



The Scope and Standards for the Practice of Diabetes Education by Pharmacists

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Introduction

In 2005, the American Association of Diabetes Educators (AADE) published the Scope of Practice, Standards of Practice, and Standards of Professional Performance for Diabetes Educators, written by a multidisciplinary team.¹ Nurses and dietitians developed and published complementary, discipline-specific documents.^{2,3} Similarly, this document addresses the specific role of the pharmacist in the delivery of diabetes education, and is meant to complement the AADE Scope of Practice, Standards of Practice and Standards of Professional Performance for Diabetes Educators.

The purpose of this document is to:

- 1) Review the current issues in diabetes;
- 2) Describe the scope of diabetes-related services offered by pharmacists in different practice settings to individuals with diabetes;
- 3) Summarize relevant published articles describing successful pharmacist involvement;
- 4) Provide a set of practice guidelines in support of optimal care for patients with diabetes when delivered by the profession of pharmacy in a variety of practice settings.

Background

The end of the 20th century marked an alarming increase in diabetes mellitus in our society, with more than 20 million people in the United States currently estimated to have the disease. Type 2 diabetes is the most common variant, accounting for approximately 90 percent of all cases. It is estimated that 6 million cases of type 2 diabetes remain undiagnosed, secondary to the slow onset and mild symptoms present during the early stages of the disease. Diabetes mellitus has a higher prevalence in certain ethnic groups, including American Indians, Alaska Natives, African Americans and Hispanic/Latino Americans.⁴ Not only has there been a rise in certain ethnic minorities, but there has also been an alarming rise of type 2 diabetes in children and adolescents. Currently approximately 200,000 children have diabetes.⁴ Although type 1 diabetes currently comprises the majority of cases in children, the prevalence of type 2 diabetes in children is increasing and 2.5 million adolescents are thought to have impaired fasting glucose or pre-diabetes.⁵ Recent changes in the American lifestyle, which include inactivity and unhealthy diet, have contributed to the rise of this disease.

Diabetes places an enormous disease burden on patients, as well as on their families and on society at large. Diabetes is associated with long-term microvascular and macrovascular complications, including a two to four fold increased risk for cardiovascular events, and an annual mortality rate two to three times higher than that of individuals without diabetes.⁴ One out of every ten health care dollars is spent on diabetes and its complications.⁶ The estimated total cost of managing diabetes in 2007 was approximately \$174 billion dollars and is estimated to continue increasing.⁶ To reduce the risks of micro- and macrovascular diabetes complications, patients need to learn about this complex disease and incorporate a variety of self-management behaviors into their daily lives. With appropriate education and support, individuals may increase their type 2 diabetes self-management knowledge, skills, and behaviors, in order to optimize wellness and prevent or reduce diabetes-related complications.⁷

Diabetes Self-Management Training (DSMT)

The American Association of Diabetes Educators (AADE) developed a framework to generate an optimal practice of DSMT for individuals with diabetes. DSMT is an interactive collaborative ongoing process involving the person with diabetes and the diabetes educator(s). The process should undergo continual evaluation and include the following:

- Assessment of the individual's specific education needs;
- Identification of the individual's specific diabetes self-management goals;
- Education and behavioral intervention directed toward helping the individual achieve identified self-management goals;
- Evaluation of the individual's progress in attaining identified self-management goals.^{7,8}

The DSMT program framework includes a written curriculum that reflects evidence-based practice guidelines and criteria for evaluating outcomes. The American Diabetes Association (ADA) Clinical Practice Guidelines reflect the need to evaluate individuals with both pre-diabetes and diabetes.⁹ A needs assessment of these individuals determines which of the following content areas will be provided:

- Describing the diabetes disease process and treatment options;
- Incorporating nutritional management into lifestyle;
- Incorporating physical activity into lifestyle;
- Using medications safely and for maximum therapeutic effectiveness;
- Monitoring blood glucose and other parameters and interpreting and using the results for self-management decision making;
- Preventing, detecting, and treating acute complications;
- Preventing, detecting, and treating chronic complications;
- Developing personalized strategies to address psychosocial issues and concerns;
- Developing personalized strategies to promote health and behavior change.⁸

The AADE has adopted *behavior change* as the outcome of DSMT.¹⁰ Seven key self-care behaviors, called the AADE7TM (www.diabeteseducator.org/ProfessionalResources/AADE7), have been identified as necessary for diabetes self-management.¹⁰ These key behaviors include:

- Healthy eating
- Physical activity
- Medication taking
- Monitoring
- Problem solving
- Healthy coping
- Reducing risks

Pharmacists involved in diabetes care and management play a pivotal role in helping patients achieve therapeutic and lifestyle goals outlined by the AADE7TM. This active participation in diabetes care and management requires that the pharmacist's practice extend beyond the traditional pharmacist role.³ Pharmacists should promote and support behavior change as the key tenet of diabetes education. Hence, pharmacists should understand the concepts of medical nutritional therapy, exercise, and motivational interviewing to help patients achieve their goals.

Pharmacists should exercise cultural sensitivity and assess learning barriers when providing diabetes education. They should be prepared to practice in diverse settings and work with other diabetes educators to provide optimal care for patients. Pharmacists involved in diabetes care and management should be challenged to work side by side with other diabetes educators in a mutually respectful environment that highlights the patient's best interests.

Several important events impact the role of pharmacists and are of particular importance in provision of DSMT:

- The reports of the Institute of Medicine (www.iom.edu) noted needed changes in our health care system to improve medication safety and patient outcomes, including the five competencies that all health care professionals should attain during their education and training.

- The proliferation, now in more than 40 states, of collaborative health care practice legislation includes an expanded patient care role for pharmacists. Collaborative practice involves an agreement between a pharmacist and a collaborating physician where, through a pre-specified protocol, a pharmacist may have the autonomy to select, initiate, adjust a therapeutic regimen, or discontinue a medication.¹¹
- The Center for the Advancement of Pharmaceutical Education (CAPE), which is within the American Association of Colleges of Pharmacy, revised the pharmacy curriculum educational outcomes in 2004 under the guidance of a panel composed of practitioners and educators. These educational outcomes are patient focused and intended to be the target toward which the evolving pharmacy curriculum should be aimed.
- The Medicare Modernization Act of 2003 established the need for medication therapy management services provided to targeted beneficiaries with medications and multiple chronic conditions (www.cms.hhs.gov).

Diabetes Prevention

The increasing prevalence of type 2 diabetes has generated growing interest in developing safe and successful strategies for prevention.¹² An important initial intervention by pharmacists is identification of individuals with pre-diabetes, who are therefore at risk for developing type 2 diabetes. There is a need to increase community awareness about the importance of healthy lifestyle and early screening in high-risk individuals. The accessibility of pharmacists provides a unique opportunity to raise community awareness about the importance of programs and facilities for physical activity and resources for healthy nutrition. Pharmacists may refer patients to other diabetes educators who specialize in physical activity and nutrition. Pharmacists may work closely with communities to design better prevention and treatment programs that are culturally relevant.

Although there have been no definitive studies that prove that type 1 diabetes is preventable, there are several studies that have shown that type 2 diabetes may be delayed or prevented. Lifestyle intervention prevention studies include the Da Qing Study, the Finnish prevention study, and the Diabetes Prevention Program (DPP), which included persons with impaired glucose tolerance.¹³⁻¹⁵ Studies that demonstrate the benefit of pharmacological agents include the metformin arm of the DPP, the Troglitazone in Prevention of Diabetes Study (TRIPOD) in a group of Hispanic women with a history of gestational diabetes, the Pioglitazone in Prevention of Diabetes (PIPOD), the Study to Prevent Non-Insulin-Dependent Diabetes Mellitus (STOPNIDDM) using acarbose, and the rosiglitazone component of the Diabetes Reduction Assessment with ramipril and rosiglitazone Medication (DREAM) trial (see Table 1).¹⁵⁻¹⁹

Table 1 – Type 2 Diabetes Prevention: Outcomes of Randomized Controlled Studies

Study (ADA evidence grading*)	Intervention	RRR
Da Qing Study ¹³	Therapeutic lifestyle change	31-46%
Finnish Diabetes Prevention Study ¹⁴	Therapeutic lifestyle change	58%
Diabetes Prevention Program ¹⁵ (A)	Therapeutic lifestyle change	58%
Diabetes Prevention Program ¹⁵ (E)	Metformin	31%
TRIPOD ¹⁶ (E)	Troglitazone	55%
PIPOD ¹⁷ (E)	Pioglitazone	N/A**
STOP-NIDDM ¹⁸ (E)	Acarbose	25%
DREAM ¹⁹ (E)	Rosiglitazone	62%

RRR = Relative Risk Reduction

* Per the ADA evidence grading system for clinical practice recommendations (Standards of medical care in diabetes-2007. Available at: http://care.diabetesjournals.org/content/vol30/suppl_1/1), only the DPP Therapeutic Lifestyle Changes has been given a rating of level A; the trials involving medications have been graded as E, due to the possibility of adverse effects and cost and insufficient evidence to support the use of drug therapy. The Da Qing and Finnish Diabetes Prevention Study were not given an evidence grade.

**N/A= Relative Risk Reduction not calculated for the PIPOD Trial; annual rate was 4.6%

Other prevention studies are included in the ADA Standards of Medical Care.⁹

Diabetes Management

Two large prospective intervention studies include the Diabetes Care and Complications Trial (DCCT) in type 1 diabetes and the United Kingdom Prospective Diabetes Study (UKPDS) in type 2 diabetes.^{20,21} These studies

demonstrated that intensive diabetes management resulted in lower rates of microvascular complications. The Epidemiology of Diabetes Interventions and Complications (EDIC) trial, a follow up of the DCCT, has shown that initial intensive management has resulted in lower rates of retinopathy, nephropathy, neuropathy, and macrovascular disease.²²⁻²⁵

Pharmacists are an integral part of the health care delivery system in the United States and are the most accessible health care professionals in most communities. Pharmacists may help bridge the education gap, since it has been reported that only 30% of patients receive formal diabetes education.²⁶ Pharmacists are uniquely positioned to provide diabetes education since patients with diabetes see their pharmacists seven times more often than they see their primary care physician.^{5,27}

There are currently over 230,000 pharmacists in the United States.²⁸ Almost all medically managed patients with diabetes interact on an ongoing basis with a pharmacist. As such, pharmacists may have a profound influence on improving the lives of the patients with diabetes whom they see in their daily practice.²⁷

The role of the pharmacist in DSMT is well established. Common practice sites where DSMT is provided include community pharmacies, ambulatory care settings, hospitals, long-term care facilities, rehabilitation facilities, and physician offices. Other sites may include, but are not limited to, the Public Health Service (e.g., Indian Health Service) clinics, Community Health Centers, and private consulting practices. Numerous studies have shown that pharmacist interventions improve medication adherence, treatment outcomes, and quality of life for patients with diabetes.²⁹⁻³² Studies have also shown that pharmacists have demonstrated cost savings by providing diabetes care in community settings as well as in Veterans Health Administration Clinics.³³⁻³⁷ Pharmacists have even developed a business model to provide pharmacy services.³⁸

Pharmacists are able to build strong relationships with patients and become a reliable source of information. Pharmacists may also have ongoing communication with physicians and may serve as the 'bridge' between other health care providers and the patient, thus ensuring continuity of care. In addition, pharmacists may provide ongoing recommendations to the patients and their providers to optimize diabetes care.²⁷ These factors position pharmacists to profoundly impact the health outcomes and quality of life for their patients with diabetes.⁶

Effectiveness of Pharmacists to Improve Diabetes Health-Related Outcomes

The literature supports pharmacist involvement with diabetes education and related care in a variety of health care settings, including government, institutional, managed care, and outpatient health care settings. Collaboration with physicians and other health care providers has been a successful model for pharmacist provision of diabetes-related services. This section is organized by these practice settings and summarizes information available in the literature that evaluates or describes pharmacist involvement in diabetes care.

Government Settings

Several published articles describe the diabetes outcomes of patients referred to pharmacist-run diabetes management clinics in Veterans Affairs Medical Centers (VAMC), Community Health Centers (CHCs), and other federal facilities (Army and Navy).^{32,37,39-46} Pharmacists in these clinics worked in collaborative agreements with physicians in their facilities to provide diabetes education and intensive pharmacologic management (including initiation and titration of insulin and oral glucose lowering agents), and to improve adherence to standards of care for patients. Patients were scheduled for visits frequently (as often as weekly) for education and titration of drug therapy based on facility protocols or in consultation with the referring physician. The majority of the pharmacists were certified diabetes educators. The primary outcome of these studies was the change in hemoglobin A1C (A1C), with secondary outcomes including changes in blood pressure, LDL-cholesterol, and adherence with standards of care. All studies reported a significant decrease in the A1C, in the range of 1.3 to 3.4%. In the CHC summary report of 16 centers with established pharmacist-delivered diabetes management programs, an average drop in A1C of 1.4% was sustained over 24 months for patients remaining in the program.⁴² In the VAMC and CHC clinics there were also significant reductions in the systolic and diastolic blood pressure and LDL-cholesterol values. The CHC and federal facility clinics reported increased adherence to diabetes standards of care (e.g., eye and foot exams, A1C and lipid monitoring, aspirin and ACE inhibitor use) with some programs reporting a 99% completion rate. A federal facility clinic reported a 90% decline in diabetes related hospitalizations over a three-year period.⁴⁵

Managed Care Settings

Articles evaluating the impact of pharmacist interventions to improve diabetes care in managed care settings have shown a positive impact on medical costs and adherence to standards of care. One study evaluated the impact of three pharmacist consultation models on total direct medical costs (defined as cost of hospitalizations, medications, and office visits) over a two year period for patients with diabetes receiving care from Kaiser Permanente of Southern California.⁴⁷ Over 6,000 patients were randomly assigned to one of three pharmacies on a medical center campus with each pharmacy providing one of three models of care. In the first model, pharmacists consulted with patients when deemed necessary or when requested by a patient. In the second model, the pharmacist consulted patients on all new and changed prescriptions. The third model was a high-risk patient focused pharmacist consultation (Kaiser Permanente model). For these patients, pharmacists performed a medication review, assessed adherence, provided patient education on hypo- and hyperglycemia symptoms and treatment, medication side effects, and adherence.⁷ Patients whose problems required more intervention than that provided by the Kaiser model were referred to either a diabetes educator or their primary physician. The two focused pharmacist consultation models that were able to show a significant reduction in total direct medical costs, 21.9% for patients assigned to the Kaiser model and 9.9% for patients receiving a pharmacist consultation for their new or changed prescription medication.

An intervention to improve lisinopril use among hospitalized patients with diabetes and coronary artery disease by a Clinical Pharmacy Cardiac Risk Service was evaluated at Kaiser Permanente of Colorado.⁴⁸ Upon discharge from the hospital, the pharmacist initiated and/or titrated lisinopril (target dose of 20 mg or highest tolerated) in eligible patients. The pharmacist intervention more than doubled the number of patients achieving target doses of lisinopril.

Clinical pharmacists working with physicians in a Chicago managed care group were able to demonstrate significant reductions in A1C (average 1.4% decrease), LDL-cholesterol (14 + 41.1 mg/dl) and triglyceride (42 + 97.6 mg/dl) in 316 adults with diabetes referred to their service.

There were also significant increases in the frequency of retinopathy screenings, monofilament foot examinations, and daily aspirin use.⁴⁹ A self-insured employer plan partnered with pharmacists that developed a model called "Raising Energy and Awareness in Campus Health" (REACH). The pharmacists were in an academic setting and provided a variety of services including ways for patients and providers to minimize the impact of diabetes and other disease states. The overall program saved an estimated 1.6 million dollars.⁵⁰

Clinic-based Practice Sites

Several articles have been published describing pharmacists' involvement in diabetes care delivered in clinic-based practices in academic health care settings and in private medical practices. Pharmacists working with primary care providers (internal medicine or family medicine physicians) in academic centers using collaborative drug therapy management have improved glycemic control and increased adherence to diabetes standards of care.^{29,31,51-55}

Pharmacists provided diabetes education, adjustment or titration of medications, and completed standards of care in these clinics. The evaluation period of these studies ranged from three to 15 months with pharmacists providing follow-up visits ranging in frequency from weekly to quarterly. The primary outcome measure was a change in A1C from baseline, with secondary outcome measures including adherence to standards of care and percent of patients achieving A1C goals. Hemoglobin A1C values decreased significantly in all studies reported, ranging from 1.7 to 3.4%. Five of seven studies reported greater compliance meeting standards of care, including significantly higher completion rates for A1C and lipid profile determinations, eye and foot examinations, microalbumin screening, higher aspirin use, and increased statin prescribing.^{29,51,52,54,55} Two studies demonstrated that a significant percent of patients achieved and sustained an A1C of < 7% at one year (40 to 50% vs. 12 to 19% at baseline).^{52,55} Two studies estimated cost saving based on improved A1C as \$61,500(50) and \$244,500.⁵¹

Pharmacists providing diabetes education and collaborative drug therapy management in private physician practices have demonstrated a reduction in A1C in patients who had been unable to reach the target goal.^{56,57} One intervention involved home visitation by pharmacists and pharmacy students to provide education and reinforce education on lifestyle changes.

While the reduction in A1C was not significant compared to the control group, there was a significant reduction in the number of emergency department visits in the intervention group (2 vs. 16).⁵⁷ Another clinic reported a significant reduction in A1C and a significant increase in the number of patients achieving a A1C levels <7% and systolic blood pressure levels <130 mm Hg with pharmacist intervention in addition to their physicians in comparison to patients without pharmacist involvement.⁵⁶

Community Pharmacy Practice Sites

A variety of pharmacist interventions to improve diabetes outcomes have been reported by pharmacists in community pharmacies. These interventions included diabetes education and pharmacologic management to improve glycemic control as well as lowering blood pressure and cholesterol. These programs were done in collaboration with physicians, local formal diabetes education programs, and the patient's insurer.

The Asheville Project, a milestone achievement in community pharmacy, involved a community pharmacist intervention in patients with diabetes who participated in a self-funded insurance plan.³⁶ Community pharmacists scheduled individual appointments to review home blood glucose monitoring and glycemic control, to establish goals of therapy and discuss diabetes needs. Pharmacist intervention was provided in concert with regular physician follow-up visits and formal diabetes education programs offered by local diabetes education centers.

Over 50% of patients had an improvement in A1C values relative to baseline. Average LDL- and HDL-cholesterol levels improved at every visit. Estimated total medical costs decreased between \$1200 and \$1872 per patient per year even after factoring in increased costs for pharmacist services, blood glucose self-testing and education. Two other reports were published that replicated the "Asheville model".^{58,59} The pharmacist intervention resulted in a decrease in A1C of 0.6 to 0.8% at one year, significant decreases in LDL-cholesterol and blood pressure, and increased rates of influenza vaccinations, and eye and foot examinations. One site reported that the total annual medical costs were \$918 less per patient than projected.⁵⁹

Three observational studies reported the impact of a diabetes education program, one of which was an ADA-recognized diabetes self-management training program, provided by pharmacists in community pharmacies on patients' diabetes control. Patients were seen individually for diabetes education sessions with follow-up for 6 to 12 months. The average decrease in A1C ranged from 1.2 to 2.2%.⁶⁰⁻⁶²

Two studies described collaboration between a regional HMO (Ohio and West Virginia) and community pharmacies to identify patients with diabetes not attaining goals of therapy and institute a pharmacist intervention to improve intermediate clinical outcomes.^{63,64} Patients were either referred by their primary care providers or could self-refer for a pharmacist consultation to evaluate A1C and lipid results, blood pressure, and receive diabetes education. Pharmacists provided three one-hour sessions and quarterly follow-up visits to assess patient progress toward goals. After each visit, the pharmacist sent a report of the patient's lab and blood pressure with recommendations for drug therapy changes to the patient's physician. The pharmacist implemented these changes after receiving verbal or written authorization from the physician.⁹

Thirty-two of 47 (68 %) patients initially enrolled continued the patient management program for at least 6 months (median duration of nine months). The reported average A1C reduction was 0.4%. In a subset of patients whose A1C baseline was >8%, average A1C decreased 1.2% (p<0.015). Additionally, significant reductions in total cholesterol and LDL-cholesterol were obtained. Pharmacists in three chain pharmacies in the northwest published an economic evaluation of a disease management services for diabetes, asthma, dyslipidemia, and hypertension.⁶⁵

Pharmacists provided patient education on medications, target diseases, progress toward goals of therapy, and intensified pharmacologic management to reach therapeutic goals. Total monthly medical and pharmacy cost saving were estimated to be \$144 to \$293 per patient per month for those patients seen by the disease management service.

Conclusions Regarding Studies of Pharmacist Effectiveness in Improving Diabetes Health-Related Outcomes

The articles discussed in this section provide evidence that pharmacists in collaboration with other health care providers can improve diabetes outcomes through the provision of education and intensifying pharmacologic management of diabetes and common co-morbid diseases resulting in improved glycemic, lipid and blood pressure

control and adherence to standards of care. Pharmacists working in partnership with other health care providers are capable of addressing the growing economic and health threats of diabetes. These collaborative relationships can occur in the majority of health care systems where patients receive care and pharmacists practice. A systematic review of published studies of pharmacists involved in diabetes care and management has also been published.⁶⁶ The articles described here are representative of the growing body of literature describing the role of the pharmacist in the care of individuals with diabetes.¹⁰

Pharmacist Scope of Practice

The Scope of Practice for pharmacist diabetes educators defines a range of practice for the specialty, and provides a framework for appropriate and effective pharmacist practice in diabetes care. All pharmacists must be knowledgeable of the disease state and coexisting diseases, to provide safe, competent care to persons with, or at risk, for diabetes. As the intensity of care increases, so must a pharmacist's knowledge base increase through experience, continuing education, individual study, mentorship, and potentially, certification.

Pharmacists providing diabetes care utilize established principles of education strategies, learning theory, and provide lifestyle counseling to help patients effectively manage their disease. Instruction is individualized for persons of all ages, incorporating cultural preferences, health beliefs, and preferred learning styles of the patient.¹

Practice Sites

Any pharmacist is eligible to become a diabetes educator. The pharmacist diabetes educator provides services beyond basic counseling about medications. The pharmacist educator includes learning theory and educational principles regarding behavioral change in teaching self-management skills to people with diabetes, their families and communities. These services may occur in a variety of settings including, but not limited to, the following:

- 1) Community pharmacy
 - Chain
 - Independent
 - Grocery store
 - Mass merchandiser
 - Clinic setting
- 2) Clinic
 - Private practice
 - Physician group practice
- 3) Hospital
 - Member of a diabetes education team
 - Diabetes coordinator
 - Other inpatient teams
- 4) Managed care
 - Hospital
 - Clinics
- 5) Long term care facilities
 - Assisted living facilities
 - Other facilities
- 6) Government
 - Department of Veterans Affairs Medical Centers
 - Community Health Centers
 - Indian Health Service
- 7) Academic
 - Teaching students about diabetes education
 - Providing CE programs for pharmacists about diabetes education
 - Performing research in clinical trials and or practice-related and outcomes research

Education and Certification

The scope of practice for pharmacists participating in diabetes care ranges from brief medication counseling, to formal education programs, to protocol-driven medication management, to independent direct patient care. In support of this continuum are a variety of personal education/involvement options for pharmacists. The

designation that all pharmacists should aspire to reach and which serves as the foundation for an advanced education-based practice is the CDE credential.

Certificate Programs

Certification programs designate a pharmacist as having a particular didactic, working knowledge base. The rigor of any given certification depends on qualifications for taking and passing the certification exam. Although these programs may require in-depth training and knowledge, certification is primarily used for intra/inter-disciplinary recognition of a minimum knowledge or diabetes skill set. Such programs are not a substitute for residency training or other longitudinal training experiences. Pharmacists interested in participating in diabetes certificate programs are encouraged to select programs that are themselves approved by the Accreditation Council on Pharmacy Education (ACPE). Examples of such programs include the following:

- Diabetes Disease State Management Program
- Offered by University of Texas at Austin College of Pharmacy
- www.utexas.edu/pharmacy/ce
- Diabetes Certificate Program via the Internet
- Offered by University of North Carolina School of Pharmacy
- <http://www.pharmacy.unc.edu/programs/continuing-education/certificateprogram>
- Diabetes Self-Management Certificate Program
- Offered by Purdue University Division of Pharmacy Continuing Education
- <http://www.phpr.purdue.edu/~phprce/diabetes.html>
- Pharmaceutical Care for Patients with Diabetes
- Offered by American Pharmacists Association and AADE
- <http://www.pharmacist.com/CTP/diabetes>
- Diabetes Certificate Program
- Offered by the University of Southern Indiana
- <http://health.usi.edu/certificate/diabetesmgmt/index.php>
- Certified Disease Manager (CDM)
- Offered by the National Institute for Standards in Pharmacist Credentialing
- (NISPC) – The CDM is no longer available as a new credential. Pharmacists who currently hold this certification may qualify for recertification by maintaining a current pharmacy license in good standing with their state board of pharmacy and 30 hours of ACPE approved, disease specific, continuing pharmaceutical education every 3 years.¹²
- www.nispcnet.org

Interdisciplinary Certification

Certified Diabetes Educator (CDE)

Individuals who obtain the designation of CDEs meet the academic, professional, and experiential requirements set forth by the National Certification Board for Diabetes Educators (NCBDE). Certification is valid for a period of 5 years and is maintained either through repeat examination or through documented participation in relevant continuing education activities every five years. Information about certification as a CDE is available from the National Certification Board for Diabetes Educators at: www.ncbde.org.

Board Certified in Advanced Diabetes Management (BC-ADM)

The BC-ADM credential is an advanced-practice certification offered to nurse practitioners, clinical nurse specialists, dietitians, and registered pharmacists. Four discipline-specific examinations are offered. Candidates must document at least 500 hours of clinical diabetes experience (after discipline licensure) within 48 months prior to application. A pharmacist with a BC-ADM credential may or may not be a CDE.

The discipline-specific educational requirements to take the examinations include a master's degree in nursing (nurse practitioners and clinical nurse specialists); a relevant clinical master degree (dietitians), and masters or doctorate of pharmacy or currently practicing in a state recognized collaborative diabetes clinical practice (registered pharmacists). Certification is valid for 5 years and is maintained either through repeat examination or through qualified continuing education activities as defined by the American Nurses Credentialing Center.

Information related to certification as a BC-ADM is available from the American Nurses Credentialing Center at: <http://www.nursingworld.org/>¹³

Standards of Practice for Pharmacists in Diabetes Education

The Standards of Practice and Standards of Professional Performance for Pharmacists in Diabetes Education have been developed by the Pharmacy Specialty Practice Group within AADE to: 1) define nationally acceptable standards of practice for pharmacists in diabetes education; and 2) ensure quality and accountability in the professional practice of diabetes education. The pharmacist diabetes educator is individually responsible for adhering to these standards. Standards of practice are authoritative statements that describe the competent level of practice and describe the responsibilities for which diabetes educators are accountable. Standards of practice reflect the values and priorities of the profession and provide a framework for the evaluation and improvement of practice. Standards of professional performance are defined statements that describe a competent level of behavior in the professional role. They describe the minimum level of performance expected regardless of the setting, project, case, or situation. Adapted from the American Dietetic Association Practice Definitions Task Force.

Standards of Practice

Although pharmacists in some practice settings may focus on only a few aspects of care, in general the pharmacist identifies, retrieves, evaluates, interprets and provides appropriate drug and diabetes-related information to achieve safe and effective patient care. By establishing standards of practice

Pharmacists gain:

- a framework for professional practice in diabetes care and education
- guidelines against which to assess the quality of their practice
- and direction for improving practice.

Persons with or at risk for diabetes gain:

- a basis for forming expectations of the diabetes self-management training (DSMT) experience and
- a means to assess the quality of DSMT services provided by pharmacists.

Health care professionals who do not specialize in diabetes management gain:

- conceptual understanding of the role of the pharmacist as a diabetes educator,
- an appreciation of the importance of DSMT as an integral component of the clinical care of the person with or at risk for diabetes, and
- a way to assess the quality of DSMT services provided by pharmacists. Insurers, policy makers, purchasers, employers, government agencies, industry, and the general public gain
- a description of the specialized diabetes services provided by pharmacists,¹⁴
- an understanding of the importance of DSMT to improve quality of life and health care outcomes for persons with or at risk for diabetes, and
- a description of how processes and outcomes related to DSMT can be systematically collected and evaluated.

Standard 1: Assessment

The pharmacist identifies factors such as current medications, lifestyle, diet and exercise, tobacco and alcohol use, health problems or conditions of the patient with diabetes, and financial constraints that may impact drug therapy. A medication includes prescription medications, nonprescription medications, and complementary and alternative medicine (CAM).

Measurement Criteria

The pharmacist:

- identifies and evaluates appropriate sources of relevant information;
- determines the credibility of information sources and critically evaluates drug and diabetes specific information from the various sources;
- identifies whether appropriate laboratory tests have been performed at the recommended interval(s);

- identifies fulfillment of recommended services, such as dilated eye examinations, dental examinations complete foot examinations, and immunization status;
- assesses patient's readiness to change regarding medication use; the pharmacist also assesses the patient's medication use, including how often they miss medications. A pharmacist determines the patient's commitment to taking medications. If the patient is not committed to taking medications, the pharmacist assesses the patient's readiness to change medication-taking behavior and takes steps to help the patient become motivated to taking medications.
- uses evidence-based guidelines to evaluate appropriateness of the current drug therapy and determines whether the patient requires additional medications, or would benefit from consolidation of therapies; and
- determines if the correct amount of medication is being received by the patient and taken appropriately.

When managing the care of a patient with diabetes, the pharmacist assesses the patient's ability to use diabetes and related equipment (monitoring devices, syringes, injection devices, blood pressure monitors, ketone test strips, etc.). The pharmacist assesses the patient's ability to interpret results of self-monitoring and to select appropriate strategies to correct readings that are not at goal. The pharmacist assesses whether the patient understands what behavior(s) to change to correct out of target readings. The pharmacist determines the patient's readiness to change behavior and provides motivational interviewing to help the patient optimize diabetes care.¹⁵

Measurement Criteria

The pharmacist:

- determines and assesses the condition or symptoms to be treated and the patient's and practitioner's perception of what needs to be done;
- recommends appropriate therapy;
- provides instruction for proper use;
- discusses expected outcomes within defined time periods and how clinical labs and diabetes equipment are used to monitor response to therapy;
- advises the patient on when to seek the attention of another health care provider; and
- refers the patient to another qualified person when required.

Standard 2: Outcome Identification

The pharmacist interacts with the patient to identify the desired outcomes of drug therapy and diabetes self-management training (DSMT).

Measurement Criteria

The pharmacist works with the patient to enhance the patient's knowledge of diabetes and its comorbidities in order to help the patient understand the desired outcomes of drug therapy, as well as other educational interventions. Specifically, the pharmacist:

- collects information regarding health status to help the patient identify desirable treatment outcomes (for instance, diabetes, hypertension, hyperlipidemia, along with hepatic, renal, and other clinical parameters) and uses it to enhance the patient's knowledge of diabetes and other educational and therapeutic options;
- evaluates and describes potential outcomes to the patient and healthcare providers; and
- encourages and supports the patient's right to make choices, with a full disclosure of the potential consequences of the patient's choices.

Standard 3: Planning

In consultation with the patient and other health care providers, the pharmacist determines appropriate options to solve or prevent identified problems.

Measurement Criteria

The pharmacist:

- prioritizes identified problems;
- proposes and assesses alternative strategies;
- establishes a positive working relationship with local health care providers in order to realize the objectives of positive health outcomes;

- selects with the patient and through consultation with other health care providers the most appropriate options; and
- explains the rationale of the proposed treatment to the patient.¹⁶

Standard 4: Implementation

The pharmacist communicates essential information to patients about any prescription or nonprescription drug (especially those related to diabetes and its co-morbidities), CAM therapies, and diabetes devices. The pharmacist evaluates whether the patient is committed to taking all prescription and nonprescription medications. If the pharmacist determines the patient is not completely committed to taking medications or performing diabetes-related assessments such as blood glucose testing, the pharmacist evaluates the patient's readiness to change to optimize medication use and perform self-monitoring evaluations. The pharmacist provides motivational interviewing to help the patient take steps to change behavior in order to improve diabetes management.

Implementation of the patient's management plan may also involve collaboration with other health professionals, community resources, and services. The pharmacist is able to refer the patient to key personnel, such as dietitians, exercise physiologists, or other behavior interventionists to help the patient change behavior.

Measurement Criteria

The pharmacist communicates with the patient regarding drug therapy and other assessments, including but not necessarily limited to, a confirmation of:

- drug allergy status;
- name, general description of the drug dispensed, and directions for use;
- the intended therapeutic response;
- common or important side effects and appropriate management; and
- storage requirements, security and disposal of drugs and medical devices.

To minimize the impact of medication errors, the pharmacist:

- documents medication errors and discusses the error with the patient, prescriber and other health care professionals, as appropriate;
- resolves drug related problems (i.e., such as doubling the dose when a dose is missed or taking both a generic and trade name product) resulting from drug errors;
- assumes responsibility for recognizing drug errors;
- takes the necessary steps to resolve issues arising through medication discrepancies and errors, and implements measures to prevent recurrence.

When a patient is seeking to self-medicate with a nonprescription drug or CAM therapy, the pharmacist, in consultation with the patient, determines:

the condition or symptoms to be treated and the patient's self-diagnosis or practitioner's diagnosis of the situation;

- the background and history of the patient's complaint, disease state and urgency of the situation;
- the history of current disease states (as they relate to the condition being treated);
- other medications or treatments the patient is currently taking that may contribute to this condition or interact with suggested therapy;¹⁷
- known contraindications to prescription or nonprescription drug use; known patient risk factors for adverse drug reactions, drug allergies or sensitivities;
- dietary restrictions;
- the patient's self-care objectives;
- other medications or treatments that the patient may have previously tried for this condition and subsequent efficacy or problems;
- the seriousness of the symptoms which may indicate the need for referral to another health care provider or an emergency treatment center; and if applicable, to the drugs available and the appropriateness of the self-selected product.

Standard 5: Evaluation

The pharmacist monitors and evaluates outcomes on a continual basis. The pharmacist collects and interprets pertinent information from patients and health care providers whenever possible.

Measurement Criteria

The pharmacist:

- identifies important clinical indicators (signs and symptoms) and pertinent laboratory measurements;
- identifies and applies appropriate self-monitoring techniques;
- establishes an effective plan which includes the onset, frequency and duration of monitoring;
- secures involvement of the patient in the implementation and maintenance of the plan;
- defines measurable outcomes in consultation with the patient and/or health care professionals if required.

To ensure patient safety, the pharmacist assesses whether the patient is able to appropriately use diabetes equipment and interpret readings. Hence the pharmacist determines whether the patient recognizes untoward reactions of diabetes or the therapies used to treat diabetes and its comorbidities. The pharmacist is able to assess whether the patient is ready to change behavior to actually use the diabetes equipment. After assessing readiness to change, the pharmacist provides motivation to help the patient take steps to make necessary changes.

Measurement Criteria

The pharmacist:

- assesses whether the patient uses equipment appropriately to recognize and take steps to avoid or minimize adverse outcomes or drug interactions (e.g., hypoglycemia or hyperglycemia);
- assesses whether the patient recognizes and takes steps to avoid or minimize side effects or toxicity of medications;
- provides information so that the patient uses equipment to recognize and address patterns of inappropriate use of drugs, tobacco and alcohol;¹⁸
- provides appropriate diabetes-related information to facilitate the patient's understanding of his or her drug therapy and ability to comply with the therapy regimen.

Standard 6: Documentation

The pharmacist has access to and either develops or contributes to a database, preferably electronic, containing relevant information about the patient's health to facilitate real time critical evaluation of a patient's problems and needs. Ideally this database is shared electronically with all members of the healthcare team.

Measurement Criteria

The pharmacist:

- is aware of the purpose(s) for the documentation;
- maintains a patient information database which includes a medication and education profile and pertinent medical history; this database includes a list of prescription and nonprescription medications, CAM therapies, devices, and monitors used to evaluate diabetes and its co-morbidities;
- documents specific education that has been provided to the patient regarding medications and lifestyle. The pharmacist includes nutrition and exercise education that has been provided to the patient, including an assessment of the patient's readiness to change. The documentation includes specific lifestyle changes that the patient is willing to make and if readiness to change is not apparent, the pharmacist documents the motivational steps that have been provided to facilitate behavior change. The pharmacist documents the major observations of patient information assessment, including behavioral and lifestyle goals the patient has set and when to expect achievement of those goals;
- stores recommendations made and actions taken, in a readily retrievable format;
- records the patient's current problems and priority for resolution;
- documents the actual intervention;
- documents the patient's outcome and follow-up assessment;
- documents communication with the patient and other health care providers.

Standards of Professional Performance

Pharmacists use unique knowledge and skills to meet drug and education related needs of patients with or at risk for diabetes.

Pharmacists gain:

- a framework for personal/professional appraisal of DSMT and diabetes care activities,
- documentation guidelines to facilitate the ongoing processes of performance appraisal and professional development, and
- direction for improving professional performance.¹⁹

Persons with or at risk for diabetes gain:

- documented support, via DSMT research and continuous quality improvement activities, of evidence-based DSMT practice.

Insurers, policy makers, purchasers, employers, government agencies, industry, and the general public gain:

- a framework for evaluation of pharmacist performance in relation to health system decisions affecting retention, promotion, transfer, salary increases or decreases, or admission into a training program, and
- assurances of appropriate use of time, money, facilities, and human resources, which facilitates quality DSMT services provided by pharmacists.

Standard 1: Quality of Care

In caring for patients with diabetes, pharmacists practice patient-centered care in partnership with other health care providers to achieve positive health outcomes and to maintain or improve quality of life for the patient.

Measurement Criteria

The pharmacist:

- demonstrates excellence and professionalism in the practice of DSMT through actions that are consistent with established professional practice guidelines and established local, state, and federal regulations;
- identifies both process and outcome measures; these may include A1C levels, fasting and postprandial blood glucose goals, blood pressure and lipid goals and improved quality of life as measured by tools such as the SF-12v2TM (<http://www.sf-36.org/tools/sf12.shtml#Version2>).
- helps the patient develop behavioral and lifestyle goals that will benefit diabetes and its co-morbidities; assesses readiness to change lifestyle and provides motivational interviewing so the patient may achieve change;
- systematically reviews, evaluates, and documents both processes and outcomes of
- DSMT;
- implements appropriate actions to address discrepancies between planned processes and expected outcomes and actual processes and outcomes; and
- advocates for the provision of diabetes care and education as part of public policy.

Standard 2: Professional Performance Appraisal

The pharmacist demonstrates personal and professional integrity, recognizes and practices within personal abilities, accepts responsibility for professional actions and decisions, and develops and implements a plan for personal improvement and growth.

Measurement Criteria

The pharmacist develops and implements a plan that demonstrates:²⁰

- engagement in planned, systematic self-evaluation at regular intervals to identify professional strengths and weaknesses;
- commitment to seek and use input from colleagues such as dietitians, nurses, behavioral therapists, and exercise physiologists, as well as patients in the self-evaluation process;
- description of specific needs for professional development;
- commitment to current and future professional development; and
- documentation of professional appraisal findings and monitoring for professional development needs.

Standard 3 Professional Development

The pharmacist continuously strives to gain knowledge and maintain professional competence.

The pharmacist identifies learning needs and seeks, evaluates and participates in learning opportunities to meet these needs to enhance practice through didactic education and experiential learning.

Measurement Criteria

The pharmacist:

- develops, implements, and continually evaluates a plan for professional growth based
- on findings from the performance appraisal;
- pursues professional continuing education, progressing from basic through advanced curricula;
- strives to meet academic, professional, and experiential requirements to achieve and maintain certification within the diabetes specialty; and
- documents professional development activities, to facilitate ongoing monitoring and awareness of progress to achieve personal and professional goals.

Standard 4: Collegiality

While assuming responsibility for ensuring optimal medication therapy outcomes on the patient care team, the pharmacist recognizes and respects the unique knowledge and experience of professional colleagues from a variety of disciplines.

Measurement Criteria

The pharmacist:

- shares his or her unique diabetes knowledge and skills with colleagues (health care providers in related disciplines, students, interns, or other individuals in training), lay leaders, and policy makers involved in diabetes care programs, particularly when new drug therapies, information, and technological advancements in diabetes care occur;
- acknowledges and supports aspects of DSMT provided by other team members;
- contributes to the development of students, interns, and other trainees through formal education and mentorship;²¹
- collaborates with colleagues and patients to influence public policy so that quality and availability of DSMT are improved; and
- provides constructive feedback to colleagues regarding practices to improve diabetes care.

Standard 5: Ethics

While respecting the patient's right to confidentiality, the pharmacist communicates and provides education to optimize care and promote health of patients with pre-diabetes, metabolic syndrome, and diabetes. The pharmacist demonstrates sensitivity, respect and empathy when communicating with others.

Measurement Criteria

The pharmacist:

- respects and upholds basic human rights;
- demonstrates a caring and professional attitude;
- demonstrates professional integrity;
- maintains patient confidentiality;
- discloses all potential or perceived conflicts of interest when appropriate;
- respects the uniqueness, dignity, and autonomy of each individual; and
- accepts responsibility and accountability for professional competence.

Standard 6: Collaboration

The pharmacist develops a professional relationship with the patient to determine the patient's needs, values, desired level of care and outcomes regarding education and drug therapy. The pharmacist develops and maintains appropriate inter-professional relationships to communicate patient-derived information to other members of the healthcare team. The pharmacist works in partnership with each participant to achieve mutually accepted goals.

Measurement Criteria

The pharmacist:

- establishes and maintains rapport with the patient by using effective communication skills to initiate dialogue;
- elicits the needs, values, desired level of care and desired outcomes of the patient;

- assesses the impact of factors that facilitate or impede the health of individual patients;
- participates in developing and maintaining a multidisciplinary patient-centered team that may include (but is not limited to) nurses, dietitians, pharmacists, other health professionals, referring providers, and members of the community with special interest or expertise relative to the care of persons with or at risk for diabetes;
- discusses the responsibilities of the patient, the pharmacist, and other health care providers in health care management and outcomes, outlining the benefits of acceptance of these responsibilities and the consequences of not accepting these responsibilities;²²
- promotes positive conflict resolution strategies to resolve differences;
- promotes delivery of consistent information among patients and health care providers;
- provides referrals for appropriate follow-up; and
- shares the diabetes education plan and progress with referring providers.

Standard 7: Research

The pharmacist continuously strives to enhance practice by seeking, critically evaluating, and applying current research findings. When appropriate, the pharmacist initiates research or participates with a group of investigators and reports the findings through presentations and peer reviewed publications.

Measurement Criteria

The pharmacist:

- seeks and critically evaluates research to enhance practice; and
- applies research findings to develop or revise policies, procedures, practice guidelines, protocols, education, behavior change strategies, and clinical pathways.

When appropriate, the pharmacist:

- identifies and prioritizes research problems, identifies sources and applies for funding for research;
- promotes research through alliances and collaborations with other professions and organizations;
- conducts research activities in compliance with human subject protection and HIPAA regulations; and
- reports research findings through presentations and peer reviewed publications.

Standard 8: Resource Use

The pharmacist is aware of available health care resources and agencies, and utilizes appropriate resources to promote the overall care and education of the patient. The pharmacist refers the patient to appropriate health care resources and agencies after determining with the patient that such a referral is necessary. The pharmacist is knowledgeable of necessary procedures to make referrals to health care resources and agencies.

Measurement criteria

The pharmacist:

- assesses personal limitations in knowledge and/or scope of practice and delegates care based on the need of the person with or at risk for diabetes;
- serves as an advocate for the patient in obtaining medications, supplies and DSMT;
- develops a plan with the person with diabetes and their families that takes into account the patient's resources;²³
- uses an environment that is conducive to DSMT;
- documents what resources have been used;
- incorporates emerging technologies (including new drugs, information, studies) in the care of patients and conveys these to other health care providers;
- identifies available and needed resources to support a personal plan for professional development;

The pharmacist may recommend patient referral to another health care provider or health care agency if:

- information from the patient indicates a potentially severe or worsening condition;
- the patient is uncertain about the symptoms or condition;
- there is doubt about the accuracy of the patient's self-diagnosis;
- an appropriate treatment fails to remedy a condition within a predetermined period of time;

- risk factors exist that should be addressed by another provider or agency to maintain health, avoid adverse outcomes, and/or achieve standards of care.

Summary

The Scope of Practice, Standards of Practice, and Standards of Professional Performance are intended to highlight the complementary role of pharmacists working with other diabetes educators to facilitate delivery of DSMT to persons with or at risk for diabetes and achieve optimal care. Pharmacists must be devoted to learning about new technologies, treatments, and emerging evidence-based information to deliver appropriate care and improve diabetes outcomes. This document will continue to evolve to meet the needs of patients and to promote pharmacist collaboration with other diabetes educators and health care providers. The intent of these guidelines is to provide a framework to support high quality care and education for patients with diabetes and related co-morbidities.²⁴

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