

A Treatise on the Theory of Regulatory Compliance

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Abstract

This treatise provides some insights into certain assumptions related to regulatory compliance and the implications for regulatory researchers and policy-makers for the future development of rules and regulations. Once regulatory compliance decision making moves from requiring full compliance with all rules to a substantial regulatory compliance decision making approach, the measurement and monitoring systems employed to assess programs and facilities change dramatically.

Keywords: regulatory compliance, risk assessment, key indicators, licensing, monitoring, measurement

1. Introduction

Regulatory compliance is a sub-discipline within regulatory science that focuses on measurement, monitoring systems, risk assessment, and decision making based on regulatory compliance scoring. Regulatory compliance is dominated by nominal scale measurement, that is, either a facility is in or out of compliance with specific rules. There is no middle ground with regulatory compliance as there is with most quality measurements, which are generally made on an ordinal scale. However, some regulators feel that certain regulations are not or should not be subjected to nominal measurement.

A factor with regulatory compliance data is that they generally follow a very skewed frequency distribution, which limits analyses to non-parametric statistics. Because of the skewed data distribution, dichotomization of data is warranted, given the lack of variance in the regulatory compliance frequency distribution - the majority of facilities¹ are either in full or substantial regulatory compliance.

An assumption within regulatory compliance is that full regulatory compliance, that is, 100 percent compliance with all rules², is the best (i.e., risk is minimized) possible scenario for the services being delivered and assessed. It is also assumed that all promulgated rules have an equal weight in their relative impact on the desired service delivery model, although this thinking has been changing over time regarding how rules are

reviewed and complied with. This short treatise will examine the past 40 years of research delving into regulatory compliance measurement, and will provide some guidance to regulatory researchers and policy-makers as they move forward with both research and policy development related to rules. The data from these research studies have led to a Theory of Regulatory Compliance that demonstrates that substantial regulatory compliance - and not full regulatory compliance - is a more effective and efficient public policy as it relates to decision making on monitoring and licensing.

The results reported herein are drawn from human services delivery systems in the United States and Canada, such as early care and education, as well as child and adult residential services. The results are from state and provincial level licensing systems involving over 10,000 facilities serving over 100,000 clients. All the data are part of an international regulatory compliance database (<https://data.mendeley.com/datasets/kzk6xssx4d/1>) maintained at the Research Institute for Key Indicators and the Pennsylvania State University.

2. Methods

Alternate methodologies, logic models, and algorithms were developed directly from the Theory of Regulatory Compliance once it was determined that substantial regulatory compliance produced better results than full regulatory compliance. These methodologies created a differential monitoring or targeted monitoring approach based on risk assessment, which measures client morbidity and/or mortality when individual rule

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¹The term “facilities” is used when referring to programs and/or facilities.

²The term “rules” is used when referring to rules and/or regulations.

non-compliance is assessed, and the determination of key statistical predictors for overall regulatory compliance [3].

Briefly, the above methodologies provide cost-effective and efficient means for the ongoing monitoring of human service delivery systems by selecting and reviewing only those rules that either have a positive impact on clients, statistically predict overall regulatory compliance, or protect the health and safety of clients [3]. Based on regulatory compliance historical data, decisions could be made as to the frequency and depth of the reviews or inspections. Abbreviated reviews (inspections in which a subset of rules are measured), such as licensing key indicator rules or risk assessment rules, would only be done in those facilities having a history of high regulatory compliance. Those facilities with a history of high regulatory non-compliance would continue to receive full regulatory compliance reviews as they did in the past.

3. Results

Prior to 1979, it was always assumed that there was a linear relationship between regulatory compliance measures and program quality measures of human service facilities. In a study conducted in that year, which compared results from early care and education programs, in particular child care centers, this assumption did hold up when one went from low regulatory compliance to substantial regulatory compliance. However, the results from substantial regulatory compliance to full (100 percent) regulatory compliance did not show the same linear relationship. Rather, it showed that those programs that were in substantial instead of full compliance were actually scoring higher on the program quality measures.

Since 1979, this result has been replicated in many other early care and education delivery system studies, both nationally in the United States (Head Start) [1] and in several states (Georgia, Indiana, Pennsylvania) [2]. In all these studies, one finds a non-linear - rather than a linear - relationship between regulatory compliance and the overall quality of the facilities being assessed.

4. Discussion

Based on the results above, there are several assumptions within regulatory compliance that need to be reconsidered:

1. Public policies that require full (100 percent) compliance with all rules may not be in the best interest of the clients being served, nor an effective use of limited regulatory resources. Potentially, emphasis on substantial regulatory compliance may be a more effective and efficient public policy related to client outcomes when it comes to their health, safety, and quality of life. Note that substantial compliance is still very high regulatory compliance (99-97 percent compliance with all rules) and produces positive client outcomes. As stated above, regulatory compliance data are extremely skewed and not normally distributed. There is very little variance in the data and the majority of programs are in either full or substantial regulatory compliance.
2. If a jurisdiction focuses on a substantial regulatory compliance public policy it opens up many system enhancements, such as differential or targeted monitoring, risk assessment analysis, and statistical key indicator rules that have been demonstrated to be cost effective and efficient approaches to reviewing program performance. In a full regulatory compliance public policy approach, none of these system enhancements can be employed, with the possible exception of the key indicator approach as delineated in number four below.
3. If a jurisdiction takes the position that all rules are not equal, then a risk assessment or weighting approach becomes an alternative based on the assumption that certain rules place clients at greater risk of death, serious injury, or other types of harm.
4. Even if a jurisdiction does not have a licensing law that allows issuing licenses on the basis of substantial compliance, there is the possibility that key indicators could still be used for abbreviated reviews or inspections, if there is no prohibition in statute or regulation that expressly forbids the use of this approach, since key indicators statistically predict full regulatory compliance. In other words, all rules are statistically predicted to be in regulatory compliance based on the results of the key indicators. Therefore, technically, all rules have been reviewed albeit short of a full review or inspection.
5. Based on previous research, utilizing a risk assessment approach along with a key indicator approach is the most cost effective and efficient differential monitoring system model. The reason is that both predictive rules and those rules that place clients at greatest risk are always assessed when a site visit review or inspection is done. Many more jurisdictions use a risk assessment approach at this point, but there is a loss of predictive regulatory compliance by just using it.
6. Based on previous regulatory compliance history, only those facilities in high regulatory compliance would be eligible for abbreviated key indicator and risk assessment reviews, whereas those with a history of high regulatory non-compliance would continue to receive full regulatory compliance reviews. This gets at the essence of the differential monitoring approach, which is cost neutral. Regulatory resources may then be re-allocated from the abbreviated reviews to more in-depth full regulatory compliance reviews.
7. Based on the use of the key indicator and risk assessment methodologies within a differential monitoring approach, it is possible to identify over multiple jurisdictions if there are generic rules that meet the criteria of risk abatement and prediction. Such an application has occurred in the United States with the creation of early care

and education standards entitled *Caring for Our Children Basics*, published by the Administration for Children and Families, US Department of Health and Human Services (2015).

5. Conclusion

Regulatory compliance is relatively new in applying empirical evidence and basic scientific principles to its decision making. In the past, it had been dominated by case studies and long narrative reports that did not lend themselves to quantitative analysis. There is a need to more clearly apply empirical evidence and the scientific method to rule development. Certain assumptions, such as full regulatory compliance as a sound public policy, are lacking in empirical evidence. This treatise on a theory of regulatory compliance is provided for its heuristic value for both regulatory researchers and policymakers in rethinking some basic regulatory compliance assumptions. It is not about more or less, rules but finding the “right rules” that protect clients, predict overall regulatory compliance, and produce positive client outcomes.

6. Declaration of Conflicting Interest

The authors declare no conflicts of interest.

7. Article Information

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