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A Holistic Approach To Compliance For Cannabis Cos.

By **Gary Kaminsky** (February 22, 2019, 3:09 PM EST)

Running a successful and compliant cannabis business is a challenging exercise, one which has little frame of reference and presents unusual and unique complexities. Name one other legitimate business that is technically illegal on a federal level yet perfectly legal within a majority of states. You can't. This legal dichotomy creates innumerable issues for operators which can be barriers to executing their business plans effectively.

Unlike other regulated industries, where regulatory compliance is a part of the business, in cannabis, regulatory compliance permeates the entire business. Nearly every aspect of a cannabis enterprise is impacted by regulatory edicts, edicts which differ for state to state and are being amended and updated continuously. To further complicate matters, within each state, cannabis licensees must also navigate each individual locality in which it conducts business as these can also vary greatly.

Effectively running a multistate cannabis business not only requires a commitment to compliance but a dedicated commitment to developing, implementing and maintaining a robust system of regulatory enterprise risk management. Regulatory ERM is the process of organizing, controlling and governing the activities of a cannabis company's operational, financial and compliance systems in order to adhere to relevant rules and regulations and facilitate lawful moneymaking.

Cannabis is currently legal for medical use in 33 states (plus Washington, D.C.) and for adult/recreational use in 10 states (plus D.C.). New York, New Jersey, Pennsylvania and Illinois are among the larger states that are considering adult use, while other jurisdictions continue to review their regulations. Late last year, the president signed the Agricultural Improvement Act, or the Farm Bill, which removed hemp from the definition of marijuana under the Controlled Substances Act.

This development, while a positive move for the cannabis industry, also formalized the federal government's role as it relates to hemp by making the U.S. Food and Drug Administration and the U.S. Department of Agriculture its primary regulatory authorities. Within hours of the Farm Bill becoming law, FDA Commissioner Scott Gottlieb issued a statement clarifying the agency's authority over hemp and THC (the psychoactive cannabinoid found in the cannabis plant) products.

Notably, Commissioner Gottlieb provided a glimpse of the FDA's views towards THC in stating that it intends to hold a public meeting in the near future to gather and evaluate additional input relevant to legal pathways by which products containing CBD or THC can be marketed. While it remains unclear how aggressive the FDA may be in its exercise of authority over cannabis-related products other than hemp, what is clear is that the agency has THC in its sights. Accordingly, cannabis operators are well advised to consider "FDA-lite" additions to their policies and procedures, or, at a minimum, consider the applicability of the federal Food, Drug and Cosmetic Act and Section 351 of the Public Health Services Act to their operations.



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Particularly, when it comes to packaging and labeling, operators should consider whether “claims” are being made that may run afoul of FDA guidelines. The agency has issued warning letters in this regard, citing companies for testimonials of intended use which suggest efficacies beyond which there is scientific support. Marketing cannabis infused products as “dietary supplements” can be problematic as FDA has determined that CBD products are excluded from the dietary supplement definition under the act.

Regulatory compliance is a prerequisite to a cannabis company’s ability to execute on its business plan effectively. The myriad of regulations and laws, federal, state and local, and the disparity of jurisdictions mandate robust internal regulatory ERM. Cannabis regulatory ERM is a multidiscipline exercise, involving legal and compliance, finance, operations, risk management and technology. A holistic approach to ensure regular and effective interaction and communication among these groups is essential to the effective running of an organization. Companies need to devote sufficient resources to each of these areas in order to meet the challenges that a cannabis business presents.

A dedicated team of legal/compliance professionals proficient in navigating the ever-changing regulatory environment and in counseling the business team is critical. Since compliance is inextricably connected to the successful execution of a cannabis operation, the legal compliance team needs to be able to work closely with the business people to navigate the regulatory issues but to also facilitate lawful money-making.

An experienced finance team with knowledge of the intricacies of cannabis-related tax issues and their impact on overall firm accounting is also essential. As a result of cannabis’ status as a Schedule 1 drug, certain operating expenses are not eligible for deduction under Section 280E of the IRS Code. Expertise and resources are required to allocate costs and expenses to maximize available appropriate business deductions. Cannabis companies also cannot succeed without a strong operations group able to flexibly work within the different regulatory constraints and efficiently execute the business plan buildout. Establishing infrastructure that has strong internal communication lines and strategic intersection of key personnel is important to effectively operate the complex vertical business units that comprise a multistate cannabis operation.

All three of these departments should be part of an internal risk management effort to ensure that unnecessary lapses do not occur in the regulatory ERM system that could compromise the overall business. The cannabis industry can be very unforgiving in this regard, as even the slightest transgression could result in the suspension or termination of a company’s license, its most precious commodity. The final element of an effective regulatory ERM program is identifying and implementing the appropriate technology tools to drive the system. Given the number of moving parts to a cannabis organization and the multitude of regulations and laws, it is hard to manage without the utilization of technology. Operators should implement regulatory technology tools that can bring work flow efficiencies to the overall operations and provide searchable access to the disparate state and local regulations.

Cannabis is a generational opportunity, a unique business that offers extraordinary upside potential. However, the opportunity has substantial barriers to entry that can only be overcome by the appropriate commitment to regulatory ERM.

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