



Federal Regulation 21 CFR 1301.72: What It Means for You

November 9, 2016 by [Rebecca Cicarelli](#) and [Matt Gifford](#) [0 Comments](#)

To say that the pharmaceutical industry is highly regulated by the Drug Enforcement Administration (DEA) is perhaps the understatement of the century. DEA and FDA oversight is critical to consumer safety; therefore requirements and documentation can appear to be endless. Having played in this sandbox for decades, we are well-versed in the intricacies of federal rules, as they specifically apply to security for controlled substances. The 21 CFR 1301.72 is just that—the overriding DEA Code of Regulation as it applies to physical security controls for pharmaceuticals, and it details exactly what is required for each class of drug, of which there are five (5).

The agency categorizes pharmaceuticals based on accepted medical use and the potential for abuse, illegal sale or dependency. While not legalized nationally, marijuana is currently considered a Schedule I drug by the Federal Government and the DEA. Schedule I pharmaceuticals, like heroin, are defined as those having no accepted medical use and a high potential for abuse. Schedule II drugs, while recognized as having limited medical applications, are still considered dangerous and highly addictive. Oxycodone and Vicodin are on the list of Schedule II pharmaceuticals. Both Schedule I and II are the most controlled of ‘controlled substances’ and are subsequently subject to the most stringent security requirements.

Marijuana Facility Security

Physical storage must afford protection against surreptitious entry (30 man-minutes), forced entry (20 man-hours), lock manipulation (20 man-hours) and radiological techniques (20 man-hours). Where small quantities permit, this can be best achieved with a certified safe that is bolted or cemented in place. Larger quantities, however, dictate the need for a vault per the Code of Regulation. Parameters are specified in great detail, including wall thickness and steel rod reinforcements, and modular vaults best address all regulatory requirements. This option also affords greater flexibility in installation and supports the ability to expand or move secure storage as

needed. No matter what physical security plan is implemented, complementing it with access control/alarm and close monitoring is critical to compliance. Ultimately, results are optimized via a layered system of physical and electronic security.

What does this mean? At the end of the day, there is no easy way around security for your marijuana facility. Not only is it in your best business interest to optimize secure storage for product and cash, but for the former, it is simply a government mandate. No application is viable without a well thought out security plan, and no facility is 'safe enough' for employees and customers without one.

Adopting the most stringent security measures, including safes, vaults and electronic security, is the cost of doing business. Therefore, it is critical that you partner with an experienced security equipment provider for guidance in the application and implementation phases to ensure optimal security design and compliance. There are no second chances, at least not without incurring significant costs.

Possibilities for Marijuana Security

There has recently been rampant discussion about the possibility of rescheduling or even descheduling marijuana, especially in light of election day outcomes in Massachusetts, Maine, Nevada and other states. Some wonder if it is necessary to set the high-bar with regard to security, if change is coming. The simple answer is *yes*.

Rescheduling, while not common, is certainly not out of the realm of possibility. In 2014, the DEA upscheduled Hydrocodone Combination Drugs from Schedule III (requiring storage in wire cages) to Schedule II (vault storage). That said, as recently as August of this year, the DEA denied a petition to initiate proceedings for marijuana rescheduling.

If downscheduling marijuana were to occur, both industry and government experts agree that it would most likely be reclassified as Schedule II. This would definitely lead to expanded marijuana research; a very exciting prospect for the industry. Among other benefits, it would also reduce the level of friction between state and federal regulation. And critically, it would boost prescriptions in those states where medical marijuana is legal due to improved credibility as an acceptable treatment option. But the change would not affect marijuana security requirements.

Will security requirements ever be alleviated? This will only happen if and/or when the federal government progresses to a point where the drug is downscheduled to Schedule III-V, moving it out of vaults and into wire cages, or if cannabis is descheduled altogether. Don't hold your breath

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