Second Regular Session Sixty-ninth General Assembly STATE OF COLORADO

PREAMENDED

This Unofficial Version Includes Committee Amendments Not Yet Adopted on Second Reading

LLS NO. 14-0850.01 Michael Dohr x4347

SENATE BILL 14-155

SENATE SPONSORSHIP

Steadman, Hodge, Lambert

HOUSE SPONSORSHIP

May and Duran, Gerou

Senate Committees

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House Committees

Health & Human Services Finance Appropriations

A BILL FOR AN ACT

CONCERNING GRANT FUNDING FOR MEDICAL MARIJUANA HEALTH 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 http://www.leg.state.co.us/billsummaries.)

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

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.

Be it enacted by the General Assembly of the State of Colorado:

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2 **SECTION 1. Legislative declaration.** (1) The general assembly finds and declares that:

- (a) Over 100,000 Coloradans currently use medical marijuana for relief from constitutionally authorized debilitating medical conditions that do not respond to conventional treatments;
- (b) More information is needed to further understand potential therapeutic uses of <u>marijuana and its component parts</u>. Research on the therapeutic effects of marijuana <u>and its component parts</u> could benefit thousands of Coloradans who suffer from additional debilitating medical

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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.
- (d) The state health agency needs additional medical research on 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 of prescribed 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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1	SECTION 2. In Colorado Revised Statutes, 25-1.5-106, amend
2	(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.)
16	(b.5) Notwithstanding any provision of paragraph (a) of this
17	subsection (17) to the contrary, on June 30, 2011, the state treasurer shall
18	deduct three million dollars from the medical marijuana program cash
19	fund and transfer such sum to the general fund.
20	(c) Repealed.
21	(d) (I) THERE IS CREATED A HEALTH RESEARCH SUBACCOUNT,
22	REFERRED TO AS "SUBACCOUNT" IN THIS SECTION, IN THE MEDICAL
23	MARIJUANA PROGRAM CASH FUND. THE SUBACCOUNT IS ESTABLISHED TO
24	SUPPORT FUNDING FOR MEDICAL MARIJUANA HEALTH RESEARCH. THE
25	DEPARTMENT SHALL HAVE CONTINUOUS SPENDING AUTHORITY OVER THE
26	SUBACCOUNT. THE DEPARTMENT MAY DIRECT THE STATE TREASURER TO
27	TRANSFER MONEY FROM THE MEDICAL MARIJUANA PROGRAM CASH FUND

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1	TO THE SUBACCOUNT BASED ON THE COST OF HEALTH RESEARCH PROJECTS
2	APPROVED BY THE STATE BOARD OF HEALTH PURSUANT TO SECTION
3	25-1.5-106.5. THE STATE TREASURER SHALL NOT TRANSFER MORE THAN
4	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.
11	(III) THIS PARAGRAPH (d) IS REPEALED, EFFECTIVE JULY 1, 2019.
12	Any money remaining in the subaccount on June 30, 2019, must
13	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 AND ITS

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1	<u>COMPONENT PARTS</u> AS PART OF MEDICAL TREATMENT. IT IS THE INTENT OF
2	THE GENERAL ASSEMBLY THAT THE DEPARTMENT GATHER OBJECTIVE
3	SCIENTIFIC RESEARCH REGARDING THE EFFICACY OF ADMINISTERING
4	${\tt MARIJUANA} \underline{{\tt ANDITSCOMPONENTPARTS}} {\tt ASPARTOFMEDICALTREATMENT}.$
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 <u>AND ITS COMPONENT PARTS</u> 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:
22	(I) THE PROCEDURES AND TIMELINES BY WHICH AN ENTITY MAY
23	APPLY 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 AND ITS
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;
15	(III) CRITERIA FOR SELECTING ENTITIES TO RECEIVE GRANTS AND
16	DETERMINING THE AMOUNT AND DURATION OF THE GRANTS, WHICH SHALL
17	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
21	(B) THE RESEARCHERS' EXPERTISE IN THE SCIENTIFIC SUBSTANCE
22	AND METHODS OF THE PROPOSED RESEARCH AND THEIR LACK OF BIAS OR
23	CONFLICT OF INTEREST REGARDING THE TOPIC OF, AND THE APPROACH
24	TAKEN IN, THE PROPOSED RESEARCH; AND
25	(IV) REPORTING REQUIREMENTS FOR ENTITIES THAT RECEIVE
26	GRANTS PURSUANT TO THIS SECTION.
27	(c) PDOCDAM CDANTS WILL BE DAID EDOM THE HEALTH DESEADON

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1	SUBACCOUNTINTHEMEDICALMARIJUANAPROGRAMCASHFUNDCREATED
2	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
13	(II) ALL DONORS SHALL BE ADVISED THAT MONEYS GIVEN FOR
14	PURPOSES OF THIS SECTION WILL BE USED TO STUDY BOTH THE POSSIBLE
15	${\tt MEDICALBENEFITSANDDETRIMENTSOFMARIJUANA\underline{ANDITSCOMPONENT}}$
16	<u>PARTS</u> AND THAT HE OR SHE WILL HAVE NO CONTROL OVER THE USE OF
17	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

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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

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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.
10	(III) MEMBERS OF THE COUNCIL SHALL EVALUATE RESEARCH
11	PROPOSALS AND SUBMIT RECOMMENDATIONS TO THE DEPARTMENT AND
12	THE STATE BOARD OF HEALTH FOR RECOMMENDED GRANT RECIPIENTS,
13	GRANT AMOUNTS, AND GRANT DURATION.
14	(b) Grant approval. (I) The council shall submit
15	RECOMMENDATIONS FOR GRANTS TO THE STATE BOARD OF HEALTH. THE
16	STATE BOARD OF HEALTH SHALL APPROVE OR DISAPPROVE OF GRANTS
17	SUBMITTED BY THE COUNCIL. IF THE STATE BOARD OF HEALTH
18	DISAPPROVES A RECOMMENDATION, THE COUNCIL MAY SUBMIT A
19	REPLACEMENT RECOMMENDATION WITHIN THIRTY DAYS.
20	(II) The state board of health shall award grants to the
21	SELECTED ENTITIES, SPECIFYING THE AMOUNT AND DURATION OF THE
22	AWARD. A GRANT AWARDED PURSUANT TO THIS SECTION SHALL NOT
23	EXCEED THREE YEARS WITHOUT RENEWAL. THE SIZE, SCOPE, AND NUMBER
24	OF STUDIES FUNDED SHALL BE COMMENSURATE WITH THE AMOUNT OF
25	APPROPRIATED AND AVAILABLE GRANT PROGRAM FUNDING.
26	(4) Reporting. (a) Nolater 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

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L	excluded from the limitations specified in this section:
2	(bb) The medical marijuana program cash fund, but only
3	WITH RESPECT TO THE PORTION OF THE FUND TRANSFERRED TO OR
4	AVAILABLE FOR TRANSFER TO THE HEALTH RESEARCH SUBACCOUNT
5	CREATED IN SECTION 25-1.5-106 (17) (d), C.R.S.
5	SECTION 5. Effective date. This act takes effect July 1, 2014.
7	SECTION 6. Safety clause. The general assembly hereby finds,
3	determines, and declares that this act is necessary for the immediate
)	preservation of the public peace, health, and safety.

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