

AN EVALUATION OF THE EFFECTS OF POLICY CHANGES ON PHARMACY
PARTICIPATION IN THE WISCONSIN MEDICAID PHARMACEUTICAL CARE
PROJECT

by
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To my parents

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ABSTRACT

The Wisconsin Medicaid Pharmaceutical Care Project (WMPCP) began July 1st, 1996, providing pharmacists financial incentives for pharmaceutical care services given to Wisconsin Medicaid fee-for-service recipients. There have been two major changes in the WMPCP. A point-of-sale (POS) system was adopted in September, 1999, allowing pharmacists to submit pharmaceutical care claims electronically rather than submitting paper claims; in February 2001, Wisconsin Medicaid began using prospective drug utilization review (PDUR) designed to identify Medicaid patients' drug therapies problems for pharmacists. Theoretically, POS can potentially reduce barriers to submitting pharmaceutical care claims for pharmacists; PDUR increases pharmacists' awareness of drug therapy problems increasing awareness of opportunities for pharmaceutical care services.

The primary objective was to evaluate the effects of POS and PDUR on: (1) pharmacy participation in the WMPCP; (2) the intensity of participation among participating pharmacies; and (3) the composition of the reason and level codes for paid pharmaceutical care claims. The secondary objective was to examine whether pharmacy type, location, and the volume of Medicaid prescription drug claims were associated with outcome measures.

The study was conducted in a retrospective, interrupted time series design and used administrative datasets for evaluation. A total of 1,848 Wisconsin Medicaid pharmacy providers during state fiscal years 1997 and 2003 were the study population.

The study found that rates of pharmacy participation in pharmaceutical care services remained low. Approximately one-fifth of Medicaid pharmacy providers participated in the WMPCP. Neither POS nor PDUR had immediate effects on the number of participating pharmacies per month and the number of PC claims per month. However, POS showed sustained, positive effects on these two outcome measures, and PDUR showed a sustained, negative effect on the number of participating pharmacies. After implementation of POS and PDUR, more claims were submitted by pharmacists for the reason Drug Use: Patient Behaviors, and more claims were associated with shorter service time (6-15 minutes). Pharmacy type, geographic location, and the volume of Medicaid prescription drug claims were pharmacy characteristics significantly associated with the number of participating pharmacies and the number of pharmaceutical care claims.

The results suggest that POS and PDUR had significant effects on pharmacy participation in the WMPCP. More research can help understand whether and how pharmacy participation in pharmaceutical care services can be promoted to a higher level.

CHAPTER 1

INTRODUCTION

In traditional pharmacy practice, a pharmacist dispenses medications. Unsatisfied with these limited responsibilities, however, pharmacy advocates sought to expand possibilities for the pharmacist and to define better the pharmacy profession.¹ These people argued that the pharmacist's role within the health care team should be repositioned so that pharmacists become more involved with a patient's drug therapy management. For the profession to survive, pharmacists could not afford to be viewed by the public as mere dispensing machines.¹ To combat this misconception, advocates introduced pharmaceutical care. Pharmaceutical care, an outcome-oriented, cooperative, and systematic concept, offers a philosophy of pharmacy practice through which pharmacists would work to address drug-therapy problems through patient-centered interventions.²

In 1975, Mikeal et al. first defined pharmaceutical care as "the care that a given patient requires and receives which assures safe and rational drug usage."³ Brodie, Parish, and Poston elaborated this new concept of patient-focused care in 1980 when they suggested that "pharmaceutical care includes the determination of the drug needs for a given individual and the provision not only of the drug required but also of the necessary services (before, during, or after treatment) to assure optimally safe and effective therapy."⁴ Brodie's definition includes a feedback mechanism that facilitates the continuity of care by providers. Hepler gave another definition of pharmaceutical care

when describing pharmaceutical care as a “covenantal relationship between a patient and a pharmacist in which the pharmacist performs drug-use-control functions (with appropriate knowledge and skill) governed by awareness of and commitment to the patient’s interest.”⁵

In 1990, an influential article by Hepler and Strand emphasized the importance of pharmaceutical care: “The mission of pharmacy practice is not only what we have come to call clinical pharmacy...The mission of pharmacy practice, which is consistent with its mandate, is to provide pharmaceutical care.” They also provided the most widely accepted definition of pharmaceutical care, as care that “is the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life.” According to them, pharmaceutical care “involves the process through which a pharmacist cooperates with a patient and other professionals in designing, implementing, and monitoring a therapeutic plan that will produce specific therapeutic outcomes for the patient. This in turn involves three major functions: (1) identifying potential and actual drug-related problems, (2) resolving actual drug-related problems, and (3) preventing potential drug-related problems.”⁶

Hepler and Strand’s definition of pharmaceutical care implies that pharmaceutical care is care provided by a pharmacist and drug therapy is the center of care.⁷ The American Pharmacists Association expanded this rather narrow definition of pharmaceutical care to include non-drug services. “The mission of pharmacy is to serve society as the profession responsible for the appropriate use of medications, devices, and services to achieve optimal therapeutic outcomes.”⁸ In short, these definitions lay the

foundation of pharmaceutical care and have become the cornerstone of contemporary pharmacy practice. If traditional pharmacy practice centers on dispensing medications, then contemporary practice based on the pharmaceutical care model focuses on the patient.

Pharmaceutical care requires the pharmacist to work in concert with the patient and with the patient's healthcare providers in order to promote health, to prevent disease, and to assess, monitor, initiate, and modify medication use so that drug therapy regimens are safe and effective. Thus, pharmaceutical care is a process of drug therapy management that requires both a change in the orientation of traditional professional attitudes and activities, and a re-engineering of the traditional pharmacy environment.

To provide good pharmaceutical care, pharmacists must engage in several activities.⁹ Once the pharmacist receives prescriptions from the patient, s/he dispenses the exact medications prescribed by physicians to the patient. These dispensing activities, however, are just one of the essential components of pharmaceutical care. When dispensing a new prescription, the pharmacist now needs to evaluate whether it is the drug of choice for the patient based on the patient's medical records and medication history. The pharmacist also assesses potential drug interactions, physician prescriptions, dosage, and the patient's understanding as to when and how the medication should be taken and what effects to expect.

When refilling a prescription, the pharmacist monitors the patient's medical outcomes and assesses whether the patient has achieved his or her treatment goal. Before processing that prescription, the pharmacist evaluates patient adherence to the treatment

plan, uncovers any adverse drug reactions, and determines if the medication and its dosage are still the right choice for the patient whose health condition may have changed. The pharmacist then designs or modifies a patient-specific drug therapy plan along with strategies to help the patient cope with his/her disease. For example, the pharmacist might explain the importance of diet and exercise to patients with diabetes. This is the concept of disease management by the pharmacist. The pharmacist also continues to monitor and to document the patient's outcomes for future evaluation.

By providing pharmaceutical care, the pharmacist treats a patient's disease and can help prevent future health problems. Through patient education programs, the pharmacist promotes safe medication use and provides preventive services, such as blood pressure checks and immunizations.

Indisputably, these activities differ dramatically from the traditional dispensing services provided by the pharmacist. In order to accomplish these activities, both pharmacists and pharmacies have to make many changes. For example, the pharmacist has to have broader knowledge and more time to provide services, and the pharmacy has to have appropriate layout of space for different activities. All of these present new challenges for the pharmacy profession in the health care system.

The value of pharmaceutical care in the health care system has been well documented. Scientific and clinical literature has shown the human and financial cost of drug therapy misadventures, the need for improved pharmaceutical care services, and the clinical and economic impact of pharmacists who have taken on the job of providing pharmaceutical care.¹⁰ Specifically, pharmaceutical care has had positive effects on

disease states such as asthma,¹¹⁻¹³ diabetes,^{14,15} and hyperlipidemia.¹⁶ Evidence has been found in preventive care such as immunizations as well.¹⁷ To detail some studies, Leape *et al.* found that the rate of preventable adverse drug events decreased by 66 percent when physicians accepted 99 percent of pharmacist recommendations at the time of drug prescribing.¹⁰ In that study, the pharmacist completed a report form for each intervention that could potentially lead to a change in prescribing orders, by noting the date, drug, nature of the order, and offering a specific recommendation. In an asthma management program coordinated by pharmacists, all patients participating in the program had access to pharmacists 24 hours each day at the earliest signs of symptoms. After following the pharmacist's instructions, patients had a significant reduction in their emergency room visits.¹¹

Although the value of pharmaceutical care services has been widely identified, and pharmacists generally recognize their positive benefits, the rates of implementation of pharmaceutical care services remain low. For example, patient counseling is a key component of pharmaceutical care, and no optimal pharmaceutical care can be provided without communication between patients and pharmacists. However, pharmacists have reported that they counseled only 33 percent to 74 percent of the patients with new prescriptions and 54 percent to 72 percent of patients have reported that they have received no counseling or other services when presenting new prescriptions.¹⁸⁻²⁶ A national survey also showed that, as of 2000, pharmacists were still devoting the majority of their time to medication dispensing activities although they would rather take on more professional responsibilities such as consultation and drug use management.²⁷ If

pharmaceutical care is valued among pharmacists and other health care professionals, then why has its implementation been so slow?

Various barriers, real or perceived, continue to prevent pharmacists from implementing pharmaceutical care. According to the classification system created by McDonough et al., the barriers derive from the following categories – pharmacists' attitudes, lack of advanced practice skills, resource-related constraints, system-related constraints, intraprofessional obstacles, and academic/educational obstacles.²⁸ In the next chapter, I discuss these barriers in greater length. Among the barriers, lack of financial incentives is frequently identified as the most important one impeding the implementation of pharmaceutical care.²⁹⁻³⁸

To address the issue regarding financial incentives, in 1996, Wisconsin Medicaid developed an incentive-based pharmacy payment system for pharmaceutical care services provided by the pharmacist. The Wisconsin Medicaid Pharmaceutical Care Project (WMPCP) began on July 1 of that year, providing pharmacies with an enhanced dispensing fee for pharmaceutical care services provided for Wisconsin Medicaid fee-for-service recipients. The enhanced fee reimbursed pharmacies for additional actions to identify and solve drug therapy problems that went beyond simply dispensing prescription drugs.

There have been two major changes in the WMPCP. In September 1999, a Point-of-Sale system was adopted, allowing pharmacists to submit pharmaceutical care claims electronically rather than submitting paper claims; and in February 2001, Wisconsin Medicaid began using prospective drug utilization review, a system designed to identify

Medicaid patients' drug therapy problems for the pharmacist. Theoretically, both changes could be considered mechanisms that potentially reduce pharmacist participation barriers. Electronic claims submission using the point-of-sale system reduces the burden of completing paper claims, saving time for pharmacists, while prospective drug utilization review reduces the burden of having to identify a certain class of drug-related problems.

An important question is the effect that the policy changes have had on pharmacy participation. Preliminary findings show that the number of pharmacies paid for a pharmaceutical care claim and the number of pharmaceutical care claims submitted changed after point-of-sale and prospective drug utilization review were implemented.³⁹ This study, therefore, aims to examine the impact of the two policy changes on pharmacy participation in the WMPCP and intensity of participation among participating pharmacies. Not only can the findings inform policy makers of the effect of point-of-sale and prospective drug utilization review, but they can be potentially informative about any similar incentive-based payment system for pharmaceutical care services, such as the Medicare prescription drug coverage that took effect January 1, 2006.

CHAPTER 2

LITERATURE REVIEW

This chapter proceeds in the following manner. First, the barriers for pharmacists to integrate pharmaceutical care services into their daily practice are discussed. Specifically, it reviews the barriers (or obstacles) to the implementation of pharmaceutical care using a classification system from McDonough *et al.*²⁸ to organize the discussion. Second, it provides a brief description of a demonstration project in the state of Washington as well as other publicly funded pharmaceutical care reimbursement programs that offer financial incentives from several state Medicaid programs to encourage pharmacists to provide pharmaceutical care. Third, it provides a detailed description of the Wisconsin Medicaid Pharmaceutical Care Project and the two policy changes, point of sale and prospective drug utilization review, in the project. Fourth, a review of existing evaluation studies of public pharmaceutical care reimbursement programs reveals what and how the assessments have been done. Fifth, it reviews how previous studies examined the impact of a policy change, followed by a general introduction of interrupted time series analysis, a specific statistical technique used in evaluating the effect of a policy change. Due to the panel nature of the data available for this study, another longitudinal data analysis method, the generalized estimating equations approach, is introduced. Finally, the chapter concludes with a brief summary of the literature review.

2.1 Barriers/Obstacles to Implementing Pharmaceutical Care

Despite evidence of the value of pharmaceutical care and that pharmaceutical care has become a goal of the pharmacy profession, pharmacists whose practices are undergoing a transition to pharmaceutical care experience difficulty. In order to better understand problems associated with this translation, many researchers have attempted to identify factors that prevent pharmacists from providing optimal patient-centered care.

An early attempt to categorize barriers involved collecting data from 73 pharmacists in community pharmacies. Raisch identified four types of barriers to performing pharmaceutical care: (1) situational barriers, including working conditions and economic factors; (2) cognitive barriers, which include lack of knowledge or the ability to perform the service; (3) legal barriers, including regulations for the practice of pharmacy; and (4) attitudinal barriers such as pharmacists' beliefs about themselves, other health professionals, and patients.⁴⁰ Later, Odedina *et al.* studied factors that influenced the implementation of pharmaceutical care and identified a number of barriers that pharmacists experienced.⁴¹ These researchers identified the physical layout of the pharmacy, qualifications of personnel, practice orientation, patient expectation, physician cooperation, computer support and competency as important barriers. More efforts that are recent have involved classifying barriers systematically. In 1998, McDonough and colleagues provided another classification system that has since been adopted by the American Pharmacists Association.^{28,42} They grouped the barriers to the implementation of pharmaceutical care in the community setting into six categories: pharmacists' attitudes, lack of advanced practice skills, resource-related constraints, system-related

constraints, intraprofessional obstacles, and academic/educational obstacles. Table 2.1 is a summary of key factors within each category. This classification system serves as the skeleton of the review in this section, and the descriptions of each category are consistent with the publications of McDonough *et al.*^{28,42}

McDonough and colleagues preferred the term *obstacles* instead of *barriers* because in their opinion the latter term implies immovability and impenetrability. In contrast, the term *obstacles* reflects the temporary nature of those impediments as well as pharmacists' ability to overcome them through proper planning, training, and education.^{28,}

⁴² While differentiation between these two terms, if any, is not the main point in this study, henceforth I use them interchangeably, in a manner consistent with each article reviewed.

2.1.1 Pharmacists' Attitudes

Pharmacist attitude is a key to the successful implementation of pharmaceutical care. Either not having a clear understanding of pharmaceutical care or lacking confidence in one's personal ability to implement a pharmaceutical care practice makes some pharmacists reluctant to accept the new model and to view it with pessimism.⁴²

In a study using a sample of twenty community pharmacists and semi-structured, in-depth interviews, Bell *et al.* showed that pharmacists' depth of understanding of the concept of pharmaceutical care was variable and in most cases limited.⁴³ The degree of implementation of pharmaceutical care into pharmacists' routine practice was therefore restricted.⁴³ Moreover, Venkataraman, Madhavan, and Bone suggested that pharmacists'

Table 2.1. Obstacles to implementing pharmaceutical care^{28, 42}

Pharmacists' attitudes

- Limited comprehension of pharmaceutical care
- Misconceptions about pharmaceutical care
- Fear of change
- Lack of motivation

Lack of advanced practice skills

- Therapeutics knowledge
- Clinical problem-solving skills and experience
- Communication skills
- Documentation skills
- Drug information resources and knowledge

Resource-related constraints

- Lack of time
- Financial concerns
- No space for providing patient care
- Limited personnel
- Weak or nonexistent support from management

System-related constraints

- Lack of reimbursement
- Lack of patient demand for services
- Physician/nurse resistance
- Lack of data on value

Intraprofessional obstacles

- Lack of cooperation among professional disciplines
- Limitations imposed by boards of pharmacy
- Inconsistent support from colleges of pharmacy

Academic/educational obstacles

- Lack of mentors and role models
 - Curricular limitations of schools and colleges of pharmacy
-

positive attitudes toward patient care significantly influence the provision of pharmaceutical care services.⁴⁴

2.1.2 Lack of Advanced Practice Skills

Advanced practice skills include skills in therapeutics, clinical problem solving, communication, documentation, and drug information. Theoretically, pharmacists already possess these skills. Lack of skill and education among pharmacy staff, however, are still reported as barriers to implementing pharmaceutical care.^{45,46} Rossing, Hansen, and Krass found that one of the most important initiatives taken to implement pharmaceutical care was the post-graduate training of pharmacists and technicians.⁴⁷ If pharmacists do not recognize or feel confident about their skills, then they remain unmotivated to implement pharmaceutical care.⁴⁴

Additionally, Martin reported that lack of documentation skill among pharmacy staff is another potential obstacle.³² Studies also have suggested that pharmacists do not know how to provide pharmaceutical care services with limited access to patient medical information.²⁹

2.1.3 Resource-Related Constraints

Reasonable workload, adequate staffing, management support, availability of a counseling area within a pharmacy, and time are often perceived as factors impeding the implementation of pharmaceutical care services. A survey of 400 community pharmacies in Massachusetts found that the barrier considered most significant to pharmacists in their

ability to implement OBRA '90 regulations (that is, patient counseling) was excessive workload.⁴⁸ Other studies also cited excessive workload or lack of time as key barriers.^{29, 40, 44, 45, 47, 49} For example, Raisch found that excessive workload limits the pharmacist's ability to provide patient counseling and to interact with the prescriber.⁴⁰ The respondents reported that, under their current working conditions, they simply did not have time to perform more pharmaceutical care services.

A survey conducted in Danish community pharmacies (n=288) identified several barriers to implementing pharmaceutical care in that country.⁴⁷ The most significant barrier to the implementation of pharmaceutical care concerned lack of resources in the pharmacy. The pharmacist also pointed to a lack of time as a major obstacle.

To provide pharmaceutical care to patients, pharmacists have to devote less time to dispensing activities. Pharmacies cannot provide optimal pharmaceutical care without adequate staffing, delegation of dispensing activities, rearrangement of workflow, and support from managers in pharmacies.^{42, 44}

2.1.4 System-Related Constraints

Another possible group of constraints comes from patients and other health care providers. Some patients may be reluctant to spend additional time with the pharmacist because they are unfamiliar with the pharmacist's expertise or they believe the pharmacist is encroaching on their physicians' decisions. Others may be concerned about possible costs and values resulting from receiving pharmaceutical care services. And some do not regard the pharmacist as an expert and they do not expect any services.^{43, 46}

Pharmacists in community pharmacies reported that patients' attitudes, such as being uninterested in counseling, was an important factor in their ability to implement or to comply with OBRA '90 regulations.⁴⁸ This specific finding is similar to what Schommer and Wiederholt found in a survey of 697 Wisconsin pharmacists.⁵⁰ They examined pharmacists' perceptions of patients' needs for counseling and found that patient motivation was the most frequently cited determinant of the amount and type of counseling given.

In addition to patients, other health care professionals may not see the value in pharmaceutical care. Physicians, for example, may view drug therapy outcomes as their domain and show no willingness to accept pharmacy's advances in pharmaceutical care.⁴² Lack of data showing the value of pharmaceutical care to society and to the health care system may partially explain why low awareness and acceptance of pharmaceutical care services from patients and health care providers occur. Smith found that physicians do not know what to expect from pharmacists because they do not fully understand the range of services that pharmacists can provide.⁵¹

The most significant barrier in this category, however, is lack of reimbursement.²⁹⁻³⁸ Many pharmacists have expressed the desire to be compensated for their pharmaceutical care.⁴⁸

2.1.5 Intraprofessional Obstacles

McDonough suggested that organizations representing pharmacists have not worked together efficiently for the common good of the pharmacy profession.⁴² This has

fragmented the profession and made it a less unified force in the political arena. In addition, some outdated regulations and rules from boards of pharmacy do not support pharmaceutical care while others fail to provide desired practicing environments, such as limits on technician activities and pharmacist-technician ratios. Lastly, while their support is essential, colleges of pharmacy also do not provide consistent support in creating the capacity of pharmacy for pharmaceutical care. Many things can be done to address this concern. Pharmacy colleges, for example, can give practitioners access to important resources, including educational programs and faculty expertise.²⁸

2.1.6 Academic and Educational Obstacles

Lack of mentors and role models and the need for curriculum changes are the top obstacles in this category.²⁸ Many pharmacy students express disappointment about the lack of mentors who provide pharmaceutical care to patients. In addition to providing training about pharmaceutical care to pharmacy students, colleges of pharmacy can help them develop mentoring relationships with innovative practitioners.

2.1.7 Summary of Barriers/Obstacles to Implementing Pharmaceutical Care

In daily community pharmacy practice, optimal pharmaceutical care has not been implemented very well. The literature demonstrates that pharmacists perceive a number of barriers to implementing pharmaceutical care services.²⁸ Different barriers might exist in different practice settings; different settings may, however, still identify with similar barrier patterns. Among those potential barriers, lack of financial reimbursement and

lack of time were often cited by pharmacists as the most significant factors that influence the implementation of pharmaceutical care. As one of the key steps in providing pharmaceutical care is identifying actual or potential drug therapy problems, the importance of other significant barriers such as lack of therapeutics knowledge and clinical problem-solving skills were emphasized as well. Moreover, even where the same perceived barriers exist, pharmacists behave differently.^{28, 46} Thus, in a dynamic pharmacy environment, overcoming barriers to providing pharmaceutical care is a complex challenge.

2.2 Public Pharmaceutical Care Reimbursement Programs

In recognition of the value of pharmaceutical care services, both the public and private sectors have recently developed payment systems that reimburse pharmacists for their service activities that go beyond dispensing prescription drugs. The public compensation models are mainly funded by state governments through the Medicaid program, and currently seven states (Wisconsin, Florida, Iowa, Missouri, Mississippi, Ohio, and Wyoming) have initiated their own reimbursement systems for pharmaceutical care.⁵² This section briefly introduces Washington's demonstration project and describes the other public pharmaceutical care reimbursement programs (except Wisconsin, which will be discussed in a later section) chronologically.

2.2.1 Washington State CARE Project

The Washington State Cognitive Activities and Reimbursement Effectiveness (CARE) Project was a demonstration project in which the government paid community pharmacies for pharmaceutical care provided to Medicaid patients.³⁸ The study period was between February 1994 and September 1995. The premise of this demonstration study was that direct reimbursement for pharmaceutical care would increase the pharmaceutical care pharmacists provide by removing the financial barrier.

The CARE project consisted of three groups of approximately 100 pharmacies each. Community pharmacies serving ambulatory Medicaid patients in the state were randomly allocated to a documentation-and-payment group (group A), documentation-only group (group B), and control group (group C). Pharmacies in group A performed and documented pharmaceutical care provided to Medicaid recipients, and received a fee (\$4.00 or \$6.00) for each intervention, as well as a \$40.00 monthly stipend for their participation in the demonstration. Pharmacies in group B received a \$40.00 monthly participation fee to perform and document pharmaceutical care without additional reimbursement. The control group neither documented pharmaceutical care nor received any reimbursement. Pharmaceutical care was reported using a problem-intervention-result classification system embedded within a pseudo-National Drug Code format.³⁸ The National Drug Code is a universal product identifier for human drugs, and usually a unique 10-digit, 3-segment code is in one of the following configurations: 4-4-2; 5-3-2; or 5-4-1. Structuring pharmaceutical care services codes using pseudo-National Drug Code format facilitates the billing procedure.

2.2.2 Mississippi Medicaid⁵²

Starting in 1998, the Mississippi Medicaid system provided payment for disease state management for asthma, diabetes, hyperlipidemia, and coagulation disorders. Pharmacists must undergo specialized training to participate and secure certification in these services. Either a physician or nurse practitioner must refer patients to receive the service. The referring physician requests pharmacy disease management services from any credentialed participating pharmacist in Mississippi. With the appropriate transfer of pharmacy care records, including a written referral from the physician to the pharmacist, the referral is considered documented. To be cost-effective for the Medicaid program, the pharmacy disease management services performed by the pharmacist cannot duplicate those provided by the physician.

The pharmacist evaluates the patient and consults with the physician concerning the prescribed drug therapy. After the drug therapy review with the physician, the pharmacist counsels the patient regarding compliance issue and provides the patient with educational and informational materials specific to the disease or drug. The pharmacist acts as an educator to ensure patient understanding and compliance with the proper usage of all drugs prescribed by the physician,

Pharmacy disease management services are reimbursed on a per encounter basis. Pharmacy disease management providers must use the Current Procedure Terminology (CPT) code 99402 (Preventive Medicine Counseling, approximately thirty minutes) when billing for an encounter. CPT codes were developed by the American Medical

Association in the 1960s, and soon became part of the standard code set for Medicare and Medicaid to describe health care services in electronic transactions (Appendix A). An encounter must be at least fifteen minutes in duration. This program allows each patient twelve visits with a pharmacist annually. These visits are reimbursed at a rate of \$20 per visit.⁵³ Pharmacists bill the Medicaid system using a CMS-1500 form, a medical insurance form used when submitting for payment of services (Appendix B).

2.2.3 Iowa Medicaid⁵²

The Iowa Medicaid Pharmaceutical Case Management (PCM) Program began with funds appropriated during the 2000 Iowa legislative session and was designed to benefit a subset of individuals who are at very high risk of adverse effects from medications. Through the program, pharmacists and physicians are paid for assessment and intervention, and as care teams they have to meet specific criteria in order to provide PCM services. Physicians have to be licensed to practice medicine. Pharmacists have to present the Iowa Department of Human Services with evidence of competency, including state licensure, submission of five acceptable patient care plans, and successful completion of professional training. Both pharmacists and physicians have to complete an Iowa Medicaid provider agreement and have an Iowa Medicaid provider number. Eligible patients, non-institutionalized Medicaid beneficiaries of any age, must have at least one of twelve specified diseases and use four chronic, non-topical medications supplied by an eligible pharmacy.

The unique features of the PCM program are that both pharmacist and physician team members are paid equally for their services and that the pharmacist can implement a collaboratively determined action plan without requiring a patient to visit a physician. Each patient is allowed one initial visit and each provider earns \$75 in compensation. Follow-up visits, are allowed as follows: one preventive follow-up visit is allowed every six months (\$25 per provider), two new problem assessments are allowed every 12 months (\$40 per assessment per provider), and four follow-up assessments are allowed every 12 months (\$40 per assessment per provider).⁵⁴

Pharmacists and physicians using the selection criteria identify high-risk patients for the program. It is the pharmacist's responsibility to contact the patient for an initial assessment. After the assessment, the pharmacist contacts the physician to formulate a mutually agreed upon action plan. Follow-up visits are scheduled as needed and allowed. The pharmacist and the physician each bill the Medicaid system using either a manual or electronic CMS-1500 form.

2.2.4 Florida Medicaid⁵²

Since 1999, the Florida Agency for Health Care Administration (AHCA) has actively pursued a viable pharmacist service model designed to improve medication use substantially among Medicaid recipients in Florida. With the introduction of continuous quality improvement requirements for pharmacists and the delineation of quality related event (QRE) categories for medication use, it was determined that an evaluation of QREs within the Medicaid population and the pharmacist ability to identify and resolve QREs

was needed.⁵⁵ QRE is of any failure occurred in the prescription dispensing process when medication errors happen, such as number of staff on duty, number of orders or prescriptions filled that day, etc. In 2002, AHCA was able to conduct a study funded from GlaxoSmithKline to the State's Florida Medicaid program, with the following objectives: (1) examine the types of QREs that exist within the AHCA covered recipient population; (2) measure the impact of advanced training on pharmacist ability to identify and resolve QREs; and (3) measure and report the impact of Florida pharmacists on identification and resolution of QREs. After more than a year of evaluating potential options for completing the study, the Florida Medicaid Pharmacy Association (FPA) was selected, under contract with the AHCA, to manage the Florida Medicaid Quality Related Events Program in four Florida counties: Hillsborough, Pinellas, Pasco and Polk.

Under the Florida Medicaid Quality Related Events Program, four types of pharmaceutical care services are eligible for reimbursement, including identification and management of drug therapy problems, patient education and monitoring, comprehensive medication review, and physician refusal and patient refusal. It is worth noting that in this program, "quality related event," "drug therapy problem," and "encounter" have identical definitions and can be used interchangeably. A brief description of each type of eligible service follows.⁵⁵

Identification and Management of Drug Therapy Problems. When patients covered by the plan have prescriptions filled, participating pharmacists review their medications to identify problems with utilization, therapeutic duplication, contraindications, interactions, or suboptimal dosage. Pharmacists who detect an issue

consult with the prescriber or the patient to resolve the problem. Drug therapy problems requiring physician consultation are reimbursed at \$20 per problem and those involving patient compliance are reimbursed at \$15 per problem.

Patient Education and Monitoring. Each time a covered patient begins a treatment with a new medication or has a change in his or her medication, the participating pharmacist will: (1) provide detailed information about the purpose and appropriate use of the medication; and (2) complete a one-time follow-up call to make sure the drug is working properly and that the patient is not experiencing unforeseen side effects. A \$10 fee is payable to the pharmacist for each new or changed prescription medication for which education and monitoring is completed.

Comprehensive Medication Review. Pharmacists may schedule a face-to-face appointment to conduct a comprehensive medication review if the eligible patient's medication regimen includes at least five unique and active medications. The base fee for this service is \$30. Drug therapy problems identified and resolved as a result of the review are submitted as separate and additional encounter claims.

Physician Refusal and Patient Refusal. Each time a recommendation is made to a physician, but the physician chooses not to change the original medication order, the pharmacist will be paid a \$2 fee. In the event a patient refused a covered service, it should be documented, but it is not a payable service.

Participating pharmacists use the Outcome Encounter Program, an intervention-based program, to submit encounter claims that follow the reason-action-result format along with estimated cost avoidance and supporting note.

2.2.5 Missouri Medicaid⁵²

The Missouri Medicaid program implemented its Disease State Management program in July 2002. The program is designed to improve the health care of patients who suffer from chronic conditions such as asthma, diabetes, heart failure, and depression. Pharmacists and physicians work as a team to improve patient care and health outcomes, reduce emergency department visits and inpatient hospitalizations, lower total costs, and better educate patients and providers.⁵⁶

In this program, high-risk patients are identified and they choose their health care provider team – made up of a physician and an individual pharmacist – who collaboratively provide disease management services. Pharmacists must undergo specialized training before providing these services. Patients may use only this team for their disease management services, but may use other providers for unrelated services. Since patients choose their pharmacist-physician team, pharmacists may partner with different physicians for different patients. Enrolled disease management team members are reimbursed at a fixed per encounter rate for all disease management services provided. Four possible services are reimbursed: initial assessment (\$75, one per patient); new problem assessment (\$40, two per patient per 12 months); new problem follow-up assessment (\$40, four per patient per 12 months); and preventive follow-up assessment (\$25, one per patient per 12 months).⁵⁶

Services are billed on a CMS-1500 form. Each type of assessment has its own unique procedure code, and each pharmacist has a provider number that is used for billing.

2.2.6 Wyoming PharmAssist Program⁵²

The Wyoming PharmAssist program started in December 2003, and was developed by the Wyoming Department of Health and the University of Wyoming, supported by AARP, and funded by the Wyoming State Legislature to offer pharmacist consultations to patients in that state.⁵⁷ Residents of Wyoming who are concerned about their medications or their associated costs can call a toll-free number to determine whether they are eligible for the program. If eligible, they provide information about all medical conditions, medications (prescription, nonprescription, and dietary supplements), and all physicians and pharmacists that they use. Wyoming PharmAssist then arranges for patients to meet with a program pharmacist for a one-on-one counseling session and a medication review. Program pharmacists analyze patient information for potential drug interaction, therapeutic duplications, and cost alternatives and then provide recommendations to help patients and their health care teams make informed decisions about medication use. This program is different from other public pharmaceutical care reimbursement programs in the sense that the patient population served is not limited to Medicaid recipients or specific populations only.

Program pharmacists are paid \$75 for each completed evaluation (\$70 from the state and a \$5 copay from the patient). Six-month reviews may occur as necessary.⁵⁷

2.2.7 Ohio Department of Health

Pharmacists are considered providers under the Ohio Department of Health's Bureau for Children with Medical Handicaps (BCM^H).⁵² The mission of the Bureau for Children with Medical Handicaps is to assure, through the development and support of high quality coordinated systems, that children with special health care needs and their families obtain comprehensive care and services which are family-centered, community-based, and culturally sensitive. As one of the core team members in BCM^H, pharmacists who have completed a specialized training course are issued their own provider identification numbers and bill directly for these services under a pilot program. Services must be provided under a collaborative practice agreement with other team members.

Pharmacists bill the program under specific CPT codes. They are paid \$70 for an initial visit and \$45 for maintenance visits.⁵²

2.3 Description of the Wisconsin Medicaid Pharmaceutical Care Project

In 1996, the Wisconsin Legislature and Governor Tommy Thompson understood that pharmacists were providing valuable services to the state's Medicaid population. They also realized that pharmacists could have an even greater impact on the health of Medicaid recipients and on decreasing expenditures associated with non-drug budget items in the Medicaid program. The idea led to the creation of the Wisconsin Medicaid Pharmaceutical Care Project (WMPCP).⁵⁸

Before the approval of the project, the Wisconsin Pharmacists Association and the Wisconsin Bureau of Healthcare Financing developed a potential list of services that pharmacists provide and for which they should receive reimbursement. During development, these codes were subsequently revised in favor of the National Council for Prescription Drug Programs (NCPDP) professional pharmacy service codes that it was believed would become a universal standard. NCPDP was developed by a not-for-profit ANSI-Accredited Standards Development Organization consisting of over 1,300 members representing virtually every sector of the pharmacy services industry, and was named the official standard in the Health Insurance Portability and Accountability Act (HIPAA).⁵⁹ Hence, a modified version of the NCPDP standard codes was adopted by the WMPDP. Each service code is made up of a two-digit number for each event, and overall these codes are used to represent four aspects characterizing the activities of a pharmacist: reason, action, result, and level (time). Medicaid pharmacy providers bill Medicaid using the NCPDP telecommunication standard-universal claim form for their pharmaceutical care services.

Aiming at maximizing the effectiveness of medications for the patient through pharmacist intervention, the WMPDP provides pharmacists with an enhanced dispensing fee for pharmaceutical care services given to Medicaid fee-for-service recipients.⁵⁸ This enhanced fee reimburses pharmacists for additional actions they take beyond the standard dispensing a prescription drug. Pharmacies may receive an enhanced dispensing fee when their service increases patient compliance or prevents potential adverse drug problems and results in a positive outcome for the Medicaid program. Each of the

reimbursable services represents situations that lead to outcomes such as enhanced patient medication compliance, enhanced delivery of medication, and reduced drug and potential non-drug costs. The pharmaceutical care dispensing fee includes all reimbursement, except drug cost, for the dispensed medication associated with the pharmaceutical care intervention. That is, there is no separate or additional reimbursement for dispensing the drug because the previous dispensing fee is included in the pharmaceutical care fee.⁵⁸

Before Wisconsin Medicaid Pharmacy providers' prescription database and claim submission software programs could support on-line claims submission, the pharmacy submitted pharmaceutical care on a paper claim. In addition to the coding and payment system, documentation of patient-medication information and events surrounding the interventions is required as part of the program. This is the first time that pharmacists had an opportunity to document the services they provide to patients could improve patient outcomes and potentially save them money.⁵⁸ For the Wisconsin Pharmacists Association, the former is even more important because the ultimate goal of the WMPCP is not simply how much money pharmacists can make, but rather how much of an impact they can have on patients' drug therapies.

After the completion of technical changes in the pharmacy database and software program, in September 1999, a Point-of-Sale system was implemented in the WMPCP, which allowed pharmacists to submit pharmaceutical care claims electronically rather than on paper. It is the same billing system as Medicaid for pharmacists to submit prescription claims. Later in February 2001, Wisconsin Medicaid began using

prospective drug utilization review, a system designed to identify Medicaid patients' drug therapy problems for the pharmacist. Pharmacists are required to respond to all alerts before a drug claim will be paid. The pharmacist must indicate the action taken to address the potential drug problem and the outcome of the action. All prospective drug utilization review alerts are recorded and put into the data warehouse. The next two sections provide a more detailed synopsis of the point-of-sale system and prospective drug utilization review.

Pharmaceutical care reimbursement is based on the reason for the intervention, the action taken by the pharmacist, the result of that action, and the time spent performing the activity. The service provided would be assigned a number based on the complexity of service and on the time involved. Pharmacists use a series of two-digit codes to represent reasons, actions, results (outcomes), and levels of service when billing Medicaid. Initially, a total of forty-seven reason codes were created in three general categories: prescription-related, drug-related, and patient-related problems. Most of the pharmaceutical care services reason codes describe drug-related problems identified during dispensing. Twelve action codes describe how the pharmacist intervenes to correct problems. Twenty-two result codes provide pharmacist assessment of the outcome that resulted from the action taken. Lastly, five levels of service codes define the amount of time spent by the pharmacist in resolving the problem (up to 5 minutes, 6-15 minutes, 16-30 minutes, 31-60 minutes and over 60 minutes). Enhanced dispensing fees that are associated with each of the five levels of service are \$9.08, \$14.11, \$21.30, \$38.55, and \$40.11 respectively.⁵⁸

The significance of the WMPCP is that it was the first state-funded program, rather than pilot project, in the United States to encourage pharmaceutical care services by providing financial incentives, and it is an ongoing program.

2.3.1 Pharmacy Point-of-Sale

The Wisconsin Department of Health and Family Services (DHFS) and Medicaid began the implementation of the point-of-sale electronic claims management system for Medicaid fee-for-service providers statewide in September 1999. The system enables pharmacy providers to submit real-time claims electronically for immediate adjudication and eligibility verification. The real-time claims submission verifies recipient eligibility, including other health insurance coverage, and monitors Medicaid drug policies. Claims are also screened against recipient medical and prescription history within the Medicaid system. Once these processes are complete, the provider receives an electronic response indicating payment or denial within seconds of submitting the real-time claim. The average system response time is 0.4 seconds. The largest benefit of the point-of-sale system to pharmacies is that it takes some of their risk away. Pharmacies know up front if the claim will be paid and if so, at what rate.⁶⁰ This system is also the prerequisite for the implementation of an on-line prospective drug utilization review system.

2.3.2 Drug Utilization Review

The federal Omnibus Budget Reconciliation Act of 1990 (CFR Section 456.703-456.705) calls for a drug utilization review program that includes retrospective drug

utilization review, prospective drug utilization review, and an educational program for all state Medicaid outpatient drugs in order to improve the quality and cost-effectiveness of recipient care. By both federal law and Wisconsin administrative codes and statutes, individual pharmacies are responsible for prospective drug utilization review. Wisconsin Medicaid is responsible for providing the retrospective drug utilization review program and the educational program.⁶¹ The following is a brief description for the retrospective drug utilization review and education program, and an introduction to the prospective drug utilization review from the state of Wisconsin.⁶¹

Retrospective Drug Utilization Review. The primary idea of the Medicaid retrospective drug utilization review program is to provide for an ongoing periodic examination of paid claims data and other records in order to identify patterns of fraud, abuse, gross overuse or inappropriate or medically unnecessary care associated with specific drugs or groups of drugs, and to take corrective actions. Wisconsin Medicaid has had monthly retrospective drug utilization review since 1984. With the implementation of the point-of-sale system, Wisconsin Medicaid continues to look for trend data among physicians and pharmacists through retrospective drug utilization review.⁶¹ However, drug therapy problems can only be detected after the drug has been dispensed.

Education Program. The Department of Health and Family Services uses data from the drug utilization review program to educate prescribers and dispensers on common drug therapy problems with the aim of improving prescribing and dispensing practices.

Prospective Drug Utilization Review. Since February 2001, the Wisconsin Medicaid Prospective Drug Utilization Review system requires and assists pharmacy providers in screening medications for clinically important drug therapy problems before the prescription is dispensed. These problems include therapeutic duplication, drug/drug interactions, early and late refills, cumulative side effects, and drug contraindications for pregnancy, certain diseases, and specific ages.⁶¹ The screening is done electronically in real-time using Wisconsin Medicaid's Point-of-Sale system. Wisconsin's Medicaid system provides the pharmacist with drug and medical information from most claims submitted to Medicaid regardless of its origin. Thus, pharmacists are provided with more complete information than they otherwise would be able to obtain. Medicaid prospective drug utilization review does not include screening for drug allergies because that information is not in the claims system. To maximize its effectiveness, the prospective drug utilization review program should be combined with the pharmacist review. The ultimate goal of the prospective drug utilization review is to enhance clinical quality and cost-effective drug use.

While the appearance of the system is similar to other prospective drug utilization review services available through the private sector, the Wisconsin Medicaid Prospective Drug Utilization Review system provides more advantages over currently available private sector systems.⁶¹ A big difference can be observed when one considers the amount of patient profile information driving the screening process. Wisconsin's Prospective Drug Utilization Review system reviews not only the prescriptions at an individual pharmacy, but all of the prescriptions reimbursed by Medicaid fee-for-service

providers. In addition, because Medicaid pays for many over-the-counter medications (OTC), the drug utilization review alerts also pick up any drug therapy problems caused by OTCs. The changes do not stop with the expanded drug profile data. Medicaid's Prospective Drug Utilization Review system also includes information on a recipient's disease states and pregnancy status. For the first time, pharmacies are provided with information that takes more than the patient's drug therapy into consideration. Together these additions supply pharmacists with improved information, creating opportunities for improved patient care.

Another feature that distinguishes Prospective Drug Utilization Review has to do with how pharmacists respond to alerts. When an alert notifies a pharmacy provider of a potential problem, the provider is required to respond to the alert in order to obtain reimbursement for medications from Wisconsin Medicaid. Pharmacists may respond by choosing not to dispense the prescribed drug or by overriding alerts once they have been activated. In order to override alerts, pharmacists must indicate the reason for the override in the appropriate drug utilization review fields. Pharmacy providers are also able to pre-override alerts if the drug in claims history that activates the alert was dispensed from the same pharmacy. That is, the Wisconsin Medicaid Prospective Drug Utilization Review system allows pharmacists to exert their clinical judgment and to have the final say, and this is different from private sector systems.⁶²

In summary, Wisconsin Medicaid's Prospective Drug Utilization Review system provides pharmacists with a lot of new information that they were unable to obtain easily before. With this new information, pharmacists are better able to care for and manage the

drug therapy of Medicaid recipients. Pharmacy providers who also perform pharmaceutical care services have the capability to bill for pharmaceutical care services and to respond to prospective drug utilization review alerts in the same real-time claims submission. While it does not mean that every drug utilization review alert is a pharmaceutical care opportunity, this system points out to the pharmacist some increased opportunities for pharmaceutical care billing because it identifies potential drug problems requiring additional interventions by the pharmacist. When appropriate, and if the pharmacist meets all the necessary requirements, the pharmacist can bill for and receive an enhanced dispensing fee for pharmaceutical care. It is expected that prospective drug utilization review encourages more pharmacies to take advantage of billing for pharmaceutical care services.⁶²

2.4 Evaluation Studies of Public Pharmaceutical Care Reimbursement Programs

Several studies have been conducted to evaluate the demonstration project and public pharmaceutical care reimbursement programs. Christensen and his colleagues did a series of evaluations of the Washington State CARE Project.^{38, 63, 64} The objectives of their evaluations were to assess the effectiveness of the implementation of the project and to determine the effects of a financial incentive on the number and type of drug-related problems identified and resolved by pharmacists, as well as the cost of drug therapy.⁶⁴ They also assessed pharmacist and pharmacy factors associated with the provision of pharmaceutical care.^{38, 63} They used a prospective randomized trial for the evaluation, presenting detailed descriptive statistics from administrative data, and some findings

from comparisons between treatment and control groups, such as characteristics of pharmacies and pharmacists, based on cross-sectional survey data.⁶³ Among their descriptive statistics, they found that of 200 community pharmacies, the overall participation rate was 86 percent.³⁸ It is important to remember that this high pharmacy participation rate was the result of a randomized trial of the demonstration CARE Project, and may not predict actual participation rates for ongoing programs.

Other relatively comprehensive evaluation studies come from a group of researchers in Iowa.^{54, 65, 66} Their assessment of the Iowa Medicaid PCM Program, similar to the studies of the CARE Project, provided extensive descriptive statistics as to the extent and content of PCM services provided by pharmacists, and pharmacist follow-up of patients with identified drug therapy problems based on either mailed questionnaires, or Medicaid claims files, or patient pharmacy records in cross-sectional study designs.^{54, 66} Overall, 40 percent to 60 percent of the pharmacies provided little or no PCM services within three months of notification of patient eligibility, and only a few pharmacies implemented PCM services effectively.⁵⁴ When examining the effect of the PCM program on medication safety and the effect of PCM services on the health care utilization of PCM-eligible patients, they used longitudinal statistical analysis to account for correlations between repeated measures over time of medication safety and health care utilization.⁶⁵

Recently, Mott and colleagues completed an evaluation of the WMPCP,³⁹ and it appears to be the only remaining evaluation study for any public pharmaceutical care reimbursement programs other than the CARE Project and the PCM Program in the

literature. Funded by the Community Pharmacy Foundation, they reported a summary of descriptive statistics of pharmacy participation in the WMPCP and characteristics of the pharmaceutical care claims paid between 1996 and 2003 as well as for each year of the program. They found approximately one-fifth of unique Medicaid pharmacy providers (n=359) have been paid for at least one pharmaceutical care claim under the WMPCP.³⁹

Although not found in the literature, Florida Medicaid provided regular updates of the QRE Program in its "fact sheet."⁵⁵ Of more than 3,300 Medicaid pharmacy providers in Florida, 176 pharmacists from 128 pharmacies have submitted pharmaceutical care claims, as of November 23, 2004.⁵⁵ Other information, such as total fees paid to pharmacies, total estimated costs avoided, average fees per claim, is also included.

To summarize, only a few articles in the literature evaluating publicly funded pharmaceutical care reimbursement programs are available. The majority of them are descriptive studies, which are essential for program evaluation. In order to draw causal inferences about the effect of a program or intervention, however, more sophisticated study design and statistical analysis may be necessary. For example, previous evaluation studies presented information on pharmacy participation based on cross-sectional data and did not provide further assessment, in terms of what factor(s) influenced the extent and the content of pharmacy participation, or whether the pharmacy participation rate changed over time in the context of long period of follow-up. Repeated measures were used in one evaluation study of the Iowa PCM Program,⁶⁵ but the outcomes of interest were medication safety and health care utilization, not pharmacy participation.

When examining the WMPCP, Mott *et al.* found some spikes in the number of pharmacy providers participating in the program and the number of paid claims per participating pharmacy seemed to be around the timing of two policy changes associated with point-of-sale and prospective drug utilization review.³⁹ It is yet unknown if there is any association between the spikes and the implementation of point-of-sale, or prospective drug utilization review. Such evaluation is anticipated to add knowledge to current understanding of pharmacy participation in the implementation of pharmaceutical care.

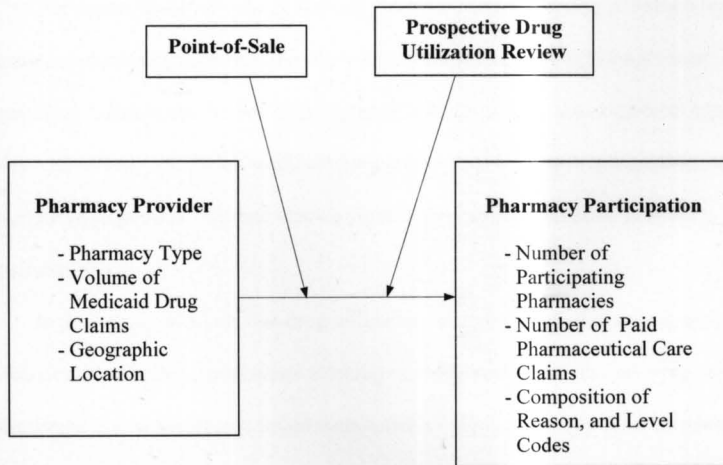
2.5 Conceptual Framework

Given the gaps identified from the literature thus far, this study aims to evaluate the impacts of two policy changes with respect to point-of-sale and prospective drug utilization review on: (1) pharmacy participation in the WMPCP; (2) intensity of participation among participating pharmacies; and (3) composition of the reason and level codes for pharmaceutical care claims paid between state fiscal years 1997 and 2003.

A conceptual framework that depicts the relationships, pathways, and potential sources of influence on pharmacy participation in the WMPCP guides this study (see Figure 2.1). The model proposes that two policy changes increased pharmacy participation in the WMPCP.

Two policy changes refer to point-of-sale and prospective drug utilization review. Both happened at different times and existed thereafter. Pharmacy participation is operationalized in three different ways: (1) number of participating pharmacy providers

Figure 2.1. Conceptual framework



in the WMPCP; (2) intensity of participation – that is, number of pharmaceutical care claims submitted; and (3) composition of pharmaceutical care claims paid – specifically, the reasons why pharmaceutical care services occurred and level of services (time).

The model includes several pharmacy characteristics that may influence their responses to the policy changes: pharmacy type (chain; hospital outpatient/clinic; independent; health maintenance organization (HMO)/manage care; long-term care facility; unknown), volume of Medicaid drug claims, and pharmacy geographic location (urban; rural; unknown). Several studies support the inclusion of these pharmacy characteristics.

In their study of an on-line drug utilization review system, Armstrong and Markson concluded that pharmacists working in independent pharmacies were more responsive to the messages and found them useful.³⁰ Chui and Rupp reported pharmacy type and prescription volume as possible factors influencing pharmacists' response to prospective drug utilization review messages.⁶⁷ Christensen and Hansen found prescription volume and rural pharmacies were significant factors predicting higher documentation rates of pharmaceutical care services.⁶³ Paluck, Stratton, and Eni also demonstrated that independent pharmacies and pharmacies in isolated rural areas were significantly related to higher pharmacists' participation in health promotion and disease prevention counseling activities.⁶⁸ These studies show the importance of selected pharmacy characteristics when evaluating pharmacy participation.

Overall, this dissertation project primarily concentrates on the impact of the policy changes on pharmacy participation, and the relationships between outcome measures and pharmacy characteristics.

2.6 Methods of Estimating Effects of Intervention (Policy Change)

2.6.1 Study Designs

The randomized controlled trial is regarded as the standard methodology for the evaluation of treatments or interventions. It is not always possible, however, to randomize study populations or to find comparable controls. For example, political or ethical concerns might prohibit randomization. Another example could be identified in retrospective studies in which interventions have been implemented without prior knowledge of the researcher. In addition, it is impossible or impractical to randomize or to identify control groups for many administrative policies and programs because changes to policies and programs frequently encompass entire populations. In these situations, one should consider nonrandomized or quasi-experimental designs to evaluate the effects of treatments or interventions.^{69,70}

A common quasi-experimental design used to evaluate such interventions is a one-group pretest-posttest design. That is, some measure of outcome is taken before the intervention and then the same measure is taken after the intervention has occurred. Any changes are then inferred to have occurred because of the intervention.^{70,71} However, this study design provides little information on whether there exists a secular trend before the intervention or whether the changes between pre-post outcome measures are due to

seasonal change or just a random fluctuation. These questions demonstrate the potential weakness of the pretest-posttest design and make the conclusions of a study dubious.⁷²

Another possible solution might be to use a control group that is outside the geographic boundaries of the population that was subject to change. This strategy, however, has many problems, including variation between the populations that are studied, different methods of data collection, and secular trends.⁷³

An interrupted time series design is useful for the evaluation of policy changes. It can be used to strengthen pretest-posttest designs.^{69, 73} It also avoids problems resulting from finding external control groups because it uses the same population for the period before and after policy implementation (that is, nonconcurrent control group.)⁷⁴ The term *interrupted* refers to the implementation of the intervention under study. In this design, data are collected at multiple instances over time before and after a policy (interruption) is introduced to detect whether the policy has an effect significantly greater than the underlying trend. The researcher assesses the outcome (dependent) variable before the introduction of a policy in order to establish a baseline for comparison. Then the policy (independent) variable is introduced and followed by additional assessments of the dependent variable to determine whether the policy change alters the baseline pattern of the dependent variable in terms of either slope or level.⁷⁵

Interrupted time series analysis requires knowing the specific time point in the series when a policy change occurred. The purpose of the analysis is to infer whether the policy change had an impact. If it did, then the observations after the policy change are expected to be different from those before. The series should therefore show signs of

interruption at the point in time when the policy change occurred. The pre- and post-intervention series can then be tested for statistically significant differences.

Because using a nonconcurrent control group in interrupted time series designs have difficulty in separating the effects of policy change from those of secular trends or other concomitant changes,^{70, 73} interrupted time series analysis addresses this major limitation by testing for abrupt changes in study outcomes after policy implementation and by using regression analysis to control for secular trends.⁷⁰

In the area of legal impact assessment, interrupted time series designs have been used to test and measure the impacts of new policies or policy changes.⁷⁶⁻⁷⁸ It was also used to evaluate the impacts of community development initiatives that are place-based local development strategies.⁷⁹ This design is now being increasingly used to evaluate clinically relevant therapeutic effects or health care behavior (e.g., compliance; physician prescribing behavior, etc.) change interventions.^{72, 75, 80-86}

Even though an interrupted time series design from a quasi-experimental study is powerful for evaluating intervention effects, studies have found that researchers rarely used appropriate analytic techniques to analyze data due to their limited understanding about the complexities involved in this study design and in data analyses.^{72, 87, 88} The first problem is the number of data points. Time series analysis requires an extensive series of observations over time.⁷³ Although there is no definite answer to how many time points are required, the conventional wisdom considers it appropriate to have at least fifty time points available.^{76, 88, 89} Many researchers failed to include enough data points and the number could be as low as just one or two during pre- and post-intervention periods.^{87, 88}

Another common problem is inadequate statistical analysis. Many researchers either did not perform data analysis at all and simply relied on visual inspection of outcome changes, or used inappropriate statistical tests (e.g., t-test of pre- and post-intervention mean data) rather than analysis of time trends for their data.⁸⁸ Consequently, studies might provide poor quality evaluations of interventions (or policy changes) with misleading conclusions.^{72, 87}

For example, in an interrupted time series, comparison of the mean of data between pre- and post-intervention periods can either overestimate or underestimate the effect size of the intervention. On the one hand, overestimation occurs when there is a constant downward or upward trend over time even without the intervention. That is, when the outcome measures show a change in level after the intervention begins, the change may not be attributable to the intervention, and the difference between two mean values exaggerates the effect of the intervention. On the other hand, underestimation may occur when there is a large change in level of the outcome measures when the intervention begins. Dependent on what the trends before and after the intervention look like over time, the differences between two mean values could be much smaller than the real effect of the intervention.^{73, 87} By and large, these flawed methodologies make interpretation of the results unreliable, leading to deceptive conclusions.^{70, 73}

2.6.2 Segmented Regression Analysis

There are a number of statistical methods that can be used for analyzing time series data. The choice of which method to use depends on the data and the nature of

expected outcomes.⁸¹ A powerful statistical method for estimating intervention effects in interrupted time series studies is segmented regression analysis.⁹⁰ It is a recommended technique especially in health services research because it allows researchers to estimate, in statistical terms, how much an intervention (or policy change) changed an outcome of interest, immediately and over time; instantly or with delay; and whether factors other than the intervention could explain the change.^{70, 90}

Segments in a time series are defined when the sequence of measures is divided into two or more portions before and after change points. Change points are specific points in time where the values of the time series show a change from the previously established patterns because of an identifiable event, a policy change, or an experimental intervention.^{90, 91}

Two parameters define each segment of a time series: level and slope. A change in level is a jump or drop in the outcome after the intervention, which indicates an abrupt intervention effect. Change in level is measured as the difference between the last point pre-intervention and the first point post-intervention. A change in slope is defined by an increase or decrease in the slope after the intervention in comparison with the slope before the intervention and represents a gradual change over time. Depending on the direction of change in slope, it can either reverse or enhance a change in level.⁹⁰ The advantage of analysis of change in level and slope is that it provides information about the immediate impact of the intervention and about its sustained impact over time.

Segmented regression analysis requires data collected regularly over time and organized at equally spaced intervals. Outcome measures for analysis can be expressed

as average, proportion, or rates.^{83,90} A sufficient number of time points before and after the intervention is preferred to conduct segmented regression analysis. A general recommendation is at least twelve data points before and twelve data points after the intervention. With 24 monthly measures, the analyst can adequately evaluate seasonal variation. A minimum of 100 observations at each data point of time series is also desirable to achieve an acceptable level of variability of the estimate at each time point.⁹⁰

As time is a predictor in segmented regression analysis, error terms of consecutive observations often correlate with each other. Failing to correct for autocorrelation may lead to underestimated standard errors and overestimated significance of the effects of policy changes or interventions.⁷⁰ When using segmented regression analysis, researchers can use the Durbin-Watson statistic to test the whole time series for serial autocorrelation of the error terms in the regression model.⁹²

A segmented regression model assumes a linear trend in the outcome within each segment.⁹⁰ It is important, therefore, to examine whether the assumption of linearity holds. In the case of non-linear trends, data transformation or other types of statistical models such as autoregressive integrated moving average (ARIMA) models may help.⁷⁰

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However, Wagner and colleagues⁹⁰ argued that ARIMA models are widely used for predicting future trends (that is, forecasting), and of less use in examining changes in trend that occur at defined time points. The literature also suggests when the assumption of linearity roughly holds, there appears to be no distinct advantage of ARIMA modeling over other statistical methods even when autocorrelation is present in the data.⁸¹

2.6.3 Summary of Time Series Analysis

Time series analysis is a longitudinal data analysis technique, and it is different from other longitudinal techniques such as the study of cohorts or panel studies. Normally, time series analysis has specific requirements for the collected data. It requires relatively numerous data points over time with equally spaced intervals.⁹³ It also typically aggregates individual-level data by time point; that is, data in a time series come either from one individual only, or from a group of individuals with data aggregated to one observation at one time point. Because administrative programs usually collect the outcome measures of interest on large aggregates on a regular basis over time, time series analysis is an appropriate analysis technique for policy and program analysis using administrative databases.⁷⁴

Yet, time series analysis has its own limitations. It aggregates individual-level data by time point; individual-level characteristics, therefore, are not included in regression models of time series data. In other words, unless the outcome measures from all individuals have the same patterns over time, it is difficult to capture heterogeneity among individuals using aggregated data.

Time series analysis does not require repeated measures from the same individuals. If repeated measures from the same group of individuals are available, then longitudinal data analysis techniques such as panel studies can consider individual-level characteristics while modeling correlated outcomes.^{94,95} The generalized estimating

equations (GEEs) approach is a method commonly used for statistically modeling of correlated responses.^{94, 95}

2.7 Generalized Estimating Equations (GEEs) Approach

The GEEs were introduced by Liang and Zeger as a way of handling correlated data that, except for the correlation among responses, can be modeled with a generalized linear model (GLM).⁹⁶ GLMs are traditional linear models relating a mean response to a vector of explanatory variables through a link function:⁹⁷

$$g(E(y_i)) = g(\mu_i) = x_i' \beta$$

where y_i is a response variable ($i = 1, 2, \dots, n$), $\mu_i = E(y_i)$, g is a link function, x_i is a vector of independent variables, and β is a vector of regression parameters to be estimated.

GEEs are an extension of GLMs to accommodate correlated data. The difference between the GLM and GEE methods is that GEE accounts for the structure of the covariances of the response outcomes through its specification in the estimating process, and therefore creates robust parameter estimates.⁹⁶⁻⁹⁸ That is, GEE methods give consistent estimators of the regression coefficients and of their variances under weak assumptions about the actual correlation among a subject's observations. However, the closer the working correlation matrix is to the true structure, the more efficient the estimates will be.

The GEE approach, a semiparametric approach, is a practical strategy for the analysis of both categorical and continuous repeated measurements.⁹⁹ It can be used for Poisson, binominal, gamma, and normal distribution analyses. It handles continuous explanatory variables, categorical explanatory variables, and time-dependent explanatory variables. It can also deal with missing values, that is, the number of data points for each subject can vary from 1 to t . The assumptions of the GEEs are the independence between subjects and correlations within a subject's observations.

This approach is usually applied in medical research to assess the relationship between risk factors and health outcomes taking account of the dependence among observations from the same subject.^{98, 100-102} For example, in a Multi-center AIDS Cohort Study that followed more than 4,500 gay/bisexual men since 1984 to study the natural history of AIDS, the investigators were interested in how sexual practice has changed since 1984 and which factors predict continued sexual behaviors that put men at high risk for HIV infection.¹⁰¹ The primary outcome is the number of sexual partners in the six months before each visit. There were up to 15 visits for each individual. Compared to medical research, the GEE approach is rarely used in pharmacy research and evaluation studies of public policies. It is desirable to explore its use in pharmacy research.

2.8 Summary of Literature Review

In spite of evidence of its value, the implementation of pharmaceutical care has not yet become routine in pharmacists' daily practice. Literature attributes this phenomenon to many barriers, either real or perceived. Pharmacists frequently cited lack

of financial incentives, time, therapeutics knowledge, and clinical problem-solving skills as significant barriers influencing the implementation of pharmaceutical care.

Several states have initiated reimbursement programs to encourage pharmacists in their transition to pharmaceutical care. Although the governments should be interested in knowing how their programs work, very few evaluation studies have been done. A common result of evaluations is low pharmacy participation rates. Pharmacy participation in the program is a proxy for delivered pharmaceutical care services, and no study has yet engaged in further research about it. Additionally, more evaluation studies of publicly funded pharmaceutical care reimbursement programs are needed overall.

Two major policy changes, adoption of a point-of-sale system and later a prospective drug utilization review, in the WMPCP seemed to be associated with fluctuations in the rate of pharmacy participation. No information is available in the literature regarding how point-of-sale or prospective drug utilization review influences pharmacy participation in pharmaceutical care. The proposed study seeks to fill these gaps in the literature, and to add to current understanding about pharmacy participation, and the effects of point-of-sale and prospective drug utilization review that are operating parts of many State Medicaid programs. Findings would be useful to Medicaid officials and State Drug Utilization Review Boards with information needed to assess and improve program performance.

The point-of-sale system allows pharmacists to submit claims electronically instead of completing time-consuming paper work. It also takes some of pharmacists' risk away by providing them information up front about whether and how much the claim

will be paid. The prospective drug utilization review system alerts pharmacists to possible drug therapy problems. The author, therefore, hypothesizes that both systems would increase pharmacy participation in pharmaceutical care services, because the former can help ease pharmacists' concerns of lacking time and financial reimbursement, and the latter can increase pharmacists' ability to detect certain kinds of drug therapy problems and potentially present them with more opportunities for pharmaceutical care services. Figure 2.1 shows the initial conceptual framework of the hypotheses.

Both point-of-sale and prospective drug utilization review are full coverage policies in the WMPCP. This presents special difficulties to evaluators attempting impact assessments because there are no unaffected targets available to use as controls. In this case, interrupted time series design, a quasi-experimental design, is an appropriate choice for evaluating the impact of policy changes.

Although time series designs have had a long tradition in political, economic, and business research, and have been used frequently in medical research, in general they are still less well known and underutilized, especially in the field of pharmacy administration research. Yet, they have never been used to evaluate any pharmaceutical care reimbursement programs. In addition, interrupted time series designs are often analyzed inappropriately (e.g., t-test of pre- and post-intervention mean data rather than analysis of time trend), underpowered, and poorly reported in implementation research. The author applies time series designs to evaluate two policy changes in the WMPCP, using recommended statistical techniques for analyses. It is hoped that the study will help pharmacy researchers advance understanding about the importance and usefulness of

interrupted time series designs and appropriate statistical methods in evaluating intervention impacts.

Because time series analysis typically aggregates individual-level data by time point, individual-level characteristics are not taken into account. Therefore, aside from time series analysis, the generalized estimating equations (GEEs) approach is applied in the study to offset this deficit of time series analysis. GEE is an extension of generalized linear models that provides a semiparametric approach to longitudinal data analysis with univariate outcomes for which the quasi-likelihood formulation is sensible, for example, normal, Poisson, binomial, and gamma response variables. This approach encompasses a broad range of data situations, including missing observations, continuous independent variables, and time-dependent variables.^{96,98} It is expected that using multiple statistical techniques will strengthen the analysis, and give a complete and robust assessment in the study.

CHAPTER 3

RESEARCH QUESTIONS AND HYPOTHESES

3.1 Aims

This study aims to accomplish three main objectives. The primary objective is to evaluate the impact of two policy changes on: (1) pharmacy participation in the WMPCP; (2) the intensity of participation among participating pharmacies; and (3) the composition of the reason and level codes for paid pharmaceutical care claims. The time frame for this study is the fiscal years 1997 to 2003.

A secondary objective is to examine whether various characteristics of pharmacy providers are associated with outcome measures. Pharmacy characteristics that will be examined include pharmacy type, geographic location, and volume of Medicaid prescription drug claims.

3.2 Research Questions and Hypotheses

Primary research questions and hypotheses to test include:

1. Were the policy changes in the WMPCP associated with pharmacy participation?

Specifically, did point-of-sale and prospective drug utilization review affect pharmacy participation?

H₁: Point-of-sale increased pharmacy participation.

H₂: Prospective drug utilization review increased pharmacy participation.

2. Were the policy changes in the WMPCP associated with the intensity of participation among participating pharmacy providers (that is, the number of pharmaceutical care claims submitted)? Specifically, did point-of-sale and prospective drug utilization review influence the number of paid pharmaceutical care claims?

H₃: Point-of-sale increased the number of paid pharmaceutical care claims.

H₄: Prospective drug utilization review increased the number of paid pharmaceutical care claims.

3. Were the policy changes in the WMPCP associated with change in the composition of pharmaceutical care claims? Specifically, did point-of-sale and prospective drug utilization review impact the reasons, and levels of pharmaceutical care services provided by pharmacy providers?

H₅: Point-of-sale changed the composition of reasons.

H₆: Point-of-sale increased level (time) of pharmaceutical care services.

H₇: Prospective drug utilization review changed the composition of reasons.

H₈: Prospective drug utilization review increased level (time) of pharmaceutical care services.

CHAPTER 4

RESEARCH METHODS

This chapter provides detailed information pertaining to the methods used to accomplish the objectives of the study. The chapter describes the design of the study, and explains why it was chosen; defines the study population (pharmacy providers); describes the data files and their uniqueness; defines the outcome measures (dependent variables) and explanatory (independent) variables; and delineates the statistical plans for the study.

4.1 Study Design

A retrospective, interrupted time series design using longitudinal panel data was used. A quasi-experimental design was used in this study because randomization of Medicaid pharmacy providers to either a treatment (experience policy changes) or control group was not possible as both point-of-sale and prospective drug utilization review were implemented statewide; in other words, they were both full-coverage policies. Thus, the use of a quasi-experimental design was the best option. An interrupted time series design is a quasi-experimental research design with “the presence of a periodic measurement process on some group or individual and the introduction of an experimental change into this time series of measurements.”^{69, 73}

An interrupted time series design is regarded as the strongest quasi-experimental design, and can be used whenever appropriate to strengthen single-group pre- and post-

test design.⁶⁹ In an interrupted time series design, data are collected at multiple points over time before and after an intervention (interruption) is introduced to detect whether the intervention has an effect different than the underlying secular trend. An advantage of this design is that it allows for the statistical investigation of potential biases in the estimate of the effect of the intervention. These potential biases include secular trends, seasonal effects, random fluctuations, and autocorrelation.⁷⁰

An interrupted time series design constitutes an important class of research designs for gaining causal knowledge when the required data are available across many time points. It gains its advantage from the pre-intervention series that allows many potential threats to internal validity to be examined, and from the post-intervention series that allows the form of the causal relationship to be described in terms of the speed of onset and the degree of persistence of the effect.⁷³

The interrupted time series design can be diagrammed thus:⁶⁹

O₁ O₂ O₃ O₄ X O₅ O₆ O₇ O₈

The X represents the intervention, and the Os represent the observations.

In this study, the author examined pharmacy participation in the WMPCP before and after the implementation of point-of-sale and prospective drug utilization review. The point-of-sale system was adopted by the WMPCP in September 1999 and prospective drug utilization review in February 2001. The following diagram represents the current study:

O₁ O₂ O₃O₃₈ X₁ O₃₉ O₄₀ O₅₅ X₂ O₅₆ O₅₇O₈₄

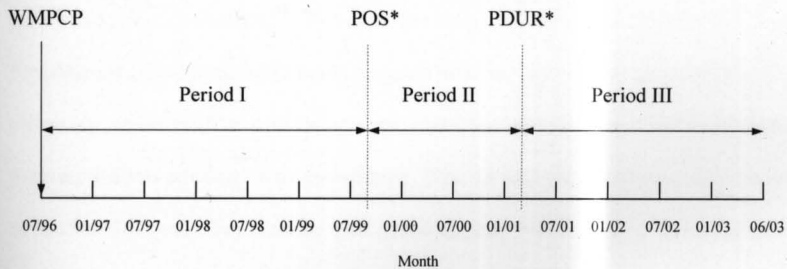
The Xs represent policy changes in the program – X₁ represents point-of-sale and X₂ represents prospective drug utilization review. Each O represents a monthly observation of an outcome measure. There are 84 time points because data are available from July 1996 to June 2003.

Three periods were defined to evaluate the impact of the two policy changes: the time period before the implementation of point-of-sale, between July 1996 and August 1999 (period I: 38 months); the time period after point-of-sale and before prospective drug utilization review, between September 1999 and January 2001 (period II: 17 months); and the time period after prospective drug utilization review, between February 2001 and June 2003 (period III: 29 months). Figure 4.1 shows these three periods in the time series.

4.2 Study Population

Medicaid pharmacy providers in Wisconsin during state fiscal years 1997 and 2003 were the study population. In total, there were 1,848 pharmacy providers that had ever existed in the Wisconsin Medicaid during the seven years. Because the WMPCP was a full-coverage program, all pharmacy providers could bill the WMPCP, receiving enhanced dispensing fees for their pharmaceutical care services if they provided and billed for those activities.

Figure 4.1. Time frame



*POS: point-of-sale (September 1999)

*PDUR: prospective drug utilization review (February 2001)

4.3 Data

Administrative databases are a useful source of data for retrospective studies of policy and program changes.⁷⁴ Two data files were available for the study. The first data file obtained from the state Medicaid program included information about all Medicaid pharmacy providers. The data included the identification information of the pharmacy provider such as provider name and address. The file also contained summary statistics of Medicaid program participation such as the number of Medicaid recipients and the number of prescription claims paid to each pharmacy provider for each fiscal year.

The second data file was a database of pharmaceutical care claims paid by Wisconsin Medicaid to pharmacy providers. The data file was obtained from the state Medicaid program and contained information for every pharmaceutical care claim paid under the WMPCP from July 1996 to June 2003. Data elements for each claim included pharmacy name and provider identification number, date of pharmaceutical care service (mm/dd/yyyy), reason code, action code, result code, level (time) code, amount paid, and the name of up to three prescription drugs associated with the claim where applicable. The state fiscal year was assigned to each claim based on the date of service (fiscal years begin July 1st and end June 30th).

Available data files provided a unique strength to this study. Up to and including fiscal year 2003, the database contained 18,395 pharmaceutical care claims, which represented all claims paid. Therefore, the database provided the study a full population of subjects (pharmacy providers) for evaluation. This minimized concern about the generalizability of the findings to Wisconsin.

Based on the date of pharmaceutical care service, a longitudinal panel dataset of pharmacy providers was created using monthly indicators, which allowed longitudinal data analysis to be performed to evaluate the impact of the policy changes on pharmacy participation. In general, longitudinal research is preferred over cross-sectional research because the former can distinguish changes over time within study subjects (aging effects) from differences among study subjects in their baseline levels (cohort effects) and the latter cannot. In addition, because the data contained repeated measures from the same groups of pharmacy providers over a relatively long period, various longitudinal data analysis techniques were possible. In this study, the researcher performed time series analysis and longitudinal data analysis using the GEE approach to evaluate the effects of POS and PDUR on pharmacy participation in the WMPCP.

4.4 Measures

4.4.1 Dependent Variables

Pharmacy participation in the WMPCP was the dependent variable of interest. It was operationalized in three ways to represent both *quantity* and *quality* aspects of participation for time series analysis. Two dependent variables representing the *quantity* aspect of participation were (1) the number of pharmacy providers that were paid for at least one PC claim in a particular month, and (2) the monthly number of paid PC claims.

A large number of PC claims may not suggest that more clinically important pharmaceutical care services were provided. The researcher, therefore, sought to capture the *quality* aspect of pharmacy participation by evaluating the changes in reason and level

codes of PC claims. The third dependent variable consisted of a series of rates of general reason and level codes for analysis. The rate of a particular reason (or level) code was calculated from the total number of the reason (or level) divided by the total number of all reasons (or levels) in each month.

Pharmacists used a series of two-digit codes to represent reasons and levels of service when billing the WMPCP for their pharmaceutical care services. In total, there are forty-seven reason codes specifying problems identified during dispensing a prescription. There are five level codes defining the amount of time spent by the pharmacist in resolving the problem (0-5 minutes; 6-15 minutes; 16-30 minutes; 31-60 minutes; and >60 minutes). To generate general reason and level codes, individual codes were categorized to reflect the general types of reasons or levels for pharmaceutical care services, respectively, based on previous research (see Table 4.1).³⁹ Overall, four general types of reason codes (drug use; patient behaviors; drug choice; drug use issues/problems; and other), and five level codes were defined.

4.4.2 Independent Variables

Point-of-sale and prospective drug utilization were the two main independent variables. They were both indicator variables for time series analysis where a value equal to one represented the period after the policy change, and zero represented the period before the policy change.

Table 4.1. Categorization of reason and level codes

Group	General Type	Individual Codes
Reason	Drug Use: Patient Behaviors	Late Refill, In-home Medication Management, Suboptimal Compliance, Early Refill, Possible Drug Misuse
	Drug Choice	Product Selection Opportunity, Drug-drug Interaction, Therapeutic Duplication, Suboptimal Regimen, High Dose, Drug Allergy, Suboptimal Dosage Form, Low Dose, Additive Toxicity, Unnecessary Drug, Excessive Duration, Excessive Quantity, Insufficient Quantity, Missing Information on Prescription, Insufficient Duration, IV Drug Incompatibility, Prior Authorization, Drug-Disease Interaction, Drug-Age Interaction, Drug-Pregnancy Interaction, Drug-Gender Interaction, Drug-Alcohol Interaction
	Drug Use Issues/Problems	Patient Complaint/Symptom, Side Effect Precaution, Chronic Disease Management – Asthma, New Drug, Additional Drug Needed, Adverse Drug Reaction, Disease- Diabetes, Patient Request, Drug Reaction, MD Requested Information, Iatrogenic
	Other	Forgery Possible, Lab Test Need, Lock-in Recipient
Level	0-5 minutes	0-5 minutes
	6-15 minutes	6-15 minutes
	16-30 minutes	16-30 minutes
	31-60 minutes	31-60 minutes
	>60 minutes	>60 minutes

Another independent variable was time. It was hypothesized that time would be a significant factor predicting the value of the dependent variable. Time was a monthly indicator in regression models for time series analysis.

Other variables that were included in this study to evaluate the characteristics of pharmacy providers, where data analysis allowed, were pharmacy type, location, and volume of Medicaid prescriptions. Pharmacy type and location were determined by pharmacy provider name and address recognition. Six pharmacy types included chain (e.g., Walgreens), hospital outpatient/clinic (e.g., UW pharmacy), HMO (health maintenance organization)/managed care, independent, LTC (long-term care) facility (e.g., nursing home), and unknown. In cases where the Medicaid pharmacy providers could not be categorized by type due to missing information or they were actually medical providers, these providers were assigned to the category of "unknown."

Three categories were created for geographic location: urban, rural, and unknown. The categories were defined based on the Rural-Urban Continuum Codes, a classification scheme that distinguishes metropolitan counties by population size (codes one to three) and nonmetropolitan counties by degree of urbanization and proximity to metro areas (codes four to nine). Pharmacies with codes one to three were labeled as URBAN and pharmacies with codes four to nine were labeled as RURAL. If a pharmacy provider could not be categorized into urban or rural due to missing address information, it was labeled as UNKNOWN.

4.5 Statistical Analysis

All analyses were conducted using SAS for Windows 9.1.3. The level of statistical significance was set at 0.05.

4.5.1 Descriptive Statistics

A number of descriptive statistics were calculated to assess the characteristics of Medicaid pharmacy providers and the characteristics of pharmaceutical care claims. Date of claim submission was used to determine when pharmacy providers were paid for PC claims.

4.5.2 Time Series Analysis

4.5.2.1 Visual Inspection

Visual inspection of the time series plot can give an initial impression of the nature of the dataset, such as presence or absence of change, trends, and seasonal patterns. This helps researchers become familiar with the data and allows for the detection of outliers. Thus, the first step in analyzing serial data was visual inspection of the series. This was achieved by plotting values of the dependent variables of interest over time.

4.5.2.2 Segmented Regression Analysis

Segmented regression analysis is a powerful statistical method for estimating the effects of interventions conducted as part of a randomized trial as well as of interventions that constitute a natural experiment in interrupted time series studies.⁹⁰ The interventions

in this study are two policy changes, point-of-sale and prospective drug utilization review. Segments in a time series are defined when the sequence of measures is divided into two or more portions at change points. In this study, the three time periods represented the segments in regression models.

To estimate the level and slope of the trend of outcome measures (dependent variables) before the implementation of the policies and the changes in level and slope following the implementation of the policies, the following model was specified:⁹⁰

$$Y_t = \beta_0 + \beta_1 * \text{time}_t + \beta_2 * \text{POS}_t + \beta_3 * \text{POS}_t * (\text{time after POS}_t) + \beta_4 * \text{PDUR}_t + \beta_5 * \text{PDUR}_t * (\text{time after PDUR}_t) + e_t$$

$$e_t = \varepsilon_t - \varphi_1 e_{t-1} - \dots - \varphi_m e_{t-m}$$

$$\varepsilon_t \sim N(0, \sigma^2)$$

In this model:

- Y_t = outcome measures (dependent variables) in month t
- time_t = a continuous variable indicating time in months at time t from the start of the study period (e.g., the first month = 1)
- POS_t = a dummy indicator of point-of sale at time t ; value 0 represents before policy change and 1 after policy change
- time after POS_t = a continuous variable counting the number of months after POS at time t (e.g., five months after policy change will be coded 5; coded 0 before POS)

- $PDUR_t$ = a dummy indicator of prospective drug utilization review at time t ; value 0 represents before policy change and 1 after policy change
- time after $PDUR_t$ = a continuous variable counting the number of months after $PDUR$ at time t (e.g., two months after policy change will be coded 2; coded 0 before $PDUR$)

In this model, β_0 estimates the baseline level of an outcome measure at time zero; β_1 estimates the change in the outcome measure that occurs with each month before POS (that is, the baseline slope); β_2 estimates the level change in the outcome measure immediately after POS (a change in level constitutes an abrupt intervention effect); β_3 estimates the monthly change in the slope in the outcome measure after POS, compared to the monthly slope before POS; β_4 estimates the level change in the outcome measure immediately after $PDUR$, compared to the outcome value at the end of the previous period; and β_5 estimates the monthly change in the slope in the outcome measure after $PDUR$, compared to the monthly slope before $PDUR$ and after POS. The error term e_t at time t represents the random variability not explained by the model. It consists of a normally distributed random error and an error term at time t that may be correlated with errors at preceding time points, e.g., assuming an autoregressive error structure.

To detect autocorrelation, a plot of residuals against time was inspected and statistical tests were conducted. Randomly scattered residuals without a pattern indicate that there is no autocorrelation. Positive autocorrelation exists when consecutive

residuals tend to lie on the same side of the regression line; whereas negative autocorrelation exists when consecutive residuals tend to lie on different sides.¹⁰³

The Durbin-Watson statistic was used to test for serial autocorrelation of the error terms in the regression model. A value close to 2.0 indicates no serious autocorrelation.⁹² When serious autocorrelation was found, segmented autoregressive error models were used to take account of autocorrelation between data points so that the accuracy of time series analysis was achieved. The SAS[®] AUTOREG procedure allowed estimation of segmented regression models, controlling for autoregressive effects.

4.5.2.3 Subgroup Analysis

All dependent variables used in the segmented regression model represented aggregated data, which made including individual pharmacy characteristics in the model impossible. The secondary objective of this study was to examine whether the characteristics of pharmacy providers influenced outcome measures. Subgroup analysis sought to explore the association between pharmacy characteristics (that is, type and location) and the dependent variables.

Subgroup data were created based on pharmacy type or location, and segmented regression models were fitted individually for each subgroup. Comparing the significance level, the magnitude and the sign of estimated coefficients between subgroups allowed the researcher to assess the existence of possible associations between pharmacy characteristics and the dependent variables.

4.5.2.4 Sensitivity Analysis

To examine the robustness of the conclusions from time series analysis, the researcher performed two sensitivity analyses. When the researcher fitted segmented regression models, immediate effects from POS and PDUR were assumed. To evaluate this assumption, three segmented regression models were fitted. The first model used all 84 data points. The second model excluded the data point representing the first month after POS (the 39th month) and the data point representing the first month after PDUR (the 56th month). The third model excluded two data points representing the first two months after POS (the 39th and 40th month) and after PDUR (the 56th and 57th month).

In an interrupted time series design, the time interval between successive data points should be chosen with care. The interval should be short enough to detect secular trends, but not too short so that any intervention effect disappears into the model's "noise."⁸¹ Therefore, the second sensitivity analysis was performed for time series data with an alternative definition of time interval, e.g., change monthly indicators to bi-monthly. Two segmented regression models were fitted. One model used 84 monthly data points. The other model used 48 bi-monthly data points that were created from combing two consecutive monthly data points in the original time series.

The researcher examined the significance, the magnitude, and the sign of the estimated coefficients in segmented regression models to determine the consistency of the findings.

4.5.3 Longitudinal Data Analysis

Time series analysis was used for the hypothesis testing of the primary objectives in this study, and it did not take into account individual-level pharmacy characteristics in the segmented regression model. To investigate whether various characteristics of pharmacy providers were associated with the outcome measures of the study, the generalized estimating equations approach was used to analyze a panel data set of pharmacy providers from a subgroup of the study population.

4.5.3.1 Sample Population

Medicaid pharmacy providers in Wisconsin during state fiscal years 1997 through 2003 were the study population for time series analysis. Not every pharmacy provider existed in the Wisconsin Medicaid program at all times. Thus, the researcher applied two selection criteria to create a panel dataset that was used for longitudinal data analysis.

The sample population, a subgroup of the study population, was defined as (1) the Medicaid pharmacy providers that existed all seven years during fiscal years 1997 and 2003, and (2) these pharmacy providers were also paid for at least for one PC claim during the whole study period.

4.5.3.2 Descriptive Statistics of Sample Population

The distribution of the pharmacy providers with seven-year continued enrollment in Wisconsin Medicaid program between fiscal years 1997 and 2003, by pharmacy type and location, was assessed. The researcher also evaluated the associations of type and

location with whether a pharmacy provider was paid for one or more PC claims during the study period. Fisher's exact test was used to evaluate these associations.

4.5.3.3 Dependent Variables

The unit of analysis in the panel data analyses was the individual pharmacy provider. Pharmacy participation in the WMPCP was the dependent variable of interest, and was operationalized as follows:

- 1) Whether a pharmacy was paid for at least one PC claim at time points; value 1 represents yes and value 0 otherwise.
- 2) The number of paid PC claims at time points.
- 3) The number of months that a pharmacy provider was paid for at least one PC claim at time points.

The first dependent variable was used for the assessment of the effects of independent variables on whether or not pharmacy providers participated in the WMPCP. The other two dependent variables were used to evaluate the intensity of pharmacy participation in the WMPCP. The third dependent variable represents the proportion of participation at time points.

4.5.3.4 Independent Variables

In addition to the variables time, POS and PDUR, individual pharmacy characteristics including pharmacy type, location, and the number of Medicaid prescriptions were included in regression models. The researcher evaluated the significance of these variables. Both type and location were categorical variables in the

models, using independent pharmacy and rural pharmacy as the reference group, respectively. The number of Medicaid prescriptions was treated as a continuous variable.

4.5.3.5 Generalized Estimating Equations (GEEs)

Generalized linear models can be used to examine the association of independent variables with dependent variable if the observations are independent of each other. For correlated data, however, generalized linear models are not sufficient and alternative approaches that can address the dependence are needed. To analyze correlated data, one must model both the regression of the dependent variable on independent variable(s) and the dependence of within-subject observations (repeated measures). In this study, the GEE method accounts for correlations between a pharmacy's repeated measures (that is, monthly observations).

Three dependent variables were modeled using the GEE method. First, the indicator of participation was equal to zero if the pharmacy did not have any paid pharmaceutical care claims at the time point, and one otherwise. The logit link function was used for this binomial outcome. The link function in generalized linear models specifies a nonlinear transformation of the predicted values so that the distribution of predicted values is one of several special members of the exponential family of distributions (e.g., gamma, Poisson, binomial, etc.). The link function is therefore used to model responses when a dependent variable is assumed to be nonlinearly related to the predictors.

The other two dependent variables were the number of paid PC claims and the proportion of pharmacy participation at each time point. If there were no paid PC claims, the number was zero. Both variables were treated as observed count data and followed the Poisson distribution. The log link function was used for these two dependent variables.

Overdispersion is a common issue when dealing with Poisson data. It occurs when the assumption of equal mean-variance property of the Poisson distribution is not satisfied, and it results in underestimating standard errors of regression coefficients and overestimating significance.¹⁰⁴ The researcher found overdispersion in data analysis and corrected the problem of overdispersion by fitting the Pearson dispersion parameter in the generalized linear model for adjustments.

The SAS[®] GENMOD procedure allowed analysis of GEE parameter estimates.

4.5.3.6 Sensitivity Analysis

It is uncommon for the GEE model to have 84 repeated measures for each subject. The GEE method may be applied for longer series. The key is the number of subjects relative to the number of repeated measures (that is, the length of the series). The idea is to use as many subjects as possible to overcome misspecification of the correlation function. To examine the robustness of the conclusions from longitudinal data analysis using 84 repeated measures, the researcher performed data analysis using six and nine repeated measures per pharmacy provider for comparisons.

Six or nine repeated measures per pharmacy provider were chosen for the following reasons: (1) at least two data points existed in each period in order to better capture secular trends; and (2) the number of repeated measures was usually less than 10. In the panel data files with six or nine repeated measures per pharmacy, each data point included data from multiple months. Table 4.2 is a summary of how 84 data points per pharmacy provider were grouped into either six or nine per pharmacy provider for sensitivity analysis. Because each data point contained different length of time in the regression models using six or nine observations per pharmacy, an offset variable was used to adjust the difference. The offset variable was the log of months at exposure. It can be viewed as an observed predictor with a known regression coefficient equal to one.¹⁰⁴

Table 4.2. Categorization of 84 data points at the individual pharmacy level for sensitivity analysis using the GEE method

Period	6 OBS	9 OBS
I	1 (1-19)	1 (1-9)
		2 (10-19)
		3 (20-28)
	2 (20-38)	4 (29-38)
II	3 (39-47)	5 (39-47)
	4 (48-55)	6 (48-55)
III	5 (56-69)	7 (56-64)
		8 (65-74)
	6 (70-84)	9 (75-84)

Note:

1) Period I: before POS; between July 1996 and August 1999.

Period II: after POS and before PDUR; between September 1999 and January 2001.

Period III: after PDUR; between February 2001 and June 2003.

2) The numbers of the original 84 data points are in parentheses.

CHAPTER 5

RESULTS

This chapter presents the complete results of data analysis for this study. First, descriptive statistics of the study population and characteristics of the paid PC claims are provided. Next, the results of the time series analysis using the segmented regression model are presented. Lastly, this chapter provides the results of the longitudinal data analysis for a subset of the study population.

5.1 Characteristics of Pharmacy Providers

Table 5.1 through Table 5.6 display the descriptive statistics for Medicaid pharmacy providers in the WMPCP. Table 5.1 contains the number of paid PC claims, the number of Medicaid pharmacy providers that were paid for at least one PC claim, and the total number of Medicaid pharmacy providers for fiscal years 1997 through 2003. The participation rate in the WMPCP ranged from 5.8 percent of all Medicaid pharmacy providers in 2000 to 13.9 percent of Medicaid pharmacy providers in 2001. Overall, about one-fifth (20.9 percent) of Medicaid pharmacy providers were paid for at least one PC claim over the seven-year period.

The first two years of the program were very similar, in terms of total claims paid. From the fiscal year 1998 to 1999, there was a 45 percent decrease in the number of paid claims to the lowest number of claims across the seven years. Thereafter, there was a consistent increase in the number of claims paid each year. The large increase in claim

volume in 2000 was likely due to the ability of pharmacy providers to submit claims electronically.

The number of pharmacies participating in the program showed two decreasing trends, with the highest numbers of participating pharmacies in the first (1997) and fifth (2001) years. The large increase in the number of pharmacy providers paid for claims from fiscal year 2000 to 2001 was likely due to the prospective drug utilization review program initiated in February 2001. The trend of increasing claims since 1999 coupled with a decreasing trend in the number of participating pharmacies since 2001 resulted in an increasing intensity of claims per pharmacy in the latter years of the program.

Table 5.1. Number of paid PC claims, pharmacy providers, and mean number of claims per provider in WMPCP

Fiscal year	Number of paid PC claims	Number of pharmacy providers paid for at least one PC claim	Number of Medicaid pharmacy providers	Percent of Medicaid pharmacy providers paid for at least one PC claim	Mean Number of paid claims per participating pharmacy
1997	1,439	159	1,286	12.4	9.05
1998	1,452	126	1,269	9.9	11.52
1999	806	74	1,246	5.9	10.89
2000	1,309	73	1,249	5.8	17.93
2001	3,235	172	1,235	13.9	18.81
2002	3,653	118	1,238	9.5	30.96
2003	6,501	103	1,248	8.3	63.12
Total	18,395	387^a	1,848^b	20.9	47.53

^a Represents the number of unique pharmacy providers paid for at least one PC claim between FY 1997 and 2003.

^b Represents the number of unique Medicaid pharmacy providers between FY 1997 and 2003.

Table 5.2 summarizes all Medicaid pharmacy providers categorized based on pharmacy type and location. Of 1,848 Medicaid pharmacy providers, 635 (34.4 percent) were independent pharmacies; 552 (29.9 percent) were chain pharmacies. A small number of pharmacy providers (n=15) were under HMO/managed care category. More than 56 percent of pharmacy providers (n=1,046) were located in urban areas. Participation rates were different among types. Independent pharmacies had the highest participation rate (29.1 percent), followed by hospital outpatient/clinic (21.2 percent), and chain (18.1 percent) pharmacies. There was not a large difference in participation rates between urban and rural pharmacy providers.

Table 5.2. Types and locations of Medicaid pharmacy providers: FY 1997-2003

	Number of pharmacy providers paid for at least one PC claim	Number of all Medicaid pharmacy providers	Percent Participation
By Type			
Chain	100	552	18.1
Hospital Outpatient/Clinic	93	439	21.2
Independent	185	635	29.1
HMO/Managed Care	0	15	0
LTC facility	9	172	5.2
Unknown	0	35	0
By Location			
Urban	253	1,046	24.2
Rural	134	646	20.7
Unknown	0	156	0
Total	387	1,848	20.9

Note: pharmacy providers were put in the unknown category if their addresses and names of pharmacy were missing.

Table 5.3 contains information regarding the number of paid PC claims by pharmacy type and location between fiscal years 1997 and 2003. Overall, independent pharmacy providers contributed 12,465 (67.8 percent) out of 18,395 PC claims. On average, each independent pharmacy had 67.4 paid PC claims over seven years. This number was higher than the average number from hospital outpatient/clinic (25.6) and chain (10.7) pharmacy providers.

Pharmacy providers in LTC facilities had the highest average number of paid PC claims per pharmacy. Although only nine LTC pharmacies were paid for at least one PC claim, these nine pharmacy providers averaged 274.9 paid PC claims. The average number of paid PC claims per pharmacy provider in rural areas (73.1) was more than twice as much as the average number in urban areas (34.0).

Table 5.3. Number of paid PC claims and number of participating pharmacy providers by pharmacy type and location

	Number of paid PC claims	Number of pharmacy providers paid for at least one PC claim	Average number of paid PC claims per pharmacy
By Type			
Chain	1,074	100	10.7
Hospital Outpatient/Clinic	2,382	93	25.6
Independent	12,465	185	67.4
HMO/Managed Care	0	0	-
LTC facility	2,474	9	274.9
Unknown	0	0	-
By Location			
Urban	8,597	253	34.0
Rural	9,798	134	73.1
Unknown	0	0	-
Total	18,395	387	47.5

Note: pharmacy providers were put in the unknown category if their addresses and names of pharmacy were missing.

Table 5.4 shows the distribution of the number of months in which pharmacy providers were paid for PC claims. Of 387 Medicaid pharmacy providers that were paid for at least one PC claim, 107 (27.6 percent) were paid for PC claims in only one month across 84 possible months for participation. A total of 280 pharmacy providers (72.4 percent) were paid for PC claims in eight or fewer months. Among the pharmacy providers having at least one paid PC claim, only 27.6 percent of pharmacy providers were paid for PC claims for more than one-tenth (eight months) of the 84-month period.

The distribution of types and locations of pharmacy providers that were paid for only one PC claim over seven years is contained in Table 5.5. Overall, about one-fourth (23.8 percent) of pharmacy providers were paid for only one PC claim. When compared with other types of pharmacies, 33 percent of chain pharmacy providers were paid for only one PC claim. Independent pharmacies were more likely to be paid for more than one PC claim, as were LTC pharmacies. Pharmacy providers in rural areas were less likely to have only one paid PC claim compared to pharmacies in urban areas.

In contrast to Table 5.5, Table 5.6 displays the characteristics of the pharmacy providers that had the largest numbers of paid PC claims between fiscal years 1997 and 2003. Of 11 pharmacy providers, eight were independent pharmacies. In total, the top 11 pharmacy providers were paid for 10,905 paid PC claims that accounted for 59.3 percent of overall 18,395 claims.

Table 5.4. Frequency of number of months in which pharmacy providers were paid for PC claims (N=1,848 pharmacies)

Number of months	Frequency	Percent	Number of months	Frequency	Percent
0	1,461	79.06	26	3	0.16
1	107	5.79	27	1	0.05
2	55	2.98	28	3	0.16
3	37	2.00	29	1	0.05
4	27	1.46	30	2	0.11
5	21	1.14	32	3	0.16
6	15	0.81	33	3	0.16
7	9	0.49	34	2	0.11
8	9	0.49	35	1	0.05
9	9	0.49	37	1	0.05
10	8	0.43	41	1	0.05
11	6	0.32	42	2	0.11
12	10	0.54	43	1	0.05
13	2	0.11	45	1	0.05
14	4	0.22	51	1	0.05
15	6	0.32	53	1	0.05
16	5	0.27	55	1	0.05
17	4	0.22	58	1	0.05
18	6	0.32	61	1	0.05
19	1	0.05	65	1	0.05
20	3	0.16	68	1	0.05
22	1	0.05	71	1	0.05
23	3	0.16	75	1	0.05
24	3	0.16	82	1	0.05
25	1	0.05			

Note: The maximum possible number of participating months is 84.

Table 5.5. Characteristics of Medicaid pharmacy providers that had only one paid PC claim during FY 1997-2003 (n=92 pharmacies)

	Number of pharmacy providers paid for only one PC claim	Number of pharmacy providers paid for at least one PC claim	Percent
By Type			
Chain	33	100	33.0
Hospital Outpatient/Clinic	23	93	24.7
Independent	35	185	18.9
HMO/Managed Care	0	0	-
LTC facility	1	9	11.1
Unknown	0	0	-
By Location			
Urban	69	253	27.3
Rural	23	134	17.2
Unknown	0	0	-
Total	92	387	23.8

Table 5.6. Characteristics of the top 11 pharmacy providers in terms of the number of paid PC claims between FY 1997 and 2003

Pharmacy	Number of PC claims	Number of participating months	Type	Location
1	2,918	43	I	Rural
2	1,632	58	I	Rural
3	1,327	82	I	Rural
4	1,182	9	T	Urban
5	1,000	15	T	Urban
6	870	61	I	Rural
7	575	32	I	Urban
8	389	35	H	Urban
9	359	75	I	Urban
10	341	45	I	Urban
11	312	71	I	Rural

Note:

- 1) Top 11 pharmacy providers were determined based on the total number of paid PC claims between FY 1997-2003. Each pharmacy had more than 300 claims in total. Overall, these 11 pharmacy providers had 10,905 paid PC claims.
- 2) The maximum possible number of participating months is 84.
- 3) Abbreviations of pharmacy type: I: independent; T: LTC facility; H: hospital outpatient/clinic.

5.2 Characteristics of Pharmaceutical Care Claims

Table 5.7 contains the distribution of paid PC claims per pharmacy between fiscal years 1997 and 2003. The distribution of the number of claims per pharmacy was skewed with 51.5 percent of pharmacy providers paid for five or fewer PC claims. There were only 47 pharmacy providers (12.2 percent) with more than 50 paid PC claims; however, this number of pharmacies accounted for 84.2 percent of all paid PC claims. One provider accounted for 15.9 percent (n=2,918) of all paid PC claims.

Table 5.8 contains the frequency of general reason codes and level codes between fiscal year 1997 and 2003. Individual reason codes were categorized to reflect the general types of reasons for PC services: drug use: patient behavior, drug choice, and drug use issues/problems. Drug use: patient behavior (46.5 percent) was the most common reason category, followed by drug choice (32.3 percent) and then drug use issues/problems (20.5 percent). The most common individual reason codes in the drug use: patient behavior, drug choice, and drug use issues/problems categories were late refill, product selection opportunity, and patient complaint/symptom, respectively.

Overall, more than one-half (56.3 percent) of PC services were paid for the lowest two levels of time categories representing services consuming 15 minutes or less. The most common level of service time code was 6-15 minutes.

Table 5.7. Distribution of paid PC claims by pharmacy providers: FY 1997-2003

Number of claims per pharmacy	Number of pharmacies	Total number of paid PC claims
1	92 (23.8%)	92 (0.5%)
2-5	107 (27.7%)	319 (1.7%)
6-10	53 (13.7%)	405 (2.2%)
11-20	41 (10.6%)	579 (3.1%)
21-50	47 (12.1%)	1,513 (8.2%)
51-100	17 (4.4%)	1,276 (6.9%)
>100	30 (7.8%)	14,211 (77.3%)
Total	387	18,395

Note:

1) The largest number of claims per pharmacy was 2,918.

2) Of overall 1,848 unique pharmacy providers, 1,461 (79.1%) had never been paid for a PC claim between FY 1997-2003.

Table 5.8. Frequency of reason and level code categories: FY 1997-2003

	N	Percent
Reason		
Drug use: patient behaviors	8,556	46.5
Drug choice	5,948	32.3
Drug use issues/problems	3,780	20.5
Other	111	0.7
Level		
0-5 minutes	3,235	17.6
6-15 minutes	7,110	38.7
16-30 minutes	3,462	18.8
31-60 minutes	4,397	23.9
>60 minutes	191	1.0
Total	18,395	100

Note:

Drug Use: Patient Behaviors includes Late Refill, In-home Medication Management, Suboptimal Compliance, Early Refill, and Possible Drug Misuse.

Drug Choice includes Product Selection Opportunity, Drug-drug Interaction, Therapeutic Duplication, Suboptimal Regimen, High Dose, Drug Allergy, Suboptimal Dosage Form, Low Dose, Additive Toxicity, Unnecessary Drug, Excessive Duration, Excessive Quantity, Insufficient Quantity, Missing Information on Prescription, Insufficient Duration, IV Drug Incompatibility, Prior Authorization, Drug-Disease Interaction, Drug-Age Interaction, Drug-Pregnancy Interaction, Drug-Gender Interaction, Drug-Alcohol Interaction.

Drug Use Issues/Problems includes Patient Complaint/Symptom, Side Effect Precaution, Chronic Disease Management – Asthma, New Drug, Additional Drug Needed, Adverse Drug Reaction, Disease- Diabetes, Patient Request, Drug Reaction, MD Requested Information, and Iatrogenic.

Other includes Forgery Possible, Lab Test Need, and Lock-in Recipient.

5.3 Time Series Analysis

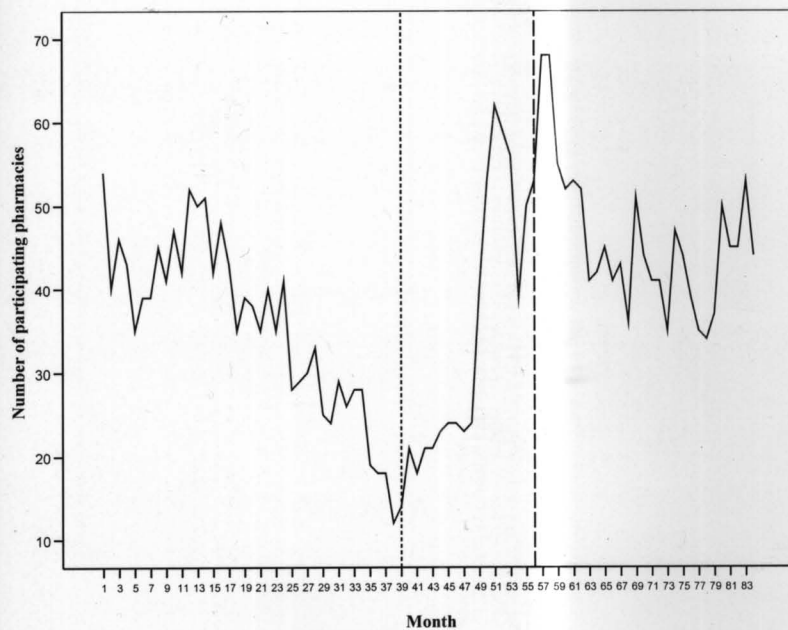
5.3.1 Visual Inspection

Figure 5.1 through Figure 5.4 present time series plots of the number of participating pharmacies, the number of paid PC claims, the rates of general reason codes, and the rates of level of service time for PC, respectively.

Figure 5.1 is a time series plot of the number of participating pharmacies per month. A participating pharmacy in a particular month was defined as a pharmacy with at least one paid PC claim in that month. There were 84 monthly measures between fiscal years 1997 and 2003. Before the inception of POS in September 1999 (the 39th month), the number of participating pharmacies showed a downward trend. After POS, the trend line was increasing with a drop between the 51st and 54th month. PDUR started in February 2001 (the 56th month) which was associated with a short-term increase in the number of participating pharmacies, followed by a relatively stable trend line at a lower level.

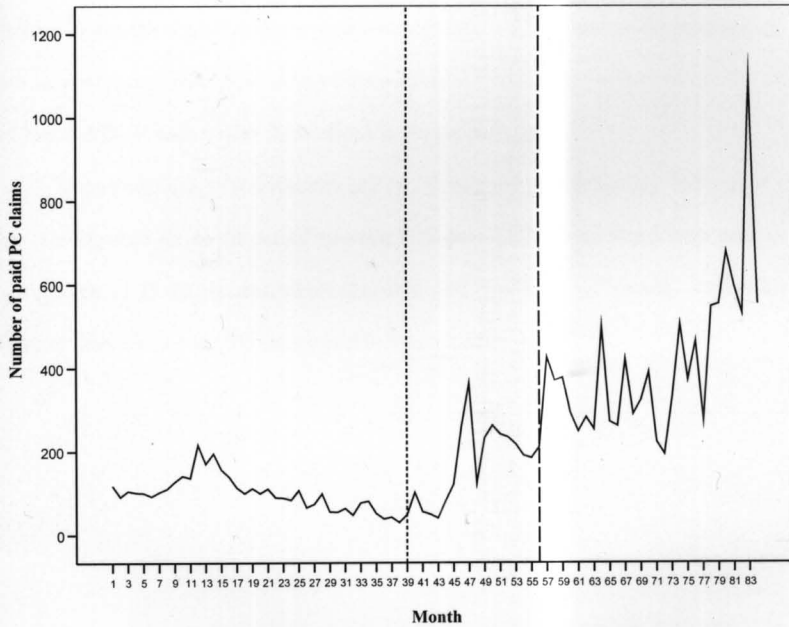
Figure 5.2 is a time series plot of the number of paid PC claims per month. A slightly decreasing trend line was observed before POS started. Although there was a peak in the 47th month, overall, the trend line showed a relatively slow increasing pattern after POS.

Figure 5.1. Time series plot of the number of participating pharmacies per month



..... POS (September 1999)
----- PDUR (February 2001)

Figure 5.2. Time series plot of the number of paid PC claims per month



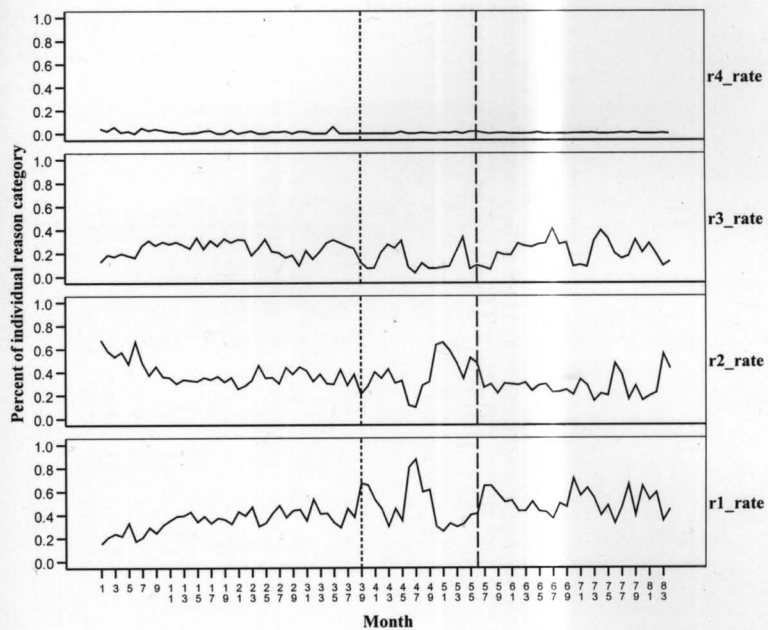
..... POS (September 1999)

----- PDUR (February 2001)

Figure 5.3 and Figure 5.4 are time series plots of the rates of general reason codes and level codes, respectively. The trend lines for Drug Use: Patient Behavior and Drug Choice presented a complementary profile to each other. In general, the percentage of each general reason code fluctuated within a stable range, except for the period after POS and before PDUR with wilder fluctuations in the percentages.

The percentages of 0-5 minutes and 16-30 minutes were relatively stable over time (see Figure 5.4). In the period between POS and PDUR, there was a large peak in the trend line of 31-60 minutes, which started to decrease in the 47th month. Altogether, the trend lines had a complementary profile to each other.

Figure 5.3. Time series plot of the rates of the four reason categories



..... POS (September 1999)

----- PDUR (February 2001)

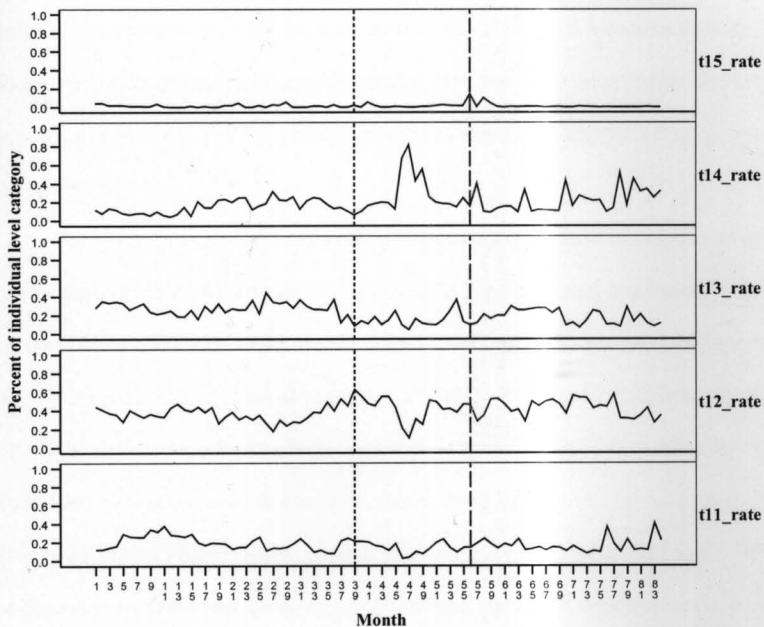
r1_rate: Drug Use: Patient Behaviors

r2_rate: Drug Choice

r3_rate: Drug Use Issues/Problems

r4_rate: Other

Figure 5.4. Time series plot of the rates of the five level categories



..... POS (September 1999)

----- PDUR (February 2001)

- t11_rate: 0-5 minutes
- t12_rate: 6-15 minutes
- t13_rate: 16-30 minutes
- t14_rate: 31-60 minutes
- t15_rate: >60 minutes

5.3.2 Segmented Regression Analysis

Time series data were analyzed by fitting data in segmented regression models. Tests for the autocorrelation of residuals showed the existence of autocorrelation in all models for the dependent variables. Because of the presence of autocorrelations, first-order autoregressive error (AR1) models were used to perform segmented regression analysis in this study.

Table 5.9 summarizes the maximum likelihood estimates of time series analysis for two dependent variables of interest: the number of participating pharmacies per month and the number of PC claims per month. Overall, the number of participating pharmacies per month significantly decreased over time ($p < .001$). Estimated coefficients for POS and PDUR showed significant effects on change in slope. After POS was implemented, about three more pharmacies had paid PC claims every month. On the other hand, PDUR decreased pharmacy participation by approximately three pharmacies per month. When the dependent variable was the number of PC claims per month, significant effects were found only for POS. POS significantly increased pharmacy participation by approximately 14 paid PC claims per month.

Table 5.9. Maximum likelihood estimates of time series analysis of number of participating pharmacies per month and of number of PC claims per month (N=1,848 pharmacies)

Dependent Variable: Number of participating pharmacies per month	
Time	-0.856*** (.175)
POS	
Change in level	-6.438 (5.680)
Change in slope	3.177*** (.555)
PDUR	
Change in level	1.406 (5.622)
Change in slope	-2.843*** (.600)
Dependent Variable: Number of PC claims per month	
Time	-2.357 (1.645)
POS	
Change in level	.236 (64.981)
Change in slope	14.381** (5.672)
PDUR	
Change in level	-52.443 (65.057)
Change in slope	1.344 (5.981)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

To understand better how the reason for a PC claim changed and how the amount of time pharmacists spent in providing PC services changed due to the implementation of POS and PDUR, the rates of general reason codes and level codes were studied. Table 5.10 and Table 5.11 contain the maximum likelihood estimates of time series analysis for reason and level codes.

All estimated coefficients were statistically significant in the model with the rate of Drug Use: Patient Behaviors as the dependent variable. Both POS and PDUR increased the level of rates for the general reason Drug Use: Patient Behaviors. The increase from POS faded gradually, but the increase from PDUR further increased gradually over time. The changes in rates were the consequence of a re-distribution among different reason codes. One can find the complementary changes from Drug Choice and Drug Use Issues/Problems to the changes found in Drug Use: Patient Behaviors.

The level of time spent on PC services by pharmacists was relatively stable (see Table 5.11). The results show that POS had a significant and immediate impact on the categories of 6-15 minutes and 16-30 minutes. The direction shows that pharmacists were less likely to spend 16-30 minutes on PC services after POS implementation.

Table 5.10. Maximum likelihood estimates of time series analysis of rates of reason categories (N=1,848 pharmacies)

Variable	Drug Use: Patient Behaviors	Drug Choice	Drug Use Issues/Problems
Time	.005** (.002)	-.005** (.002)	.001 (.002)
POS			
Change in level	.194** (.081)	-.090 (.083)	-.113* (.067)
Change in slope	-.022** (.007)	.021** (.008)	-.001 (.006)
PDUR			
Change in level	.150* (.081)	-.182** (.083)	.050 (.067)
Change in slope	.016** (.008)	-.016* (.008)	.001 (.007)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.11. Maximum likelihood estimates of time series analysis of rates of level categories (N=1,848 pharmacies)

Variable	0-5 minutes	6-15 minutes	16-30 minutes	31-60 minutes
Time	-0.002 (.001)	-0.001 (.002)	-0.0003 (.001)	.004 (.002)
POS				
Change in level	.006 (.054)	.156** (.074)	-.174** (.050)	-.006 (.092)
Change in slope	.00004 (.005)	-.007 (.007)	.006 (.004)	.002 (.008)
PDUR				
Change in level	.023 (.054)	.076 (.074)	.026 (.050)	-.187** (.092)
Change in slope	.004 (.005)	.006 (.007)	-.008* (.005)	-.0002 (.009)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Previous descriptive statistics show that LTC pharmacies had the highest average number of paid PC claims per pharmacy across all pharmacy types (Table 5.3). LTC pharmacies are different from other types of Medicaid pharmacy providers in terms of the patient populations they serve, and may not be similar to those community pharmacies. To examine the effects of POS and PDUR on community pharmacies, I removed LTC pharmacies (n=172) from the study population (N=1,848) and repeated the segmented regression analysis. Table 5.12 through Table 5.14 summarize the maximum likelihood estimates of time series analysis and provide a parallel comparison with Table 5.9 through Table 5.11. Despite of the exclusion of LTC pharmacies, similar results to those of Table 5.9 through Table 11 repeat.

Table 5.12. Maximum likelihood estimates of time series analysis of number of participating pharmacies per month and of number of PC claims per month (n=1,676 pharmacies, after excluding 172 LTC pharmacies)

Dependent Variable: Number of participating pharmacies per month	
Time	-.824*** (.164)
POS	
Change in level	-6.431 (5.431)
Change in slope	3.020*** (.523)
PDUR	
Change in level	.986 (5.380)
Change in slope	-2.698*** (.565)
Dependent Variable: Number of PC claims per month	
Time	-2.391* (1.376)
POS	
Change in level	-14.489 (48.277)
Change in slope	12.613** (4.487)
PDUR	
Change in level	.209 (47.959)
Change in slope	-1.349 (4.812)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.13. Maximum likelihood estimates of time series analysis of rates of reason categories (n=1,676 pharmacies, after excluding 172 LTC pharmacies)

Variable	Drug Use: Patient Behaviors	Drug Choice	Drug Use Issues/Problems
Time	.005*** (.001)	-.005** (.002)	.001 (.002)
POS			
Change in level	.142** (.055)	-.075 (.070)	-.105 (.068)
Change in slope	-.021*** (.005)	.020** (.007)	-.0001 (.006)
PDUR			
Change in level	.156** (.055)	-.161** (.070)	.041 (.067)
Change in slope	.019*** (.005)	-.021** (.007)	.001 (.007)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.14. Maximum likelihood estimates of time series analysis of rates of level categories (n=1,676 pharmacies, after excluding 172 LTC pharmacies)

Variable	0-5 minutes	6-15 minutes	16-30 minutes	31-60 minutes
Time	-.002 (.001)	-.001 (.002)	-.0001 (.001)	.004** (.001)
POS				
Change in level	.0005 (.044)	.188** (.055)	-.159** (.053)	-.072 (.047)
Change in slope	.001 (.004)	-.005 (.005)	.006 (.005)	.002 (.004)
PDUR				
Change in level	.042 (.044)	.046 (.055)	.011 (.053)	-.178*** (.047)
Change in slope	-.001 (.005)	.005 (.006)	-.009* (.005)	.004 (.005)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

5.3.3 Subgroup Analysis

To assess the influence of pharmacy type and location, subgroup analysis was performed. Tables 5.15 and Table 5.16 display the estimated coefficients from the analyses. Table 5.15 summarizes the subgroup analysis by pharmacy type on the number of participating pharmacies per month and the number of PC claims per month. When the dependent variable was the number of participating pharmacies per month, the results showed that both POS and PDUR had significant impacts on change in slope. POS increased the number of participating pharmacies over time across different types, and PDUR decreased the number of participating pharmacies over time.

When the dependent variable was the number of PC claims per month, PDUR showed no significant effect for all pharmacy types. POS had positive impacts on change in slope of the trend line across all types, except for LTC pharmacies.

Table 5.15. Summary of subgroup analysis by pharmacy type in number of participating pharmacies per month and number of PC claims per month

Number of participating pharmacies per month	Chain	Hospital outpatient /clinic	Independent	LTC
Time	-.294*** (.067)	-.103** (.051)	-.397** (.101)	-.026** (.011)
POS				
Change in level	-.630 (2.143)	-2.206 (1.863)	-6.146* (3.665)	-.752* (.445)
Change in slope	1.205*** (.211)	.757*** (.169)	1.179** (.334)	.216*** (.039)
PDUR				
Change in level	-3.359 (2.120)	.920 (1.856)	2.642 (3.648)	-.333 (.446)
Change in slope	-1.073*** (0.229)	-.668** (.180)	-1.110** (0.357)	-.203*** (.041)
Number of PC claims per month	Chain	Hospital outpatient /clinic	Independent	LTC
Time	-.598** (.264)	-.234 (.284)	-1.548 (1.053)	-.039 (.869)
POS				
Change in level	.739 (8.120)	6.558 (10.016)	-25.415 (38.748)	26.049 (35.246)
Change in slope	2.001** (.821)	2.148** (.929)	8.635** (3.506)	1.082 (3.039)
PDUR				
Change in level	3.600 (8.021)	-2.179 (9.952)	-1.895 (38.598)	-48.900 (35.372)
Change in slope	-1.654* (0.892)	-1.576 (.996)	1.774 (3.737)	3.495 (3.190)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.16 contains the results from the subgroup analysis for pharmacy location. When the dependent variable was the number of participating pharmacies per month, the results showed that both POS and PDUR had significant impacts on change in slope. POS significantly increased the number of participating pharmacies per month over time, and PDUR significantly decreased the number of participating pharmacies over time. Their impacts could be found among both urban and rural pharmacy providers.

When the dependent variable was the number of PC claims per month, POS had a positive impact on change in slope, especially for rural pharmacies. POS increased the number of PC claims by approximately seven per month after POS started. PDUR, on the other hand, did not show any significant impact for both urban and rural pharmacies.

Table 5.16. Summary of subgroup analysis by pharmacy location in number of participating pharmacies per month and number of PC claims per month

Number of participating pharmacies per month	Urban	Rural
Time	- .603*** (.113)	- .238** (.084)
POS		
Change in level	-4.425 (3.729)	-3.519 (3.070)
Change in slope	2.317*** (.359)	.961** (.278)
PDUR		
Change in level	-2.074 (3.694)	2.518 (3.057)
Change in slope	-1.684*** (.387)	-1.277*** (.297)
Number of PC claims per month	Urban	Rural
Time	-1.667 (1.277)	-.712 (.749)
POS		
Change in level	4.069 (51.086)	-3.267 (28.782)
Change in slope	7.535* (4.433)	6.983** (2.547)
PDUR		
Change in level	-66.488 (51.201)	10.061 (28.752)
Change in slope	3.239 (4.665)	-1.897 (2.698)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

5.3.4 Sensitivity Analysis

5.3.4.1 Changing the Time Point When POS and PDUR Started to Take Effect

One of the assumptions in this study is that POS and PDUR took effect immediately at the time of inception. The purpose of this sensitivity analysis was to examine the existence of the diffusion of POS and PDUR, and the robustness of previous findings. Table 5.17 through Table 5.20 illustrate the results of sensitivity testing.

These tables contain the estimated coefficients from regression models for (1) the complete time series data; (2) the time series data set with one data point from the first month after POS (the 39th month) and one data point from the first month after PDUR (the 56th month) excluded (model A); and (3) the data set with two data points from the first two months after POS (the 39th and 40th months) and two data points from the first two months after PDUR (the 56th and 57th months) excluded (model B).

Table 5.17 presents the comparison of the estimated coefficients of segmented regression models for the number of participating pharmacies per month. The results from the original model, model A and model B showed similar patterns, in terms of the significance of independent variables, and the size and the direction of change in significant coefficients. Both POS and PDUR showed significant effects on change in slope. POS had a significantly positive impact and PDUR had a significantly negative impact on change in slope.

Table 5.17. Comparison of maximum likelihood estimates of time series analysis for the number of participating pharmacies per month by changing the time point when POS and PDUR started to take effect (N=1,848 pharmacies)

Dependent Variable: Number of participating pharmacies per month	
> Original Model	
Time	-0.856*** (.175)
POS	
Change in level	-6.438 (5.680)
Change in slope	3.177*** (.555)
PDUR	
Change in level	1.406 (5.622)
Change in slope	-2.843*** (.600)
> Model A	
Time	-0.894*** (.205)
POS	
Change in level	1.748 (6.098)
Change in slope	2.508** (.672)
PDUR	
Change in level	11.111* (6.004)
Change in slope	-2.324** (.737)
> Model B	
Time	-0.854*** (.190)
POS	
Change in level	-.235 (6.050)
Change in slope	2.704** (.680)
PDUR	
Change in level	7.989 (5.954)
Change in slope	-2.484** (.746)

Note:

1) Model A: the first month after POS implementation and the first month after PDUR implementation were deleted.

2) Model B: the first two months after POS implementation and the first two months after PDUR implementation were deleted.

3) Standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.18 presents the comparison of the estimated coefficients of segmented regression models for the number of PC claims per month. The results from the original model, model A and model B showed similar patterns, in terms of the significance of independent variables, and the extent and the direction of change in significant coefficients.

POS showed significantly positive effects on change in slope and PDUR did not. POS significantly increased the number of paid PC claims by adding approximately 14 PC claims per month. POS and PDUR did not seem to have significant impact on change in level.

Table 5.18. Comparison of maximum likelihood estimates of time series analysis for the number of PC claims per month by changing the time point when POS and PDUR started to take effect (N=1,848 pharmacies)

Dependent Variable: Number of PC claims per month	
> Original Model	
Time	-2.357 (1.645)
POS	
Change in level	.236 (64.981)
Change in slope	14.381** (5.672)
PDUR	
Change in level	-52.443 (65.057)
Change in slope	1.344 (5.981)
> Model A	
Time	-2.382 (1.651)
POS	
Change in level	24.136 (66.856)
Change in slope	13.010** (6.187)
PDUR	
Change in level	-21.263 (66.926)
Change in slope	2.390 (6.529)
> Model B	
Time	-2.352 (1.565)
POS	
Change in level	25.017 (65.479)
Change in slope	14.099** (6.440)
PDUR	
Change in level	-48.752 (65.523)
Change in slope	3.060 (6.787)

Note:

- 1) Model A: the first month after POS implementation and the first month after PDUR implementation were deleted.
- 2) Model B: the first two months after POS implementation and the first two months after PDUR implementation were deleted.
- 3) Standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.19 presents the comparison of the estimated coefficients of segmented regression models for the rates of general reason codes. The results from the original model, model A and model B were similar, in terms of the significance of independent variables and the extent and the direction of change in significant coefficients.

In general, pharmacists cited the reasons from the category of Drug Use: Patient Behaviors more frequently in their submission of PC claims when POS and PDUR started. The increase from POS was gradually eroded after POS.

Table 5.19. Comparison of maximum likelihood estimates of time series analysis for the rates of general reason codes by changing the time point when POS and PDUR started to take effect (N=1,848 pharmacies)

Dependent Variable	Drug Use: Patient Behaviors	Drug Choice	Drug Use Issues/Problems
► Original Model			
Time	.005** (.002)	-.005** (.002)	.001 (.002)
POS			
Change in level	.194** (.081)	-.090 (.083)	-.113* (.067)
Change in slope	-.022** (.007)	.021** (.008)	-.001 (.006)
PDUR			
Change in level	.150* (.081)	-.182** (.083)	.050 (.067)
Change in slope	.016** (.008)	-.016* (.008)	.001 (.007)
► Model A			
Time	.005** (.002)	-.005** (.002)	.001 (.002)
POS			
Change in level	.183** (.084)	-.066 (.083)	-.133* (.069)
Change in slope	-.023** (.008)	.023** (.008)	.001 (.007)
PDUR			
Change in level	.205** (.083)	-.262** (.083)	.051 (.068)
Change in slope	.015* (.008)	-.015 (.009)	-.002 (.007)
► Model B			
Time	.005** (.002)	-.006** (.002)	.001 (.002)
POS			
Change in level	.129 (.085)	-.013 (.086)	-.118* (.069)
Change in slope	-.021** (.009)	.020** (.009)	-.00006 (.007)
PDUR			
Change in level	.176** (.085)	-.245** (.085)	.065 (.068)
Change in slope	.013 (.009)	-.012 (.010)	-.001 (.008)

Note:

1) Model A: the first month after POS implementation and the first month after PDUR implementation were deleted.

2) Model B: the first two months after POS implementation and the first two months after PDUR implementation were deleted.

3) Standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.20 presents the comparison of the estimated coefficients of segmented regression models for the rates of level codes. The results from the original model, model A and model B were similar, in terms of the significance of independent variables and the extent and the direction of change in significant coefficients.

The results showed that POS had a significant impact on change in level in the category of 16-30 minutes. The direction indicated that pharmacists were less likely to spend 16-30 minutes on PC services when POS was implemented. PDUR showed a significant effect on change in level in the category of 31-60 minutes, which indicated pharmacists were less likely to spend 31-60 minutes on PC services when PDUR was implemented.

Table 5.20. Comparison of maximum likelihood estimates of time series analysis for the rates of level codes by changing the time point when POS and PDUR started to take effect (N=1,848 pharmacies)

Dependent Variable	0-5 minutes	6-15 minutes	16-30 minutes	31-60 minutes
► Original Model				
Time	-.002 (.001)	-.001 (.002)	-.0003 (.001)	.004 (.002)
POS				
Change in level	.006 (.054)	.156** (.074)	-.174** (.050)	-.006 (.092)
Change in slope	.00004 (.005)	-.007 (.007)	.006 (.004)	.002 (.008)
PDUR				
Change in level	.023 (.054)	.076 (.074)	.026 (.050)	-.187** (.092)
Change in slope	.004 (.005)	.006 (.007)	-.008* (.005)	-.0002 (.009)
► Model A				
Time	-.002 (.001)	-.001 (.002)	-.0003 (.001)	.004 (.002)
POS				
Change in level	-.003 (.056)	.088 (.077)	-.160** (.050)	.055 (.093)
Change in slope	.0004 (.005)	.0004 (.008)	.005 (.005)	-.004 (.009)
PDUR				
Change in level	.032 (.055)	-.005 (.076)	.047 (.050)	-.128 (.093)
Change in slope	.003 (.006)	-.0002 (.008)	-.009* (.005)	.005 (.009)
► Model B				
Time	-.002 (.001)	-.001 (.002)	-.0002 (.001)	.004 (.002)
POS				
Change in level	-.015 (.057)	.041 (.075)	-.163** (.050)	.096 (.091)
Change in slope	.001 (.006)	.003 (.008)	.006 (.005)	-.006 (.009)
PDUR				
Change in level	.034 (.056)	.029 (.074)	.065 (.050)	-.191** (.090)
Change in slope	.002 (.006)	-.005 (.008)	-.010* (.005)	.011 (.010)

Note:

- 1) Model A: the first month after POS implementation and the first month after PDUR implementation were deleted.
- 2) Model B: the first two months after POS implementation and the first two months after PDUR implementation were deleted.
- 3) Standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

5.3.4.2 Using Bi-Monthly Data Points

The purpose of the second sensitivity analysis was to assess the appropriateness of the defined time interval. An alternative definition of time interval was adopted that used bi-monthly data points to examine the robustness of the original findings. Table 5.21 through Table 5.24 contain the estimated coefficients of the regression models for sensitivity testing.

Table 5.21 presents the comparison of the estimated coefficients of segmented regression models for the number of participating pharmacies per data point. The results from the models using monthly or bi-monthly data points were similar, in terms of the significance of independent variables and the direction of change in significant coefficients.

Both POS and PDUR had significant effects on change in slope. The extent of change in slope was similar between POS and PDUR, but the directions were opposite (POS: 3.177 and PDUR: -2.843 in the monthly model; POS: 9.987 and PDUR: -9.537 in the bi-monthly model).

Table 5.21. Comparison of maximum likelihood estimates of time series analysis of the number of participating pharmacies per data point by changing original monthly data points to bi-monthly data points (N=1,848 pharmacies)

Dependent Variable: Number of participating pharmacies per data point	
> Original Model	
Time	-0.856*** (.175)
POS	
Change in level	-6.438 (5.680)
Change in slope	3.177*** (.555)
PDUR	
Change in level	1.406 (5.622)
Change in slope	-2.843*** (.600)
> Bi-monthly	
Time	-3.256** (.907)
POS	
Change in level	-5.521 (14.735)
Change in slope	9.987** (3.015)
PDUR	
Change in level	26.778* (14.017)
Change in slope	-9.537** (3.279)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.22 presents the comparison of the estimated coefficients of segmented regression models for the number of PC claims per data point. The results from the models using monthly or bi-monthly data points were different. In the bi-monthly model, neither POS nor PDUR showed any significant effects on the number of PC claims. However, POS had a significant effect on change in slope when monthly data points were used for data analysis.

Table 5.22. Comparison of maximum likelihood estimates of time series analysis of the number of PC claims per data point by changing original monthly data points to bi-monthly data points (N=1,848 pharmacies)

Dependent Variable: Number of PC claims per data point	
► Original Model	
Time	-2.357 (1.645)
POS	
Change in level	.236 (64.981)
Change in slope	14.381** (5.672)
PDUR	
Change in level	-52.443 (65.057)
Change in slope	1.344 (5.981)
► Bi-monthly	
Time	-9.225 (7.856)
POS	
Change in level	44.849 (158.101)
Change in slope	47.267 (28.915)
PDUR	
Change in level	-23.410 (151.006)
Change in slope	15.905 (30.679)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.23 presents the comparison of the estimated coefficients of segmented regression models for the rates of general reason codes. The results from the original model using monthly data points were consistent with the results from the model using bi-monthly data points, in terms of the significance of independent variables, and the extent and the direction of change in significant coefficients.

The results showed both POS and PDUR immediately increased the rates of the general reason Drug Use: Patient behaviors. The increase from POS started to fade gradually, but the increase from the PDUR showed slight gains over time. The changes from Drug Choice and Drug Use Issues/Problems were complementary to the changes found in Drug Use: Patient Behaviors.

Table 5.23. Comparison of maximum likelihood estimates of time series analysis of rates of reason categories by changing original monthly data points to bi-monthly data points (N=1,848 pharmacies)

Dependent Variable	Drug Use: Patient Behaviors	Drug Choice	Drug Use Issues/Problems
► Original Model			
Time	.005** (.002)	-.005** (.002)	.001 (.002)
POS			
Change in level	.194** (.081)	-.090 (.083)	-.113* (.067)
Change in slope	-.022** (.007)	.021** (.008)	-.001 (.006)
PDUR			
Change in level	.150* (.081)	-.182** (.083)	.050 (.067)
Change in slope	.016** (.008)	-.016* (.008)	.001 (.007)
► Bi-monthly			
Time	.010** (.003)	-.010** (.004)	.001 (.004)
POS			
Change in level	.173** (.066)	-.067 (.091)	-.120 (.076)
Change in slope	-.038** (.011)	.041** (.016)	.001 (.014)
PDUR			
Change in level	.138** (.064)	-.232** (.087)	.055 (.073)
Change in slope	.026** (.012)	-.027 (.017)	-.001 (.015)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.24 presents the comparison of the estimated coefficients of segmented regression models for the rates of level codes. The results from the original model using monthly data points were similar to the results from the model using bi-monthly data points but with a little difference. In the monthly model, POS had significant impact on change in level in the categories of 6-15 minutes and 16-30 minutes, and PDUR had significant impact on change in level in the category of 31-60 minutes. In the bi-monthly model, POS showed significant impact on change in level in the category of 16-30 minutes only.

The amount of time spent on PC services by pharmacists was relatively steady, and there was little change found among different categories of level codes after POS and PDUR. The results showed that POS had a significantly negative impact on the category of 16-30 minutes, indicating that pharmacists were less likely to choose this category when submitting PC claims when POS started.

Table 5.24. Comparison of maximum likelihood estimates of time series analysis of rates of level categories by changing original monthly data points to bi-monthly data points (N=1,848 pharmacies)

Dependent Variable	0-5 minutes	6-15 minutes	16-30 minutes	31-60 minutes
► Original Model				
Time	-.002 (.001)	-.001 (.002)	-.0003 (.001)	.004 (.002)
POS				
Change in level	.006 (.054)	.156** (.074)	-.174** (.050)	-.006 (.092)
Change in slope	.00004 (.005)	-.007 (.007)	.006 (.004)	.002 (.008)
PDUR				
Change in level	.023 (.054)	.076 (.074)	.026 (.050)	-.187** (.092)
Change in slope	.004 (.005)	.006 (.007)	-.008* (.005)	-.0002 (.009)
► Bi-monthly				
Time	-.005 (.003)	-.001 (.005)	-.001 (.003)	.008 (.006)
POS				
Change in level	.005 (.066)	.074 (.092)	-.150** (.056)	.051 (.114)
Change in slope	-.002 (.012)	-.003 (.017)	.012 (.010)	-.005 (.021)
PDUR				
Change in level	.030 (.063)	.039 (.087)	.036 (.053)	-.141 (.109)
Change in slope	.010 (.013)	-.0001 (.018)	-.018 (.011)	.008 (.022)

Note: standard errors are in parentheses.

*** $p < .001$ ** $p < .05$ * $p < .10$

5.4 Longitudinal Data Analysis

To create a panel dataset, the researcher applied selection criteria to all Medicaid pharmacy providers that served as the study population in this project. Figure 5.5 displays a flow chart of how the sample size was reduced after the selection criteria were applied. Initially, there were 1,848 unique Medicaid pharmacy providers found in the Wisconsin Medicaid database between fiscal years 1997 and 2003. Of these Medicaid pharmacy providers, 785 participated in the Wisconsin Medicaid program for all seven years. A total of 237 pharmacy providers were paid by the WMPCP for at least one PC claim during the study period.

Figure 5.5. Flow chart of sample size reduction after applying selection criteria

Unique Medicaid pharmacy providers
found in the administrative database of
the State of Wisconsin

(N=1,848)



Pharmacy providers that participated
for all seven years in Wisconsin
Medicaid program between FY 1997
and FY 2003

(n=785)



Pharmacy providers that had been paid
for at least one PC claim between
FY 1997 and FY 2003

(n=237)

Table 5.25 displays the distributions of these two groups of pharmacy providers based on pharmacy type and their geographic locations.

Of chain, hospital outpatient/clinic, independent, and LTC facility pharmacy providers, 25.6 percent, 26.6 percent, 38.5 percent and 8.7 percent had at least one paid PC claim, respectively. Independent pharmacy providers had a relatively higher proportion of having paid PC claims. Whether a pharmacy provider had one or more paid PC claims was significantly associated with pharmacy type ($\chi^2, p=0.0002$).

For the pharmacy providers in urban areas and rural areas, 31.1 percent and 29.3 percent, respectively, had at least one paid PC claim during the study period. There was no significant association between location and having at least one paid PC claim.

Table 5.25. Distribution of the pharmacy providers with seven-year continued enrollment in Wisconsin Medicaid program between FY 1997 and FY 2003 by type and location

	Number of pharmacy providers that had at least one paid PC claim	Number of pharmacy providers that had no paid PC claims
By Type		
Chain	78 (25.6%)	227 (74.4%)
Hospital Outpatient/Clinic	37 (26.6%)	102 (73.4%)
Independent	120 (38.5%)	192 (61.5%)
HMO/Managed Care	0	0
LTC facility	2 (8.7%)	21 (91.3%)
Unknown	0	6
By Location		
Urban	145 (31.1%)	321 (68.9%)
Rural	92 (29.3%)	222 (70.7%)
Unknown	0	5
Total	237	548

Table 5.26 through Table 5.28 provide the results from longitudinal data analyses using the GEE approach. Table 5.26 summarizes the results of a GEE model examining the factors associated with having paid PC claims. The dependent variable was a binary outcome, with one representing that a pharmacy had at least one PC claim, and with zero indicating otherwise. A logit link function was used for binary outcomes. If b is the coefficient of an independent variable X , then $\exp(b)$ is the odds ratio corresponding to a one unit change in X .

The researcher considered three situations: six, nine, or 84 observations for each pharmacy provider. Results from all three models suggest that the effect of POS significantly depends on the time after POS. The effect of POS on whether a pharmacy provider had at least one paid PC claim increased with time after POS started. The effect of PDUR also depends on the time after PDUR. In contrast, whether a pharmacy provider had at least one paid PC claim decreased with time after PDUR began.

Table 5.26 shows that chain pharmacy providers had a significantly lower probability of having paid PC claims compared to independent pharmacy providers (odds ratio <1). Pharmacy providers in urban areas had a significantly lower probability of having paid PC claims compared with those in rural areas (odds ratio <1).

Table 5.26. Comparison of GEE parameter estimates from the models for whether Medicaid pharmacy providers had paid PC claims by changing number of observations per pharmacy (n=237 pharmacies)

Dependent variable: Pharmacy had paid PC claims (y=1) or not (y=0)			
	6 OBS	9 OBS	84 OBS
Time	-.952*** (.138)	-.353*** (.057)	-.029*** (.006)
POS	-1.709*** (.311)	-1.162** (.302)	-.268 (.212)
PDUR	.614** (.275)	.095 (.202)	-.070 (.117)
POS*time after POS	2.054*** (.240)	1.425*** (.194)	.111*** (.017)
PDUR*time after PDUR	-1.598*** (.257)	-1.319*** (.208)	-.099*** (.018)
Type			
Chain	-.498** (.145)	-.389** (.149)	-.852** (.244)
Hospital outpatient /clinic	-.143 (.183)	-.087 (.189)	-.169 (.248)
LTC	.771 (1.674)	.282 (1.463)	-1.365 (2.270)
Independent	-	-	-
Location			
Urban	-.386** (.146)	-.323** (.146)	-.392* (.205)
Rural	-	-	-
Number of Medicaid prescriptions	.000 (.000)	.000 (.000)	.0002 (.0002)

Note:

- 1) Analysis of GEE parameter estimates are shown in the table with empirical standard errors estimates in parentheses.
- 2) Link function: logit.
- 3) Correlation structure: AR(1).

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.27 presents the estimated coefficients of the Poisson GEE models for factors associated with the number of paid PC claims. The dependent variable was the number of paid PC claims during a time period. A log link function was used with a Poisson distribution specified when the researcher fitted the models. The offset variable was log of the total number of months included at each data point. If b is the coefficient of an independent variable X , then $\exp(b)$ expresses the incidence density ratio corresponding to a one unit change in X – in a similar manner to exponentiating parameters in logistic regression to obtain odds ratios.

The researcher considered three situations: six, nine, or 84 observations for each pharmacy provider. Results from all three models suggest that the effect of POS significantly depends on the time after POS. The effect of POS on the number of paid PC claims increased with time after POS started. The effect of PDUR also depends on the time after PDUR except the situation with 84 observations for each pharmacy provider. The effect of PDUR on the number of paid PC claims decreased with time after PDUR began.

Both chain and LTC pharmacy providers had a significantly lower number of PC claims compared to independent pharmacy providers. Exponentiating the parameter estimate for the increment for chain pharmacies, $\exp(-1.727)=0.178$, indicates the ratio of the incidence of having one more paid PC claim for the chain pharmacy providers relative to the independent pharmacy providers. Lastly, the number of Medicaid prescriptions was a positively significant predictive factor in the models.

Table 5.27. Comparison of GEE parameter estimates from the models for the number of paid PC claims in each time period by changing number of observations per pharmacy (n=237 pharmacies)

Dependent variable: Number of paid PC claims per data point			
	6 OBS	9 OBS	84 OBS
Time	-.693*** (.114)	-.278*** (.054)	-.033*** (.005)
POS	-.642 (.529)	-.537 (.459)	.426 (.393)
PDUR	.079 (.218)	.176 (.143)	.137 (.172)
POS*time after POS	1.651*** (.285)	1.147*** (.263)	.086** (.029)
PDUR*time after PDUR	-.707** (.277)	-.664** (.231)	-.026 (.029)
Type			
Chain	-1.727*** (.393)	-1.604*** (.393)	-1.540*** (.360)
Hospital outpatient /clinic	-.854* (.504)	-.731 (.485)	-.563 (.393)
LTC	-6.413** (1.833)	-6.021** (1.628)	-6.098** (1.877)
Independent	-	-	-
Location			
Urban	-.649 (.577)	-.740 (.590)	-.841* (.504)
Rural	-	-	-
Number of Medicaid prescriptions	.000** (.000)	.0001** (.000)	.001** (.0001)

Note:

1) Analysis of GEE parameter estimates are shown in the table with empirical standard errors estimates in parentheses.

2) Link function: log.

3) Correlation structure: AR(1).

*** $p < .001$ ** $p < .05$ * $p < .10$

Table 5.28 displays the estimated coefficients of the Poisson GEE models for factors associated with the proportion of pharmacy participation in the WMPCP. The dependent variable was the proportion of months that pharmacies had at least one paid PC claim at each data point (observation), which was operationalized as the proportion of pharmacy participation. A log link function was used with a Poisson distribution specified when the researcher fitted the models. The offset variable was log of the total number of months included at each data point.

The researcher considered two situations: six, and nine observations for each pharmacy provider. The situation of 84 observations for each pharmacy provider was not included because there was only one month at each data point. Results from both models show that the effect of POS significantly depends on the time after POS. The effect of POS on the proportion of pharmacy participation increased with time after POS started. The effect of PDUR also depends on the time after PDUR. However, the effect of PDUR on the proportion of pharmacy participation decreased with time after PDUR began.

For pharmacy characteristics, chain pharmacy providers had a significantly lower proportion of participation in the WMPCP compared to independent pharmacy providers (incidence ratio=0.48 for the model with six observations and 0.58 for the model with nine observations). The number of Medicaid prescriptions was a significantly predictive factor in the models.

Table 5.28. Comparison of GEE parameter estimates from the models for the proportion of participation at each time point by changing number of observations per pharmacy (n=237 pharmacies)

Dependent variable: Proportion of months that pharmacies had PC claims per data point (proportion of participation)		
	6 OBS	9 OBS
Time	-.459*** (.109)	-.216*** (.049)
POS	-1.204*** (.265)	-1.087*** (.238)
PDUR	.098 (.125)	.169* (.102)
POS*time after POS	1.409*** (.203)	1.139*** (.159)
PDUR*time after PDUR	-1.163*** (.174)	-1.089*** (.152)
Type		
Chain	-.735** (.232)	-.553** (.213)
Hospital outpatient/clinic	-.124 (.224)	-.080 (.225)
LTC	-1.527 (1.600)	-1.460 (1.362)
Independent	-	-
Location		
Urban	-.240 (.176)	-.205 (.170)
Rural	-	-
Number of Medicaid prescriptions	.000** (.000)	.000** (.000)

Note:

- 1) Analysis of GEE parameter estimates are shown in the table with empirical standard errors estimates in parentheses.
- 2) Link function: log.
- 3) Correlation structure: AR(1).

*** $p < .001$ ** $p < .05$ * $p < .10$

CHAPTER 6

DISCUSSION

This chapter begins with a summary of the hypothesis tests conducted in this study. It then presents a discussion and interpretation of the results. Limitations of the study are also presented. Next, the chapter discusses the implications for policy makers, the pharmacy profession and future research. Finally, it closes with conclusions.

6.1 Summary of Hypothesis Testing

This section summarizes the hypothesis tests conducted in this study that included three primary research questions and eight hypotheses.

The first research question asked if POS and PDUR were associated with pharmacy participation in the WMPCP. Two corresponding hypotheses were:

H₁: Point-of-sale increased pharmacy participation.

H₂: Prospective drug utilization review increased pharmacy participation.

The results show that POS significantly increased the number of participating pharmacies over time after its inception, and PDUR significantly decreased the number of participating pharmacies. It is concluded that H₁ is supported and H₂ is not supported by the results.

The second research question asked if POS and PDUR were associated with the intensity of participation among participating pharmacy providers. Two corresponding hypotheses were:

H₃: Point-of-sale increased the number of paid pharmaceutical care claims.

H₄: Prospective drug utilization review increased the number of paid pharmaceutical care claims.

The results show that POS significantly increased the number of paid PC claims over time after its inception, and PDUR did not have any significant effect on the number of paid PC claims. It is concluded that H₃ is supported and H₄ is not supported by the results.

The third research question asked if POS and PDUR were associated with change in the composition of PC claims. Four corresponding hypotheses were:

H₅: Point-of-sale changed the composition of reasons.

H₆: Point-of-sale increased level (time) of pharmaceutical care services.

H₇: Prospective drug utilization review changed the composition of reasons.

H₈: Prospective drug utilization review increased level (time) of pharmaceutical care services.

The results show that both POS and PDUR significantly changed the composition of the reason codes of paid PC claims. The change mainly occurred between the general

reasons Drug Use: Patient Behaviors and Drug Choice. POS immediately increased the proportion of the general reason Drug Use: Patient Behaviors at its inception, and the increase faded gradually afterward. PDUR increased the proportion of the general reason Drug Use: Patient Behaviors over time. H_5 and H_7 are supported by the results.

The results also show that both POS and PDUR significantly decreased the proportion of level codes associated with longer service time. POS significantly transferred the level 16-30 minutes to the level 6-15 minutes. PDUR significantly decreased the proportion of the level 31-60 minutes. H_6 and H_8 , therefore, are not supported by the results.

6.2 Pharmacy Participation

Overall, about one-fifth of Medicaid pharmacy providers participated in the WMPCP. The low percentage of pharmacy participation in providing PC services is consistent with the findings of existing literature.¹⁸⁻²⁶ However, the increase in the mean number of paid PC claims per participating pharmacy over time suggests that the pharmacy providers that participated had developed systems to incorporate providing PC services and getting paid from the WMPCP into the routine of practice in the pharmacy. This is an important finding for the future of pharmacy profession to observe the routinization of providing and billing for PC services. Future research could examine what aspects of changes in the pharmacy practice environment have promoted the routinization of providing and billing for pharmacists provided PC services.

Pharmacy participation in the WMPCP was associated with type of pharmacy. The results show that independent pharmacies had higher participation rates relative to other types of pharmacies, which is consistent with past research.³⁸ The average number of paid PC claims per participating pharmacy was higher in independent pharmacies relative to chains and hospital outpatient/clinic pharmacies. The number was higher in rural pharmacies relative to urban pharmacies. Both of these results are also consistent with past research.^{38,63} One explanation is that independent pharmacies and rural pharmacies were more likely to offer patient-centered services and had better relationships between the pharmacist and the patients.¹⁰⁵ As a result, patient loyalty may be higher and this gives pharmacists the desire to provide more PC services to patients. Recent studies have also found that independent pharmacies had a higher number of pharmacists on duty that was associated with more pharmacy services being offered, and had a lower daily prescription workload that contributed to more time spent in PC services.^{106,107} Additional studies are needed to further examine the reasons behind the differences among different pharmacy types.

LTC pharmacies had the highest average number of paid PC claims per pharmacy across all pharmacy types in this study. One explanation is that patients staying in the LTC facility were likely to be sicker and use more prescription drugs that demanded more PC services.

A low proportion of participation was prevalent among the pharmacies that ever participated in the WMPCP. This was assessed from calculating the number of months that participating pharmacies were actually paid for at least one PC claim. More than

one-fourth of participating pharmacies only participated in one month and never participated again across the seven-year period. The results show that those were more likely to be chain pharmacies. The percentage of one-month participation was higher in urban pharmacies relative to rural pharmacies. Both findings suggest that pharmacy type and geographic location were factors associated with the proportion of pharmacy participation across the study period.

A small number of participating pharmacies was paid for a considerable concentration of PC claims over numerous months. Of the top 11 pharmacies in terms of the PC claim volume, most (72.7 percent) were independent pharmacies. Most of these top 11 pharmacies also had the highest number of months with paid PC claims among 387 participating pharmacies in the WMPCP. The comparison between the top 11 pharmacies and the pharmacies with only one-month participation raises the question of sustainability of pharmacy participation in PC services, which is an important issue for policy makers, the pharmacist, and the patient. Additional research could examine how to engage pharmacists in constantly providing PC services and billing for reimbursement from the experience that the top 11 pharmacies had to offer.

6.3 Characteristics of Pharmaceutical Care Claims

The original reason codes were categorized to reflect the problems related to patient's compliance (Drug Use: Patient Behavior), the problems related to prescription (Drug Choice), and the problems with drug use (Drug Use Issues/Problems). Patient related problems, both in the form of patient behavior and drug use issues/problems, were

the most common reason for pharmacists to provide PC services (67.0 percent of all paid PC claims), and the results are in agreement with past research.⁶⁴ These results suggest that patient compliance with medication regimen were an issue in drug therapy. The results also suggest that pharmacists were able to identify patient related problems and were willing to take care of those problems in addition to handling the prescription drug.

In general, PC services consumed a relatively small amount of pharmacists' time (6-15 minutes), suggesting that not much time was taken away from the busy activities of pharmacy practice in the pharmacy. This can be an informative message to pharmacists and have pharmacists not panic about the amount of time needed for PC services in their busy schedule.

6.4 Effects of Point-of-Sale and Prospective Drug Utilization Review

To investigate the effects of POS and PDUR, the researcher applied the segmented regression model to analyze time series data. The advantage of using the segmented regression model is that the model can examine change in level and change in slope of outcome measures in a time series. A change in level is a jump or drop in the outcome measures after the policy change, which indicates an immediate effect of the policy change; a change in slope is an increase or decrease in the slope after the policy change in comparison with the slope before the policy change and represents a gradual change over time.

Overall, the results suggest that neither POS nor PDUR had any significant and *immediate* effect on the number of participating pharmacies per month and the number of

PC claims per month. Instead, POS and PDUR showed *sustained* effects on these two outcome measures. The number of participating pharmacies increased about 3 per month after POS began and before PDUR, and it decreased about 3 per month after PDUR began. The results suggest that because the magnitude of the effects of POS and PDUR were similar but in opposite value, the total increase in the number of participating pharmacies due to POS vanished about 19 months after PDUR began.

POS had a sustained effect on the number of PC claims per month, adding approximately 14 PC claims every month after its inception. The trend line of the number of PC claims per month remained an identical increasing pattern after PDUR began, because PDUR did not show any significant effects to change the level or the slope of the trend line.

It was surprising to discover PDUR decreased the number of participating pharmacies and did not have significant effects on the number of PC claims. It was hypothesized that PDUR could help pharmacists identify potential drug therapy problems when dispensing prescriptions to the patient; thus, more Medicaid pharmacy providers would participate and have more PC claims. To obtain opinions from community pharmacists' perspective, the researcher visited Medicine Shoppe, a community pharmacy in Two Rivers, Wisconsin that has been among the pioneers of providing PC services in years, and talked with its manager/owner Pharmacist Marvin Moore. From Dr. Moore's experiences of pharmacy practice, unlike POS in making the claim submission process easier, PDUR in fact hindered pharmacists from submitting PC claims due to the complexity of the program design.

A couple of examples can explain why PDUR might decrease pharmacy participation in the WMPCP. When a drug interaction alert message came up in a claim submission process, and the pharmacist realized that the alert message was false positive because the patient was not currently taking any other medications that could possibly cause a drug interaction with present prescription drug, if the pharmacist chose to override the message, still dispensing the prescribed medication, in that case, no PC claim could be submitted. Another example is when the real drug therapy problem with a prescribed medication was different from the false positive drug interaction alert message, the pharmacist could not submit a PC claim associated with that particular medication because the pharmacist overrode the alert message, even if a patient education was given for patient's sub-optimal compliance problem. In that case, the opportunity of submitting a PC claim was taken away from the pharmacist by PDUR.

In the occasions that pharmacists could address the alert messages from PDUR to the WMPCP, it happened that pharmacists were still not able to submit any PC claims because they could not comprehend the system. These three examples demonstrate that under many circumstances, pharmacists would get rejections back from the WMPCP for their PC claims submission. Frustrated by the system, many pharmacists simply gave up, eventually quitting the WMPCP.

Since the inception of the WMPCP, the trend line of the number of participating pharmacies was gradually decreasing before POS possibly because pharmacists were tired of tedious paper work and complicated PC claim submission system. In the period of after POS and before PDUR, some pharmacists were encouraged by the convenience

that POS offered to submit claims electronically, resulting in a temporary increase in the number of participating pharmacies. After PDUR began, pharmacies encountered more and more problems when dealing with the WMPCP as well as the alert messages. Those problems eventually accumulated enough frustrations for some pharmacies to quit the program completely. Other pharmacies were able to comprehend the system of the WMPCP, having more paid PC claims over time. Previously, the results from descriptive statistics showed that the concentration of paid PC claims per participating pharmacy became higher over time. Because the overall increase in the number of paid PC claims from pharmacies remaining in the program outweighed the overall loss of the number of paid PC claims from pharmacies that quit, no effects of PDUR on the number of paid PC claims were observed in data analysis.

Similar conclusions about the effects of POS and PDUR can be drawn from the results of subgroup analysis across different pharmacy types or locations except LTC pharmacies. When the dependent variable was the number of PC claims per month, neither POS nor PDUR showed any significant effects on the outcome measure of LTC pharmacies. The average number of paid PC claims per LTC pharmacy was the highest when comparing to the number of paid PC claims per pharmacy from different types of pharmacies (see Table 5.3). Only nine LTC pharmacies (5.2 percent) were paid for at least one PC claim across seven fiscal years (see Table 5.2). Having no significant effects from POS and PDUR on the number of PC claims per month suggests that it was not easy to have LTC pharmacies participate in the WMPCP. However, once those

pharmacies started to participate, the intensity of their participation was high regardless of any policy changes.

When comparing the size of estimated coefficients among different pharmacy types, POS and PDUR had larger effects on the number of participating pharmacies per month from chain and independent pharmacies. POS increased the number of PC claims per month more for independent pharmacies than for other types of pharmacies, suggesting that independent pharmacies responded to POS better than other pharmacies. When comparing the size of estimated coefficient among different locations, all were similar but the sustained effects that POS had on urban and rural pharmacies. POS increased the number of participating pharmacies per month in urban area about 2.5 times as many as that in rural area. This suggests that urban pharmacies welcomed POS as a convenient tool for claim submission process more than rural pharmacies did due to a more serious concern about limited time for PC services that urban pharmacies had.

POS and PDUR also changed the composition of PC claims. The results of time series analysis of general reason codes show that in general more PC claims were submitted by pharmacists for the reason Drug Use: Patient Behaviors after the implementation of POS and PDUR, and these gains were mainly from the reduction in the reason Drug Choice. These results have important implications because they suggest that pharmacists focused more on patient related problems (Drug Use: Patient Behavior) than prescription related issues (Drug Choice). Pharmacists were addressing patient related drug use problems over time -- it may be an indication of pharmacists revealing more humanitarian component of pharmacy practice and providing more patient-centered

services. The results also suggest that over time, patient compliance problem remained an issue and relied on pharmacists' assistance for correction. Physicians, on the other hand, may have learned from experience when pharmacists contacted them for the reason Drug Choice and modified the prescribing behavior over time, resulting in a decrease in the number of paid PC claims that were associated with the reason Drug Choice.

The results from the time series analysis of the length of service time (level) codes show that POS had immediate effects on the level codes of 6-15 minutes and 16-30 minutes, and PDUR had an immediate effect on the level code of 31-60 minutes. Both POS and PDUR changed the composition of level codes in PC claims by reducing the proportion of the level codes associated with longer service time. The estimated coefficients of segmented regression models across level codes suggest that the level code 6-15 minutes became more frequent over time after policy changes, and this length of service time code was consistent with the average amount of time spent providing PC services in past research.^{38, 63} Overall, the results from data analysis for changes in the composition of PC claims suggest that solving patient-related problems may not have to be a time-consuming task. The pharmacist, for example, can spend a relatively short time to improve patient's compliance to prescription drugs, and this is an important message for pharmacists who have concern about their limited time for providing PC services. More research is needed to better understand the dynamic between the reason and the length of service time in the WMPCP.

Two kinds of sensitivity analysis were performed to examine the robustness of the findings. The first was changing the time point when POS and PDUR started to take

effect, and the second was using bi-monthly data points instead of monthly data points for data analysis. Wisconsin Medicaid implemented POS in September 1999 and PDUR in February 2001, and it was assumed that the time of inception was one definite time point used to create segments for the segmented regression model. The first sensitivity analysis aimed to assess the influence of this assumption. The results show that consistent conclusions stated above can be reached from three regression models using the original time series data, the time series data with the first month excluded since policy inception, and the time series data with the first two months excluded since policy inception, respectively.

The second sensitivity analysis tried to assess the influence of the time interval between successive data points on findings. The results show that consistent conclusions stated above can be reached from two regression models using monthly time series data and bi-monthly time series data, respectively, except when the dependent variable was the number of PC claims per data point. When using monthly time series data, the researcher found POS had a significantly positive effect on the number of PC claims over time. The researcher found no significant effects from either POS or PDUR when using bi-monthly time series data. This was the consequence of having larger standard errors in the regression model when fewer time series data points were used. The results suggest that the conclusions about the sustained effects of POS on the number of PC claims should be drawn with caution. The trend line of the number of PC claims per month shows wide fluctuations between the period after POS and before PDUR, suggesting that

using monthly data points for hypothesis testing was appropriate because monthly data points could better catch those fluctuations over time.

6.5 Effects of the Characteristics of Pharmacy Providers

The secondary objective of this study was to examine whether characteristics of pharmacy providers influence pharmacy participation in the WMPCP. To achieve this goal, the GEE method was applied to perform longitudinal data analysis for a panel data set consisting of a sample population of 237 pharmacies. According to Fisher's exact tests, the sample population appeared to be different from other Wisconsin Medicaid pharmacy providers. It is, therefore, questionable to generalize the findings from the longitudinal data analysis to all Wisconsin Medicaid pharmacy providers between fiscal years 1997 and 2003.

The results show that among those 237 pharmacies, chain pharmacy providers were less likely to participate in the WMPCP compared to independent pharmacies. Participating chain pharmacy providers were less likely to have more paid PC claims and less likely to have more months with paid PC claims when comparing with independent pharmacy providers. LTC pharmacies were also found to have fewer incidences of having one more paid PC claim when comparing to independent pharmacies. These results are again in agreement with past research, suggesting that independent pharmacy providers had higher pharmacy participation in PC services and higher intensity of providing PC services than other pharmacy types.^{63, 67, 68}

Urban pharmacy providers had lower participation rates in the WMPCP relative to rural pharmacy providers, and this is consistent with past research.^{63, 68} However, once urban pharmacies participated, the intensity of their participation showed no difference from their counterpart. Also consistent with past research is the finding that the number of paid PC claims and the number of months with paid PC claims were higher in pharmacies with higher volume of Medicaid prescriptions.^{63, 67} One possible explanation is that higher volume of Medicaid prescriptions presented more opportunities for pharmacists to provide PC services, especially for those pharmacists who were willing to participate.

In this part of longitudinal data analysis, the researcher performed sensitivity analysis using different numbers of repeated measures per pharmacy to test the robustness of the findings. The results show that one can obtain similar conclusions from the regression models using different data sets.

6.6 Limitations

Although efforts have been made to ensure the integrity of the study, certain inherent limitations remained. One limitation comes from the study design. An interrupted time series design can deal with all single-group threats to internal validity except the history threat. This problem may seem serious because any observed effects may be due to other concurrent events and beyond the exposure to the intervention of interest. Although this is a potential limitation in the study, little evidence suggests the

existence of other factors (e.g., state laws or regulations changes) that may significantly change pharmacy participation in the WMPCP.

Some limitations are from the data. A common concern with administrative databases is that they do not provide information about “non-users.” In the WMPCP claims database, if pharmacy providers provided pharmaceutical care services to Medicaid fee-for-service recipients but did not bill the Medicaid program for reimbursement, that piece of information is not captured. It remains unclear how frequent this occurred in the study population.

The variable containing date of service was used to determine when PC claims occurred for data analysis; however, this variable does not necessarily reflect the actual date of PC service. When a PC service is completed on a day different from date the drug involved was dispensed, the PC service should be documented as occurring on the actual date the service occurred but the PC claim may be billed in conjunction with the drug on the date the drug was actually dispensed. It is unknown that how frequent the discrepancy happened when pharmacists submitted PC claims.

Limited information regarding pharmacy characteristics was available. This is another common concern with secondary databases – researchers may not have all variables they need for studies. Besides pharmacy type, Medicaid claims volume, and geographic location, other pharmacy characteristics may also influence pharmacy participation in the WMPCP, such as management style within the pharmacy organization, employment status of the pharmacist (part-time versus full-time employees), staffing^{11, 106} etc. Additional research with these potential factors, if available, would

enhance the understanding about the findings of this study. Specifically, it could help answer why differential patterns in providing PC services among different types of pharmacies were observed.

Information regarding disease states of patients was not available. This limited the capacity of the study to evaluate the effects of two policy changes on pharmacy participation in pharmaceutical care services to patients with clinically significant diseases such as diabetes or asthma or arthritis. Policy changes increased pharmacy participation in the WMPCP, but it was unclear whether more pharmaceutical care claims meant that more pharmaceutical care services were provided to those in need. It would be helpful if this piece of clinical information was available.

To combat this deficit, one approach is to look at drugs associated with the pharmaceutical care claims, and to decide the disease state of those claims based on specific drug use. Unfortunately, the fact that either some claims contained incomplete drug information or some were associated with multiple drugs diminished the feasibility of this approach. Nevertheless, the quality aspect of pharmacy participation could be to some extent captured by analyzing the composition of reason and level codes of pharmaceutical care claims paid.

Another possible limitation of the data relates to reason and level codes. Although it was assumed that every pharmacist interpreted the meaning of codes in exactly the same way and assigned codes correctly when submitting pharmaceutical care claims, little evidence was available to assure the consistency of interpretation behaviors across different pharmacy providers. The approach used in the study to categorize codes

into groups, however, may limit this problem because of the broad nature of the grouping strategy.

6.7 Implications of the Study

In spite of the intrinsic limitations, suggestions can be made to promote understanding about pharmacy participation in providing PC services. Previous studies of the pharmacy profession regarding implementation of PC services focused on two major dimensions: surveying rates of pharmacy participation in PC services or identifying barriers (sometimes facilitators) to implementing PC services.^{28,40,41} This study investigated the issue of implementation of PC services from a different angle, and it examined the relationships between pharmacy participation and barriers to implementing PC services. The findings of this study make contributions to the current understanding about implementation of PC services, and also have significant implications for policy makers, pharmacy profession and future research.

6.7.1 Implications for Policy Makers

When POS and PDUR began, the Wisconsin Medicaid program expected POS and PDUR would encourage more pharmacies to bill for PC service.⁶² This study found that POS increased pharmacy participation as well as the intensity of participation. However, PDUR decreased pharmacy participation. It is evident that the findings do not meet Wisconsin Medicaid's initial expectation for PDUR, and this suggests the

importance of program evaluation and communication between policy makers and pharmacy providers for the construction of policies.

It is speculated that the negative effects of PDUR on pharmacy participation were likely to result from the poor design of the computerized alert system, so pharmacists eventually gave up submitting PC claims to the WMPCP. This is the consequence of poor communication between policy makers and pharmacists before the implementation of policy changes. In light of the study, policy makers are encouraged to critically evaluate the context of the issue of interest in order to construct a new policy or intervention from which every stakeholder can benefit. The PDUR alert system may be better designed to avoid the occurrence of pharmacists' frustrations and the negative effects of PDUR, if Wisconsin Medicaid had better understanding about, for example, what pharmacists needed and how their practice activities worked.

Currently, the Centers for Medicare and Medicaid Services provide prescription drug coverage under the Medicare Modernization Act of 2003. This long-awaited program creates exciting new opportunities for pharmacists to develop and get reimbursed for PC services for Medicare beneficiaries from the MTM (Medication Therapy Management) program. Policy makers certainly will benefit from communication among stakeholders for a well-designed policy. They will also benefit from studies that evaluate the effects of the program or policy changes for ongoing improvement of the program.

6.7.2 Implications for the Pharmacy Profession

This study is the third comprehensive assessment of a public pharmaceutical care reimbursement program after the studies for the Washington CARE (Cognitive Activities and Reimbursement Effectiveness) project and the Iowa PCM (Pharmaceutical Case Management) program. More research on pharmaceutical care reimbursement program is needed by pharmacy profession because research findings can enhance current knowledge of implementation of PC services.

It is also the first study to examine the associations of pharmacy participation and POS and PDUR. The findings of POS having positively sustained effects on pharmacy participation in providing PC services send an important message to the pharmacy profession, suggesting possibilities of engaging pharmacists in PC services with some changes in practice exist.

For the pharmacy profession, the negative effects of PDUR on the number of participating pharmacies in the WMPCP provoke considerations for the usefulness of PDUR alert messages. Whether PDUR should be implemented in PC reimbursement programs or how to improve the design of PDUR to positively assist pharmacists in PC services is a significant issue, because pharmacy profession can be well established by having more pharmacists involved in providing PC services and helping improve patient's health outcomes.

6.7.3 Implications for Future Research

Several of the results obtained in the current study may be worthy of further investigation by policy analysts and health services researchers. This study unexpectedly found that PDUR had negative effects on pharmacy participation. Although the researcher suspects that it might be due to a complex design of the WMPCP and PDUR alert system that frustrated some pharmacies in attempting PC claim submission, reasons behind this finding are still under speculation. The study also found that other pharmacies somewhat became familiar with the system and had more paid PC claims over time. Reasons behind these differential patterns of pharmacy participation can be the key to the future success of similar PC reimbursement programs. Future research projects might investigate this issue within community pharmacies to discover the truth.

Other interesting findings include changes in proportions of general reason codes and level of service time for PC. Why more paid PC claims were associated with patient compliance problems and/or shorter length of service time after POS and PDUR remains unclear. The WMPCP has regulations for some specific reason codes to be used with certain level codes, and whether and how those regulations had any effects on the changes in proportion of reason codes and level of service time should be explored further in future research. The findings have implications for the quality aspect of PC services provided by pharmacists that ultimately lead to the improvement of health outcomes of population.

Consistent with previous observational studies, this study found pharmacy characteristics were associated with the likelihood of implementing PC services.

However, the speculations provided in these studies about why independent pharmacies or rural pharmacies were more likely to participate in PC services are not necessarily sufficient and more research is needed. Understanding the reasons behind the discrepancies of pharmacy responses to implementation of PC services will help policy makers and pharmacy profession to find the solutions to address this issue.

Another implication for future research is the application of time series analysis and panel data analysis. As mentioned in the chapter of literature review, time series analysis, in particular, was rarely applied in pharmacy research due largely to its complexity. Routinely maintained medication use and other health care records, as well as cost data are commonly used sources of time series data, and appropriate analysis plans should be warranted. Segmented regression analysis provides an easy alternative to analyzing time series data. This study is a demonstration of how to apply segmented regression analysis to evaluate policy changes using an interrupted time series design.

The GEE method used in this study has another methodological implication for future research. When a continuous enrolled cohort for the whole study period is available, longitudinal data analyses at the individual level is preferred. In policy evaluation studies, researchers usually do not have continuous enrollment and thus time series analysis at an aggregate level is more appropriate. This is why this study performed time series analysis for primary research questions and longitudinal data analysis using the GEE method for secondary research questions among a subgroup of the study population. The GEE method is a population-average model approach and is not the only method for longitudinal data analysis. Min and Agresti suggested a subject-

specific model approach specifically for repeated measures of zero-inflated count data that suits the needs of this study.¹⁰⁸ This approach can model associations between independent variables and dependent variables at subject-specific level and provide coefficient estimates from a different perspective. Unfortunately, the researcher failed to obtain estimates when applying this approach due to extremely large numbers of zeros in the data set. If data with a better profile is available for the study, this approach can be applied to examine the associations between pharmacy characteristics and outcomes measures.

6.8 Conclusions

The goals of this study were to provide a program evaluation for the WMPCP and better understand how POS, PDUR and pharmacy characteristics were associated with pharmacy participation in the WMPCP. The study was conducted in a retrospective, interrupted time series design and used administrative data sets for evaluation.

The study found that rates of pharmacy participation in PC services remained low. Approximately one-fifth of Medicaid pharmacy providers participated in the WMPCP. The mean number of paid PC claims per participating pharmacy increased over time, suggesting that pharmacies might have developed some systems to incorporate providing and billing for PC services from the WMPCP into the routine of practice.

The results show that both POS and PDUR had significant and sustained effects on pharmacy participation. The number of participating pharmacies increased over time after POS began and decreased over time after PDUR began. Similar effects from POS

and PDUR could be found across pharmacy types and locations. When the intensity of pharmacy participation among participating pharmacies was evaluated, only POS showed a significantly positive effect on the number of paid PC claims. The results also show that after POS and PDUR implementation, pharmacists focused more on patient related problems, suggesting they covered more humanitarian component of pharmacy practice. POS and PDUR increased the proportion of paid PC claims associated with shorter length of service time for PC services.

The associations between pharmacy characteristics and pharmacy participation and the intensity of participation were examined within a subgroup of the study population using the GEE method for modeling. The subgroup included 237 participating pharmacies with continued eligibility between fiscal years 1997 and 2003 in the Wisconsin Medicaid program. It is evident that pharmacy type, location, and the volume of Medicaid prescriptions were significant factors predicting pharmacy participation and the intensity of participation.

This study raises a more general question about whether and under what circumstances pharmacy participation in PC services can be promoted to a higher level. The study has explored this question within a limited area (that is, evaluating the effects of policy changes on pharmacy participation in the WMPCP) and calls for additional work in this area for a better understanding.

REFERENCES

1. Hepler CD. The future of pharmacy: Pharmaceutical care. *Am Pharm.* 1990; NS30: 23-29.
2. Hepler CD. Pharmaceutical care. *Pharmacy World & Science.* 1996;18: 233-235.
3. Mikeal RL, Brown TR, Lazarus HL, Vinson MC. Quality of pharmaceutical care in hospitals. *Am J Hosp Pharm.* 1975; 32: 567-574.
4. Brodie DC, Parish PA, Poston JW. Societal needs for drugs and drug-related services. *Am J Pharm Educ.* 1980; 44: 276-278.
5. Hepler CD. The third wave in pharmaceutical education: The clinical movement. *Am J Pharm Educ.* 1987; 51: 369-385.
6. Hepler CD, Strand LM. Opportunities and responsibilities in pharmaceutical care. *Am J Hosp Pharm.* 1990; 47: 533-543.
7. Rupp MT, Kreling DH. The impact of pharmaceutical care on patient outcomes: What do we know? *Drug Benefit Trends.* 1997; 9: 35-47.
8. American Pharmaceutical Association Board of Trustees. *Am Pharm.* 1991; NS31(3): 29.
9. American Pharmacists Association. Practice Guidance Documents. Available at: http://www.aphanet.org/Content/NavigationMenu/PharmacyPractice/Pharmacy_Practice_Resources/default.htm. Accessed May 21, 2005.
10. Leape LL, Cullen DJ, Clapp MD, et al. Pharmacist participation on physician rounds and adverse drug events in the intensive care unit. [erratum appears in JAMA 2000 mar 8; 283(10): 1293]. *JAMA.* 1999; 282: 267-270.
11. Pauley TR, Magee MJ, Cury JD. Pharmacist-managed, physician-directed asthma management program reduces emergency department visits. *Ann Pharmacother.* 1995; 29: 5-9.
12. Kelso TM, Abou-Shala N, Heilker GM, Arheart KL, Portner TS, Self TH. Comprehensive long-term management program for asthma: Effect on outcomes in adult african-americans. *Am J Med Sci.* 1996; 311: 272-280.

13. Munroe WP, Kunz K, Dalmady-Israel C, Potter L, Schonfeld WH. Economic evaluation of pharmacist involvement in disease management in a community pharmacy setting. *Clin Ther.* 1997; 19: 113-123.
14. Sczupak CA, Conrad WF. Relationship between patient-oriented pharmaceutical services and therapeutic outcomes of ambulatory patients with diabetes mellitus. *Am J Hosp Pharm.* 1977; 34: 1238-1242.
15. Borgsdorf LR, Miano JS, Knapp KK. Pharmacist-managed medication review in a managed care system. *Am J Hosp Pharm.* 1994; 51: 772-777.
16. Bluml BM, McKenney JM, Cziraky MJ. Pharmaceutical care services and results in project IMPACT: Hyperlipidemia. *J Am Pharm Assoc (Wash).* 2000; 40: 157-165.
17. Morton MR, Spruill WJ, Cooper JW. Pharmacist impact on pneumococcal vaccination rates in long-term-care facilities. *Am J Hosp Pharm.* 1988; 45:73.
18. Carroll NV, Gagnon JP. The relationship between patient variables and frequency of pharmacist counseling. *Drug Intell Clin Pharm.* 1983; 17: 648-652.
19. Eng HJ, Bulfer, Doering PL, Kimberlin CL. Assessment of the florida pharmacist self-care consultant law using a trained shopper method. *J Pharm Mark Manage.* 1991; 5: 27-52.
20. Lamsam GD, Kropff MA. Community pharmacists' assessments and recommendations for treatment in four case scenarios. *Ann Pharmacother.* 1998; 32: 409-416.
21. Svarstad BL, Bultman DC, Mount JK. Patient counseling provided in community pharmacies: Effects of state regulation, pharmacist age, and busyness. *Journal of the American Pharmacists Association: JAPhA.* 2004; 44: 22-29.
22. Kirking DM. Pharmacists' perceptions of their patient counseling activities. *Contemp Pharm Pract.* 1982; 5: 230-238.
23. Laurier C, Archambault A, Contandriopoulos AP. Communication of verbal information by community pharmacists. *DICP.* 1989; 23: 862-868.
24. Morris LA. A survey of patients' receipt of prescription drug information. *Med Care.* 1982; 20: 596-605.

25. Perri M, Kotzan J, Pritchard L, Ozburn W, Francisco G. OBRA '90: The impact on pharmacists and patients. *Am Pharm*. 1995; NS35: 24-28.
26. Wiederholt JB, Clarridge BR, Svarstad BL. Verbal consultation regarding prescription drugs: Findings from a statewide study. *Med Care*. 1992; 30: 159-173.
27. Schommer JC, Pedersen CA, Doucette WR, Gaither CA, Mott DA. Community pharmacists' work activities in the united states during 2000. *J Am Pharm Assoc*. 2002; 42: 399-406.
28. McDonough RP, Rovers JP, Currie JD, Hagel H, Sobotka J. Obstacles to the implementation of pharmaceutical care in the community setting. *J Am Pharm Assoc*. 1998; 38: 87-95.
29. Miller MJ, Ortmeier BG. Factors influencing the delivery of pharmacy services. *Am Pharm*. 1995; NS35: 39-45.
30. Armstrong EP, Markson TJ. On-line DUR messages: Pharmacists' attitudes and actions in response. *J Am Pharm Assoc*. 1997; NS37: 315-320.
31. Gruda B. Pharmaceutical care or business as usual. *J Am Pharm Assoc*. 1996; NS36: 544.
32. Martin S. Teaching pharmacists to provide and bill for clinical services. *Am Pharm*. 1990; NS30: 24-26.
33. Nightengale B, Reeder CE. The financial impact of OBRA-90 on community pharmacies: An overview. *Clin Ther*. 1993; 15: 581-592.
34. Norwood GJ, Sleath BL, Caiola SM, Lien T. Costs of implementing pharmaceutical care in community pharmacies. *J Am Pharm Assoc*. 1998; 38: 755-761.
35. Sansgiry SS, Sikri S, Kawatkar A. Consumer knowledge and perceptions of formularies. *Manag Care Interface*. 2004; 17: 21-26.
36. Schatz R, Belloto RJ, Jr, White DB, Bachmann K. Provision of drug information to patients by pharmacists: The impact of the omnibus budget reconciliation act of 1990 a decade later. *Am J Ther*. 2003; 10: 93-103.
37. Snella KA, Trewyn RR, Hansen LB, Bradberry JC. Pharmacist compensation for cognitive services: Focus on the physician office and community pharmacy. *Pharmacotherapy*. 2004; 24: 372-388.

38. Christensen DB, Holmes G, Fassett WE, et al. Influence of a financial incentive on cognitive services: CARE project design/implementation. *J Am Pharm Assoc (Wash)*. 1999; 39: 629-639.
39. Mott D.A., Kreling D.H., Hermansen-Kobulnicky C., Chou C.H. Medicaid pharmaceutical care program. *JPSW*. 2005; March/April: 12-16.
40. Raisch DW. Barriers to providing cognitive services. *Am Pharm*. 1993; NS33: 54-58.
41. Odedina FT, Segal R, Hepler CD, Lipowski E, Kimberlin C. Changing pharmacists' practice pattern: Pharmacists' implementation of pharmaceutical care factors. *Journal of Social & Administrative Pharmacy*. 1996; 13: 74-88.
42. John P. Rovers et al., ed. *A Practical Guide to Pharmaceutical Care*. 2nd ed. ed. Washington, D.C.: American Pharmaceutical Association; 2003.
43. Bell HM, McElnay JC, Hughes CM, Woods A. Qualitative investigation of the attitudes and opinions of community pharmacists to pharmaceutical care. *Journal of Social & Administrative Pharmacy*. 1998; 15: 284-295.
44. Venkataraman K, Madhavan S, Bone P. Barriers and facilitators to pharmaceutical care in rural community practice. *Journal of Social & Administrative Pharmacy*. 1997; 14: 208-219.
45. van Mil JW, Tromp TF. Pharmaceutical care in the netherlands. history, definition and projects. *Pharmacy World & Science*. 1996; 18: 237-240.
46. Odedina FT, Segal R, Hepler CD. Providing pharmaceutical care in community practice: Differences between providers and non-providers of pharmaceutical care. *Journal of Social & Administrative Pharmacy*. 1995; 12: 170-180.
47. Rossing C, Hansen EH, Krass I. Barriers and facilitators in pharmaceutical care: Perceptions and experiences among danish community pharmacists. *Journal of Social & Administrative Pharmacy*. 2002; 19: 55-64.
48. Barnes JM, Riedlinger JE, McCloskey WW, Montagne M. Barriers to compliance with OBRA'90 regulations in community pharmacies. *Ann Pharmacother*. 1996; 30: 1101-1105.
49. Tully MP, Seston EM. Impact of pharmacists providing a prescription review and monitoring service in ambulatory care or community practice. *Ann Pharmacother*. 2000; 34: 1320-1331.

50. Schommer JC, Wiederholt JB. Pharmacists' perceptions of patients' needs for counseling. *Am J Hosp Pharm.* 1994; 51: 478-485.
51. Smith WE, Ray MD, Shannon DM. Physicians' expectations of pharmacists. *American Journal of Health-System Pharmacy.* 2002; 59: 50-57.
52. American Pharmacists Association, ed. *Understanding Medicare Reform: What Pharmacists Need to Know.* 2004.
53. State of Mississippi. Medicaid Provider Policy Manual. Available at: http://www.dom.state.ms.us/Provider/Provider_Manuals/Section_31_Pharmacy.pdf. Accessed May 6, 2005.
54. Carter BL, Chrischilles EA, Scholz D, Hayase N, Bell N. Extent of services provided by pharmacists in the iowa medicaid pharmaceutical case management program. *J Am Pharm Assoc (Wash).* 2003; 43: 24-33.
55. Florida Medicaid Quality Related Events Program. Available at: <http://www.rxcaresystems.com/floridaqre/>. Accessed April 28, 2005.
56. Missouri Medicaid Disease Management Program. Available at: <http://www.heritage-info.com/mocaidrx/files/dm/Detailed%20DSM%20Descrip1.doc>. Accessed April 28, 2005.
57. Wyoming PharmAssist. Available at: <http://wdh.state.wy.us/pharmacy/wypharmassist.asp>. Accessed May 8, 2005.
58. Gillard M, Whitmore S. The wisconsin medicaid pharmaceutical care project. *Wisconsin Pharmacist.* 1996; May/June: 7-14.
59. National Council for Prescription Drug Programs. Available at: http://www.ncdp.org/main_frame.htm. Accessed June 30, 2005.
60. Vavra J. Wisconsin Medicaid's Pharmacy Program. Available at: <http://www.uwex.edu/ces/familyimpact/reports/fis16four.pdf>. Accessed June 16, 2005.
61. Mergener MA. Wisconsin's DUR program. *JPSW.* 2003; Jan/Feb: 15-19.
62. Professional Advocacy -- Wisconsin Medicaid's New Prospective Drug Utilization Review System. Available at: <http://pswi.org/professional/reimbursement/dur.htm>. Accessed June 12, 2005.

63. Christensen DB, Hansen RW. Characteristics of pharmacies and pharmacists associated with the provision of cognitive services in the community setting. *J Am Pharm Assoc (Wash)*. 1999; 39: 640-649.
64. Christensen DB, Neil N, Fasset WE, Smith DH, Holmes G, Stergachis A. Frequency and characteristics of cognitive services provided in response to a financial incentive. *J Am Pharm Assoc (Wash)*. 2000; 40: 609-617.
65. Chrischilles EA, Carter BL, Lund BC, et al. Evaluation of the iowa medicaid pharmaceutical case management program. *J Am Pharm Assoc (Wash DC)*. 2004; 44: 337-349.
66. Becker C, Bjornson DC, Kuhle JW. Pharmacist care plans and documentation of follow-up before the iowa pharmaceutical case management program. *Journal of the American Pharmacists Association: JAPhA*. 2004; 44: 350-357.
67. Chui, Rupp MT. Evaluation of online prospective DUR programs in community pharmacy practice. *Journal of Managed Care Pharmacy*. 2000; 6: 27-32.
68. Paluck EC, Stratton TP, Eni GO. Pharmacists and health promotion: Study of thirteen variables. *Journal of Social & Administrative Pharmacy*. 1996; 13: 89-98.
69. Campbell DT, Stanley JC. *Experimental and Quasi-Experimental Designs for Research*. Chicago: Rand McNally; 1963.
70. Cook TD, Campbell DT. *Quasi-Experimentation: Design and Analysis Issues for Field Settings*. Boston: Houghton Mifflin Company; 1979.
71. Royal College of Radiologists Working Party. Influence of royal college of radiologists' guidelines on referral from general practice. *BMJ*. 1993; 306: 110-111.
72. Ramsay CR, Matowe L, Grilli R, Grimshaw JM, Thomas RE. Interrupted time series designs in health technology assessment: Lessons from two systematic reviews of behavior change strategies. *Int J Technol Assess Health Care*. 2003; 19: 613-623.
73. Shadish WR, Cook TD, Campbell DT. *Experimental and Quasi-Experimental Designs for Generalized Causal Inference*. Boston: Houghton Mifflin; 2002.
74. Ray WA. Policy and program analysis using administrative databases. *Ann Intern Med*. 1997; 127: 712-718.

75. Calsyn RJ, Fergus EO, York JL. Interrupted time series analysis: A research technique for evaluating social programs for the elderly. *J Gerontol.* 1977; 32: 89-96.
76. McDowall D, McCleary R, Meidinger EE, Hay RAJ. *Interrupted Time Series Analysis.* Beverly Hills and London: Sage Publications: Sage University Paper series on Quantitative Applications in the Social Sciences, 07-021; 1987.
77. White MD. Examining the impact of external influences on police use of deadly force over time. *Eval Rev.* 2003; 27: 50-78.
78. Webster DW, Vernick JS, Hepburn LM. Effects of maryland's law banning "saturday night special" handguns on homicides. *Am J Epidemiol.* 2002; 155: 406-412.
79. Galster G, Temkin K, Walker C, Sawyer N. Measuring the impacts of community development initiatives: A new application of the adjusted interrupted time-series method. *Eval Rev.* 2004; 28: 502-538.
80. Jensen L. Guidelines for the application of ARIMA models in time series. *Res Nurs Health.* 1990; 13: 429-435.
81. Matowe LK, Leister CA, Crivera C, Korth-Bradley JM. Interrupted time series analysis in clinical research. *Ann Pharmacother.* 2003; 37: 1110-1116.
82. Mol PG, Wieringa JE, Nannanpanday PV, et al. Improving compliance with hospital antibiotic guidelines: A time-series intervention analysis. *J Antimicrob Chemother.* 2005; 55: 550-557.
83. Soumerai SB, Mah C, Zhang F, et al. Effects of health maintenance organization coverage of self-monitoring devices on diabetes self-care and glycemic control. *Arch Intern Med.* 2004; 164: 645-652.
84. Meara E, Kotagal UR, Atherton HD, Lieu TA. Impact of early newborn discharge legislation and early follow-up visits on infant outcomes in a state medicaid population. *Pediatrics.* 2004; 113: 1619-1627.
85. Brufsky JW, Ross-Degnan D, Calabrese D, Gao X, Soumerai SB. Shifting physician prescribing to a preferred histamine-2-receptor antagonist. effects of a multifactorial intervention in a mixed-model health maintenance organization. *Med Care.* 1998; 36: 321-332.

86. Mott DA, Collins TM. Comparison of targeting a DUR letter intervention at pharmacists separate from and in addition to physicians. *J Am Pharm Assoc.* 1998; 38: 325-332.
87. Ramsay C, Brown E, Hartman G, Davey P. Room for improvement: A systematic review of the quality of evaluations of interventions to improve hospital antibiotic prescribing. *J Antimicrob Chemother.* 2003; 52: 764-771.
88. Streiner DL. Thinking small: Research designs appropriate for clinical practice. *Canadian Journal of Psychiatry - Revue Canadienne de Psychiatrie.* 1998; 43: 737-741.
89. Hser YI, Shen H, Chou CP, Messer SC, Anglin MD. Analytic approaches for assessing long-term treatment effects. examples of empirical applications and findings. *Eval Rev.* 2001; 25: 233-262.
90. Wagner AK, Soumerai SB, Zhang F, Ross-Degnan D. Segmented regression analysis of interrupted time series studies in medication use research. *Journal of Clinical Pharmacy & Therapeutics.* 2002; 27: 299-309.
91. Gillings D, Makuc D, Siegel E. Analysis of interrupted time series mortality trends: An example to evaluate regionalized perinatal care. *Am J Public Health.* 1981; 71: 38-46.
92. Durbin J, Watson GS. Testing for serial correlation in least square regression. *Biometrika.* 1951; 37: 409-428.
93. Rossi PH, Freeman HE, Lipsey MW. *Evaluation: A Systematic Approach.* 6th ed. Sage Publications, Inc.; 1998.
94. Markus GB. *Analyzing Panel Data.* Beverly Hills and London: Sage Publications: Sage University Paper series on Quantitative Applications in the Social Sciences, 07-018; 1979.
95. Diggle PJ, Heagerty P, Liang K-, Zeger SL. *Analysis of Longitudinal Data.* 2nd ed. Oxford ; New York : Oxford University Press; 2002.
96. Liang KY, Zeger SL. Longitudinal data analysis using generalized linear models. *Biometrika.* 1986; 73: 13-22.
97. McCullagh P. Quasi-likelihood functions. *Annals of Statistics.* 1983; 11: 59-67.

98. Zeger SL, Liang KY. Longitudinal data analysis for discrete and continuous outcomes. *Biometrics*. 1986; 42: 121-130.
99. Zeger SL, Liang K, Albert PS. Models for longitudinal data: A generalized estimating equation approach. *Biometrics*. 1988; 44: 1049-1060.
100. Liang KY, Zeger SL. Regression analysis for correlated data. *Annu Rev Public Health*. 1993; 14: 43-68.
101. Kaslow RA, Ostrow DG, Detels R, Phair JP, Polk BF, Rinaldo CR, Jr. The multicenter AIDS cohort study: Rationale, organization, and selected characteristics of the participants. *Am J Epidemiol*. 1987; 126: 310-318.
102. Klag MJ, Ford DE, Mead LA, et al. Serum cholesterol in young men and subsequent cardiovascular disease. *N Engl J Med*. 1993; 328: 313-318.
103. Bowerman BL, O'Connell RT. *Time Series Forecasting: Unified Concepts and Computer Implementation*. 2nd ed. Boston: Duxbury Press; 1987.
104. Palta M. *Quantitative Methods in Population Health: Extensions of Ordinary Regression*. Hoboken, New Jersey: John Wiley & Sons, Inc.; 2003.
105. Sisson EM, Israel MK. Extent of community-based delivery of pharmaceutical care in virginia. *Pharmacotherapy*. 1996; 16: 94-102.
106. Doucette WR, Kreling DH, Schommer JC, Gaither CA, Mott DA, Pedersen CA. Evaluation of community pharmacy service mix: Evidence from the 2004 national pharmacist workforce study. *J Am Pharm Assoc (Wash DC)*. 2006; 46: 348-355.
107. Kreling DH, Doucette WR, Mott DA, Gaither CA, Pedersen CA, Schommer JC. Community pharmacists' work environments: Evidence from the 2004 national pharmacist workforce study. *J Am Pharm Assoc (Wash DC)*. 2006; 46: 331-339.
108. Min Y, Agresti A. Random effect models for repeated measures of zero-inflated count data. *Statistical Modelling*. 2005; 5: 1-19.

APPENDIX A
CURRENT PROCEDURE TERMINOLOGY (CPT)^a

^a Source: The American Medical Association (AMA) CPT® Editorial Panel.

Current Procedure Terminology (CPT) codes are part of the code set standard selected by HIPAA, used to describe health care services in electronic transactions.

CPT was developed by the American Medical Association (AMA) in the 1960s, and soon became part of the standard code set for Medicare and Medicaid. In subsequent decades it was adopted by private insurance carriers and managed care companies, and became the de facto standard.

CPT® Background and Categories of CPT® Codes

The American Medical Association (AMA) CPT® Editorial Panel accepted recommendations from the CPT-5 Executive Project Advisory Group for the creation of codes in CPT to allow for the identification of new and emerging technologies and the collection of data to facilitate performance measures.

The CPT-5 Project is structured to address challenges presented by emerging user needs including changes to enhance the use of CPT by practicing physicians, managed care and other payer organizations, and researchers. The CPT-5 Project will make improvements in the structure and processes of the CPT codes with deliberate emphasis on maintaining what works and has made CPT successful, while correcting problems and extending the applicability of CPT into new areas. As part of the drive to extend the function of CPT, thus adding to its value, these new categories of CPT are being developed.

In conjunction with the acceptance of these recommendations, the Coding Change Request Form and the Instructions for completion have been revised. These forms now include coding changes for three different categories of CPT codes.

Category I CPT Codes

Category I CPT codes describe a procedure or service identified with a five-digit CPT code and descriptor nomenclature. The inclusion of a descriptor and its associated specific five-digit identifying code number in this category of CPT codes is generally based upon the procedure being consistent with contemporary medical practice and being performed by many physicians in clinical practice in multiple locations.

In developing new and revised Category I CPT codes the Advisory Committee and the Editorial Panel requires:

- that the service/procedure receive approval from the Food and Drug Administration (FDA) for the specific use of devices or drugs;
- that the service/procedure is performed across the country in multiple locations;
- that many physicians or other health care professionals perform the service/procedure; and
- that the clinical efficacy of the service/procedure has been well established and documented.

Category II CPT Codes – Performance Measurement

Category II CPT codes are intended to facilitate data collection by coding certain services and/or test results that are agreed upon as contributing to positive health outcomes and quality patient care. This category of CPT codes is a set of optional tracking codes for performance measurement. These codes may be services that are typically included in an Evaluation and Management (E/M) service or other component part of a service and are not appropriate for Category I CPT codes. The use of tracking codes for performance measures

will decrease the need for record abstraction and chart review, thus minimizing administrative burdens on physicians and survey costs for health plans.

CPT Performance Measurement codes will be assigned an alphanumeric identifier with a letter in the last field (e.g., 1234A). These codes will be located in a separate section of CPT, following the Medicine section. Introductory language will be placed in this code section to explain the purpose of these codes. The use of these codes is optional, and not required for correct coding.

Requests for Category II CPT codes will be reviewed by the CPT/HCPAC Advisory Committee just as requests for Category I CPT codes are reviewed. In addition, a Performance Measurement Advisory Group will be established to perform initial review of proposals for Category II codes and then forward appropriate recommendations to the CPT/HCPAC Advisory Committee for review through the CPT Process.

The Performance Measurement Advisory Group will be comprised of representatives from various organizations involved in the development of performance measures, AMA CPT staff and clinical quality improvement staff, the CPT Editorial Panel, health services researchers and other knowledgeable experts.

The Performance Measurement Advisory Group will serve as an advisory body to the CPT/HCPAC Advisory Committee and the Editorial Panel in the development of performance measurement codes. Proposals for performance measurement codes must receive a two-thirds majority opinion at the Advisory Group level before they are passed on to the CPT/HCPAC Advisory Committee for review. In keeping with the existing procedures

of the CPT Advisory Committee, at least one advisor must vote affirmatively in order to forward the proposal for a performance measurement code to the Editorial Panel.

CPT codes for performance measurement will not be referred to the AMA/Specialty RVS Update Committee (RUC) for valuation because no relative value units (RVUs) will be assigned. Since some of the performance measurement codes will be services embedded within E/M codes, the aggregate service is already valued.

CPT codes for performance measures will be released annually through the usual CPT publication process for that CPT cycle.

Category III CPT Codes – Emerging Technology

The purpose of this category of codes is to facilitate data collection on and assessment of new services and procedures. These codes are intended to be used for data collection purposes to substantiate widespread usage or in the FDA approval process. As such, the Category III CPT codes may not conform to the usual CPT code requirements that:

- services/procedures be performed by many health care professionals across the country;
- FDA approval be documented or be imminent within a given CPT cycle; and
- the service/procedure has proven clinical efficacy.

The service/procedure must have relevance for research, either ongoing or planned.

Category III CPT codes will be assigned an alphanumeric identifier with a letter in the last field (e.g., 1234B). These codes will be located in a separate section of CPT, following the Medicine section. Introductory language will be placed in this code section to explain the purpose of these codes.

Requests for Category III CPT codes will follow the existing procedures for new or revised CPT codes. These codes will not require an additional advisory group. The CPT/HCPAC Advisory Committee, as it is currently constituted, is well informed of new and emerging technologies and procedures. If a particular Advisor is not aware of some new technology in their specialty, they can contact colleagues or make use of the specialty society resources. For these reasons, a separate advisory group for Category III CPT codes is not necessary.

Category III CPT codes will not be referred to the RUC for valuation because no RVUs will be assigned.

Once approved by the Editorial Panel, the newly added Category III CPT codes will be made available on a semi-annual (twice a year) basis via electronic distribution on the AMA/CPT website. The full set of Category III codes will be included in the next published edition for that CPT cycle.

These codes will be sunset after five years if the code has not been accepted for placement in the Category I section of CPT, unless demonstrated that a Category III code is still needed. These codes will not be reused.

CPT is a registered trademark of the American Medical Association. This document was last updated on May 14, 2006 and provided by CPT Editorial & Info Services.

APPENDIX B
CMS-1500 FORM^b

^b Source: Professional paper claim form. Available at <http://www.cms.hhs.gov/>.

The medical insurance form used when submitting for payment of services rendered is the AMA Council on Medical Service approved form called the Health Insurance Claim Form-1500, also called CMS-1500 (see next page). The CMS-1500 form and instructions are used by non-institutional providers and suppliers to bill Medicare, Part B covered services. It is also used for billing some Medicaid covered services. The CMS-1500 form is a standard generic medical claim form used for all claim processing and is colored red for electronic scanning. All information on the form must be complete and accurate. However, some spaces are left blank on purpose, i.e., Line 29 amount paid.

The CMS-1500 form is divided into two basic sections. The top section with Lines 1-13, pertains to the patient's personal and insurance information. The lower section, Lines 14-20, pertains specifically to the diagnosis and treatment. Line 21 is the place where the diagnosis codes are listed. Line 24 is the place where procedure codes are listed. Incomplete questions or failure to report accurate information in any area may result in claim denial. Additionally, a narrative report may be required.

PLEASE
DO NOT
STAPLE
IN THIS
AREA



CARRIER

HEALTH INSURANCE CLAIM FORM

PICA <input type="checkbox"/> <input type="checkbox"/>										PICA <input type="checkbox"/> <input type="checkbox"/>												
1. MEDICARE <input type="checkbox"/> (Medicare #) <input type="checkbox"/> MEDICAID <input type="checkbox"/> (Medicaid #) <input type="checkbox"/> CHAMPUS <input type="checkbox"/> (Sponsor's SSN) <input type="checkbox"/> CHAMPVA <input type="checkbox"/> (VA File #) <input type="checkbox"/> GROUP HEALTH PLAN <input type="checkbox"/> (SSN or ID) <input type="checkbox"/> FECA BLK LUNG <input type="checkbox"/> (SSN) <input type="checkbox"/> OTHER <input type="checkbox"/> (ID) <input type="checkbox"/>					2a. INSURED'S I.D. NUMBER					(FOR PROGRAM IN ITEM 1)												
2. PATIENT'S NAME (Last Name, First Name, Middle Initial)					3. PATIENT'S BIRTH DATE MM DD YY M SEX F					4. INSURED'S NAME (Last Name, First Name, Middle Initial)												
5. PATIENT'S ADDRESS (No., Street) CITY STATE ZIP CODE TELEPHONE (Include Area Code)					6. PATIENT RELATIONSHIP TO INSURED Self <input type="checkbox"/> Spouse <input type="checkbox"/> Child <input type="checkbox"/> Other <input type="checkbox"/>					7. INSURED'S ADDRESS (No., Street) CITY STATE ZIP CODE TELEPHONE (INCLUDE AREA CODE)												
9. OTHER INSURED'S NAME (Last Name, First Name, Middle Initial)					10. IS PATIENT'S CONDITION RELATED TO: a. EMPLOYMENT? (CURRENT OR PREVIOUS) YES <input type="checkbox"/> NO <input type="checkbox"/> b. AUTO ACCIDENT? PLACE (State) YES <input type="checkbox"/> NO <input type="checkbox"/> c. OTHER ACCIDENT? YES <input type="checkbox"/> NO <input type="checkbox"/> 10d. RESERVED FOR LOCAL USE					11. INSURED'S POLICY GROUP OR FECA NUMBER a. INSURED'S DATE OF BIRTH MM DD YY M SEX F b. EMPLOYER'S NAME OR SCHOOL NAME c. INSURANCE PLAN NAME OR PROGRAM NAME d. IS THERE ANOTHER HEALTH BENEFIT PLAN? YES <input type="checkbox"/> NO <input type="checkbox"/> <i>If yes, return to and complete item 9 a-d.</i>												
12. PATIENT'S OR AUTHORIZED PERSON'S SIGNATURE I authorize the release of any medical or other information necessary to process this claim. I also request payment of government benefits either to myself or to the party who accepts assignment below. SIGNED _____ DATE _____										13. INSURED'S OR AUTHORIZED PERSON'S SIGNATURE I authorize payment of medical benefits to the undersigned physician or supplier for services described below. SIGNED _____												
14. DATE OF CURRENT ILLNESS (First symptom) OR INJURY (Accident) OR PREGNANCY(LMP) MM DD YY					15. IF PATIENT HAS HAD SAME OR SIMILAR ILLNESS. GIVE FIRST DATE MM DD YY					16. DATES PATIENT UNABLE TO WORK IN CURRENT OCCUPATION FROM MM DD YY TO MM DD YY												
17. NAME OF REFERRING PHYSICIAN OR OTHER SOURCE					17a. I.D. NUMBER OF REFERRING PHYSICIAN					18. HOSPITALIZATION DATES RELATED TO CURRENT SERVICES FROM MM DD YY TO MM DD YY												
19. RESERVED FOR LOCAL USE					20. OUTSIDE LAB? \$ CHARGES <input type="checkbox"/> YES <input type="checkbox"/> NO					22. MEDICAID RESUBMISSION CODE ORIGINAL REF. NO.												
21. DIAGNOSIS OR NATURE OF ILLNESS OR INJURY. (RELATE ITEMS 1,2,3 OR 4 TO ITEM 24E BY LINE) 1. _____ 3. _____ 2. _____ 4. _____					23. PRIOR AUTHORIZATION NUMBER																	
24. A DATE(S) OF SERVICE, From To		B Place of Service		C Type of Service		D PROCEDURES, SERVICES, OR SUPPLIES (Explain Unusual Circumstances) CPT/HCP/CS MODIFIER			E DIAGNOSIS CODE		F \$ CHARGES		G DAYS OR UNITS		H EP/SDT Family Plan		I EMG		J COB		K RESERVED FOR LOCAL USE	
25. FEDERAL TAX I.D. NUMBER SSN EIN		26. PATIENT'S ACCOUNT NO.		27. ACCEPT ASSIGNMENT? (For gov. claims, see back) YES <input type="checkbox"/> NO <input type="checkbox"/>		28. TOTAL CHARGE \$		29. AMOUNT PAID \$		30. BALANCE DUE \$		33. PHYSICIAN'S, SUPPLIER'S BILLING NAME, ADDRESS, ZIP CODE & PHONE #										
31. SIGNATURE OF PHYSICIAN OR SUPPLIER INCLUDING DEGREES OR CREDENTIALS (I certify that the statements on the reverse apply to this bill and are made a part thereof.) SIGNED _____ DATE _____					32. NAME AND ADDRESS OF FACILITY WHERE SERVICES WERE RENDERED (If other than home or office)					PIN# _____ GRP# _____												

PATIENT AND INSURED INFORMATION

PHYSICIAN OR SUPPLIER INFORMATION