Amendment 2, "Use of Marijuana for Debilitating Medical Conditions," was enshrined into the Florida Constitution on Nov. 8, 2016, with 71 percent of Floridians voting in favor of the initiative. While many Floridians were excited about the Amendment's passage, those looking to obtain medical marijuana on Nov. 9 were disappointed. Because the Amendment did not contain an effective date, pursuant to Article XI, section 5.e. of the Florida Constitution, it did not become effective until the first Tuesday after the first Monday in January (Jan. 3). Now that the Amendment is "in effect," both physicians and patients need to know exactly what this means.

- Can physicians who have a patient with a "debilitating medical condition" as defined in Amendment 2 begin certifying that the medical use of medical marijuana would likely outweigh the potential health risks for the patient?
- Can patients use this certification to obtain medical marijuana from a dispensing entity?
- Can physicians continue to order and patients receive low-THC cannabis pursuant to the Compassionate Medical Cannabis Act of 2014?
- Can physicians continue to order and patients receive medical cannabis pursuant to the provisions of HB 307, which passed the Legislature and was signed into law by the Governor in 2016?

The only guidance from the Department of Health comes from the website of the Office of Compassionate Use, which states:

"Amendment 2, and the expanded qualifying medical conditions, will become effective on January 3, 2017. Section 381.986 F.S. remains in effect and the Florida Department of Health, physicians, dispensing organizations, and patients remain bound by existing law and rule. Following Amendment 2’s effective date, the Department is directed to promulgate rules to implement Amendment 2 within 6 months, and to implement those regulations within 9 months.

Florida law permits qualified physicians to order low-THC cannabis or medical cannabis for patients diagnosed with certain conditions. There are two types of cannabis products that may be ordered by qualified physicians:

1. Low-THC Cannabis: Patients with cancer or a condition that causes chronic seizures or muscle spasms may qualify to receive low-THC cannabis. Low-THC cannabis has very low amounts of the psychoactive ingredient THC and does not usually produce the "high" commonly associated with cannabis.

2. Medical Cannabis: If a patient is suffering from a condition determined to be terminal by two physicians, he or she may qualify for medical cannabis. This product can contain significant levels of the psychoactive ingredient THC and may produce the "high" commonly associated with cannabis."
The department recommends speaking to your health care professional to determine if low-THC or medical cannabis products are right for you or your loved one. List of Physicians Who Have Completed the Required Training.

Medical marijuana is available in Florida, however, remains illegal under federal law.

While the Florida Legislature has begun committee meetings and the Senate has held a workshop on the issue of Amendment 2, implementing legislation — if any passes this session — will most likely not be sent to the Governor until sometime in May.

In the absence of implementing legislation or DOH regulations, physicians and patients are left to decipher what exactly the Office of Compassionate Use's statement means from a practical standpoint.

The complicated interplay between the newly amended Florida Constitution, existing Florida statutes, and federal law make it difficult to provide answers. The following analysis is designed to help Florida physicians understand the current medical cannabis landscape.

Low-THC cannabis was legal before Amendment 2, but is it still?

In 2014, the Florida Legislature passed SB 1030, the “Compassionate Medical Cannabis Act of 2014” (also referred to as the “Compassionate Use Act”). This act legalized the ordering, possession and usage of “low-THC cannabis” in Florida. Under the Act, an M.D. or D.O. can order low-THC cannabis for use by a qualified patient. The qualified patient and the qualified patient’s legal representative may purchase and possess for the patient’s medical use up to the amount of low-THC cannabis ordered for the patient.

The Act defines a “qualified patient” as a resident of this state who has been added to the compassionate use registry by a Florida-licensed M.D. or D.O. to receive low-THC cannabis from a dispensing organization.

The conditions under which an M.D. or D.O. may order low-THC cannabis are strict – only patients who suffer from “cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms” are eligible. Low-THC cannabis may only be ordered to treat such disease, disorder or condition or to alleviate symptoms of such disease, disorder or condition. In addition, NO OTHER SATISFACTORY ALTERNATIVE TREATMENT OPTIONS MUST EXIST FOR THE PARTICULAR PATIENT, and a number of other conditions must apply.

Physicians who wish to order low-THC cannabis for their eligible patients must first complete the Florida Physician Cannabis Course, which can be accessed here.

If an eligible physician wishes to order low-THC cannabis for a patient, it appears that the physician can do so now under state law. The OCU website clearly states that section 381.986 (the Compassionate Use Act) remains in effect. It is unclear, however, whether the OCU has considered the effect of Amendment 2 on the Compassionate Use Act. While Florida courts will endeavor to harmonize existing statutes with the Amendment, an argument can be made that the eligible conditions under the Compassionate Use Act impermissibly expand the definition of “Debilitating Medical Condition” in Amendment 2, and that all patients who are certified to receive any type of medical marijuana, including low-THC cannabis, must have a patient identification card before they can receive medical marijuana. Nevertheless, given the OCU pronouncement, it appears unlikely that physicians will face any type of administrative discipline from DOH for ordering low-THC cannabis. Still, until the Compassionate Use Act is harmonized with Amendment 2 either by the Legislature, DOH or the courts, there will remain an uncomfortable level of uncertainty.

The Legislature further legalized medical cannabis in 2016. Is this statute affected by Amendment 2?

Building on the 2014 legislation, the Legislature passed HB 307, which allows for the possession and use of medical cannabis, in addition to low-THC cannabis, by eligible patients.

“Medical cannabis” is defined as “all parts of any plant of the genus Cannabis, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every com-
pound, manufacture, sale, derivative mixture, or preparation of the plant or its seeds or resin that is dispensed only from a dispensing organization for medical use by an eligible patient.”

Unlike “qualified patients” eligible to receive low-THC cannabis, “eligible patients” must meet the following conditions to receive medical cannabis:

- Have a terminal condition that is attested to by the patient’s physician and confirmed by a second independent evaluation by a board-certified physician in an appropriate specialty for that condition;
- Have considered all other treatment options for the terminal condition currently approved by the United States Food and Drug Administration;
- Have given written informed consent for the use of an investigational drug, biological product, or device; and
- Have documentation from his or her treating physician that the patient meets the above requirements.

A “terminal condition” is defined as a “progressive disease or medical or surgical condition that causes significant functional impairment, is not considered by a treating physician to be reversible even with the administration of available treatment options currently approved by the United States Food and Drug Administration, and, without the administration of life-sustaining procedures, will result in death within one year after diagnosis if the condition runs its normal course.”

As with low-THC cannabis, a physician wishing to order medical cannabis for his or her patients must first complete the Florida Physicians Cannabis Course. An additional requirement added by the 2016 legislation applicable for both low-THC cannabis and medical cannabis is that the ordering physician must have treated the patient for at least three months immediately preceding the patient’s registration in the compassionate use registry.

As with low-THC cannabis, it appears that any eligible physician may currently order medical cannabis for an eligible patient consistent with state law. However, the same arguments made above in relation to the 2014 legislation apply here as well, and the same uncomfortable level of uncertainty exists.

While Amendment 2 has technically gone “into effect,” it arguably requires regulations to be functionally effective.

Amendment 2 was not written to automatically go into effect upon receiving the required 60-percent favorable vote on Election Day. Nor was it written to amend and fit seamlessly within the framework of the Compassionate Medical Cannabis Act of 2014. Rather, Amendment 2 contemplates a different regulatory scheme applicable to different medical conditions.

A key provision in Amendment 2 is the requirement that a “qualifying patient” eligible to receive medical marijuana must have a patient identification card issued by the Department of Health. Amendment 2 directs DOH to begin issuing qualifying patient and caregiver identification cards no later than nine months after the Amendment’s effective date. Since no effective date was specified in the Amendment, it went into effect on the first Tuesday after the first Monday in January (Jan. 3, 2017). DOH will then have to start issuing identification cards by the first week of October. If DOH fails to do so, a valid physician certification will serve as the required patient identification card. Until DOH starts issuing patient identification cards, or the nine months expire without DOH having done so, no patient will be eligible to receive medical marijuana as contemplated by Amendment 2.

In addition to the patient identification cards, there are other regulations that must be put into place before patients can start receiving medical marijuana. Within six months after Jan. 3, 2017, DOH must promulgate regulations on the following:
1. Procedures for the issuance and annual renewal of qualifying patient identification cards to people with physician certifications and standards for renewal of such identification cards. Before issuing an identification card to a minor, the Department must receive written consent from the minor’s parent or legal guardian, in addition to the physician certification.

2. Procedures establishing qualifications and standards for caregivers, including conducting appropriate background checks, and procedures for the issuance and annual renewal of caregiver identification cards.

3. Procedures for the registration of MMTCs that include procedures for the issuance, renewal, suspension and revocation of registration, and standards to ensure proper security, record keeping, testing, labeling, inspection, and safety.

4. A regulation that defines the amount of marijuana that could reasonably be presumed to be an adequate supply for qualifying patients’ medical use, based on the best available evidence. This presumption as to quantity may be overcome with evidence of a particular qualifying patient’s appropriate medical use.

One can argue that all of the regulations required above can be encompassed within the Compassionate Use Act. For example, a dispensing organization approved by the Department pursuant to section 391.986 (6) could be deemed to be a “Medical Marijuana Treatment Center.” The actual language of Amendment 2, however, appears to require actual action by the Department to effectuate this metamorphosis. The argument that a dispensing organization can serve as a Medical Marijuana Treatment Center with only the tacit nod of approval from DOH contravenes the actual text of Amendment 2, and any physician, patient or dispensing organization that relies on this argument does so at their own peril. Until the Department actually promulgates rules to harmonize the provisions of the Compassionate Use Act with the regulatory requirements of Amendment 2, all parties would be well advised to consult private legal counsel before getting involved in the expanded access to medical marijuana contemplated by Amendment 2.

If the six months expire and DOH hasn’t promulgated the required regulations, or nine months go by and DOH hasn’t begun issuing patient identification cards, the Amendment provides that “any Florida citizen shall have standing to seek judicial relief to compel compliance with the Department’s constitutional duties.” How the courts will respond is anyone’s guess. It is possible the Legislature will pass a bill that will set up the required structure without DOH involvement, or will provide DOH with specific instructions on how to proceed. Until such legislation is signed by the Governor, however, uncertainty will prevail.

Even the OCU’s own statement does not come out and explicitly state that physicians can certify patients with the expanded qualifying medical conditions as provided in Amendment 2 as eligible for medical marijuana. In fact, this ambiguous statement would seem to prohibit such. The OCU states that there are “two types of cannabis products that may be ordered by qualified physicians.”

- Low-THC cannabis for patients with cancer or a condition that causes chronic seizures or muscle spasms.
- Medical cannabis for patients with a condition determined to be terminal by two physicians.

Medical marijuana for patients with a “Debilitating Medical Condition” is not included.

Given this uncertainty, physicians would be well advised to wait for the Department, the Legislature or the courts to provide clarity before attempting to incorporate the expanded access to medical marijuana provided by Amendment 2 into their medical practices. According to information the FMA received just this morning, there may be a more detailed official statement coming from the Department this afternoon. We will provide an update as soon as possible if the information coming from the Department changes the analysis in this article.

**Even with the passage of Amendment 2, marijuana use is still illegal under federal law.**

The possession of marijuana, whether it is low-THC cannabis or medical marijuana as defined in Florida statutes, violates federal law. Writing a prescription for medical marijuana violates federal law. Writing an order for medical marijuana arguably violates federal law. Under the Obama administration, the federal government has taken a position of not investigating or prosecuting physicians who order or certify the need for medical marijuana in states that have legalized such. It is unclear whether the Trump Administration will follow suit. Physicians who order low-THC or medical cannabis under the Compassionate Use Act, or who wish to certify the need for medical marijuana pursuant to Amendment 2 should pay close attention to any statements issued by the Justice Department after President-Elect Trump is sworn into office.

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Footnote: 1 Amendment 2 defines “Debilitating Medical Condition” to mean “cancer, epilepsy, glaucoma, positive status for human immunodeficiency virus (HIV), acquired immune deficiency syndrome (AIDS), post-traumatic stress disorder (PTSD), amyotrophic lateral sclerosis (ALS), Crohn’s disease, Parkinson’s disease, multiple sclerosis, or other debilitating medical conditions of the same kind or class as or comparable to those enumerated, and for which a physician believes that the medical use of marijuana would likely outweigh the potential health risks for a patient.”