

Schedule 13 Funding Request for the 2014-15 Budget Cycle

Department: Public Health & Environment

Request Title: Marijuana Research Studies

Priority Number: R-1

Dept. Approval by: *[Signature]* Date: 10/24/13

OSPB Approval by: *[Signature]* Date: 10/24/13

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|-------------------------------------|--------------------------------|
| <input checked="" type="checkbox"/> | Decision Item FY 2014-15 |
| <input type="checkbox"/> | Base Reduction Item FY 2014-15 |
| <input type="checkbox"/> | Supplemental FY 2013-14 |
| <input type="checkbox"/> | Budget Amendment FY 2014-15 |

Line Item Information		FY 2013-14		FY 2014-15		FY 2015-16
		1	2	3	4	5
	Fund	Appropriation FY 2013-14	Supplemental Request FY 2013-14	Base Request FY 2014-15	Funding Change Request FY 2014-15	Continuation Amount FY 2015-16
Total of All Line Items	Total	180,906	-	320,388	7,084,656	79,953
	FTE	2.0	-	4.0	1.0	1.0
	GF	-	-	-	-	-
	GFE	-	-	-	-	-
	CF	180,906	-	320,388	7,084,656	79,953
	RF	-	-	-	-	-
	FF	-	-	-	-	-
(8) Disease Control & Environmental Epidemiology Division,	Total	180,906	-	320,388	7,084,656	79,953
(C) Environmental Epidemiology, Cannabis Health Environmental & Epidemiology Training, Outreach, & Surveillance	FTE	2.0	-	4.0	1.0	1.0
	GF	-	-	-	-	-
	GFE	-	-	-	-	-
	CF	180,906	-	320,388	7,084,656	79,953
	RF	-	-	-	-	-
	FF	-	-	-	-	-

Letternote Text Revision Required? Yes No: If yes, describe the Letternote Text Revision:
 Since this is a new appropriation there is currently not a letternote. If this request is authorized fund 14v would be the cash source.
 Cash or Federal Fund Name and COFRS Fund Number: Medical Marijuana Cash Fund 14V
 Reappropriated Funds Source, by Department and Line Item Name:
 Approval by OIT? Yes No Not Required :
 Schedule 13s from Affected Departments: N/A
 Other Information:



COLORADO

Department of Public Health and
Environment

Priority: R-1
Marijuana Research Studies
FY 2014-15 Change Request

Cost and FTE

- The Department is requesting 1.0 FTE and \$7,084,656 in cash fund spending authority to make grants for research on the health effects of marijuana.
- \$7,000,000 will be available to researchers to research the health effects of marijuana. \$84,656 is for the 1.0 requested FTE and operating costs.
- The Medical Marijuana Cash Fund is the funding source and has adequate balance for the request.

Problem or Opportunity

- There is a lack of scientific information on health impacts of marijuana.
- This lack of information prevents individuals and health care providers from having the information they need to make important health decisions.
- There is speculation on the health impact of marijuana on conditions such as Post Traumatic Stress Disorder and seizures, but there is no scientific evidence to support or refute health effects.
- Using the Medical Marijuana Cash Fund to support scientific research on the impacts of marijuana is consistent with the legislative and constitutional intent for the use of the fund and is in the best interests of public health.

Consequences of Problem

- Without this research, there will continue to be a lack of scientific evidence-based information available to health care providers and individuals regarding the health effects of marijuana use.

Proposed Solution

- The Department is requesting 1.0 FTE and \$7,084,656 cash fund spending authority to issue grants to study the health effects of marijuana on various medical conditions.
- The Department anticipates that entities such as universities and hospitals within Colorado will apply for and be granted funds to conduct research on a variety of issues related to marijuana.
- Studies include researching the effectiveness of marijuana on managing conditions such as Post Traumatic Stress Disorder and seizure disorders.
- The studies might also evaluate any potential negative health impacts of marijuana, such as on brain development in the pediatric population.
- The Department anticipates that it will need 9 to 12 months for planning to be ready to issue a request for proposals in July of 2014.
- A Technical Advisory Board, along with the Board of Health, will provide input into the development of the RFP criteria, selection of the awardees and monitor project progress.
- The Department estimates that the average cost per research project will be between \$500,000 and \$1,000,000, depending on size and scope.

FY 2014-15 CHANGE REQUEST

*Priority: R -1 Marijuana Research Studies
Request Detail*

Problem or Opportunity:

The Department is requesting 1.0 FTE and \$7,084,656 in one-time roll-forward cash fund spending authority to make grants for research on the health effects of marijuana. The Medical Marijuana Cash Fund would be the source of funds for this grant program.

In November 2012, Colorado voters approved Amendment 64 which legalized adult marijuana use. There is a significant amount of controversy, speculation and anecdotal discussion about the health impacts of marijuana use, but there is very little scientific research on the subject. When the voters approved the constitutional amendment to allow use of medical marijuana, several health conditions were identified as authorized for the use of medical marijuana.

Since then, there have been several attempts to add new conditions to the list of authorized conditions but there is little available research to substantiate the belief that marijuana is beneficial in the management of these conditions, so the Department has been unable to add them. For example, there is a belief that there are beneficial impacts of marijuana in managing seizures, as well as Post-traumatic Stress Disorder, but there is limited research available to either support or refute the health impacts of medical marijuana on these conditions. In addition, there have been multiple pediatric applicants for medical marijuana licenses to control seizures, but the health effects of medical marijuana use in the pediatric population have not been well studied in scientific literature, making it difficult to approve the use of marijuana for this population. Also, there have been questions raised about the effects of marijuana on brain development, particularly in children, but there is little research available. These examples illustrate the how the lack of scientific information available prevents individuals and health care providers from having the information they need to make important health decisions related to marijuana.

Proposed Solution:

The Department is requesting \$7,084,656 in one-time roll-forward cash fund spending authority to make grants to support research on the impacts of marijuana use. Conducting health research is guaranteed to take longer than one year, and therefore the Department is requesting that these funds be authorized as roll-forward. The Department is also requesting 1.0 FTE to manage the project.

The Medical Marijuana Cash Fund has a considerable fund balance of approximately \$13,400,000. The Department believes that this request follows the legislative and constitutional intent for the use of the fund and that funding medical marijuana research is in the best interest of public health. Utilizing \$7,480,392 of the fund balance to gather scientific evidence would not negatively impact the Department's ability to operate the Medical Marijuana Registry and would leave a significant fund balance for other projects.

The Department anticipates that it will need 9 to 12 months for planning to be ready to issue a Request For Proposals (RFP) in July, 2014. Part of this preparation will be to review what data already exists, and where the gaps are in the knowledge base around marijuana and medical uses.

Proposals will be solicited for observational studies related to marijuana use and health effects. This might include conducting patient interviews or medical chart reviews or monitoring of emergency room visit data. It will not include any type of clinical or pharmacologic research involving the actual administration of marijuana. Proposals will be evaluated based on their scientific soundness and the value the data would bring to health providers, the scientific literature, and to public health. The Department will conduct a second request for proposals if there are remaining funds after the initial awards are made. While it is not possible at this time to predict how many studies are needed (i.e. what the knowledge gap is) there has been express interest in conducting studies on this issue. For example, the University of California, San Francisco has conducted studies regarding the use of marijuana use with pain reducers. The physician in charge of that study indicated a desire to study how various strains of marijuana act differently.¹

A Technical Advisory Board with experience reviewing and evaluating health research will be established. This board will consist of health care and scientific professionals with expertise in clinical pharmacology and toxicology, addiction and substance abuse research, public health surveillance, and other related fields. This board, along with the Board of Health, will provide input into the development of the RFP criteria, selection of awardees and monitoring project progress.

Scientific research requires significant planning, internal review, establishment of protocols, and identification of participants before data collection can begin. Health research often takes years due to the need to evaluate impacts over time. The Department assumes that the majority of the projects that will be selected for funding will take up to 3 years to complete and that the project as a whole will take five years.

One of the goals of this project is to increase the body of scientific, evidence-based research on the health effects of marijuana use. Therefore, one mandatory deliverable for each selected grantee will be to produce a scientific manuscript for submission to a peer-reviewed journal by the end of the grant period. This requirement is a major reason why the Department believes the project will take 5 years to complete and why the Department is requesting continuous spending authority.

The cost of funding research can be significant depending on variables such as the number of participants and how labor intensive the data collection is, such as individual interviews or review of medical records. The Department estimates that the average cost per project will be between \$500,000 and \$1,000,000, depending on size and scope. The Department anticipates 7 to 14 proposals may meet funding criteria.

The Federal Government will not provide financial support for this type of marijuana research since marijuana is still an illegal substance in most of the United States. Therefore, research conducted by other institutions such as universities, pharmaceutical manufacturers and hospitals rarely focuses on the health

¹ Donald Abrams, MD, professor of clinical medicine at UCSF and chief of the Hematology-Oncology Division at San Francisco General Hospital and Trauma Center (SFGH). *Clinical Pharmacology & Therapeutics* 90, 844-851 (December 2011) | doi:10.1038/clpt.2011.188

impacts of marijuana. The legalization of marijuana in Colorado and the existence of the Medical Marijuana Cash Fund balance significantly reduce these two barriers to conducting research. The research supported with this funding will make information available to medical providers and individuals using medical marijuana. Therefore the Department believes that this is an appropriate use of the Medical Marijuana Cash Fund.

Without this research, there will continue to be a lack of scientific evidence-based information available to health care providers and individuals regarding the health effects of marijuana use.

Anticipated Outcomes:

If authorized, this \$7,084,656 will be used to support research into the health effects of marijuana. The Department anticipates that entities such as universities and hospitals within Colorado will apply for and be granted funds to conduct research on a variety of issues related to marijuana. Studies might review medical records or interview patients in order to assess the effectiveness of marijuana on managing conditions such as Post Traumatic Stress Disorder and seizures, as well as any potential negative health impacts marijuana might have in certain populations. Proposals will be solicited and grants awarded based on the scientific merit of the proposals and the value of the results. Scientific articles submitted to peer reviewed journals for publication will be a specific deliverable for each grant. The data that is collected will help health care providers and individuals to be better informed as they make decisions about marijuana use.

Assumptions and Calculations:

This request is for 1.0 FTE and \$84,656 cash spending authority as well as one time roll-forward funding for grants in the amount of \$7,000,000.

The requested 1.0 FTE will

- Develop a strategic project plan.
- Coordinate review and monitoring of research and literature on health impacts of marijuana use.
- Hold a technical symposium to educate potential applicants and ascertain interest in and capacity to conduct research on the health effects of marijuana.
- Develop and convene a Technical Advisory Board.
- Work with the Technical Advisory Board and Board of Health to establish the criteria for request for proposals.
- Manage the RFP process including educating potential submitters, managing submissions and coordinating proposal review by the Technical Advisory Board.
- Develop contracts including establishing deliverables, timelines and project metrics.
- Manage a second RFP process if funds remain available.
- Monitor grantee progress in meeting deliverables, timelines and performance metrics.
- Provide technical assistance to grantees.
- Facilitate dialogue and information sharing amongst grantees.
- Provide quarterly briefings to the Board of Health and Technical Advisory Board on grantee progress.

- Coordinate the review of manuscripts for publication.

Based on this workload, the Department believes it will need approximately 1.0 FTE for 5 years:

- 1 year to prepare for and select grantees.
- 3 years of monitoring and reporting grantee progress and providing technical assistance.
- 1 year to close out grants, develop a report and facilitate the publication of findings.

The requested \$84,656 is based on \$69,003 for a health Professional III at 25% above the minimum and \$6,153 for telephone, computer, travel and other operating costs. Given the expertise required for the population, the Department believes it appropriate to offer the position above the minimum pay grade. \$9,500 is also being requested for travel and meeting costs for Technical Advisory Board members. These costs are based on similar Board of Health travel and meeting costs. See appendix A for detailed expenditures.

The Department is requesting \$7 Million for grants. This amount is in recognition of the costly nature of health research and to achieve the Department's goals of funding research that provides meaningful, useful and worthwhile results and that contributes to a body of research on health impacts of marijuana. The Department anticipates that many of the research projects will take 3 years or longer. Therefore, the Department is requesting roll-forward spending authority for the grant portion of the request, to ensure sufficient time for projects to be completed. In order to facilitate expenditure monitoring, the Department is planning to set up a separate accounting structure for the grant funds.

Authorizing the requested amount would leave a balance of more than \$6,000,000 in the Medical Marijuana Cash Fund. This amount is more than sufficient to sustain the Medical Marijuana Registry and fund other projects that may be identified.

Appendix A – Calculations

Description	Base cost	Calculation Adjustments	Total cost first year	Total cost out years (no salary survey)	Source of calculation
Grants	\$7,000,000	\$7,000,000	\$7,000,000	\$0	
Salary (Health Professional III)	\$49,468	\$12,366	\$61,830	\$61,830	25% above the minimum
PERA Costs	10.15%		\$6,276	\$6,276	common policy
Medicare Costs	1.45%		\$897	\$897	common policy
Computer			\$900		common policy
Office suite software			\$330	\$0	common policy
Telephone			\$450	\$450	common policy
Office Furniture			\$3,473	\$0	common policy
Travel			\$1,000	\$1,000	
Meeting expenses			\$4,500	\$4,500	based on BOA costs
Board member travel			\$5,000	\$5,000	based on BOA costs
Total Personal Services and Operating costs			\$84,656	\$79,953	
Total Program costs			\$7,084,656	\$79,953	