COSMOS
Navigate the Compliance Universe

Compliance Today - June 2018
Compliance risk and the legalization of marijuana

by Dan Coney, CCEP, CFE, CFCS

Daniel Coney (Danconey@comcast.net) is Assistant Special Agent in Charge at U.S. Department of the Interior, Office of Inspector General in Lakewood, CO.

- linkedin.com/in/danielconey

The business of compliance is in large part an exercise in identifying risks. Often a retrospective look helps pinpoint those areas, but sometimes risk is about prognosticating the future. The proliferation of states that have legalized marijuana in recent years is one such risk area, although this has been an issue since 1996, when California was the first to legalize "medical" marijuana. Thirty states and the District of Columbia have laws legalizing the drug, with eight of those states legalizing recreational use.[1] The tax revenue generated by legal marijuana sales is an intoxicant to state coffers, so the likelihood of those laws being repealed is small, while the chance that more states will want in on this revenue stream is sure, despite the societal consequences. Both public expectations (i.e., demand) and a lack of understanding about which laws impact the provision of healthcare services could pose a compliance risk to your operation.

Federal vs. State

One of the primary conditions of participation in federal healthcare programs is that a healthcare entity must follow federal law related to the health and safety of patients (42 CFR 482.11), and that the dispensing of pharmaceutical services must be consistent with federal law (42 CFR 482.25). States' rights advocates take a back seat on this one, because we are talking about programs funded by federal dollars, and even if it wasn't, the Federal Supremacy Clause (Article VI, Clause 2 of the U.S. Constitution) means that federal law overrides conflicting state laws. So as a matter of first things first, we should be clear that federal law is what compliance plans should be geared to.

Ever since 1970, the Controlled Substances Act has classified marijuana as a Schedule I drug, meaning that as a function of law, it is explicitly an illicit substance that has no valid medical use, has a high potential for abuse, and has no accepted safety standards for using the drug in a medical treatment. Some suggest the designation was a political issue related to the war on drugs, but as a whole, the medical community has never advocated for marijuana as a legitimate medical intervention. As recently as the last legislative session, Congress passed on removing marijuana from the Schedule I classification. Because federal law prohibits prescribing Schedule I substances, there is no coverage under any federal healthcare program — or, for that matter, any private insurance plans.

Indeed, the empirical evidence speaks for itself concerning the use of the drug. Marijuana use has been associated with negative impacts on IQ,[2] persistent decrements in neurocognitive performance,[3] and overall adverse health effects.[4] A 20-year review shows increased risk of accidents, dependence, and poor psychosocial outcomes and mental health.[5]

The U.S. Food and Drug Administration (FDA) has neither recognized nor approved marijuana as a medicine. The

rigorous process of obtaining FDA approval for new drugs acts as a standard by which patient safety and pharmaceutical efficacy are measured, and marijuana does not meet that standard. FDA approval is a key risk measure for insurance companies when deciding what coverages to offer. Legalization efforts have resulted in variations in cannabis potency and significant increases in tetrahydrocannabinol (THC) levels, which introduces more uncertainty. This lack of standardization seems to affect the THC component, while the cannabidiol (CBD) component that allegedly has therapeutic value has decreased. Recent reports are that THC potency has increased to values around 30%, up from the 10% of years past.[6]

Further risk factors have to do with the enforcement landscape. The current U.S. Department of Justice has made it clear that it expects to continue to enforce federal drug laws, regardless of state laws that may legalize marijuana. In looking for low-hanging fruit, it is not out of the realm of possibility that medical providers who facilitate the marijuana trade could be targets. Federal regulations at 42 C.F.R. §§422.503 and 423.504 specify the requirements for providers to implement an effective compliance program. Section 6401 of the Affordable Care Act provides that a "provider of medical or other items or services or a supplier within a particular industry sector or category" shall establish a compliance program as a condition of enrollment in Medicare, Medicaid, or the Children's Health Insurance Program (CHIP). Multiple avenues thus exist to pursue enforcement actions against providers whose compliance plans fail to identify the risks associated with medical marijuana, and subject your organization to a host of further monitoring and compliance efforts.

Most compliance plans in a healthcare setting likely already have considered this risk, but it is worth a second look to make sure this exposure is covered. Your compliance programs should have a strong education component, and that is your first stop. Onboarding procedures, messaging to current staff, and routine training that not only instructs employees about this risk, but also tests scenarios where they are presented with marijuana-based ethical dilemmas should be key parts of your education program.