



Senate Bill 8-A

Medical Cannabis Update

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During the recently completed special session, the Florida Legislature was able to reach a compromise on medical marijuana that had eluded them during the regular session. Not part of the initial call, medical marijuana was added to the special session only after the framework of a compromise was reached between the House and Senate. After being amended both in committee and on the floor, Senate Bill 8-A passed out of both chambers and was sent to the Governor on June 19th. Governor Scott, as expected, signed the bill into law on June 23, 2017.

Senate Bill 8-A (SB 8-A) is the Legislature's response to Amendment 2, "Use of Marijuana for Debilitating Medical Conditions," the constitutional amendment initiative that was approved on November 8, 2016 by 71 percent of the Florida electorate. Amendment 2 technically became effective

on January 3, 2017. The Amendment, however, was not self-executing. The Department of Health (Department) was directed to promulgate rules to implement Amendment 2 within six months, and to implement those regulations within nine months. Without the regulations in place, there was a good deal of confusion as to whether patients were authorized to receive medical marijuana under Amendment 2 ([click to read the FMA article on this issue here](#)). While the Department initiated the rulemaking process, with a legislative session beginning in March, it became apparent that the Department would wait to see if the Legislature would intervene and pass legislation that would relieve the Department of having to develop rules on their own in what was likely to be a process fraught with almost certain litigation.

Date published June 29, 2017

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Fortunately for the Department, the Legislature delivered with a 78-page bill that provides detailed directions for the Department on a multitude of issues, ranging from who is eligible to receive medical marijuana under Amendment 2, to who is eligible to produce and dispense the substance, and in what form. Unfortunately for the Department, they have been given the Herculean task of developing numerous rules to implement the directions they have been given.

For physicians, SB 8-A sets up a detailed process for enabling patients to obtain medical marijuana, and most likely ensures that any physician who does so will be in violation of federal law.¹ In order to be eligible to receive marijuana in any form, a patient must have the active assistance of their physician. The physician must ensure that the patient has a "qualifying medical condition" as defined by the bill and then "certify" the patient by adding the patient to the medical marijuana use registry. Only after this "certification" may a patient obtain, possess and engage in the "medical use" of marijuana.

To provide this certification, a physician must be a "qualified physician" under the provisions of the bill. To qualify, an individual must be a physician licensed under chapter 458 or 459, and must have completed a two-hour CME course provided by the FMA or FOMA that explains the requirements and rules that implement Amendment 2. Physicians who took the previous

eight-hour course will be in compliance with the new law until 90 days after the two-hour course becomes available.

Once properly qualified, a physician may issue a certification for medical marijuana only if the physician (1) conducts a full in-person history and physical of the patient; (2) diagnoses the patient with at least one qualifying medical condition; (3) determines that the medical use of marijuana would likely outweigh the potential health risks for the patient³; (4) ensures that the patient is not pregnant; (5) checks the patient's prescription drug history in the PDMP; (6) reviews the medical marijuana use registry to ensure the patient is not already certified by another physician; (7) registers as the issuer of the physician certification in the medical marijuana use registry^{4 5}; and (8) obtains the voluntary and informed written consent of the patient for medical use of marijuana **EACH TIME** the physician issues a certification for the patient.

The informed consent provision requires the use of a standardized form adopted in rule by the Board of Medicine and the Board of Osteopathic Medicine. There is no exception provided. Until the Board creates and adopts the form via rulemaking, physicians will not be able to certify any patients for medical marijuana usage. Whether this was the Legislature's intent, or whether this was an unintended consequence is unknown.

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Regardless, the requirements for the informed consent form imposed by the Legislature are substantial. The form must include, at a minimum, information related to:

1. The Federal Government's classification of marijuana as a Schedule I controlled substance;
2. The approval and oversight status of marijuana by the FDA;
3. The current state of research on the efficacy of marijuana to treat the qualifying conditions set forth in the bill;
4. The potential for addiction;
5. The potential effect that marijuana may have on a patient, including a warning against operating heavy machinery;
6. The potential side effects of marijuana use;
7. The risks, benefits, and drug interactions of marijuana; and
8. That the patient's de-identified health information may be used for research purposes.

This will obviously not be an easy task. Anyone who has access to an informed consent form that arguably complies with the above requirements is encouraged to share it with the FMA Legal Department at legal@flmedical.org. We will remove any identifying information and pass it on to the Board.

If a physician wishes to certify a patient for medical marijuana based on a diagnosis of a condition that is of the "same kind or class as or comparable to" an enumerated condition, there are extra steps the physician must take. Within 14 days after the certification, the physician must submit, to the applicable board (presumably the Board of Medicine (BOM) or the Board of Osteopathic Medicine (BOOM)), the following:

1. Documentation supporting the physician's opinion that the medical condition is of the same kind or class as an enumerated condition;
2. Documentation that establishes the efficacy of marijuana as treatment for the condition;
3. Documentation supporting the qualified physician's opinion that the benefits of medical use of marijuana would likely outweigh the potential health risks;
4. Any other documentation required by board rule.

Regardless of the patient's qualifying medical condition, the physician may not issue a certification for more than a 210-day supply of medical marijuana (limited to a 70-day supply at any one time, filled no more than three times).⁶ There is an exception process in which a physician may certify more than the daily dose amount limit. Such requests shall be made on a form developed by the Department in rule, and shall be deemed approved if the Department fails to act within 14 days after receipt.

If the physician wishes to issue a new certification after the initial 210-day supply has been exhausted,⁷ the physician is required to reevaluate the patient, and must:

1. Determine if the patient still meets the requirements to be issued a physician certification under the physician certification section of the bill (apparently this would require the physician to again conduct an in-person physical examination, diagnose the patient with at least one qualifying medical condition, obtain voluntary and written informed consent, etc.);
2. Identify and document in the medical records whether the patient experienced an adverse drug interaction with any medication or experienced a reduction in the use of or dependence on other types of controlled substances;
3. Submit the findings, as specified in number two above, to the Department of Health.

SB 8-A took effect upon being signed into law. A question exists as to what effect this has on patients who are using low-THC cannabis and medical cannabis under the existing Compassionate Use Act. The new law provides that active orders for low-THC cannabis and medical cannabis obtained by patients who were registered with the compassionate use registry prior to June 23, 2017, are deemed physician certifications. Patients with such orders are deemed qualified patients, and are allowed to obtain and use medical marijuana until the Department begins issuing medical marijuana identification cards. While rules yet to be adopted will probably provide greater clarity, under the plain language of the legislation, the first time the Department issues a patient identification card,⁸ all orders issued pursuant to the Compassionate Use Act become null and void. Patients will need to get a physician certification issued pursuant to the provisions of SB 8-A.

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Finally, it should be noted that there will be an unprecedented level of scrutiny involved in the process of providing patients with medical marijuana. The Department is required to monitor physician registration and certification practices in the medical marijuana use registry and take disciplinary action if they discover practices that “could facilitate” unlawful diversion or misuse of marijuana. Additionally, the BOM and the BOOM are tasked with creating a “physician certification pattern review panel” that shall review ALL physician certifications submitted to the medical marijuana use registry. Information regarding the number of certifications issued, the qualifying medical conditions involved, and the dosage, supply

amount and form of marijuana certified will be submitted by the panel to the Governor and the presiding officers of the Legislature. Members of the public, therefore, will have access to this information.

More information on what the enactment of SB 8-A means for physicians should be forthcoming from the Department as directives are issued and rules are promulgated. The FMA will monitor this process and will provide our members with updated information as it becomes available. In the meantime, if you have any questions or need additional information, please contact the Legal Department at legal@flmedical.org. 

Footnotes

- Despite state laws permitting the possession and use of medical marijuana, cannabis remains a Schedule I controlled substance, possession and use of which is a violation of federal law. Any physician that actively aids and abets a patient in procuring cannabis violates federal law. Despite efforts to avoid this result, Senate bill 8-A establishes a system, that while labeled certification, requires far more than a mere recommendation that would benefit from First Amendment protections.*
- A “qualifying medical condition” is defined as at least one of the following:*
 - Cancer
 - Epilepsy
 - Glaucoma
 - Positive status for HIV
 - AIDS
 - PTSD
 - ALS
 - Crohn’s disease
 - MS
 - Medical conditions of the same kind or class as or comparable to those above
 - A terminal condition diagnosed by a physician other than the qualified physician issuing the physician classification
 - Chronic nonmalignant pain (which is defined as “pain that is caused by a qualifying medical condition or that originates from a qualifying medical condition and persists beyond the usual course of that qualifying medical condition)
- This must be documented in the patient’s medical record. A second opinion is required for patients younger than 18.*
- The certifying physician must enter into the registry the contents of the certification, which must include:*
 - The patient’s qualifying condition
 - The dosage (not to exceed the daily dose amount determined by the Department)
 - The amount and forms of marijuana authorized for the patient
 - The types of delivery devices needed by the patient
- The physician is also responsible for updating the registry within 7 days of any change to the original certification, and must deactivate the registration when the physician no longer recommends the medical use of marijuana for the patient.*
- The Department has been tasked with developing a rule setting forth a daily dose amount for each allowable form of marijuana dispensed from a treatment center. The 70 day supply shall be calculated on the daily dose amount.*
- The bill actually states that a “qualified physician must evaluate an existing qualified patient at least once every 30 weeks before issuing a new physician certification.”*
- The Department is required to begin issuing qualified patient identification cards by October 3, 2017.*