

Oct. 7, 2015

LETTER TO HOUSE HEALTH QUALITY SUBCOMMITTEE



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Tallahassee, Fla. — Please see the [letter](#) the Florida Department of Health sent today to Chair Pigman and the House Health Quality Subcommittee in response to questions related to the implementation of the Compassionate Medical Cannabis Act of 2014.

Oct. 7, 2015

The Honorable Cary Pigman
Florida House of Representatives
House Office Building, Room 214
402 South Monroe Street
Tallahassee, Florida 32399-1300

Dear Chair Pigman:

Thank you for the opportunity to present an update on the implementation of the Compassionate Medical Cannabis Act of 2014 to the House Health Quality Subcommittee yesterday. The Department of Health remains committed to the full implementation of this legislation in the midst of a challenging legal environment and potent economic interests.

Please find below responses to requests from your committee as well as additional information on the implementation timeline:

- A great deal has been accomplished in the 16 months since the bill was signed. In June 2014, immediately following the signing of Senate Bill 1030, the Compassionate Medical Cannabis Act, the Department rapidly developed rules through workshops and using best practices from other states. These rules were first promulgated in September 2014, but were immediately challenged and subsequently invalidated on November 14, 2014. Given the urgent need for sound rules, the Department decided to utilize negotiated rulemaking. The negotiated rulemaking committee developed a new set of rules that were promulgated on February 6, 2015. These rules were also immediately challenged. The final order upholding the rules was issued on May 27, 2015, less than a year after the bill signing.
- The Department moved quickly to open the 21-day application window that closed on July 8, 2015. The Department received 28 timely applications ranging from 350 to 2,500 pages in length. These applications required review for completeness before being

delivered to the selection committee, and applicants required additional time to fill gaps identified in their applications. The three-member selection committee is currently in the process of conducting a comparative review of the applications, and the Department anticipates awarding licenses this fall.

- Regarding staffing for inspections, the Department is projecting the need for five employees, who will each work, on average, 20 hours per week as inspectors. They will have other duties for the remaining 20 hours per week. By law, there will be only five licensees in the state, and the five inspectors will work in the county health department for the county in which the licensee is located. For example, if a nursery located in Orlando is issued a license, the inspector will be housed at the Orange County Health Department.
- Regarding the nature of the specialties for the 48 physicians who have successfully completed the coursework to become participating physicians, and the 30 eligible medical directors, the majority have a specialty in family medicine, internal medicine or neurology. A full list of specialties is enclosed for your review.
- As requested, the goal of Dr. Paul Carney's study is to provide treatment with cannabidiol (CBD) to children with drug resistant epilepsy through an Expanded Access Investigation New Drug protocol. The primary objective of the study is to evaluate the safety and efficacy of CBD when administered as adjunctive therapy in children who have exhausted FDA-approved antiepileptic drug treatment options. Additional objectives include evaluation of cognitive and adaptive behaviors in children taking CBD in combination with antiepileptic drugs and development of an online portal to disseminate information to improve health care provider and family understanding about CBD for epilepsy. The full research protocol is enclosed.

Thank you again for the opportunity to appear before your committee. Please let me know how I can be of further assistance.

Sincerely,

Nichole Geary
General Counsel
Department of Health

About the Florida Department of Health

The department works to protect, promote and improve the health of all people in Florida through integrated state, county and community efforts.

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