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## FISCAL IMPACT REPORT

**ORIGINAL DATE**  
**SPONSOR** Armstrong      **LAST UPDATED** 02/23/15      **HB** 466

**SHORT TITLE** Medical Cannabis Research, Board & Fund      **SB** \_\_\_\_\_

**ANALYST** Dunbar

### REVENUE (dollars in thousands)

Estimated Revenue			Recurring or Nonrecurring	Fund Affected
FY15	FY16	FY17		
	*Indeterminate	*Indeterminate	Recurring	Cannabis Research Fund

(Parenthesis ( ) Indicate Revenue Decreases)

\*Reference is made to Fiscal Implications

Duplicates SB 516  
 Relates to HB 160  
 Relates to SJR 2

Relates to Appropriation in the General Appropriation Act

### SOURCES OF INFORMATION

Responses Received From  
 Department of Health (DOH)  
 State Treasure Office (STO)  
 University of New Mexico (UNM)

### SUMMARY

#### Synopsis of Bill

House Bill 466 establishes a “Cannabis Research Fund,” within the Department of Health to be administered by DOH, for the purpose of supporting research into the uses, effects and efficacy of medical cannabis. The fund would be created by transferring ten percent of the monthly fees collected by the medical cannabis program, under the Lynn and Erin Compassionate Use Act, to the medical cannabis research fund.

HB 466 also establishes a “Cannabis Research Board” within DOH, consisting of three members holding five year terms, appointed by the Secretary of Health. The Secretary of Health would serve as board chair. One member would have a doctoral/terminal degree in a social or

behavioral science; one would hold a similar degree in a biomedical science and one would be a practitioner. Money in the cannabis research fund would be appropriated to the cannabis research board and distributed to fund medical cannabis research projects.

The Cannabis Research Board would meet, identify researchers conducting research pursuant to HB 466, ensure that research conducted under this program is approved by an institutional review board and that it complies with requirements protecting human subjects.

HB 466 offers exemption from criminal and civil penalties to researchers for the production, possession, distribution or dispensing of cannabis if this activity was solely for the purpose of conducting research pursuant to the amended Lynn and Erin Compassionate Use Act.

The board shall oversee research conducted on the use, effects and efficacy of medical cannabis. It shall report annually to the LFC and every three years to the Health and Human Services Committee.

### **FISCAL IMPLICATIONS**

The DOH reports that the fund does not contain a fund balance. The current operating budget reflects \$777,000. The appropriation request for FY 16 contains a revenue increase to \$1.4 million. This increase in revenue is due to a change in regulations which take effect on 02/27/15. These changes allow licenses producers to increase plant productions by 50 at a cost of \$10,000. The total increase of plants allowed is 450. Personal production licenses fees are \$30. Most of the fees are waived based on the most current poverty guidelines.

The revenue generated will be used to hire three investigators and two office staff. Staff is needed to keep up with the applications of 1000 patients per month. These applications include new applications and renewal of applications. The point noted by DOH below pertains to the insufficient amount of funds the Cannabis Research Board will acquire to achieve its purpose.

DOH did not submit Fund Balance Projections (5-10) as required with its appropriation request nor has it submitted this information in response to this bill. As a result, LFC staff are unable to evaluate the impact of this bill on the Medical Cannabis Program.

HB 466 creates the Cannabis Research Fund in the state treasury. The fund consists of money transferred from the medical cannabis fund, appropriations, income from investment of the fund and money otherwise accruing to the fund. Money in the fund is appropriated to the Cannabis Research Board for research related to medical cannabis and provided for in the Lynn and Erin Compassionate Use Act. Any balance remaining in the fund at the end of the fiscal year shall not revert to the general fund.

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.

The proposal to divert funds from the Medical Cannabis Program to conduct the activities for HB 466 is not part of the DOH Executive Budget. DOH states that the cost to the Department of properly conducting the activities proposed in HB 466 are not adequately covered by the bill.

DOH recognizes that the proposed funding derived from diverting 10 percent of the Medical Cannabis Program (MCP) funds to support the Cannabis Research Board would be insufficient to support high quality research that would contribute meaningfully to a nuanced and deep understanding of medical cannabis effects and hazards.

DOH mentions that the indirect costs of conducting medical research on a clinical population incur large indirect costs, as high as 50-100 percent of the direct research costs. These are incurred by both the researcher and the organization overseeing the research. Colorado has created a cannabis research program that is funded by tax revenues from cannabis sales; its proposed budget is up to 8 million dollars. The MCP relies entirely on the collection of fee revenue to fund its operations, and the program receives no general funds. DOH is concerned that ten percent would represent a significant dent in the Program's already limited budget; as well as, the amount would be insufficient to conduct clinical or other studies on the uses, effects and efficacy of medical cannabis.

### **SIGNIFICANT ISSUES**

DOH is concerned that the legalization of cannabis production and distribution for medical use in New Mexico and 21 other states and the District of Columbia in the past few years has created a surge in activity to create various specific strains of medical cannabis with amplified concentrations of one or more specific targeted "cannabinoid" chemicals. These modified cannabis strains, as well as extracts, concentrates and food products that further increase cannabinoid concentration and dose, are being produced and sold to patients, despite the paucity of knowledge about dose effects, efficacy of the different chemicals to treat specific medical conditions and adverse effects on individuals receiving these substances.

DOH acknowledges that 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." HB 466 attempts to create a means by which this research could be undertaken in New Mexico independent of federal funding.

HB 466 amends subsection 26-2B-4(E) to include an immunity clause for members of the Cannabis Research Board and anyone assisting the board, to permit them to accomplish their research. However, the AG indicates that the immunity afforded to these individuals is likely greater than that afforded to others under the Lynn and Erin Compassionate Use Act. Immunity under the Act protects the recipient against arrest, prosecution or civil penalty. The AG goes on to say that the immunity afforded to the Cannabis Research Board, and anyone assisting the board, includes protection against denial of any "right or privilege." Since no further definition is included as to what "rights or privileges" are referred to by this clause, such immunity may be considered unconstitutionally vague. Rights and privileges may be imposed or denied in many contexts, including employment, constitutional, parental, etc.

### **ADMINISTRATIVE IMPLICATIONS**

The bill would administratively attach a "Cannabis Research Board" to DOH, requiring that the Department appoint members to the board and hold hearings. HB 466 would substantially increase the need for DOH medical staffing to oversee patients involved in clinical research trials. Grant management and other overhead activities that are not included in HB 466. Funding this project through the 10 percent diversion of MCP funds would mean the elimination of a

position within MCP and would likely impact the program's ability to meet regulatory requirements.

## **DUPLICATION; RELATIONSHIP**

Duplicates SB 516

Relates to HB 160 which enacts the "Cannabis Revenue and Freedom Act" (CRFA), which allows for the legal production, processing and sale (to persons  $\geq$  21 years) of industrial hemp, marijuana and marijuana products.

Relates to SJR 2 which allows for possession and personal use of marijuana.

## **TECHNICAL ISSUES**

DOH realizes that the proposed attachment of the Cannabis Research Board to DOH seems inappropriate. The research appears to fall more appropriately within the mission, expertise and activity of the state's biomedical and behavioral research institutions (e.g. University of New Mexico, New Mexico State University, et al), which already have the administrative structures, staffing and mechanisms to evaluate, select and oversee this research activity safely and effectively.

HB 466 does not identify the type or scope of research to be conducted. However, if clinical or biomedical research were indicated to determine the uses, effects and efficacy of medical cannabis, DOH has no Institutional Review Board to oversee or approve research conducted on human subjects, or biomedical research personnel to properly conduct oversight of clinical trials in order to ensure the safety of patients involved in clinical trials of pharmacologic agents on medically fragile populations.

HB 466 adds a new activity that is outside of the DOH mission; namely, that of funding and overseeing clinical research trials of pharmaceutical agents on medically fragile populations. This would be taken on with no additional resources or staffing to do so.

## **ALTERNATIVES**

Removing the phrase "or denied any right or privilege" in 26-2B-4(E) would resolve the ambiguity of the statute and ensure consistency of the immunity afforded by the Lynn and Erin Compassionate Use Act.

BD/bb/aml/je