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DATE PREPARED: December 03, 2015
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LB 643

Revision: 02

FISCAL NOTE

Revised for the 2016 Legislative Session

LEGISLATIVE FISCAL ANALYST ESTIMATE

ESTIMATE OF FISCAL IMPACT – STATE AGENCIES (See narrative for political subdivision estimates)

	FY 2016-17		FY 2017-18	
	EXPENDITURES	REVENUE	EXPENDITURES	REVENUE
GENERAL FUNDS	1,352,138		See Below	
CASH FUNDS	40,000	40,000	See Below	See Below
FEDERAL FUNDS				
OTHER FUNDS				
TOTAL FUNDS	1,392,138	40,000	1,038,708	See Below

Any Fiscal Notes received from state agencies and political subdivisions are attached following the Legislative Fiscal Analyst Estimate.

This bill creates the Medical Cannabis Act. This bill allows for the use of cannabis in treating or alleviating symptoms associated with a variety of debilitating medical conditions. It is assumed for this fiscal note that all dates are moved back one year. The bill contains the following provision:

--Register two manufacturers by December 1, 2016 or notify the committee as to why. One six month extension is allowed. Each manufacturer shall operate four distribution facilities with distribution beginning by July 1, 2017, with one six-month extension.
-- Review and report on scientific and medical reports.
-- Consult with the independent lab contracted by the manufacturers. The department is required to approve the lab before the manufacturer can enter into the contract.
-- Establish a registry program to evaluate data on patient demographics, effective treatment options, clinical outcomes and quality of life outcomes.
-- Establish rules and regulations for the registry by January 1, 2017. Patient shall apply to the registry and pay an annual fee of $200 or $50 on public assistance or SSI.
-- -- Create a certification to be used by health care professionals to certify a patient qualifies medically and whether the patient is unable to self-administer or acquire medication.
-- Supervise participation of practitioners in conducting patient treatment and medical records reporting in a manner that ensures stringent security and record-keeping requirements.
-- Develop safety criteria for patient's participation in the registry.
-- Conduct research and studies based on data from medical records submitted to the registry. The department may contract with a third party to complete the requirements.
-- Develop a patient application for enrollment into the registry program.
-- Develop a disclosure form.
-- Register designated caregivers. Conduct criminal background checks on designated caregivers. The cost borne by applicant.

A five-member Medical Cannabis Board is established. Costs are estimated to be $15,840 in FY 17 and $10,560 in FY 18.

The manufacturer's application fee is $20,000 in FY 17. The revenue would be $40,000. The annual fees from the manufacturers shall be established equal to the cost of regulating and inspecting the manufacturer in that year. Employees of the manufacturer shall submit to a criminal records check paid for by the employee. Manufacturer shall submit and annual certified financial audit. The costs for the review shall be paid by the manufacturer. Additional revenue would be generated from patients applying to the registry in FY 18. FY 18 revenue costs are difficult to determine. The act provides for a six-month extension for the registration of the manufacturer and another six month extension for the manufacturers to have distribution sites operating. It is also difficult to determine the estimated number of patients who will sign up for the registry.

The Department of Health and Human Services will need eight regulatory FTEs. Salary and benefit costs will be $547,802 in FY 16 and FY 17. The patient registry is estimated to cost $500,000 in FY 16 and $150,000 for ongoing maintenance. Contractual costs, other operating costs and the costs for the Medical Cannabis Board are estimated to be $462,423 in FY 16 and $456,723 in FY 17. The

total cost of the bill in the first two years is projected to be $1,352,138 General Funds and $40,000 cash in FY 17 and $1,038,708 in FY18. The bill requires all the costs to be covered by fees. If adequate revenue is not generated, the shortfall would need to be covered by General Funds.

LB(1) 643 AM1254 FISCAL NOTE 2016

ESTIMATE PROVIDED BY STATE AGENCY OR POLITICAL SUBDIVISION

State Agency or Political Subdivision Name:(2) Department of Health and Human Services

Prepared by: (3) Pat Weber | Date Prepared:(4) 12-2-15 | Phone: (5) 471-6351

	FY 2016-2017		FY 2017-2018	
	EXPENDITURES	REVENUE	EXPENDITURES	REVENUE
GENERAL FUNDS	$1,411,267		$1,055,214	
CASH FUNDS	$123,120	$40,000	$123,120	
FEDERAL FUNDS				
OTHER FUNDS				
TOTAL FUNDS	$1,534,387	$40,000	$1,178,334	$0

Return by date specified or 72 hours prior to public hearing, whichever is earlier.

Explanation of Estimate:

LB 643 creates the Medical Cannabis Act to regulate the prescribing and medical use of cannabis for treatment of patients with debilitating medical conditions. The purpose of Medical Cannabis Care Act is to protect patients with debilitating medical conditions, practitioners and providers from criminal prosecution.

Acceptable delivery methods of the medical cannabis described with the exception of smoking which is prohibited.

Physicians (health care practitioner) would be permitted to prescribe cannabis to persons having a registration document; within a bona fide doctor-patient relationship and meet the qualifying conditions as outlined in the Medical Cannabis Act.

Definition and registering requirements of a designated caregiver

Register two manufactures for production of all medical cannabis with the State of Nebraska. Adopt rules and regulations necessary for a manufacturer to begin distribution of medical cannabis to patients.

The department shall review and publicly report the existing medical and scientific literature regarding the range of recommended dosages for each qualifying medical condition and the range of chemical compositions of any plant of the genus cannabis that will likely be medically beneficial for each of the qualifying medical conditions. The department will report the range of recommended dosages for each qualifying medical condition, the range of chemical compositions that will likely be medically beneficial, and any risks of noncannabis drug interactions. The department shall consult with each manufacturer on an annual basis on medical cannabis offered by the manufacturer. The department shall publish a list of medical cannabis offered by each manufacturer on the department's web site.

The department shall establish a registry program to evaluate data on patient demographics, effective treatment options,clinical outcomes, and quality-of-life outcomes for the purpose of reporting on the benefits, risks, and outcomes regarding patients with a qualifying medical condition engaged in the therapeutic use of medical cannabis.

The department shall:

(a) Give notice of the registry program to health care practitioners in the state who are eligible to serve as health care practitioners and explain the purposes and requirements of the registry program. In order to be eligible, a health care practitioner shall not have a financial interest in a manufacturer;

(b) Allow each health care practitioner who meets or agrees to meet the requirements of the registry program, and who requests to participate, to be included in the registry program to collect data for the registry program;

(c) Provide explanatory information and assistance to each health care practitioner in understanding the nature of therapeutic use of medical cannabis within the requirements of the registry program;

(d) Create and provide a certification to be used by a health care practitioner for the practitioner to certify whether a patient has been diagnosed with a qualifying medical condition and include in the certification an option for the practitioner to certify whether the patient, in the health care practitioner's medical opinion, has a developmental disability or a physical disability and, as a result of that disability, the patient is unable to self-administer medication or acquire medical cannabis from a distribution facility;

(e) Supervise the participation of the health care practitioner in conducting patient treatment and medical records reporting in a manner that ensures stringent security and record-keeping requirements and that prevents the unauthorized release of private data;

(f) Develop safety criteria for patients with a qualifying medical condition as a requirement of the patient's participation in the registry program in order to prevent the patient from undertaking any task under the influence of medical cannabis that would constitute negligence or professional malpractice on the part of the patient; and

(g) Conduct research and studies based on data from medical records submitted to the registry program and submit reports electronically on intermediate or final research results to the Legislature. The department may contract with a third party to complete the requirements of this subdivision. Any reports submitted shall comply with this act.

Licensed health care professionals would not be subject to disciplinary action by licensing boards for being in the vicinity of medical cannabis usage, nor for assisting a patient to use cannabis or administer cannabis.

The bill requires, of the department, a system of verification of the qualifying patients and a disclosure form which will be a requirement for the patient. The bill authorizes department of Health and Human Services to collect fees for initial issuance and renewal of registrations to support the cost of implementing the Act.

There would be anti-discrimination provisions.

Each manufacturer shall report to the department on a monthly basis the following information on each individual patient for the month prior to the report:

(1) The amount and dosages of medical cannabis distributed;

(2) The chemical composition of the medical cannabis; and

(3) The tracking number assigned to any medical cannabis distributed.

The manufacturer shall submit the results of an annual certified financial audit to the department no later than May 1 of each year. The annual audit shall be conducted by an independent certified public accountant. The costs of the audit shall be the responsibility of the manufacturer. Results of the audit shall be provided to the manufacturer and the department. The department may also require another audit of the manufacturer by a certified public accountant chosen by the department with the costs of the audit paid by the manufacturer.

(1) The department or its designee may examine the business affairs and conditions of any manufacturer, including, but not limited to, a review of the financing, budget, revenue, sales, and pricing.

(2) An examination may cover the manufacturer's business affairs, practices, and conditions, including, but not limited to, a review of the financing, budget, revenue, sales, and pricing. The department shall determine the nature and scope of each examination and in so doing shall take into account all available relevant factors concerning the financial and business affairs, practices, and conditions of the manufacturer. The costs incurred by the department in conducting an examination shall be paid for by the manufacturer.

(3) When making an examination under this section, the department may retain attorneys, appraisers, independent economists, independent certified public accountants, or other professionals and specialists as designees. A certified public accountant retained by the department shall not be the same certified public accountant providing the annual certified financial audit under section 46 of this act.

(4) The department shall make a report of an examination and provide a copy to the manufacturer. The department shall then post a copy of the report on its web site.

The bill requires the creation of an 5 member Medical Cannabis Board to advise the Department regarding administration of the Act and recommendations for legislative changes regarding regulation of medical cannabis.

The department would promulgate regulations and rules pursuant to the statute for manufacturers, practitioners, patients, and care givers as outlined in the Medical Cannabis Act and, establish fees, and establish policies and procedures: establish a verification system.

The bill requires Department of Health and Human Services to provide an annual report to the Legislature and makes information in the verification system confidential.

Revenue:
Except for the application fee of $20,000 for the manufacture, the revenue that can be collected cannot be determine at this time because of the unknown number of patients that would qualify under the Act.

Expenditures:

Program 262
There will be a fiscal impact to the Department of Health and Human Services. Additional staffing resources needed to implement this legislation include a DHHS Program Manager II, a Health Licensing Coordinator, a Health Licensing Specialist, an IT Business Systems Analyst, a Pharmacy Inspector, an Epidemiology Coordinator, and a Staff Assistant II. There will be the cost of establishing and maintaining the web-based verification system required by the bill. The bill includes very specific requirements for the functionality of the verification system, a system for gathering data for research and it is unknown whether such a system currently exists or whether it would need to be created.

It is estimated that the costs for technology are estimated at $500,000 for the procurement of a system in FY2016-17 and $150,000 for FY2017-18 maintenance of the system in each out year.

It is estimated that the cost for examination of the manufacture's business affairs, practices, and conditions, including, but not limited to, a review of the financing, budget, revenue, sales, and pricing under this section, the department may retain attorneys, appraisers, independent economists, independent certified public accountants, or other professionals and specialists as designees, would be approximately $100,000 per review or $200,000 annually.

Indirect cost used to cover items that are not directly charged to the program covers such items as telephone, supplies, printing, legal, computers, and covers TSB. $248,383 per year.

The travel cost for the medical cannabis board in is estimated to meet 12 times in FY2016-2017 and the cost estimated at $15,840 in FY2017-18 and meeting 8 times for FY2017-18 for an estimated cost of $10,560. These estimates include Board subsistence for 5 members averaging 300 miles round trip with an overnight stay for each of meeting.

Total cost for program 262 for FY2016-17 is $1,411,267 and for FY2017-18 is $1,055,214.

Program 178
A Professional & Occupational Investigator/RN will be need to handle the investigation of Health Professionals.

Total Cost for Program 178 for FY2016-17 is $123,120 and for FY2017-18 is $123,120

MAJOR OBJECTS OF EXPENDITURE

PERSONAL SERVICES:

POSITION TITLE	NUMBER OF POSITIONS 15-16	16-17	2015-2016 EXPENDITURES	2016-2017 EXPENDITURES
X62462 Professional; & Occupational Investigator/RN	1.00	1.00	$51,447	$51,447
V78792 DHHS Program Manager II	1.00	1.00	$60,690	$60,690
H74932 Epidemiology Coordinator	1.00	1.00	$58,924	$58,924
X01740 Health Licensing Coordinator	1.00	1.00	$39,339	$39,339
X0750 Health Licensing Specialist	1.00	1.00	$31,978	$31,978
N77760 Pharmacy Inspector	1.00	1.00	$93,475	$93,475
A107081 IT Business System Analyst	1.00	1.00	$49,036	$49,036
V01842 Staff Assistant II	1.00	1.00	$37,708	$37,708
Per Diem Employees (board members)	5.00	5.00	$1,200	$800
Benefits			$135,701	$135,573
Operating			$959,049	$608,804
Travel			$15,840	$10,560
Capital Outlay				
Aid				
Capital Improvements				
TOTAL			$1,534,387	$1,178,334