.org
Web site: www.diabetes.org

The ADA is the nation’s leading nonprofit organization providing diabetes research, information, and advocacy. In order to promote quality education for people with diabetes, the Association endorses the National Standards for Diabetes Self-Management Education Programs.

LifeScan, Inc.
1000 Gibraltar Drive, Milpitas, CA 95035
Telephone: (800) 524-SCAN (7226)
Web site: www.lifescan.com

LifeScan is a leading maker of blood glucose monitoring systems for home and hospital use. It provides a course called Pharmacy Partners in Diabetes Care (PPDC) for U.S. pharmacists who are highly motivated to specialize in diabetes care and provide pharmaceutical care services to patients.

Managing Your Diabetes—Basic Facts About Type 2 Diabetes
Lilly Answers Center: 1-800-LillyRx (545-5979)
Web site: www.lillydiabetes.com

This free book, published by Eli Lilly, discusses basic topics about diabetes.
Endnotes


18. The SF-12(r) is a generic health status instrument that measures the physical and mental health of an individual in 12 key areas. It is derived from the SF-36 (also called the Short-Form 36(r)), that has been validated and widely used for about 10 years. The SF-12(r) is also accepted by the FDA for proving improved functioning and patient-reported outcomes.