

SESSION OF 2016

**SUPPLEMENTAL NOTE ON SENATE BILL NO. 489**

As Amended by Senate Committee on Public  
Health and Welfare

**Brief\***

SB 489, as amended, would allow the use of medical hemp preparations to treat or alleviate the following conditions in patients 21 years of age or older: Alzheimer's disease, cancer, multiple sclerosis, post-traumatic stress disorder, or a condition causing seizures, including those characteristic of epilepsy. Patients under 21 years of age would be allowed to use medical hemp preparations only for a condition causing seizures, including those characteristic of epilepsy. Patients would be able to obtain or receive medical hemp preparations only from a facility or organization located and operating outside the state that is verified and approved by the Secretary of Health and Environment (Secretary). The bill also would establish the maximum amount of tetrahydrocannabinol (THC) and the minimum amount of cannabidiol (CBD) for medical hemp preparations. The provisions of the bill would be known and cited as Otis's Law.

Additional bill details follow.

***Definitions (New Section 2)***

Several terms would be defined in the bill, including "department," "parent," and "patient." The additional terms that would be defined are the following:

- "Cannabis" would mean all parts of all varieties of the plant *cannabis sativa L.*;

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\*Supplemental notes are prepared by the Legislative Research Department and do not express legislative intent. The supplemental note and fiscal note for this bill may be accessed on the Internet at <http://www.kslegislature.org>

- “Cardholder” would mean a patient or designated caregiver to whom the Kansas Department of Health and Environment (KDHE) has issued a medical hemp preparation registration card or who has documentation that is deemed to be a medical hemp preparation registration card;
- “Designated caregiver” would mean a person who is at least 21 years old or a parent of the patient; has significant responsibility for managing the well-being of a patient; and has been approved by KDHE to assist a patient in obtaining medical hemp preparations;
- “Medical hemp preparation” would mean:
  - For a patient 21 years of age or older, cannabis plant material that is no more than 1 percent THC by weight and no less than 15 percent CBD by weight or an extract, mixture, or preparation containing cannabis plant material that is no more than 1 percent THC by weight and no less than 15 percent CBD by weight; or
  - For a patient under 21 years of age, cannabis plant material that is no more than 0.3 percent THC by weight and no less than 15 percent CBD by weight or an extract, mixture, or preparation containing cannabis plant material that is no more than 0.3 percent THC by weight and no less than 15 percent CBD by weight;
- “Medical use” would include the acquisition, administration, delivery, possession, purchase, transfer, transportation, or use of hemp preparations and paraphernalia related to the administration of hemp preparations to treat or alleviate a patient cardholder’s qualifying medical condition;

- “Physician” would mean a person who is licensed by the Kansas State Board of Healing Arts (Board) to practice medicine and surgery, who is certified by the Board to issue a written certification for medical hemp preparations pursuant to Section 12 of the bill, and amendments thereto, and who is practicing in a healthcare facility licensed by the state;
- “Qualifying medical condition” would mean:
  - For a patient 21 years of age or older, Alzheimer’s disease, cancer, multiple sclerosis, post-traumatic stress disorder, or a condition causing seizures, including those characteristic of epilepsy; or
  - For a patient under 21 years of age, a condition causing seizures, including those characteristic of epilepsy;
- “Registration card” would mean a medical hemp preparation registration card issued by KDHE;
- “Written certification” would mean a document signed and dated by a physician stating the patient may receive therapeutic or palliative benefit from the use of medical hemp preparations to treat or alleviate a patient’s qualifying medical condition; and
- “Visiting cardholder” would mean a person who meets the qualifications of a cardholder except that the person is not a resident of Kansas, or has been a resident of Kansas for less than 30 days, but does possess a valid registration card, or the equivalent, that allows the person to lawfully possess medical hemp preparations in another state or jurisdiction and has submitted any required documentation to KDHE if such registration is required.

### ***Hemp Preparation Registration Card (New Section 3)***

The KDHE would be required to issue a medical hemp preparation registration card to a patient applicant who is over the age of 18 who:

- Provides KDHE with a written certification signed by a physician that was issued within 90 days immediately preceding the date of an application;
- Pays the fee required by KDHE; and
- Submits the required application or renewal form created by KDHE.

The KDHE would be required to issue a registration card to each patient applicant under the age of 18 whose parent:

- Submits the information required of patients over the age of 18; and
- Agrees to serve as a designated caregiver for the patient.

The KDHE would be required to issue a registration card to each designated caregiver applicant who is designated in a patient's application and submits an application to KDHE on the required form. A patient would be allowed to designate only one caregiver unless it could be demonstrated a greater number would be needed due to the patient's age or medical condition.

The KDHE would have not more than 30 days from receipt of the completed application to issue a registration card with a unique random identification number. Until KDHE issues a decision about an application, a copy of the application, a copy of the certification, and proof the application was submitted would be deemed a registration card. The bill would make provisions for designated registration cards and designated caregiver registration cards until the KDHE applications were made available.

Registration cards would expire one year after date of issuance unless a physician certifies in writing the card should expire at an earlier date.

***KDHE Requirements and Responsibilities  
(New Section 4)***

The KDHE would be required to maintain a confidential list of cardholder information, in accordance with the Health Insurance Portability and Accountability Act of 1996 (HIPAA), exempt from the Kansas Open Records Act. These confidentiality provisions would expire on July 1, 2021, unless the Legislature reviews and reenacts such provisions pursuant to KSA 45-225, and amendments thereto, prior to such expiration date.

The KDHE also would be prohibited from combining or linking a confidential list of cardholder information with any other list or database, or utilizing cardholder information for any purpose not set forth in the bill. The following activities would not be precluded:

- Authorized employees of KDHE accessing the information to perform official duties;
- KDHE employees notifying law enforcement about falsified or fraudulent information submitted to KDHE;
- KDHE employees notifying the Board if KDHE has reasonable suspicion to believe a physician violated the applicable standard of care or committed other violations of Otis's Law;
- KDHE verifying registration cards *via* the secure phone or web-based verification system KDHE would be required to establish; and
- At a cardholder's request, KDHE confirming the cardholder's status to a third party, such as a landlord, school, medical professional, or court.

The KDHE would be allowed to release data to researchers at institutions of higher education and to release aggregate data, provided no identifying information pertaining to cardholders, visiting cardholders, or physicians would be disclosed.

The KDHE would be required to establish a secure phone or web-based verification system within 120 days of the effective date of Otis's Law. The verification system would be required to allow law enforcement personnel to enter a registry identification number and determine whether the number corresponds with a current, valid registration card. The bill would limit the information to be made available in the verification system. Visiting cardholders could be included in the verification system database.

***Rules and Regulations (New Section 5)***

The KDHE would be required to promulgate rules and regulations within 120 days of the effective date of Otis's Law establishing:

- The form and content of registration and renewal applications and registration cards; and
- Procedures for suspending or terminating registration cards of cardholders who commit multiple or serious violations of Otis's Law or any rules and regulations adopted under this law.

The KDHE would be allowed to promulgate rules and regulations as follows:

- Establishing a presumptive maximum quantity of medical hemp preparations a cardholder or a visiting cardholder may possess, provided that:
  - The amount would be a 30-day supply with no refills; and

- A patient would be allowed to apply for a waiver if a physician provides a substantial medical basis in a signed, written statement asserting that, based on the patient's medical history, in the physician's professional judgment, the amount established by KDHE is an insufficient amount to properly alleviate the patient's qualifying medical condition or associated symptoms; and
- Requiring any visiting cardholder to submit a healthcare professional's statement confirming the patient has a qualifying medical condition and documentation demonstrating the visiting cardholder is authorized to possess cannabis or medical hemp preparations in the jurisdiction where such person resides. If KDHE requires the visiting cardholders to submit such documentation, KDHE would be required to issue confirmation to the individual no later than seven calendar days after the documentation is submitted.

#### ***Registration Card Fees (New Section 6)***

The bill would require KDHE to adopt rules and regulations to establish fees for applications and registration cards in an amount no greater than reasonably necessary to cover the cost KDHE incurs to implement this law. The fees for registration cards or visiting cardholder documentation would be required to be no greater than the amount reasonably necessary to cover the cost of processing registration cards. KDHE would be required to incorporate a sliding scale for cardholders who receive Medicaid, Supplemental Security Income, or Social Security Disability Insurance benefits for any fee structure. The following statutory caps would be established:

- Individual medical hemp preparation registration card – \$75; and

- Visiting cardholder documentation – \$80.

### ***Criminal Provisions (New Section 7)***

A cardholder or visiting cardholder would not be subject to arrest, prosecution, or denial of any right or privilege for the medical use of hemp preparations, being in the presence or vicinity of the use of medical hemp preparations, or assisting a patient with a registration card in the act of using or administering hemp.

Mere possession of, or application for, a registration card would not constitute probable cause or reasonable suspicion. Unless probable cause exists on other grounds, the use or the possession of, or application for, a registration card to support the search of the person, property, or home of the person possessing or applying for the registration card would be prohibited.

For state law purposes, the use of medical hemp preparations by a cardholder or visiting cardholder would be considered lawful if undertaken according to Otis's Law.

### ***Medical Care and Parenting (New Section 8)***

For the purposes of medical care, including organ and tissue transplants, a patient's medical use of hemp preparations would be the equivalent of the authorized use of any other medication prescribed by a physician and would not constitute the use of an illicit substance.

A person otherwise entitled to custody of or visitation or parenting time with a minor would not be denied such a right unless the person's actions in relation to medical hemp preparations were such that they created an unreasonable danger to the safety of a minor as established by clear and convincing evidence.



***Penalties and Insurance Costs (New Section 9)***

Nothing in Otis's Law would authorize a person to engage in the following conduct:

- Undertaking a task under the influence of medical hemp preparations when doing so would constitute negligence or professional malpractice; or
- Operating, navigating, or being in actual physical control of a motor vehicle, aircraft, or motorboat while impaired by medical hemp preparations.

Nothing in Otis's Law would require a government medical assistance program or private insurer to reimburse a person for costs associated with the use of medical hemp preparations.

***Required Verification and Approval of Medical Hemp Preparation Facilities or Organizations (New Section 10)***

The bill would require a patient cardholder to obtain or receive medical hemp preparations only from a facility or organization located and operating outside of the state of Kansas and verified and approved by the Secretary. A violation of this requirement would constitute unlawful possession of a controlled substance and a violator would be subject to the statutory penalties for such violation.

The Secretary would be required to adopt rules and regulations regarding the verification and approval of dispensing facilities or organizations located outside of the state of Kansas from which patient cardholders could obtain or receive medical hemp preparations. The rules and regulations would be required to include, at a minimum, requirements that the dispensing facility or organization has procedures to:

- Maintain accurate recordkeeping;
- Verify a patient cardholder's documentation purporting to allow such cardholder to obtain or possess medical hemp preparations;
- Package and label accurately any medical hemp preparations dispensed by the organization or facility, including sealing the preparations in a child-resistant package and indicating the preparation's ingredients and percentages of THC and CBD by weight;
- Test samples of medical hemp preparations randomly to verify accuracy of labeling for contents and potency; and
- Initiate and facilitate mandatory and voluntary recalls of medical hemp preparations.

***Severability (New Section 11)***

If any section of the bill were found to be invalid, the bill would state such invalidity would not affect the other sections.

***Medical Hemp Preparation Certification (New Section 12)***

The bill would establish the designation of medical hemp preparation certification. The Board would be authorized to issue a medical hemp preparation certification to any person who holds an active license to practice medicine and surgery issued by the Board and who makes written application for such certification on a form provided by the Board and remits the established fee. Every holder of a medical hemp preparation certification would be required by the Board to acknowledge and agree, in writing, to abide by the guidelines set forth by the Board's policy statement regarding experimental treatments.

The certification would be canceled on the date established by Board rules and regulations which could provide renewal throughout the year on a continuing basis. Any certification would expire no later than one year after the date of issuance. The provisions for notice of cancellation, cancellation, renewal, and reinstatement of a license in KSA 65-2809, and amendments thereto, would apply to any medical hemp preparation certification.

The Board would be required to adopt rules and regulations necessary to administer medical hemp preparation certification. The provisions related to medical hemp preparation certification would be part of and supplemental to the Kansas Healing Arts Act.

***Fees for Medical Hemp Preparation Certification  
(Section 14)***

Fees for medical hemp preparation certification would be established by the Board by rules and regulations and collected by the Board in an amount not to exceed \$2,000 annually. The Board would be required to review annually the costs associated with issuing the certifications and to adjust the fee to cover the costs of administering the certification program, not to exceed \$2,000 annually.

***Health Care Stabilization Fund Liability (Section 13)***

Notwithstanding any provision in the Health Care Provider Insurance Availability Act (HCPAAA), the Health Care Stabilization Fund (Fund) would not be liable for any claims against a healthcare provider issuing a written certification for a medical hemp preparation pursuant to Otis's Law. The Fund could pay reasonable and necessary expenses for attorney fees incurred in defending the Fund against such a claim. The Fund would be allowed to recover all or a portion of the attorney fees if an adverse judgment is returned against the health care provider for damages resulting from issuing a

written certification for a medical hemp preparation under Otis's Law.

## **Background**

The bill was introduced by the Senate Committee on Ways and Means. The bill was referred to the Senate Committee on Public Health and Welfare. At the Senate Committee hearing, Representative Wilson and five private citizens testified in support of the bill. Representative Wilson stated Otis's Law is a limited high-CBC, low-THC medical hemp bill designed to allow regulated access to products which contain the active ingredient CBD, which has no intoxicating effects. Representative Wilson stated the bill was carefully crafted to balance the need for positive health outcomes with the need to protect public and patient safety. The private citizens generally testified legalization of medical hemp preparation would provide an alternative treatment to those who have not been helped by traditional medical treatments. Written-only proponent testimony was provided by six private citizens.

Opponent testimony was provided by a physician and Chairman of the Institute on Global Drug Policy and representatives from the Kansas Association of Chiefs of Police, Kansas Sheriffs' Association, and Kansas Peace Officers Association and the Kansas Family Partnership. Written-only opponent testimony was provided by the Director of the Kansas Bureau of Investigation. Opponents testified the bill establishes high THC limits without specifying a minimum amount of CBD, would lead to the inevitable expansion to legalization of stronger cannabis and, to date, there is no evidence of any medical disorder or group of suffering patients for which marijuana or CBD is the only alternative or is superior to the available medicines.

Neutral testimony was provided by representatives of Children's Mercy Hospital, the Kansas Health Institute, and the Kansas Pharmacists Association.

The Senate Committee amended the bill by eliminating the establishment of medical hemp establishments, registered medical hemp preparation centers, and registered medical hemp testing laboratories and removing all language related to those facilities. The Senate Committee also amended the bill to require medical hemp preparations be obtained only from a facility or organization located and operating outside the state of Kansas verified and approved by the Secretary; establish penalties for violation of Otis's Law; and require the Secretary to adopt rules and regulations regarding the verification and approval of dispensing facilities or organizations from which medical hemp preparations could be obtained or received. Additionally, the Senate Committee amended the definitions of a "physician" to add those practicing in a healthcare facility licensed by the state and certified by the Board to recommend hemp preparations, "cannabis" to exclude the amount of THC, and "qualifying medical condition" to allow patients under the age of 21 to use medical hemp preparations only for a condition causing seizures, including those characteristic of epilepsy. It also amended the bill to establish the designation of medical hemp preparation certification, the certification process, and the fees for certification; establish the maximum allowable amounts of THC in medical hemp preparations for a patient 21 years of age or older and for a patient under 21 years of age and the minimum amount of CDB for all patients; reduce the amount of medical hemp preparations a cardholder or visiting cardholder may possess; clarify the applicability limits of the HCPIAA; amend the bill title; and make technical amendments.

According to the fiscal note prepared by the Division of the Budget on the bill, as introduced, the Board states enactment of the bill could result in additional complaints regarding practitioners alleged to have violated provisions of the bill. An increase in complaints or corresponding investigations that would need to be performed by Board staff could result if medical diagnoses do not meet the standard of care, are delayed, or are missed. The Board indicates agency staff is currently at full workload capacity, so any increase in

complaints and investigations would require an increase in FTE positions, as well as additional expenses for office supplies and equipment. The Board indicates, because the bill establishes a new program, it would be difficult to estimate the number of practitioners who would participate in the provision of services related to medical hemp, so a precise fiscal effect is unknown.

The Department of Revenue indicates passage of the bill would have no fiscal or administrative effect on operations because the possession of marijuana and substances manufactured from marijuana under the bill's provisions would be exempt from the Kansas tax on marijuana and controlled substances.

The KDHE estimates passage of the bill would require 2.00 additional FTE positions and an increase of \$445,000 in State General Fund expenditures in FY 2017; however, KDHE is unable to estimate any new revenue related to the passage of the bill. The expenditure increase would include: salaries and wages for an Inspector FTE position (\$65,000) and a Public Service Administrator position (\$60,000); operating expenditures for the two FTE positions (\$10,000); a HIPAA compliant reporting and registration system that would include identification management software (\$300,000); and funding for background checks for laboratory, production, and distribution employees (\$10,000). The ongoing costs in FY 2018 and subsequent years would include \$75,000 for system maintenance, salaries and wages of \$125,000 for the two positions, and \$10,000 for background checks for a total of \$210,000. Any fiscal effect associated with the bill is not reflected in *The FY 2017 Governor's Budget Report*.