

HOUSE OF REPRESENTATIVES STAFF ANALYSIS

BILL #: HB 1313 Low-THC Cannabis

SPONSOR(S): Brodeur

TIED BILLS: None **IDEN./SIM. BILLS:**

REFERENCE	ACTION	ANALYST	STAFF DIRECTOR or BUDGET/POLICY CHIEF
1) Health Quality Subcommittee	12 Y, 0 N	O'Callaghan	O'Callaghan
2) Health Care Appropriations Subcommittee	12 Y, 0 N	Pridgeon	Pridgeon
3) Health & Human Services Committee		O'Callaghan	Calamas

SUMMARY ANALYSIS

In 2014, the Legislature enacted the Compassionate Medical Cannabis Act (CMCA) to authorize dispensing organizations approved by the Department of Health (DOH) to manufacture, possess, sell, and dispense low-THC cannabis for medical use by patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms. A physician may only order low-THC cannabis for medical use if the patient is a permanent resident of Florida, no other satisfactory alternative treatment option exists, the physician has determined that the risks of ordering the low-THC cannabis are reasonable in light of the potential benefit for the patient, and the physician has obtained voluntary informed consent to such treatment.

Under the CMCA, an applicant for approval as a dispensing organization has to meet certain criteria to be selected by DOH and DOH may select only five dispensing organizations in the state to grow, process, and dispense low-THC cannabis. Although there is specific criteria that must be met before DOH may approve an applicant as a dispensing organization, the CMCA does not include regulatory standards for the operation, security, and safety of dispensing organizations or the growing, processing, testing, packaging, labeling, dispensing, or transportation of low-THC cannabis.

The bill creates new regulatory standards for dispensing organizations, including standards for the growing, processing, testing, packaging, labeling, dispensing, and transportation of low-THC cannabis. The bill also provides DOH with greater regulatory oversight by authorizing DOH to perform inspections, create a patient and caregiver registration card system, assess fees and take disciplinary action, and create standards for laboratories testing low-THC cannabis.

The bill also increases the criteria a physician must meet to be eligible to order low-THC cannabis for a patient by requiring the physician to specialize in certain practice areas and specifying the length of time the physician must have treated the patient. The bill also limits a physician's order to a 30-day supply of low-THC cannabis. The bill prohibits a physician ordering low-THC cannabis from being employed by a dispensing organization and authorizes the appropriate regulatory board to take disciplinary action against a physician who orders low-THC cannabis and receives compensation from a dispensing organization related to the order.

The bill has an indeterminate negative fiscal impact on DOH; however DOH has authority to impose fees sufficient to cover the cost of the regulation of the program. There is no fiscal impact on local governments.

The bill has an effective date of July 1, 2016.

FULL ANALYSIS

I. SUBSTANTIVE ANALYSIS

A. EFFECT OF PROPOSED CHANGES:

Background

Marijuana, also called cannabis, has been used for a variety of health conditions for at least 3,000 years.¹ Currently, the U.S. Food and Drug Administration (FDA) hasn't approved the use of cannabis to treat any health condition due to the lack of research to show that the benefits of using cannabis outweigh the risks.² However, based on the scientific study of cannabinoids, which are chemicals contained in cannabis, the FDA has approved two synthetic prescription drugs that contain certain cannabinoids.³

Although there are more than 100 cannabinoids in a marijuana plant, the two main cannabinoids of medical interest are delta-9-tetrahydrocannabinol (THC) and cannabidiol (CBD). THC is a mind-altering chemical that increases appetite and reduces nausea and may also decrease pain, inflammation, and muscle control problems. CBD is a chemical that does not affect the mind or behavior, but may be useful in reducing pain and inflammation, controlling epileptic seizures, and possibly treating mental illness and addictions.⁴

Research on the Medical Use of Cannabis

During the course of drug development, a typical compound is found to have some medical benefit and then extensive tests are undertaken to determine its safety and proper dosage for medical use.⁵ In contrast, marijuana has been widely used in the United States for decades. In 2014, just over 49% of the U.S. population over 12 years old had tried marijuana or hashish at least once and just over 10% were current users.⁶ The data on the adverse effects of marijuana are more extensive than the data on its effectiveness.⁷ Clinical studies of marijuana are difficult to conduct as researchers interested in clinical studies of marijuana face a series of barriers, research funds are limited, and there is a daunting thicket of federal and state regulations to be negotiated.⁸ In fact, recently, there has been an exponential rise in the use of marijuana compared to the rise in scientific knowledge of its benefits or adverse effects because some states have allowed the public or patients to access marijuana while the federal government continues to limit scientific and clinical investigators' access to marijuana for research.⁹

In 1999, the Institute of Medicine published a study based on a comprehensive review of existing scientific data and clinical studies pertaining to the medical value of marijuana.¹⁰ The study concluded that there is potential therapeutic value of cannabinoid drugs, primarily THC, for pain relief, control of nausea and vomiting, and appetite stimulation.¹¹ The study reports that smoked marijuana, however, is a crude THC delivery system that also delivers harmful substances.¹²

¹ U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *Medical Marijuana*, available at <https://nccih.nih.gov/health/marijuana> (last visited on December 27, 2015).

² U.S. Department of Health & Human Services, National Center for Complementary and Integrative Health, *What is medical marijuana?*, available at <http://www.drugabuse.gov/publications/drugfacts/marijuana-medicine> (last visited on December 27, 2015).

³ *Id.*

⁴ *Id.*

⁵ Institute of Medicine, *Marijuana and Medicine: Assessing the Science Base*, The National Academies Press, 1999, available at <http://www.nap.edu/catalog/6376/marijuana-and-medicine-assessing-the-science-base> (last visited on December 27, 2015).

⁶ Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality, *Results from the 2014 National Survey on Drug Use and Health: Detailed Tables*, available at <http://www.samhsa.gov/data/population-data-nsduh/reports> (last visited on December 27, 2015).

⁷ *Supra* note 5 at 137.

⁸ *Id.*

⁹ Friedman, Daniel, M.D., Devinsky, Orrin, M.D., *Cannabinoids in the Treatment of Epilepsy*, NEW ENG. J. MED., September 10, 2015, on file with the Health Quality Subcommittee.

¹⁰ *Supra* note 5 at 179.

¹¹ *Id.*

¹² *Id.*

The Institute of Medicine's study, which warned that smoking marijuana is harmful, was corroborated by a study published in the *New England Journal of Medicine* in 2014.¹³ The 2014 study further warned that long-term marijuana use can lead to addiction and that adolescents have an increased vulnerability to adverse long-term outcomes from marijuana use.¹⁴ Specifically, the study found that, as compared with persons who begin to use marijuana in adulthood, those who begin in adolescence are approximately 2 to 4 times as likely to have symptoms of cannabis dependence within 2 years after first use.¹⁵ The study also found that cannabis-based treatment with THC may have irreversible effects on brain development in adolescents as the brain's endocannabinoid system undergoes development in childhood and adolescence.¹⁶

More recently, a study published in 2015 in the *Journal of the American Medical Association* found that there is moderate-quality evidence to support the use of cannabinoids for the treatment of chronic pain and spasticity and that there is low-quality evidence suggesting that cannabinoids are associated with improvements in nausea and vomiting due to chemotherapy, weight gain in HIV infection, sleep disorders, and Tourette syndrome.¹⁷

Despite the uncertainty of the efficacy of marijuana on various medical conditions, there has recently been much interest in the use of marijuana, especially the compound CBD, to treat epilepsy.¹⁸ A few factors contributing to the interest of the public, media, and researchers in such treatment are that new anti-seizure drugs have not substantially reduced the proportion of patients with medically refractory seizures, the side effects of such drugs continue to have negative side effects to the central nervous system and affect quality of life, and there appears to be some evidence-based efficacy of such treatment based on case stories and limited preclinical and clinical studies.¹⁹

Federal Regulation of Cannabis

The Federal Controlled Substances Act²⁰ lists cannabis as a Schedule 1 drug, meaning it has a high potential for abuse, has no currently accepted medical use, and has a lack of accepted safety for use under medical supervision.²¹ The Federal Controlled Substances Act imposes penalties on those who possess, sell, distribute, dispense, and use cannabis.²² A first misdemeanor offense for possession of cannabis in any amount can result in a \$1,000 fine and up to a year in prison, climbing for subsequent offenses to as much as \$5,000 and three years.²³ Selling and cultivating cannabis are subject to even greater penalties.²⁴

In August of 2013, the United States Department of Justice (USDOJ) issued a publication entitled "Smart on Crime: Reforming the Criminal Justice System for the 21st Century."²⁵ This document details the federal government's changing stance on low-level drug crimes announcing a "change in Department of Justice charging policies so that certain people who have committed low-level, nonviolent drug offenses, who have no ties to large-scale organizations, gangs, or cartels will no longer be charged with offenses that impose draconian mandatory minimum sentences. Under the revised policy, these people would instead receive sentences better suited to their individual conduct rather

¹³ Volkow, N.D., Baler, R.D., Compton, W.M. and Weiss, S.R., *Adverse Health Effects of Marijuana Use*, *NEW ENG. J. MED.*, June 5, 2014, available at dfaf.org/assets/docs/Adverse%20health%20effects.pdf (last visited on December 27, 2015).

¹⁴ *Id.* at 2219.

¹⁵ *Id.* at 2220.

¹⁶ *Id.* at 2219.

¹⁷ American Medical Association, *Cannabinoids for Medical Use: A Systematic Review and Meta-analysis*, *JAMA*, June 2015, on file with the Health Quality Subcommittee.

¹⁸ *Supra* note 9 at 1048.

¹⁹ *Supra* note 9 at 1048, 1052-1053, and 1056.

²⁰ 21 U.S.C. ss. 801-971.

²¹ 21 U.S.C. s. 812.

²² 21 U.S.C. ss. 841-65.

²³ 21 U.S.C. s. 844.

²⁴ 21 U.S.C. ss. 841-65.

²⁵ U.S. Department of Justice, *Smart on Crime: Reforming the Criminal Justice System for the 21st Century*, available at <http://www.justice.gov/ag/smart-on-crime.pdf>. (last visited on December 27, 2015).

than excessive prison terms more appropriate for violent criminals or drug kingpins.”²⁶

On August 29, 2013, United States Deputy Attorney General James Cole issued a memorandum to federal attorneys that appeared to relax the federal government’s cannabis-related offense enforcement policies.²⁷ The memo stated that the USDOJ was committed to using its limited investigative and prosecutorial resources to address the most significant threats in the most effective, consistent, and rational ways, and outlined eight areas of enforcement priorities.²⁸ These enforcement priorities focused on offenses that would result in cannabis being distributed to minors, cannabis sale revenues going to criminal gangs or other similar organizations, and cannabis being grown on public lands.²⁹ The memo indicated that outside of the listed enforcement priorities, the federal government would not enforce federal cannabis-related laws in states that have legalized the drug and that have a robust regulatory scheme in place.³⁰

In 2014, Congress enacted the Consolidated and Further Continuing Appropriations Act of 2015 (Appropriations Act of 2015). Section 538 of the Appropriations Act of 2015 prohibits the USDOJ from expending any funds in connection with the enforcement of any law that interferes with a state’s ability to implement its own state law that authorizes the use, distribution, possession, or cultivation of medical marijuana.³¹ Despite this prohibition in the Appropriations Act of 2015, the USDOJ has continued to take some enforcement measures against medical cannabis dispensaries. However, in October 2015, the United States District Court for the Northern District of California held that section 538 plainly on its face prohibits the Department of Justice from taking such action.³² Congress recently re-enacted the prohibition in section 542 of the Consolidated Appropriations Act of 2016.³³

Regulation of Cannabis in Other States

Currently, 23 states³⁴ and the District of Columbia have comprehensive laws that permit and regulate the use of cannabis for medicinal purposes.³⁵ While these laws vary widely, most specify the medical conditions a patient must be diagnosed with to be eligible to use cannabis for treatment, allow a caregiver to assist with such treatment, require the registration of the patient and caregiver and a registration ID card to be issued to the patient and caregiver, restrict where cannabis can be used, and provide standards pertaining to the growing, processing, packaging, transport, and dispensing of medical cannabis.

Patients’ Use of Medical Cannabis

While nearly every state has a list of medical conditions for which the patient may be treated with medical cannabis, the particular conditions vary from state to state. Most states also provide a mechanism for the list of qualifying medical conditions to be expanded, usually by allowing a state agency or a board to add qualifying medical conditions to the list or by providing a physician with some

²⁶ *Id.*

²⁷ U.S. Department of Justice, *Guidance Regarding Marijuana Enforcement*, August 29, 2014, available at <http://www.justice.gov/iso/opa/resources/3052013829132756857467.pdf> (last visited on December 27, 2015).

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.*

³¹ Pub. L. 113-235 (2014).

³² *U.S. v. Marin Alliance for Medical Marijuana*, 2015 WL 6123062 (N.D. Cal. Oct. 19, 2015).

³³ Pub. L. 114-113 (2015).

³⁴ These states include: Alaska, Arizona, California, Colorado, Connecticut, Delaware, Hawaii, Illinois, Maine, Maryland, Massachusetts, Michigan, Minnesota, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, Oregon, Rhode Island, Vermont, and Washington. California was the first to establish a medical marijuana program in 1996 and New York was the most recent state to pass medical marijuana legislation which took effect in July 2014. National Conference of State Legislatures, *State Medical Marijuana Laws*, available at <http://www.ncsl.org/issues-research/health/state-medical-marijuana-laws.aspx> (last visited on December 27, 2015).

³⁵ According to the National Conference of State Legislatures, 17 other states allow the use of low-THC cannabis for medical use or allow a legal defense for such use, including Florida. National Conference of State Legislatures, *State Medical Marijuana Laws*, available at <http://www.ncsl.org/research/health/state-medical-marijuana-laws.aspx> (last visited on December 27, 2015).

discretion in determining whether such treatment would benefit the patient.³⁶ The most common qualifying conditions named³⁷ in the statutes of the states with comprehensive medical cannabis laws are:³⁸

- Cancer- 22 states
- HIV/AIDS- 22 states
- Multiple sclerosis- 20 states
- Epilepsy- 20 states
- Glaucoma- 19 states
- Crohn's disease- 12 states
- Amyotrophic lateral sclerosis- 10 states
- Hepatitis C- 8 states
- Alzheimer's disease- 8 states

Most states require that at least one, but sometimes states require two, physicians to certify that the patient has a qualifying condition. Some states require physicians to have certain qualifications to be able to order medical cannabis for qualifying patients.³⁹ Qualifying patients are usually required to be registered in an electronic registry and must be issued a registration ID card, usually from a state agency.⁴⁰

Most states place general restrictions on where medical cannabis may be used. Typically, medical cannabis may not be used in public places, such as parks and on buses, or in areas where there are more stringent restrictions placed on the use of drugs, such as in or around schools or in prisons.⁴¹

There are two general methods by which patients can obtain medical cannabis. They must either self-cultivate the cannabis in their homes, or buy cannabis from specified points of sale or dispensaries. Regulations governing the amount of medical cannabis that may be grown or dispensed varies widely. For example, the amount of medical cannabis patients are allowed to have ranges from 1 ounce of usable⁴² cannabis to 24 ounces of usable cannabis, depending on the state. Furthermore, the number of cannabis plants that patients are allowed to grow ranges from 2 mature marijuana plants to 18 seedling marijuana plants. At least 10 states limit the amount of medical cannabis that may be ordered by specifying the number of days or months of a supply a physician may order.⁴³

Caregivers

³⁶ For example, see the following state laws allowing an agency to approve other conditions: AS § 17.37.070 (Alaska), A.R.S. § 36-2801 (Arizona), C.R.S.A. Const. Art. 18, § 14 (Colorado), C.G.S.A. § 21a-408 (Connecticut), 16 Del.C. § 4902A (Delaware), HRS § 329-121 (Hawaii), 410 ILCS 130/10 (Illinois), M.C.L.A. 333.26423 (Michigan), M.S.A. §152.22 (Minnesota), N.R.S. 453A.050 (Nevada), N.H. Rev. Stat. §126-X:1 (New Hampshire), N.J.S.A. 24:61-3 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), O.R.S. § 475.302 (Oregon), and Gen. Laws 1956, § 21-28.6-3 (Rhode Island). For examples of states allowing for physician discretion in treating other conditions with medical cannabis, see M.G.L.A. 94C App. §1-2.

³⁷ These are diseases specified in states' statutes. The state statutes also included symptoms or conditions of diseases that could apply to several other diseases, such as cachexia or wasting syndrome, severe pain, severe nausea, seizures, or muscle spasms.

³⁸ Information based on research performed by Health Quality Subcommittee staff. The laws of each state are on file with the subcommittee.

³⁹ For example, the following states require the ordering physician to be a neurologist: Iowa (I.C.A. § 124D.3), Missouri (V.A.M.S. 192.945), Utah (U.C.A. 1953 § 26-56-103), and Wyoming (W.S.1977 § 35-7-1902). Additionally, Vermont requires a physician to establish a bona fide relationship with the patient for not less than 6 months before ordering such treatment. See 18 V.S.A. § 4472.

⁴⁰ *Supra* note 38.

⁴¹ For example, see N.R.S. 453A.322 (Nevada), N.J.S.A. 18A:40-12.22 (New Jersey), 5 CCR 1006-2:12 (Colorado), and West's Ann.Cal.Health & Safety Code § 11362.768 (California).

⁴² "Usable cannabis" generally means the seeds, leaves, buds, and flowers of the cannabis plant and any mixture or preparation thereof, but does not include the stalks and roots of the plant or the weight of any non-cannabis ingredients combined with cannabis. For example, see 410 ILCS 130/10 (Illinois) and OAR 333-008-0010 (Oregon).

⁴³ See C.G.S.A. §21a-4089 (Connecticut), 410 ILCS 130/10 (Illinois), MD Code, Health-General, § 13-3301 (Maryland), M.G.L.A. 94C App. §1-2 (Massachusetts), M.S.A. § 152.29 (Minnesota), N.R.S. 453A.200 (Nevada), N.H. Rev. Stat. § 126-X:8 (New Hampshire), N.J.S.A. 24:61-10 (New Jersey), N.M.S.A. 1978, § 26-2B-3 (New Mexico), and McKinney's Public Health Law § 3362 (New York).

Caregivers are generally allowed to purchase or grow cannabis for the patient, be in possession of a specified quantity of cannabis, and aid the patient in using cannabis, but are strictly prohibited from using cannabis themselves. Some states may also require the caregiver to be at least 21⁴⁴ and may prohibit the caregiver from being the patient's physician.⁴⁵ Like the patient receiving treatment, the caregiver is usually required to be registered and have a registration ID card, typically issued by a state agency.⁴⁶

Quality and Safety Standards

States vary in their regulations of entities that grow, process, transport, and dispense medical cannabis. However, most states with comprehensive medical cannabis laws require such entities to meet certain standards to ensure the quality and safety of the medical cannabis and standards to ensure the security of the facilities possessing the medical cannabis. For example, some states require a state agency to establish and enforce standards for laboratory testing of medical cannabis.⁴⁷ States may also require certain packaging and labeling standards for medical cannabis, including the requirement for packaging to meet the standards under the United States Poison Prevention Packaging Act.⁴⁸ States' security measures may require facilities that grow, process, transport, and dispense medical cannabis to implement an inventory tracking system that tracks the cannabis from "seed-to-sale."⁴⁹

Florida's Cannabis Laws

Criminal Law

Florida's drug control laws are set forth in ch. 893, F.S., entitled the Florida Comprehensive Drug Abuse Prevention and Control Act (Drug Control Act).⁵⁰ The Drug Control Act classifies controlled substances into five categories, ranging from Schedule I to Schedule V.⁵¹ Cannabis is currently a Schedule I controlled substance,⁵² which means it has a high potential for abuse, it has no currently accepted medical use in treatment in the United States, and its use under medical supervision does not meet accepted safety standards.⁵³ 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 compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. The term does not include "low-THC cannabis," as defined in s. 381.986, if manufactured, possessed, sold, purchased, delivered, distributed, or dispensed, in conformance with s. 381.986.⁵⁴

The Drug Control Act contains a variety of provisions criminalizing behavior related to cannabis:

- Section 893.13, F.S., makes it a crime to sell, manufacture, deliver, purchase, or possess cannabis. The penalties for these offenses range from first degree misdemeanors to second degree felonies.⁵⁵

⁴⁴ See, for example, 22 M.R.S.A. § 2423-A (Maine), 105 CMR 725.020 (Massachusetts), and Gen.Laws 1956, § 44-67-2 (Rhode Island).

⁴⁵ For an example of a law prohibiting a physician from being a caregiver, see the definition of "primary caregiver" in C.R.S.A. § 25-1.5-106 (Colorado).

⁴⁶ *Supra* note 38.

⁴⁷ See HRS § 329D-8 (Hawaii), N.R.S. 453A.368 (Nevada), and West's RCWA 69.50.348 (Washington).

⁴⁸ See C.R.S.A. § 12-43.3-104 (Colorado) and Haw. Admin. Rules (HAR) § 11-850-92 (Hawaii).

⁴⁹ See C.R.S.A. § 35-61-105.5 (Colorado), OAR 333-064-0100 (Oregon), and West's RCWA 69.51A.250 (Washington- effective July 1, 2016).

⁵⁰ s. 893.01, F.S.

⁵¹ s. 893.03, F.S.

⁵² s. 893.03(1)(c)7., F.S.

⁵³ s. 893.03(1), F.S.

⁵⁴ s. 893.02(3), F.S.

⁵⁵ A first degree misdemeanor is punishable by up to one year in county jail and a \$1,000 fine; a third degree felony is punishable by up to five years imprisonment and a \$5,000 fine; and a second degree felony is punishable by up to 15 years imprisonment and a \$10,000 fine. ss. 775.082 and 775.083, F.S.

- Section 893.135(1)(a), F.S., makes it a first degree felony⁵⁶ to traffic in cannabis, i.e., to possess, sell, purchase, manufacture, deliver, or import more than 25 pounds of cannabis or 300 or more cannabis plants. Depending on the amount of cannabis or cannabis plants trafficked, mandatory minimum sentences of three to 15 years and fines of \$25,000 to \$200,000 apply to a conviction.⁵⁷
- Section 893.147, F.S., makes it a crime to possess, use, deliver, manufacture, transport, or sell drug paraphernalia.⁵⁸ The penalties for these offenses range from first degree misdemeanors to second degree felonies.⁵⁹

Medical Necessity Defense

Florida courts have held that persons charged with offenses based on the possession, use, or manufacture of marijuana may use the medical necessity defense, which requires a defendant to prove that:

- He or she did not intentionally bring about the circumstance which precipitated the unlawful act;
- He or she could not accomplish the same objective using a less offensive alternative; and
- The evil sought to be avoided was more heinous than the unlawful act.⁶⁰

In *Jenks v. State*,⁶¹ the defendants, a married couple, suffered from uncontrollable nausea due to AIDS treatment and had testimony from their physician that they could find no effective alternative treatment. The defendants tried cannabis, and after finding that it successfully treated their symptoms, decided to grow two cannabis plants.⁶² They were subsequently charged with manufacturing and possession of drug paraphernalia. Under these facts, the First District Court of Appeal found that “section 893.03 does not preclude the defense of medical necessity” and that the defendants met the criteria for the medical necessity defense.⁶³ The court ordered the defendants to be acquitted.⁶⁴

Seven years after the *Jenks* decision, the First District Court of Appeal again recognized the medical necessity defense in *Sowell v. State*.⁶⁵ More recently, the State Attorney’s Office in the Twelfth Judicial Circuit cited the medical necessity defense as the rationale for not prosecuting a person arrested for cultivating a small amount of cannabis in his home for his wife’s medical use.⁶⁶

Compassionate Medical Cannabis Act of 2014

The Compassionate Medical Cannabis Act of 2014⁶⁷ (CMCA) legalized a low tetrahydrocannabinol (THC) and high cannabidiol (CBD) form of cannabis (low-THC cannabis)⁶⁸ for the medical use⁶⁹ by

⁵⁶ A first degree felony is punishable by up to 30 years imprisonment and a \$10,000 fine. ss. 775.082 and 775.083, F.S.

⁵⁷ s. 893.13(1)(a), F.S.

⁵⁸ Drug paraphernalia is defined in s. 893.145, F.S., as:

All equipment, products, and materials of any kind which are used, intended for use, or designed for use in the planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of ch. 893, F.S., or s. 877.111, F.S.

⁵⁹ s. 893.147, F.S.

⁶⁰ *Jenks v. State*, 582 So.2d 676, 679 (Fla. 1st DCA 1991), *rev. denied*, 589 So.2d 292 (Fla. 1991).

⁶¹ 582 So.2d 676 (Fla. 1st DCA 1991).

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ 739 So.2d 333 (Fla. 1st DCA 1998).

⁶⁶ *Interdepartmental Memorandum*, State Attorney’s Office for the Twelfth Judicial Circuit of Florida, SAO Case # 13CF007016AM, April 2, 2013, on file with the Health Quality Subcommittee.

⁶⁷ See ch. 2014-157, L.O.F., and s. 381.986, F.S.

⁶⁸ The act defines “low-THC cannabis,” as the dried flowers of the plant *Cannabis* which contain 0.8 percent or less of tetrahydrocannabinol and more than 10 percent of cannabidiol weight for weight, or the seeds, resin, or any compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin. See s. 381.986(1)(b), F.S.

⁶⁹ Section 381.986(1)(c), F.S., defines “medical use” as “administration of the ordered amount of low-THC cannabis. The term does not include the possession, use, or administration by smoking. The term also does not include the transfer of low-THC cannabis to a

patients suffering from cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms.

The CMCA provides that a Florida licensed allopathic or osteopathic physician who has completed certain training⁷⁰ and has examined and is treating such a patient may order low-THC cannabis for that patient to treat the disease, disorder, or condition or to alleviate its symptoms, if no other satisfactory alternative treatment options exist for the patient. To meet the requirements of the CMCA, each of the following conditions must be satisfied:

- The patient must be a permanent resident of Florida.
- The physician must determine that the risks of ordering low-THC cannabis are reasonable in light of the potential benefit for that patient.⁷¹
- The physician must register as the orderer of low-THC cannabis for the patient on the compassionate use registry (registry) maintained by the Department of Health (DOH) and must update the registry to reflect the contents of the order.
- The physician must maintain a patient treatment plan and must submit the plan quarterly to the University of Florida College of Pharmacy.
- The physician must obtain the voluntary informed consent of the patient or the patient's legal guardian to treatment with low-THC cannabis.⁷²

Under the CMCA, DOH was required to approve five dispensing organizations by January 1, 2015, with one dispensing organization in each of the following regions: northwest Florida, northeast Florida, central Florida, southeast Florida, and southwest Florida. DOH was also authorized to impose an initial application and biennial renewal fee that is sufficient to cover the costs of regulating the program.⁷³ To be approved as a dispensing organization, an applicant must establish that it:

- Possesses a certificate of registration issued by the Department of Agriculture and Consumer Services for the cultivation of more than 400,000 plants;
- Is operated by a nurseryman;
- Has been operating as a registered nursery in this state for at least 30 continuous years;
- Has the technical and technological ability to cultivate and produce low-THC cannabis;
- Employs a medical director, who must be a physician and have successfully completed a course and examination that encompasses appropriate safety procedures and knowledge of low-THC cannabis; and
- Other specified requirements.⁷⁴

Implementation by DOH of the dispensing organization approval process was delayed due to litigation challenging proposed rules that addressed the initial application requirements for dispensing organizations, revocation of dispensing organization approval, and inspection and cultivation authorization procedures for dispensing organizations. Such litigation was resolved on May 27, 2015, with an order entered by the Division of Administrative Hearings holding that the challenged rules do not constitute an invalid exercise of delegated legislative authority.⁷⁵ Thereafter, the rules took effect on June 17, 2015.⁷⁶

person other than the qualified patient for whom it was ordered or the qualified patient's legal representative on behalf of the qualified patient." Section 381.986(1)(e), F.S., defines "smoking" as "burning or igniting a substance and inhaling the smoke. Smoking does not include the use of a vaporizer."

⁷⁰ Section 381.986(4), F.S., requires such physicians to successfully complete an 8-hour course and examination offered by the Florida Medical Association or the Florida Osteopathic Medical Association which encompasses the clinical indications for the appropriate use of low-THC cannabis, appropriate delivery mechanisms, contraindications for such use, and the state and federal laws governing its ordering, dispensing, and processing

⁷¹ If a patient is younger than 18 years of age, a second physician must concur with this determination, and such determination must be documented in the patient's medical record. s. 381.986(2)(b), F.S.

⁷² s. 381.986(2), F.S.

⁷³ s. 381.986(5)(b), F.S.

⁷⁴ *Id.*

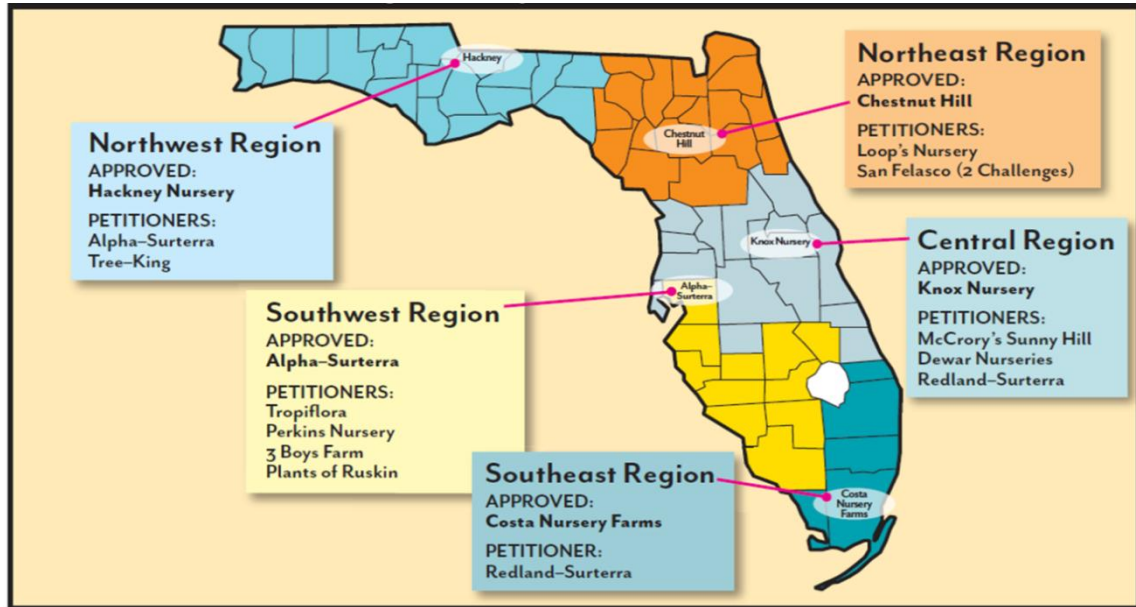
⁷⁵ *Baywood v. Nurseries Co., Inc. v. Dep't of Health*, Case No. 15-1694RP (Fla. DOAH May 27, 2015).

⁷⁶ Rule Chapter 64-4, F.A.C.

STORAGE NAME: h1313d.HHSC
DATE: 2/8/2016

The application process to become a dispensing organization closed on July 8, 2015, with 28 applications received by DOH. On November 23, 2015, DOH announced the five approved dispensing organizations: Hackney Nursery in the northwest region, Chestnut Hill Tree Farm in the northeast region, Knox Nursery in the central region, Costa Nursery Farms in the southeast region, and Alpha Foliage in the southwest region. To date, 13 petitions⁷⁷ have been filed contesting DOH's approval of these five dispensing organizations.⁷⁸

APPROVED DISPENSING ORGANIZATIONS AND PENDING CHALLENGES



SOURCE: Department of Health, Office of Compassionate Use.

The CMCA provides that it is a first degree misdemeanor for:

- A physician to order low-THC cannabis for a patient without a reasonable belief that the patient is suffering from a required condition; or
- Any person to fraudulently represent that he or she has a required condition to a physician for the purpose of being ordered low-THC cannabis.⁷⁹

The CMCA specifies that notwithstanding ss. 893.13, 893.135, or 893.147, F.S., or any other law that:

- Qualified patients⁸⁰ and their legal representatives may purchase and possess low-THC cannabis up to the amount ordered for the patient's medical use.
- Approved dispensing organizations and their owners, managers, and employees may manufacture, possess, sell, deliver, distribute, dispense, and lawfully dispose of reasonable quantities, as established by DOH rule, of low-THC cannabis. Such dispensing organizations and their owners, managers, and employees are not subject to licensure or regulation under ch. 465, F.S., relating to pharmacies.⁸¹

⁷⁷ A copy of each petition is available at <http://www.floridahealth.gov/programs-and-services/office-of-compassionate-use/> (last visited on December 28, 2015).

⁷⁸ Chestnut Hill Tree Farm also filed a counter-petition to San Felasco Nurseries' challenge to the Chestnut Hill Tree Farm being approved as the northeast region dispensing organization. *Chestnut Hill Tree Farm, LLC v. San Felasco Nurseries, Inc.*, Case No. 15-007276, (Fla. DOAH, Dec. 18, 2015).

⁷⁹ s. 381.986(3), F.S.

⁸⁰ Section 381.986(1)(d), F.S., provides that a "qualified patient" is a Florida resident who has been added by a physician licensed under ch. 458, F.S. or ch. 459, F.S., to the compassionate use registry to receive low-THC cannabis from a dispensing organization.

⁸¹ s. 381.986(7), F.S.

The CMCA requires DOH to create a secure, electronic, and online registry for the registration of physicians and patients.⁸² Physicians must register as the orderer of low-THC cannabis for a named patient on the registry and must update the registry to reflect the contents of the order.⁸³ The registry must prevent an active registration of a patient by multiple physicians and must be accessible to law enforcement agencies and to a dispensing organization to verify patient authorization for low-THC cannabis and to record the low-THC cannabis dispensed.⁸⁴

Effect of Proposed Changes

This bill creates additional regulatory standards under the Compassionate Medical Cannabis Act (CMCA) for dispensing organizations approved by DOH to grow, process, transport, and dispense low-THC cannabis. Additionally, the bill strengthens the criteria for physicians to be able to order low-THC cannabis, the criteria for physicians to become medical directors of dispensing organizations, and DOH's responsibilities under the CMCA. The bill includes other measures to increase the accountability of those who have access to low-THC cannabis, to increase the safety and quality of the low-THC cannabis being dispensed, and to increase the security of premises and personnel in possession of low-THC cannabis.

Dispensing Organizations

Current law requires approved dispensing organizations to maintain compliance with certain criteria required to be met prior to their selection, but it does not provide standards specifically relating to the quality or safety of low-THC cannabis or the security of entities possessing or transporting low-THC cannabis. The bill establishes new quality and safety standards for growing, processing, transporting and dispensing low-THC cannabis and security standards for those entities performing such acts.

⁸² s. 381.985(5)(a), F.S.

⁸³ s. 381.986(2)(c), F.S.

⁸⁴ s. 381.985(5)(a), F.S.

Growing Low-THC Cannabis

When growing low-THC cannabis, the bill provides that a dispensing organization may use pesticides determined by DOH to be safely applied to plants intended for human consumption and requires the dispensing organization to:

- Grow and process low-THC cannabis within an enclosed structure and in a room separate from any other plant;
- Inspect seeds and growing plants for plant pests that endanger or threaten the horticultural and agricultural interests of the state, notify the Department of Agriculture and Consumer Services within 10 calendar days of a determination that a plant is infested or infected by such plant pest, and implement and maintain phytosanitary policies and procedures; and
- Perform fumigation or treatment of plants or the removal and destruction of infested or infected plants in accordance with ch. 581, F.S., or any rules adopted thereunder.

Processing Low-THC Cannabis

When processing low-THC cannabis, a dispensing organization must:

- Process the low-THC cannabis in an enclosure separate from other plants or products;
- Package the low-THC cannabis in compliance with the United States Poison Prevention Packaging Act (15 U.S.C. §§1471-1477);⁸⁵
- Package the low-THC cannabis in a receptacle that has a firmly affixed and legible label stating the following information:
 - The name of the dispensing organization.
 - The quantity of low-THC cannabis contained within.
 - The cannabinoid profile of the low-THC cannabis, including the THC level.
 - Any ingredient other than low-THC cannabis contained within.
 - The date the low-THC is dispensed.
 - The patient's name and registration identification number.
 - A statement that the product is for medical use and not for resale or transfer to another person.
 - A unique serial number that will match the product with the original batch of low-THC cannabis from which the product was made to facilitate necessary warnings or recalls by DOH.
 - A recommended "use by" date or expiration date; and
- Reserve two processed samples per each batch, retain such samples for at least one year, and make those samples available for testing.

Dispensing Low-THC Cannabis

The bill prohibits a dispensing organization from dispensing more than a 30-day supply of low-THC cannabis to a patient or the patient's caregiver or selling any other type of retail product other than the physician ordered low-THC cannabis or paraphernalia. The bill also requires the dispensing organization to:

- Have the dispensing organization employee dispensing the low-THC cannabis enter into the compassionate use registry his or her name or unique employee identifier;
- Verify in the compassionate use registry that a physician has ordered low-THC cannabis or a specific type of paraphernalia for the patient;
- Verify the patient or patient's caregiver holds a valid and active registration card; and

⁸⁵ The Poison Prevention Packaging Act requires packaging to be designed or constructed in a manner to make it significantly difficult for children under five years of age to open within a reasonable time, and not difficult for normal adults to use properly. See U.S. Consumer Product Safety Commission, *Poison Prevention Packaging Act*, available at <http://www.cpsc.gov/en/Regulations-Laws-Standards/Statutes/Poison-Prevention-Packaging-Act/> (last visited on December 29, 2015).

- Record in the compassionate use registry the paraphernalia dispensed, if any, in addition to the other information required under current law to be recorded in the registry.

Safety and Security Measures

The bill also requires the dispensing organization to implement and maintain certain safety and security measures relating to its facilities and certain safety and quality measures for low-THC cannabis dispensed or transported by the dispensing organization. Specifically, the bill requires the dispensing organization to:

- Maintain a fully operational security alarm system;
- Maintain a video surveillance system that records continuously 24 hours per day and meets specific minimum criteria;
- Retain video surveillance recordings for a minimum of 45 days, or longer upon the request of law enforcement;
- Enclose the perimeter of any buildings used in the cultivation, processing, or dispensing of low-THC cannabis with at least a six-foot high fence;
- Ensure that the outdoor premises of the dispensing organization has sufficient lighting from dusk until dawn;
- Dispense low-THC cannabis or paraphernalia only between the hours of 9 p.m. and 7 a.m., but allows the dispensing organization to perform all other operations 24 hours per day;
- Establish and maintain a tracking system approved by DOH that traces the low-THC cannabis from seed to sale, including key notification of events as determined by DOH;
- Store low-THC cannabis in secured, locked rooms or a vault;
- Have at least 2 employees of the dispensing organization or of a contracted security agency be on the dispensing organization premises at all times;
- Have all employees wear a photo identification badge at all times while on the premises;
- Have visitors wear a visitor's pass at all times while on the premises;
- Implement an alcohol and drug free workplace policy; and
- Report to local law enforcement within 24 hours of the dispensing organization being notified or becoming aware of the theft, diversion, or loss of low-THC cannabis.

To ensure the safe transport of low-THC cannabis to dispensing organization facilities, laboratories, or patients, the bill requires dispensing organizations to:

- Maintain a transportation manifest, which must be retained for at least one year;
- Ensure only vehicles in good-working order are used to transport low-THC cannabis;
- Lock low-THC cannabis in a separate compartment or container within the vehicle;
- Have at least two persons in a vehicle transporting low-THC cannabis and at least one person remain in the vehicle while the low-THC cannabis is being delivered; and
- Provide specific safety and security training to those employees transporting low-THC cannabis.

Physicians

Current law requires a physician to meet certain criteria, including additional training and education, to be qualified to order low-THC cannabis. The bill increases the qualification criteria and allows the physician to order paraphernalia for the administration of low-THC cannabis. "Paraphernalia" is defined by the bill as objects used, intended for use, or designed for use in preparing, storing, ingesting, inhaling, or otherwise introducing low-THC cannabis into the human body. The additional criteria in the bill require the physician to:

- Be board-certified as an oncologist, neurologist, or epileptologist or specialize in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms. When treating a patient who is a minor and a second physician's concurrence for treatment using low-THC cannabis is required, the second physician must also meet this criterion.

- Have treated the patient for cancer or a physical medical condition that chronically produces symptoms of seizures or severe and persistent muscle spasms for at least six months.
- Include in the registry the ordered amount of low-THC cannabis that will provide the patient with not more than a 30-day supply and any paraphernalia needed by the patient for the medical use of low-THC cannabis.

The bill prohibits a physician ordering low-THC cannabis from being employed as a medical director of a dispensing organization and provides that a physician who orders low-THC cannabis and receives compensation from a dispensing organization related to the ordering of low-THC cannabis may be subject to disciplinary action under the applicable practice act and under s. 456.072(1)(n), F.S.

The bill also increases the qualification criteria for medical directors of dispensing organizations by requiring the medical director to be board-certified as an oncologist, neurologist, or epileptologist or provide proof that he or she specializes in the treatment of cancer, epilepsy, or physical medical conditions that chronically produce symptoms of seizures or severe and persistent muscle spasms.

Testing Laboratories

Current law does not require the testing of low-THC cannabis by laboratories to ensure the composition of the low-THC cannabis to be dispensed complies with law or to ensure that it is safe. The bill requires a dispensing organization to contract with a laboratory approved by DOH for purposes of testing low-THC cannabis for compliance with the law and to detect any mold, bacteria, or other contaminant which may result in adverse effects to human health or the environment. The contract must require the laboratory to report to the dispensing organization, within 48 hours of a test, the cannabinoid composition of the product and whether the laboratory has detected any mold, bacteria, or other contaminant in the product which may result in adverse effects to human health or the environment.

The bill also creates an exemption from criminal law for DOH approved laboratories and their employees, allowing the laboratories and laboratory employees to possess, test, transport, and lawfully dispose of low-THC cannabis.

Department of Health

The bill grants DOH greater regulatory oversight of dispensing organizations by authorizing DOH to conduct inspections, set certain standards for laboratory testing of low-THC cannabis, establish a registration card system for patients and caregivers, and assess fines or take disciplinary action for certain violations. The bill also grants DOH authority to conduct additional acts to administer the CMCA. Specifically, the bill provides that DOH:

- May conduct announced or unannounced inspections of dispensing organizations to determine compliance with the law.
- Must inspect a dispensing organization upon complaint or notice provided to DOH that the dispensing organization has dispensed low-THC cannabis containing any mold, bacteria, or other contaminant that may cause or has caused an adverse effect to human health or the environment.
- Must conduct at least an annual inspection to evaluate dispensing organization records, personnel, equipment, processes, security measures, sanitation practices, and quality assurance practices.
- May inspect laboratories to ensure laboratories are using standardized procedures to test low-THC cannabis.
- May adopt standards for the approval of laboratories contracting with dispensing organizations, including standardized procedures, required equipment, and conflict of interest provisions.
- May enter into interagency agreements with the Department of Agriculture and Consumer Services, the Department of Business and Professional Regulation, the Department of Transportation, the Department of Highway Safety and Motor Vehicles, and the Agency for Health Care Administration, and such agencies are authorized to enter into an interagency

agreement with DOH, to conduct inspections or perform other responsibilities assigned to DOH under the CMCA.

- Make a list of all approved dispensing organizations and qualified ordering physicians and medical directors publicly available on its website.
- May establish a system for issuing and renewing patient and caregiver registration cards, establish the circumstances under which the cards may be revoked by or must be returned to DOH, and establish fees to implement such system. DOH must require, at a minimum, the registration cards to:
 - State the name, address, and date of birth of the patient or caregiver.
 - Have a full-face, passport-style photograph of the patient or caregiver that has been taken within 90 days prior to registration.
 - Identify whether the cardholder is a patient or caregiver.
 - List a unique numerical identifier for the patient or caregiver that is matched to the identifier used for such person in DOH's compassionate use registry.
 - Provide the expiration date, which shall be from one year from the physician's initial order of low-THC cannabis.
 - For the caregiver, provide the name and unique numerical identifier of the patient the caregiver is assisting.
 - Be resistant to counterfeiting or tampering.
- Must create a schedule of violations in rule to impose reasonable fines not to exceed \$10,000 on a licensee, and before assessing a fine must consider the severity of the violation, any actions taken by the licensee to correct the violation or to remedy complaints, and any previous violations.
- May suspend, revoke, or refuse to renew the license of a licensee for having a license, or the authority to practice any regulated profession or the authority to conduct any business, revoked, suspended, or otherwise acted against, including the denial of licensure by the licensing authority, for a violation that would constitute a violation under Florida law.
- May adopt rules necessary to implement the CMCA.

DOH is also responsible for overseeing a dispensing organization's advertising as the bill only allows a dispensing organization to use an insignia or logo approved by DOH.

The bill provides an effective date of July 1, 2016.

B. SECTION DIRECTORY:

Section 1. Amends s. 381.986, F.S., relating to compassionate use of low-THC cannabis.

Section 2. Provides an effective date of July 1, 2016.

II. FISCAL ANALYSIS & ECONOMIC IMPACT STATEMENT

A. FISCAL IMPACT ON STATE GOVERNMENT:

1. Revenues:

Section 381.986, F.S., authorizes DOH to impose an initial application and biennial renewal fee that is sufficient to cover the costs of administering the CMCA. This bill also authorizes DOH to establish fees to implement the registration card system should DOH create such a system. DOH estimates that the patient fees associated with the registry card system will be \$30 per patient and estimates that, initially, the patient pool applying for such cards will be approximately 10,000 to 20,000 patients.⁸⁶

DOH may also generate revenue from any fines assessed against dispensing organizations in violation of the CMCA, which would also positively affect revenues.

⁸⁶ Department of Health, *2016 Agency Legislative Bill Analysis for HB 1313*, January 22, 2016, on file with the Health Quality Subcommittee.

2. Expenditures:

The DOH will incur costs associated with the regulatory standards for the operation, security, and safety of dispensing organizations or the growing, processing, testing, packaging, labeling, dispensing, or transportation of low-THC cannabis. DOH estimates that it will incur approximately \$110,000 to \$120,000 in costs associated with performing inspections and will require 1 full-time equivalent (FTE)⁸⁷ and 1 OPS related to the inspections.⁸⁸ These costs will be offset by the initial application and biennial renewal fees collected under s. 381.986, F.S.

DOH will also incur expenditures associated with implementation of the registration card system; however implementation of this system is permissive and the bill authorizes DOH to establish fees to implement the system. DOH has estimated that creation and implementation of the system will cost between \$350,000 and \$400,000.⁸⁹ Those expenses are related to printing cards, implementing anti-counterfeiting measures, establishing a HIPAA compliant card monitoring system, providing system security, and training and paying registry system personnel.⁹⁰

DOH may also incur minimal costs associated with rulemaking and may incur significant costs associated with litigating rule challenges.⁹¹ DOH estimates that, to retain outside counsel to defend against such challenges, it could incur costs of up to \$600,000.⁹²

DOH may also incur costs of approximately \$65,000 to \$110,000 associated with altering the existing statewide registry to include information required under the bill.⁹³

B. FISCAL IMPACT ON LOCAL GOVERNMENTS:

1. Revenues:

The bill does not appear to have any impact on local government revenues.

2. Expenditures:

The bill does not appear to have any impact on local government expenditures.

C. DIRECT ECONOMIC IMPACT ON PRIVATE SECTOR:

Dispensing organizations may incur costs associated with meeting the bill's new quality, safety, and security standards unless they already meet such standards. Dispensing organizations will also incur costs associated with contracting with testing laboratories. The contract cost is indeterminate and may vary within each dispensing organization.

D. FISCAL COMMENTS:

None.

III. COMMENTS

A. CONSTITUTIONAL ISSUES:

1. Applicability of Municipality/County Mandates Provision:

⁸⁷ The FTE would be an Environmental Specialist II, which would cost DOH approximately \$73,859, including salary, fringe benefits, travel, and other expenses. *Id.*

⁸⁸ *Supra* note 86.

⁸⁹ *Id.*

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² *Id.*

⁹³ *Id.*

Not applicable. This bill does not appear to affect county or municipal governments.

2. Other:

None.

B. RULE-MAKING AUTHORITY:

DOH appears to have sufficient rulemaking authority to carry out its responsibilities under the bill.

C. DRAFTING ISSUES OR OTHER COMMENTS:

None.

IV. AMENDMENTS/ COMMITTEE SUBSTITUTE CHANGES