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DEA ANNOUNCEMENT: INCREASING NUMBER OF FEDERALLY AUTHORIZED MARIJUANA GROWERS

08/12/2016

Enhanced Opportunities for Universities and Vertically Integrated Health Systems under Pennsylvania Medical Marijuana Act

In a document scheduled to be published in the August 12, 2016 *Federal Register*, the United States Department of Justice, Drug Enforcement Agency ("DEA") will announce a new policy designed to increase the number of entities registered to grow/manufacture marijuana to supply legitimate researchers in the United States. Citing its "full[] support[] [of] expanding research into the potential medical utility of marijuana and its chemical constituents," and in coordination with the Food and Drug Administration ("FDA") and National Institutes of Health ("NIH"), DEA will accept applications from persons seeking to grow marijuana to supply federally funded researchers, academic researchers and commercial endeavors funded by the private sector aimed at drug development outside the current National Institute on Drug Abuse (NIDA)-contract system.

DEA will evaluate each application it receives to determine whether adding that applicant to the list of registered growers is necessary to provide an adequate and uninterrupted supply of marijuana (including extracts and other derivatives thereof) to researchers in the United States. In addition to having previous experiences handling controlled substances in a lawful manner, DEA will expect applicants to provide written support, including but not limited to an explanation of how the applicant would be able to augment the nation's supply of research-grade marijuana. Persons who become registered growers may only distribute marijuana with prior, written approval from DEA, supplying only DEA-registered researchers whose protocols have been determined by the Department of Health and Human Services ("DHHS") to be scientifically meritorious, and will be subject to all DEA regulations, including those related to quotas, record keeping, order forms, security and diversion control.

Pennsylvania's Medical Marijuana Act ("Act") establishes a research program to study medical marijuana funded as part of a 5% tax to be imposed on gross receipts of medical marijuana sales to dispensaries by state-authorized growers/processors. This research program is set forth in Chapter 19 of the Act, and requires the state Department of Health ("DOH") to petition DEA and FDA for approval to study the treatment of certain "serious medical conditions" with medical marijuana. This requirement is triggered when at least 25 patients with the same "serious medical condition" have been identified in the program's database by physicians registered to issue certifications to patients to use medical marijuana.

Concurrent with the request to DEA and FDA, DOH must also publicly announce the formation of the research study, soliciting the participation of vertically integrated health systems and

universities in the Commonwealth. Upon the approval of DEA and FDA, DOH will select the organization(s) to conduct the research study and designate the form(s) of medical marijuana which will be used to treat the "serious medical condition." "Serious medical conditions" include: cancer; HIV positive status/AIDS; ALS; multiple sclerosis; damage to nervous tissue of the spinal cord with objective indication of intractable spinal spasticity; epilepsy; inflammatory bowel disease; neuropathies; Huntington's disease; Crohn's disease; post-traumatic stress disorder; intractable seizures; glaucoma; sickle cell anemia; severe chronic or intractable pain of neuropathic origin or severe chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or ineffective; and, autism.

It is anticipated that universities and vertically integrated health systems participating in Chapter 19 research studies will develop unique experience and reputational status vis-à-vis the efficacy of marijuana-related treatments in each of the identified serious medical condition areas. Marijuana dispensed in these research studies must be received from a grower/processor that holds a valid DOH permit or grown and processed by the vertically integrated health system conducting the study, as approved by the DOH (a "health care medical marijuana organization," as defined by the Act).

Universities, health systems and others desiring guidance in connection with becoming a registered grower under the new DEA policy or Pennsylvania's Medical Marijuana Act, or exploring related research study opportunities, may contact Karen Palestini at kpalestini@dilworthlaw.com, or Jerry DeSiderato at jdesiderato@dilworthlaw.com, of Dilworth Paxson's Medical Marijuana Industry Advisory Group.

Read the Sacks Weston Diamond press release here.