ABSTRACT

KASTEN, JENNIFER MURPHY. Determinants of Organizational Change: The Impact of Institutional and Market Forces on Compliance with Federal Regulations in Opioid Treatment Programs. (Under the direction of Dr. Elizabeth O’Sullivan).

Improving federal efforts to implement public health policy will require a better understanding of the impact of institutional and market forces on organizational change mandated by federal regulations. Previous institutional literature assumed that institutional change driven by federal regulatory agencies is relatively easy to accomplish because of the direct administrative and financial effects of politics on organizations. However, as supported by early public administration literature underlying a politics-administration dichotomy, there is a growing belief that other forces may obstruct or impede the impact of policies steered by government, limiting the extent to which government agencies are able to influence institutional change.

There is an extensive body of literature that examines the causes and consequences of regulation and regulatory reform as well as the environmental forces shown to impact organizational change; but there is limited research that examines the organizational construct and the impact of external and internal forces on organizational action toward regulatory compliance. Overall, the knowledge base lacks clarity about what explanatory factors are most important to implement and measure organizational change. This dissertation focuses on the application of organizational institutional theories to the area of federally regulated programs, specifically to opioid treatment programs in the Unites States.

Each year, opioid treatment programs treat thousands of individuals for opiate dependence. Within the constraints of decreasing program budgets, these programs attempt
to balance providing high-quality, individualized patient care, with adhering to both state and federal regulations.

Recently, the opioid dependence treatment field underwent a dramatic shift in regulatory oversight aimed at improving the quality of care provided through opioid treatment programs nationally. This shift and the subsequent mandate of new federal regulations represent a punctuated change in the field that offers a unique opportunity to study the influences of institutional and market forces on change within organizations under federal regulation.

This dissertation uses data collected through a Center for Substance Abuse Treatment funded project (Contract No. 270-97-7002 to RTI International) from 1998 to 2001. The initial assessment (1998–1999) occurred during the growth and redesign of federal regulations overseeing opioid dependence treatment, whereas the second assessment (2000–2001) occurred after the publication of the notice for proposed rulemaking and during the publication of the final rule modifying oversight and federal regulations for treatment.

For the purposes of this study, organizational change focuses on three areas of opioid dependence treatment targeted within the federally mandated regulations for policies and practice changes: (1) take-home medications, (2) medication dosage, and (3) quality assurance systems. These areas represent the organizational policies and practices impacted most by the legislative change and new regulations.
DETERMINANTS OF ORGANIZATIONAL CHANGE:
THE IMPACT OF INSTITUTIONAL AND MARKET FORCES
ON COMPLIANCE WITH FEDERAL REGULATIONS
IN OPIOID TREATMENT PROGRAMS

by

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Biography

Jennifer Murphy Kasten was born to Terry Orville Murphy and Elizabeth Veronica Persico Murphy on September 19, 1969, in DeWitt, Iowa. She graduated from Mendota High School in 1987 and received her Bachelor of Arts degree in biology and psychology from North Central College in Naperville, Illinois, in 1991. She then worked in the nonprofit public sector as a Qualified Mental Retardation Specialist until 1996. Jennifer withdrew from public service to attend the University of South Carolina in Columbia; she graduated with a Masters in Social Work degree in 1998. Prior to graduating, she accepted a position as a Health Policy Analyst at RTI International in Research Triangle Park, North Carolina. Jennifer is currently employed with RTI International in the division for Behavioral Health and Criminal Justice Research.

In 2000, Jennifer was accepted into the Doctor of Philosophy in Public Administration program at North Carolina State University in Raleigh. During her time there she assisted in teaching Introduction to Political Science courses and was nominated for membership in the North Carolina State University chapter of Pi Alpha Alpha, the national honor society for public affairs and administration. She was admitted to candidacy in November 2005, and successfully defended her dissertation on the impact of institutional and market forces on federal regulation in opioid treatment programs in November 2006. Jennifer received her Doctor of Philosophy degree in December 2006.

Jennifer is currently a Senior Health Policy Analyst at RTI International where she leads federal contracts focused on the evaluation and analysis of substance abuse prevention and treatment policy.
Acknowledgments

I would first like to thank the members of my Dissertation Committee, chaired expertly by Elizabeth O’Sullivan. Thank you Liz, for the combination of mentoring and instruction you provided, without which I could not have completed this project. Thank you to Jason Allaire, whose consultation improved my analyses and my subsequent findings. And to Wendee Wechsberg, whose perspective from the field, familiarity with the literature, and ongoing support and encouragement contributed greatly to the content of my work.

I would like to express my appreciation to RTI International for providing me with both financial support and the freedom to pursue my research interests. I appreciate the support allowing me to pursue my doctoral degree while working within the field of substance abuse treatment. I would also like to acknowledge the Center for Substance Abuse Treatment for supporting the original data collection.

I also wish to acknowledge the support of all members of my family. Thank you most to my husband Mark for supporting me during the long hours of research and for continually encouraging me to take the time necessary to complete this project. Throughout the past six years you have given me the space I needed to complete this project while reminding me of the important things in life. Thanks also to my children, Ryan and Jacob, who endured my absence while I completed both my coursework and this dissertation.

And finally, thanks to the staff and faculty with the Public Administration program, from the reception desk to the computer lab to the classroom. They do a marvelous job on behalf of the students.
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<td>AATOD</td>
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<td>FDA</td>
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<td>GEE</td>
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<td>IDU</td>
<td>injecting drug user</td>
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<td>INTPRB</td>
<td>Interagency Narcotic Treatment and Policy Review Board</td>
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CHAPTER 1

Statement of the Problem and Conceptual Approach

1.1 Statement of the Problem

Change is an all-pervasive phenomenon that happens continuously and often rapidly. Previous institutional literature assumed that institutional change driven by federal regulation of agencies is relatively easy to accomplish because of the direct administrative and financial effects of politics on organizations. However, as supported by the historical public administration politics-administration dichotomy, there is a growing belief within organizational theory that other forces may obstruct or impede the impact of policies steered by government, limiting the extent to which government agencies are able to influence institutional change. In spite of that, there is limited research examining organizational characteristics and the impact of external and internal forces on organizational action toward regulatory compliance.

Beginning with general open systems theory (Boulding, 1956; Betalanffy, 1962) and carrying through to the present work of institutional theory (Meyer & Rowan, 1977; Meyer & Scott, 1983), there has been considerable speculation about the relationships between organizations and their environments. Explaining how and why organizations change has been a central and persistent theme among scholars in public administration, sociology, psychology, and other social science disciplines (Van de Ven & Poole, 1995). While many researchers have pondered and examined the capacity of organizations to readily and successfully change (Hawley, 1968; Hannan & Freeman, 1977, 1989; Meyer & Rowan, 1977; DiMaggio & Powell, 1983; Meyer & Scott, 1983; Winum, Ryterband, & Stephensen,
1997), uncertainty remains as to what specific organizational and environmental factors have the most impact on organizational adaptation.

Organizational change theory has demonstrated that governmental influence on organizational adaptation may be limited because of other forces in the organizational field and because specific organizational characteristics act as barriers to action (Segal, 1974; Vermeulen, Greenwood, Buch, & Smit, 2003). The current understanding, however, is unclear about what explanatory factors are the most important to implement and measure organizational change. The present research fills a gap in the current knowledge base by examining, through empirical analyses, the organizational characteristics associated with organizational adaptation to federal regulations. The importance of this research encompasses both conceptual and policy domains.

One important aspect of change is adaptation; specifically the organizational characteristics that support adaptation. Less than positive outcomes reported for organizational change efforts have been a pressing concern to legislators, practitioners, and researchers (Moe, 1991). Organizational change success rates have been shown to be as low as 18%, drawing attention to the barriers that result in such a low success rate (Moe, 1991). Identifying the impact of environmental factors, such as institutional and market forces, on organizational change mandated by federal regulations may yield a formal model capable of predicting or guiding organizational change outcomes. Such a tool would greatly benefit legislators and practitioners in identifying “failing” policies and guiding organizations toward successful adaptation through the implementation of new regulations, policies, or practices.
1.2 Purpose of the Study

This study aims to better understand organizational response to environmental influences, including the impact of institutional and market forces on organizational change mandated by federal regulations. It also seeks to provide insight into the bureaucratic and administrative relationship influencing organizations undergoing a regulatory change. Focusing on political and administrative aspects of organizational behavior supports Meier’s perspective (Meier, 1985) that regulatory policy is a product of both regulatory bureaucracies and environmental forces (West, 1988).

Government regulation has long been viewed as a controversial and important aspect of organizational structure and performance, yet it has not been well studied (Moe, 1985; West, 1988; Hill & Lynn, 2004). Organizational literature has previously assumed that organizational change driven by regulatory agencies is relatively easy to accomplish because of the direct effects of policies on organizations (DiMaggio & Powell, 1983; Dobbin & Dowd, 1997). However, recent studies have found that environmental forces may obstruct or impede the impact of regulatory management (Vermeulen, Greenwood, Buch, & Smit, 2003).

Of particular interest is the impact of market forces (e.g., competition, centralized administration) and institutional forces (e.g., ownership, managerial leadership) on organizational adaptation and development. Some studies have concentrated on the importance of competition, organizational leadership, organizational size, and other organizational structural variables to examine organizational adaptation and development (Montjoy & O’Toole, 1979; West, 1988; Robertson & Seneviratne, 1995; Meier & O’Toole, 2002; Boyne, 2003; Meier, O’Toole, & Nicholson-Crotty, 2004; Walker & Boyne, 2006).
Organizational leadership has demonstrated its discretion to ignore regulatory compliance standards, despite nationwide laws that mandate adoption of uniform compliance practices and policies (Lorence & Richards, 2003). As a result of these influencing factors, regulatory adoption and compliance vary significantly across organizational characteristics, suggesting the existence of barriers to uniform regulatory compliance (Flood & Fennell, 1995).

Additionally, researchers have found that organizational resistance to change may be caused by poorly planned implementation of change initiatives (Winum, Ryterband, & Stephensen, 1997). A common mistake made in regulatory change is to assume that all organizations are ready to take action. Further, there is support for the notion that imposing action with the force of authority on organizations that are not prepared will result in organizational opposition (Lorence & Richards, 2003). Moreover, previous literature examining the influence exerted by federal regulations suggests that government controls may actually serve to constrain organizational behavior (Fligstein, 1991). While a body of literature exists examining the causes and consequences of regulation and regulatory reform (Gilliland, & Manning, 2002; Vermeulen, Greenwood, Buch, & Smit, 2003; Delmas & Toffel, 2004; Joskow, 2005), there is limited research regarding specific environmental forces shown to enhance or impede organizational adaptation of regulatory reform.

Regulatory reform represents a central debate in organizational theory: how organizations evolve and change. There are two diametrically opposed points of view. Adaptation theorists predict that change occurs as fluid organizations adjust to meet shifting environmental demands, whereas selection theories predict that change occurs through the differential selection and replacement of inert organizations by new organizations as

The present study utilizes aspects of a punctuated equilibrium framework (Gould & Eldredge, 1977) to examine organizational—in this case, opioid treatment programs (OTPs)—responses to a punctuational (i.e., episodic or sporadic) regulatory change. Recent research (Fligstein, 1991) supports the notion of regulation as a mechanism to create opportunities for innovation and organizational change by functioning as a control mechanism constraining organizational behavior and a “shock” to otherwise stable environments. This framework is consistent with the concept that changes in government regulations are considered to be punctuated changes (Haveman, Russo, & Meyer, 2001).

Recently, organizational change literature has focused on the disruptive or punctuated changes in organizations (Sastry, 1997; Sammut-Bonnici & Wensley, 2002), such as those demonstrated by the implementation of regulatory reform. Political, functional and social pressures, technological innovations, and regulatory changes have been examined as “environmental jolts” that disrupt organizational practices (Oliver, 1992; Greenwood, Suddaby, Hinings, 2002). The idea of regulatory change as an environmental jolt has received increasing attention within healthcare organizations (Flood & Fennell, 1995). Analyses conducted for this study will serve to enhance the understanding of organizational change and adaptation as examined within the context of a regulatory environmental jolt disrupting the policies and practices of OTPs.
1.3 Federal Regulatory Change in Opioid Treatment Programs

The National Survey on Drug Use and Health (Substance Abuse and Mental Health Services Administration [SAMHSA], Office of Applied Studies [OAS], 2005) estimated that 3.1 million people in the United States have used heroin in their lifetime and 31.8 million people have used an opiate pain reliever for nonmedical purposes. Furthermore, estimates indicate that 226,000 persons were dependent on heroin in the past year and 970,000 persons were dependent on opiate pain relievers (SAMHSA OAS, 2005).

Methadone is an approved, highly regulated, pharmacological adjunctive treatment for opiate dependence (Molinari, Cooper, & Czechowicz, 1994; Rettig & Yarmolinsky, 1995). There are more than 1,200 OTPs in the United States serving approximately 175,000 patients on any given day (SAMHSA OAS, 2004). With appropriate dosing levels, methadone maintenance treatment (MMT) has been shown to be effective in treating opiate dependence and enabling persons seeking treatment to reduce heroin use, drug-seeking criminal behaviors, and HIV risk (Simpson, Joe, & Bracy; 1982; Ball, Lange, Meyers, & Friedman, 1988; Gerstein & Harwood, 1990; Ball & Ross, 1991; Yancovitz, Des Jarlais, Peyser, 1991; Glass, 1993; Serpelloni et al., 1994; Ralston, & Watson, 1996).

In the late 1970s, the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA) jointly promulgated standards for opioid dependence treatment. These standards were developed to regulate the safety and improve the effectiveness of opioid dependence treatment through a formal regulatory process. Almost since the inception of these regulations, there has been strong criticism of the regulatory process governing the provision of opioid dependence treatment.
In January 2001, Congress released new federal regulations to improve the quality and clinical outcomes of OTPs (Pellier & Hoffman, 2001). These regulatory changes were brought about in part as a result of the findings by the General Accounting Office that existing regulations for MMT did not ensure treatment services linked to successful patient outcomes (GAO, 1990). Under the new regulations, OTP oversight shifted from an FDA inspection model to a SAMHSA-administered accreditation model. The new federal regulations target the improvement of the quality of opioid dependence treatment.

The implementation of new federal regulations in the field of opioid dependence treatment represents over a decade of confrontation and collaboration across multiple federal agencies—such as the General Accounting Office (now known as the Government Accountability Office [GAO]), SAMHSA, and the Office of National Drug Control Policy—state substance abuse treatment authorities, and other provider and patient stakeholder groups (e.g., advocates, opioid dependence treatment providers, the American Association of Treatment for Opioid Dependence [AATOD]) (Pellier & Hoffman, 2001). Thus, there is considerable interest in the successful adoption of these regulations by federal agencies, treatment providers, and legislative policymakers.

With recent research findings questioning the capability of federal regulations to orchestrate organizational change, the ability of newly legislated federal regulations to impact the field of opioid dependence treatment is uncertain. To better understand organizational change, this study examines the impact of federal regulations within one industry, opioid dependence treatment, and focuses on examining how organizations do or do
not change in the aftermath of an environmental shift, such as the mandate to implement new industry regulations.

OTPs are the unit of analysis within this study, which uses the recent shift in regulatory oversight of OTPs and the subsequent mandate of new federal regulations to examine the influences of market and institutional forces on organizational change. Organizational change is defined by three areas of opioid dependence treatment targeted for reform within the new federal regulations: (1) take-home medications policies and practices, (2) medication dosage policies and practices, and (3) quality assurance (QA) system policies and practices. These areas represent the organizational policies and practices impacted most by the recent legislative change and new regulations.

To further examine organizational change, this study focuses on both external (market) and internal (institutional) forces that impact an organization’s capacity for change. Market forces examined here include location of the organization, size of the organization, previous accreditation, and parent affiliation (e.g., multiple organizational structure versus freestanding). Institutional forces examined include ownership (e.g., for-profit versus nonprofit/public), program age, and leadership (clinical supervisor and medical director tenure). The dependent variables of interest are the three areas of organizational change listed above.

1.4 Organization of the Dissertation

The remainder of this dissertation is organized around seven chapters. Chapter 2, Organizational Change Theory Applied to the Study of Opioid Dependence Treatment, provides a literature review of institutional, change, and regulatory theory. It also gives an
overview of punctuated equilibrium theory and describes how this theory fits within the conceptual framework of the study.

Chapter 3, Conceptual Model for Change and the Study Hypotheses, defines the conceptual framework for the study and outlines specific study hypotheses. It also links organizational theory discussed in Chapter 2 to the application of market and institutional forces and their impact on organizational adaptation. Market and institutional forces are examined as critical factors influencing or impeding organizational change. Particular attention is given to these factors and their influence on public health organizations, including OTPs. Federal regulations as an agent for organizational change are also discussed along with a detailed review of the federal regulation of OTPs.

Chapter 4, Study Design, Sampling, and Methods, discusses the sample population, survey instruments used for data collection in the parent study from which the data for the present study are derived, and the methods used for data analyses. This chapter also describes the measures used to operationalize the conceptual framework and the hypotheses discussed in Chapter 3.

Chapter 5, Univariate Analyses, presents descriptive data on the organizational aspects of the OTPs included in the study. Chapter 6, Multivariate Analyses, presents the results from the bivariate analyses and the generalized estimating equations (GEE) conducted to test the hypotheses presented in Chapter 3. The GEE approach facilitates analysis of data collected in repeated measure designs (Ballinger, 2004). GEE uses the generalized linear model to estimate more efficient and unbiased regression parameters relative to ordinary least squares regression, in part because analyses permit specification of a working correlation
matrix that accounts for the within-subject correlation of repeated measure responses (Zeger & Liang, 1986).

Chapter 7, Conclusions, Implications and Next Steps, discusses the implications of the study results for regulatory oversight, organizational change, and public policy implementation. It also discusses the implications of the findings as they relate to the recent movement in public administration toward empirical data analysis examining governance. While the findings presented here focus on the direct examination of organizational structure and adaptability to regulatory change, they have indirect implications for the expanding network of researchers interested in questions of governance and public management. Chapter 7 concludes with the limitations to the present research and suggests areas where additional research could expand the current knowledge base.
CHAPTER 2

Organizational Change Theory Applied to the Study of Opioid Dependence Treatment

2.1 A Brief History of Organizational Theory

2.1.1 Development of Organizational Theory

During the 1950s, organizations became a bona fide field of social science study incorporating aspects of scientific management, bureaucratic theory, and administrative theory (Armenakis & Bedeian, 1999). Early theorists focused on such issues as bounded rationality (Simon, 1945; March & Simon, 1958), unintended consequences of purposive action (Merton, 1949), dilemmas of bureaucracy (Blau, 1955), and organizations as systems of coercion and consent (Gouldner, 1954).

Taylor (1917) developed scientific management theory, which was very successful at improving production. Scientific management is based on matching the best tools and people, and closely supervising the production process. While scientific management theory yielded large increases in production in simple industrialized companies, it has not fared well in modern, more complicated organizations (DiMaggio & Powell, 1991).

Weber’s (1947) theories emphasized diversity and ambiguity within organizations. Weber’s bureaucratic theory stressed an organization’s need for a hierarchical structure of authority and control, and emphasized division of labor and specialization. Weber expanded the concept of organizational behavior as connected human interactions explained by simple cause and effect. While rigid and mechanistic in their application, these examples of classical management theory form the basis of modern organizational theory.
Neoclassical organizational theory evolved as a reaction to the rigidity of classical theory during a time focused on human relations and concern for human needs. One of the first experiments defining the split from classical theory was conducted by Mayo and Roethlisberg in the late 1920s at the Western Electric plant in Hawthorne, Illinois (Mayo, 1933). The experiment showed that manipulation of the work environment, regardless of the type of manipulation, had a positive impact on employee productivity.

During this formative period, organizational theorists concentrated on examining organizational structure, with a focus on describing distinctive organizational features. Particular attention was given to organizational actors and processes. Simon (1945) contributed to the early work in organizational theory through his model of “limited rationality” and the implementation of rigorous scientific methods to legitimize the study of organizations.

Barnard (1968) expanded the concepts of classical and neoclassical theory by defining the organization as a system of consciously coordinated activities impacted by executive leadership. Barnard’s theory posited that management authority is derived from subordinate acceptance rather than hierarchical structure within the organization. During the Simon and Barnard era, researchers formulated system models focusing on common elements and processes across varied systems (Buckley, 1967), and systems theory developed into the study of organizations as functional components within a broader environment (Katz & Kahn, 1966; Thompson, 2003).

The early work completed to develop organizational theory led toward three overall contrasting perspectives on the nature of organizations and different sets of external and
internal organizational elements and processes (Scott, 1992). The *organizations as rational system* perspective, for example, views organizations as instruments to accomplish specified goals, with an emphasis on formalization, efficiency, and performance. The *organizations as natural systems* perspective focuses on the behavior of organizations and the evolution of firms, viewing organizations as collectivities engaging informally in survival activities. The more recent *organizations as open systems* perspective concentrates on the external environment of organizations, viewing organizations as interdependent in which systems are dependent on and respond to their external environments. The context of viewing organizations within a broader environment served to expand the parameters of organizational theory, giving rise to institutional theory and organizational ecology.

A more detailed description of institutional theory, organizational change theory, and regulatory theory follows. These three aspects of organizational theory directly impact organizational adaptation, and the present research examines how each of these aspects of organizational theory impacts adaptation.

### 2.1.2 Institutional and Neo-institutional Theory

Institutional theory has evolved into a body of literature encompassing multiple levels of analysis: nation, industry, organization, group, and individual. Research applying this theory has been conducted in a large number of institutional environments where institutions may be defined as the “cognitive, normative and regulative structures and activities that provide stability and meaning to social behavior” (Floyd, Kramer, & Born, 2005, p. 238). The cognitive structures are the mental frameworks, beliefs, and assumptions shared by people about their common purpose, the work they do together, and how they interact. The
normative element includes the standards and values that identify what is desirable and define what is expected of people (i.e., roles and status) as well as routine ways of completing tasks. Finally, the regulatory aspects of institutions include the formal rules of official bodies, such as licensing and review committees, as well as the informal rules that often develop, such as communication protocols and standard business practices.

While several organizational theories ensued during the 1960s and 1970s (e.g., contingency theory, transaction cost theory, resource dependence theory, network theory), institutional theory serves as a starting point to discuss organizational change because it represents one of the more robust theoretical perspectives within organizational theory (Perrow, 1979). Institutional theory is not usually regarded as a theory of organizational change, but rather as an explanation of the similarity (isomorphism) and stability of organizational arrangements in a given population or field of organizations (Greenwood & Hinings, 1996). Some research has concluded that institutional theory offers little guidance regarding change (Ledford, Mohrman, & Lawler, 1989) and, in fact, supports the notion of institutional pressures that serve as a powerful force against transformational change (Buckho, 1994). However, other research has indicated that institutional theory provides an excellent base to examine change, first by providing a convincing definition of radical (as opposed to convergent) change, and second by signaling the contextual dynamics that precipitate the need for organizational adaptation (Oliver, 1991).

Based on the latter research, institutional theory can provide a means of accounting for organizational changes. The institutional theory of organizational environments suggests that organizations conform appropriately to their environment either at the time of creation or
through adapting to the existing environment, which serves to legitimatize organizations. As a result, organizations in similar environments tend to resemble one another because all of them are attempting to adopt what is perceived to be the legitimate accepted form. This process by which organizations become more similar to each other is known as isomorphism (Meyer & Rowan, 1977; Scott, 1992), which serves to deter organizational variation as well as change from the accepted norms.

Building on the theory of institutionalism, neo-institutionalism emphasizes organizational legitimacy and focuses on the role of schemas, typifications, and scripts in shaping organizational structure and behavior (DiMaggio & Powell, 1983; Meyer & Rowan, 1977). As formulated, however, neo-institutional theory is weak when used to analyze the internal dynamics of organizational change. Consequently, the theory is silent on why some organizations adopt radical change, whereas others do not despite experiencing the same institutional pressures (Greenwood & Hinings, 1996). Nevertheless, neo-institutional theory contains insights and suggestions that, when elaborated, provide a model of change that links organizational context and intraorganizational dynamics.

To better understand how these theories impact organizational change, a brief review of these theoretical approaches is needed. Meyer and Rowan (1977) were among the first to explore and document the notion of rationalized institutional elements (popular beliefs or practices that over time become taken for granted). The support of rationalized institutional elements led to the presence and elaboration of formal organizations. Legitimacy of organizations is believed to be affected by both conformity with institutional norms and concerns for organizational efficiency (Meyer & Rowan, 1977).
While institutional and neo-institutional theories are presented in relation to organizational change, the primary focus of early organizational theory was the technical environment of the organization rather than organizational adaptation. Early researchers concentrated on the exchange of a product through an effective and efficient process. The work of Meyer and Rowan differs from previous theoretical approaches because it incorporates both institutional and technical environments. Meyer and Rowan expanded institutional theory by including institutional environments characterized by the elaboration of rules and requirements necessary to gain legitimacy (Scott & Meyer, 1983). Organizations that adhere to a strict adaptation of rules governing legitimacy are believed to have less flexibility in their behavior, making it more difficult to cope successfully with a changing environment.

2.1.3 Organizational Ecology Theory

Organizational ecology theory was developed during the same period as institutional theory. Similar to institutional theory, organizational ecology theory suggests that previous organizational theories exaggerated the extent to which organizations are able to undergo fundamental change (Hannan & Freeman, 1977). Organizational ecology, however, supports the study of change rather than stability and emphasizes the study of organizational populations rather than individual members of the population (Scott, 2004). To that end, organizational ecologists have adapted Darwinian evolutionary models and applied them to explain the evolution of organizational systems. More recently, ecologists have broadened their efforts to analyze rates of organizational change as well as ways in which new types of
organizations arise, grow, and complete over extended periods (Hannan & Freeman, 1989; Haveman, 1992; Amburgey, Kelly, & Barnett, 1993; Carroll & Hannan, 2000).

From the vantage of institutional theory and organizational ecology theory, organizations are typically seen as being subject to strong inertial forces and seldom succeeding in making radical changes in strategy and structure even in the face of environmental threats (Hannan & Freeman, 1984). Organizational ecology (Hannan & Freeman, 1977, 1984, 1989) posits that organizational change is limited by strong inertial pressures. The assumption of strong structural inertia has two implications: (1) organizational change is infrequent and much less frequent than environmental change, and (2) when change occurs, it sets back the liability-of-newness clock (Haveman, 1992). The liability-of-newness phenomenon describes the different risks experienced by an organization during its life course. This concept states that at the point of origination an organization is at the highest risk for termination and this risk decreases as the organization ages (Stinchcombe, 1965). Change is seen to “reset” the liability-of-newness clock, placing the organization at a high risk for closure or dying.

Moreover, undertaking change diverts resources from operating to reorganizing, which reduces the efficiency of organizational operations. Some of the factors that generate structural inertia are internal to organizations, including personnel characteristics, dynamics of political coalitions, and the tendency for normative standards. Other factors are external, such as when the level of structural inertia increases with organizational size. Still other factors are legal or political, which create barriers to entry and exit from realms of activity.
However, to claim that organizational structures are subject to strong inertial forces is not the same as claiming that organizations never change. The difference is what distinguishes organizational ecology theory from institutional theory. When an organization undertakes nontrivial change, it needs to adopt new work routines to fill new job functions and manage the altered flow of work, and to forge new relations with suppliers and clients (Hannan & Freeman, 1984; Singh, House, & Tucker, 1986). Organizational change may be worth the risk when the transformation of environmental conditions renders previous organizational strategies and orientations obsolete (Tushman & Romanelli, 1985) so that an organizational form—an entire population of organizations—is faced with extinction (Haveman, 1992). Organizations can face extinction when a dramatic change occurs in their environment. Regulatory change that threatens organizational closure (as a result of noncompliance) is one example of this type of dramatic change.

2.2 Organizational and Political Theory

Organizational theory has served as a natural foundation for understanding the structure and operation of government. Organizational theory originally supported the notion that organizations could be understood in a similar way (Moe, 1991). Original organizational theories dealt with issues of structure, management, and efficiency. They did not, however, offer any foundation for understanding how organizations behave in a political environment. Therefore, while a historical review of organizational theory is important, it does not capture a comprehensive view of organizational influences because intertwined with an organization’s environment are the politics that drive certain environmental norms. Thus, it is necessary to review political theory as it relates to organizations and their regulation.
Initially, organizational theorists were generally nonpolitical in their theoretical design and development, but theorists have since come to link politics and organizations through the open systems theory (Warwick, 1975). This linkage is critical to understanding the context of organizational adoption and compliance with federal regulations.

Meier (1994) played a critical role in expanding theoretical development in the area of politics and policy. In the *Politics of Sin*, Meier provides a model in which policy (represented through laws, implementation, and outcomes) results from an interaction among citizen groups, industry groups, political forces, and bureaucracies. This model provides a base for understanding environmental pressures that impact policy formation and implementation. As such, it provides a framework in which to view policy implementation and organizations.

For example, every aspect of opioid dependence treatment is the product of specific decisions by state and federal legislatures and bureaucracies that have public authority to determine the components of organizational structure and treatment practices. Local and federal bureaucracies are under constant pressure from special interest groups and constituencies to exercise their authority over OTPs in particular ways. This is where the structure of treatment comes from and has little to do with environmental adaptation or requirements of legitimacy (Moe, 1991). The driving force behind these decisions is political power: Who has the power? What are their interests? and How do they impose decisions/regulations to see those interests pursued (Moe, 1991)?

While there is legitimacy in institutional and organizational ecology theory, it is important to note that there is also legitimacy in political theory. To fully comprehend
organizational change, organizational structure and adaptation within both an institutional and political context need to be considered. For this reason, the analysis for the present research included state location of an OTP because each state has its own infrastructure that influences the organizational environment, which therefore influences an organization’s ability to adapt. Additionally, this research focuses on adaptation and implementation of policy as enhanced or hindered by organizational characteristics. As Meier emphasized in the *Politics of Sin*, “the real politics of drug control is in how the policies are implemented” (Meier, 1994, p.130).

2.3 Organizational Adaptation

Up to this point, the discussion of organizational theory has highlighted organizational adaptation. However, to better understand organizational change, it is important to expand on the notion of adaptation.

Adaptation refers to organizational efforts to respond to changing environmental circumstances (Lawrence & Lorsch, 1967; Thompson, 1967). Organizational changes can occur at the institutional, managerial, and technical levels of the organization (Parsons, 1956). Organizations can adapt to environmental changes through modifications in structure and practices (Cook, 1983). The purpose of adaptation is to attain and maintain organizational homeostasis. Achieving homeostasis is believed to promote control, organizational survival, and growth (Meyer, Scott, & Deal, 1981).

Adaptation, however, has consequences because specific structures or technologies have been added or changed that may impact the organization and result in decreased effectiveness or increased costs. The present research, while focused on organizational
change, specifically examines organizational adaptation. Understanding how organizational characteristics either facilitate or impede adaptation will enhance the understanding of organizational change.

While research has examined organizational change, the field of change theory within organizational theory is still developing, thus leaving questions unanswered. The following section reviews change theory as it has been applied to organizations and discusses how the current research builds on the results of previous research.

2.4 Organizations and Change Theory

The complexity of political, regulatory, and technological change confronting most organizations has made organizational change and adaptation a central area of research (Greenwood & Hinings, 1996). The ability to cope with dramatically altering contextual forces has become a key determinant of competitive advantage and organizational survival (D’Aveni, 1994). Building on the historical review of organizational change, this section discusses how previous theories have been applied to examine organizational change.

To understand how organizations change, scholars have borrowed from and built on concepts and theories from multiple disciplines, ranging from evolutionary biology to population ecology (Hannan & Freeman, 1984; Singh & Lumsden, 1990; Kelly & Amburgey, 1991; Kraatz & Zajac, 1996; Sammut-Bonnici & Wensley, 2002). Notable to organizational change theory are institutional theory (Meyer & Rowan, 1977; DiMaggio & Powell, 1983), neo-institutional theory (Scott, 2001), organizational ecology theory (Hannan & Freeman, 1977), evolution theory (Tushman & Romanelli, 1985; Lichtenstein, 1995), and political theory (Moe, 1991).
According to early contributors to institutional theory, the organizational field supports the concept that organizations accept prevailing templates as appropriate, right, and the proper way of doing things. For this reason, institutional theorists stress the stability of organizational arrangements and the characteristic of inertia rather than change (Tolbert, 1985; Tolbert & Zucker, 1983). Radical change is thus problematic because organizations are inert to their processes that hinder their ability to learn and adapt (as emphasized by strategic choice theorists, such as Kanter [1983] and Johnson [1987]). Additionally, radical change confronts the normative embeddedness of an organization within its institutional context (Baum & Oliver, 1991). Powell and DiMaggio (1991) noted that the greater the extent to which organizations are tightly coupled to a prevailing archetypal template within a highly structured field, the greater the degree of instability in the face of external shocks. To the extent that virtually all OTPs in the United States are governed by similar institutions, they can be interpreted as having similar highly structured templates that increase their instability in the face of an external shock.

Brit and Karabel (1991) observed that institutional theory emphasizes the details of an organization’s interaction with its environment over time and pays attention to the beliefs and actions of external influences that have the power to define directions and interests. Neoinstitutionalism emphasizes the regulative, the normative, and the cognitive. Oliver (1992), building on the work of Zucker (1987), began to bring these two perspectives together in an examination of the antecedents of deinstitutionalization by suggesting that the persistence and longevity of institutionalized values and activities may be less common than the emphasis that institutional theory places on cultural persistence and that the diffusion of
enduring change implies. Oliver’s framework involved both environmental and organizational features that can produce change.

A large body of literature has focused on investigating the process and implementation of organizational change (Kelly & Amburgey, 1991), including issues of how change occurs (Quinn, 1980; Kanter, 1983), who initiates change (Ticky & Ulrich, 1984; Robbins & Duncan, 1988), and what organizational barriers impede change (Stinchcombe, 1965; Staw, Sandelands, & Dutton, 1981; Pettigrew, 1985; Boeker, 1989; Aldrich & Auster, 1988). Building on the work of the early theorists, change has been consistently conceptualized in two basic ways: as the outcome of a rational, strategic process of decision-making in which the organization chooses a new course of action and adapts to change (Thompson, 1967; Kimberly & Zajac, 1985; Hinings & Greenwood, 1988; Fennell & Alexander, 1993), or as the outcome of evolutionary selection in which the organization is seen primarily as inert and resistant to change (Kaluzny & Hernandez, 1983; Hannan & Freeman, 1984; Flood & Fennell, 1995). This dichotomy supports the earlier viewpoints of adaptation versus replacement; that is, organizations resistant to change will be replaced.

This dichotomous view of change has given way to such distinctions as convergent versus radical change (Greenwood & Hinings, 1996) and revolutionary versus evolutionary change (Barrett & Carroll, 1995). Radical organizational change involves the separation from an existing orientation (Johnson, 1987) and the transformation of the organization. Convergent change is viewed as fine-tuning the existing orientation. Similarly, revolutionary change happens swiftly and affects virtually all parts of the organization simultaneously,
while evolutionary change occurs gradually. Theorists previously considered these views to be mutually exclusive alternatives (Scott, 1987).

Tushman and Romanelli (1985), however, provided an explanation of organizational change that supports a process through which organizations are seen as alternating between an adaptive and inertial mode of behavior responding to both revolutionary and evolutionary changes throughout the organization’s life span. Building on a model that reconciles differing organizational theories, Sastry (1997) used a punctuated change model to integrate adaptationist and environmental selection views of organizational change.

### 2.4.1 Punctuated Equilibrium Theory and Organizational Change

Within the organizational theory literature, Gersick (1991) has urged researchers to investigate how organizations and industries react to punctuated environmental changes. If an organization does not adjust when its environment undergoes punctuated change, its performance and chances of survival will be diminished. By contrast, if an organization changes in response to environmental transformation, two outcomes are possible: (1) change will decrease performance and chances of survival because the liability-of-newness clock is reset and resources are diverted to restructuring, or (2) change could improve performance and chances of survival because it enables organizations to meet new environmental demands.

A number of theorists have used punctuated equilibrium to describe the evolutionary process as extended periods of consistency disrupted by short jolts of dramatic change (Eldredge & Gould, 1972; Tushman & Romanelli, 1985; Baumgartner & Jones, 1993). Tushman and Romanelli applied the theory of punctuated equilibrium to organizations and
described an evolutionary process by which organizations alternate between convergence (incremental adjustments) and revolutionary shifts, which results in dramatic change.

As the first researchers to formally test a model of punctuated equilibrium as it relates to organizational theory, Tushman and Romanelli concluded that (1) a large majority of organizational transformations were accomplished via rapid and discontinuous change over most or all domains of organizational activity, (2) small changes in strategies or organizational structure did not produce fundamental change, and (3) major environmental changes and chief executive officer changes influenced dramatic transformations. These findings strongly affected the thinking around organizational change, which led to additional work in this area.

In fact, the body of research on punctuated equilibrium theory has grown and it has critically influenced organizational change theory and the associated research (Sammut-Bonnici & Wensely, 2002). Work in this area has integrated punctuated change theory with such organizational interests as clock-resetting (the belief that organizations enjoy increased freedom in the period immediately following revolutionary change) (Amburgey, Kelly, & Barnett, 1993), organizational downsizing (Freeman & Cameron, 1993), and the technological impact on an organization (Van de Ven & Garud, 1987). The theory has found empirical support across a variety of industrial sectors, including the airline industry (Kelly & Amburgey, 1991), savings and loan associations (Haveman, 1992), minicomputers (Tushman, Virany, & Romanelli, 1995), the concrete industry (Anderson & Tushman, 1990), and the newspaper industry (Amburgey, Kelly, & Barnett, 1993). D’Aunno, Sutton, and Price
(1991) also applied punctuated equilibrium theory to public health organizations, finding empirical support in the healthcare industry.

However, the use of punctuated equilibrium to explore organizational change is still developing. Romanelli and Tushman (1994) noted that the processes within the organization that shape convergence and punctuations are poorly understood and give rise to the need for further research. For the most part, punctuated equilibrium within organizational theory has been examined at the industry level rather than at the organizational level (Romanelli & Tushman, 1994). One exception is recent work by Wollin (1996) that incorporated a multilevel analysis to explain change in organization and industry systems. According to Wollin, a punctuated equilibrium model can be a useful tool to better understand complex systems, such as organizations. More research is needed to explore the theory of punctuated equilibrium within organizations and to link organizational characteristics and their impact on organizational action. One area that could benefit from additional research is that of organizational regulation.

2.5 Regulatory Change

Institutional theorists state that regularized organizational behaviors are the product of ideas, values, and beliefs that originate in the institutional context (Meyer & Rowan, 1977; Meyer, Scott, & Deal, 1983; Zucker, 1983). To survive, organizations must accommodate institutional expectations, even though these expectations may have little to do with technical notions of performance accomplishment (D’Aunno, Sutton, & Price, 1991; DiMaggio & Powell, 1991; Scott, 1987).
Regulation has become increasingly popular as an institutional means to structure and confine organizational discretion (West, 1983). The rationale of regulatory control is to make treatment more effective by imposing desirable traits onto an organization. Regulatory agencies exercise this control through rule-making (as was the case with opioid dependence treatment—see Appendix A: Regulatory Requirements for Opioid Treatment Programs) and adjudication. Rule-making has been advocated as a more rational and expedient means to develop policy because rules can be used to establish regulatory standards quickly and efficiently (West, 1983). However, rule-making is less directive than adjudication and provides organizations with potentially expansive interpretation of the regulations (West, 1983).

Based on the institutional theory of open systems and enhanced by the lesser directive nature of rule-making, regulatory reforms are at risk for failure (Chubb & Moe, 1988). Organizations are open systems and thus products of their environments. This concept calls into question the ability of regulatory reform to impact organizations within varying environments. However, in federally regulated organizations, state and federal governments have legitimate roles to play in defining and standardizing the organizational environment. While rationality has a rich history as a guiding principle for regulatory implementation within public administration (Simon, 1947), political theory of regulation is still in a growth and development stage (Moe, 1985), making it difficult to determine the influence of bureaucracy on environment.

The prevalent perspective in studies of regulation is that organizations are “black boxes” whose output can be explained solely as a reaction to external demands (including
regulation) and technical constraints (internal forces) (West, 1988). This open-systems approach has provided the foundation for the leading general theories of regulation and has informed numerous empirical analyses that have sought to account for organizational behavior as a function of interest group activity, partisanship ideology, judicial activism, economic conditions, and a variety of other external factors (West, 1988; Meier & O’Toole, 2002). Few studies have sought to explain organizational behavior as the result of external and internal forces. For this reason, as pointed out by Meier (1985), the prevalent perspective of regulation is incomplete because regulatory policy is a combination of regulatory bureaucracies and environmental forces.

2.5.1 The Role of Regulatory Agencies and Change

The role of regulatory agencies, such as SAMHSA, in organizational change has been studied to a limited extent (Dobbin & Sutton, 1998). Federal and state interventions on the economy of organizations have most often been the focus of the regulatory literature (Cox, 1986; Hall, 1986; Campbell & Linderg, 1990; Roy, 1997; Dobbin & Dowd, 1997). These studies, while focused primarily on economic interventions, support the notion of mandated regulations as being constraining and directive in the selection of choices within organizations. Some researchers support the idea that federal regulations assist shaping organizations through clear demands, effective surveillance, and significant sanctions (Meyer & Rowan, 1977; DiMaggio & Powell, 1983).

Empirical research in the area of regulatory change has examined specific factors external to the organization that drive the adoption of regulations (Arragon-Coorea, 1998; Christmann, 2000; Sharma & Vredenburg, 1998; Nehrt, 1998). Other research has explored
organizational context as it relates to the adoption of regulations. This research includes work on the influences of organizational context and design (Ramus & Steger, 2000) and organizational learning (Marcus & Nichols, 1999). Still other research has focused on internal organizational characteristics, such as leadership values (Egri & Herman, 1999) and managerial attitudes (Cordano & Frieze, 2000). While each of these studies has added to the knowledge base concerning regulatory adoption, there remains a lack of understanding of the impact of organizational characteristics and environmental conditions on the adoption of regulatory compliance (Klassen, 2001; Gunnningham, Kagan, & Thorton, 2003).

2.5.2 Regulatory Punctuations

The present study focuses on regulatory punctuations, which are sudden and extensive shifts in organizational processes and business operations. Regulatory punctuations alter both external and institutional features of organizational environments (Haveman, Russo, & Meyer, 2001) and can affect institutional environments by altering standards for accountability.

Institutional theorists argue that organizations are driven by coercive isomorphic pressure to conform to the legal and cultural expectations of the regulatory oversight agency (Meyer & Rowan, 1977; DiMaggio & Powell, 1983). The regulatory literature indicates that many regulatory changes are of great magnitude and drive organizations to fundamentally alter their strategies, structures, and activities. Less understood, however, is what specific organizational characteristics enhance or impede the ability to comply with punctuated regulatory change.
Major regulatory initiatives rarely come as a complete surprise; instead, they often arise from extensive public reflection, debate, and negotiation. Prolonged public discourse may facilitate efforts by affected organizations to anticipate legislation. However, organizations are often barred from extensive preparation until specific dates in the legislation are released. Prior to such dates, organizations cannot implement change. It is perhaps the political environment that hinders gradual change and leads to punctuated change in response to an external event.

2.6 Federal Regulation of Opioid Treatment Programs

Regulatory regimes and regulatory punctuations vary greatly. Therefore, it is not reasonable to develop a general theory of the consequences of regulatory punctuations. Instead, midrange theories have been developed that are sensitive to context (e.g., the airline industry, the newspaper industry). Accordingly, this section provides in some detail the regulatory punctuations that occurred in OTPs.

Since the early 1970s, there have been regulations in place designed to ensure the quality of care provided by OTPs and to prevent the diversion of opioid for nontreatment uses (see Appendix B: A Chronology of the Regulations of Methadone Treatment). The first FDA opioid dependence treatment guidelines were enacted in 1972, and almost since their inception strong criticism of the regulatory process has surfaced. Critics argue that the regulations enacted in 1972 were too restrictive and have served to impede both treatment quality and treatment capacity. Additionally, as opioid dependence treatment has expanded, which has been driven by the number of patients and demand, it became increasingly difficult for FDA to consistently monitor OTPs. Hence, a variation in treatment quality
developed across programs. Finally, during this period of the FDA regulations, there was a dramatic increase in the need to provide accessible and effective treatment to heroin addicts as the HIV/AIDS epidemic increased significantly among injecting drug users (IDUs).

The combination of unchanged federal regulations for nearly two decades, the increased need for treatment among IDUs, and a heightened focus on accountability in the late 1980s prompted questions regarding the level of care provided by OTPs (Ball & Corty, 1988; GAO, 1990). A GAO report, *Methadone Maintenance: Some Treatment Programs Are Not Effective, Greater Federal Oversight Needed*, recommended that the Secretary of the Department of Health and Human Services (DHHS) direct NIDA and FDA to address performance standards in opioid dependence treatment (GAO, 1990). In response, NIDA funded a study to develop and test a performance-based reporting and feedback system for programs; however, after 10 years, only a fraction of OTPs had implemented performance-based strategies.

In 1995, the Institute of Medicine (IOM), having been asked by DHHS to evaluate the existing treatment standards, published recommendations proposing changes to the federal regulation of opioid dependence treatment. The report suggested modifying regulations to encourage comprehensive care for patients, continual reassessment of patient progress and needs, treatment based on clinical practice guidelines, and humane treatment of patients (Rettig & Yarmolinsky, 1995). At the request of the Secretary of DHHS, these recommendations were reviewed by the Interagency Narcotic Treatment and Policy Review Board (INTPRB), a working group that was originally convened under the auspices of the Special Action Officer of Drug Abuse Policy (SAODAP). Representatives from involved
Executive branch agencies in DHHS and the Department of Justice (DOJ) met regularly to
share information and discuss issues involved in administering the Narcotic Addiction
Treatment Act. Over time, INTPRB moved from SAODAP to FDA, and more recently has
been shifted to SAMHSA. INTPRB concluded that existing federal and state regulations
limited the ability of physicians and other healthcare professionals to provide opioid
dependence treatment services to patients.

Movement toward an accreditation-based system followed recommendations made by
INTPRB, which concluded that a system centered on a core set of federal treatment
standards, in conjunction with monitoring of treatment programs through private
accreditation, would be both feasible and preferable to the existing system. A 1997 National
Institutes of Health (NIH) Consensus Panel supported the INTPRB findings regarding
accreditation. The NIH Panel also suggested implementing alternative means of oversight,
such as accreditation, for improving the quality of MMT.

Thus, recognizing the need to improve quality of care in OTPs and better monitor
treatment operations, DHHS convened an interagency workgroup to draft revised regulations.
The Center for Substance Abuse Treatment (CSAT), in collaboration with other federal
agencies, convened a consensus panel to develop treatment service guidelines. The
guidelines were developed through a series of meetings with federal and state officials,
treatment experts, and patient/consumer advocates, which laid the groundwork to transition
to an accreditation-based system of regulation.

Following the GAO and IOM reports, as well as the INTPRB recommendations,
concerns about the variability in type and quality of services provided in OTPs received
urgency that was previously lacking. With the Clinton Administration’s emphasis on devolution, the political mood was supportive of a solution, such as accreditation, that reduced the involvement of the federal government in the delivery of services. Additionally, much of the stigma associated with the use of methadone for the treatment of opioid dependence has been dispelled by three decades of clinical and evaluation research proving both the clinical effectiveness and cost-effectiveness of opioid dependence treatment.

The implementation of the revised Final Rule repealing the regulatory structure administered by FDA involved a 15-year process. New opioid dependence treatment regulations requiring accreditation from a SAMHSA-approved accreditation body were published on January 17, 2001, and became effective May 18, 2001. These regulations gave OTPs until May 2003 to obtain accreditation and become SAMHSA-certified.

SAMHSA concluded that the proposed accreditation system offered several potential benefits for purchasers and payers of drug dependence treatment services, including improved and consistent operational processes and clinical practices, improved federal oversight through regularly required accreditation surveys, a greater likelihood of individual treatment by clinicians, treatment based on current best practices, and improved consistency in the quality of comprehensive assessment and treatment services. An overview of the current regulatory requirements is outlined in Appendix A.

2.7 Organizational Structures and their Environment

While previous sections have discussed the role of environment in organizational development and adaptation, this section directly examines organizational structure and environment. In the early 1970s, the relationship of organizations to their environments
(Segal, 1974) gained the interest of researchers and theorists. Institutional theory shows how organizational behaviors are responses not solely to market pressures (defined as influences on an organization threatening the organization’s capability to provide or allocate goods and services), but also to institutional pressures (e.g., pressure from regulatory agencies, such as the state and the professions, and pressure from general social expectations and the actions of leading organizations) (Blau & Scott, 1962).

Researchers need to look at internal aspects of organizations in conjunction with the manner in which the organization responds to its external environment (Segal, 1974). Hill and Lynn (2004) emphasized a need to answer the question, “Are particular organizational structures better than others for accomplishing goals?” The present study addresses the question of organizational structures as they enhance adaptability. Answers to questions about organizational structure and adaptability would allow policymakers and practitioners to assess how to replicate successful regulatory compliance or avoid compliance failure.

The present research builds on the growing body of work that explores organizational change, governance, and public management by examining a defined set of specific organizational structures from both an external market-driven environment and an internal institutional-driven environment. Market influences examined include competition as analyzed through program location and size, product delivery analyzed through parent program affiliation, and program legitimacy as analyzed through accreditation. Internal influences examined include ownership, age of the organization, and organizational leadership. Figure 2–1 highlights the progression from open systems theory, institutional
theory, and organizational ecology theory to regulatory theory and a growing interest in the governance of organizations through external and internal influences.

2.8 Summary

The premise that organizational change is difficult and that organizations are subject to strong inertial forces is central to organizational theory. One key issue is that the existence of strong inertial tendencies limits the ability of adaptationist theories to account for diversity in organizational communities. A stream of research investigating the occurrence of change in organizational populations and its consequences has recently emerged (Singh, House, & Tucker, 1986; Delacroix, Swaminathan, & Solt, 1989; Miner, Amburgey, & Streams, 1990; Amburgey, Kelly, & Barnett, 1990; Kelly & Amburgey, 1991).
Figure 2-1. Organizational Theory and Change
The present study performs two functions. First, it provides descriptive evidence about the occurrence of change in one population of organizations, opioid treatment programs. Second, it assesses the impact of market and institutional forces on organizational compliance with federal regulations.

To accomplish these two functions, this research builds on previous institutional theory to examine how market and institutional forces impact an organization’s adaptation to a punctuated change in the environment. Institutional theorists examined patterns of institutionalization, including differences in organizational adaptation, varying interactions with their environments, and organizational attributes that impact organizational structure and performance. These early theories led to the belief that organizations adapt to changes in their environment, although the process for adaptation varies considerably across organizations.

Building on the organizational theory of adaptation, organizations are driven to survive. When faced with replacement or adaptation, organizations often do not act rationally, but rather are reactive to their immediate environment, which is made up of both market and institutional forces. The examination of these market and institutional forces provides context to organizational adaptation and is discussed in detail in Chapter 3.
CHAPTER 3

Conceptual Model for Change and the Study Hypotheses

3.1 Introduction

This chapter describes the principal dimensions of a conceptual model for change that depicts the relationships of environmental forces (both market and institutional forces) on the adaptive behaviors of organizations. The model draws on an eclectic collection of theories and concepts (e.g., general open systems theory, institutional theory, political regulatory theory) and a variety of organizational concepts (e.g., institutionalism and technology), which results in a set of testable hypotheses that form the basis for the empirical investigation discussed in the remaining chapters.

3.2 Conceptual Model for Change

Organizations often arrange their core activities according to accepted models, or templates, in their field (D’Aunno, Succi, & Alexander, 2000). In the case of OTPs, a significant component of the institutional template has typically been the federal regulations in place since 1972. These templates represent predictable patterns for arranging organizational behavior. The recent reform in opioid dependence treatment regulations and oversight provides an opportunity to examine the impact of environmental forces on organizations experiencing a punctuated change (Oliver, 1991).

Research has shown that organizations evolve and abandon long-term institutional templates—such as those practiced by OTPs under the FDA regulatory structure—and actively choose to adopt or reject organizational practices driven by regulatory compliance
(Cook, Shortell, Conrad, & Morrisey, 1983). Understanding the impact of environmental factors, specifically market and institutional forces, on organizational change mandated through federal regulations may help to establish a formal model that is capable of predicting or guiding organizational change outcomes. Such a model would provide legislators and practitioners with an important tool to better identify failing policies and to guide organizations toward successful adaptation through the implementation of new regulations, policies, or practices.

Federal regulators often expect organizations to adopt change but they have limited knowledge as to what characteristics promote or block this adoption. The present study explores organizational adaptation within OTPs as defined by an external organizational change in regulatory policy addressing (1) take-home medication policies and practices, (2) dosage medication policies and practices, and (3) quality assurance system policies and practices. Choosing two dosing variables and one QA variable to define change will help to capture the most divergent dimensions of change represented in the new regulations while maintaining consistency with existing research in opioid dependence treatment.

Theorists have proposed several explanations for organizational change (DiMaggio & Powell, 1983; Oliver, 1992; Thornton, 1995); however, only recently has research emphasized the importance of both market competition and institutional factors in causing such change (D’Aunno, Folz-Murphy, & Lin, 1999). Institutional theory (Dacin, 1997; Scott, 1987; Scott & Meyer, 1983; Meyer & Rowan, 1977) emphasizes that organizational fields vary in their reaction to the relative strength and heterogeneity of institutional and market pressures. While recent studies (Davis, Diekmann, & Tinsley, 1994; Greenwood & Hinings,
1996; Kraatz & Zajac, 1996; Leblebici, Salancik, & King, 1991) shed some light on understanding organizational adaptation, limited research has examined organizational change in the substance abuse treatment field. Because few research studies have used organizational frameworks to study change in substance abuse treatment systems, a number of unanswered questions remain pertaining to organizational adaptation and survival in a time of environmental change. The present study builds on the work of earlier theorists to develop and apply a conceptual framework of organizational change under regulatory reform.

Seven forces are proposed—a set of four market forces and a set of three institutional forces—that have direct effects on organizational change (Figure 3-1). Of specific interest in this study are the areas of change that surround dispensing methadone doses (i.e., take-home doses and doses greater than 100mg) and QA policies and practices.

3.3 Conceptualizing Organizations

Organizations may be conceptualized as heterogeneous entities composed of functionally differentiated groups pursuing goals and promoting interests. How organizations respond to change is a function of individual internal dynamics (D’Aunno, Sutton, & Price, 1991). An organizational perspective has been useful in describing major changes that have occurred in the healthcare sector and in mental health services (Scott, 1993) and some researchers believe that an organizational perspective may provide the basis for organizing research within the changes seen in the substance abuse treatment system (Marsden, 1998).
3.4 Conceptual and Empirical Definition of Organizational Change

Several theorists have attempted to define organizational change. For example, Burnes (1996) noted that organizational change refers to understanding alterations within organizations at the broadest level among individuals, groups, and at the collective level across the entire organization. Van de Ven and Poole (1995) defined change as the observation of difference over time in one or more dimensions of an entity. Generally,
change can be defined as differences within an organization. The ensuing question is, Why does an organization change?

Opioid dependence treatment recently underwent a significant change in accepted institutional practice. As discussed in Chapter 2, Organizational Change Theory Applied to the Study of Opioid Dependence Treatment, OTPs were operating under regulatory guidelines in place since 1972. New regulatory guidelines were finalized by CSAT in June 2001. This shift in institutional practice presents a unique opportunity to study the process of organizational behavior in response to a punctuated change within opioid dependence treatment. However, before examining change it is critical to identify and operationalize measures of change.

The newly mandated regulatory guidelines released by CSAT discuss three domains that diverge significantly from previous opioid dependence treatment practice:

- Unsupervised Approved Use of Methadone (“Take-home Medication”)
- Expanded Guidelines for Therapeutic Dosage in Excess of 100 mg
- Quality Assurance Systems and Procedures

3.4.1 Take-home Medication

Opioid dependence treatment requires a daily dose of medication. However, going to an OTP every day can be a burden for patients who are attempting to maintain employment and care for families; thus, some treatment programs allow clients to earn the right to “take home” methadone doses. Because methadone can produce a high (i.e., a euphoric or stupefied state) for persons not accustomed to being treated with it, allowing patients to take
home doses for unsupervised use involves the risk of medication misuse or diversion of methadone for nontreatment uses.

Unsupervised approved use (take-home medication), as defined in the CSAT Guidelines (CSAT, 2001), must meet the following criteria for determining the number of take-home (unsupervised) doses per week:

- first 90 days of treatment—maximum of one unsupervised dose per week
- second 90 days of treatment—maximum of two unsupervised doses per week
- third 90 days of treatment—maximum of three unsupervised doses per week
- remainder of year one and year two—maximum of six unsupervised doses per week
- year three—a maximum of 30 unsupervised doses per month
- one-time or temporary (usually not to exceed three days) take-home medication may be approved for documented family or medical emergencies or other exceptional circumstances

Under the previous FDA requirement, OTPs had to follow more stringent requirements for take-home privileges, including a maximum take-home privilege of 6 days of medication and only after 3 years of successful treatment compliance. Additionally, under the FDA regulations, take-home privileges were not permitted for patients with a daily dose of greater than 100 mg of methadone. With the less stringent criteria outlined in the CSAT Guidelines, take-home policies and practices represent one of the most significant changes in institutional norms under the new regulatory legislation in opioid dependence treatment.

To capture the percentage of patients receiving take-home medications, researchers for the Evaluation Study used a dosing abstraction log to determine the number of “methadone patients who were on a take-home dose on [reference date] (day of site visit).”
This measure was collected by 172 OTPs at two separate points in time (Time 1 and Time 2) (Wechsberg, Kasten, Berkman, & Roussel, 2006).

### 3.4.2 Therapeutic Doses of Methadone

Prescribing and administering the appropriate dosage of methadone to a patient is the crux of opioid dependence treatment. Inadequate methadone dose levels may fail to curb a patient’s cravings for the drug of addiction (e.g., heroin). Objective evidence of low concentrations of methadone in the blood serum can be recorded; however, subjective effects of inadequate dosing can only be experienced and reported by the patient. As a result, even with empirical evidence supporting the effectiveness of methadone in preventing drug cravings (Ball & Ross, 1991), there is a history of debate regarding dose levels and how much influence a patient should have over his or her own dose levels.

Guidelines for therapeutic dosage as defined in the CSAT Guidelines (CSAT, 2001) state that

- the dose of methadone/LAAM [levo-alpha acetyl methadol] maintenance medication is individually determined on the basis of good clinical judgment after review by a physician or other professional practitioner with prescribing privileges who is knowledgeable about, and experienced in, addiction medicine including methadone/LAAM therapy.

- the maintenance dose is individually determined with careful and caring attention to the essential information provided by the patient; the dose should be determined by a physician experienced in addiction treatment and should be adequate to achieve the desired effects for 24 hours or more, with allowance for day-to-day fluctuations and elimination patterns.

- methadone is a medication and it should not be standard practice to manipulate doses to reinforce positive behavior or to punish negative behavior.

- methadone is continued as long as benefit is derived from treatment and the treatment is desired by the patient.
FDA regulatory guidelines required physicians practicing in OTPs to justify in writing any prescription of more than 100 mg of methadone, despite numerous research studies supporting the use of higher doses of methadone in opioid dependence treatment (Ball & Ross, 1991; Leavitt, Shinderman, Maxwell, Eap, & Paris, 2000; Seivewright, 2000). Therefore, individualized dosing for opioid dependence treatment has become a critical issue in the delivery of treatment services, specifically as it relates to doses greater than 100 mg of methadone.

To capture the percentage of patients receiving a specific dose of methadone, researchers for the Evaluation Study used a dosing abstraction log to document the “number of patients dosed with methadone on site on [reference date].” Of the total number of patients that received methadone, researchers documented the specific number that received doses within each of the following categories:

- < 45 mg
- 45–59 mg
- 60–100 mg
- > 100 mg

This measure was collected by 172 OTPs at two separate points in time (Time 1 and Time 2).

### 3.4.3 Quality Assurance

With the growing interest in performance measurement and quality treatment services, QA systems within substance abuse treatment programs have gained considerable attention. This is especially true within the field of opioid dependence treatment because of concerns raised throughout the past decade regarding quality service delivery and
standardization of care. In support of these growing concerns, GAO evaluated opioid
dependence treatment specifically and found that none of the 24 programs reviewed
evaluated the effectiveness of services provided (GAO, 1990).

As defined in the CSAT Guidelines (CSAT, 2001) quality assurance pertaining to
OTPs includes the following:

- provide regular and continuous staff education
- review and recertify program policies and procedures at least annually
- develop a diversion control plan that demonstrates accountability to its patients
  and to the community
- measure and monitor treatment outcomes and processes, such as
  - reducing or eliminating the use of illicit opioids, illicit drugs, and the
    problematic use of licit drugs;
  - reducing or eliminating associated criminal activities;
  - reducing behaviors contributing to the spread of infectious diseases; and
  - improving quality of life by restoration of physical and mental health and
    functional status

FDA regulatory guidelines did not require OTPs to have a formal QA system in
place. As such, measuring services through formal performance measurement activities
within opioid dependence treatment have become a critical component for evaluating quality
of care.

To capture organizational QA activities, clinical supervisors were asked by
Evaluation Study researchers to answer 12 survey questions (see Appendix C). These
questions were asked of clinical supervisors in 172 OTPs at two separate points in time
(Time 1 and Time 2).
Further discussion of how the three dependent variables for change were operationalized is presented in Chapter 4.

3.5 Impact of Market and Institutional Forces on Organizations

Professional norms, the need to be seen as acting appropriately by the community, and demands of federal agencies all influence the structures and practices of organizations in their institutional environments. Because organizations are driven to survive, they adapt in whatever ways they must to the demands, needs, and requirements of society to gain support and legitimacy (March & Olsen, 1976; March & Olsen, 1984). Organizations do not act rationally in this situation; rather, they are reflections of the larger society as defined through market and institutional forces (March & Olsen, 1984).

Therefore, it is critical to the examination of organizational change to better understand the impact of both market and institutional forces on organizational behavior. Theorists have hypothesized that organizational change is more likely to occur within organizational fields that have strong local market forces and strong but heterogeneous institutional forces (D’Aunno, Sutton, & Price, 1991). Organizations are believed to face strong, local market forces to the extent that there is relatively low local demand for their products and services and intense local competition from competing organizations (Zucker, 1989). Low local demand for an organization’s product (e.g., opioid dependence treatment services) and intense competition among neighboring organizations have been shown to drive organizational change, pushing less competitive (or failing) organizations to either relocate their services or close down (Haveman, 1993; Greve, 1998).
While much of the economic research on organizational change has focused on external market forces, social science research supports the value of examining internal institutional factors in addition to external market forces (Schilling, 2002; D’Aunno, Sutton, & Price, 1991). An organization’s internal choices and practices influence its ability to adapt to a changing environment. To the extent that the environment consists of influential but diverse regulations, as is the case in opioid dependence treatment, organizations may find it easier to adapt to changes in structure and practice (Scott, 1995). Organizational change is supported when internal institutional elements are inconsistent with the accepted norms. This condition provides the organization with the flexibility to abandon the accepted rules previously guiding organizational behavior (Oliver, 1991, 1992).

This study focuses on the regulatory demands of the federal oversight agency for substance abuse and mental health, SAMHSA, and the impact environmental market and institutional forces have on organizational behavior and regulatory compliance. A more detailed description of specific market and institutional forces of interest is provided below.

### 3.5.1 Market Forces

Previously, researchers believed that the demand for substance abuse treatment services was unlike that for other economic goods and therefore it was unresponsive to traditional market forces. Recently, however, research from two distinct fields, economics and behavioral psychology, has coalesced to provide evidence that substance abuse treatment services do respond to market forces (Chaloupka, Grossman, Bickel, & Saffer, 1999).

While substance abuse treatment organizations may respond to market forces, an additional aspect for consideration is that opioid dependence treatment is not only governed
by market forces, but also by political forces. Market forces systematically promote
characteristics in opposition to those promoted through political forces (e.g., burdensome
bureaucracy) (Chubb, 2003).

The term *market* refers to the group of consumers or organizations that is interested in
the product, has the resources to purchase the product, and is permitted by law and other
regulations to acquire the product (Tomic, 2006). Market forces are grounded in the notion of
supply and demand; that is, what influences impact the supply and demand for a particular
product (in this case, opioid dependence treatment services).

This study focuses on three areas of market forces: competition, product delivery, and
legitimacy. Competition is examined through two specific variables: program location and
program size. Product delivery is examined through affiliation with a parent organization,
and program legitimacy is examined through previous accreditation of the program.

The need to inject greater competition into service markets was the dominant theme
of public management reform during the 1980s and 1990s (Boyne, 2002). Researchers
universally agree that competition is a primary force driving the market (Succi, 1996).
Competition, by definition, is dependent on program location and program size, and it is
believed to promote organizational efficiency, innovation, and consumer responsiveness -
first primarily in the private sector, with later support in the public sector. Many researchers
believe that competition behavior rather than organizational ownership is the key variable for
understanding organizational behavior (Boyne, 2002).

An additional aspect of the market is the ability to supply the product, which
translates into a program’s ability to provide services to patients to meet the demand for
treatment. Program association with a parent organization impacts the ability to supply services (Hannan & Freeman, 1977; Baum & Haveman, 1997) through efficiencies gained by a centralized administration.

Finally, market forces concentrate on resources; that is, who has the purchasing power for the product. In the healthcare field generally and in substance abuse treatment specifically, the majority of treatment services are purchased through public funding sources, such as state funding, Medicaid, or Medicare (D’Aunno, 2004). Public funding or reimbursement for services is often linked to the certification or licensure of a program (Council on Accreditation, 2006), making it important to examine the impact of accreditation as a market force driving program legitimacy and the demand for treatment services. The four market force concepts introduced here—location, program size, accreditation, parent affiliation—are discussed in more detail below.

3.5.1.1 Location

The results from several empirical studies show that the addition of an organization to a population impacts neighboring organizations (Baum & Singh, 1994; Lomi, 1995; Baum & Haveman, 1997). For example, competition for opioid dependence treatment is much higher in large urban areas because the majority of OTPs are located in inner-city, large urban communities (D’Aunno, 2002). In these large urban areas, competition for patients seeking treatment services is fierce, whereas treatment programs located in rural areas do not experience the same level of competition.

OTPs located in urban or large urban areas will face relatively strong competition to attract patients from the same limited pool of consumers. Organizations located in these local
markets with highly competitive environments may be more likely to adapt to environmental changes in an attempt to remain competitive within the field. This acceptance of adaptation would encourage organizational compliance with new regulatory guidelines.

<table>
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<th>Hypothesis 1</th>
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<td><strong>H1:</strong> Opioid dependence treatment programs located in large urban areas are more likely to adopt regulatory change than their treatment program counterparts located in less populous areas.</td>
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### 3.5.1.2 Program Size

The size of an organization directly impacts its ability to respond to service demands. A program can only serve a maximum number of patients as determined by building capacity guidelines and staffing. While larger organizations are able to serve more patients, thus increasing their market presence, previous research has shown that these larger organizations are often resistant to change (Hannan & Freeman, 1984). As organizations grow in size, they incorporate static behaviors and become inert (Downs, 1967). Organizational behavior among large organizations has been seen to be predictable and rigid, practically as a mechanism of protecting their market share within a specific location (Quinn & Cameron, 1983). Large organizations have more power and leverage over their environments, and as a result, they are more able to resist immediate pressure for change (Pfeffer & Salancik, 1978).

In addition to the research documenting the tendency toward inertia in larger programs, research has also documented the movement of smaller organizations toward environmental adaptation or change (Baum, 1996). Smaller programs suffer a competitive disadvantage—compared with their larger counterparts—that has been associated with the
need to adapt to environmental changes to enhance survival (D’Aunno, Sutton, & Price, 1991; Marsden, 1998).

**Hypothesis 2**

**H2:** Small opioid dependence treatment programs are more likely to adopt regulatory change than their larger treatment program counterparts.

### 3.5.1.3 Previous Accreditation

Accreditation provides program legitimacy in the field of healthcare. While healthcare organizations often vary in service delivery and quality, OTPs accredited by a national accrediting organization prior to regulatory change were seen as providing a standard set of services at a high level of quality (D’Aunno, Sutton, & Price, 1991). One benefit of accreditation is that it requires organizations within a field to comply with a distinct set of standards for care. Therefore, OTPs that were accredited prior to the change in regulatory oversight were seen to be functioning under a set of specific standards that controlled their processes (D’Aunno, Sutton, & Price, 1991).

In addition to quality of service, accreditation is also linked to reimbursement for services. Recent literature has documented that nearly one-third of all program revenue comes from public funds (D’Aunno & Pollack, 2002). A critical aspect of market assessment is the identification and recognition of the population eligible to purchase services. Within the field of healthcare generally and substance abuse treatment specifically, the majority of services are purchased with public funds; therefore, it is critical to examine aspects of service funding that impact reimbursement and thus program revenues.
Accreditation is one specific area that impacts reimbursement for services. Nonprofit and private programs alike are dependent on public funding to a certain extent. In today’s market, both private and public insurance companies are recognizing accreditation as a mechanism to monitor quality services and as a metric to determine reimbursement. As a result, accreditation is linked with the purchase of substance abuse treatment services.

Conforming to accreditation standards, however, may prove contradictory to change. A central argument in structural inertia theory (Hannan & Freeman, 1984) is that, over time, routine reduces an organization’s ability to change. Neo-institutional theorists support this notion through the argument that routines can contribute to inertia (Zucker, 1977). Research examining Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) standards supports the notion of inertia within programs achieving accreditation (McCaughrin, 1990). Conforming to specific JCAHO standards was found to be associated with greater effectiveness, but also with less efficiency and greater isomorphism. Accredited organizations may also view change as a “risk” to their current funding sources decreasing their likelihood to change.

**Hypothesis 3**

**H3:** Nonaccredited opioid dependence treatment programs are more likely to adopt regulatory change than their accredited treatment program counterparts.

### 3.5.1.4 Parent Affiliation

The field of opioid dependence treatment has evolved on many dimensions over the past 40 years. With the expansion of market demand (Ball & Ross, 1991; D’Aunno, Folz-Murphy, & Lin, 1999), both publicly owned and privately owned OTPs needed to find ways
to increase their capacity to serve patients while decreasing the extent of administrative burden. As a result of this market opportunity, the number of investment-owned programs (i.e., multiple programs managed by a single parent organization) has increased within the field (D’Aunno, Folz-Murphy, & Lin, 1999). This type of organizational arrangement increases efficiency by decreasing administrative costs, and increases competitive strength by increasing service capacity. Additionally, affiliation with a parent organization provides the individual organizations with a network or partnership of other service providers that allows the organization to mobilize more skills, as compared with a single organization functioning in isolation (Boyne, 2002).

Affiliation with a parent organization plays an important part in promoting organizational change because it dictates how programs are organized (Fligstein, 1996). Research has documented that organizations controlled by a central parent organization are more likely to accept and incorporate change. This is, in part, because central control weakens the importance and identity of the subunits, which makes change seem less threatening (Douglas, 1986; Davis, Diekmann, & Tinsley, 1994).

### Hypothesis 4

**H4:** Opioid dependence treatment programs owned by a parent organization are more likely to adopt regulatory change than their independently owned treatment program counterparts.

#### 3.5.2 Institutional Forces

While the examination of market forces offers insight into environmental influences and organizational change, market forces cannot be viewed in isolation. Previous research has pointed to the need to look at institutional forces to better understand organizational
behavior by accounting for variance within systems (Tweedie, 1990). Traditionally, healthcare service organizations have responded more to institutional forces than to market forces (Cook, Shortell, Conrad, & Morrisey, 1983), with medical professionals establishing a norm for treatment practice and delivery.

Institutional forces involve the social and political structures to which organizations must conform. By definition, organizational change occurs when a program abandons an institutionalized template (Oliver, 1991). Organizations having heterogeneity in institutional elements are believed to be more adaptive to change (Oliver, 1992). Because of the strong regulatory control over opioid dependence treatment in the presence of disassociated sources of authority—including local community, state, and federal levels of authority—opioid dependence treatment organizations are seen as possessing a strong heterogeneity in institutional elements (Scott & Meyer, 1983).

Three aspects of institutional forces are considered within the constraints of this study: ownership, program age, and leadership. Ownership defines who has legal claim to program assets and profits (Fama, 1980). Program age defines how long administrative and clinical practices have been in place. Strong leadership within a heterogeneous organization can act to either enhance or impede organizational shifts in policies and practices (Meyer, Scott, & Strang, 1987). These three concepts are discussed in detail below.

3.5.2.1 Ownership

Studies have shown that the type of organizational structure, including ownership, is a significant factor influencing organizational practice (Teruya, Hardy, Hser, & Evans, 2006). Property rights are defined by who owns or has claim on the profits for an organization
(Jensen & Meckling, 1976; Fama, 1980). Both publicly and privately owned organizations exist within the field of opioid dependence treatment, with an approximately equal distribution of each (Ball & Ross, 1991). Generally, privately owned organizations receive less of their revenue from public funds and are more dependent on patient fees for revenues. Additionally, private organizations, while regulated by state and federal governments, are less accountable to the demands of local community and legislative members (D’Aunno, Sutton, & Price, 1991). Government-owned (of which there are very few remaining) and nonprofit OTPs serve local communities and are responsible for providing services to patients who would not be able to afford treatment without assistance. These programs are expected to meet the social needs of society in an equitable manner (Durkin, 2000).

Previous research has found that public ownership diffuses the costs and benefits of organizational performance and, as a result, creates inertia rather than supporting change (Meyer & Zucker, 1990). Public programs operate in larger, more complex governing systems that tend to be less adaptable (Chubb & Moe, 1988). Private programs enjoy more autonomy, which makes adaptation more likely (Chubb & Moe, 1988). Overall, the more the property rights in an organization consist of public rather than private ownership, the less likely it is that organizational change will occur (D’Aunno, Sutton, & Price, 1991).

**Hypothesis 5**

**H5:** For-profit funded organizations are more likely to adopt regulatory change than nonprofit organizations.
3.5.2.2 Program Age

Program age has been associated with program survival (Nelson & Winter, 1982; Hannan & Freeman, 1984), with age having an inverse relationship with organizational mortality (Hannan & Freeman, 1989). One explanation for this inverse relationship is that organizations tend to become more effective with age. For example, an older organization may be seen as having acquired skills and knowledge over time that increase the organization’s competence and lowers its risk of mortality (Nelson & Winter, 1982). Hannan & Freeman (1989) expanded on this theory by proposing that not only does time provide benefits of learning, it also promotes organizations with high levels of reliability and accountability. Reliability is enhanced by the development of highly standardized routines that form the basis of continuity of behavior over time. Program age may promote reliability and decrease risk of mortality; however, this is true in stable environments, not during environmental change.

Because program age is associated with high reliability and accountability, it serves as a defining concept for program inertia. Researchers supporting the theory of organizational inertia believe that older organizations function under a set of formalized policies and practices that make them more resistant to change (Stinchcombe, 1965). Structural stability increases inertia (Hannan & Freeman, 1984), and as a result, older organizations are seen as dependent on the status quo (D’Aunno, Sutton, & Price, 1991).

**Hypothesis 6**

**H6:** Younger organizations are more likely to adopt regulatory change than older organizations.
3.5.2.3 Leadership

Research in public administration has emphasized good public management as the difference between success and failure in the delivery of public policy outcomes. Good management has been shown to be a critical contributor to program success (Meier & O’Toole, 2002). However, public management must incorporate the notion of leadership, which is a theme of substantial importance among researchers, as good leadership has been directly linked with organizational success (Meier & O’Toole, 2002).

A program’s management is important to the organizational structure because leaders within an organization frame the system’s goals and have the power to influence policies and practices (Hage & Dewar, 1973). Within OTPs, there are two distinct positions providing leadership within an organization: (1) the clinical supervisor who oversees all daily operations of the program, and (2) the medical director who oversees all medical aspects of care, including methadone dosing. Physician acceptance of certain practices has been examined and is seen as necessary to reforming the substance abuse treatment system (Floyd, Kramer, & Born, 2005). Assuming that professional socialization influences a leader’s values and priorities, leaders with more opioid dependence treatment experience will be more likely to adopt regulatory change aimed at improving services.

<table>
<thead>
<tr>
<th>Hypothesis 7</th>
</tr>
</thead>
<tbody>
<tr>
<td>H7: Organizations in which the clinical supervisor has more experience in opioid dependence treatment will be more likely to adopt regulatory change than organizations with less experienced clinical supervisors.</td>
</tr>
</tbody>
</table>
Hypothesis 8

H8: Organizations in which the medical director has more experience in opioid dependence treatment will be more likely to adopt regulatory change than organizations with less experienced medical directors.

3.6 Summary

The present research examines change through three dimensions—take-home medication policies, dosing policies exceeding 100 mg of methadone per day, and quality assurance policies and systems. These three dimensions of change are examined using eight independent variables to capture four market forces and three institutional forces influencing organizational performance and adaptation. Figure 3-2 summarizes organizational theories presented in Chapter 2 as they relate to organizational adaptation and the eight proposed hypotheses.

As depicted in Figure 3-2, early organizational researchers (Meyer & Rowan, 1977; Meyer & Scott, 1981, Hannan & Freeman, 1989; Haveman, 1992) believed that organizations were inert. Through theories of rationalization, researchers supported the idea of isomorphic organizations that develop strong norms and schemas to gain legitimacy. Through theories of ecology, researchers supported the idea of organizations that gradually evolve along a life course. These organizations are typically structurally inert and are most vulnerable at their early stages in development (liability-of-newness).
Figure 3-2. Organizational Theory for Change
Organizational theory continued to develop and grow, however, with new researchers (Gersick, 1991; Moe, 1991; Oliver, 1992; Meier, 1994; Romanelli & Tushman, 1994; Sastry, 1997) supporting the idea of organizations as open systems that could develop and adapt to change. Adaptation research emphasizes demands and pressures on the organization. These demands are seen as a combination of political and environmental forces.

From the adaptation literature, new researchers are continuing to examine organizational structure and environmental influences, including politics and governance (Hill & Lynn, 2004). Researchers across various disciplines continue to examine the influences of market pressures and institutional forces (Baum, 1996; Haveman, 1997; D’Aunno, 2002; D’Aunno, 2004). Through this ongoing research, hypotheses can be developed as to the impact of specific market and institutional forces on organizational change. The examination of these forces and their impact on opioid treatment program change is the focus of the following chapters.

Chapter 4, Study Design, Sampling, and Methods, details the original Evaluation Study design, discussing instrumentation, internal and external validity, and sample selection. It also presents the research methods used to test the proposed hypotheses. Chapter 5 presents the results of the univariate and bivariate analyses. Chapter 6 details the multivariate model used to test each of the hypotheses and the results from these analyses.
CHAPTER 4

Study Design, Sampling, and Methods

4.1 Introduction

To test the hypotheses proposed in Chapter 3, data were drawn from the Accreditation Evaluation Study (Evaluation Study), a two-wave panel study of OTPs (Wechsberg, Kasten, Berkman, & Roussel, 2006). Each wave of the study consisted of a 2-day on-site visit with the OTP clinical supervisor, treatment program medical director, other program staff, and patients.

This chapter describes in detail the Evaluation Study’s data collection and sampling techniques. In addition, it outlines how the dependent and independent variables are measured and addresses the reliability and validity of the data collected. The chapter concludes with a discussion of the methods used to test the hypotheses. The results of the univariate, bivariate, and multivariate data analyses are presented in Chapters 5 and 6.

4.2 Description of the Data Set

Data used in the present analysis were collected under a CSAT-funded project (Contract No. 270-97-7002 to RTI International) tasked with evaluating the impact of accreditation on the field of opioid dependence treatment. The Evaluation Study was designed as a systematic evaluation of the processes, barriers, and costs associated with changing from an FDA-regulated system to a SAMHSA oversight, accreditation-based system of opioid dependence treatment. The Evaluation Study was also charged with
identifying changes in clinical policies and practices, service accessibility and delivery, and
patient characteristics in OTPs that underwent accreditation.

RTI International (RTI) conducted the study from 1998 to 2001. The time of initial
assessment (1998–1999) occurred during the growth and redesign of federal regulations
overseeing opioid dependence treatment, whereas the second assessment in 2000–2001
occurred after the publication of the notice for proposed rulemaking (NPRM) and during the
publication of the final rule modifying oversight and federal regulations for treatment.
Access to the Evaluation Study data set can be obtained through SAMHSA’s Office of
Applied Studies (OAS), which provides public use files for on-line analysis through the
Substance Abuse and Mental Health Data Archive (SAMHDA) system managed by the Inter-
University Consortium for Political and Social Research (ICPSR) at the University of
Michigan. SAMHDA can be accessed through SAMHSA’s Web site at www.samhsa.gov.

4.3 Study Units

The unit of analysis used in this study is the organizational program. The term
program refers to the single OTP recognized by the DEA and FDA through separate
registration identification and is consistent with the FDA language stating that “the primary
facility and each outpatient facility are separate programs,” where each would “conduct
initial evaluations of patients and administer and dispense medication.” Likewise, the term
program is consistent with the DEA phrase program site.
4.4 Sampling Frame and Design

The Evaluation Study was designed as an experimental study to capture both a pre- and post-intervention (accreditation) measurement of the same constructs in OTPs randomly assigned as either experimental or control sites. In the control sites, an accreditation standards review did not occur until after the Evaluation Study research staff concluded data collection.

A multistage stratified sampling process was used to recruit organizations for the sample. The first stage of sampling was the state. The sample included 15 states that were chosen to satisfy one or more of the following criteria:

- geographically dispersed throughout the four U.S. Census regions
- strategically recruited for inclusion in the study because they encompassed a large number of OTPs and represented different models of treatment and/or regulation
- representative of states that participated in the Methadone Treatment Quality Assurance Study (MTQAS)
- states that currently mandated accreditation or deemed status (the acceptance of accreditation in lieu of licensure requirements)

Figure 4-1 depicts the 15 states chosen for participation in the Evaluation Study. The sampling frame for the study included all OTPs in these 15 states; with the exception of hospital-based detoxification OTPs, Department of Veterans Affairs OTPs, and OTPs administered through correctional facilities. These programs were excluded from the study because of their unique structure and treatment procedures.

Program selection was the second stage of the multistage sampling process. The number of programs selected from each state was designed to be proportional to the overall distribution of OTPs in each state (i.e., states with the highest number of OTPs had the
Figure 4-1. States Participating in the Evaluation of the Opioid Treatment Program Accreditation Study

largest representation in the sample). The sampling strategy also sought to achieve a balance between several key organizational characteristics. As directed by CSAT, organizational structure (as determined by the number of programs within the parent organization—single or multiple) was identified as a key organizational characteristic to consider when selecting sites within each sample state. Additional organizational features included the size of sites (as measured by patient census) and ownership (as determined by for-profit or nonprofit/public status).

Based on these three key organizational characteristics, minimum quotas were set for selecting specific programs to include in the study. Therefore, oversampling for these three
criteria occurred to meet the CSAT required quota of at least 20% small (<100 patients) programs in the final sample, at least 30% for-profit sites in the final sample, and at least 20% of programs that were part of a larger parent organization in the final sample.

4.5 Contamination in the Control Group

While the initial intent of the Evaluation Study was to maintain a “controlled” environment to compare changes in an experimental group of OTPs with changes in a control group of OTPs, the release of NPRM during data collection for the study contaminated the purity of the control group. To test the impact of this contamination, the present study examined differences between experimental and control group OTPs at Time 2 for each of the dependent variables (Table 4-1).

Table 4-1. Bivariate Analysis of Experimental and Control Differences

<table>
<thead>
<tr>
<th>Dependent Variable</th>
<th>Wave of Study</th>
<th>Time 1 (n = 172)</th>
<th>Time 2 (n = 147)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Experimental</td>
<td>Control</td>
<td>Experimental</td>
</tr>
<tr>
<td>% Patients on methadone take-home doses</td>
<td>0.21 (0.16)</td>
<td>0.24 (0.21)</td>
<td>0.25 (0.18)</td>
</tr>
<tr>
<td>% Patients on &gt;100 mg methadone</td>
<td>0.06 (0.08)</td>
<td>0.05 (0.05)</td>
<td>0.07 (0.08)</td>
</tr>
<tr>
<td>Quality Assurance</td>
<td>9.23 (2.54)</td>
<td>8.90 (3.33)</td>
<td>10.15 (1.59)</td>
</tr>
</tbody>
</table>

The expectation was that the control group programs would display little to no change in organizational behavior as expressed through the three dependent variables. Control group organizations should have been unaware of (i.e., not exposed to) the changing regulations. The experimental group programs, on the other hand, were expected to show significant
change from Time 1 to Time 2 in each of the dependent variables because they were exposed to the changing regulations depicting differences in each of the dependent variables. As a result, one would expect to find difference in means for all three dependent variables between the experimental and control cohorts.

Bivariate analyses of the three dependent variables at Time 2, however, found no significant differences at the $p<.05$ level between experimental and control group programs. This analysis supports the belief that exposure to the changing regulations through the public release of NPRM resulted in organizational changes in each dependent variable from Time 1 to Time 2 for both experimental and control group programs. The changes in dependent variables observed in the control group programs, combined with the known exposure of the control group to treatment effects during the study period, led to the decision to combine the experimental and control groups to form a single sample of 172 OTPs. For purposes of the analyses here, a sample combining the experimental and control group programs was used.

4.6 Program Attrition

For a variety of reasons, a select number of OTPs did not complete the Evaluation Study. A program was considered to be a dropout only after CSAT received formal notification of its withdrawal from the project or the site was no longer in business. Of the 24 programs that dropped out of the study between Time 1 and Time 2, not having enough time to participate in the ongoing data collection was cited by 10 of the 24 programs as the reason for dropping out. Six programs cited staff turnover as the reason for dropping out, two programs closed, and six programs were not available for contact.
Analyses were conducted to compare drop-out programs with programs that remained in the study. No significant differences were found on the three stratification variables: 1) ownership; 2) size; and 3) parent affiliation. Although there was some attrition of OTPs between Time 1 (n = 172) and Time 2 (n = 147), the overall attrition rate among programs was moderate given the size and scope of the study. It is, therefore, determined that bias is not a concern for programs remaining in the study.

4.7 Instrumentation

Multiple instruments were designed for the Evaluation Study. Questionnaires were used to capture administrative and clinical data, and were developed using items from other national substance abuse treatment studies, including the Drug Abuse Treatment Outcome Studies (DATOS) (Simpson & Brown, 1999) and MTQAS (Ducharme & Luckey, 2000). Original questions were also created to capture specific effects of accreditation on clinical policies and practices, service accessibility and delivery, and patient outcomes. These questions provided critical information on the full scope of OTP characteristics necessary for capturing organizational change from Time 1 to Time 2.

Abstraction instruments were developed to capture data at the organizational level on four areas of interest: (1) types and amount of recent patient discharges, (2) patient dosing levels and frequencies, (3) the presence and extent of program waiting lists for services, and (4) toxicology testing of patients through urinalysis results. Table 4-2 outlines the data collection instruments that yielded data used in the present analyses.
Table 4-2. Evaluation Study Instrumentation

<table>
<thead>
<tr>
<th>Instrument</th>
<th>Provides information on...</th>
<th>Level of Data Collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Site Director Survey</td>
<td>Organizational characteristics</td>
<td>Organizational data</td>
</tr>
<tr>
<td>Staff Surveys</td>
<td>Staff experience</td>
<td>Staff data</td>
</tr>
<tr>
<td>Dosing Logs</td>
<td>Dosing levels and take-home medication privileges</td>
<td>Patient data</td>
</tr>
</tbody>
</table>

4.8 Survey Respondents

Surveys were administered to a cohort of OTP administrators and staff during data collection. At Time 2, data were sought from the same organization and the same staff position (e.g., clinical administrator; medical director), although staff positions were often filled with different individuals than seen at Time 1.

This process maintains the focus on the organization as the unit of analysis. Table 4-3 provides detail on the survey respondents by position within the organization.

Table 4-3. Sample Size from Time 1 and Time 2 Data Collection

<table>
<thead>
<tr>
<th></th>
<th>Time 1</th>
<th>Time 2</th>
</tr>
</thead>
<tbody>
<tr>
<td>Opioid Treatment Programs</td>
<td>172</td>
<td>147</td>
</tr>
<tr>
<td>Clinical Administrators</td>
<td>172</td>
<td>147</td>
</tr>
<tr>
<td>Medical Directors</td>
<td>172</td>
<td>147</td>
</tr>
<tr>
<td>Patients</td>
<td>6,860</td>
<td>5,776</td>
</tr>
</tbody>
</table>

4.9 Data Reliability and Validity

The Evaluation Study incorporated several steps to ensure high-quality survey data. First, all data collection instruments were pre-tested in local OTPs. Second, interviewers for the Evaluation Study completed a 2-day training and orientation specific to the survey and instrumentation. Third, the instruments contained probes and follow-up questions to
standardize how interviewers would handle problem responses or inquiries. Research shows that self-reported surveys using similar procedures produce highly reliable and valid data (Rosen, Moos, Finney, & Henson, 2000; Brown, Kranzler, & Del Boca, 1992).

In addition to the procedures described above, internal consistency checks in the survey instruments were used to verify the accuracy of the data as they were being recorded. If later checks revealed additional inconsistencies, then respondents were called back for clarification. To check reliability after the data were collected, a number of comparisons of logical consistency were performed, including comparing (1) responses to related items within each survey, (2) reported totals to the sum of reported detail, (3) responses from the clinical administrator to responses from the medical director and abstraction logs, and (4) responses over time. These comparisons revealed high levels of consistency.

The validity of the data collected through the Evaluation Study has been confirmed through several studies (see Appendix D: Opioid Study Comparison). For example, Evaluation Study descriptive organizational data mirrored findings from the Ball & Ross (1991) study and the Services Research Outcomes Study (SROS) (SAMHSA, 1998). Additionally, data reported by Magura and colleagues (Magura, Nwakeze, Kang, & Demsky, 1999) were similar to Evaluation Study data for clinical administrator and staff experience. D’Aunno and Vaughn (1995) reported an average daily maintenance dose of 59 mg per day; a variation of only 5 mg compared with the Evaluation Study.

With regard to patient demographics, findings from the Evaluation Study are consistent with the findings from the California Drug and Alcohol Treatment Assessment (CALDATA) (Gerstein, Johnson, Harwood, & Fountain, 1997), DATOS (Wechsberg,
Craddock, & Hubbard, 1998), the National Treatment Improvement Evaluation Studies (NTIES) (USDHHS, 1997), and SROS (SAMHSA, 1998). The Evaluation Study found that 78% of patients were aged 35 or older, similar to the findings of other studies: SROS found that 72% were aged 35 or older, NTIES found that 83% were in this age range, and DATOS found that 43% of female patients and 63% of male patients were aged 36 or older. The 25% of Hispanics reported in the Evaluation Study compares with 12% in SROS and 25% in NTIES and DATOS. Together, these examples support the validity of the Evaluation Study data.

4.10 Measures

Descriptions of the measures used to test the current hypotheses appear below. First, the dependent variables used in the analyses are discussed, followed by a description of the theoretically driven independent variables, and the explanation for the inclusion of one control variable.

4.10.1 Dependent Variables

The outcome of interest for this study is organizational change. Three different dependent variables are used in the analyses to examine organizational change.

4.10.1.1 Change in Proportion of Patients Receiving Take-home Medication

The first dependent variable is a continuous variable based on the answer recorded on the dosing abstraction form listing the number of persons with take-home privileges on a specific date. For the purposes of the present study, the number of patients receiving a take-home dose was converted into the proportion of patients—based on patient census within an
organization—receiving a take-home dose. Converting this variable to a proportion allows comparison across programs equally, regardless of program size.

### 4.10.1.2 Change in Proportion of Patients Receiving Greater Than 100 mg/Day Dosing Level

The second dependent variable is a continuous variable based on the answer recorded on the dosing abstraction form listing the dosing levels for each patient on a specific date. For the purposes of the present study, the number of patients receiving a specific dose of methadone is converted into the proportion of patients—based on patient census within an organization—receiving a dose. Converting this variable to a proportion allows comparison across programs equally, regardless of program size. For the purposes of these analyses, a change in the proportion of persons receiving a methadone dose of greater than 100 mg per day is used as the dependent variable of interest.

### 4.10.1.3 Change in Quality Assurance System

The third dependent variable is an ordinal variable based on the answers to 12 questions (see Appendix C) on the organizational QA systems in OTPs. Programs received a score ranging from 0–12 indicating the number of QA activities within the organization.

Table 4-4 shows bivariate results analyzing change in the dependent variables from Time 1 to Time 2.

### 4.10.2 Independent Variables

Two groups of independent variables are included in this study. Market force comprises four variables: location, program size (number of patients currently enrolled in
Table 4-4. Change Analysis of Dependent Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>Wave of Study</th>
<th></th>
<th>Wave of Study</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Time 1 (n = 172)</td>
<td></td>
<td>Time 2 (n = 147)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mean</td>
<td>Standard Deviation</td>
<td>Mean</td>
<td>Standard Deviation</td>
</tr>
<tr>
<td>% Patients on Take-home methadone*</td>
<td>0.21</td>
<td>0.18</td>
<td>0.25</td>
<td>0.19</td>
</tr>
<tr>
<td>% Patients on &gt;100 mg methadone**</td>
<td>0.06</td>
<td>0.08</td>
<td>0.07</td>
<td>0.08</td>
</tr>
<tr>
<td>Quality Assurance**</td>
<td>9.20</td>
<td>2.70</td>
<td>9.97</td>
<td>1.78</td>
</tr>
</tbody>
</table>

*change from Time 1 to Time 2 = \( p < .05 \)

**change from Time 1 to Time 2 = \( p < .01 \)

Institutional force comprises three variables: ownership/profit status, program age (in years), and leadership (clinical supervisor number of years of experience in opioid dependence treatment and medical director number of years of experience in opioid dependence treatment).

Table 4-5 presents each question as it appeared on the Evaluation Study survey along with the type of variable.

4.10.3 Control Variables

Frequently, multiple variables are included in research as control variables. For the purpose of these analyses, organizational descriptive variables are defined as the independent variables representing market and institutional forces rather than controls. As a result, the analyses include only one control variable: state regulation. Controlling for state regulations serves to control for the varying state regulatory policies, thus focusing analyses on the change in federal regulations.
Table 4-5. Description and Type of Independent Variables

<table>
<thead>
<tr>
<th>Market Force Variable</th>
<th>Large Urban = County Population &gt;1,000,000 (n = 94)</th>
<th>Categorical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Geographic Location Using Beale Code</td>
<td>Urban/Rural = County Population up to 1,000,000 (n = 53)</td>
<td></td>
</tr>
<tr>
<td>Size (Site item B9): How many patients are currently enrolled at this site for methadone treatment?</td>
<td>Mean Patient Census (n=147)</td>
<td>Continuous</td>
</tr>
<tr>
<td>Previously Accredited (Site item F40): Is this site accredited by any of the following organizations: JCAHO, CARF; any other organization?</td>
<td>Yes (n = 49) No (n = 98)</td>
<td>Categorical Dichotomous</td>
</tr>
<tr>
<td>Parent Organization (Site item B4): Is this site a unit of a larger entity/agency/corporation (i.e., a parent organization)?</td>
<td>Yes (n = 102) No (n = 45)</td>
<td>Categorical Dichotomous</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Institutional Force Variable</th>
<th>For-profit (n = 63) Nonprofit/public (n = 84)</th>
<th>Categorical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ownership (Site item B3): Who is the owner of this substance abuse site?</td>
<td>Mean Program Age in Years (n=146)</td>
<td>Continuous</td>
</tr>
<tr>
<td>Program Age (Site item B7): How many years has this site been approved to dispense methadone for patients with narcotic addiction problems?</td>
<td>&lt;1 to 5 years (n = 37) 6 or more years (n = 65)</td>
<td>Categorical Dichotomous</td>
</tr>
<tr>
<td>Clinical Administrator Leadership (Staff item A6): How many years have you worked in opioid treatment programs in any capacity?</td>
<td>&lt;1 to 5 years (n = 67) 6 or more years (n = 78)</td>
<td>Categorical Dichotomous</td>
</tr>
<tr>
<td>Medical Director Leadership (Physician item A6): How many years have you worked in opioid treatment programs in any capacity?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

In addition to controlling for state regulations, the analyses control for time through the use of GEE in multivariate analyses. GEE allows for time-dependent and time-independent variables in the model and accounts for the correlation between repeated measures (Zeger & Liang, 1986).

4.11 Longitudinal Data Analysis

Data analysis is driven by a set of factors, some of which include sample size, study design, and data collection methods. As described earlier, the Evaluation Study was a two-wave longitudinal panel design with Time 1 data collected in 1998 from a cohort of 172
opioid treatment units and Time 2 data collected from 147 of the same opioid treatment units approximately 15 to 18 months after Time 1.

It has been well documented that change occurs at a systems level (Engel & Reinecke, 1996); however, change also takes place below the systems level. How political changes, such as those seen in the regulatory change for opioid dependence treatment, impact a system is largely dependent on how individual behaviors (seen here as organizational and staff behavior) change (Engel & Reinecke, 1996). In fact, system inertia or stability may originate as a result of little or no change at the individual level. As the need to understand this level of change continues to grow, the need for longitudinal data analysis—such as that used in the present study—also increases.

Therefore, the focus of data analysis for this study is on change in organizational units. Descriptive characteristics of organizations are measured using Time 1 data, and the study is designed to analyze organizational adaptation to a changing regulatory environment. This places the focus on organizational characteristics at a time of pre-regulatory change, or at Time 1.

A longitudinal study design, such as that used in the Evaluation Study, has a distinct advantage in that it takes measurements at two points in time, compared with a single measurement as is the case with cross-sectional studies (Diggle, Liang, & Zeger, 1994). Panel data are then able to capture both spatial and temporal dimensions. The spacial dimension refers to the cross-section of units and the temporal dimension refers to the period of observations. The two dimensions of the variables are typically subscripted in a model.
with \( i \) for the unit of observation (organization) and \( t \) for the temporal reference. Note that the error term is subscribed with both \( i \) and \( t \):

\[
Y_{it} = \beta_1 X_{1it} + \beta_2 X_{2it} + u_{it}.
\]

Although capturing repeated-measures has advantages, it also precludes the use of certain statistical methods. There are several different features of a study with repeated-measures across two-points in time that need to be considered when selecting an appropriate statistical procedure for analysis. First is the form of the outcome or response measure. If the outcome of interest is continuous and normally distributed, much simpler analyses are usually possible (Tabachnick & Fidell, 2001; Garson, 2002). In contrast, if the outcome is continuous but does not have a normal distribution, then alternative nonlinear models (e.g., a mixed-effects Poisson regression model; GEE) should be considered (Garson, 2002; Ballinger, 2004).

A second consideration for analyses is the size of the sample (e.g., the number of respondents \( N \)). The sample size is an important consideration for selecting a statistical procedure for analysis because smaller sample sizes can limit the power of the analyses (Tabachnick & Fidell, 2001). For this study, the sample size was large (\( N = 172 \) at Time 1 and \( N = 147 \) at Time 2) and will support the use of more advanced models (e.g., generalized mixed-effects regression models; GEE). These advanced models are based on large sample theory and are, therefore, appropriate for analysis of unbalanced repeated-measures data with a sample size greater than 50 (Tabachnick & Fidell, 2001).

With regard to an analytic technique for data analysis, it is important to consider that the dependent variable for quality assurance is an ordinal variable and the independent variables in this study are a mixture of continuous and/or categorical covariates—such as
program age, size, and previous accreditation. Additionally, the model includes the covariate of time. Each of these factors is important for selecting an appropriate analytical model.

What follows is a summary of specific analytic techniques previously used to assess change in longitudinal data designs and a discussion of the strengths and weakness of each technique. The discussion centers on a repeated-measures design and the impact this design has on analysis of organizational change. The review of accepted analytic approaches in repeated-measures designs is a critical first step to determining the appropriate approach for data analysis of the Evaluation Study data.

4.11.1 Generalized Linear Regression Models

Standard regression models assume independence across observations (Berry, 1993). With repeated-measures, however, observations from one respondent are correlated because the unobserved or unmeasured characteristics of the respondents contribute to the likelihood of their displaying a particular response. It cannot be assumed that the observations of panel data are distributed independently across time (i.e., that unobserved or unmeasured factors captured in the error term are uncorrelated across time). For example, the likelihood of any OTP clinical administrator responding similarly on more than one occasion is higher than would be expected by chance because certain unmeasured characteristics of that unit make a given response more likely. As a result of these limitations, standard regression models are not a good choice for analyzing designs with repeated-measures.
4.11.2 One-way ANOVA of Follow-up Scores

Analysis of Variance (ANOVA) can be used to analyze follow-up data within a panel study. Research has supported this approach in the past (Lavori, 1990), defending the notion that change is captured in the final wave of data. This approach involves ignoring the pretest data and is therefore not recommended. The direct result of ignoring the within-panel correlation is that the estimated standard errors are not a reliable measure for testing purposes. Less biased estimates result from explicitly modeling the correlation between observations from the same unit, instead of ignoring this correlation.

4.11.3 ANCOVA of the Follow-up Scores

Similar to the use of ANOVA to analyze follow-up data, Analysis of Covariance (ANCOVA) can also be used to compare scores between the baseline and final measurement using the pretest score as a covariate control (Gueorguieva & Krystal, 2004). When the pooled within-groups regression coefficient is less than 1.0, the ANCOVA measure can be an acceptable approach for analysis. ANOVA and ANCOVA, however, have stricter assumptions that must be met before either of these analytic approaches can be used.

4.11.4 One-way ANOVA of Difference Scores

For \( ni = 2 \) for all respondents, as is the case with this study, a simple change score can be computed and the data can be analyzed using methods for cross-sectional data, such as ANOVA (Garson, 2002). This approach is best used when there is a close to perfect linear relation between the pretest and posttest scores. This linearity is reflected in a pooled within-groups regression coefficient of 1.0. When this coefficient approaches 1.0, this method is
more powerful than the ANCOVA method. This approach, however, requires that each respondent has a final measure and can, therefore, impact analyses if the sample has a lot of missing data. Additionally, difference of change scores have been documented as leading to fallacious conclusions, primarily because such change scores are systematically related to any random error of measurement (Cronbach & Furby, 1970). Assumptions for ANOVA, including dependent variable and error term normatility and homoscedasticity, must also be met for this approach to be a good choice for conducting analyses.

4.11.5 Repeated-Measures ANOVA

Univariate repeated-measures ANOVA is still the most commonly used statistical analysis tool for repeated-measures in social science research because of its simplicity and familiarity to researchers (Gueorguieva & Krystal, 2004). However, recently there has been movement away from this standard approach for analysis.

Repeated-measures ANOVA are limited in what they can tell researchers about the pattern of change in variability over time (Gueorguieva & Krystal, 2004). Univariate repeated-measures ANOVA also requires that correlations among measurements on the same respondent satisfy a restrictive condition called *sphericity* or *circularity*. This assumes that there is equal variability of measurements at each time point and equal correlations between measures on the same individual. This assumption, however, is rarely justified because repeated observations on the same person seem to be highly correlated. When the requirements are not met, the Type 1 error rate is inflated and there is an overestimation of the statistical significance of the treatment and time effects.
Expanding on this consideration for analysis, it should be noted that in designs such as the one seen in the Evaluation Study where data are derived from the same respondent on different occasions, computation of the sum of squares and mean square for the effect of the independent variable is the same as that seen in a between-subjects design. However, the error term is further portioned into individual differences. Additionally, in data where there are no consistent individual differences in scores or where there may be interaction between respondents and independent variables, the error term may be large and the statistical test conservative, making it more difficult to reject the null hypothesis. In this case, a repeated-measures ANOVA is a poor choice for analysis. Even with these limitations, however, some researchers advocate for the use of repeated-measures ANOVA to analyze organizational change (Jaccard & Ackerman, 1985; Vasey & Thayer, 1987).

4.11.6 Fixed-Effects, Random-Effects, and Mixed-Effects Models

Repeated-measures can be analyzed using a fixed-effects, random-effects, or mixed-effects model, which use both fixed and random effects. Effect models are a covariance model. To account for correlation among repeated observations, fixed-effects and random-effects models introduce respondent-specific effects into the standard regression model, thus removing from the model’s error term any influences caused by this correlation (Hedeker & Mermelstein, 1996). This approach has advantages over a repeated-measures approach because it uses all available data on each respondent, it is unaffected by randomly missing data, and it can flexibly model time effects.

Fixed-effects methods are increasingly used with longitudinal data because they can control for all stable characteristics of an organization, including characteristics that are not
observed or measured. The unobserved or unmeasured component is commonly referred to as “unobserved heterogeneity.” The specifications for fixed-effects models may be hierarchically tested using F-tests of restrictions.

However, fixed-effects models also have some drawbacks. First, fixed-effects models may frequently have too many cross-sectional units of observations requiring too many dummy variables for their specification. Too many dummy variables may deplete the model of sufficient number of degrees of freedom for adequately powerful statistical tests. Second, a model with many such variables (including interactions) may be plagued with multicollinearity, which increases the standard errors and thereby also drains the model of statistical power to test parameters. Although the model residuals are assumed to be normally distributed and homogenous, there could easily be unit-specific heteroscedasticity or autocorrelation over time that would further plague estimation.

Random-effects models have an advantage over fixed-effects models in that the between-unit model is no longer saturated and time-constant covariates can be included. However, these advantages come at the cost of relying on several assumptions, such as zero correlations between the random intercept and the covariates.

Random-effects and mixed-effects models consider both a respondent’s repeated-measures and information about the population-level trend over time to estimate respondent-specific effects. This type of analysis maximizes the likelihood of observed values rather than ANOVA’s approach of minimizing error variance (Tabachnick & Fidell, 2001). Mixed-effects models provide a very flexible approach for the analysis of repeated-measures data because they allow for assessment of individual and population trends over time, for the use
of time-independent and time-dependent covariates, and irregular measurement occasions. They use all available data on each individual and provide a choice of appropriate covariance pattern that may lead to more efficient estimation.

In general, mixed-effects models are a preferable method of analysis of repeatedly measured outcomes when there are missing data, the repeated measures are irregularly spaced over time, the sample sizes are modest to large, and the dependent variables are continuous (Lee & DeMets, 1991; Spiessens, Laffre, & Verbeke, 2003). While mixed-effects models are preferred with continuous variables, they can also be used in the case of binary, categorical, or other non-normal data (Diggle, Liang, & Zeger, 1993).

Mixed-effects models, however, should be used with caution because of their complexity and because of vulnerability toward misuse (Guerin & Stroup, 2000; Ahn, Tonidandel, & Overall, 2000; Delucchi & Bostrom, 1999). Additionally, specific guidelines for the use of mixed-effects methods for the analysis of longitudinal data in the social sciences are still under development and are not yet available (Gueorguieva & Krystal, 2004).

4.11.7 Generalized Estimating Equations

GEE is an extension to generalized linear models (GLM); however, GEE does not require independent observations and thus can be used to analyze clustered and longitudinal data. At the simplest level, a variance-covariance matrix (which describes the correlation between observations) is specified, and multivariate weighted least squares are used to estimate a GEE model.
The term *generalized estimating equation* indicates that an estimating equation is not the result of a likelihood-based derivation, but that it is obtained by generalizing another estimating equation (Ballinger, 2004). The modification made to obtain a GEE is an introduction of second order variance components directly into a pooled estimating equation (Hardin & Hilbe, 2003). In the likelihood-based approaches discussed above, additional variance components are addressed parametrically.

Liang and Zeger (1986) published a landmark paper providing the first introduction to GEE. For binary, count, and categorical data, a GEE approach can provide a strong tool for analysis (Lee, Kim, & Tsiatis, 1996; Ballard, 2004). However, GEE is only valid under the assumption that data are missing completely at random, while the random-effects method is valid under the less stringent assumption of missing at random (Spiessens, Lasaffre, & Verbeke, 2003). Additionally, a GEE model estimates the average population effect, whereas random-effects models measure the effect conditional on the random-effects.

The GEE approach established by Liang and Zeger, however, does provide organizational researchers with an analytic technique for use with data collected in longitudinal or repeated-measures (Ballinger, 2004). Organizational researchers are beginning to increasingly use GEE because it allows for responses that are not normally distributed (Ballinger, 2004). In the past, organizational researchers have had to rely on suboptimal methods for analyzing responses that did not meet the criteria for normality, which often produced results that lacked precision and clarity (Garnder, Mulvey & Shaw, 1995; Harrison, 2002). GEE provides researchers using longitudinal data with a method that
is efficient and provides unbiased parameter estimates for analyzing non-normal data without requiring transformation (Harrison & Hulin, 1989).

There are, however, limitations to be considered with the use of GEE. For example estimates of variation can be highly biased when the number of subjects within nested observations is small (Prentice, 1988). Additionally, goodness-of-fit statistics for GEE are still being examined and developed. The technique is also more complex than other approaches often used to analyze repeated-measures; therefore, ease of use is not as simple as with a one-way ANOVA for differences of change or a repeated-measures ANOVA.

The use of GEE in organizational research is still developing. As such, this approach requires special attention to the emerging body of literature specific to GEE and analysis of organizational data. Additionally, GEE models are sensitive to errors in specification, and researchers who use this approach need to pay close attention to specification of the distribution of the dependent variable and the link function used in GEE to linearize the equations (Ballard, 2004).

4.12 Statistical Modeling

Table 4-6 summarizes the analysis techniques presented in the previous section and highlights the capabilities of each approach to handle situations that are specific to repeated-measures. Generally, research is gradually moving away from the use of ANOVA and ANCOVA to analyze repeated-measures and is progressing toward the more frequent use of random-effects or mixed-effects models or GEE. Specifically, recent literature has recommended the use of random-effects or mixed-effects models with continuous dependent variables, and the use of GEE with binary, categorical, and continuous dependent variables.
Table 4-6. Comparison of Analytic Approaches for the Analysis of Repeated-Measures Data

<table>
<thead>
<tr>
<th></th>
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<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Individual Estimation</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Covariation across Time</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Robust to Missing Values</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes*</td>
<td>Yes</td>
</tr>
<tr>
<td>Robust for Irregular Repeated-Measures</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Categorical Dependent Variables</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Population Estimation</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Robust to Nonnormal data</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Ease of Implementation</td>
<td>Simple</td>
<td>Simple</td>
<td>Simple</td>
<td>Simple</td>
<td>Simple</td>
<td>Moderate</td>
<td>Complex</td>
<td>Complex</td>
</tr>
</tbody>
</table>

*Assumes randomness of missing values
that are not normally distributed (Lee, Kim, & Tsiatis, 1996; Spiessens, Lesaffre & Verbeke, 2003; Ballard, 2004).

4.13 Summary

The Evaluation Study data set provided a unique opportunity to test the proposed research questions using a nationally representative sample of OTPs from which data were collected over a 3-year period. The Evaluation Study was a two-wave panel study with repeated measures at Time 1 and Time 2. All the hypotheses focus on the impact of organizational characteristics on organizational change behavior. Generally, data analysis sought to answer two questions that are critical to all change analysis: (1) How does the outcome change over time? and (2) Can differences in these changes be predicted? From this perspective, the present study is designed to answer two questions: (1) How do take-home medication policies, dosing policies, and quality assurance procedures change over time in OTPs? and (2) What organizational characteristics are associated with differences in these changes?

The dependent variables used in the analyses include the proportion of patients receiving a take-home medication, proportion of patients receiving daily doses of methadone greater than 100 mg, and quality assurance procedures within the OTP. The dependent and independent variables were derived from institutional theory, change theory, and other organizational theories, as detailed in Chapter 2. In addition, varying state regulatory policies were accounted for by including a control variable for state regulation.

Of the three dependent variables used in the study, two are expressed as proportions and thus restricted in their response to answers ranging from 0 to 1.0, and one ordinal variable that takes on one of 12 possible values. Because one of these variables is
noncontinuous, this analysis requires the use of either an effects model or GEE. Based on recent literature and the restrictions of these dependent variables, GEE was selected to analyze the data necessary to answer the research hypotheses presented earlier. GEE presents a robust approach for analyzing repeated measures by allowing for time-dependent and time-independent variables. Additionally, GEE models can handle missing data, assuming that missing values are missing at random. This allows for the use of data from the 172 programs measured at baseline by allowing for missing data at follow-up. A more detailed description of model specification and multivariate findings is presented in Chapter 6.
CHAPTER 5

Univariate Analyses

5.1 Descriptive Statistics

The primary focus of this dissertation is not on describing the field of opioid treatment, but rather on analyzing the association of organizational characteristics and organizational change. However, given that change cannot be analyzed without first examining organizational characteristics, descriptive statistics are presented here.

This chapter includes the univariate statistical analyses of the three dependent variables and all seven independent variables. The major goal of the univariate statistical analysis is to better understand the distribution and normality of the individual variables and to examine the individual change in the three dependent variables through a paired $t$ test. Variable means and standard deviations are presented for continuous variables, and proportions are provided across established categories. Both means and categorical proportions are provided to offer more detail on the distribution of the sample within variables.

Additionally, skewness and kurtosis are presented for all dependent variables. Skewness is the tilt (or lack of it) in variable distribution. Skew is expected to be within the $+2$ to $−2$ range when the data are normally distributed (Tabachnick & Fidell, 2001). Kurtosis is the peakedness of the variable distribution. Kurtosis is also expected to be within the $+2$ to $−2$ range when the data are normally distributed (Tabachnick & Fidell, 2001).
The Shapiro Wilks W test is a formal test of normality. This statistic is often thought of as the correlation between a given variable and its corresponding normal score, with W=1 when the given data are perfectly normal in distribution. Kolmogorov-Smirnov D test is an alternate test of normality for large samples. This test is presented for dependent variables as an additional reference to the Wilks test for normality.

A P-P plot is provided for dependent variables, as well. A P-P plot tests the distribution of the variable and plots the variable’s cumulative proportions against the cumulative proportions of the normal distribution. The straighter the line formed by the P-P plot, the more the variable’s distribution conforms to a normal distribution (Tabachnick & Fidell, 2001).

Finally, independent variables are examined through initial regression analysis to aid in interpreting the isolated variance accounted for by each individual independent variable. This exercise informs future decisions regarding possible interactions or variable elimination.

5.2 Dependent Variables

5.2.1 Take-home Medications

The proportion of patients on a take-home medication is the first dependent variable presented for descriptive analyses. The take-home medication variable is a continuous variable presented as a proportion. The values for this variable were computed for 170 OTPs at Time 1 and 146 OTPs at Time 2. The maximum possible score is 1.0. Table 5-1 and Figures 5-1 and 5-2 offer the results of the statistical analysis of the take-home medication variable.
### Table 5-1. Take-home Medication Statistics

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Time 1 Value</th>
<th>Time 2 Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>.2130</td>
<td>.2489</td>
</tr>
<tr>
<td>Median</td>
<td>.1765</td>
<td>.2282</td>
</tr>
<tr>
<td>Range (Maximum)</td>
<td>.8714</td>
<td>.8305</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>.1750</td>
<td>.1883</td>
</tr>
<tr>
<td>Variance</td>
<td>.030</td>
<td>.035</td>
</tr>
<tr>
<td>Skewness</td>
<td>1.156</td>
<td>.696</td>
</tr>
<tr>
<td>Kurtosis</td>
<td>1.320</td>
<td>.012</td>
</tr>
<tr>
<td>n=</td>
<td>170</td>
<td>146</td>
</tr>
<tr>
<td>Test for Normality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shapiro-Wilks W</td>
<td>.909</td>
<td>.944</td>
</tr>
<tr>
<td>Kolmogorov-Smirnov D</td>
<td>.112</td>
<td>.093</td>
</tr>
</tbody>
</table>

#### Figure 5-1. Take-home Medication Histograms
While both Time 1 and Time 2 take-home variables are slightly skewed to the left, the skewness value was within the expected range. The Shapiro Wilks W test supported this slight deviation from the expected $W = 1.0$ with a reported $W = .909, .944$ for Time 1 and Time 2, respectively.

The assumption was that the proportion of take-home medications would increase from Time 1 to Time 2 as a result of the change in regulations. This assumption is supported by the mean increase at Time 2 ($M = .25, SD = .19$) compared with Time 1 ($M = .21, SD = .18$), $t(145) = t -2.0, p = .046$.

### 5.2.2 Methadone Dosing

The proportion of patients on a greater than 100 mg per day level of methadone dosing is the second dependent variable presented for descriptive analyses. This methadone dosing variable was collected as a continuous variable and is represented as a proportion. Regulatory change in methadone dosing focused largely on increasing the flexibility of OTPs.
to administer doses exceeding 100 mg of methadone daily. This focus is the justification for concentrating data analysis on the proportion of methadone patients receiving a dose greater than 100 mg per day.

The values for this variable were computed for 172 OTPs at Time 1 and 146 OTPs at Time 2. The maximum score is 1.0. Table 5-2 and Figures 5-3 and 5-4 offer the results of the statistical analysis for the greater than 100 mg of methadone per day dosing variable.

Table 5-2. Greater Than 100 mg/Day Dosing Statistics

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Time 1 Value</th>
<th>Time 2 Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>.0583</td>
<td>.0716</td>
</tr>
<tr>
<td>Median</td>
<td>.0297</td>
<td>.0451</td>
</tr>
<tr>
<td>Range (Maximum)</td>
<td>.3604</td>
<td>.3401</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>.0756</td>
<td>.0751</td>
</tr>
<tr>
<td>Variance</td>
<td>.006</td>
<td>.006</td>
</tr>
<tr>
<td>Skewness</td>
<td>1.850</td>
<td>1.328</td>
</tr>
<tr>
<td>Kurtosis</td>
<td>3.615</td>
<td>1.589</td>
</tr>
<tr>
<td>n=</td>
<td>172</td>
<td>146</td>
</tr>
<tr>
<td>Test for Normality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shapiro-Wilks W</td>
<td>.770</td>
<td>.854</td>
</tr>
<tr>
<td>Kolmogorov-Smirnov D</td>
<td>.220</td>
<td>.170</td>
</tr>
</tbody>
</table>
Both Time 1 and Time 2 dosing variables are skewed to the left; however, the skewness value was within the expected range. The histogram and the normal probability plot indicate departures from normal distribution, with the Shapiro-Wilks W = .770, .854 for Time 1 and Time 2, respectively. With a large study sample size, deviations from normality are of less concern based on the assumption of the Central Limit Theorem (Tabachnick &
Fidell, 2001), which states that with a sufficiently large sample size, sampling distribution of the mean will be normally distributed regardless of the distribution of the variable. Proportions of persons receiving a greater than 100 mg/day dose of methadone spike at the lowest levels, with 48 programs (27.4%) reporting a 0.0 proportion at Time 1 and 26 programs (14.9%) reporting 0.0 proportion at Time 2.

The assumption was that the proportion of patients receiving a daily dose of greater than 100 mg would increase from Time 1 to Time 2 as a result of the change in regulations. This assumption is supported by the mean increase at Time 2 ($M = .07, SD = .08$) compared with Time 1 ($M = .06, SD = .08$), $t(145) = -3.4, p = .001$.

### 5.2.3 Quality Assurance

The number of QA procedures within an organization is the third dependent variable presented for descriptive analyses. The QA variable was collected as an ordinal variable. The values for this variable were computed for 172 OTPs at Time 1 and 147 OTPs at Time 2. The maximum possible score is 12.0. Table 5-3 and Figures 5-5 and 5-6 offer the results of the statistical analysis of the QA variable.

Both Time 1 and Time 2 QA variables are skewed to the right with skewness values outside the expected range. The histogram and the normal probability plot also indicate certain departures from normality; however, these departures are largely the result of the trend for OTPs to report high values of QA procedures, as seen through the reported mean equal to 9.20 and 9.97 for Time 1 and Time 2, respectively.
Table 5-3. Quality Assurance Statistics

<table>
<thead>
<tr>
<th>Statistic</th>
<th>Time 1 Value</th>
<th>Time 2 Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mean</td>
<td>9.20</td>
<td>9.97</td>
</tr>
<tr>
<td>Median</td>
<td>10.0</td>
<td>11.0</td>
</tr>
<tr>
<td>Range (Maximum)</td>
<td>11.0</td>
<td>11.0</td>
</tr>
<tr>
<td>Standard Deviation</td>
<td>2.699</td>
<td>1.784</td>
</tr>
<tr>
<td>Variance</td>
<td>7.286</td>
<td>3.184</td>
</tr>
<tr>
<td>Skewness</td>
<td>−2.195</td>
<td>−3.065</td>
</tr>
<tr>
<td>Kurtosis</td>
<td></td>
<td></td>
</tr>
<tr>
<td>n=</td>
<td>172</td>
<td>147</td>
</tr>
<tr>
<td>Test for Normality</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shapiro-Wilks W</td>
<td>.680</td>
<td>.618</td>
</tr>
<tr>
<td>Kolmogorov-Smirnov D</td>
<td>.253</td>
<td>.281</td>
</tr>
</tbody>
</table>

Figure 5-5. Quality Assurance Histograms
The assumption was that the number of QA procedures would increase from Time 1 to Time 2 as a result of the change in regulations. This assumption is supported by the mean increase at Time 2 ($M = 9.97, SD = 1.78$) compared with Time 1 ($M = 9.20, SD = 2.70$), $t(146) = t -3.9, p = .000$.

5.3 Independent Market Force Variables

5.3.1 Location

In the literature and in previous studies of OTPs, geographic location of OTPs is concentrated in large urban areas (county population of $>1,000,000$). In these areas, organizations face more competition for patients seeking treatment services.

Geographic location is a dichotomous categorical variable. Based on the Evaluation Study sample, less than half (32.6%) of OTPs (see Figure 5–7) were located in rural/urban areas (county population $<1,000,000$).
The distribution of the variable is skewed toward large urban geographic locations, which is expected. On initial regression analysis, geographic location was not found to be significantly associated with changes in the proportion of patients on take-home medication or the proportion of persons receiving greater than 100 mg of methadone daily. Geographic location was significantly \( (p<.01) \) associated with QA practices, \( F = 7.26, R^2 = .09 \).

### 5.3.2 Program Size

As indicated through the literature review, the size of an organization is believed to directly impact its ability to respond to service demands. A program can only serve a maximum number of patients as determined by building capacity guidelines and staffing. Larger organizations are able to serve more patients, thus increasing their market presence. Previous research has shown, however, that larger organizations are often resistant to change (Hannan & Freeman, 1984). Therefore, a review of program size is important to further the understanding of organizational change.
Program size is a continuous variable based on patient census. The mean size of all programs was 248 patients. For the purposes of summarizing these data, three size categories have been created: small (less than 100 patients); medium (100–300 patients); large (more than 300 patients). Based on the Evaluation Study sample, less than a quarter of opioid treatment programs (see Figure 5.8) were considered small. Nearly half of all programs are medium in size and just over a quarter of programs are large.

\[
\begin{array}{ccc}
100 \text{ or Less Patients} & 101-299 \text{ Patients} & 300 \text{ or More Patients} \\
20.6 & 47.4 & 30.3
\end{array}
\]

Figure 5-8. Univariate Analysis: Program Size

On initial regression analysis, size was not found to be significantly associated with changes in the proportion of patients on take-home medication, changes in the proportion of persons receiving greater than 100 mg of methadone daily, or quality assurance. Because size is considered to be a cornerstone variable in the analysis of organizations; however, it is critical that this variable be maintained for further multivariate analyses.
5.3.3 Previous Accreditation

Both nonprofit and for-profit programs are dependent on public funding to a certain extent. In today’s market, insurance companies (both private and public) are recognizing accreditation as a mechanism to monitor quality services and as a metric to determine reimbursement. As a result, accreditation is linked with the purchase of substance abuse treatment services. Accredited OTPs are functioning under a set of specific standards that focus on controlling their processes, resulting in a difference from other OTPs that are not accredited. It is, therefore, important to examine the distribution of programs that were previously accredited.

Accreditation is a dichotomous variable. Based on the Evaluation Study sample, over one-third of OTPs (see Figure 5–9) had been accredited prior to the regulatory change.

On initial regression analysis, previous accreditation was not found to be significantly associated with changes in the proportion of patients on take-home medication, changes in the proportion of persons receiving greater than 100 mg of methadone daily, or quality assurance.
5.3.4 Parent Affiliation

Affiliation with a parent organization plays an important role in promoting organizational change because it dictates how programs are organized. Researchers have documented that organizations that are controlled by a central parent organization are more likely to accept and incorporate change. This is, in part, because central control weakens the importance and identity of the subunits, making change seem less threatening.

Parent organization is a dichotomous variable. Based on the Evaluation Study sample, just under three-quarters of OTPs (see Figure 5-10) were part of a parent organization.

On initial regression analysis, affiliation with a parent organization was not found to be significantly associated with changes in the proportion of patients on take-home medication, changes in the proportion of persons receiving greater than 100 mg of methadone daily, or quality assurance.
5.4 Independent Institutional Force Variables

5.4.1 Ownership

Studies have shown that type of organizational structure, including ownership, is a significant factor influencing organizational practice. Both publicly and privately owned organizations are present within the field of opioid dependence treatment, with previous studies estimating nearly equal distribution. For the purposes of these analyses, government-owned (public) programs were combined with nonprofit programs. This was done because of the small sample size of government programs \((n = 3)\) and because the descriptive characteristics of both government and nonprofit programs were very similar.

While findings show a greater percentage of nonprofit/public OTPs, the Evaluation Study data support the findings from recent literature, with the distribution of nonprofit/public and for-profit programs being nearly equal (see Figure 5-11).
On initial regression analysis, ownership was not found to be significantly associated with changes in the proportion of patients on take-home medication. Ownership was significantly \((p<.05)\) associated with the proportion of patients receiving greater than 100 mg of methadone daily, \(F = 5.28, R^2 = .04\) and QA practices, \(F = 4.67, R^2 = .03\).

### 5.4.2 Program Age

The age of a program serves as a defining concept for program inertia. Researchers supporting the theory of organizational inertia believe that older organizations function under a set of formalized policies and practices that make them more resistant to change. As a result, older organizations are seen as routine in practice and relying on the status quo.

The age of the program is a continuous variable that was measured in years in operation. The mean age of all programs was 15 years. For the purposes of summarizing these data, three categories for age have been created: 10 years or less in operation; 11–20 years in operation; 21 or more years in operation. Based on the Evaluation Study sample, just
over 40% of OTPs (see Figure 5-12) were in operation less than 10 years. Just over a third of programs had been in operation for 21 or more years.

![Bar Chart](image)

**Figure 5-12. Univariate Analysis: Program Age**

On initial regression analysis, program age was not found to be significantly associated with changes in the proportion of patients on take-home medication or quality assurance. Program age was significantly ($p<.05$) associated with the proportion of patients receiving greater than 100 mg of methadone daily, $F = 4.85$, $R^2 = .03$.

### 5.4.3 Leadership

A program’s management is important to the organizational structure because leaders within an organization frame the system’s goals and have the power to influence policies and practices. Within opioid dependence treatment, there are two distinct positions providing leadership within the organization: (1) the clinical supervisor who oversees all daily operations of the program, and (2) the medical director who oversees all medical aspects of care, including methadone dosing.
Leadership as expressed through tenure of the clinical supervisor and medical director is a dichotomous variable. Based on the Evaluation Study sample, nearly half of all clinical directors had 6 years or more experience in OTPs (see Figure 5-13). It should be noted that nearly a third of clinical supervisors did not answer this question, resulting in 59 missing cases. Over half of medical directors had 6 or more years of experience in OTPs (see Figure 5-14).

Figure 5-13. Univariate Analysis: Clinical Supervisor Experience

Figure 5-14. Univariate Analysis: Medical Director Experience
On initial regression analysis, neither clinical supervisor nor medical director leadership was found to be significantly associated with changes in the proportion of patients on take-home medication, changes in the proportion of persons receiving greater than 100 mg of methadone daily, or quality assurance.

5.5 Control Variable

5.5.1 State Regulation

The control variable of state regulation was also examined. State regulations were reviewed within two areas: medication regulations and quality assurance regulations.

Univariate analyses found that seven states reported state medication regulations more restrictive than the required federal regulations and eight states reported state regulations equivalent to federal regulations. Univariate analyses also found that seven states reported state QA regulations more restrictive than the required federal regulations and eight states reported state QA regulations equivalent to federal regulations.

5.6 Summary

Generally, OTPs were found to be located in large urban areas, with the majority of programs ranging in size from 101 to 299 patients. More programs reported an affiliation with a parent organization than reported operating as a stand-alone program. While some programs reported being accredited prior to the regulatory mandate, a greater percentage reported no previous accreditation.

Programs reported nearly equal ownership between nonprofit/public and for-profit status, with just a slightly greater percentage in the nonprofit/public category. The highest
percentage of programs reported being in operation for 10 years or less. And a higher percentage of clinical supervisors reported having more than 6 years of experience in opioid dependence treatment compared with medical directors.

Univariate analyses revealed slight deviations in normality for two of the three dependent variables; however, these deviations did not warrant transformation. Analyses of the independent variables supported inclusion of all eight variables in the multivariate model for hypothesis testing.
CHAPTER 6
Multivariate Analyses

The research hypotheses laid out in Chapter 3 were tested using the methods and the data set described in Chapter 4. The results of these analyses are presented here. However, first some bivariate descriptive data are provided on the market and institutional force independent variables. This background descriptive data analysis aids in interpreting the results of the multivariate statistical analyses. Finally, this chapter focuses on the implications of the multivariate analysis results as they relate to the research hypotheses and concentrates on whether the analyses provide statistical evidence to support the research hypotheses, whereas Chapter 7, Conclusions, Implications and Next Steps, addresses the implications of the findings for both public administration theory and practice.

6.1 Bivariate Analysis

Bivariate relationships are tested using Pearsonian correlation, which measures the degree of linear relationship between two variables. This technique is used to measure the relationship between two continuous variables or between continuous and categorical variables.

Several goals can be accomplished by studying bivariate correlations. For example, correlation analysis shows whether the direction of relationship between the dependent variable and each of the independent variables is consistent with the hypotheses presented in Chapter 3. It also demonstrates strength and significance between two variables. Finally,
examining bivariate correlations allows for the detections of multicollinearity between the independent variables. According to Tabachnick & Fidell (2001), when a bivariate correlation between independent variables equals or exceeds .70 there is a multicollinearity problem within a correlation matrix.

In addition to the bivariate correlation analysis, the \( t \)-test and chi-square tests are utilized as statistics to test the hypothesis that two groups have different means. A \( t \)-test is a parametric test used to compare means of categorical and continuous variables. The \( t \)-test considers each group as a separate sample, and then completes a two-sample test (O’Sullivan & Rassel, 1999). The chi-square test is a nonparametric measurement used with cross tabulations to compare means of two categorical variables.

6.2 Multivariate Analyses

Multivariate analyses were conducted using the GEE method, which is an extension of the widely used generalized linear model (GLM). GEE is widely used in longitudinal data analysis, particularly within longitudinal data where the primary focus is the relationship between the outcome variables and the covariates.

In public administration and public health research, longitudinal studies are increasingly being used. Often the goal of these studies is to examine the outcomes of interest before and after some event or intervention. Correlation between observations on the same subject is anticipated for longitudinally collected data and must be accounted for to obtain correct statistical inference for covariate effects.

GEE is very similar to GLM. The estimated mean increase is the same for both methods, but the standard error plays a key role in determining statistical significance. GEE
analysis adjusts the GLM, which fits a model of completely independent observations, to account for correlated observations (e.g., two points in time). The GEE approach accounts for this individual correlation by first computing naive standard errors assuming complete independence (the standard GLM) and then computing an adjustment to the naive standard errors. This adjustment results in robust standard errors that are asymptotically equivalent to standard errors based on matching observations (Liang & Zeger, 1986).

In studies comparing trends with time, longitudinal (panel) data have an advantage over repeated cross-sectional data because they facilitate the use of methodologies, such as GEE, to separate the nuisance variation due to population-wide behavior from the variation related to trends with time. The naive variance still has the variation due to population-wide behavior incorporated into it. The correlation structure, however, is considered to be a nuisance (not of interest in itself) (Liang & Zeger, 1986).

Because the GEE method does not require that all data come in matched sets, GEE can also be used on a full data set where data is missing from specific time points. The quasi-likelihood–based GEE approach of Liang and Zeger (1986) is then an intuitive and easily implementable approach for data with a covarying dimension. An additional attractive point of GEE is that the researcher does not need to specify the correlation structure correctly; a tentative or “working” correlation matrix is used to obtain consistent and asymptotically normal regression coefficient estimates.

The GEN MOD procedure in SAS uses GEE methodology to estimate the regression parameters. Before this procedure can be implemented, however, data must be structured in such a way that SAS recognizes the repeated observations present for each unit. The main
effect of interest for this study was the time-varying covariate indicating whether the organization had adopted regulatory changes.

6.3 **Bivariate Correlations and Relations: Market Force Variables**

Previously, researchers believed that the demand for substance abuse treatment services was unlike that for other economic goods and therefore it was unresponsive to traditional market forces. Recently, however, research from two distinct fields, economics and behavioral psychology, has coalesced to provide evidence that substance abuse treatment services do respond to market forces (Chaloupka, Grossman, Bickel, & Saffer, 1999).

The term *market* refers to the group of consumers or organizations that is interested in the product, has the resources to purchase the product, and is permitted by law and other regulations to acquire the product (Tomic, 2006). Market forces are grounded in the notion of supply and demand; that is, what influences impact the supply and demand for a particular product (in this case, opioid dependence treatment services).

This study focuses on three areas of market forces: competition, product delivery, and legitimacy. Competition is examined through two specific variables: program location and program size. Product delivery is examined through affiliation with a parent organization, and program legitimacy is examined through previous accreditation of the program.

Analyses are conducted to examine the bivariate correlations between the dependent variables (take-home dosing, greater than 100 mg/day dosing levels, and quality assurance) and organizational market force variables. Correlations among the independent variables were also examined (see Table 6-1). None of the correlations causes concern for multicollinearity.
Table 6-1. Correlations for Dependent and Market Force Variables

<table>
<thead>
<tr>
<th>Variable</th>
<th>1</th>
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<tr>
<td>2. Diff in &gt;100 mg meth</td>
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<tr>
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*p<.05; **p<.01

6.3.1 Location

Location is positively correlated with both a difference in the proportion of patients receiving a take-home dosage of methadone ($r = .187, p<.05$) and the proportion of patients receiving greater than 100 mg/day of methadone ($r = .170, p<.05$). Program location and size represent the strongest correlation ($r = .270, p<.01$).

The results of the independent $t$-test indicate that the mean take-home medication scores are significantly different than mean location scores ($t = -5.847; p<.001$). The results of the independent $t$-test also indicate that the mean greater than 100 mg/day dosing scores are significantly different than mean location scores ($t = 18.57; p<.001$).

The chi-square test of independence is a nonparametric test and was performed to examine the relation between program location and program size. The relation between these variables was significant, $X^2(2, N = 172) = 12.87, p<.01$. As Figure 6-1 depicts, OTPs were more likely to be located in large urban areas across all program sizes. For programs with
300 or more patients, there is nearly a 1:10 ratio of programs located in rural/urban areas compared with programs located in large urban areas.

### 6.3.2 Previous Accreditation

Previous accreditation is positively correlated with the proportion of patients receiving greater than 100 mg/day of methadone ($r = .165$, $p < .05$). Previous accreditation is also positively correlated with parent affiliation ($r = .177$, $p < .05$).

The results of the independent $t$-test also indicate that the mean greater than 100 mg/day dosing scores are significantly different than mean previous accreditation scores ($t = 3.41; p < .001$). A chi-square test of independence was performed to examine the relation between previous accreditation and parent affiliation. The relation between these variables was significant, $X^2(2, N = 172) = 5.36$, $p < .05$. As Figure 6-2 depicts, programs that were previously accredited were over three times as likely to have a parent affiliation.
6.3.3 Null Findings

Neither program size nor program affiliation was significantly correlated with organizational change. Based on the literature, these variables were found to have an important effect on adoption of regulatory change (see Chapters 2 and 3 for detailed discussion). Failing to form bivariate correlations with the dependent variables does not exclusively eliminate these variables from further analyses. Variable relation may change while simultaneously controlling for other independent variables in the dataset. The relationships between the market force variables and organizational change are revisited in Section 6.5, Results of Generalized Estimation Equation Analysis.
6.4 Bivariate Correlations and Relations: Institutional Force Variables

While the examination of market forces offers insight into environmental influences and organizational change, market forces cannot be viewed in isolation. Previous research has pointed to the need to look at institutional forces to better understand organizational behavior by accounting for variance within systems (Tweedie, 1990). Traditionally, healthcare service organizations have responded more to institutional forces than to market forces (Cook, Shortell, Conrad, & Morrisey, 1983), with medical professionals establishing a norm for treatment practice and delivery.

Institutional forces involve the social and political structures to which organizations must conform. This study focuses on three areas of institutional forces: ownership, program age, and leadership. Organizational ownership defines who has legal claim to program assets and profits (Fama, 1980). Program age defines how long administrative and clinical practices have been in place. Strong leadership within a heterogeneous organization can act to either enhance or impede organizational shifts in policies and practices (Meyer, Scott, & Strang, 1987).

Analyses are conducted to examine the bivariate correlations between the dependent variables (take-home dosing, dosing levels, and quality assurance) and organizational institutional force variables. Correlations among the independent variables were also examined (see Table 6–2). None of the correlations causes concern for multicollinearity.

6.4.1 Ownership

Ownership is negatively correlated with a difference in the proportion of patients receiving a take-home dosage of methadone ($r = -.183, p<.05$) and positively correlated with
Table 6-2. Correlations for Dependent and Institutional Force Variables

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*p<.05; **p<.01

Quality assurance ($r = .195, p<.05$). Ownership and age represent the strongest correlation ($r = -.383, p<.01$).

The results of the independent $t$-test indicate that the mean greater than 100 mg/day dosing scores are significantly different than mean ownership scores ($t = 10.83; p<.001$).

The chi-square test of independence is a nonparametric test and was performed to examine the relation between the mean difference for quality assurance and ownership. A chi-square test was also completed to examine the relation between ownership and program age. As Figure 6-3 depicts, the relation between ownership and age was significant, $X^2(32, N = 170) = 64.69, p<.01$. 
6.4.2 Program Age

Program age was negatively correlated with the proportion of patients receiving greater than 100 mg/day of methadone \((r = -0.187, p < 0.05)\). The results of the independent \(t\)-test also indicate that the mean greater than 100 mg/day dosing scores are significantly different than mean previous accreditation scores \((t = 19.69; p < 0.001)\).

Program age was also positively correlated with clinical supervisor tenure \((r = 0.210, p < 0.05)\). As Figure 6-4 depicts, clinical supervisors within large programs were 3 times more likely to have 6 or more years experience in opioid dependence treatment. The results of the chi-square test for the relation between program age and clinical supervisor tenure were not significant.
6.4.3 Medical Director Tenure

Medical Director tenure was negatively correlated with quality assurance ($r = -0.189$, $p < 0.05$). A chi-square test of independence was performed to examine the relation between the mean difference for quality assurance and medical director tenure. No significant relation was found.

6.4.4 Null Findings

Clinical supervisor tenure was not significantly correlated with organizational change. Based on the literature, this variable was found to have an important effect on leadership and the adoption of regulatory change (see Chapters 2 and 3 for detailed discussion). Failing to form bivariate correlations with the dependent variables does not exclusively eliminate this variable from further analyses. Variable relation may change while simultaneously
controlling for other independent variables in the dataset. The relationships between the institutional variables and organizational change are revisited in Section 6.5.

6.5 Results of Generalized Estimation Equation Analysis

Multivariate analyses were conducted using the GEE method. GEE is an extension of the widely used GLM. GEE is widely used in longitudinal data analysis, particularly within longitudinal data where the primary focus is the relationship between the outcome variables and the covariates.

To analyze longitudinal data, the ‘PROC GENMOD’ in the SAS/STAT system was used along with the ‘repeated’ option to fit generalized linear models by the GEE method (with ‘Link’ = identity and ‘Correlation matrix’ = autoregressive [AR]).

6.5.1 Full Model Bivariate Correlations

Bivariate relationships are tested across both market and institutional variables using Pearsonian correlation, which measures the degree of linear relationship between two variables. This technique is used to measure the relationship between two continuous variables or between continuous and categorical variables. Correlation analysis shows whether the direction of relationship between the dependent variable and each of the independent variables is consistent with the hypotheses presented in Chapter 3 (see Table 6-3). None of the correlations causes concern for multicollinearity.
Table 6-3. Correlations for Dependent and Market and Institutional Force Variables

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<td>4. Location</td>
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<td>5. Program Size</td>
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<td>-.017</td>
<td>.270**</td>
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<td>6. Previous Accreditation</td>
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*p<.05; **p<.01

6.5.2 Change in Proportion of Patients on Take-home Medications

For each hypothesis explored in this study, the issue is whether there is a relationship between market and institutional forces and organizational change. The first four hypotheses posit a relationship between market force variables and organizational change in medication and QA practices; the second four hypotheses focus on the relationship between institutional force variables and organizational change.

To test the eight research hypotheses, multivariate analyses were conducted using three models. Model 1 was specified with market variables, a control variable for state regulations, and time as a covariate. Model 2 was specified with institutional variables, a control variable for state regulations, and time as a covariate. Model 3 represented a full model combining Models 1 and 2.
**Research Hypotheses**

### Market Forces

**H1:** Opioid dependence treatment programs located in large urban areas are more likely to adopt regulatory change than their treatment program counterparts located in less populous areas.

**H2:** Small opioid dependence treatment programs are more likely to adopt regulatory change than their larger treatment program counterparts.

**H3:** Nonaccredited opioid dependence treatment programs are more likely to adopt regulatory change than their accredited treatment program counterparts.

**H4:** Opioid dependence treatment programs owned by a parent organization are more likely to adopt regulatory change than their independently owned treatment program counterparts.

### Institutional Forces

**H5:** For-profit funded organizations are more likely to adopt regulatory change than nonprofit organizations.

**H6:** Younger organizations are more likely to adopt regulatory change than older organizations.

**H7:** Organizations in which the clinical supervisor has more experience in opioid dependence treatment will be more likely to adopt regulatory change than organizations with less experienced clinical supervisors.

**H8:** Organizations in which the medical director has more experience in opioid dependence treatment will be more likely to adopt regulatory change than organizations with less experienced medical directors.

### 6.5.2.1 Model 1—Take-home: Market Force Impact

On review of the bivariate correlation matrix, location was the only independent variable significantly correlated with a difference in the proportion of patients receiving a take-home dosage of methadone \( r = -.187, p < .05 \).

The specified model for analysis of market force variables and proportion of patients on take-home medications was:

\[
\text{Proportion Take-home} = B_{\text{statefedmoremed}} + B_{\text{lgurban}} + B_{\text{size}} + B_{\text{accredno}} + B_{\text{parentyes}} + B_{T1} + B_{T2} + e.
\]
The results of the multivariate analysis are presented in Table 6-4. The partial model (with only market variables specified) supports a change in take-home medication policies from Time 1 to Time 2; however, results do not support either the H1 or H4 hypotheses.

Table 6-4. GEE Model for Take-home Medication and Market Variables

| Model Parameter | Estimate | SE  | Z     | Pr>|Z| | Hypothesis Support |
|-----------------|----------|-----|-------|------|-------------------|
| Intercept       | 0.2802   | 0.0378  | 7.41  | <.0001 |                   |
| Statea          |          |       |       |       |                   |
| More Restrictive| 0.0140   | 0.0262 | 0.54  | 0.5923 |                   |
| Locationb       |          |       |       |       |                   |
| Large Urban     | -0.0409  | 0.0293 | -1.39 | 0.1634 | —                 |
| Size            |          |       |       |       |                   |
| Patient Census  | -0.0001  | 0.0001 | -1.89 | 0.0589 | X                 |
| Accreditationc  |          |       |       |       |                   |
| Not Accredited  | 0.0080   | 0.0271 | 0.29  | 0.7685 | X                 |
| Parent Organizationd |          |       |       |       | —                 |
| Yes             | -0.0262  | 0.0272 | -0.96 | 0.3359 | —                 |
| Timee           |          |       |       |       |                   |
| Time 2—Follow-up| 0.0310   | 0.0140 | 2.21  | 0.0270 |                   |

*Equal to or equivalent to federal regulations is the referent category.
*Urban/Rural is the referent category.
*Previous accredited is the referent category.
*No parent organization is the referent category.
*Time 1 is the referent category.

The statistics do support the H2 hypothesis indicating that smaller programs would be more likely to adopt changes in take-home medication practices. A test of the effect of size on change in proportion of patients receiving take-home medication was conducted on the score statistic. This statistic was significant, $X^2(1, N = 172) = 4.21, p<.05.$
The statistics support the direction of the H3 hypothesis that “not accredited” programs would be more likely to adopt federal regulatory changes; however, this finding is not statistically significant.

6.5.2.2 Model 2—Take-home: Institutional Force Impact

On review of the bivariate correlation matrix, there were no institutional force variables that were significantly correlated with a change in the proportion of patients on take-home medication.

The specified model for analysis of institutional force variables and proportion of patients on take-home medications was:

\[
\text{Proportion Take-home} = B_{\text{statefedmoremed}} + B_{\text{forprofit}} + B_{\text{age}} + B_{\text{clinicleader6+years}} + B_{\text{medleader6+years}} + B_{T1} + B_{T2} + e
\]

The results of the multivariate analysis are presented in Table 6-5. The partial model (with only institutional variables specified) supports a change in take-home medication policies from Time 1 to Time 2; however, results do not support either leadership hypothesis H7 or H8.

The statistics do support the H5 hypothesis indicating that for-profit programs would be more likely to adopt changes in take-home medication practices. A test of the effect of ownership on change in proportion of patients receiving take-home medication was conducted on the score statistic. This statistic was significant, \(X^2(1, N = 172) = 5.41, p<.05\).
Table 6-5. GEE Model for Take-home Medication and Institutional Variables

| Model Parameter | Estimate | SE  | Z      | Pr>|Z|  | Hypothesis Support |
|-----------------|----------|-----|--------|------|-------------------|
| Intercept       | 0.2404   | 0.0498 | 4.83   | <.0001 |                  |
| State           |          |      |        |      |                   |
| More Restrictive| 0.0049   | 0.0320 | 0.15   | 0.8791 |                   |
| Ownership       |          |      |        |      |                   |
| For-Profit      | 0.0865   | 0.0358 | 2.42   | 0.0157 | X                 |
| Age             |          |      |        |      |                   |
| Time in Operation| −0.0025 | 0.0015 | −1.67  | 0.0954 | X                 |
| Clinical Supervisor |      |      |        |      |                   |
| 6+ Experience   | −0.0404  | 0.0326 | −1.24  | 0.2155 |                   |
| Medical Director |      |      |        |      |                   |
| 6+ Experience   | −0.0093  | 0.0333 | −0.28  | 0.7796 |                   |
| Time            |          |      |        |      |                   |
| Time 2—Follow-up| 0.0342   | 0.0187 | 1.83   | 0.0677 |                   |

*a* Equal to or equivalent to federal regulations is the referent category.

*b* Nonprofit/public is the referent category.

*c* Less than 6 years experience is the referent category.

*d* Time 1 is the referent category.

The statistics support the direction of the H6 hypothesis that younger programs would be more likely to adopt federal regulatory changes; however, this finding is not statistically significant.

6.5.2.3 Model 3—Take-home: Market and Institutional Impact

The specified model for analysis of market and institutional force variables and proportion of patients on take-home medications was:

\[
\text{Proportion Take-home} = B_{\text{statefedmoremed}} + B_{\text{lgurban}} + B_{\text{size}} + B_{\text{accredno}} + B_{\text{parentyes}} + B_{\text{forprofit}} + B_{\text{age}} + B_{\text{clinicleader6+years}} + B_{\text{medleader6+years}} + B_{T1} + B_{T2} + e
\]
The results of the multivariate analysis are presented in Table 6-6. The full model supports a change in take-home medication policies from Time 1 to Time 2; however, results do not support the H1, H3, H7, or H8 hypotheses. This varies slightly from the partial model findings, but with no significant results.

**Table 6-6. GEE Model for Take-home Medication and Market and Institutional Forces**

| Model Parameter | Estimate | SE   | Z      | Pr>|Z| | Hypothesis Support |
|-----------------|----------|------|--------|------|-------------------|
| Intercept       | 0.2555   | 0.0596 | 4.29   | <.0001 |                   |
| State           |          |       |        |       |                   |
| More Restrictive| 0.0152   | 0.0332 | 0.46   | 0.6471 |                   |
| Location        |          |       |        |       |                   |
| Large Urban     | -0.0315  | 0.0380 | -0.83  | 0.4068 |                   |
| Size            |          |       |        |       |                   |
| Patient Census  | -0.0002  | 0.0001 | -2.98  | 0.0029 | X                 |
| Accreditation   |          |       |        |       |                   |
| Not Accredited  | -0.0143  | 0.0341 | -0.42  | 0.6743 |                   |
| Parent Organization |        |       |        |       |                   |
| Yes             | 0.0415   | 0.0392 | 1.06   | 0.2893 | X                 |
| Ownership       |          |       |        |       |                   |
| For-Profit      | 0.1146   | 0.0374 | 3.07   | 0.0022 | X                 |
| Age             |          |       |        |       |                   |
| Time in Operation| -0.0013  | 0.0015 | -0.88  | 0.3806 | X                 |
| Clinical Supervisor |       |       |        |       |                   |
| 6+ Experience   | -0.0280  | 0.0321 | -0.87  | 0.3839 |                   |
| Medical Director |          |       |        |       |                   |
| 6+ Experience   | -0.0119  | 0.0335 | -0.36  | 0.7220 |                   |
| Time            |          |       |        |       |                   |
| Time 2—Follow-up| 0.0336   | 0.0188 | 1.79   | 0.0734 |                   |

*Equal to or equivalent to federal regulations is the referent category.
*Urban/Rural is the referent category.
*Previous accredited is the referent category.
*No parent organization is the referent category.
*Nonprofit/public is the referent category.
*Less than 6 years experience is the referent category.
*Time 1 is the referent category.
The statistics support the H2 and H5 hypotheses, indicating that small and for-profit programs are more likely to adopt changes in take-home medication practices. A test of the effect of size on change in proportion of patients receiving take-home medication was conducted on the score statistic. This statistic was significant, $X^2(1, N = 172) = 6.20, p < .05$—indicating that the H2 hypothesis can be accepted that small programs are more likely to adopt regulatory change.

A test of the effect of ownership on change in proportion of patients receiving take-home medication was conducted on the score statistic. This statistic was significant, $X^2(1, N = 172) = 7.85, p < .01$—indicating that the H5 hypothesis can be accepted that for-profit programs are more likely to adopt regulatory change. The statistics support the direction of the H4 and H6 hypotheses; however, these finding are not statistically significant.

6.5.3 Change in Proportion of Patients Receiving Greater Than 100 mg/Day of Methadone

To test the eight research hypotheses for change in proportion of patients receiving greater than 100 mg/day of methadone, multivariate analyses were completed following the same process as that for examination of change in proportion of patients on take-home medications. Model 1 was specified with market variables, a control variable for state regulations, and time as a covariate. Model 2 was specified with institutional variables, a control variable for state regulations, and time as a covariate. Model 3 represented a full model combining Models 1 and 2.
6.5.3.1 Model 1—Dosing: Market Force Impact

On review of the bivariate correlation matrix, location \((r = .170, p < .05)\) and parent affiliation \((r = .165, p < .05)\) were both significantly correlated with a difference in the proportion of patients receiving greater than 100 mg/day of methadone.

The specified model for analysis of market force variables and proportion of patients on greater than 100 mg/day of methadone was:

$$\text{Dosing >100mg/day} = B_{\text{statefemedmed}} + B_{\text{urban}} + B_{\text{size}} + B_{\text{accredno}} + B_{\text{parentyes}} + B_{T1} + B_{T2} + e$$

The results of the multivariate analysis are presented in Table 6-7. The partial model (with only market variables specified) supports a change in take-home medication policies from Time 1 to Time 2; however, results do not support the H1, H2, or H3 hypotheses. Program size is significantly associated with a change in dosing policies and practices; however, larger programs were more likely to change rather than the predicted smaller programs.

The statistics do support the H4 hypothesis, indicating that programs with a parent affiliation would be more likely to adopt changes in higher dosing practices. A test of the effect of size on change in proportion of patients receiving greater than 100 mg/day of methadone was conducted on the score statistic. This statistic was significant, \(X^2(1, N = 172) = 8.14, p < .01\).
Table 6-7. GEE Model for Greater Than 100 mg/Day Dosing and Market Variables

| Model Parameter | Estimate | SE   | Z      | Pr>|Z| | Hypothesis Support |
|-----------------|----------|------|--------|------|-------------------|
| Intercept       | 0.0155   | 0.0191 | 0.81  | 0.4189 |                    |
| State<sup>a</sup> |          |       |        |       |                   |
| More Restrictive | 0.01460  | 0.0101 | 1.44  | 0.1499 |                   |
| Location<sup>b</sup> |        |       |        |       |                   |
| Large Urban     | −0.0164  | 0.0119 | −1.38 | 0.1685 | —                 |
| Size            |          |       |        |       |                   |
| Patient Census  | 0.0001   | 0.0000 | 3.24  | 0.0012 | X                 |
| Accreditation<sup>c</sup> |    |       |        |       |                   |
| Not Accredited  | −0.0051  | 0.0121 | −0.42 | 0.6724 | —                 |
| Parent Organization<sup>d</sup> | | | | | |
| Yes             | 0.0313   | 0.0106 | 2.96  | 0.0031 | X                 |
| Time<sup>e</sup> |          |       |        |       |                   |
| Time 2—Follow-up | 0.0153   | 0.0046 | 3.31  | 0.0009 |                   |

<sup>a</sup>Equal to or equivalent to federal regulations is the referent category.
<sup>b</sup>Urban/Rural is the referent category.
<sup>c</sup>Previous accredited is the referent category.
<sup>d</sup>No parent organization is the referent category.
<sup>e</sup>Time 1 is the referent category.

6.5.3.2 Model 2—Dosing: Institutional Force Impact

On review of the bivariate correlation matrix, ownership ($r = −.183, p<.05$) and program age ($r = .187, p<.05$) were both significantly correlated with a difference in the proportion of patients receiving greater than 100 mg/day of methadone.

The specified model for analysis of institutional force variables and proportion of patients on greater than 100 mg/day of methadone was:

$$\text{Proportion >100 mg/day} = B_{\text{statefedmoremed}} + B_{\text{forprofit}} + B_{\text{age}} + B_{\text{clinicleader6+years}} + B_{\text{medleader6+years}} + B_{T1} + B_{T2} + e$$

The results of the multivariate analysis are presented in Table 6-8. The partial model (with only institutional variables specified) supports a change in take-home medication
Table 6-8. GEE Model for Greater Than 100 mg/Day Dosing and Institutional Variables

| Model Parameter | Estimate | SE  | Z    | Pr>|Z| | Hypothesis Support |
|-----------------|----------|-----|------|------|-------------------|
| Intercept       | 0.0025   | 0.0134 | 0.19 | 0.8513 |                   |
| State<sup>a</sup> |          |      |      |       |                   |
| More Restrictive | 0.0279   | 0.0128 | 2.18 | 0.0292 |                   |
| Ownership<sup>b</sup> |       |      |      |       |                   |
| For-Profit      | −0.0074  | 0.0109 | −0.68 | 0.4969 |                   |
| Age             |          |      |      |       |                   |
| Time in Operation | 0.0010  | 0.0006 | 1.83 | 0.0678 |                   |
| Clinical Supervisor<sup>c</sup> |       |      |      |       |                   |
| 6+ Experience   | 0.0435   | 0.0131 | 3.33 | 0.0009 | X                 |
| Medical Director<sup>c</sup> |       |      |      |       |                   |
| 6+ Experience   | −0.0144  | 0.0130 | −1.11 | 0.2685 |                   |
| Time<sup>d</sup> | 0.0163   | 0.0058 | 2.82 | 0.0047 |                   |
| Time 2—Follow-up | 0.0342  | 0.0187 | 1.83 | 0.0677 |                   |

<sup>a</sup>Equal to or equivalent to federal regulations is the referent category.
<sup>b</sup>Nonprofit/public is the referent category.
<sup>c</sup>Less than 6 years experience is the referent category.
<sup>d</sup>Time 1 is the referent category.

policies from Time 1 to Time 2; however, results do not support the H5, H6, or H8 hypotheses.

The statistics do support the H7 hypothesis, indicating that programs with clinical supervisors having 6 or more years of experience would be more likely to adopt changes in high-dosing practices. A test of the effect of clinical supervisor tenure on change in proportion of patients receiving greater than 100 mg/day of methadone was conducted on the score statistic. This statistic was significant, $X^2(1, N = 172) = 9.80, p < .01$. 

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6.5.3.3 Model 3—Dosing: Market and Institutional Impact

The specified model for analysis of market and institutional force variables and proportion of patients on greater than 100 mg/day of methadone was:

\[
\text{Dosing >100mg/day} = B_{\text{state fed more med}} + B_{\text{lg urban}} + B_{\text{size}} + B_{\text{accred no}} + B_{\text{parent yes}} + B_{\text{for profit}} + B_{\text{age}} + B_{\text{clin leader 6+ years}} + B_{\text{med leader 6+ years}} + B_{T1} + B_{T2} + e
\]

The results of the multivariate analysis are presented in Table 6-9. The full model supports a change in take-home medication policies from Time 1 to Time 2; however, results only support the H7 hypothesis. This varies from the partial model findings removing a significant impact of parent affiliation on change in high-dosing practices when both market and institutional variable were specified in the model.

The statistics support the H7 hypothesis, indicating that programs with a clinical supervisor having 6 or more years experience are more likely to adopt changes in high-dosing practices. A test of the effect of clinical supervisor tenure on change in proportion of patients receiving greater than 100 mg/day of methadone was conducted on the score statistic. This statistic was significant, \(X^2(1, N = 172) = 7.97, p < .01\) indicating that the H7 hypothesis can be accepted that programs with more experienced clinical supervisors are more likely to adopt regulatory change.

While the direction of the H2 hypothesis is not supported, program size was found to be significantly associated with changes in high-dosing practices. A test of the effect of size on change in proportion of patients receiving greater than 100 mg/day of methadone was conducted on the score statistic. This statistic was significant, \(X^2(1, N = 172) = 6.00, p < .05\),
Table 6-9. GEE Model for Greater Than 100 mg/Day Dosing and Market and Institutional Forces

| Model Parameter | Estimate | SE   | Z     | Pr>|Z| | Hypothesis Support |
|-----------------|----------|------|-------|------|-------------------|
| Intercept       | -0.0071  | 0.0272 | -0.26 | 0.7932 |                   |
| Statea          |          |       |       |       |                   |
| More Restrictive| 0.0262   | 0.0112 | 2.35  | 0.0187 |                   |
| Locationb       |          |       |       |       |                   |
| Large Urban     | -0.0154  | 0.0153 | -1.01 | 0.3132 | —                 |
| Size            |          |       |       |       |                   |
| Patient Census  | 0.0001   | 0.0000 | 2.47  | 0.0137 | —                 |
| Accreditationc  |          |       |       |       |                   |
| Not Accredited  | -0.0016  | 0.0170 | -0.09 | 0.9255 | —                 |
| Parent Organizationd |        |       |       |       |                   |
| Yes             | 0.0110   | 0.0128 | 0.86  | 0.3913 | X                 |
| Ownershipe      |          |       |       |       |                   |
| For-Profit      | -0.0101  | 0.0116 | -0.87 | 0.3836 | —                 |
| Age             |          |       |       |       |                   |
| Time in Operation| 0.0004  | 0.0007 | 0.56  | 0.5724 | —                 |
| Clinical Supervisorf |       |       |       |       |                   |
| 6+ Experience   | 0.0445   | 0.0146 | 3.06  | 0.0022 | X                 |
| Medical Directorf |        |       |       |       |                   |
| 6+ Experience   | -0.0113  | 0.0127 | -0.89 | 0.3713 | —                 |
| Timeg           |          |       |       |       |                   |
| Time 2—Follow-up| 0.0163   | 0.0058 | 2.82  | 0.0048 |                   |

*Equal to or equivalent to federal regulations is the referent category.
^Urban/Rural is the referent category.
^Previous accredited is the referent category.
^No parent organization is the referent category.
^Nonprofit/public is the referent category.
^Less than 6 years experience is the referent category.
^Time 1 is the referent category.

but did not surpass the critical value for $p<.01$. Based on these findings, it is questionable to reject the null hypothesis.
6.5.4 Change in Quality Assurance Practices

To test the eight research hypotheses for change in quality assurance practices, multivariate analyses were completed following the same process as that for examination of change in proportion of patients on take-home medications. Model 1 was specified with market variables, a control variable for state regulations, and time as a covariate. Model 2 was specified with institutional variables, a control variable for state regulations, and time as a covariate. Model 3 represented a full model combining Models 1 and 2.

6.5.4.1 Model 1—Quality Assurance: Market Force Impact

On review of the bivariate correlation matrix, there were no market force variables that were significantly correlated with a change in QA practices.

The specified model for analysis of market force variables and QA practices was:

\[
\text{Quality Assurance} = B_{\text{statefedmoreqa}} + B_{\text{urban}} + B_{\text{size}} + B_{\text{accredno}} + B_{\text{parentyes}} + B_{T1} + B_{T2} + e
\]

Results of the multivariate analysis are presented in Table 6-10. The partial model (with only market variables specified) supports a change in take-home medication policies from Time 1 to Time 2; however, results do not support the H1, H2, or H3 hypotheses.

The statistics do support the H4 hypothesis, indicating that programs with a parent affiliation would be more likely to adopt changes in QA practices. A test of the effect of size on change in QA practices was conducted on the score statistic. This statistic was significant, \(X^2(1, \, N = 172) = 10.46, \, p<.01\).
Table 6-10. GEE Model for Quality Assurance and Market Variables

| Model Parameter       | Estimate | SE    | Z     | Pr>|Z| | Hypothesis Support | Direction | Strength |
|-----------------------|----------|-------|-------|-----|-------------------|-----------|----------|
| Intercept             | 8.2978   | 0.5676|       |     |                   |           |          |
| State\(^a\)           |          |       | 14.62 | <.0001 |                   |           |          |
| More Restrictive      | -0.0100  | 0.2973| -0.03 | 0.9732 |                   |           |          |
| Location\(^b\)        |          |       |       |      |                   |           |          |
| Large Urban           | 0.2196   | 0.3092| 0.71  | 0.4775 | X                 | —         |          |
| Size                  |          |       |       |      |                   |           |          |
| Patient Census        | 0.0000   | 0.0005| 0.07  | 0.9438 | —                 | —         | —        |
| Accreditation\(^c\)   |          |       |       |      |                   |           |          |
| Not Accredited        | -0.3211  | 0.2601| -1.23 | 0.2169 | —                 | —         |          |
| Parent Organization\(^d\) |          |       |       |      |                   |           |          |
| Yes                   | 1.3634   | 0.4016| 3.39  | 0.0007 | X                 | X         |          |
| Time\(^e\)            |          |       |       |      |                   |           |          |
| Time 2—Follow-up      | 0.8062   | 0.1998| 4.03  | <.0001|                   |           |          |

\(^a\) Equal to or equivalent to federal regulations is the referent category.

\(^b\) Urban/Rural is the referent category.

\(^c\) Previous accredited is the referent category.

\(^d\) No parent organization is the referent category.

\(^e\) Time 1 is the referent category.

6.5.4.2 Model 2—Quality Assurance: Institutional Force Impact

On review of the bivariate correlation matrix, ownership \((r = .195, p<.05)\) and medical director tenure \((r = -.189, p<.05)\) were both significantly correlated with a difference in QA practices.

The specified model for analysis of institutional force variables and change in QA practices was:

\[
\text{Quality Assurance} = B_{\text{statefedmoreqa}} + B_{\text{forprofit}} + B_{\text{age}} + B_{\text{clinicleader6+years}} + B_{\text{medleader6+years}} + B_{T1} + B_{T2} + e
\]
Results of the multivariate analysis are presented in Table 6-11. The partial model (with only institutional variables specified) supports a change in QA practices from Time 1 to Time 2; however, results do not support any of the research hypotheses.

### Table 6-11. GEE Model for Quality Assurance and Institutional Variables

| Model Parameter       | Estimate | SE  | Z     | Pr>|Z| | Hypothesis Support | Direction | Strength |
|-----------------------|----------|-----|-------|-----|-------------------|-----------|----------|
| Intercept             | 9.7009   | 0.5452 | 17.81 | <.0001 |                    |           |          |
| State<sup>a</sup>     |          |      |       |      |                   |           |          |
| More Restrictive      | -0.4095  | 0.3821 | -1.07 | 0.2839 |                   |           |          |
| Ownership<sup>b</sup> |          |      |       |      |                   |           |          |
| For-Profit            | -1.0093  | 0.4241 | -2.38 | 0.0173 | X                 | X         | X        |
| Age                   |          |      |       |      |                   |           |          |
| Time in Operation     | 0.0005   | 0.0160 | 0.03  | 0.9748 | —                 | —         | —        |
| Clinical Supervisor<sup>c</sup> |  |  |  |  |  |  |  |
| 6+ Experience         | -0.3650  | 0.3613 | -1.01 | 0.3124 | —                 | —         | —        |
| Medical Director<sup>c</sup> |  |  |  |  |  |  |  |
| 6+ Experience         | 0.5150   | 0.3337 | 1.54  | 0.1228 | —                 | —         | —        |
| Time<sup>d</sup>      |          |      |       |      |                   |           |          |
| Time 2—Follow-up      | 0.9131   | 0.2645 | 3.45  | 0.0006 |                  |           |          |

<sup>a</sup>Equal to or equivalent to federal regulations is the referent category.
<sup>b</sup>Nonprofit/public is the referent category.
<sup>c</sup>Less than 6 years experience is the referent category.
<sup>d</sup>Time 1 is the referent category.

The statistics do support a significant relationship between ownership and change in QA practices. A test of the effect of ownership on quality assurance was conducted on the score statistic. This statistic was significant, \( \chi^2(1, N = 172) = 5.32, p<.05 \), but did not surpass the critical value for \( p<.01 \).
6.5.4.3 Model 3—Quality Assurance: Market and Institutional Impact

The specified model for analysis of market and institutional force variables and QA practices was:

\[
\text{Quality Assurance} = B_{\text{statefedmoreqa}} + B_{\text{lgurban}} + B_{\text{size}} + B_{\text{accredno}} + B_{\text{parentyes}} + B_{\text{forprofit}} + B_{\text{age}} + B_{\text{clinicleader6+years}} + B_{\text{medleader6+years}} + B_{T1} + B_{T2} + e
\]

Results of the multivariate analysis are presented in Table 6-12. The full model supports a change in QA practices from Time 1 to Time 2; however, results only support the H4 hypothesis. This is consistent with partial model findings.

The statistics support the H4 hypothesis, indicating that programs with a parent affiliation are more likely to adopt changes in QA practices. A test of the effect of parent affiliation on change in QA practices was conducted on the score statistic. This statistic was significant, \(X^2(1, N = 172) = 10.41, p < .01\)—indicating that the H4 hypothesis can be accepted that programs with a parent affiliation are more likely to adopt regulatory change.

6.6 Summary

This chapter discussed the results of applying GEE to investigate the relationships between the dependent change variables (proportion of patients on take-home medications; proportion of persons on greater than 100 mg/day of methadone; and QA practices) and the two sets of independent variables—market force influences and institutional force influences.

The second goal of GEE was to determine the strength of the effects of individual independent variables on the dependent variables. For this purpose, the full model was used. Significant and nonsignificant multivariate relationships between the dependent variables and
Table 6-12. GEE Model for Quality Assurance and Market and Institutional Forces

| Model Parameter       | Estimate | SE    | Z      | Pr>|Z| | Hypothesis Support |
|-----------------------|----------|-------|--------|-----|-------------------|
|                       |          |       |        |     | Direction | Strength |
| Intercept             | 8.1493   | 0.8107| 10.05  | <.001| X          | —        |
| State                 |          |       |        |     | —         | —        |
| More Restrictive      | -0.3072  | 0.3489| -0.88  | 0.3786| —         | —        |
| Location              |          |       |        |     | —         | —        |
| Large Urban           | 0.3181   | 0.3181| 0.93   | 0.3525| X          | —        |
| Size                  |          |       |        |     | —         | —        |
| Patient Census        | 0.0004   | 0.0008| 0.50   | 0.6203| —         | —        |
| Accreditation         |          |       |        |     | —         | —        |
| Not Accredited        | -0.3947  | 0.3457| -1.14  | 0.2535| —         | —        |
| Parent Organization   |          |       |        |     | —         | —        |
| Yes                   | 1.6888   | 0.4971| 3.40   | 0.0007| X          | X        |
| Ownership             |          |       |        |     | —         | —        |
| For-Profit            | -0.2522  | 0.3480| -0.72  | 0.4686| —         | —        |
| Age                   |          |       |        |     | —         | —        |
| Time in Operation     | -0.0073  | 0.0163| -0.45  | 0.6548| X          | —        |
| Clinical Supervisor   |          |       |        |     | —         | —        |
| 6+ Experience         | -0.3646  | 0.3522| -1.04  | 0.3005| —         | —        |
| Medical Director      |          |       |        |     | —         | —        |
| 6+ Experience         | 0.4463   | 0.3013| 1.48   | 0.1385| X          | —        |
| Time                  |          |       |        |     | —         | —        |
| Time 2—Follow-up      | 0.9172   | 0.2642| 3.47   | 0.0005| —         | —        |

*Equal to or equivalent to federal regulations is the referent category.
*Urban/Rural is the referent category.
*Previous accredited is the referent category.
*No parent organization is the referent category.
*Nonprofit/public is the referent category.
*Less than 6 years experience is the referent category.
*Time 1 is the referent category.

the independent variables were discussed. The final goal of the GEE was to determine which independent variables were good predictors of change. The theoretical and practical relevance of this analysis was discussed in Chapters 1 and 2.
The results of this analysis are presented in Table 6-13. Overall, there was no one independent variable that was significantly associated with all three change variables. For-profit ownership was significantly associated with change in the proportion of persons on take-home medications, but association was not seen for a change in high-dosing practices and quality assurance practices. Size was also significantly associated with changes in the proportions of patients on take-home medications. Clinical supervisor was significantly associated with change in high-dosing policies. Conclusions and implications of these results are discussed in Chapter 7.

Table 6-13. Results of Hypothesis Testing

<table>
<thead>
<tr>
<th>Hypothesis</th>
<th>Take-home</th>
<th>&gt;100 mg/day</th>
<th>Quality Assurance</th>
</tr>
</thead>
<tbody>
<tr>
<td>H1: Location—Large programs more likely to change</td>
<td>Accept Null</td>
<td>Accept Null</td>
<td>Accept Null</td>
</tr>
<tr>
<td>H2: Size—Smaller programs more likely to change</td>
<td>Reject Null</td>
<td>Accept Null</td>
<td>Accept Null</td>
</tr>
<tr>
<td>H3: Parent Affiliation—Parent affiliation more likely to change</td>
<td>Accept Null</td>
<td>Accept Null</td>
<td>Reject Null</td>
</tr>
<tr>
<td>H4: Accreditation—Previously accredited more likely to change</td>
<td>Accept Null</td>
<td>Accept Null</td>
<td>Accept Null</td>
</tr>
<tr>
<td>H5: Ownership—For-profit programs more likely to change</td>
<td>Reject Null</td>
<td>Accept Null</td>
<td>Accept Null</td>
</tr>
<tr>
<td>H6: Age—Younger programs more likely to change</td>
<td>Accept Null</td>
<td>Accept Null</td>
<td>Accept Null</td>
</tr>
<tr>
<td>H7: Clinical Supervisor—Program with more experienced clinical supervisor more likely to change</td>
<td>Accept Null</td>
<td>Reject Null</td>
<td>Accept Null</td>
</tr>
<tr>
<td>H8: Medical Director—Program with more experienced medical director more likely to change</td>
<td>Accept Null</td>
<td>Accept Null</td>
<td>Accept Null</td>
</tr>
</tbody>
</table>
CHAPTER 7
Conclusions, Implications, and Next Steps

7.1 Conclusions

This study explored the impact of market and institutional forces on organizational change and specifically examines the impact of these forces on organizational adoption of regulatory changes in opioid treatment programs. It analyzed changes within organizational policies and practices in three areas: (1) take-home medications, (2) greater than 100 mg/day dosage of methadone, and (3) quality assurance systems. These areas represent the organizational policies and practices that are impacted most by the legislative change and new regulations targeted for examination in this study. This chapter summarizes the conclusions regarding the operationalization of organizational change and the impact of specific market and institutional variables on this change.

7.1.1 Operationalizing Organizational Change

This study places a great deal of importance on measuring and operationally defining organizational change. Organizations are complex systems impacted by political, regulatory, and technological change. While the study of organizational change and adaptation is rapidly becoming a central tenet in public administration literature (Greenwood & Hinings, 1996), operational definitions of change are variable and developmental.

Defining organizational change leads to a key finding of this study. For all three dependent variables (take-home practices, greater than 100 mg/day dosage of methadone practices, and quality assurance policies and practices), time was found to be significant in
the multivariate model (marginally significant for take-home practices). This finding indicates that organizational practice within these three areas changed significantly, thus supporting the use of these three variables as dependent variables to measure organizational adoption of regulatory change.

**Conclusions:** Take-home medication practices, greater than 100 mg/day dosage of methadone practices, and quality assurance policies and practices are all valid measures of change in opioid treatment programs.

### 7.1.2 Impact of Market and Institutional Forces on Organizational Change

Improving federal efforts to implement public health policy is dependent on a growing understanding of the impact of market and institutional forces on organizational change mandated by federal regulations. Historical and current public administration literature documents a politics–administration dichotomy that supports the belief that other forces are obstructing or impeding the impact of policies steered by government. This interference limits the extent to which government agencies are able to influence institutional change without first better understanding the dynamics.

To date there has been limited research that examines the organizational construct and the impact of market and institutional forces on organizational action toward regulatory compliance. Overall, the knowledge base lacks clarity about what explanatory factors are most important as enhancers or barriers to organizational change.

#### 7.1.2.1 Market Variables

**Location.** While bivariate analysis found location to be significantly correlated with a change in take-home medications and greater than 100 mg/day of methadone dosing, the GEE analysis did not support these correlations. Multivariate analyses did not find location to
be significantly associated with any of the three dependent variables for change. Location does not seem to be a significant market force impacting organizational adaptation of regulatory change.

**Program Size.** Bivariate analysis found program size to have no correlation with any of the three dependent variables; however, the GEE analysis found program size to have a significant association with a change in take-home medication practices. It can be concluded that small programs were significantly more likely to adopt changes in take-home medication practices.

**Previous Accreditation.** Previous accreditation had no significant correlation with any of the three dependent variables and was not found to be significantly associated with any of the three dependent variables using the GEE analysis. Previous accreditation does not seem to be a significant market force impacting organizational adoption of regulatory change.

**Parent Affiliation.** Bivariate analysis found parent affiliation to be significantly correlated with greater than 100 mg/day methadone dosing practices. The GEE analysis did not support this association; however, it did find parent affiliation to have a significant association with a change in QA practices. It can be concluded that organizations with a parent affiliation were significantly more likely to adopt changes in QA practices.

**Conclusion:** Small programs were significantly more likely to adopt changes in take-home medication practices.

**Conclusion:** Organizations with a parent affiliation were significantly more likely to adopt changes in quality assurance practices.
7.1.2.2 **Institutional Variables**

**Ownership.** While bivariate analysis found ownership to be significantly correlated with a change in greater than 100 mg/day of methadone dosing and change in QA practices, the GEE analysis did not support these associations. Multivariate analyses did find ownership to be significantly associated with a change in take-home medication practices. It can be concluded that for-profit programs were significantly more likely to adopt changes in take-home medication practices.

**Program Age.** Bivariate analysis found program size to have a significant correlation with greater than 100 mg/day methadone dosing practices; however, the GEE analysis did not support this association. Multivariate analyses did not find program age to be significantly associated with any of the three dependent variables for change. Program age does not seem to be significant institutional force impacting organizational adaptation of regulatory change.

**Clinical Supervisor Tenure.** Clinical supervisor tenure had no significant correlation with any of the three dependent variables; however, the GEE analysis found clinical supervisor tenure to be significantly associated with a change in greater than 100 mg/day methadone dosing practices. It can be concluded that programs with a clinical supervisor having 6 or more years of experience in opioid dependence treatment were significantly more likely to adopt changes in high dosing practices.

**Medical Director Tenure.** Bivariate analysis found medical director tenure to be significantly correlated with a change in QA practices; however, the GEE analysis did not
support this association. Medical director tenure does not seem to be a significant institutional force impacting organizational adaptation of regulatory changes.

**Conclusion:** For-profit programs were significantly more likely to adopt changes in take-home medication practices.

**Conclusion:** Programs with a clinical supervisor having 6 or more years of experience in opioid dependence treatment were significantly more likely to adopt changes in high dosing practices.

7.1.3 Linking Conclusions and Implications

While the previous section highlights conclusions drawn from the results of the data analysis, it does not link these conclusions to implications for the field of public administration. Additionally, these conclusions make no attempt to interpret the variability in the findings, including the disparity seen in the significant associations of market and institutional force variables. Specifically, none of the four market and three institutional variables documented were significantly associated with change consistently across all three dependent variables. The next section discusses the variability across the study findings and attempts to explain the implications of these differences for future studies examining change in the field of public administration.

7.2 Implications

While the three dependent variables used in this study are variables of change and were found to have significantly changed from Time 1 to Time 2, each variable can be seen as measuring a distinct and different aspect of organizational adaptation. It is through the examination of these distinct aspects in defining and measuring organizational adaptation that this study has the greatest implications.
Through the analysis of change in take-home medication practices, greater than 100 mg/day methadone dosing practices, and quality assurance policies and practices, this study adds to the study of organizational change through the examination of three distinct areas of organizational adaptation: (1) client driven change; (2) normative change; and (3) process change. The following section details this attempt to categorize organizational adaptation and examines the impact of market and institutional forces on each of these areas of change.

### 7.2.1 Categorizing Organizational Adaptation

On further review of the dependent variables used to measure change in this study, it can be argued that each dependent variable examines a different type of organizational adaptation. Categorizing adaptation into distinct areas will aid public administration managers by providing a context for examining organizational implementation of regulatory changes and organizational characteristics that impede adaptation.

**Client-Driven Change.** Some organizational changes are driven primarily by the client and they center on client satisfaction and client responsiveness. Take-home medication practices can be seen as an example of a client-driven change. Take-home medications offer clients more flexibility and more normality in their daily lives. Because methadone is a daily dose medication, without the privilege of a take-home dose, patients are forced to come into the OTP daily. This requirement can impact a patient’s ability to get a job as well as his or her personal relationships because of the stigma attached to substance abuse treatment in general and opioid dependence in particular. Patient requests for more flexibility of the FDA federal mandate on take-home medications was a critical factor leading to the federal
regulatory change in this area (CSAT, 2001). As such, take-home medication can be categorized as a client-driven change.

**Normative Change.** Organizations by their very definitions are seen as cognitive, normative, and regulatory structures that provide stability to social behavior (Floyd, Kramer, & Born, 2005). The normative element of this definition includes the standards and values that identify what is desirable and define what is expected of people (i.e., roles and status) as well as routine ways of completing tasks. For decades, opioid dependence treatment providers have defined a “high” methadone dose as no more than 90 mg/day; any daily dose in excess of this amount was considered excessive. The tendency of OTPs to prescribe “low” methadone doses is believed to be a function of the normative focus of substance abuse treatment on abstinence (no substance use) (Payte, 1997). While current research, supported by clinical trials, has proven this belief to be erroneous, many OTP staff still consider daily dosages exceeding 100 mg/day as not desirable and not normative (Strain, Bigelow, Liebson, & Stitzer, 1999). Therefore, a change in greater than 100 mg/day dosing practices could be seen as a normative change.

**Process Change.** Historically, few OTPs have implemented QA measures (General Accounting Office, 1990). Overall, the opioid dependence treatment system was found to be inadequate in ensuring quality care for methadone treatment patients. In the past, OTPs have focused their time and resources on ensuring proper medication of patients and delivering support services, such as individual and group counseling. However, focusing on activities related to quality assurance or performance measurement is a systems change for most OTPs. Under the new CSAT guidelines (CSAT, 2001) and methadone-specific accreditation
standards, OTPs are required to engage in QA activities aimed at evaluating and enhancing services to improve patient outcomes. The change to a system that supports quality assurance/performance measurement can be seen as a process change.

Within these three categories of change, the impact of market and institutional force variables can be examined more specifically. Additionally, these categories provide context for future study surrounding the public management of organizational adaptation. The following section details how market and institutional variables impact these various categories of change.

**Implication:** This study categorizes three distinct areas of organizational adaptation: (1) client-driven change; (2) normative change; and (3) process change.

### 7.2.2 Applying Market and Institutional Forces to Organizational Adaptation

**Client-Driven Change—Take-Home Medication.** Both market and institutional variables impact adaptation driven by the client. The two variables that significantly impacted client-driven change are program size and ownership. The results of this study show that smaller organizations and for-profit organizations are more responsive to client demands. This is evidenced by the significant association in small program size and a change in take-home medication practices as well as the significant association in for-profit ownership and a change in take-home medication.

As discussed in Chapter 3, smaller organizations are seen as less rigid and more reactive to change (Pfeffer & Salancik, 1978; Quinn & Cameron, 1983). Smaller programs also suffer a competitive disadvantage—compared with their larger counterparts—resulting in a need to be responsive to client demands to enhance program survival (D’Aunno, Sutton,
& Price, 1991; Marsden, 1998). Chapter 3 also documents that for-profit organizations receive little revenue from public funds and are, therefore, dependent on patient fees for revenue. For-profit programs must be responsive to client demands to ensure that patients continue to seek services through their organization.

These findings suggest critical organizational characteristics that should be considered when implementing client-driven regulatory change. First, the size of the organization may serve as a barrier to implementation. The regulatory agency should focus on working closely with larger programs to ensure that organizational changes are implemented. Second, ownership may serve as a barrier to implementation. The regulatory agency should also focus on working closely with nonprofit/public programs to ensure that organizational changes are implemented.

**Implication:** Large patient size and nonprofit/public ownership may impede the implementation of client-driven regulatory change.

**Normative Change.** Clinical supervisor tenure was the single institutional variable impacting normative change. The results of this study show that programs with a clinical supervisor having 6 or more years of experience in opioid dependence treatment are more responsive to normative changes. This is evidenced by the significant association in clinical supervisor tenure and a change in greater than 100 mg/day methadone dosing practices.

As shown in Chapter 3, program supervision is critical to organizational structure because leaders within an organization frame the system’s goals and have the power to influence policies and practices (Hage & Dewar, 1973). Because methadone doses exceeding 100 mg/day are often seen by OTPs as being in conflict with normative beliefs and practices,
the presence of strong clinical leadership is critical to implementing this type of change. For
MMT specifically, this leadership is perceived to rest with the clinical supervisor and not the
medical director. The clinical supervisor is usually a full-time position with close ties to the
other clinical staff and medical staff, whereas the medical director is usually only present in
the program for 1 to 2 hours per week and is often not viewed as a leader (Wechsberg,
Kasten, Berkman, & Roussel, 2006).

These findings suggest a critical organizational characteristic that should be
considered when implementing normative regulatory change; namely, the leadership within
the organization may serve as a barrier to implementation. The regulatory agency should
focus on working closely with programs where the clinical supervisor is less experienced and
has not yet established himself or herself as a leader among the other staff.

**Implication:** Clinical supervisors with less than 6 years of experience in opioid dependence
treatment may impede the implementation of normative change.

**Process Change.** Parent affiliation was the single market variable impacting process
change. The results of this study show that programs with a parent affiliation are more
responsive to process changes. This is evidenced by the significant association in parent
affiliation and a change in QA practices.

As shown in Chapter 3, parent affiliation increases efficiency by decreasing
administrative costs, and increases competitive strength by increasing service capacity.
Additionally, affiliation with a parent organization provides the individual organizations with
a network or partnership of other service providers that allows the organization to mobilize
more skills, as compared with a single organization functioning in isolation (Boyne, 2002).
Research has documented that organizations controlled by a central parent organization are more capable of implementing process changes efficiently (Douglas, 1986; Davis, Diekmann, & Tinsley, 1994).

These findings suggest a critical organizational characteristic that should be considered when implementing process change. Lack of a parent organization affiliation within an individual organization may serve as a barrier to implementation. The regulatory agency should focus on working closely with stand-alone programs when implementing process regulatory change.

**Implication:** Stand-alone programs with no parent organization affiliation may impede the implementation of process change.

### 7.3 Recommendations and Next Steps

**Organizational Change.** With respect to organizational change, this study highlights specific organizational characteristics that may impede organizational adoption of regulatory change. Additionally, the results of this study show that organizational change can be categorized into three areas for adaptation: (1) client driven change, (2) normative change, and (3) process change. The impact of either market or institutional factors can be linked to the type of change. Market and institutional forces come into play when implementing a client-driven change; however, normative change is most influenced by the institutional factor for leadership, and process change is most influenced by the market factor for parent organization affiliation.

Through this categorization of change, a typology can be created impacting future work within public administration and public policy. This new typology creates a mechanism...
for examining change and provides an opportunity to tailor organizational adaptation dependent on the type/s of organizations target for change and the type of change being implemented. For example, organization adoption of client-driven changes in a primarily publicly owned system will require intervention and assistance to ensure successful integration. However, if this same type of change is targeted for a privately owned system with smaller organizations, implementation of change could be expected to occur naturally with minimal barriers.

Overall, through the development of a change typology, researchers and public managers can continue to grow and expand the current knowledge base for organizational adaptation and barriers to the implementation of change. The information presented in this dissertation should serve only as a starting point for further discussion about change and its categorization. Within the three categories of change discussed in this dissertation, the impact of market and institutional force variables can be examined more specifically. These categories provide an initial context for future study in public management and organizational adaptation.

**Program Assistance.** Organizations with impeding characteristics may need some government incentive to enhance the adoption of the specific regulatory change. This incentive could be delivered in a variety of ways, including (1) dissemination of education materials explaining the reason for change, (2) training on policy implementation specific to the needs of the organization, or (3) monetary rewards for change implementation.

**Market and Institutional Force Delineation.** For the purpose of this study, market and institutional forces have focused on seven areas. Other market and institutional forces
may be considered in future analyses. Additionally, the delineation of market and institutional forces should be further examined. As these variables should be considered jointly in a multivariate analysis, the distinction and delineation between these two groupings of variables may be blurring. Further analyses are needed to better define and differentiate these factors and the impact they have on change and on each other.

**Further Study Needed.** This dissertation touched upon the role of politics in organizational change. This topic, however, would benefit from further examination. For example, future studies should focus on the individual significance of program treatment philosophy on organizational change. Each individual program has a unique organizational environment that may impact their ability to implement change. This unique environment can be represented in substance abuse treatment programs through a program’s treatment philosophy.

Additionally, future studies should further examine the proposed categorization of change. This categorization should also be examined in fields beyond opioid treatment. As a newly introduced typology, further examination and research is needed.

Finally, future studies should build upon this current work through the linkage of organizational change to patient outcomes. Data analysis completed for this dissertation focused on organizational change and market and institutional forces impacting the ability of an organization to adapt to changing federal regulations. Future studies should expand on this focus and examine how organizational change is associated with patient outcomes. Are better patient outcomes significantly associated with organizations that implement process change?
How are patient outcomes associated with organizations that are unable to implement a normative change? These are examples of research questions for future study.

7.4 Study Limitations and Overall Summary

While the findings from this study have merit for the future examination of organizational behavior, it is important to note that there were limitations in both the study design and analysis. First, the study consisted of a nationally representative sample of OTPs. While these programs can be viewed as similar to other public health organizations, it is important to note that only one type of organization (opioid dependence treatment) is represented in the study sample. Second, the definitions for market and institutional variables are grounded in the organization and substance abuse treatment literature. The categorization of and definitions for these variables may be different within other fields of interest. Third, the study used data collected under the Evaluation Study. As such, instrumentation development and data collection were completed for a purpose outside the scope of this dissertation. Thus, the variable used for location was determined using county size rather than distance to nearest competitor, as is more often common in market analyses. In future studies, location should be a factor of proximity to competitors. The study limitations, while noted, are not viewed as invalidating the study findings.

Overall, the findings from this study contribute to the current public administration literature by providing empirical evidence about the specific forces enhancing or impeding organizational adoption of regulatory change. Additionally, this study categorizes organizational change into three distinct types, which aids in the examination and interpretation of market and institutional factor impact on organizational behavior. Finally,
the study findings can be used to guide future regulatory change implementation by providing insight into the types of organizations that may need additional assistance to implement the mandated change.
References


Kraatz, MS, & Szyliowicz, D. (1996). Organizational justifications for illegitimate change: Evidence from liberal arts colleges. Working paper, Department of Business Administration, University of Illinois, Champaign, IL.


Appendix A
Regulatory Requirements for Opioid Treatment Programs

1972
Federal Regulations for Methadone

1990
GAO Report
- Wide disparity
- Minimal Federal oversight
- Recommends results oriented standards developed

1972
MTQAS
Looks at feasibility & usefulness of a performance-based feedback system

1990
IOM Report
- Need for individualized treatment
- Increase medical discretion
- Significant economic costs for compliance with regulations

1995
INTPRB
- Recommended that Federal oversight of opioid treatment be changed to incorporate accreditation
- Lead agency designated for oversight

1996
CSAT Guidelines
Guidelines for Best Practices in opioid treatment

7/22/99
NPRM Published

1/17/01
Final Rule Published

Regulatory shift - FDA to SAMHSA

CSAT Certification Decision

OTA with FDA approval on May 18, 2001 are deemed certified under New Rules (Transitional Certification)

Transitional Certification continues for 2 years - expires May 19, 2003
Transitional Certification can be extended for no more than 1 year

Accreditation Determination Including Appeals

STATE

Certification granted up to 3 years

Certification denied, revoked or suspended
## Appendix B

### A Chronology of the Regulation of Methadone Treatment

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>1914</td>
<td>Harrison Act (International regulation of opiate trade—increases monitoring)</td>
</tr>
<tr>
<td>1919</td>
<td>Webb v. the United States (Supreme Court case determines that prescribing narcotics is a crime)</td>
</tr>
<tr>
<td>1924</td>
<td>Harrison Act amended to ban importation of opium for the manufacture of heroin</td>
</tr>
<tr>
<td>1929</td>
<td>Porter Act (Act to build two narcotic “farms” to treat convicted addicts)</td>
</tr>
<tr>
<td>1949</td>
<td>National Institute of Mental Health (NIMH) established</td>
</tr>
<tr>
<td>1962</td>
<td>Presidential Advisory Commission on Narcotic and Drug Abuse (NADA) created by Kennedy to relax sentencing and intensify research; dismantled FBN</td>
</tr>
<tr>
<td>1965</td>
<td>Bureau of Drug Abuse Control (BDAC) created in HEW</td>
</tr>
<tr>
<td>1966</td>
<td>Two federal appeals courts uphold the concept of addiction as a disease not a crime</td>
</tr>
<tr>
<td>1969</td>
<td>Methadone class changed from investigational to legal in Opioid Treatment Regulations published by FDA in 1972</td>
</tr>
<tr>
<td>1973</td>
<td>Drug Enforcement Agency (DEA) replaces BNDD</td>
</tr>
<tr>
<td>1974</td>
<td>Narcotic Addict Treatment Act (NATA) enacted requiring all treatment programs to register with DEA</td>
</tr>
<tr>
<td>1971</td>
<td>Drug Office Abuse and Treatment Act passed to create Special Action Office for Drug Abuse Prevention created by Nixon; Authorized into statute in 1972 to coordinate Federal resources for drug treatment, prevention, and research</td>
</tr>
<tr>
<td>1971</td>
<td>Cabinet Committee on International Narcotics Control created by Nixon</td>
</tr>
<tr>
<td>1991</td>
<td>ADAMHA Reorganization Act restructured to transfer NIDA, National Institute of Alcohol Abuse and Alcoholism (NIAAA), and NIMH to the National Institute of Health (NIH). SAMHSA was created to support substance abuse treatment and prevention</td>
</tr>
</tbody>
</table>

First federal agency devoted to control illicit drugs created—placed in Treasury Federal Bureau of Narcotics (FBN)—1930

Harsh legal penalties established for prescribing opiates Boggs Act—1951 Narcotic Control Act—1956

Johnson abolishes BDAC to return medical discretion to physicians by creating in Justice Bureau of Narcotics and Dangerous Drugs (BNDD)—1968

Given statutory basis in Comprehensive Drug Abuse Prevention Control Act—1970

Created by executive order with Justice—Office of Drug Abuse Law Enforcement—1972

To coordinate drug prevention and treatment Ford created Cabinet Committee for Drug Abuse Prevention—1976

As part of a funding bill Ford signed legislation creating the Office of Drug Abuse Policy (ODAP)—1976 although he was opposed to the duplicative office.

Carter signed Reorganization Plan No. 1 of 1977 dissolving ODAP—1978

Dispensing of Schedule III, IV, or V drugs approved in physician offices is approved through the Drug Addiction Treatment Act of 2000–2000

Old opioid treatment regulations repealed and administration transferred from the FDA to SAMHSA through Opioid Drugs in Maintenance and Detoxification Treatment of Opiate Addiction; Final Rule—2001
Appendix C
Example of Clinical Supervisor Questionnaire

C30. Does this site do any of the following activities as part of its QA system?

<table>
<thead>
<tr>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>□</td>
<td>□</td>
</tr>
</tbody>
</table>

- Hold regular staff meetings to discuss patients ............................................
- Review patient charts selected at random to check for record completeness (e.g., records contain assessment, updated treatment plans, etc.)
- Review patient charts selected at random to compare services received with treatment plans
- Collect data on indicators of treatment outcomes and monitor trends
- Assess effectiveness of actions taken to correct identified problems
- Communicate relevant information about QA problems to key staff
- Review records of patients who leave the program against medical advice or who are discharged because of rule violations
- Review records of patients with special serious conditions (e.g., suicidal, pregnant)
- Review records with staff in cases of patients death or other serious indicators
- Assess patient satisfaction with treatment services
- Solicit suggestions on how to improve services
- Other
Appendix D
Opioid Study Comparison

<table>
<thead>
<tr>
<th></th>
<th>CALDATA Maint.</th>
<th>SROS</th>
<th>NTIES</th>
<th>DATOS</th>
<th>Evaluation Study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Female</td>
<td>43</td>
<td>45</td>
<td>32</td>
<td>40</td>
<td>43</td>
</tr>
<tr>
<td>Age 30+</td>
<td>91</td>
<td>72</td>
<td>83</td>
<td>82</td>
<td>78&lt;sup&gt;a&lt;/sup&gt;</td>
</tr>
<tr>
<td>Race/Ethnicity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hispanic</td>
<td>38</td>
<td>12</td>
<td>25</td>
<td>13</td>
<td>25</td>
</tr>
<tr>
<td>Black non-Hispanic</td>
<td>5</td>
<td>39</td>
<td>47</td>
<td>48</td>
<td>23</td>
</tr>
<tr>
<td>White non-Hispanic</td>
<td>51</td>
<td>47</td>
<td>28</td>
<td>39</td>
<td>56</td>
</tr>
<tr>
<td>Other</td>
<td>6</td>
<td>2</td>
<td>2</td>
<td>2</td>
<td>17</td>
</tr>
<tr>
<td>Black or Hispanic</td>
<td>43</td>
<td>51</td>
<td>72</td>
<td>52</td>
<td>48</td>
</tr>
</tbody>
</table>

<sup>a</sup>Percent of patients 35 years or older.