



**Regulation Matters:
a CLEAR conversation**

Episode 63: Regulatory Sandboxes - Concept and Implementation

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Line Dempsey: Welcome back to our podcast, Regulation Matters: a CLEAR conversation. Once again, I'm your host, Line Dempsey. I'm currently the chief compliance officer with Riccobene Associates Family Dentistry here in North Carolina and Virginia, and I'm also CLEAR's president for the 2022-2023 year.

As many of you are aware, the Council on Licensure, Enforcement and Regulation, or CLEAR, is an association of individuals, agencies, and organizations that comprise the international community of professional and occupational regulation. This podcast is an opportunity for you to hear about important topics in our regulatory community.

On today's episode, we'll be exploring the concept of regulatory sandboxes. Joining us today, we have Jan Robinson, Registrar and CEO of the College of Veterinarians of Ontario, Micah Matthews, Deputy Executive Director of the Washington Medical Commission, and Bradley Chisholm, founder and principal of The Regulator's Practice Consultancy. We're glad to have you all with us today.

Jan Robinson: Great to be here!

Bradley Chisholm: Really nice to be here!

Micah Matthews: Thanks!

Line: We're happy to speak with you. I know one area of CLEAR's strategic plan that we've talked about before is exploring the use of regulatory sandboxes to engage with innovators. Now, some of our listeners may be familiar with the idea of regulatory sandboxes in the area of fintech, financial technology, where it allows innovators to test technologies, products and services in a controlled environment with some regulatory safeguards.

So, let's start today with some discussion on what that term "regulatory sandbox" means. So maybe Jan, kind of give me a definition of what that is.

Jan: A definition? Okay, let me give it a try. I think it's important to think about it like a tool. You know, it's really just a tool to relax legal and regulatory requirements to create a bit of safe space for experimenting - where you've got regulation as a presumed barrier (maybe not a real barrier, but a presumed barrier) and allowing for a bit of an incubator to trial some new things. And looking at what's the problem? What are we trying to achieve? Is reducing the barriers aligned with the public interest in its biggest way of thinking about it?

And really, to be quite honest, Line, the rest of it is really about project management then. It's really about who's the lead? What will success look like. What are those factors about? What's the work plan? Are there milestones? How are we going to measure that? And how are we going to report out on it?

So, it's putting some scaffolding around this relaxation concept, but ensuring that it doesn't go so far that what you're doing is causing harm.

Line: Gotcha! Bradley, anything to add to that?

Bradley: You know, I just think that it's a pretty simple concept. You know, people play in sandboxes. And I think, creating the constraints for those that we regulate to be able to innovate within some constraints. And again, like Jan said, we kind of pull back perhaps some of the traditional regulatory frameworks that we have, so that regulators are not barriers to professional innovation, which I think is a real danger - that regulators are seen as, but are actually at times, barriers to the shifting, changing professions and occupations that we all work with. So I think it's really important, and I also think, (and I'm happy to talk about it a little later) as regulators, we need to have our own sandboxes, too, because we actually need to be innovating as regulators as well.

Line: Well, that brings up a good question, Bradley. So, why is this experimentation important for us as regulators? And could we even go to say, this is imperative that we do? Where are we on that?

Bradley: Now, it's a great question, and I'm sure there's lots of different diverse opinions about this. But where this really became real for me – so, I was working... I'll kind of go back to where this idea of experimentation was introduced to me. So, I was working in the Attorney General's office in Alberta, the province of Alberta, Canada. We were developing what was called a safe communities initiative, and the civil servants that developed this project kind of brought the idea and said, 'We want to go around. We want to provide funding to multiple communities throughout the province where the community can create their own safe communities project. We'll evaluate the projects. We'll see what's working, see what's not working, and then we'll build future province-wide programs based on the successes or failures of these different community projects.'

Well, as a young lawyer at the time, political staff, I was like, 'That's ridiculous. Do the research. Let's figure out what the one or two best practices are, and let's engage those. Let's not waste time with, you know, going to these communities and experimenting.' And that's when these very patient civil

servants introduced me to the work of a guy named David Snowden and his framework called the Cynefin framework. It's C-Y-N-E-F-I-N. It's a Welsh word.

And he talks about different systems, and in different types of systems, we have to function differently in order to navigate and lead and innovate within those systems. And two of those systems that he talks about are a complicated system, where the means and the ends are known but often you need to be an expert in order to understand them. So he uses like an airplane engine as an example of a complicated system, where the pilot pushes the throttle, there's a thousand things that happen for that airplane to move forward, and unless you're an airplane engineer, an airplane mechanic, or a pilot potentially, you don't really know what those thousand things are. But complicated systems is where experts and best practice live.

But, these civil servants that I was working with told me that we're not really working, you know, community safety and crime is not a complicated system. It's a complex system. We could do the same thing a hundred times, and we could get a different result every time. And in those complicated systems, we have to experiment, and we have to evaluate those experiments. And even if something's working for a couple years, it might stop working.

When I think about the professions that we are regulating right now, the massive change that they are experiencing, the shifting public expectations that we, as regulators, are having to deal with - the fact that some of the professions that may have existed 30-40 years ago, people are questioning whether they should even be a profession anymore. All of those things make me believe that we're actually regulating complex systems, not complicated systems.

And therefore, this whole idea of best practice, or you know the best way of doing things, I think, has to be challenged. I say that both in terms of the people we regulate and their need to innovate and experiment and test the barriers of things, but also regulators. We have this thinking that we have to figure out best practice, and then we create these big programs that then cost millions of dollars and last 30 years. It's just, I think, not the way that we need to be regulating in these complex environments. So that's kind of why I think that experimentation is really necessary, because we're working in complex systems, and so are those who we regulate.

Line: Great! Jan, you had a comment?

Jan: Yeah, yeah, I just wanted to jump in for a sec if I could, because I do think that, to build on what Bradley's saying, our rules are really changing as well, and really evolving, in my opinion. We have been about our mandate and completing our mandate, which, of course, isn't going away, and that's important. But increasingly we're becoming conveners and influencers of scenarios and situations and problem solving. And so, this comes back to how are we contributing to agility in a regulatory environment? And how are we, to put it a different way, leading to the edge of the law? Are we simply about executing the law? Or are we about leading to the edge of the law for the public good?

I think this has been so important to the organizations I've been involved with for the last several years, around looking at where does innovation fit in that? And how do we contribute?

Line: Yeah, that's great. It definitely does sound like something that regulators really need to be considering. Which kind of brings me to the next question for Micah on that. If you're going to do it, how do you do it properly?

Micah: Sure. Well, you do want to have some constraints in place, so as not to end up with a completely unregulated disaster, such as the recent crypto meltdown of FTX and Alameda Research, or the more health care-related one that I've been following since its inception of Theranos. We just saw the convictions being handed down on that particular one. These are both great examples of disruptive innovation without a basis in reality or any real attempt at oversight. This is all about drawing clear lines where innovation can occur, and being specific to where it cannot. And to Jan's comment, I think we all should probably recognize that as regulators we only deal with a very small percentage of the folks who can't seem to deal with the law very well. And so you know, to reframe what we're looking at, leading to the edge of the law, we really should be innovating, looking to empower that arguably, say, 90% of our licensees or registrants who never really have a problem. And you're trying to enable the good work because, and especially in the health care space, that means access to care. And so, trying to find those complex systems and enable them to work well.

By drawing the clear lines, we give both the regulators and the public confidence in what areas are changing, and we have to remember that for some sectors of our stakeholders, change brings fear and uncertainty.

So, for evidence of that we can look no further (and I'm not being political here) than the health care workers and regulators trying to respond to the literal chaos that was unleashed with the U.S. Supreme Court overturning Roe. No matter what your ideology is there, if you were involved in those sectors, we can all agree that it created vast amounts of uncertainty, costs in response to both the vacuum of the standards and then addressing the stakeholder concerns of how the regulator would approach this new normal.

So, we must at a minimum address the fear through demonstrating how we will deal with potential negatives of innovation and remember it doesn't have to be a huge change. It can be small or done in phases with proof of concepts just to build that trust and to build out that system so that builds trust and confidence. And the major shift in mindset, to my mind, is the acceptance of failure, and that's really where the uncertainty on the regulated comes into play.

You know, in some sectors that's more allowable than others. In finance, it's quote "only money," despite the personal toll it takes on the retail side. But in aerospace or real estate or health care, that can lead to cascade failures that take lives. And so, we're seeing an example of this in almost real time of the aftermath of the earthquake in Türkiye -related to the regulation or the lack of regulation in building standards that was politically motivated.

And so, you know, for those reasons don't be afraid to start small. But you do need to examine your risk tolerance.

Bradley: Yeah, just to jump on that, I think that that's one of the greatest barriers is that difference between creating safe-to-fail environments, both for our registrants. What if, within those constraints, there is failure? What if there is some risk? Are we okay with that?

But also, people don't like it when regulators fail, either. And so, one of the challenges, I think, is that if regulators are experimenting with different types of regulatory programs and they're not effective or they're not as effective or they fail, is there an acceptance of that?

And I think, going back to that original story of that community safety program in Alberta, fast forward four years later when we had all the data of all those community programs, and there were some that worked and some that failed. Well, there wasn't a single politician that was willing to take money away from any of those failed. So you know, the whole concept fell apart because no one wanted to accept failure and say, 'I'm sorry; that project is failing. We're no longer going to be doing that. We're going to put our resources towards something that isn't failing.'

So, that relationship with failure at all levels - at government, at the regulator level, at the professional level - I think that's one of the biggest barriers we have of creating a sandbox.

Jan: That's so interesting actually, Bradley, because where I went to was this whole concept of we have the reputation we deserve, right? And we have a reputation of being exceptionally cautious as opposed to courageous. And I think that those are different places. And I don't necessarily want to take us down that rabbit hole; Line, it's maybe a whole new podcast conversation. But what we don't talk about as we try things and as we learn and as we create - and there's so many amazing stories about regulators and research and what we're doing - but to be able to put that out there and just say, 'You know what? This worked really well, and then this didn't work very well.' And be better able to describe why we're supporting this, and why we're not supporting that, and be able to explain it in a much better way, I think, creates a different platform for how we become a convener and influencer.

Bradley: And Jan, just because it worked here at this point in time doesn't necessarily mean it will work for you, right? That's the other thing, too, is this kind of desire to identify and articulate best practice, so that others follow suit. Well, we have to be open to what works, what worked in this environment. The environment might be totally different in another province or another state or another country.

So for people to recognize that this may or may not work for us, and we have to, therefore collect data. We have to test it. We have to ensure that we're meeting our intended outcomes. We can't just assume this is gonna work here because it worked over there. I think that's the other piece, too.

Line: Well, conceptually, I think I understand it. I think our listeners understand it. But from a practical side of things, what kind of things can we see in practice? Can we maybe talk about some emerging examples of how this can be structured and implemented? So maybe, Jan, can you speak to that a little bit about some of the stuff that you're seeing?

Jan: Sure, I can give you a couple. For veterinary medicine, interestingly, fairly late to the game on the concept of telemedicine. In Ontario, we set a professional practice standard related to the practice of telemedicine in the veterinary space in 2016, thankfully, because 3 years later we really needed it. But on the international stage it was brand new. But Covid, for many, many reasons, was the perfect petri dish, and the whole issue for veterinary medicine was related to prescribing.

We were already permitting prescribing for animals with known conditions - so an animal known to the veterinarian, with a known condition. That needed to really open up during Covid. And so, we were looking at known animals with new conditions, new owners with new animals. How did that all look with diagnosing, prescribing, and distance?

And so, it was really an opportunity to test that out for what was working, what was not working. And of course, we're also talking about multiple species. So that's a different ball game, too. But what it really did was really advanced our policy work from 2019 to 2022, when we issued a new policy last June, which really put a different kind of scaffolding around how to prescribe in a relationship that was not necessarily one where you were always seeing the animal. So that's an example.

But a different example is, and not a new problem - so sure, we have a veterinary shortage right now that's really fairly critical. But we've had that emerging with beef farmers and large animal veterinarians in rural practice for years, like a long time. So, we really needed to look at solutions around that. And so, we acted as convener. We brought together veterinarians, producers, veterinary technicians, industry; the Ontario Veterinary College brought them into a room to talk about what could these solutions look like. Where could we go? And it's not about the College running the program; it's about how do we help initiate the solution.

And so, what we have now is a new look at distributive practice related to the delivery of veterinary medicine in Northern Ontario, where they're looking at how can we challenge the delegation model - the work between the veterinary and the veterinary technician or non-veterinary auxiliaries. How is it that we look at shared facilities because we accredit facilities. Like hospitals, we accredit facilities. So, how do we look at shared facilities? And how do we look at remote dispensing? Because we're talking about 5, 6, 7 hours sometimes, between locations of where animals need to be seen. And groups have now come together. They're forming solutions. They're seeking money.

So these are organic and grassroots solutions that are coming forward to our Council. We have to look within our regulatory sandbox policy. Lots of what they're doing doesn't have a thing to do with our standards, but some things bump into them. So, what are the criteria? How can we put it together? How can we look at a two-year experiment related to this? There are two separate models that are

going to be going forward, and we're really excited about the fact that it's a multi-stakeholder initiative that we are keenly a part of that will look at what works, what maybe worked, and what didn't work. And where do we relax a bit more? And where do we say, 'No. This was here because it needed to be here, as a rule.'

Line: I think the Washington Medical Commission's got some things they're working on. Micah, what can you tell us about what you guys are doing?

Micah: Sure, we've got two items that I can discuss that we're rolling out – well, we rolled out on the first one. It was a pandemic related change where the governor was looking to facilitate practice in the health care sector and was asking for ideas on what specific statutes to waive. And so, we gave recommendation that the statute requiring practice agreements for physician assistants should be waived for the pandemic, just to provide that flexibility and reduce administrative burden. And so, this effectively severed the ties between physician assistants and physicians in a supervisory capacity for 28 months, which, you know, for my mind is a perfect study time.

And so, we looked at the data, and recently we found that there was no discernible uptick in complaints against PAs, or no noticeable increase in complaints about the lack of supervision of scope of practice issues that I would say detractors or critics would certainly be looking for.

Unsurprisingly, there is a bill proposing relaxing the restrictions on practice agreements in the Legislature currently. Unfortunately, it didn't make cut off, so it'll be a try again next year scenario for them.

The other project is introducing human-centered design into our complaint process to go beyond the paradigm of file a complaint, process it, send generic letters with the outcomes. We call it the practitioner support program.

It's one-part voluntary learning, one-part letter of guidance. But the end result is a desire to just interact more in a human-centered way, both with the licensee and the complainant. Because there's always going to be questions that get introduced when someone gets a communication from us. And so, the basics of it is, we're starting with the practitioners named in closed complaints and sending them letters with specific suggested learnings and offering a phone or video meeting to talk over what's in the complaint and the potential learnings.

And it's been well-received so far. We had a valuable learning lesson where we wanted to set up the meeting beforehand, and, as it turns out, a lot of them accepted that meeting just because they wanted to know what was in the complaint, and who it was, and once they got that information they got a whole lot less interested. But, you know, that was sort of predictable. So, we swapped that around, and ended up sending the letter first.

The goal here is that it would reduce, potentially reduce, complaints of a similar nature in the future

for this practitioner. And so, we've done 95 of them so far since it's been rolled out, and only time and analysis will tell.

So, now that we're doing that, we're now implementing the next phase where we're looking at complainants, where we'll be giving more specific direction to them and asking for more information to provide a complete complaint. Because many of the 1,800 complaints we receive per year get closed with insufficient information to make a decision, even though we ask for those sorts of things and specifically on our complaint form.

Eventually we'll scale up to having individual phone calls with complainants whose reports were closed with practitioner support. The goal is to explain the process to them and the outcome personally and answer any questions they may have. Obviously, we're booking about 30 minutes per phone call on that particular one just because we anticipate there will be a lot of back-and-forth discussion with complainants.

And then, the final phase of the project would be to have specifically trained staff contact every complainant who files a complaint regarding sexual misconduct and discrimination in health care. And then a couple of other select issues that don't lend themselves to the typical closure conversation. We just feel that those are going to need to have a bit more hands-on, more specialized training from the staff who contact them.

Because right now, you know, for our group we require that the investigators and anybody dealing with sexual misconduct receive specific training about victim interview tactics and understanding the nature of trauma.

And so, the people that will be effectively acting in kind of an Ombuds role is going to have to have that kind of training, and I anticipate that there will be some kind of training required for dealing with DEI discrimination in health care. But the trauma-informed approach for both of those, it has quite a bit of transferable skills.

We're hoping that we will get reduced repeated complaints out of that, and you know we'll have a better interaction with the public who engages with us, but not always in the most pleasant way possible.

Line: Excellent. Well, I think it's been very interesting to talk about this concept of sandboxes and how it can apply to professional regulation and kind of see what happens once we get it out into the world and how it works. So, we certainly do appreciate you, Jan, Micah, and Bradley, for speaking with us today.

Bradley: It's been a pleasure.

Micah: Thank you.

Line: Absolutely. It has been our pleasure, and we'd like to continue this conversation away from this podcast, too. So here are some things for our listeners to think about.

Do you ever come across a situation where your rules might be an impediment or barrier to implementing an innovative solution?

Has your organization had discussions about the importance of, or even the responsibility of, being more innovative?

And what policies and criteria could you put in place to give your board or organization confidence to move forward with an innovative pilot solution? We'll be posting a discussion thread in our members-only online forums, and we greatly appreciate and thank our members for your feedback.

I also want to thank our listeners for tuning in for this episode. We'll be back with another episode of Regulation Matters: a CLEAR conversation very soon. If you're new to the CLEAR podcast, please subscribe to us. You can find us on Podbean or any of your favorite podcast services. And if you've enjoyed this podcast episode, please leave a rating or comment in the app. Those reviews help us to improve our ranking and make it easier for new listeners to find us.

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