National Association for Regulatory Administration

REGULATORY SCIENCE AND THE HUMAN CARE OVERSIGHT INDUSTRY

Using Scientific Methods to inform practice and policy

Abstract

Regulatory science within the human care industry is the study of strategies and tools used to assess safety, quality and effectiveness of programs serving and caring for vulnerable populations. This paper discusses why this emerging field can use regulatory science principles to develop tools, evaluate products, and inform policy.

43 Town & Country Drive, Suite 119, #121 Fredericksburg, VA 22405
888-674-7052
www.naralicensing.org
U.S. Federal ID No. 54-1542015

About the Authors

One of the largest impacts on the field of regulatory science, specifically in the field of human care licensing, has come from Research Psychologist, Dr. Richard Fiene. Dr. Fiene has over 50 years of extensive research experience and publishes on the key components of improving child care regulatory oversight through differential monitoring systems including predictive regulatory compliance indicators (key indicators), risk assessments, and quality rating & improvement systems.

Dr. Sonya Stevens brings over a decade of experience in the regulatory field, with a strong background in analysis, methodology development, research, and project management. She currently serves as NARA's project manager, collaborating with agencies to enhance their regulatory systems.

As a final note, artificial intelligence (AI) was used to assist with portions of this paper. All citations and references presented as "Google, 2025" represent summaries and articulation of Dr Fiene's lifelong work and significant contributions to the field of regulatory science in human care licensing. This paper, along with NARA's new *Regulatory Science* course, encourages all human care licensing agencies to adopt holistic, data-driven approaches that are grounded in scientific methods when pursuing oversight improvements.

Introductory Summary and Commentary

The early learning industry has been the primary focus of human care regulatory advancements over the past 50 years. The lessons learned through early learning are adaptable to other human care fields; the same methodology can be transferred to other fields such as adult care and child welfare services. However, there is the need to conduct scientific testing and test products in all human care regulatory fields. Protecting customer safety is one of the core responsibilities of regulatory science. Human services combine various fields, including law, public policy, data analysis, and risk assessment to inform and guide regulatory decision making. The goal is to ensure regulatory compliance with licensing requirements crucial to maintaining quality standards and safeguards for the well-being of individuals receiving care.

Advancing regulatory science within human care services is ever more possible with the emergence of modern technologies. Technology allows for more efficient data collection and analysis through data management and analysis software, automation, and even real-time monitoring. These technological tools are increasing the ability for informed decision-making, particularly through tools like big data analytics, leading to streamline processes and enhanced regulatory compliance through accountability, efficiency, and transparency (ACF.gov, 2012). However, technology alone cannot fully address the risks and responsibilities of licensing agencies without sound research and methodologies to ensure the validity, reliability, and credibility of oversight structured approaches to oversight policy and systems.

What is Regulatory Science?

"What I have found in my most recent readings is that regulatory science is being applied in many different content silos from the FDA, to economics, to banking, and of course within the human services, particularly adult and child residential services. What appears to be lacking is a unifying theory that goes across these disparate content areas. The field of regulatory science is a very young field. Although regulations have been kicking around for well over 100 years, the science behind regulations is probably a quarter of this time. So, there is not a great deal of empirical evidence to draw upon which is discouraging but it is very encouraging and exciting at the same time because so much needs to be accomplished in establishing regulatory science theory." (Fiene, 2024)

The Emergence of Regulatory Science

Regulatory Science is a new and emerging discipline that specifically responds to the need to include scientific methodology into policy decision-making within the regulatory fields. The work has historically focused on fields such as medical, engineering, and environmental sciences. In fact, the term "regulatory science" first occurred in 1970 shortly after the formation of the Environmental Protection Agency (EPA) through an internal memorandum describing how science was used to develop regulations by that agency. The term, while defined in multiple ways, was not quickly accepted as it was not viewed as significantly different from other areas of scientific research. Over time, the term became more widely used in response to the need for more valid and reliable means to meet social needs. Specifically, regulatory science has evolved because policy makers and regulators struggle to apply science reliably; most commonly to limit using judgement when making policy decisions resulting in overly protective approaches to licensing oversight (Moghissi, Auffret, Calderone & Steen, 2018).

The field of regulatory science has emerged as a critical and multidisciplinary domain dedicated to understanding and enhancing the effectiveness and efficiency of regulatory systems. This field applies scientific methodologies to the study of regulations, the behavior of regulated entities, and the ultimate impact of these rules on desired outcomes. The limitations inherent in traditional regulatory approaches, which were often based on expert opinions and anecdotal evidence rather than rigorous empirical testing has highlighted the necessity for developing innovative theories and methodologies firmly rooted in research and data. (Google , 2025)

Regulatory Science as it Relates to Human Care Oversight

Regulatory science in the human care industry is a field that uses scientific methods to evaluate or develop tools, methods, standards, and systems that support a better understanding of safety, quality, and effectiveness of licensing systems. It is a crucial role in the human care licensing system development and assessment by ensuring safety, efficacy, and quality of services, products, and practices that lead to the protection and well-being of individuals receiving care.

Understanding All Aspects of Regulatory Science

Regulatory science consists of more than simply using data and analytics to guide decisions regarding licensing systems and practices. While scientific methodology is applied, scientists in this field also need to be knowledgeable and proficient in the areas of:

- **Ethics:** Remaining impartial and open to all findings, especially when they conflict with desired outcomes:
  > *"In communicating scientific information, the scientific community or an individual scientist may not exaggerate or minimize beneficial or adverse effects of an agent, a situation, a condition, or any other relevant issue." (*Moghissi, et al., 2018)
- **Communication:** The ability to translate scientific processes and finding to increase social validity (the acceptability of the outcomes, as perceived by the individuals involved in use and usability within the regulatory environment).
- **Transparency:** Providing accurate and timely information regarding methods, limitations, dependencies, and outcomes to the affected community.
  > *"Those who make a scientific claim including a claim addressing a regulatory science issue must provide their assumptions, judgments, and similar parts to the affected community in a language that is understandable to a knowledgeable nonspecialist." (*Moghissi, et al., 2018)
- **Stakeholder Engagement**: Effectively including decision makers, directly impacted groups, facilitators, and indirectly impacted groups.

Emerging Topics

Theory of Regulatory Compliance:

The foundation of Richard Fiene's contributions to regulatory science lies the Diminishing Returns Theory of Regulatory Compliance (TRC+). This theory suggests that the relationship between regulatory compliance and program quality or outcomes is not linear but rather follows a curved pattern (Google , 2025). This implies that while initial efforts to improve compliance can lead to significant gains in quality and safety, the impact of subsequent increases in compliance diminishes progressively. Eventually, a point is reached where further regulatory efforts produce only marginal, and sometimes even negative, returns in terms of improvements. Research suggests that there exists a "sweet spot" of substantial compliance, estimated to be around 80-90%, where an optimal balance is achieved between the resources invested and the positive outcomes observed. (Google , 2025)

The Relationship Between Regulatory Compliance Theory and Differential Monitoring:

Differential monitoring represents a momentous change in thinking in regulatory oversight, moving away from regular approaches towards a more targeted and adaptive strategy. At its core, differential monitoring is defined as a customized approach to regulatory oversight that adjusts the amount and frequency of monitoring activities based on a regulated entity's compliance history and identified risk profile (Google , 2023). The purpose of this approach is to optimize the use of limited resources by concentrating more attention on programs or facilities that have a history of non-compliance or that have been identified as carrying a higher level of risk (Google , 2023).

The Critical Role of Risk Assessment in Regulatory Compliance: Risk assessment plays a vital role in modern regulatory compliance. In the context of regulatory compliance, risk assessment involves the process of methodically identifying potential hazards or specific areas of non-compliance that could lead to negative consequences, such as harm to individuals, environmental damage, or financial instability. Dr. Fiene's Theory of Regulatory Compliance emphasizes the importance of integrating a risk-based approach into all regulatory practices because not all regulatory rules are equally significant in their impact on achieving desired outcomes or potential consequences if not kept in compliance. (Google , 2025)

Key Indicators: Identifying Predictors of Regulatory Compliance: Key indicators are defined as a carefully selected subset of regulatory rules or standards that have statistically demonstrated to predict overall compliance with the entire body of regulations. By focusing on the monitoring of these key indicators, regulatory agencies can gain a reliable understanding of a program's or facility's overall compliance status without conducting a full or comprehensive inspection of every single rule. The use of key indicators can lead to significant reductions in the time, resources, and costs associated with routine regulatory monitoring, particularly for programs that have a history of high compliance. (Google , 2023)

Measuring Compliance: The Development and Application of Regulatory Compliance Scales: Regulatory Compliance Scale (RCS) is an ordinal scale metric designed to provide a more nuanced assessment of regulatory compliance, moving beyond the simple binary classification of in or out of compliance (Google , 2025). The RCS allows for the measurement of varying degrees of compliance, potentially capturing instances of partial compliance or differentiating between levels of non-compliance based on their severity or scope (Google , 2025). By offering a more continuous measure of compliance, the RCS uses advanced statistical analyses to contribute to a deeper understanding of the intricate relationships between compliance levels and other important variables, such as program quality and client outcomes (Google , 2020).

Enhancing Quality in Early Childhood Programs: The Early Childhood Program Quality Improvement and Indicator Model (ECPQIM) represent a significant step towards a more integrated approach to enhancing the quality of early childhood education programs specifically. ECPQIM is a framework designed to effectively integrate regulatory compliance efforts with broader initiatives aimed at improving program quality. This model is evolving and incorporating various monitoring systems currently in use within the early care and education sector. The aim of the ECPQIM is to establish a comprehensive system for both assessing and improving the overall quality of early care and education programs through a programs adherence to regulatory requirements and a range of other critical indicators of quality (Google , 2024).

The Importance of Regulatory Science in the Human Care Field

Due to the rapid advancement of technology, licensing agencies generate substantial amounts of data that can be analyzed to make informed decisions. These data can be used to advance regulatory science frameworks through analyzing trends, patterns, and performance metrics to identify areas of concern or

improvement. Data-driven insights enable regulators to make evidence-based decisions, allocate resources effectively, and prioritize enforcement actions where they are most needed.

The practice of employing regulatory science provides a formal framework of knowledge transfer and debate through identifying, interconnecting, and characterizing methods of discovery using various data points and analysis. When regulatory science is not embedded into human service administrations, oversight systems are subject to significant risks and consequences. Most notably these risks include effectiveness, accountability, and trust.

Effectiveness: Regulatory Science can have a direct impact on the effectiveness of legislation and licensing systems exploring avenues to avoid adverse effects, provide predictability of outcome for both regulators and the licensees, and justify regulatory decisions (Hilton, Bhuller, Doe, Wolf & Currie, 2023). Regulatory science focuses on the scientific underpinnings of regulations inclusive of the administrative and legal outcomes. This includes identifying the right rules and oversight practices that ensure the safety, performance, and quality of the regulatory products. Additionally, scientific processes can help to streamline the evaluation and approval process, making it more efficient and effective.

Accountability: Licensing plays a vital role in ensuring accountability within human service systems. Accountability within regulatory science ensures that regulatory bodies and licensed professionals are responsible for upholding standards and protecting public safety, often through mechanisms like transparent processes, consequences for non-compliance, and public reporting (Mann & Rasmussen, 2023).

Trust: Trust in regulatory science and licensing is crucial for public health and safety, and it is built through transparency, accountability, and evidence-based decision-making, ensuring the safety, efficacy, and quality of regulated products. It is crucial to the field of regulatory science to manage “the reliability of scientific claims. How can a regulator; a judge; a member of a legislative body; a reporter; or anyone else judge the validity of a claim.” Without the science, subjective opinions and ideas lack the evidence to invoke public trust (Hilton et al., 2023).

Applying Regulatory Science to Your Agency

Research within regulatory science is an inclusive process whereby "moments of opportunity" are critical because key players can learn from one another – it is a process that contributes to the greater knowledge through debate around findings rather than simply solving problems. The main challenge for applying research to policy is knowing those moments of opportunity and then acting effectively to take advantage of them. These moments include the stages of idea generation, design, data gathering, analysis, and application.

Licensing agencies generate substantial amounts of data that can be analyzed to make informed decisions. Regulators can use regulatory science frameworks to analyze trends, patterns, and performance metrics to identify areas of strength, concern, or improvement. Data-driven insights enable

regulators to make evidence-based decisions regarding rules and policy, products, and systems, allocate resources effectively, and prioritize enforcement actions where they are most needed.

Final Thoughts

Regulatory science specific to human care administration is relatively new; innovative methods and strategies emerge yearly. The emergence of regulatory science specific to the field of human care licensing demonstrates a needed shift from the current practice of a top-down style of regulation to a more adaptive and evidence-based framework. A truly effective regulatory system requires a scientific understanding of human behavior, the unique dynamics of licensing agencies, and the impact of rules on achieving desired societal outcomes. While regulatory science provides these foundational concepts, it must also be translated to the workforce. In addition to scientific discoveries, agencies and leaders should consider the need for adequate and ongoing training to ensure legislators and regulators understand and comprehend scientific outcomes and their impacts on everyday work.

There is a general sense of urgency to reinforce regulatory science as a crucial science to delivering data-based decision-making in human care licensing. Unfortunately, agencies may not have the skills or resources needed to advance the science; not just the financial resources but also supportive scientific ecosystems to continue the advancements in this important work. To adequately advance this emerging field, our communities should:

1. Address the shortage of experienced regulatory scientists.
2. Advocacy to institutions of higher learning to create an academic culture that understands the need to develop regulatory scientists.
3. Increase collaborations between the regulatory and the scientific communities.
4. Create safe spaces that support collaboration and participation within regulatory research and projects.
5. Begin to create a shared understanding of the need to advance human care licensing through more developed approaches that are inclusive of client perspectives. (Institute of Medicine, 2012).

NARA is committed to advancing the field of regulatory science by building existing scientific evidence and strategies while working with agencies to develop data-driven and evidence-based licensing and assessment, and training tools. Regulatory science is not just about following regulations; it is about understanding the science behind those regulations and using that knowledge to make informed decisions.

References

ACF.gov. (2012). Use of technology to enhance licensing administration. U.S. Department of Health and Human Services. Retrieved April 1, 20205 from chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://acf.gov/sites/default/files/documents/occ/001_1209_technology_licensing_final_508c.pdf

Fiene. R. (2023). Regulatory compliance and program monitoring. Research Institute for Key Indicators. Retrieved from chrome-extension://efaidnbmnnnibpcajpcglclefindmkaj/https://nara.memberclicks.net/assets/docs/KeyIndicators/rcms-fiene-4th-edition-1.pdf

Google. (2025). Gemini Pro (Deep Search) [Large language model] from: Richard Fiene's lab. *Pennsylvania State University (Penn State) – ResearchGate*. [AI-generated summary]. Accessed March 26, 2025, https://www.researchgate.net/lab/Richard-Fienes-Data-Laboratory-Richard-Fiene

Google. (2025). Gemini Pro (Deep Search) [Large language model] from: Fiene R. (2024). Theory of regulatory compliance, regulatory compliance scale, and differential monitoring. *ResearchGate.* Accessed March 26, 2025, https://www.researchgate.net/publication/381648699_Theory_of_Regulatory_Compliance_Regulatory_Compliance_Scale_and_Differential_Monitoring

Google. (2025). Gemini Pro (Deep Search) [Large language model] from: Fiene. R. (2023). The Fiene coefficient. *ResearchGate*. Accessed March 26, 2025, https://www.researchgate.net/publication/374542658_The_Fiene_Coefficient

Google. (2025). Gemini Pro (Deep Search) [Large language model] from: Fiene. R. (2020). Grantee performance management system key indicators. Accessed March 26, 2025, https://rikinstitute.com/wp-content/uploads/2020/06/gpmskim.pdf

Hilton, G.M., Bhuller, Y., Doe, J.E., Wolf, D.C., Currie, R.A. (2023). A new paradigm for regulatory sciences. *Regulatory Toxicology and Pharmacology*. Volume 145, 105524, ISSN 0273-2300, https://doi.org/10.1016/j.yrtph.2023.105524.

Institute of Medicine. (2012). "Front Matter." *Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary*. Washington, DC: The National Academies Press. doi: 10.17226/13283.

National Academies of Sciences, Engineering, and Medicine. 2012. Strengthening a Workforce for Innovative Regulatory Science in Therapeutics Development: Workshop Summary. Washington, DC: The National Academies Press. https://doi.org/10.17226/13283.

Mann DL, Rasmussen LM. (August 28, 2023). Who Should Be Accountable for Scientific Accountability? *JACC Basic Transl Sci*. Vol.8 pp. 1040-1042. doi: 10.1016/j.jacbts.2023.08.001. PMID: 37719434; PMCID: PMC10504429.

Witte, A.D. & Queralt, M. (2004). What Happens When Child Care Inspections and Complaints are Made Available on the Internet? *Wellesley College Department of Economics and National Bureau of Economic Research*, Wellesley Child Care Research Partnership, January. Retrieved April 1, 2025, from http://www.wellesley.edu/Economics/partner/w10227.pdf .