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Ten Principles of Regulatory Science

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This paper builds off several previous research abstracts and short papers (Fiene, 2022, 2024, 2025a) dealing with this topic of the basic foundations of regulatory science. I will try to distill what I think are the ten top principles that need to be considered by regulatory scientists as they pursue their science. These principles are ever present in human care licensing and have emerged over the past 50 years of my research in the human service regulatory science field.

This paper is meant to be used as a think piece for regulatory administrators, policy makers, licensing assessors, and licensing researchers/regulatory scientists as they think about the important developments in the licensing and regulatory administration field. Its purpose is also to infuse as much regulatory science into human care licensing and the research thereof (Fiene, 2025a,b).

The application of regulatory science principles to human care licensing is a relatively new endeavor. The field of human care licensing has been driven by anecdotal and best practice documentation and not scientific methods within the regulatory science field. This is not to be taken as a criticism of the human care licensing field. Regulatory science has only been established since the early 1970s and its emphasis and presence has been in the pharmaceutical area and definitely not in the human services area. Since the beginning 2020 this has been changing radically in which the scientific methods of regulatory science are being sort out and used within human care licensing, most notably by the National Association for Regulatory Administration (NARA).

Let's take a look at the principles and see if they resonate in other industries and if some of the methodologies and results have a larger place than just in human care licensing.

So, here are my top ten principles to be aware of:

1. **Rules are not created nor administered equally**. This was an eye-opening discovery when I first started in my journey from a research psychologist to becoming a regulatory scientist. I assumed that all rules/regulations had an equal value. But it is perfectly clear that certain rules place clients at greater risk and there are some in particular that

increase the chances of morbidity or mortality significantly. This issue of unequal risk will be dealt with in an upcoming principle – Principle 3.

And because the rules are not equal, they are not administered equally either. But that makes sense. Licensors determined this very quickly and in their reviews of facilities there are particular rules that are just more important than other rules. These are the rules that deal with practice and interaction and are not paper driven. They are about how the staff interact with their clients. Records and documentation are important but being out of compliance because a signature is not in place in the majority of cases does not place the client at risk of morbidity or mortality, unless that signature prevents the client from receiving a critical service.

2. **It is not about over-regulation or de-regulation; it is about finding the "right regulations".** This is an age long discussion and battle about jurisdictions over-regulating and the need to de-regulate. And the pendulum has swung both ways back and forth over the decades depending on the political whim of the ruling party. It has been a terrible waste of time and resources. What needs to occur is to focus on a data-driven approach in finding the "right rules" which have a positive impact on client's lives. These are the rules that need to be complied with. Yes, get rid of the rules that have no or very little impact on client's outcomes but do it with data not the political tea leaves that have been used in the past.

   Having too few rules and regulations places clients at increased risk, especially if certain high-risk rules are not included. But at the same time, having too many rules and regulations puts a cognitive overload on the licensing assessors who are doing the inspections. It also leads to a cognitive overload and a financial difficult position for the facilities and providers of service. All rules and regulations have a cost attached to them. Again, in a very differential manner, staffing will be much more costly than some paper work items or simple equipment purchases.

3. **Because rules are not equal, they need to be weighted according to their risk to the client when non-compliant. The highest risk rules are generally always in compliance; the middle risk rules are generally the predictor rules; and the low-risk rules generally will show the greatest level of non-compliance.** This principle ties back to Principle 1 dealing with rules are not created equal. But this principle does something about rules not being equal and suggests using a weighting system to demonstrate the different levels of risk that non-compliance with particular rules places clients in jeopardy. This has been done using a Likert Scale such as 1 – 8 with 1 = little risk and 8 = great deal of risk. Other scaling techniques that are being experimented with build off the Fibonacci Sequence which uses a scale 1 – 100 with 1 = little risk and 100 = extreme risk.

The key is to weight each rule according to its potential risk for client morbidity or mortality if the rule is not in compliance. This is generally accomplished by asking a group of stakeholders, experts, licensors, advocates, clients, and researchers to do the actual weighting of the rules. It can be a time-consuming process if the rules and/or regulations are extensive. And this can be done via paper questionnaire format or by utilizing a new "relative weighting poker" in-person approach.

Keep in mind that if rules are not weighted than by default one is saying that all rules have an equal weight which we know not to be the case.

4. **Regulatory compliance is a balancing of "do no harm" and "do good".** This is a key principle in that it defines what regulatory compliance and ultimately the goal of regulatory science. This can be a very difficult balancing act but for rules and/or regulations to be effective it is critical that each is assessed in how much a particular rule is safety based versus quality based. Most rules fall under the safety based rubric but there are an increasing number of rules that are beginning to fall under the quality-based banner (Fiene, 2025c).

   "Do no harm" and "do good" have always been and continue to be the twin pillars of regulatory science. Finding the key elements in utilizing scientific methods to deal with rules and regulations should be the focus of regulatory science. Taking them out of the political arena and putting them into the scientific domain (Fiene, 2022).

5. **False negatives should be avoided at all times in licensing decision making which means not assuming compliance when in reality that is not the case.** From a measurement and protection point of view this principal is critical. This is when an assessor says a facility is "in compliance" on a particular rule when in reality the facility is "out of compliance" with the rule. Depending on the rule's risk value, this could place the client in serious risk of morbidity or mortality and should be avoided at all times.

   Specific adjustments based upon regulatory science have been made to focus attention and address this concern about false negatives in the math being used to make predictions for licensing key indicators and in the decision-making process via the Uncertainty-Certainty Matrix for Licensing Decision Making (Fiene, 2025b).

6. **With regulatory compliance, a "ceiling" effect is ever present and, in some cases, a "diminishing returns" effect.** This phenomenon has to do with the relationship between regulatory compliance and the program quality of a specific facility. It was discovered in a series of studies in the 1970s and 1980s in human care licensing and then replicated in the 2010s and 2020s that when regulatory compliance data and program quality data from facilities were compared to each other, a ceiling effect or in some cases since then

a diminishing returns effect were observed. Data obeyed a linear relationship when comparing low quality and mediocre quality programs when it came to their regulatory compliance scores. However, the linear relationship between regulatory compliance and program quality started to break down when one moved from mediocre to substantial to full regulatory compliance and program quality. This is where the ceiling or diminishing returns effects began to demonstrate themselves (Fiene, 2025a).

This led to the policy change of issuing full licenses to facilities that were in substantial regulatory compliance as well as full regulatory compliance. Prior to this discovery, full licenses were only issued to facilities that were in full regulatory compliance with all rules and regulations. This was a big paradigm shift in the public licensing domain when this occurred.

7. **Rules and regulations are all about a "gatekeeper" function vs an "enabler" function.** At times this is forgotten in that the public equates a license with program quality. The purpose of licensing is to keep the "bad apples" out. It is not driven by quality standards that have a more open system effect where there is not a ceiling effect. Quality has no limits utter than the limits of creative thought in envisioning how far it can climb. Licensing is providing that floor of quality, the foundation. It also has a ceiling. Program quality builds off of licensing rules and extends beyond the ceiling into the openness to be defined by the individual program facility.

   This is the difference between an open vs a closed system of rules or standards. Generally licensing would be characterized as a closed system of rules while a program quality system would be characterized as an open system of standards, such as a QRIS (Fiene, 2025c).

8. **"Differential monitoring" is generally more cost effective and efficient than "one size fits all monitoring" or "uniform monitoring".** Uniform monitoring is how monitoring has been done for decades prior to the CCDBG:Child Care Development Block Grant Legislation which encouraged states to utilize differential monitoring. Differential monitoring is an abbreviated approach to program monitoring that utilizes statistical predictor rules and high-risk rules to focus the review. This differs substantially from "uniform monitoring" or a "one size fits all" monitoring approach in which all rules are assessed each time a review is done regardless of previous regulatory compliance history.

   Differential monitoring is both cost effective and efficient because it focuses on risk and predictability which saves time and resources. Assessors are not overwhelmed with

excessive rules and regulations and can do an in-depth dive into a core set of rules and regulations that have a positive impact on client outcomes (Fiene, 2026).

9. **With regulatory compliance data, dichotomization of the data distribution is necessary to account for the lack of variance in the data.** Regulatory compliance data are very unique. Actually, they are more than unique, the data are, well, a "pain in the ass" to deal with from a statistical point of view. There is very little variance in the data, there is an assumption of equality when there is none, the data are terribly skewed, and the data are nominal. So, with all these shortcomings, how do we make sense of licensing data sets? I have addressed the equality/inequality issue above in Principles 1 & 3.

   There have been recent developments to move licensing nominal-based data to more of an ordinal measurement strategy, the Regulatory Compliance Scale (Fiene, 2024, 2025a, 2025c, 2026). In preliminary pilot studies, the new proposed Scale appears to perform slightly better. With additional fine tuning I think it will provide an advancement in regulatory compliance measurement that is sorely needed in the regulatory science field.

   To deal with the lack of variance and the data being terribly skewed, dichotomization is being suggested. Generally, this is not recommended in the statistical domain, but with regulatory compliance data it is warranted. It is the only way to deal with these twin death blows to statistical analysis.

10. **With regulatory compliance data, it is easy to distinguish between the high compliant performers and the low compliant performers; however, it is difficult to distinguish between the mediocre performers and the truly high compliant performers.** This is a perennial problem that has been voiced by regulatory administrators and policy makers over the decades. This principle has a great deal to do with the purpose of regulatory compliance data. Remember, the data represent basic safety rules so the expectation is that there will be very high compliance with the individual rules. And there is, when one looks at individual jurisdictions, you will find a data distribution which is very positively skewed with the majority of facilities being in full (100%) regulatory compliance with all rules. You will not find normally shaped bell curves, trust me. In fact, if you do, please encourage families to not utilize the services because the rules and regulations and their enforcement are not on par for ensuring any safety or quality.

    So, it will be easy to distinguish the high performers from the low compliant performers. This is a good thing, the problem comes when comparing the mediocre and the high performers, that is where the water gets muddy and it is not as clear cut as we would

like it to be when looking at the data. This is complicated because of the ceiling effect and substantial regulatory compliance which was addressed in Principle 6.

This research abstract builds off an earlier paper (Fiene, 2022) dealing with regulatory compliance principles but framed in a dichotomous fashion. See Fiene, (2024). ***Regulatory Compliance Monitoring Systems***, which is the etextbook for the National Association for Regulatory Administration's Licensing and Measurement courses; Program Monitoring Systems and Regulatory Science as part of their Licensing Curriculum.

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