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Phone: +1 646 783 7100 | Fax: +1 646 783 7161 | customerservice@law360.com

A Potentially Promising Future For Pa. Medical Marijuana

By **Daniel Clearfield and Peter Murphy** (March 21, 2018, 4:37 PM EDT)

Daniel Clearfield

Peter Murphy

On March 16, 2018, the Pennsylvania Department of Health published new temporary regulations that will expand patient access to pharmaceutical-grade medical cannabis and greatly enhance the commonwealth's nascent medical marijuana program.[1] Successful implementation of Pennsylvania's unique clinical registrant program would put the commonwealth into the vanguard of science-based medical marijuana research and development in the U.S. However, provisions in the new regulations that would prohibit clinical registrant grow/processors from selling their medically based products beyond their own or other clinical registrant dispensaries severely limits the available market for these permittees and threatens the economic viability of the entire program.

Under the new regulations, the department will allow certain medical marijuana organizations to partner with Pennsylvania medical schools to conduct research regarding the use of medical marijuana to treat specific medical conditions. Through these collaborations, medical marijuana organizations will be able to work directly with the commonwealth's leading medical institutions to study specific cannabis formulations and develop products to treat Pennsylvania patients. The new program is unique to Pennsylvania and represents a significant step forward that could make the commonwealth a national research hub for medical cannabis.

The authority for the regulations comes from Chapter 20 of the Medical Marijuana Act. That chapter creates two types of new entities: academic clinical research centers, or ACRCs, and clinical registrants, or CRs. An ACRC is defined as an accredited medical school within the commonwealth that operates or partners with a licensed acute care hospital. Presently, there are nine Pennsylvania medical schools that fit this definition: University of Pennsylvania, Perelman School of Medicine; University of Pittsburgh School of Medicine; Geisinger Commonwealth School of Medicine; Drexel University College of Medicine; Pennsylvania State University College of Medicine (Hershey Medical Center); Thomas Jefferson University, Sidney Kimmel Medical College; Temple University School of Medicine; Lake Erie College of Osteopathic Medicine; and Philadelphia College of Osteopathic Medicine.

CRs, on the other hand, are entities that hold a permit as both a grower/processor and a dispensary; and, have a contractual relationship with an ACRC to obtain advice regarding patient health and safety and the management of controlled substances as well as to jointly undertake research studies on medical marijuana. The contractual relationship is

exclusive — meaning a CR may only include one certified ACRC in its application for approval. And, CR applicants are subject to far greater capital requirements than existing dispensaries or grower/processors, who must demonstrate $150,000 and $2 million in available capital, respectively. Under the new regulations, a prospective CR must submit an affidavit stating that it has at least $15 million in capital, and provide a release sufficient to obtain information from a state agency or financial institution to verify the amount.

CR applicants must also disclose the amount and nature of any payments made to the certified ACRC. Except for reasonable remuneration, as set forth in the CR/ACRC research contract for services to be performed or costs to be incurred, an ACRC may not solicit or accept anything of value from an approved CR. Reasonable remuneration may include up-front deposits or other payments to an ACRC to defray startup and ongoing costs in connection with the establishment of the research contract.

Medical marijuana organizations with existing permits to grow/process or dispense medical marijuana may request a conversion of their existing permit so they can become registered as a CR. If approved, the new CR must surrender its existing grower/processor or dispensary permit to the department, which will increase the number of total permits still available to persons applying for commercial cultivation or dispensary permits under the Medical Marijuana Act.

Pursuant to the act and the regulations, the department may not approve more than eight CRs. Once approved by the department, a CR will be issued one grower/processor permit and one dispensary permit. The CR dispensary permit allows the CR to operate six separate locations, unlike a traditional medical marijuana dispensary permit, which is limited to three locations. The total number of CR dispensary locations authorized under Chapter 20 cannot exceed 48.

However, the regulations threw a curve to potential CRs that does not appear in Chapter 20. The grower/processor of an approved CR may only sell its medical marijuana products at wholesale to its own dispensaries, and the dispensaries of other approved CRs — i.e., 48 locations at most. This market is potentially as much as three times smaller than the market available to a "commercial" grower/processor permittee — some 198 potential retail dispensaries. This particular restriction could face legal challenges since there is no corresponding prohibition contained in Chapter 20 of the act. In fact, the act repeatedly provides that CR dispensary and grower/processor facilities have the same rights and are subject to the same requirements as any other dispensary or grower/processor. Nowhere in the act does the Legislature suggest that CR grower/processors are prohibited from wholesaling to non-CR dispensaries, as the new regulations provide.

The restriction also appears contrary to the clear intent of Chapter 20: to promote both high-quality, science-based research and the distribution of the efficacious products resulting from this research to Pennsylvania medical marijuana patients throughout the commonwealth. The new restriction would also decrease the availability of CR-grown products, which had held out the potential of increasing overall supply and potentially reducing prices to patients.

Presently, nearly all dispensaries operating in Pennsylvania have limited or no inventory. Moreover, the inventory made available is not specifically tailored to the medical conditions for which it was approved. For example, some Pennsylvania grower/processors are producing medical cannabis products with extremely high delta-9-tetrahydrocannabinol, or THC, (i.e., the psychoactive component of cannabis that makes the user feel high) that may be inappropriate for some patients or medical conditions. Medical marijuana flower — or bud — has far less natural THC and is often preferred by patients as it allows greater control over dosage and is less expensive because it does not require further processing. To date, use of medical marijuana flower has not been approved by the department, which

is why Pennsylvania patients are limited to medical cannabis concentrates such as oils, tinctures, pills, topicals and liquids.

This month, however, members of the Pennsylvania Medical Marijuana Program's Advisory Board met to consider whether medical marijuana flower should be made available to patients. While no final decision has been made, early indicators suggest the advisory board will recommend adding flower to the list of approved forms of medical marijuana. If flower is permitted, the CRs and their ACRC partners could be instrumental in determining the most efficacious flower-based products, based on science-based investigation and research. But the "wholesale" restriction threatens the viability of the entire program as it reduces the potential revenue that a CR can generate to justify the much greater statutory capital requirements or to actually fund the research that they will be required to undertake.

Perhaps realizing this dilemma, the drafters of the CR regulations included a carveout whereby an approved CR may petition the department to sell its products at non-CR dispensaries — but only after its first research project is completed and reported on to the department. While this may provide an avenue for mitigating the restriction's future negative effects, it does not cure the underlying conflict with the act. Whether the CR program can be successful notwithstanding these additional restrictions that aren't grounded in the act remains unclear.

The department's clinical research program presents a unique opportunity for Pennsylvania medical cannabis researchers and patients alike by incorporating the best medical science into a field that has long been stigmatized for its lack of clinical research.

Because the products produced by CRs, in conjunction with their ACRC partners, will be part of rigorous, science-based research, Chapter 20 holds out the promise of developing better products with better results for Pennsylvania patients and expanding the available market. It remains to be seen whether this potential is stymied by the department's decision to severely limit the ability of these products to be distributed beyond the CR dispensaries thereby potentially limiting their availability to those who can most benefit from them.

Daniel Clearfield is a member and chair of the regulated industries practice group at Eckert Seamans Cherin & Mellott LLC in Harrisburg, Pennsylvania. Peter S. Murphy is a member of the firm in Wilmington, Delaware, and Philadelphia. Together they coordinate the firm's medical marijuana practice.

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[1] The regulations can be found here: https://www.pabulletin.com/secure/data/vol48/48-11/393.html.

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