Second Regular Session Sixty-ninth General Assembly STATE OF COLORADO

REREVISED

This Version Includes All Amendments Adopted in the Second House SENATE BILL 14-155

LLS NO. 14-0850.01 Michael Dohr x4347

SENATE SPONSORSHIP

Steadman, Hodge, Lambert

HOUSE SPONSORSHIP

May and Duran, Gerou

Senate Committees Health & Human Services Finance Appropriations

House Committees Health, Insurance, & Environment Appropriations

A BILL FOR AN ACT

101 CONCERNING GRANT FUNDING FOR MEDICAL MARIJUANA HEALTH

102 EFFECTS STUDIES.

Bill Summary

(Note: This summary applies to this bill as introduced and does not reflect any amendments that may be subsequently adopted. If this bill passes third reading in the house of introduction, a bill summary that applies to the reengrossed version of this bill will be available at <u>http://www.leg.state.co.us/billsummaries.</u>)

Joint Budget Committee. The bill creates a health research subaccount (subaccount) in the medical marijuana program cash fund (cash fund). The subaccount provides funding for medical marijuana health research. The department of public health and environment (department) may transfer moneys from the cash fund to the subaccount Reading Unamended May 2, 2014

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and has continuous spending authority over the subaccount. No more than \$10 million may be transferred to the subaccount.

The bill creates a medical marijuana research grant program (grant program) in the department. The grant program will provide the framework for funding research to ascertain the general medical efficacy, and appropriate administration of marijuana. The state board of health (state board) shall promulgate rules for the administration of the grant program, including:

- ! The procedures and timelines for applying for grants;
- ! Grant application contents;
- ! Criteria for selecting grantees and determining the amount and duration of the grants; and
- ! Reporting requirements for grantees.

The bill creates a scientific advisory council (council) to evaluate research proposals seeking a grant from the grant program. The executive director of the department shall appoint the members of the council, and the chief medical officer of the department will also serve on the council and act as chair. The members will serve 2-year terms that may be reappointed and will be reimbursed for travel expenses.

The grant recommendations will be submitted to the state board for a final determination.

The grant program shall report annually to the state board on the progress of the medical marijuana studies.

The bill directs the attorney general to seek federal authority to allow Colorado institutions of higher education to cultivate marijuana for research funded by this bill.

- 1 Be it enacted by the General Assembly of the State of Colorado:
- 2

SECTION 1. Legislative declaration. (1) The general assembly

3 finds and declares that:

4

(a) Over 100,000 Coloradans currently use medical marijuana for

5 relief from constitutionally authorized debilitating medical conditions that

- 6 do not respond to conventional treatments;
- 7

(b) More information is needed to further understand potential

8 therapeutic uses of <u>marijuana and its component parts</u>. Research on the

- 9 therapeutic effects of marijuana and its component parts could benefit
- 10 thousands of Coloradans who suffer from additional debilitating medical

conditions that do not respond to conventional treatments and are not
 currently permissible medical conditions for medical marijuana use.

(c) The purpose of the medical marijuana program cash fund is to
establish, operate, and maintain the medical marijuana program. The state
health agency considers proposals to include additional debilitating
medical conditions to the list of conditions for which a person may use
medical marijuana in the medical marijuana program as a part of its
operational duties for the medical marijuana program cash fund.

9 (d) The state health agency needs additional medical research on
10 the potential therapeutic benefits of marijuana <u>and its component parts</u> to:

(I) Add new debilitating medical conditions to Colorado's medical
marijuana law; and

(II) Help physicians better understand the biochemical effects ofprescribed medical marijuana;

(e) Other state-funded medical marijuana research programs have
advanced the scientific knowledge about how marijuana works and
methods to ensure appropriate dosing. Colorado can now advance that
knowledge further;

(f) Colorado can conduct observational trials that have the
possibility of leading to clinical trials with changes from the federal
government; and

(g) Colorado is a national leader in the development of new strains
of marijuana <u>and its component parts</u> that appear to have promising
therapeutic effects.

(2) Therefore, the general assembly finds it is appropriate to
establish the health research subaccount in the medical marijuana
program fund to fund medical marijuana health research.

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SECTION 2. In Colorado Revised Statutes, 25-1.5-106, amend
 (17) as follows:

3 **25-1.5-106.** Medical marijuana program - powers and duties 4 of state health agency - rules - medical review board - medical 5 marijuana program cash fund - subaccount - created - repeal. 6 (17) **Cash fund.** (a) The medical marijuana program cash fund shall be 7 subject to annual appropriation by the general assembly to the state health 8 agency for the purpose of establishing, operating, and maintaining the 9 medical marijuana program. All moneys credited to the medical 10 marijuana program cash fund and all interest derived from the deposit of 11 such moneys that are not expended during the fiscal year shall be retained 12 in the fund for future use and shall not be credited or transferred to the 13 general fund or any other fund.

14 (b) (Deleted by amendment, L. 2010, (HB 10-1284), ch. 355, p.
15 1677, § 2, effective July 1, 2010.)

(b.5) Notwithstanding any provision of paragraph (a) of this
 subsection (17) to the contrary, on June 30, 2011, the state treasurer shall
 deduct three million dollars from the medical marijuana program cash
 fund and transfer such sum to the general fund.

20 (c) Repealed.

(d) (I) THERE IS CREATED A HEALTH RESEARCH SUBACCOUNT,
REFERRED TO AS "SUBACCOUNT" IN THIS SECTION, IN THE MEDICAL
MARIJUANA PROGRAM CASH FUND. THE SUBACCOUNT IS ESTABLISHED TO
SUPPORT FUNDING FOR MEDICAL MARIJUANA HEALTH RESEARCH. THE
DEPARTMENT SHALL HAVE CONTINUOUS SPENDING AUTHORITY OVER THE
SUBACCOUNT. THE DEPARTMENT MAY DIRECT THE STATE TREASURER TO
TRANSFER MONEY FROM THE MEDICAL MARIJUANA PROGRAM CASH FUND

TO THE SUBACCOUNT BASED ON THE COST OF HEALTH RESEARCH PROJECTS
 APPROVED BY THE STATE BOARD OF HEALTH PURSUANT TO SECTION
 25-1.5-106.5. THE STATE TREASURER SHALL NOT TRANSFER MORE THAN
 TEN MILLION DOLLARS IN TOTAL TO THE SUBACCOUNT.

5 (II) FOR THE 2014-15 FISCAL YEAR AND EACH FISCAL YEAR 6 THROUGH 2018-19, THE ALTERNATIVE TARGET RESERVE FOR PURPOSES OF 7 SECTION 24-75-402 FOR THE MEDICAL MARIJUANA PROGRAM CASH FUND 8 WILL BE SIXTEEN AND FIVE-TENTHS PERCENT OF THE AMOUNT IN THE 9 FUND, EXCLUDING THE TEN MILLION DOLLARS AVAILABLE FOR TRANSFER 10 TO THE SUBACCOUNT AND ANY AMOUNT IN THE SUBACCOUNT.

(III) THIS PARAGRAPH (d) IS REPEALED, EFFECTIVE JULY 1, 2019.
 ANY MONEY REMAINING IN THE SUBACCOUNT ON JUNE 30, 2019, MUST
 REVERT TO THE MEDICAL MARIJUANA PROGRAM CASH FUND.

14 (e) NOTWITHSTANDING ANY PROVISION OF PARAGRAPH (a) OF THIS 15 SUBSECTION (17) TO THE CONTRARY, ON JULY 1, 2014, AND EACH JULY 1 16 THROUGH 2018, THE STATE TREASURER SHALL TRANSFER TWO HUNDRED 17 THOUSAND DOLLARS FROM TEN MILLION DOLLARS AVAILABLE FOR 18 TRANSFER PURSUANT TO PARAGRAPH (d) OF THIS SUBSECTION (17) IN THE 19 MEDICAL MARIJUANA PROGRAM CASH FUND TO THE SUBACCOUNT TO BE 20 USED FOR ADMINISTRATIVE PURPOSES TO ADMINISTER THE MEDICAL 21 MARIJUANA HEALTH RESEARCH GRANT PROGRAM CREATED PURSUANT TO 22 SECTION 25-1.5-106.5.

23 SECTION 3. In Colorado Revised Statutes, add 25-1.5-106.5 as
24 follows:

25 25-1.5-106.5. Medical marijuana health research grant
 26 program. (1) Legislative intent. THERE IS A NEED FOR OBJECTIVE
 27 SCIENTIFIC RESEARCH REGARDING THE EFFICACY OF MARIJUANA <u>AND ITS</u>

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<u>COMPONENT PARTS</u> AS PART OF MEDICAL TREATMENT. IT IS THE INTENT OF
 THE GENERAL ASSEMBLY THAT THE DEPARTMENT GATHER OBJECTIVE
 SCIENTIFIC RESEARCH REGARDING THE EFFICACY OF ADMINISTERING
 MARIJUANA <u>AND ITS COMPONENT PARTS</u> AS PART OF MEDICAL TREATMENT.

5 (2) Medical marijuana research grant program - rules.
6 (a) (I) THE DEPARTMENT SHALL BE RESPONSIBLE FOR THE
7 ADMINISTRATION OF THE COLORADO MEDICAL MARIJUANA RESEARCH
8 GRANT PROGRAM CREATED WITHIN THE DEPARTMENT AND REFERRED TO
9 IN THIS SECTION AS THE "GRANT PROGRAM".

10 (II) THE DEPARTMENT SHALL COORDINATE THE GRANT PROGRAM 11 TO FUND RESEARCH INTENDED TO ASCERTAIN THE GENERAL MEDICAL 12 EFFICACY AND APPROPRIATE ADMINISTRATION OF MARIJUANA AND ITS 13 COMPONENT PARTS. THE GRANT PROGRAM SHALL BE LIMITED TO 14 PROVIDING FOR OBJECTIVE SCIENTIFIC RESEARCH TO ASCERTAIN THE 15 EFFICACY OF MARIJUANA AND ITS COMPONENT PARTS AS PART OF MEDICAL 16 TREATMENT AND SHOULD NOT BE CONSTRUED AS ENCOURAGING OR 17 SANCTIONING THE SOCIAL OR RECREATIONAL USE OF MARIJUANA. THE 18 GRANT PROGRAM SHALL FUND OBSERVATIONAL TRIALS AND CLINICAL 19 TRIALS.

20 (b) THE STATE BOARD OF HEALTH SHALL PROMULGATE RULES FOR
21 THE ADMINISTRATION OF THE GRANT PROGRAM, INCLUDING:

(I) THE PROCEDURES AND TIMELINES BY WHICH AN ENTITY MAYAPPLY FOR PROGRAM GRANTS;

24 (II) GRANT APPLICATION CONTENTS, INCLUDING:

25 (A) DESCRIPTIONS OF KEY PERSONNEL, INCLUDING CLINICIANS,
26 SCIENTISTS, OR EPIDEMIOLOGISTS AND SUPPORT PERSONNEL,
27 DEMONSTRATING THEY ARE ADEQUATELY TRAINED TO CONDUCT THIS

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1 RESEARCH;

2 (B) PROCEDURES FOR OUTREACH TO PATIENTS WITH VARIOUS
3 MEDICAL CONDITIONS WHO MAY BE SUITABLE PARTICIPANTS IN RESEARCH
4 ON MARIJUANA AND ITS COMPONENT PARTS;

5 (C) PROTOCOLS SUITABLE FOR RESEARCH ON MARIJUANA <u>AND ITS</u>
6 <u>COMPONENT PARTS</u> AS MEDICAL TREATMENT;

7 (D) FOR ANY RESEARCH STUDIES, DEMONSTRATION THAT
8 APPROPRIATE PROTOCOLS FOR ADEQUATE PATIENT CONSENT AND
9 FOLLOW-UP PROCEDURES ARE IN PLACE; AND

10 (E) A PROCESS FOR A GRANT RESEARCH PROPOSAL APPROVED BY
11 THE GRANT PROGRAM TO BE REVIEWED AND APPROVED BY AN
12 INSTITUTIONAL REVIEW BOARD THAT IS ABLE TO APPROVE, MONITOR, AND
13 REVIEW BIOMEDICAL AND BEHAVIORAL RESEARCH INVOLVING HUMAN
14 SUBJECTS;

(III) CRITERIA FOR SELECTING ENTITIES TO RECEIVE GRANTS AND
DETERMINING THE AMOUNT AND DURATION OF THE GRANTS, WHICH SHALL
INCLUDE THE FOLLOWING:

18 (A) THE SCIENTIFIC MERIT OF THE RESEARCH PLAN, INCLUDING
19 WHETHER THE RESEARCH DESIGN AND EXPERIMENTAL PROCEDURES ARE
20 POTENTIALLY BIASED FOR OR AGAINST A PARTICULAR OUTCOME; AND

(B) THE RESEARCHERS' EXPERTISE IN THE SCIENTIFIC SUBSTANCE
AND METHODS OF THE PROPOSED RESEARCH AND THEIR LACK OF BIAS OR
CONFLICT OF INTEREST REGARDING THE TOPIC OF, AND THE APPROACH
TAKEN IN, THE PROPOSED RESEARCH; AND

25 (IV) REPORTING REQUIREMENTS FOR ENTITIES THAT RECEIVE26 GRANTS PURSUANT TO THIS SECTION.

27 (c) PROGRAM GRANTS WILL BE PAID FROM THE HEALTH RESEARCH

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SUBACCOUNT IN THE MEDICAL MARIJUANA PROGRAM CASH FUND CREATED
 IN SECTION 25-1.5-106 (17).

3 (d) IN ORDER TO MAXIMIZE THE SCOPE AND SIZE OF THE
4 MARIJUANA STUDIES:

5 (I) THE GRANT PROGRAM MAY SOLICIT, APPLY FOR, AND ACCEPT 6 MONEYS FROM FOUNDATIONS, PRIVATE INDIVIDUALS, AND ALL OTHER 7 FUNDING SOURCES THAT CAN BE USED TO EXPAND THE SCOPE OR 8 TIMEFRAME OF THE MARIJUANA STUDIES THAT ARE AUTHORIZED UNDER 9 THIS SECTION; EXCEPT THAT THE PROGRAM SHALL NOT ACCEPT ANY 10 MONEYS THAT ARE OFFERED WITH ANY CONDITIONS OTHER THAN THAT 11 THE MONEYS BE USED TO STUDY THE EFFICACY OF MARIJUANA AND ITS 12 COMPONENT PARTS AS PART OF MEDICAL TREATMENT; AND

(II) ALL DONORS SHALL BE ADVISED THAT MONEYS GIVEN FOR
PURPOSES OF THIS SECTION WILL BE USED TO STUDY BOTH THE POSSIBLE
MEDICAL BENEFITS AND DETRIMENTS OF MARIJUANA <u>AND ITS COMPONENT</u>
<u>PARTS</u> AND THAT HE OR SHE WILL HAVE NO CONTROL OVER THE USE OF
THESE MONEYS.

18 (3) Review of applications. (a) (I) Scientific advisory council. 19 IN ORDER TO ENSURE OBJECTIVITY IN EVALUATING RESEARCH PROPOSALS, 20 THE GRANT PROGRAM SHALL ESTABLISH A SCIENTIFIC ADVISORY COUNCIL, 21 REFERRED TO IN THIS SECTION AS THE "COUNCIL". TO PROVIDE A PEER 22 REVIEW PROCESS THAT GUARDS AGAINST FUNDING RESEARCH THAT IS 23 BIASED IN FAVOR OF OR AGAINST PARTICULAR OUTCOMES. THE EXECUTIVE 24 DIRECTOR OF THE DEPARTMENT SHALL APPOINT AT LEAST SIX MEMBERS 25 AND NO MORE THAN THIRTEEN MEMBERS TO THE COUNCIL TO PROVIDE 26 POLICY GUIDANCE IN THE CREATION AND IMPLEMENTATION OF THE GRANT 27 PROGRAM AND IN SCIENTIFIC OVERSIGHT AND REVIEW. THE CHIEF MEDICAL

1 OFFICER OF THE DEPARTMENT, OR HIS OR HER DESIGNEE, IS ALSO A 2 MEMBER OF THE COUNCIL AND IS CHAIR OF THE COUNCIL. EXCEPT FOR THE 3 REPRESENTATIVE SPECIFIED IN SUB-SUBPARAGRAPH (L) OF THIS 4 SUBPARAGRAPH (I), THE EXECUTIVE DIRECTOR SHALL CHOOSE MEMBERS 5 ON THE BASIS OF THEIR EXPERTISE IN THE SCIENTIFIC SUBSTANCE AND 6 METHODS OF THE PROPOSED RESEARCH AND FOR THEIR LACK OF BIAS OR 7 CONFLICT OF INTEREST REGARDING THE APPLICANTS OR THE TOPIC OF AN 8 APPROACH TAKEN IN THE PROPOSED RESEARCH AND MAY CHOOSE 9 MEMBERS FROM AROUND THE COUNTRY. MEMBERS OF THE COUNCIL MUST 10 INCLUDE THE FOLLOWING TYPES OF EXPERTS: 11 (A) AT LEAST ONE EPIDEMIOLOGIST WITH EXPERTISE IN DESIGNING 12 AND CONDUCTING LARGE, OBSERVATIONAL STUDIES AND CLINICAL TRIALS; 13 (B) AT LEAST ONE CLINICIAN WITH EXPERTISE IN DESIGNING AND 14 CONDUCTING CLINICAL TRIALS; 15 (C) A CLINICIAN FAMILIAR WITH THE PRESCRIPTION, DOSAGE, AND 16 ADMINISTRATION OF MEDICAL MARIJUANA UNDER CURRENT STATE LAWS; 17 (D) A MEDICAL TOXICOLOGIST; 18 (E) A NEUROLOGIST; 19 (F) A PEDIATRICIAN; 20 (G) A PSYCHIATRIST; 21 (H) AN INTERNAL MEDICINE PHYSICIAN OR OTHER SPECIALIST IN 22 ADULT MEDICINE: 23 (I) A PREVENTIVE MEDICINE SPECIALIST OR PUBLIC HEALTH 24 PROFESSIONAL; 25 (J) A SUBSTANCE ABUSE SPECIALIST; 26 (K) AN ALTERNATIVE MEDICINE SPECIALIST WITH EXPERTISE IN 27 HERBAL OR ALTERNATIVE MEDICINE;

1 (L) A PERSON WHO REPRESENTS MEDICAL MARIJUANA PATIENT 2 INTERESTS; AND

3 (M) AN AD HOC MEMBER WITH CLINICAL EXPERTISE IN THE
4 MEDICAL CONDITION UNDER STUDY.

5 (II) MEMBERS OF THE COUNCIL, OTHER THAN THE CHIEF MEDICAL
6 OFFICER OR HIS OR HER DESIGNEE, SHALL SERVE ON A VOLUNTARY BASIS
7 FOR A TWO-YEAR TERM AND MAY BE REAPPOINTED. MEMBERS SHALL BE
8 REIMBURSED FOR THEIR TRAVEL EXPENSES INCURRED IN THE COURSE OF
9 THEIR PARTICIPATION.

(III) MEMBERS OF THE COUNCIL SHALL EVALUATE RESEARCH
PROPOSALS AND SUBMIT RECOMMENDATIONS TO THE DEPARTMENT AND
THE STATE BOARD OF HEALTH FOR RECOMMENDED GRANT RECIPIENTS,
GRANT AMOUNTS, AND GRANT DURATION.

(b) Grant approval. (I) THE COUNCIL SHALL SUBMIT
RECOMMENDATIONS FOR GRANTS TO THE STATE BOARD OF HEALTH. THE
STATE BOARD OF HEALTH SHALL APPROVE OR DISAPPROVE OF GRANTS
SUBMITTED BY THE COUNCIL. IF THE STATE BOARD OF HEALTH
DISAPPROVES A RECOMMENDATION, THE COUNCIL MAY SUBMIT A
REPLACEMENT RECOMMENDATION WITHIN THIRTY DAYS.

(II) THE STATE BOARD OF HEALTH SHALL AWARD GRANTS TO THE
SELECTED ENTITIES, SPECIFYING THE AMOUNT AND DURATION OF THE
AWARD. A GRANT AWARDED PURSUANT TO THIS SECTION SHALL NOT
EXCEED THREE YEARS WITHOUT RENEWAL. THE SIZE, SCOPE, AND NUMBER
OF STUDIES FUNDED SHALL BE COMMENSURATE WITH THE AMOUNT OF
APPROPRIATED AND AVAILABLE GRANT PROGRAM FUNDING.

26 (4) **Reporting.** (a) NO LATER THAN JANUARY 1, 2016, THE GRANT
27 PROGRAM SHALL REPORT TO THE STATE BOARD OF HEALTH ON THE

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1 PROGRESS OF THE MEDICAL MARIJUANA STUDIES.

2 (b) THEREAFTER, THE GRANT PROGRAM SHALL ISSUE A REPORT TO 3 THE STATE BOARD OF HEALTH BY JANUARY 1 OF EACH YEAR DETAILING 4 THE PROGRESS OF THE MEDICAL MARIJUANA STUDIES. THE INTERIM 5 REPORTS REQUIRED UNDER THIS PARAGRAPH (b) SHALL INCLUDE DATA ON 6 ALL OF THE FOLLOWING: 7 (I) THE NAMES AND NUMBER OF DISEASES OR CONDITIONS UNDER 8 STUDY: 9 (II) THE NUMBER OF PATIENTS ENROLLED IN EACH STUDY BY 10 DISEASE: AND 11 (III) ANY SCIENTIFICALLY VALID PRELIMINARY FINDINGS. 12 (5) Cultivation authority. THE ATTORNEY GENERAL SHALL SEEK 13 AUTHORITY FROM THE FEDERAL GOVERNMENT TO PERMIT COLORADO 14 INSTITUTIONS OF HIGHER EDUCATION TO CONTRACT WITH THE NATIONAL 15 INSTITUTE OF DRUG ABUSE TO CULTIVATE MARIJUANA AND ITS 16 COMPONENT PARTS FOR USE IN RESEARCH STUDIES FUNDED PURSUANT TO 17 THIS SECTION. 18 (6) **Definition.** FOR PURPOSES OF THIS SECTION, "MARIJUANA" 19 MEANS "USABLE FORM OF MARIJUANA" AS THAT TERM IS DEFINED IN 20 SECTION 14 (1) (i) OF ARTICLE XVIII OF THE COLORADO CONSTITUTION 21 AND ALSO INCLUDES "INDUSTRIAL HEMP" AS THAT TERM IS DEFINED IN 22 SECTION 16 (2) (d) OF ARTICLE XVIII OF THE COLORADO CONSTITUTION. 23 **SECTION 4.** In Colorado Revised Statutes, 24-75-402, add (5) 24 (bb) as follows: 25 24-75-402. Cash funds - limit on uncommitted reserves -26 reduction in amount of fees - exclusions - repeal. (5) Notwithstanding 27 any provision of this section to the contrary, the following cash funds are

1 excluded from the limitations specified in this section:

(bb) THE MEDICAL MARIJUANA PROGRAM CASH FUND, BUT ONLY
WITH RESPECT TO THE PORTION OF THE FUND TRANSFERRED TO OR
AVAILABLE FOR TRANSFER TO THE HEALTH RESEARCH SUBACCOUNT
CREATED IN SECTION 25-1.5-106 (17) (d), C.R.S.

6 SECTION 5. Effective date. This act takes effect July 1, 2014.
7 SECTION 6. Safety clause. The general assembly hereby finds,
8 determines, and declares that this act is necessary for the immediate
9 preservation of the public peace, health, and safety.