Compliance experts break down New York state's new cannabis regulations

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Companies considering the adult-use cannabis space now have more guidelines on testing, marketing, labeling and packaging since the state approved regulations earlier this month.

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Michelle Bonn, CEO of Compliance Team,

The regulations make it very clear that third-party laboratories, as they or their “interested parties” can have “no interest in a registered organization, adult-use cultivator, processor, distributor, retail dispensary.”

The laboratories will need ISO 17025 accreditation, a set of standards for testing and calibration laboratories. That accreditation will be the "biggest hurdle" for labs, said Michelle Bonn, president and CEO of Compliance Team, a life sciences consulting firm. Achieving that accreditation, she said, is quite involved, as she’s worked with pharmaceutical labs that have maintained the accreditation. It includes a process on how to train

personnel, how to do sample testing and how to calibrate equipment.

“You have to build out a compliance plan that states all of your equipment is proven and validated to run specific tests on a product that will produce consistent results,” she said. “If you get false positive or negative results on a test because your equipment isn’t calibrated, that’s a huge problem."

Bonn’s firm — which has 12 employees — has worked in the compliance and regulatory space for years with food and pharmaceutical clients. Now she plans to step into the cannabis industry.

“Cannabis is a perfect fit for what we do; it’s just a different product,” Bonn said. “It’s a drug and a regulated industry with food and compliance tied to it. We work in that space, and we have people who can build plans for these businesses that pop up.”

The testing laboratory license will be difficult to get, Bonn said, partly due to the level of experience and education required of personnel. A lab must have at least one technical director responsible for developing and implementing quality systems. That director must have a doctoral or master’s degree in “chemical, environmental, physical or biological sciences, or engineering,” and at least one year of experience of laboratory work.

Cannabis products can't look like candy — or cartoons

The second set of new regulations for marketing, labeling and packaging include extensive language about the under-21 crowd. The rules require labeling for the THC concentration, potency, ingredients and nutritional information.

Sam Hoyt, president of Upstate Strategic Advisors and former New York State Assemblyman, is concerned about including a vast amount of warnings and labeling on small packages.

“Environmental sustainability is one of the overall goals in these regulations, so you don’t necessarily want to encourage over-packaging,” he said, who started his compliance and regulatory consulting firm four years ago. He has several cannabis clients.

The regulations stipulate that packaging can't have neon colors, cartoons or names like "candy." That type of advertising is considered attractive to those under 21. Bonn said this requirement is close to the FDA's updated requirements on e-cigarettes, which originally had targeted youth with fruity flavors and high school-specific advertising.

"The state wants to produce a safe industry with a safe product and know that the businesses are doing the back end work to ensure safety for their consumers and their patients," Bonn said. "The warnings are going to have to be crystal clear, with risks and benefits."

Hoyt said New York State is known for tight regulation and for being "very punitive for people who violate."

"New York is going to make it very clear that marketing to underage individuals is a no-no and that if you do it, we'll come down very hard on you," he said. "But the regulations are going to need to be very clear on this."

Cannabis products also can't make medical claims

Because these future adult-use cannabis products are not approved by the FDA to treat medical conditions, companies cannot make medical claims, Bonn added.

"If there's labeling on a package that makes a medical claim on an adult-use product, the FDA can step in," she said. "Even though they doesn't regulate cannabis, the FDA can step in if cannabis products start to touch the areas that they control. They can shut you down and take your product off the market."

The two sets of regulations are in a 60-day public comment period before final approval.

"There's an awful lot of detail here, and I don't think the OCM will be surprised that there's going to be a robust response," Hoyt said. "The cannabis community is concerned about a tight timeline."

Bonn said the best advice she has for companies and entrepreneurs entering the new industry is not to push the boundaries set by the state..

“The biggest lesson for anyone getting into the industry," she said, "is that they need to fully embrace and understand that they’re entering a regulated space.”

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