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# FISCAL IMPACT REPORT

	Armstrong,D/	<b>ORIGINAL DATE</b>	02/07/17		
SPONSOR	McCamley	LAST UPDATED	03/01/17	HB	155/aHAFC

SHORT TITLE Medical Cannabis Research

ANALYST Daly

SB

#### **ESTIMATED ADDITIONAL OPERATING BUDGET IMPACT (dollars in thousands)**

	FY17	FY18	FY19	3 Year Total Cost	Recurring or Nonrecurring	Fund Affected
Total	\$270.0	\$270.0	\$270.0	\$810.0	Recurring	DOH Operating Funds

(Parenthesis () Indicate Expenditure Decreases)

Relates to HB 89, SB 278, HB 102, and SB 8

# SOURCES OF INFORMATION

LFC Files

#### **Responses Received From**

Department of Health (DOH) University of New Mexico Health Sciences Center (HSC) Administrative Office of the Courts (AOC) Medical Board (MB) Office of the Attorney General (OAG)

#### SUMMARY

#### Synopsis of HAFC Amendments

The House Appropriations and Finance Committee amendments to HB 155 strike language providing for a funding stream (transfer of 10 percent of the fees collected each month from the medical cannabis program) for the new cannabis research fund. They also make any monies in that new fund subject to appropriation, and strike language providing mileage and per diem reimbursements to members of the newly created Cannabis Research Advisory Council.

In light of the funding change, the revenue table has been removed.

# Synopsis of Original Bill

House Bill 155 amends sections of existing law to provide for research into the production, uses, effects and efficiency of medical cannabis at the University of New Mexico Health Sciences Center (HSC). It creates a Cannabis Research Advisory Council at HSC to advise it on that research. The Council is appointed by the chancellor for health sciences and includes a qualified patient, a licensed producer, a practitioner, and a representative each from a licensed marijuana testing laboratory in New Mexico and from DOH. HB 155 establishes a Cannabis Research Fund and appropriates 10 percent of the fees collected on a monthly basis for the medical marijuana program from the cannabis fund to this new fund.

Research conducted must be in accordance with institutional and federal requirements governing protect of human subjects, and must be approved by an institutional review board (IRB). HB 155 also contains language protecting researchers from criminal liability when conducting this research. The chancellor must provide annual reports to the Legislative Finance Committee, as well as triennial reports (beginning in late 2019) to the Legislature's health and human services committee.

This bill contains an effective date of July 1, 2017.

# FISCAL IMPLICATIONS

This bill creates a new fund and provides for continuing appropriations. The LFC has concerns with including continuing appropriation language in the statutory provisions for newly created funds, as earmarking reduces the ability of the legislature to establish spending priorities.

DOH reports that based on the current budget, the medical cannabis research fund would receive approximately \$270 thousand annually. It believes that level of funding would be insufficient to support high quality research, noting that the indirect costs of conducting medical research on a clinical population are as high as 50 to 100 percent of the direct research costs.

DOH also notes the appropriation contained in HB 155 would decrease the budget available for administration of the medical cannabis program, which could result in reductions in staffing levels, impacting both current administrative operations and ultimately the program's mission of providing safe access to safe medicine to patients in the program.

# SIGNIFICANT ISSUES

DOH states that although it has concerns related to HB 155, it supports research into the efficacy of medical cannabis. It explains the benefits of this research:

Producers, practitioners and patients have an interest in understanding: 1) what clinical medical conditions and symptoms may be improved by medical cannabis and/or cannabis-derived products; 2) what specific components of medical cannabis are responsible for its clinical efficacy in specific medical conditions; 3) how the medical benefits of cannabis can be maximized in the different clinical conditions for which it is prescribed therapeutically; and 4) what the hazards are of using medical cannabis and/or certain of its components at high dosages or with certain medical conditions.

#### House Bill 155/aHAFC – Page 3

It provides this analysis concerning funding and conducting such research:

It has been extremely difficult for researchers to obtain permission and funding from the federal government to pursue these questions, owing to the classification of cannabis as a Schedule I drug, i.e. "having no medical use." HB155 attempts to create a means by which this research could be undertaken in New Mexico independent of federal funding.

MB adds this perspective:

Cannabis, and its related compounds, have been classified as Schedule 1 controlled substances, and have long been defined as having no currently accepted medical use in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse. It is not clear, in HB 155, whether or not the Federal Food and Drug Administration has changed its approach to research conducted on cannabis. Given the general lack of scientific data characterizing the appropriate medical use, effects, complications, and toxicity, it would be an important contribution to the understanding of cannabis use and safety to permit more appropriate prescription of cannabis and its derivatives.

#### But HSC warns:

The federal, DEA, and FDA regulatory burdens are very high to perform cannabis research (as opposed to research that studies how to prevent or reverse the effects of cannabis, or how to prevent the use in at risk groups). As a result, it is very unlikely that the HSC would be able to perform much research related to the restrictive nature of the bill. HSC would be able to perform other types of biomedical research, but the allowable research that would be funded is very narrow and restrictive.

Cannabis has severe negative effects, including mental health disease in young adults and adolescents. The bill does not cover research to prevent or reverse the effects of cannabis use--only research on the use of cannabis. As a result, key research areas are prevented or not allowed to be funded.

HSC points out that HB155 does not include cannabinoids (i.e. the chemicals in the plant), only the plant cannabis. Biomedical research including clinical trials and scientific studies are focused on cannabinoids, and a path toward drugs that have the good effects of cannabis while avoiding its bad effects. It recommends the bill provide for research into the use of cannabinoids or related compounds in the treatment of human disease.

DOH questions how an IRB can approve research projects given existing federal law that outlaws cannabis. OAG advises the legal immunization provided researchers in HB 155 does not avoid liability under federal law. DOH notes that that while that legal protection is provided researchers, the limitations that are in place for all other parties involved in the medical marijuana program are not applied to researchers, such as restrictions limiting the amounts a person can possess, and how the product is kept secure and may be transported. DOH also suggests restrictions barring members of the cannabis research advisory council from receiving funding or participating in a research project under HB 155 may be appropriate. As to membership on that council, MB suggests an individual with a background in pharmacology, toxicology, biochemistry and physiology could be a valuable, specified addition.

#### House Bill 155/aHAFC – Page 4

AOC notes there is no provision for DOH licensing or identification cards for researchers comparable to those issued patients and caregivers, which documentation may prevent arrests or ticketing of researchers.

### RELATIONSHIP

HB 155 relates to: HB 89 – Cannabis Revenue & Freedom Act; HB 102 – Marijuana Tax Act; SB 8 – Medical Marijuana Changes

### **OTHER SUBSTANTIVE ISSUES**

HSC notes that it can study cannabis, but not using methodology that includes smoking on campus as it is a non-smoking campus. It also reports that cannabis clinical trials in Portugal resulted in five deaths.

DOH recommends that legislation authorizing cannabis-related research and creating a funding stream should allow for use of RFP process, rather than specifying an institution to conduct the research.

# WHAT WILL BE THE CONSEQUENCES OF NOT ENACTING THIS BILL

MB comments that failure to enact this bill will perpetuate the existing lack of solid research (both basic and clinical) and knowledge of this family of compounds.

MD/al