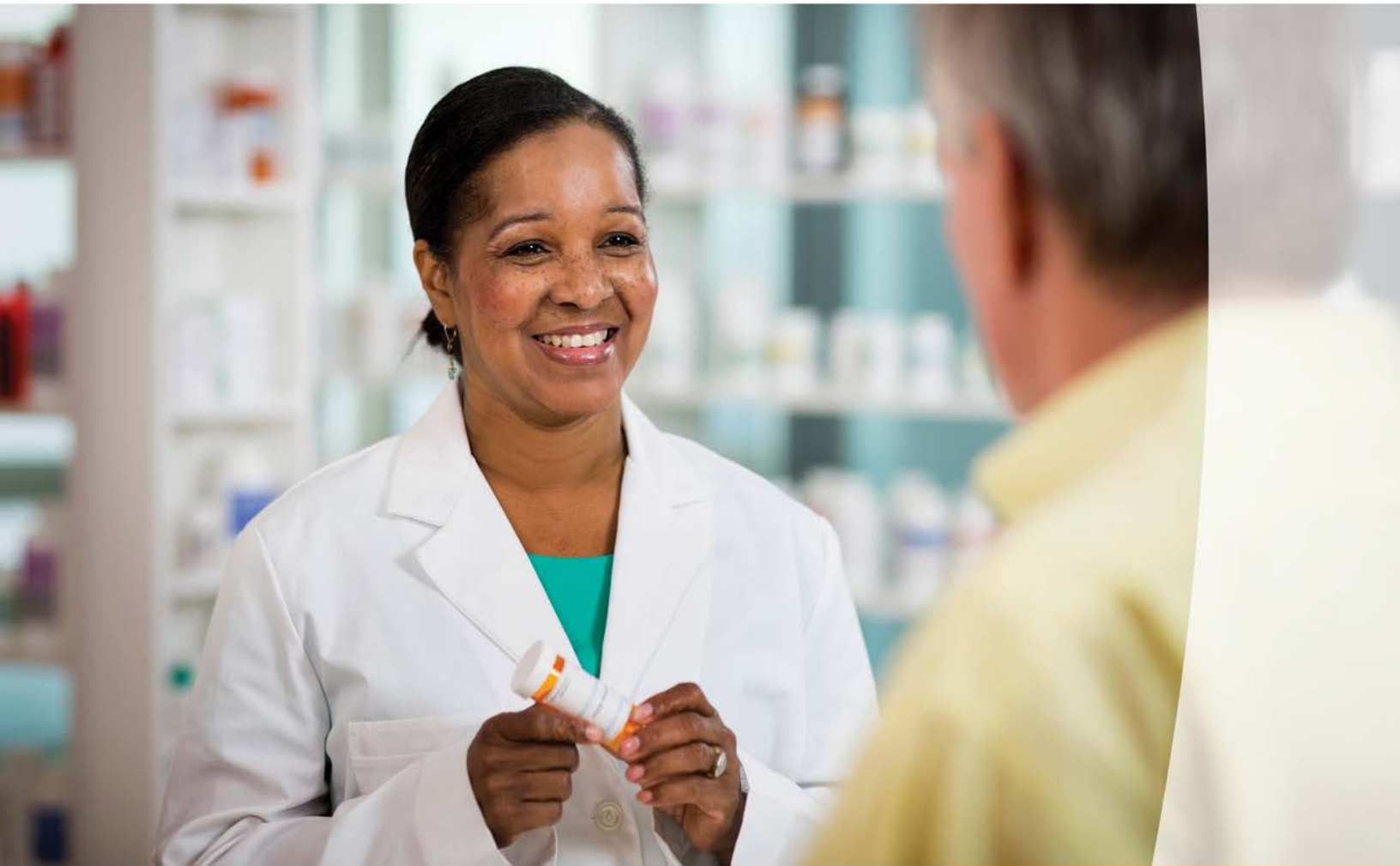


From Policy to Implementation

Collaborative Drug Therapy Management at a Federally Qualified Health Center



A CASE STUDY

National Center for Chronic Disease Prevention and Health Promotion
Division for Heart Disease and Stroke Prevention



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Background

Hypertension, which affects one in three adults in the United States, is a leading risk factor for heart disease, stroke, and diabetes—the first, fifth, and seventh leading causes of death in this country, respectively.^{1,2} High blood pressure costs an estimated \$48.6 billion each year, including \$3.6 billion in lost productivity and \$45.0 billion in direct medical expenses.³ Controlling blood pressure and other risk factors can substantially lower cardiovascular disease morbidity and mortality, but only 54% of people with high blood pressure have their condition controlled.¹

The [Community Preventive Services Task Force](#), an independent panel of public health and prevention experts, [recommends](#) team-based care to improve hypertension control. The recommendation is based on strong evidence that these approaches are effective. The Task Force found that when health care teams included pharmacists, their hypertension patients were significantly more likely to have controlled blood pressure than were hypertension patients overall. Moreover, when team members were allowed to modify antihypertensive drug therapy either independently or with the primary care provider's authorization, medication adherence was greater.⁴ Pharmacists can improve the management of chronic conditions like hypertension and diabetes by providing drug therapy management, counseling, education, and other health care services.^{5,6} In

addition, studies and systematic reviews have demonstrated reduced health care use and costs when pharmacists are included on the health care team.^{7,8}

To become pharmacists, pharmacy students must obtain a doctor of pharmacy degree (Pharm.D.) and pass a national standardized licensing exam. In addition, pharmacists can receive advanced training and certification, including clinical residencies in specialty areas, such as chronic disease management. This level of training, combined with state laws authorizing pharmacists to enter into collaborative practice agreements (CPAs) with physicians, nurses, and other prescribers, allows pharmacists to provide collaborative drug therapy management (CDTM) and other advanced coordinated patient care services.⁹ As of 2012, 46 states had authorized pharmacists to engage in CPAs or CDTM through legislation or administrative regulations, although the range of services authorized varied by state.¹⁰

This summary describes the implementation of CDTM by a federally qualified health center (FQHC), the El Rio Community Health Center in Tucson, Arizona. El Rio participated in the Collaborative Practice Agreement Case Study Project, which was launched in September 2011 to better understand how state laws authorizing CPAs were being put into action. The case study project, which included the El Rio case study, focused on community settings where pharmacists collaborated with physicians and nurse practitioners to provide services that improved chronic disease management and related health outcomes for patients. Its findings are intended to inform and guide practitioners and others who are considering adopting CPA policies or implementing CDTM. The methods and results of the full study are described in an article by Snyder and colleagues that was published in 2015.¹²

Collaborative drug therapy management

is a collaborative practice agreement between one or more health professionals and pharmacists in which qualified pharmacists working within the context of a defined protocol are permitted to assume professional responsibility for performing patient assessments; ordering drug therapy–related laboratory tests; administering drugs; and selecting, initiating, monitoring, continuing, and adjusting drug regimens.¹¹

Setting

Overview of Arizona CPA legislation

In August 2000, Arizona enacted Arizona House Bill (H.B.) 2415 (2000 Ariz. Sess. Laws Chapter 156, codified at ARIZ. REV. STAT. §32-1970), which authorized pharmacists to perform CDTM pursuant to a CPA with a physician in specified health facilities. In 2011, ARIZ. REV. STAT. §32-1970 was amended with the enactment of Senate Bill (S.B.) 1298 (2011 Ariz. Sess. Laws. Ch. 103).¹³ As amended, ARIZ. REV. STAT. §32-1970 enables pharmacists to perform CDTM in more

settings and allows nurse practitioners to enter into CPAs with pharmacists.¹³

El Rio Community Health Center

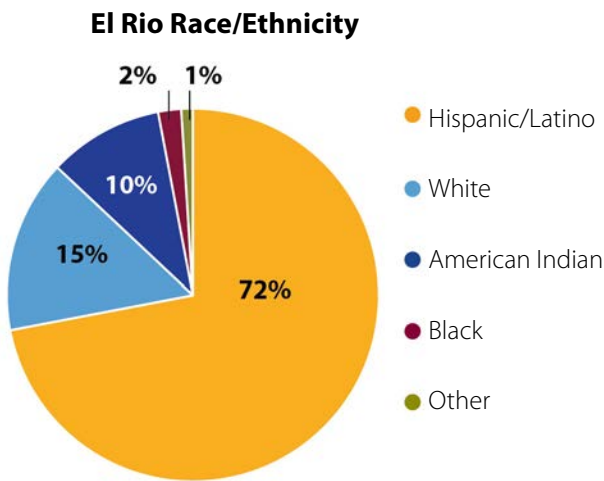
Established in 1970, El Rio is the largest provider of medical and dental services to the uninsured and Medicaid populations of Pima County, Arizona. El Rio aims to reach the underserved population of Arizona by “improving the health of [their] community through comprehensive, accessible, affordable, quality, and compassionate care.”¹⁴

The health center offers medical, dental, pharmacy, radiology, and laboratory services. Additionally, patients have access to eligibility outreach workers and transportation for medical appointments and various health education programs.¹⁴ In 2011, 20% of El Rio’s adult patients (8,954 of 44,952) had diagnosed hypertension, 67% (5,979) of whom had the condition under control.¹⁵ Of adult patients overall, 12% (5,542) had diabetes and 11% (4,853) had both diabetes and hypertension.^{15,16}

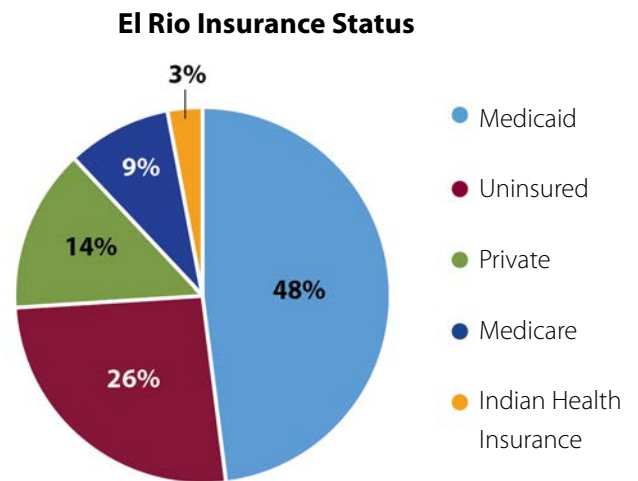
Table 1. Features of Arizona Legislation Enabling Collaborative Drug Therapy Management, 2000 and 2011

Feature	H.B. 2415 (2000)	S.B. 1298 (2011)
Authorizes a licensed pharmacist to implement, monitor, and modify drug therapy pursuant to a written agreement with a physician.	X	X
Enables nurse practitioners to enter into CPAs with licensed pharmacists.		X
Requires the Arizona State Board of Pharmacy to adopt rules approved by the Arizona Medical Board and the Board of Osteopathic Examiners in medicine and surgery.	X	
Authorizes pharmacists to implement, monitor, or modify a person’s drug therapy in any pharmacy setting.		X
Rescinds Arizona State Board of Pharmacy rules governing CPAs.		X
Permits licensed, immunization-trained pharmacists to administer vaccines for influenza to people 6 to 17 years old without a prescription and with a prescription for all other vaccines for children.		X
Authorizes immunization-trained pharmacy students to administer vaccines under the direct supervision of a licensed immunization-trained pharmacist.		X

Figure 1. Patient Demographics and Insurance Status, El Rio Community Health Center, 2011



Source: El Rio Community Health Center, 2012¹⁵



Source: Warholak et al., 2011¹⁶

El Rio: By the Numbers (2011)

- \$78 million annual budget
- 800 staff
- 85 medical or dental providers
- 17 sites across Tucson
- 900 patients seen daily
- 76,190 patients seen annually
- 311,000+ medical or dental visits annually
- 76% of patients at or below the federal poverty level

Implementation

At El Rio, pharmacists work with physicians, nurses, and other health care professionals to provide team-based care. In fact, pharmacists and physicians at the facility have a long history of collaborating: The process of developing CPA protocols for physicians to refer medically complicated patients to the care of a pharmacist began in 2000. Until ARIZ. REV. STAT. §32-1970 was amended with the passage of Arizona S.B. 1298 in 2011, participants in a CPA took the following steps:

- The patient consented to participate in CDTM under a written CPA protocol.
- Both the patient and provider signed off on the CPA.
- The patient was sent to the clinical pharmacist, who signed off on the CPA.
- The CPA protocol was sent to the Arizona State Board of Pharmacy for an annual review and approval process.
- The clinical pharmacist cared for the patient according to written, broadly outlined protocols.
- All consent documents were kept in the patient's health record.
- All consent documents had to be signed annually by the physician, pharmacist, and patient.

Following the passage of the amended law in 2011, the process of engaging in CPAs that authorize CDTM became less restrictive and more efficient. The new process:

- Allows nurse practitioners, in addition to physicians, to establish CPAs with pharmacists.
- No longer requires annual renewal of physician signatures and Arizona State Board of Pharmacy approval for CPA protocols.
- Allows one CPA to cover multiple disease states for patients with diabetes by including protocols for care of associated conditions (e.g., hypertension, hyperlipidemia).
- Allows patients with a diabetes CPA to opt out of the diabetes management program but still receive collaborative care for associated conditions without their written consent.
- Allows pharmacists to treat CDTM patients based on their immediate needs without a new physician prescription.
- Enables pharmacists to perform CDTM in more settings and allows nurse practitioners to enter into CPAs with pharmacists.

CPA Protocols Implemented at El Rio

El Rio allows clinical pharmacists to establish CPAs with its medical providers. All CPAs must adhere to five protocols, which cover the care that El Rio's clinical pharmacists deliver to approximately 800 clinic patients annually. Each protocol is crafted broadly and enables the pharmacists to work with patients to manage diabetes, hypertension, and hyperlipidemia. However, most of the CPAs at El Rio focus on a diabetes management protocol and program. Patients are enrolled in the pharmacist-led diabetes management program through the following steps:

- A physician or nurse practitioner refers a patient to El Rio's clinical pharmacists via the patient's electronic health record (EHR).
- A medical assistant at El Rio sees the referral, schedules the patient's appointment, and documents the care plan in the EHR.
- The pharmacist may prescribe medications without a sign-off by the provider, although the provider will still appear in the EHR as a cosigner for the prescription. Any changes the pharmacist makes to the medication regimen are tracked in the EHR.

Pharmacists at El Rio may also make referrals for depression screenings and other behavioral health assessments. Additionally, the chief clinical pharmacist at El Rio developed care protocols for asthma and pain management. Since 2000, the diabetes protocol is the most frequently used, because funding is available through a Health Resources and Services Administration (HRSA) grant to compensate pharmacists for their services and because of the high prevalence of diabetes in the patient population. El Rio worked to expand CDTM to include other disease states

after receiving accreditation as a patient-centered medical home (PCMH).¹⁷

CDTM Evaluation

El Rio and others that engage in CPAs in Arizona are under no legal or formal obligation to collect outcome data or demonstrate cost savings. However, collecting and sharing these data with providers has become standard practice at El Rio, and it increases accountability for providing quality patient care. A brief evaluation of CDTM at El Rio

demonstrated lower costs, more screenings, and fewer emergency room visits than were found at two matched comparison sites.^{18,19} In addition, internal evaluation showed that patients who participated in CDTM had significantly greater reductions in A1C (glycosylated hemoglobin) levels (a relative decrease of two percentage points in the mean A1C), cholesterol, and systolic and diastolic blood pressure compared with those receiving usual care.^{20,21,22} Moreover, CDTM patients expressed satisfaction with the collaborative care they received.¹⁶

Barriers to the Implementation of CDTM

Until ARIZ. REV. STAT. §32-1970 was amended in 2011, the requirements for approvals by the Arizona State Board of Pharmacy, annual renewals, and individual patient signatures for all CPAs hindered the expansion of CPAs and CDTM. Although S.B. 1298 streamlined the administrative requirements for CPAs and eliminated many of these barriers, several key barriers continue to hinder the broader use of CDTM at El Rio.

Lack of reimbursement. Because pharmacists are not recognized as providers of care and cannot bill for their services, no business model (aside from grant funding) guarantees sufficient compensation for CDTM. Pharmacists are not eligible for FQHC reimbursement

from HRSA, and Medicare Part D and Medicaid reimbursements are too low to serve as a reliable revenue stream. El Rio can bill the American Association of Diabetes Educators for diabetes services provided through CPAs, but this reimbursement does not always cover the full cost of services.

Lack of provider trust in pharmacists' care. Many physicians and nurse practitioners were reluctant to cede responsibility for their patients and expand the pharmacist's role in patient care. Because of supportive outcome data showing cost savings and improved patient health resulting from collaborative practice, however, providers have grown more comfortable

with pharmacists providing expanded care services. Even so, concerns remain about accountability for the potentially negligent clinical acts of pharmacists. The Arizona legislation attempts to protect physicians by holding pharmacists accountable for their own negligent acts and for complications arising from immunizations or emergency medicines provided by the pharmacist without a prescription from another provider.

Limited physical space to provide care. Because of limited physical space, the clinical pharmacists face challenges in conducting patient assessments and in providing care.

Facilitators of CDTM Implementation

The primary facilitators for the expanding role of pharmacists through CPAs were the passage of S.B. 1298 in 2011 and the effort to build relationships between providers and administrators to show that CPAs could be effective.

Fewer regulatory restrictions. As amended, ARIZ. REV. STAT. §32-1970 expanded the capacity of pharmacists to engage in CPAs by including nurse practitioners in the definition of providers and broadening the types of health care settings where CPAs might exist.

Broad protocols for patient care. The creation and use of broad protocols for care gave pharmacists more control over

patient care. CPAs allow pharmacists to change a patient's medication for conditions within the scope of the CPA without having to repeatedly request the physician's permission. Including multiple disease states in the CPA also increases efficiency, which is important in light of many patients' transportation and scheduling challenges. Making the protocols readily available to physicians and pharmacists reduced the burden of creating CPAs from scratch.

Administrator and provider buy-in. Increased buy-in by administrators and providers over time was a key facilitator in enabling the expansion of pharmacists' roles under CDTM. Collecting and disseminating

strong patient outcome data—and building relationships with the chief operating officer, facilities director, information technology department, and other stakeholders—helped to sell the program.

Patient satisfaction. Patients enjoyed the health education they received and the opportunity to interact with clinical pharmacists, factors that helped the program to expand. Patients often refer their families and friends to the clinic, and many patients with positions of power within the local Pascua Yaqui Tribe publicly promote El Rio in their community.

Table 2. Expanding Collaborative Drug Therapy Management at El Rio Community Health Center: Major Barriers and Key Facilitators

Key Barriers Before S.B. 1298*	Key Barriers After S.B. 1298	Key Facilitators After S.B. 1298
<ul style="list-style-type: none"> • Annual CPA renewal required • Paperwork that included a CPA required in every participating patient’s chart • Patient signature required to approve CPAs • Arizona State Board of Pharmacy approval required on all CPAs 	<ul style="list-style-type: none"> • Lack of viable compensation mechanism for clinical pharmacists’ patient care • Limited trust among providers in how clinical pharmacists provide patient care • Limited physical space to conduct patient assessments and provide patient care 	<ul style="list-style-type: none"> • Nurse practitioners allowed to provide CDTM • CPAs allowed in more health care settings • Increased buy-in over time by administrators and providers • Patient satisfaction with care received from clinical pharmacists • Broadly written CPA protocols that give pharmacists more control over patients’ care

* Senate Bill 1298, a 2011 amendment to a 2000 Arizona law authorizing pharmacists to perform collaborative drug therapy management (CDTM) pursuant to a collaborative practice agreement (CPA) with a physician in specified health facilities

Lessons Learned

Considerations for CDTM Implementation

El Rio's chief clinical pharmacist and administrators highlighted the following considerations for implementing and expanding CDTM via CPAs at El Rio:

- **Instilling mission-driven values** through training and orientation for new staff accelerates buy-in to the collaborative care model.
- **Accepting pharmacy student interns** and sponsoring a pharmacy residency program enables El Rio to see more patients and receive more accreditations.
- **Using broad strategies and networking widely** improve patient care and increase potential partnerships (both within and outside the clinic) that may expand the use of CPAs using CDTM.

Unintended Consequences of CDTM

The amendment to ARIZ. REV. STAT. §32-1970 also led to some unanticipated consequences:

- Tracking the existence of CPAs across the state became harder because the Arizona State Board of Pharmacy is no longer required to review and approve all CPAs.
- More pharmacists expressed interest in training programs for certification in diabetes and in anticoagulation treatment. This certification is no longer required for CDTM, but the pharmacists believe it increases buy-in from potential collaborating providers.

Summary and Conclusions

Since the adoption of ARIZ. REV. STAT. §32-1970 in 2000, El Rio has used clinical pharmacists to deliver CDTM pursuant to CPAs, most commonly for patients with diabetes. The passage of S.B. 1298 in 2011 amended the Pharmacy Practice Act, which made it easier for other pharmacists and providers in Arizona to engage in CPAs.

El Rio's clinical pharmacists built relationships with providers, administrators, and other stakeholders to show them the value of incorporating clinical pharmacists into a collaborative model of patient care. In addition to receiving strong administrative support, clinical pharmacists at El Rio have collected and disseminated a great deal of data that demonstrate positive patient outcomes and cost savings. These data helped El Rio receive more grant funding and convince providers who did not participate in CPAs of the value of the CPA diabetes management model.

The findings in the case study on which this summary is based are limited to pharmacists in clinical settings and are not generalizable to community or retail pharmacists. Additionally, the setting studied is not representative of all community-based CDTM practices. El Rio stands apart as both an FQHC and PCMH where clinicians, pharmacists, and other health care providers practice in close proximity. This summary is also limited because it discusses only CPAs between pharmacists and physicians and does not account for CPAs between pharmacists and other providers, such as nurse practitioners.

El Rio's status as an FQHC and now as a PCMH makes its pharmacists eligible for more forms of compensation than pharmacists at traditional retail pharmacies who want to engage in CPAs. However, because of the lack of a viable reimbursement model to compensate pharmacists, the

potential for expansion of CPAs has yet to be realized. Compensation mechanisms may follow as more stakeholders recognize pharmacists' value as providers.

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