

John H. Armstrong, MD, FACS State Surgeon General & Secretary

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Department of Health Moves Closer to Finalizing Low-THC Cannabis Rule ~ Applications could be accepted as early as next month ~

TALLAHASSEE—The Florida Department of Health is pleased to announce the conclusion of the rulemaking process to craft the low-THC cannabis rules designed to implement the Compassionate Medical Cannabis Act. A rulemaking hearing was held March 2 to allow members of the public to ask questions and raise concerns about the rule. The department remains optimistic that it is now moving forward with a regulatory structure that allows for a process to choose the five most qualified applicants to act as dispensing organizations.

"The Department of Health remains committed to ensuring safe and efficient access to this product, approved by the Florida Legislature, for children with refractory epilepsy and patients with advanced cancer," said State Surgeon General and Secretary of Health Dr. John Armstrong. "After a rule-making process guided by broad stakeholder consensus, a patient-centered rule has been created that gives patients access to the product that their doctors deem as their only option. The department looks forward to implementing this rule as soon as possible."

Monday's hearing set the stage for a productive dialogue between the department and more interested parties. The department received a significant amount of positive feedback after the hearing, specifically that it had answered many people's questions about the rules leaving no need for further changes to the rules.

Sen. Rob Bradley said, "There's no reason for further delays in getting Charlotte's Web into the hands of patients who continue to struggle. This is a solid framework to ensure that children suffering from intractable epileptic seizures and cancer patients have the relief they deserve."

Rep. Matt Gaetz said, "I'm grateful for the Department of Health's continued efforts to get this product to the children and patients who need it most in our great state of Florida. I'm hopeful this rule will move forward with no more delays to best serve the medical needs of Floridians."

Dr. Minh Le, Pediatric Epilepsy Specialist, Pediatric Neurology, P.A. & Epilepsy Center of Central Florida, said, "Children are dying all over the country from sudden unexplained death due to epilepsy (SUDEP) when there is a product that can help them—a product that should already be available to patients in Florida. The rules written by the department will ensure the safest and consistent product is created for these sick children."

Dawn Wein, Mother of Child with Epilepsy, "The department has worked diligently to ensure children like my son have access to the medicine they need to have a shot at suffering through fewer seizures. After treatment at the Cleveland Clinic, brain surgery and now two separate seizure medications, it seems Charlotte's Web is the only hope for our family."

Louis Rotundo, Florida Medical Cannabis Association, "This rule is an excellent rule, and I'm pleased the department didn't choose a rule that fit the circumstances, but chose a rule that follows the outlines of the law and the administrative law judge's order. Now it's time to finish this process so the department can move on to accepting and reviewing applications."

Kimberly Muszynski, Mother of Child with Epilepsy, "There is nothing worse as a parent than sitting by watching your child suffer through seizure after seizure knowing there is a potential cure but no way to get it to your child. At this point we are praying those with special interests step back and realize the reason we have all come together is to get this medicine to the children and others who need it—we can't afford any more delays."

Anthony Ardizzone, Ed Miller & Sons Nursery, "The department has worked hard to write these rules and then explain them to those of us who were not on the negotiating committee. The rules are now in a format that we can work with—they don't need to be challenged and slow down this process. We look forward to submitting our application as soon as the department can adopt the rules."

Dennis Deckerhoff, Father of Child with Epilepsy, "This product comes from a plant and is not nearly as complicated as creating a synthetic pharmaceutical product. It is time to move forward with the department's rules so we can help these patients. The best of the best are going to be rewarded with these licenses."

Bridget Bateman, Mother of Child with Epilepsy, "Growers think of getting this license as winning the golden ticket. Winning the golden ticket for me means curing my child. My battle everyday is not how much money I'm going to make but is my kid going to live through the day, is he going to start breathing again after this two minute seizure, is there something that can help? The rules as written right now will get the best and I have confidence that the Department of Health is the right agency to get this done."

Arianna Cabrera, Costa Farms, "Thank you for moving this rulemaking process along in an expedited fashion. We appreciate the amount of thoughtful work the Department of Health has put into this process. We support your efforts to implement this rule as quickly as possible so that we can get this out to the patients."

Barring a legal challenge to this well thought out rule by March 25, applications will be accepted as early as April 15, 2015. A copy of the rule is available at https://www.flrules.org/Gateway/View_notice.asp?id=15645147.

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